Safely

Instruments for
bowel manipulation
investigated

[illegible]

Grasping Safely

Instruments for bowel manipulation investigated

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Instruments for bowel manipulation investigated

Proefschrift

ter verkrijging van de graad van doctor
aan de Technische Universiteit Delft,
op gezag van de Rector Magnificus prof.dr.ir. J.T. Fokkema,
voorzitter van het College voor Promoties,
in het openbaar te verdedigen

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door

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werktuigbouwkundig ingenieur
geboren te Enkhuizen

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Summary

Grasping safely - Instruments for bowel manipulation investigated

Doctorate thesis of Hans de Visser, June 2003

As a part of the Minimally Invasive Surgery and Interventional Techniques (MISIT) programme of the Delft University of Technology, the project presented in this thesis was set up to develop instruments for minimally invasive surgery. To further specify this assignment a clinically driven approach was used. This approach implies that the engineer establishes a continuing interaction with surgeons through discussions, brainstorming sessions and regular visits to the operating room. Several important problems in laparoscopy, *keyhole surgery in the abdomen*, were identified and discussed with the collaborating surgeons. It was decided to improve the safety during manipulation of the bowel by improving the design of the jaws of the graspers with which the bowel is manipulated.

Assessment of the functional requirements of a bowel grasper showed that it should be able to pull at the bowel with a force of 5 N, without causing the tissue to slip out of the grasper and without causing unacceptable damage. In series of experiments on pigs a variety of different jaw shape designs was tested to investigate how well they would fulfil the required function and which features of the design played which role in this fulfilment. The main criterion that has been defined to quantify how well a jaw shape fulfils the requirement, is the so-called damage-slip-ratio: The maximum pinch force that will not cause too much damage divided by the minimum pinch force required to prevent slip. The jaw shapes have also been judged based how sensitive their performance is to variations in the tissue that is being manipulated. This is important, because the jaws have to perform well, not only on healthy bowel of a pig, but also on diseased human bowel. This sensitivity has been quantified in the so-called robustness: The variation of the tissue divided by the variation in the measured damage-slip-ratios. From the experiments it was concluded that to prevent damage a large contact area between the grasper and the bowel tissue is required. It was also found that a good way to prevent the tissue from slipping out of the jaws is to provide the jaw shapes with a profile, preferable with profile elements of limited height (approximately 0.3 mm) and diamond-shaped. Slip can be prevented further by allowing the tissue to bulge at the backside of the jaws, such that when the tissue is pulled, the jaws transmit the pull force not only on friction, but also by pushing against the backside of the tissue. The findings from the experiments have led to a set of guidelines for the design of safe, minimally traumatic grasper jaws. Besides the guidelines, a suggestion has been presented for a protocol for the assessment of the safety of newly developed 'atraumatic' graspers.

It is believed that the availability of safer, better and more reliable instruments, in which the surgeon has high confidence of safety, may contribute to the future acceptance of sophisticated laparoscopic procedures as probably well accepted alternatives to the traditional open procedures.

Samenvatting

Veilig grijpen – Instrumenten voor darmmanipulatie onderzocht (Grasping safely - Instruments for bowel manipulation investigated)

Proefschrift van Hans de Visser, juni 2003

Het project, beschreven in deze dissertatie, is onderdeel van het MISIT (Minimally Invasive Surgery and Interventional Techniques) onderzoeksprogramma van de Technische Universiteit Delft. Het project is opgezet om instrumentarium van de minimaal-invasieve chirurgie te ontwikkelen. Om deze opdracht verder te specificeren is gebruik gemaakt van een zogenaamde klinisch gedreven aanpak. Deze aanpak houdt in dat de ingenieur een doorlopende interactie met de chirurg bewerkstelligt door middel van discussies, brainstormsessies en regelmatige bezoeken aan de operatiekamer. Een aantal belangrijke problemen spelende in de laparoscopie (sleutelgatchirurgie in de buik) zijn op deze manier vastgesteld en vervolgens met de betrokken chirurgen besproken. Gekozen is om het onderzoek te richten op het verbeteren van de veiligheid tijdens het manipuleren van darmen tijdens laparoscopische chirurgie door het ontwerp van de bekjes van de hiervoor gebruikte paktangen te verbeteren.

Uit een analyse van de functionele eisen aan een darmpaktang is gebleken dat een dergelijke tang in staat moet zijn aan de dikke darm te trekken met een kracht van 5 N, zonder dat het darmweefsel uit de paktang slipt en zonder onacceptabele schade aan het weefsel te veroorzaken. In een aantal series experimenten op varkens is van een verscheidenheid aan verschillende bekvormen getest onderzocht hoe goed ze de vereiste functies vervullen en welke kenmerken daarbij een rol spelen. Om te kwantificeren hoe goed een bepaalde vorm aan de vereisten voldoet, is een nieuwe norm gedefinieerd, de zogenaamde schade-slip-ratio. Dit is de maximale knijpkracht die op het weefsel kan worden uitgeoefend zonder onacceptabele schade te veroorzaken, gedeeld door de minimale knijpkracht nodig om slip te voorkomen. Verder zijn de bekvormen beoordeeld op hun gevoeligheid voor variaties in het te manipuleren weefsel. Dit is van belang, aangezien de bekvormen niet alleen op gezonde varkensdarmen goed moeten presteren, maar ook op zieke humane darmen. Deze gevoeligheid is gekwantificeerd in de vorm van de zogenaamde robuustheid: de variatie van het darmweefsel, gedeeld door de variatie in de gemeten schade-slip-ratio's. Uit de experimenten is gebleken dat een groot contactoppervlak tussen paktang en darmweefsel nodig is om weefselschade te voorkomen. Verder is gebleken dat slip voorkomen kan worden door het oppervlak van de bekvormen te voorzien van een profiel. In de experimenten kwam een profiel met ruitvormige elementen van beperkte hoogte (0.3 mm) als beste uit de bus. Slip kan verder voorkomen worden door ervoor te zorgen dat het weefsel achter (het contactoppervlak van) het bekje kan opbollen, zodat de overdracht van de trekkracht van de paktang op het weefsel niet alleen op wrijving gebeurt, maar ook doordat er tegen (de achterkant van) het weefsel geduwd wordt. De bevindingen uit de experimenten zijn verwerkt in een aantal richtlijnen voor het ontwerp van veilige, minimaal-traumatische bekvormen voor darmpaktangen. Bovendien is een voorstel gepresenteerd voor een protocol voor het beoordelen van de veiligheid van nieuw te ontwerpen atraumatische paktangen.

Naar verwachting zal de beschikbaarheid van veiligere, betere en betrouwbaardere instrumenten, waarin de chirurg voor wat betreft de veiligheid een groot vertrouwen heeft, kunnen bijdragen aan de toekomstige acceptatie van geavanceerde laparoscopische procedures als waardige alternatieven voor de traditionele procedures.

Dankwoord

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Ruim vier jaar later sta ik aan de vooravond van wederom een promotie, maar nu de echte.

Voor pa en ma,
voor al jullie steun en begrip

To Sally,
for your conviviality

1 Introduction

1.1 Minimally Invasive Surgery

Less scar tissue, reduced postoperative pain, shorter hospital stay and a faster return to daily life: The benefits for the patient of the so-called minimally invasive surgery compared to traditional open surgery have been reported extensively (e.g. Cuschieri 1995, Liberman et al. 1996, Kohler et al. 1997, Khalili et al. 1998). Minimally invasive implies that instead of creating a large "invasive" incision in the body to reach the operation area, the surgeon operates via small portals, the so-called trocars, through which thin instruments and a camera are inserted into the body. It is therefore also referred to as

Figure 1.1. Laparoscopic surgery.
A minimally invasive surgical procedure (colectomy) in the abdomen is shown. The surgeon in the middle operates via two thin instruments while looking at a monitor. The image is provided by a camera, held by the assistant at the right side (source: Sjoerdsma 1998).

keyhole surgery. There are many different types of minimally invasive surgery, for example thoracoscopy (minimally invasive surgery in the chest area) and arthroscopy (minimally invasive surgery in the joints). This thesis will focus solely on laparoscopy: minimally invasive surgery in the abdomen. During laparoscopy the patient's abdominal cavity is inflated with gas, most commonly CO_2-gas, to provide enough workspace for the surgeon (Fig. 1.1). Trocars are inserted through the abdominal wall and thin instruments (Fig. 1.2) are introduced through these trocars, together with a laparoscope: the camera that provides the image of the operation area.

Besides the advantages mentioned, minimally invasive surgery is also associated with potential drawbacks, in particular for the surgeon (Treat 1996, Stassen et al. 1998), who is confronted with severe limitations in vision and feeling. Instead of having a direct three-dimensional view on the operating area, the surgeon now has to look at a two-dimensional camera image (Breedveld et al. 2000). Instead of being able to grasp and feel the tissue with his fingers, the surgeon now has to manipulate the tissue via instruments that have limited freedom of movement (Breedveld et al. 1999) and hardly any tactile feedback (den Boer et al. 1999a). Furthermore, the surgeon has to deal with several ergonomic problems, because the operating room and most equipment in it are usually designed for conventional open surgery. Moreover, the surgeon is facing a variety of technical challenges, as with a new surgical technique comes a whole collection of new equipment.

Laparoscopy has developed into an accepted alternative for many conventional surgical procedures particularly during the past ten years, although endoscopic (*endoscopy = look inside*) procedures have already been reported in the very beginning of the twentieth century (Paraskeva et al. 1994). For some types of surgery, such as the

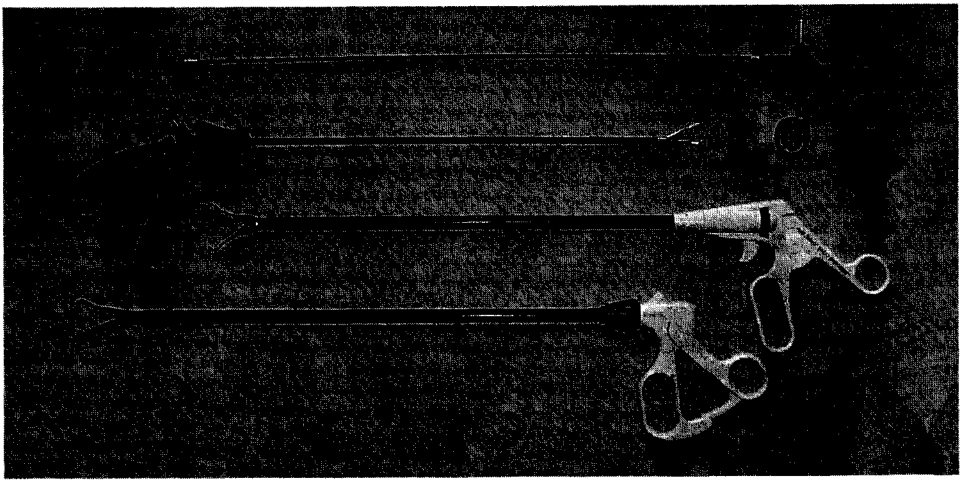


Figure 1.2. Instruments for laparoscopy.
A collection of instruments for laparoscopy. From top to bottom: scissors (Richard Wolf, Ø 3 mm), forceps with ratchet (Aesculap, Ø 5 mm, Babcock grasper without ratchet (AutoSuture, Ø 10 mm), Babcock grasper with ratchet (Ethicon, Ø 10 mm). A ratchet is a mechanism to lock the opening of the jaws of the grasper.

cholecystectomy (gallbladder removal), laparoscopy is now accepted as the *golden standard*. Remarkably, in comparison to other countries in Western Europe, The Netherlands is trailing behind when it comes to the percentages of laparoscopically performed surgery (Prismant 2001). Nevertheless, many Dutch surgeons are embracing this new technique and are consequently confronted with new technical problems. This was one of the reasons why in 1997 the Delft University of Technology started an interdisciplinary research programme on medical engineering called MISIT: Minimally Invasive Surgery and Interventional Techniques. In this programme the Delft University of Technology collaborates with several Dutch hospitals and universities. The programme aims to have the engineers solve the technical problems encountered by the surgeons during minimally invasive surgery.

1.2 Aim of the thesis

During daily practice surgeons often manage to work around technical problems associated with this new technique through experience and ingenuity. As a result, problems avoided in first instance may return later in a disguised appearance. For a clear identification of such problems interaction between surgeon and engineer is indispensable. Of the many technical problems encountered during laparoscopy some are reported to be trivial, whereas others are crucial for the outcome of the surgical procedure. Therefore, the first step of this project has been to identify a number of key problems in laparoscopy, of which 'safe manipulation of the intestines' has been selected as the main topic for further research. The aim of this research has been to improve the jaws of existing graspers used for manipulation of the bowel and to determine which jaw shape provides the best grip on bowel tissue. At the end of Chapter 2 a specific introduction to the chosen research topic will be given.

1.3 Thesis outline

In Fig. 1.3 it is displayed how the set-up of the project is reflected in this thesis. In the initial stage a general exploration of laparoscopic surgery has been performed (Chapter 2). During this stage the main research area has been identified: safe manipulation of the intestines. Within this area a specific research topic has been chosen: improvement of the shape of grasper jaws. The introduction to the chosen research topic, at the end of Chapter 2, starts the report of the core of the project. In Chapter 3 the required functions of a laparoscopic bowel grasper have been identified. From these requirements design criteria have been deducted. This step is described in Chapter 4. Chapter 5 presents the process of developing and testing prototypes that has lead to guidelines for the design of new safe grasper jaws. In this process the performance of elementary jaw shapes has been evaluated. Based on this evaluation, new, more complex jaw shapes were developed. These were also tested and evaluated. From the results of these studies, the guidelines for safe grasper jaws have been derived. In Chapter 6 this design process and the overall project are discussed. In Chapter 7 recommendations for future research are given, as well as a summary of the guidelines and a suggestion for a protocol for the safety assessment of atraumatic graspers. Chapter 8 reflects on the entire project with regard to the achievement of the aims set in the previous section. It has been intended to make this thesis comprehensive for readers with an engineering background as well as for readers from the medical world. Therefore a glossary has been included that explains many of the medical terms as well as many of the technical terms used throughout this thesis. It includes an illustration of the relevant anatomy.

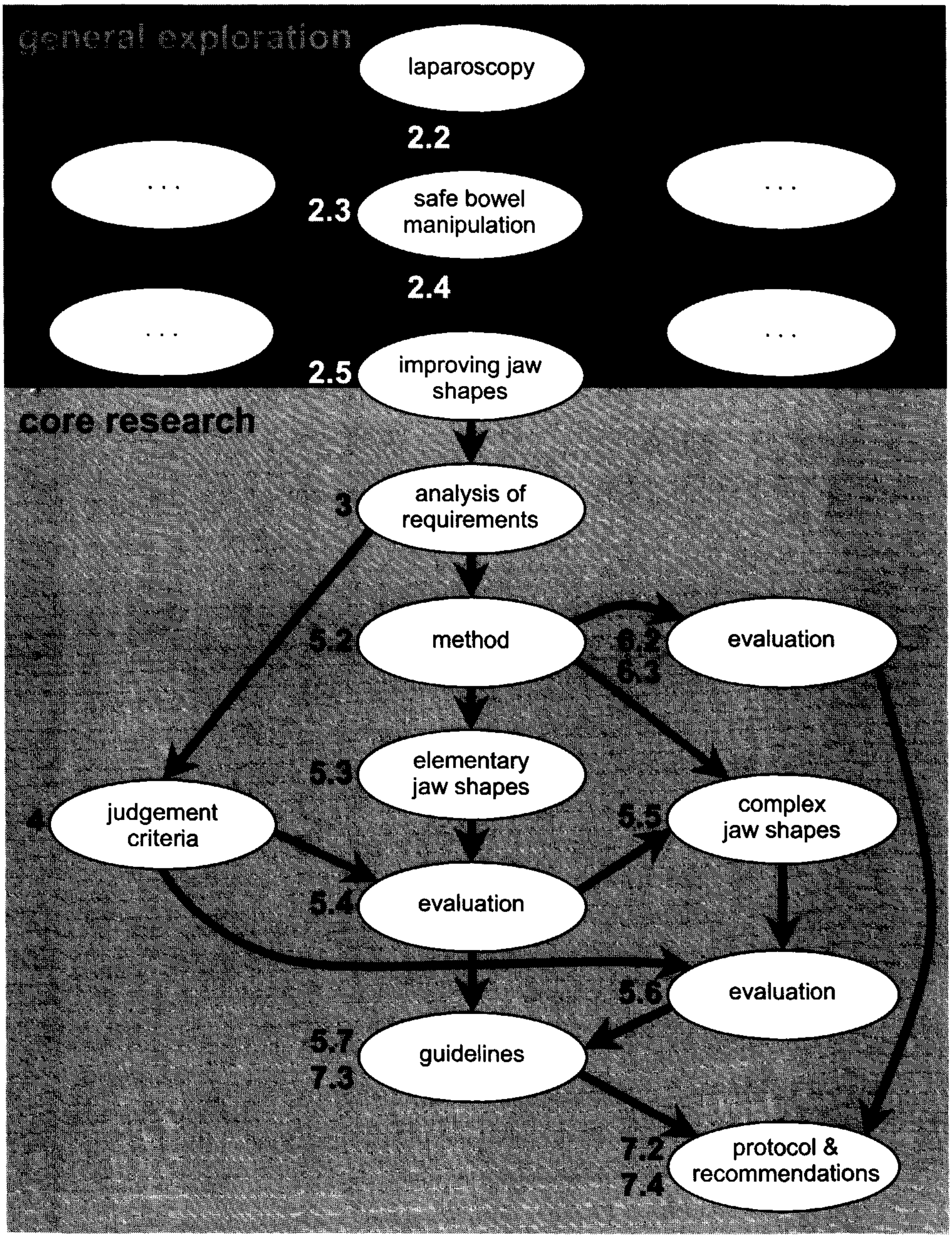


Figure 1.3. Project and thesis set-up.
The project consists of two parts. A general exploration of the laparoscopic field leading to the choice of a specific research topic and a part about the core research on the chosen topic. The numbers indicate the relevant chapters and sections in the thesis.

2 Problems in laparoscopy

Part A: Finding the research topic

2.1 Introduction

In the first part of this chapter several instrument-related problems in the field of laparoscopic surgery are identified and analysed using the so-called clinically driven approach. One of the identified problem areas is selected for further investigation. Within this area, several specific topics are identified and one of them is chosen as the main topic of this thesis. In the second part of this chapter an introduction to the chosen topic is given.

The method for identifying problems is discussed in Sect. 2.2. In Sect. 2.3 an overview is given of potential research areas that have been identified. After selecting a particular research area, the same method is used to decide which topic within this area will be the core subject of the project. Sect. 2.4 describes this process. In the final section an introduction is given to the chosen topic and the goals for the core of the project are identified.

2.2 The clinically driven approach

When a mechanical engineer starts to work in an unknown area, such as the medical field, he needs to choose between two approaches. Either he takes ideas from his own field of expertise and tries to find a medical application for it, or he uses his technological knowledge and design skills to solve a medical problem. The first approach, known as *technology push*, may not be a suitable approach to use in a doctoral project. An existing idea, design or instrument is needed to begin with, and whether or not it will find a useful purpose in the medical field is very unpredictable. The second approach mentioned, known as the *clinically driven approach*, seems to have a better chance of producing useful research. Even if the clinically driven approach yields no successful solution, it will most likely have enriched the insight into the problem under investigation. A failed technology push may provide the engineer with more knowledge of the limitations of the application of his idea or instrument, but it usually offers little to nothing to the medical world or the society. Therefore, the clinically driven approach was chosen as the basis for research and design within the MISIT programme.

The clinically driven approach clearly manifested itself in the opening phase of the project, in which a medical problem had to be chosen, which should be a suitable research topic for a doctoral research project lasting four years.

The first step of the engineer towards the identification of the medical problem to be investigated is getting to know the area of laparoscopic surgery. Besides literature research, a direct confrontation with the medical problems is indispensable. This confrontation has been done in two ways: hands-on training and attendance of surgical procedures. Hands-on experience has been obtained in pelvi-trainers, virtual reality trainers and during basic laparoscopic skill training. It provides a possibility for the engineer to first-hand experience basic problems involved in endoscopic surgery. Besides this training, several dozens of endoscopic operations have been attended throughout the starting phase of the project, to observe how surgeons deal with these problems. The opportunity to discuss the problems as they happen, makes it much easier to understand them. Of each surgical procedure attended a report was written by the engineer and sent back to the surgeon. These reports contain a list of instruments used, a description of the operation procedure including observations of the engineer and problems indicated by the surgeon, and post-operatively arisen questions, ideas and conclusions from the engineer. Usually the contents of these reports were discussed during the next visit to the operating room. An example is shown in Fig. 2.1.

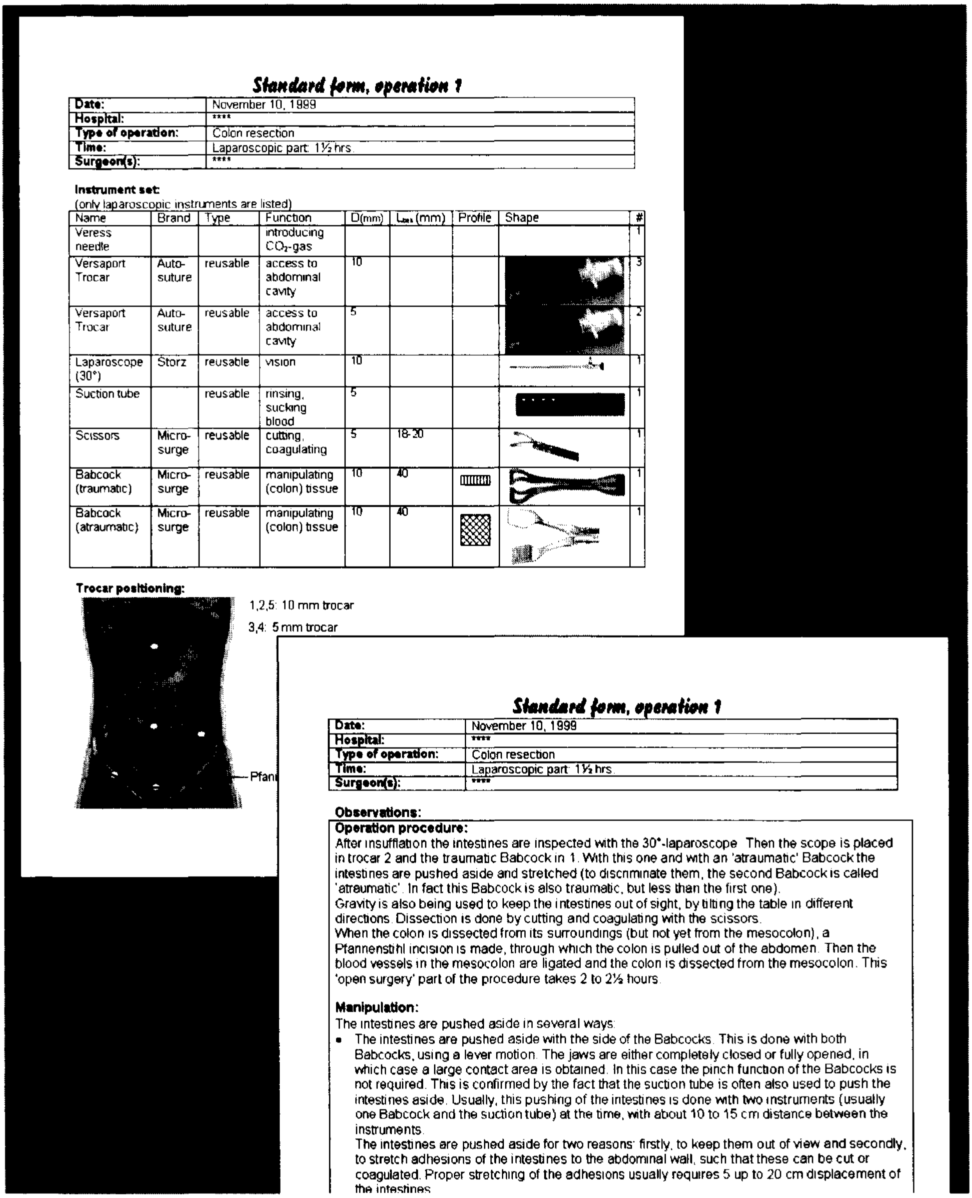
The second step is to identify the possible topics. This has done through literature research, attendance of operations and meetings with surgeons. These meetings were held either as open interviews with one surgeon at a time, or as brainstorming sessions with up to six surgeons. During the meetings, problems observed in literature (den Boer et al. 2001) and in the operating room were discussed, but also the surgeons were given the opportunity to express and discuss other problems that had not yet come to attention.

The final step is to select one topic from all the problems that have been identified. From the literature an estimate of the need for a solution to each of the problems can be made, but decisive in the final choice have been the discussions with the surgeons about the need and usefulness of each topic.

2.3 Possible research areas

Based upon literature search, operation attendance and discussions with surgeons a list has been made of possible research areas in laparoscopic surgery, which has then been discussed in a brainstorming session with six surgeons. This section describes the following areas:

- Reducing the number of actions: combining functions in a single instrument
- Improving tactile feedback in instruments
- Facilitating bowel anastomoses
- Quantifying the tightness of the wrap in Nissen fundoplications
- Removing large organs
- Creating workspace
- Safe manipulation of the intestines



Standard form, operation 1

Date:	November 10, 1999
Hospital:	****
Type of operation:	Colon resection
Time:	Laparoscopic part: 1½ hrs.
Surgeon(s):	****

Instrument set:
(only laparoscopic instruments are listed)

Name	Brand	Type	Function	D(mm)	L_{max} (mm)	Profile	Shape	#
Veress needle			introducing CO_2-gas					1
Versaport Trocar	Auto-suture	reusable	access to abdominal cavity	10				3
Versaport Trocar	Auto-suture	reusable	access to abdominal cavity	5				2
Laparoscope (30°)	Storz	reusable	vision	10				1
Suction tube		reusable	rinsing, sucking blood	5				1
Scissors	Micro-surge	reusable	cutting, coagulating	5	18-20			1
Babcock (traumatic)	Micro-surge	reusable	manipulating (colon) tissue	10	40	▥		1
Babcock (atraumatic)	Micro-surge	reusable	manipulating (colon) tissue	10	40	▦		1

Trocar positioning:

1,2,5: 10 mm trocar

3,4: 5 mm trocar

Standard form, operation 1

Date:	November 10, 1999
Hospital:	****
Type of operation:	Colon resection
Time:	Laparoscopic part: 1½ hrs.
Surgeon(s):	****

Observations:

Operation procedure:
After insufflation the intestines are inspected with the 30°-laparoscope. Then the scope is placed in trocar 2 and the traumatic Babcock in 1. With this one and with an 'atraumatic' Babcock the intestines are pushed aside and stretched (to discriminate them, the second Babcock is called 'atraumatic'. In fact this Babcock is also traumatic, but less than the first one).
Gravity is also being used to keep the intestines out of sight, by tilting the table in different directions. Dissection is done by cutting and coagulating with the scissors.
When the colon is dissected from its surroundings (but not yet from the mesocolon), a Pfannenstihl incision is made, through which the colon is pulled out of the abdomen. Then the blood vessels in the mesocolon are ligated and the colon is dissected from the mesocolon. This 'open surgery' part of the procedure takes 2 to 2½ hours.

Manipulation:
The intestines are pushed aside in several ways:

- The intestines are pushed aside with the side of the Babcocks. This is done with both Babcocks, using a lever motion. The jaws are either completely closed or fully opened, in which case a large contact area is obtained. In this case the pinch function of the Babcocks is not required. This is confirmed by the fact that the suction tube is often also used to push the intestines aside. Usually, this pushing of the intestines is done with two instruments (usually one Babcock and the suction tube) at the time, with about 10 to 15 cm distance between the instruments.
  The intestines are pushed aside for two reasons: firstly, to keep them out of view and secondly, to stretch adhesions of the intestines to the abdominal wall, such that these can be cut or coagulated. Proper stretching of the adhesions usually requires 5 up to 20 cm displacement of the intestines

Figure 2.1. Operation report.
Example of an operation report (translated from Dutch), designed specifically for this project by the engineer. The aim of these reports is to support the identification and discussion of instrument-related problems, not to provide a complete medical description of the surgical procedures. Typically, the operation reports used in this project contain a list of instruments used, a figure of the operating area with the trocar positions (top left), a description of the procedure with the observations made by the engineer (partially shown, bottom right) and a collection of questions, conclusions and remarks of the engineer (not shown).

In the following subsections each of the seven areas is described. Each description contains a short introduction to the subject, the results from the discussions on the subject during the brainstorming session and the engineer's interpretation of these discussions. The subsections mainly describe what has been discussed during the brainstorming session. It has not been the intention to perform a complete medical review of each of the subjects.

2.3.1 Reducing the number of actions: combining functions in a single instrument

Reducing the number of actions during an operation will reduce the number of instrument exchanges, and consequently both the chance of damage caused during these exchanges and the operating time are reduced. One way of reducing the number of actions is creating instruments that are designed to perform a set sequence of actions as a single action, e.g. an instrument that will place clips on the cystic duct and cut it in one action. A second way is to combine independently controllable functions in a single instrument, e.g. forceps that can also be used as scissors, a combination of a laparoscope and a liver retractor for gall bladder and gastric surgery, or bipolar forceps that allow both grasping and sealing of tissue.

Generally, the collaborating surgeons prefer a multifunctional instrument to an instrument that performs a sequence of actions in a single step. The main reason is the need of control over each action. In the example of the cystic duct, the surgeons prefer using an instrument that enables independent clip placement and cutting, allowing the surgeon to check for proper placement of the clips before the cystic duct is transsected. However, cutting the cystic duct is done only once per operation, therefore the development of a special instrument is not expected to be economically feasible. Sealing and cutting of blood vessels is done very frequently during surgery and thus justifies a specially designed multifunctional instrument. Possible instruments recently developed for this purpose are a combination of stapler and scissors, a combination of monopolar forceps and scissors and bipolar scissors. A combination of stapler and scissors is believed to have the advantage of causing less damage to surrounding tissue than the combination of monopolar forceps and scissors or the bipolar scissors, which both seal the blood vessels by coagulation. However, as normal staplers are already quite expensive, a combination of stapler and scissors will likely be too expensive to be economically feasible. An experiment by Den Boer et al. (1999) has shown that sealing of blood vessels is much faster with bipolar coagulation than with monopolar coagulation, thus at the time of the brainstorming session the already existing bipolar scissors seemed to be a better solution than a combination of monopolar forceps and scissors still to be designed.

As several companies were already producing bipolar forceps and scissors for general practice, it was decided not to choose this subject for further study.

2.3.2 Improving tactile feedback in instruments

Instruments with good tactile feedback will improve the safety of manipulation and dissection, because excessive forces will be easier to avoid. To avoid accidental cutting of blood vessels, besides having knowledge of the anatomy and careful dissecting the area of interest, it is important to be able to detect differences in stiffness of the tissue and to palpate pulsations. The latter is not possible with the instruments currently available (den Boer et al. 1999a). Instead, blood vessels within a certain structure are detected by palpating the difference in stiffness between the vessel and the surrounding tissue. The identification of tumours in open surgery is also partially based on the palpation of differences in stiffness between the tumour and the surrounding tissue. However, the differences in stiffness in these circumstances are usually too small to be detected with the laparoscopic instruments currently available.

A method to obtain good tactile feedback, by striving for a very high mechanical efficiency, has already been developed within the Man-Machine Systems Group at the Delft University of Technology and has been implemented in a prototype (Herder 1998). To maintain enough space for innovative research this subject was rejected as a main theme and merely adopted as a possible design strategy.

2.3.3 Facilitating bowel anastomoses

When a diseased part of the bowel has to be resected, the supplying blood vessels have to be ligated. After the resection, the bowel continuity has to be restored by creating an anastomosis, which means that the two remaining ends of the bowel are reconnected. Presently, ligating the vessels, transsecting the bowel and creating the anastomosis are preferably performed outside the body, because it is easier, faster and less expensive. However, it requires a relatively large incision. The fully laparoscopic procedure is beneficial for the patient, in particular for patients with a benign disease, but it is often considered to be too time-consuming and too expensive. For the fully laparoscopic procedure to become a more often used alternative, several requirements have to be met:

- Cutting the blood vessels must be quick, safe and easy.
- The resected part of the bowel should be removed safely through a small incision, otherwise there is no advantage over the easier and cheaper extracorporal approach.
- Creating the anastomosis laparoscopically should ideally be as easy and as fast as extracorporally. The tissue around the anastomosis must remain well perfused. The main complication of anastomoses is leakage, which usually occurs after three to five days. The weak spots through which leakage occurs are believed to be partially caused by biological processes like limited perfusion and local infections.
- Costs should remain as low as possible. In particular the presently available staplers are very expensive. In traditional open surgery extensive research has already been performed regarding stapler systems and therefore substantial literature is available on this subject.

Since already many stapler designs have been developed for intracorporal anastomoses and suturing and because the core problem is mainly biological, this subject was considered less interesting for a doctoral project.

2.3.4 Quantifying the tightness of the wrap in Nissen fundoplications

Patients with GastroEsophageal Reflux Disease (GERD) suffer from a malfunctioning sphincter between the oesophagus and the stomach. When the patient bends over or inhales and the sphincter does not properly close the stomach, the lower pressure in the thorax will cause the stomach acid to rise into the oesophagus, causing symptoms such as epigastric pain, burning chest pain, dysphagia, nausea and vomiting. Generally, 95 % of all patients are adequately managed by medication. For the remaining patients, a commonly used technique to cure the disease is a Nissen fundoplication. With this procedure the function of the sphincter is supported by wrapping the top of the stomach, the fundus, around the oesophagus. In open surgery this technique has shown excellent results, but in a recent randomised trial from The Netherlands the results of laparoscopic Nissen fundoplications were disappointing, because in about ten percent of the patients the wrap was too tight around the oesophagus. This leads to dysphagia and in some patients a second operation will be necessary.

A standard rule for this procedure is: The looser the wrap is put around the oesophagus, the better it is. Of course, this is only true to a certain extent: If the wrap is too loose, it will lose its supporting function. The fundus should be dissected far enough from its surroundings that it will easily remain in position when placed around the oesophagus, and no tension should be present in the wrap. In open surgery this is generally tested by checking whether the surgeon can stick his thumb and index finger between the wrap and the oesophagus. Since in laparoscopy this is not possible, another way of measuring the tightness of the wrap is required. The group of professor Buess at the University of Tübingen in Germany is already developing a sensor for this purpose (Kalanovic et al. 2000).

It appears as if there are two approaches in laparoscopic Nissen fundoplications. In the first one, a plug is placed inside the oesophagus before the wrap is created. It is assumed that the wrap will be loose enough around the oesophagus once the plug has been removed. In the second approach, no plug is used and dissection of the fundus should be continued until it can be wrapped loosely around the oesophagus. The first approach has the disadvantage that there is no guarantee that the wrap will be loose enough once the plug has been removed, and in both approaches the definition of 'loosely' is not very clear. It is the engineers' opinion that the main need in the procedure is a reproducible protocol.

Since there is already a group working on a sensor for the wrap tightness and because it is believed that the procedure will actually benefit more from a thorough analysis leading to an improved protocol than from new instruments, this subject was rejected for further study.

2.3.5 Removing large organs

Removal of large organs or organ parts often requires a relatively large incision. If the organ could be put in a bag inside the body and then ground, it could be removed through much smaller incision. Clearly, the grinding should be done in such a way that the bag cannot be damaged to avoid spreading of organ parts into the abdominal cavity, which can cause severe metastases.

Being able to safely grind an organ inside a bag and remove it through a small opening would only be beneficial in benign cases. In fact, this is already being done during some procedures. For malignant cases grinding of the organ part that contains the tumour is not acceptable, because the tumour has to remain intact for staging and pathological examination. Furthermore, even if the risk of organ parts spreading into the abdominal cavity is low, because of the severe consequences of metastases, most surgeons are reluctant to use a grinder and a bag inside the body. Because of this opposition this subject was not chosen.

2.3.6 Creating workspace

Creating the workspace needed for endoscopic surgery without using gas would have several advantages: no need for special, gas proof instruments, less disturbance of the haemodynamics, possibly less spread of tumour cells and thus less metastases, and less dehydration of the tissue, in particular the peritoneum. Also in most extra-peritoneal areas the use of gas is not possible because there is no barrier like the peritoneum to restrict the gas to the working area. Main disadvantage of gasless laparoscopy is the reduced workspace, since the available mechanical abdominal wall lifters cannot provide an equally distributed pressure and do not push the intestines down like gas does. Consequently, the intestines will block a large part of the workspace as well as the view upon the workspace. For extra-peritoneal procedures such as a hernia repair the intestines clearly do not pose a problem. For these procedures, already instruments are available that use a balloon to create extra-peritoneal workspace. However, in cases with many adhesions, this way of creating space often will not work.

Since already many different mechanical abdominal wall lifters exist, and as there is no consensus about the preference of gasless over normal laparoscopy (yet), this subject was also not chosen.

2.3.7 Safe manipulation of the intestines

For dissection of the intestines and attached tissues such as adhesions it is necessary that they can be stretched, held out of the view of the endoscope for long periods of time and positioned in such a way that they are easily accessible for dissection instruments, like forceps or scissors.

Preferably, grasping, stretching and positioning should all be done with one instrument, which would considerably reduce the number of instrument exchanges. This would reduce the risk of damage being caused to the intestines and it would reduce the operating time. Presently the three tasks are generally performed with so-called Babcocks (Fig. 2.2). However, according to the surgeons the chance of damaging the intestines with these Babcocks is considerable, in particular when the instruments are rotated about their longitudinal axis. In such situations the relatively sharp side edges of the Babcock's jaws will come in contact with the delicate tissue of the intestines or with other organs in the vicinity, for example the liver. One of the surgeons mentioned that for that reason he never lets assistants use a Babcock. The assistants are only allowed to hold the instrument in position; the surgeon performs all manipulations and changes of position, which is quite inconvenient.

Special instruments (Fig. 2.3) are already available for holding the intestines out of sight of the endoscope, but they are not very popular among the surgeons who fear the risk of the intestines getting damaged between the fingers of the fan. None of the collaborating surgeons had any experience with an alternative (Milsom et al. 1997) in which the fan is placed inside a bag, which eliminates the risk of tissue getting caught between the fingers. The surgeons believe that no particular attention needs to be given to the further development of this function, since it is expected that with instruments capable of safely grasping and manipulating the intestines it will also be possible to hold the intestines out of sight of the endoscope without damaging them.

In the area of safely manipulating the delicate intestines the surgeons would greatly appreciate improvements of the instruments, as that would make the operations safer and easier. Because of the importance of this subject and the possibilities of improvement in this area, it has been chosen as the basis for the doctoral research.

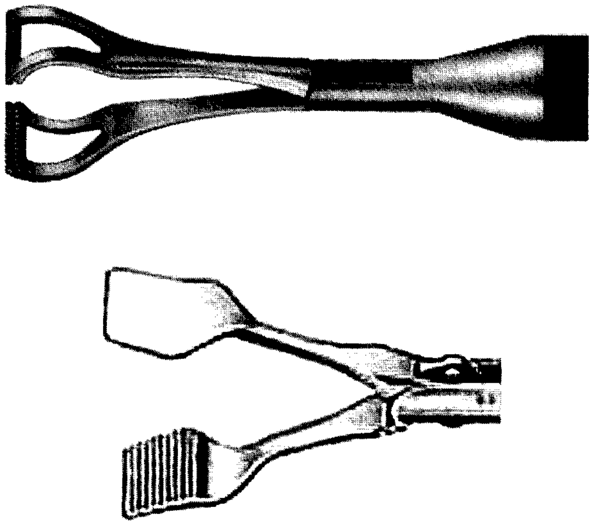


Figure 2.2. Different types of Babcocks.
Babcocks are used for handling delicate organs. Many types exist, either classified as traumatic (top figure: REMA 28-123-208), or as atraumatic (bottom figure: Storz 33510BL).

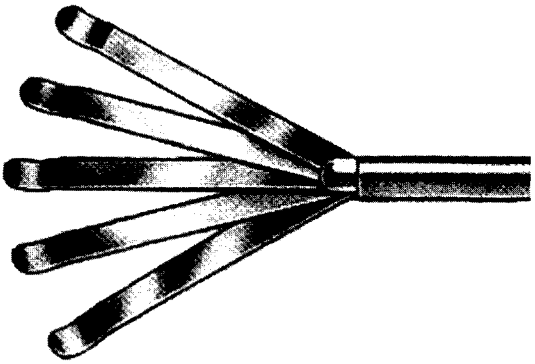


Figure 2.3. Fan for keeping intestines out of sight of the endoscope.
Model from the Karl Storz company (Storz 26173FP).

2.4 Chosen research area: Safe manipulation in laparoscopic colon surgery

After the research area was selected, borders had to be set for what should and what should not be included in the research. The question arising was whether the doctoral research should focus on development of a full instrument, or a part of it. To answer this question, another brainstorming session has been organised. During this session a large number of design ideas has been discussed, some of them full instruments, others just parts. They are shown in Fig. 2.4 and listed below:

- Large jaws (Fig. 2.4a): Increasing the contact area will decrease the pressure on the tissue, and thus reduces the risk of damaging it. The size of the jaws is limited by the size of the trocar and the working area.
- Embracing jaws (Fig. 2.4b) have the advantage of not transferring force through friction, so there is no need for large pinch forces. However, grasping around the colon has several disadvantages. It requires very large jaws, which may put unacceptable demands on the size of the trocars and the workspace. Furthermore, before such large jaws can be placed safely on the tissue, sometimes already dissection is required. Finally, it will often not be possible to see all the tissue that is being grabbed and potentially damaged.
- Grasper with thumb (Fig. 2.4c). This would allow stretching of the mesentery or mesocolon with a single instrument. However, the surgeons prefer two separate instruments for better independent manipulating possibilities, and they expect that the slippery bowel will often slide off the thumb.
- Balloons (Fig. 2.4d) provide a homogenous distribution of the pinch force and a large possible contact area. Disadvantages are the lacking ability to feel small objects, the difficulty of sterilising the balloons, which thus will have to be disposable, and complexity of the instrument.

- Suction cups (Fig. 2.4e). Instead of pinching to create friction to transfer manipulation forces to the tissue, this could also be achieved by suction to create a negative pressure component. A similar system is in use for heart stabilisation (Borst et al. 1996). The surgeons expect that the negative pressure may cause extensive damage to the bowel tissue. A normal grasper with the possibility of low pressure suction to support the grip would be a better idea, but this would yield a rather complex instrument.
- Multi-phalangal jaws (Fig. 2.4f) also have the advantage of not needing friction and the high pinch forces involved to grasp an organ. To avoid a complex control, the fingers should be controlled with a single motion and find the best grip around the organ themselves. This type of control has already been applied successfully in a prototype of a hand prosthesis (de Visser and Herder 2000). Frank and Cuschieri (1997) already developed a multi-phalangal grasper, which is now in production by The Karl Storz company, but because of the high price due to its complexity, sales so far have been very limited.
- Parallel jaws (Fig. 2.4g) provide a large contact area and homogenous distribution of pinch force. Tactile feedback and complexity may be a problem, but the surgeons expect to be able to safely grasp delicate organs with such an instrument. The Karl Storz company has this model in its collection, but for the same reasons as the multi-phalangal grasper, enthusiasm is limited.
- Placing loops around the bowel would allow the surgeon to grab the loop instead of the bowel itself. However, placing the loops would require that the bowel is already at least partially dissected from its surroundings. This implies that the bowel already needs to be grasped before this technique of safely grasping the bowel can be applied. Thus, this method seems not to be very useful.
- Gluing loops to the bowel would also allow grabbing of the loops instead of the bowel itself. However, gluing onto the wet bowel surface is expected to be very difficult. Also, it would require gluing a new loop on every point where the surgeon wants to grasp the bowel. This would result in a large number of additional actions and a lot of extra operating time. Furthermore, using glue in the abdomen may increase the risk of developing postoperative adhesions, which can cause severe complications.

In literature and in patent databases many ideas similar to the ones mentioned here can be found, but only very few have ever become successful. The most common reason for this is that most of these ideas require such complex instruments that the cost-benefit ratio is too unfavourable for most hospitals.

This has been one of the main reasons to decide not to direct the research towards designing new instruments for bowel manipulation but towards improvement of existing instruments. Improvements can be done in three main parts of each laparoscopic (grasping) instrument: the interaction between the surgeon and the instrument in the handle, the transmission of forces within the instrument in the shaft and the interaction between the instrument and the tissue at the jaws. Improvement of the handle requires a great knowledge of ergonomics. It is currently being done in several research laboratories, e.g. the department of Industrial Design of the Delft University of Technology (van Veelen and Meijer 1999). In the previous section already the research performed within the Man-Machine Systems Group concerning improved force transmission has been mentioned. Therefore, the third aspect mentioned, the interaction between instrument and tissue, has been selected as the main topic for this project. Little is known about what happens when the instrument makes contact with the tissue: How damage occurs, what type of instrument will lead to which kind of damage, what type of damage will lead to serious problems, which grasper shapes are best suitable for safe manipulation of delicate tissues etc. The collaborating surgeons agreed that this important deficit needs further attention. It has therefore been chosen as the core issue for further research.

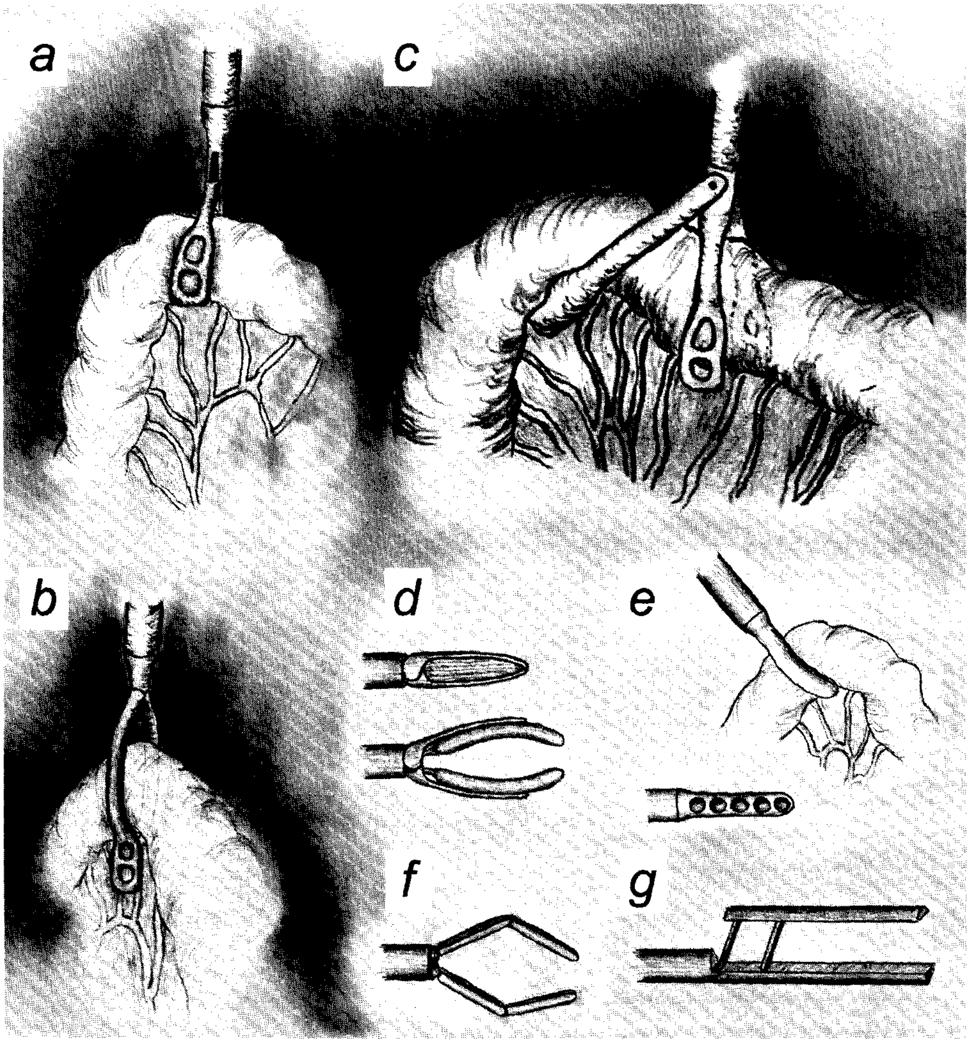


Figure 2.4. Collection of alternative grasper designs.
a. large jaws, b. embracing jaws, c. grasper with thumb, d. balloons, e. suction cups, f. multi-phalangal jaws, g. parallel jaws).

Part B: Introduction to the chosen research topic

2.5 Improvement of existing grasper jaws

It has been decided to aim this doctoral research at the improvement of the shapes of the jaws of the graspers used for grabbing and manipulating the colon (the large intestine), which is considered to be one of most delicate organs in the human body.

Less than two percent of all colon operations in The Netherlands are performed laparoscopically (Prismant 2001). The main reason for this low percentage is that laparoscopic bowel resection is not generally accepted for malignant tumours. Another important reason is believed to be the lack of safe, reliable instruments to manipulate the colon with. Furthermore, laparoscopic colon surgery is considered to be one of the most challenging laparoscopic procedures, because even though the reported occurrence of damaging the delicate colon is not high (below 1 %, Schrenk et al. 1996, Bishoff et al. 1999), the consequences can be tremendous, as perforations of the colon can be lethal. A perforation of the colon wall will result in leakage of the colon contents into the abdominal cavity, which can cause peritonitis, which sometimes leads to abdominal sepsis and even death. Perforations can occur during the procedure and if recognised be healed by closing the defect and sometimes even perform a diverting ileostomy for safety. However, perforations can also occur several days after surgery, which would require a second operation, with the previously mentioned risks and additional costs. The severe consequences of a colon perforation make laparoscopic colectomies feasible only for experienced laparoscopic surgeons. Surgeons with limited experience often lack the confidence to handle organs that can be damaged so easily with instruments that provide hardly any tactile feedback and with an operation technique that has severely reduced visual feedback compared to traditional open surgery. The lack of tactile feedback (den Boer et al. 1999a) is caused by the large internal friction in the presently available instruments (Sjoerdsma et al. 1997). As a consequence, to ensure good grip on the tissue, the surgeon will generally use a larger pinch force than necessary. Only through experience he will be able to minimise his pinch force. Besides the lack of feedback, the instruments often cause dangerously high pressure peaks in the organ tissue during pinching, because the pinch force is badly distributed over the area of contact between the instrument jaws and the tissue. A bad distribution of the pinch force can have several causes. First of all, if the instrument is placed in a not optimal position to the tissue, it is possible that only the edge or the tip of the jaws will be in contact with the tissue, reducing the contact area to a small contact line (Cartmill et al. 1999). A not optimal positioning is often unavoidable due to the restriction of instrument movements caused by the position of the trocars and the limited mobility within the rigid instruments (Breedveld et al. 1999, Treat 1996). Secondly, in many instruments the sides and the back of the jaws possess sharp edges or points. These parts are not supposed to come in contact with the tissue, but inevitably they will during the surgical procedure. Usually, a lot of effort is put into equipping the jaws with profiles to ensure a good and 'atraumatic' grip, but as little attention is given to a proper finishing of the sides and back of the jaws, potentially damaging edges will remain present (Bannenberg et al. 1994, Marucci et al. 2000). Finally, the profiles, introduced to obtain grip on the slippery tissue, sometimes do more harm than good. Often the profile possesses unnecessarily sharp points, in particular at the edges of the jaw where the profile pattern is simply cut off without any chamfering or rounding. This in combination with a not optimal positioning may cause all pinch force exerted by the jaws of the instrument to be transferred to the tissue through only one or two of the profile's edges, again reducing the effective contact area between instrument and tissue to a tiny fraction of the entire surface area of the jaws.

Clearly, a large improvement can already be made by altering and optimising the grasper jaw shapes without turning to completely new techniques as described in Sect. 2.4. Many aspects like the profile structure, the chamfering or maybe even the instrument material can be altered to improve the jaws.

In the next chapter an analysis will be made of the functions a laparoscopic grasper should be able to fulfil and of the forces involved. In Chapter 4 a criterion will be determined, which enables quick objective comparison and judgement of new designs of grasper jaws with regard to their grip and 'atraumaticity'. Such a criterion is required because testing the influence of multiple parameters is difficult and time-consuming and because the complexity of the organic material to be handled makes it impossible to simply calculate the optimal interaction between instrument and tissue. Chapter 5 deals with the comparison of basic jaw shapes, the extrapolation of these basic shapes to more complex ones and the comparison of them with existing jaw shapes. In the final chapters a discussion of the findings from these studies is presented (Chapter 6), as well as recommendations for future research and guidelines for instrument design (Chapter 7), in an attempt to answer the question: "Which jaw shape provides the best and safest grip on the delicate and slippery bowel tissue?"

3 Analysis of a laparoscopic bowel grasper

3.1 Introduction

In this chapter the requirements for a safe laparoscopic bowel grasper are identified and analysed. It will be shown that in the fulfilment of the main function of a grasper two types of forces play a key role: a pull force that needs to be imposed on the tissue, and a pinch force that is required for the transmission of the pull force from the instrument to the tissue.

The identification of the required functions of a grasper and the forces involved is done in Sect. 3.2. Sect. 3.3 investigates the mentioned pull force, while Sect. 3.4 addresses the pinch force.

3.2 Required functions of a laparoscopic bowel grasper

Interviews with surgeons and observations during surgical procedures revealed that there are two functions of a laparoscopic bowel grasper that are particularly important. The first one is moving the intestines out of the laparoscopic view. The second one is grabbing and moving the colon to stretch structures connected to the colon, for example adhesions and the mesocolon, in such a way that dissection can be performed. The fulfilment of the first function (moving the intestines out of sight) requires a force estimated to be roughly equal to the weight of the part of the intestines that is being moved. The fulfilment of the second function (stretching connected structures) requires a much larger force, since this force includes a pull force for the actual stretching of the connected structures as well as the weight of the colon part. For this reason it was assumed that with any instrument that allows safe pulling of the colon in order to stretch attached structures, it will also be possible to safely move intestines out of sight. Therefore, sole focus can be given to the safe fulfilment of the 'stretching' function, since during this stretching the largest forces are imposed upon the colon and thus the risk of damaging the organ is the greatest.

As mentioned, soft structures like the mesocolon or adhesions can only be dissected if they are stretched. Cutting a soft structure requires a certain tension within the material, otherwise one will merely be pushing it aside. These structures are attached at one side to the colon and at the other side to the rest of the body, for example the abdominal wall. Therefore, usually the only way to introduce this tension into the structures is by pulling on the colon. The required (pull) force is transmitted to the colon by the laparoscopic grasper. If this instrument could grasp completely around the colon and apply the force directly to the attached structure, the colon would not be burdened at all. However, this demands not only a very large instrument, which is very impractical in the limited working space involved in laparoscopy, but also a very flexible instrument in order to be able to grab around the large bowel from any given direction. Such an instrument would require several hinges or pivoting points within the abdomen to provide the additional degrees of freedom required, and would thus be very complex and expensive. Therefore, it seems more feasible to grab onto the colon and transmit the pull force via the colon to the attached structures.

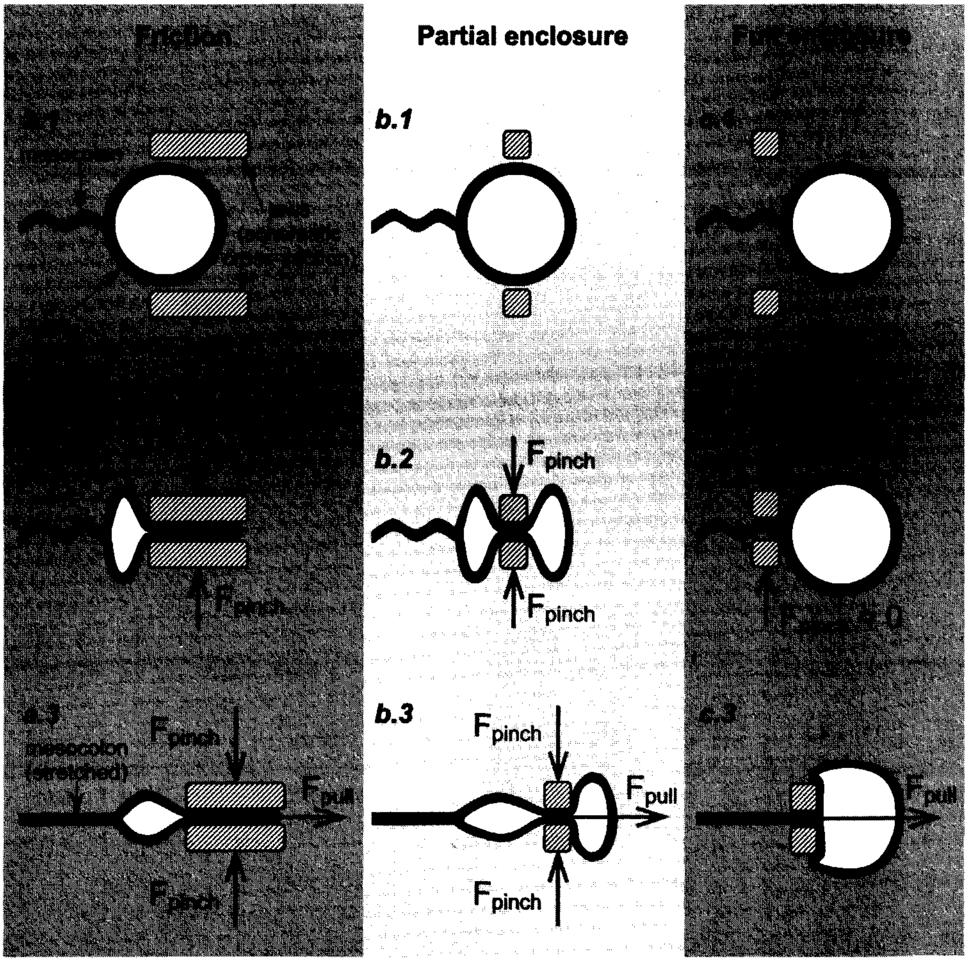


Figure 3.1. **Transmitting a pull force onto the colon.**
Schematic representation of three ways of transmitting a pull force onto the colon: a. through friction, b. through partial enclosure, c. through full enclosure. Step 1: no forces applied, step 2: only pinch force applied, step 3: pinch and pull forces applied.
Full enclosure is usually not feasible because it would require very large jaws. Therefore, whenever there is talk of 'enclosure' in the text, actually 'partial enclosure' is meant.

Transmission of the pull force from the instrument to the tissue is usually done either through friction, as shown in Fig. 3.1a, or through partial enclosure, as shown in Fig. 3.1b. Full enclosure, like in Fig. 3.1c, is usually not feasible, as explained before. In partial enclosure part of the transmission is being done through friction as well, but for ease of conversation it will be referred to as simply 'enclosure'. In both cases a certain pinch force is needed to transmit the pull force. The magnitude of this required pinch force depends on two things. Firstly, it depends on the magnitude of the pull force that is to be transmitted. Secondly, it depends on how the pull force is transmitted, or in other words, on the design of the grasper jaws. Therefore, the first thing that needs to be determined, is the magnitude of the pull force that is required for proper tissue stretching. After that, the influence of the jaw design and the pull force on the required pinch force can be investigated.

Evidently, a safe laparoscopic grasper should be able to apply the required pinch force without causing damage to the tissue. It is therefore important to know which pinch force is maximally allowable without causing damage, and how this maximally allowable pinch force is influenced by the design of the jaws and the magnitude of the pull force.

The next section describes the determination of the pull force that needs to be transmitted onto the tissue. Sect. 3.4 will then elaborate on how the jaw design and the pull force influence both the pinch force that is minimally required to transmit the pull force and the pinch force that is maximally allowable without causing damage to the colon.

3.3 Required pull forces

This section describes how the pull force, required to stretch the mesocolon sufficiently for dissection, was determined in a small series of experiments. The text is derived from an article published by the author of this thesis (de Visser et al. 2002).

Materials and Methods

Pre-experiment analysis

In literature little could be found on the forces applied to the intestines during surgery. Frank et al. (1995) determined the forces needed to clamp the small intestine, but in this study no pull forces were present. Toledo et al. (1999) calculated which forces occur at the end of a laparoscopic instrument during the performance of several tasks. In that experiment no distinction between the manipulated organs was made. This will, however, have consequences for the forces used and in our study only the forces used specifically for colon manipulation are of interest. Furthermore, the mentioned measurements were done in a laparoscopic setting. The restriction of instrument movements caused by the fixed entry points (*trocars*) and the limited mobility within the rigid instruments reduce the accessibility of the organs in the abdominal cavity. Consequently, both the trocar placement and the design of the used instruments affect the magnitude of the applied

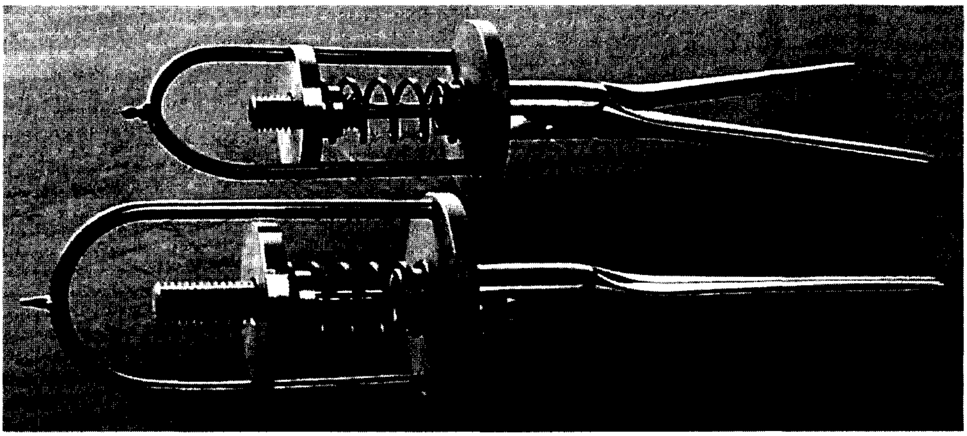


Figure 3.2. Clamps used in the experiments.
The clamps used are modified laparoscopic 'Kocher' clamps (REMA 28-150-000). The spring provides the pinch force, which can be adjusted by turning the small disc.

Figure 3.3. Set-up of the experiment.
The left figure shows how the mesocolon is stretched by application of pull forces onto the colon, via the spring scales and clamps. The right figure demonstrates the recording of the position of the clamps with the Palpator.

forces. Therefore, an "open surgery" set-up was chosen for the experiments. Without the movement restrictions and instrument limitations present, it is expected that the magnitude and direction of the forces in the ideal configuration are obtained. From the force directions guidelines for optimal trocar placement can be derived. Furthermore, using the "open set-up" method, the results will be relevant not only to laparoscopy, but to general surgery as well.

Set-up of the experiments

In total four experiments were performed by different surgeons from the Academic Medical Center in Amsterdam. Two of the surgeons were experienced laparoscopic surgeons, the other two were surgical residents. The experiments were conducted on just-terminated pigs, weighing 20 to 25 kg. Each time the surgeon was asked to apply the appropriate amount of force to the colon that would sufficiently stretch the attached mesocolon enough to be dissected, which in surgery has to be done when (part of) the colon needs to be removed. It was done on four different locations on the pig's colon, two on the cecum and two on the sigmoid. These locations were chosen because of the good resemblance with the human colon and because the cecum is regarded to be the most vulnerable part of the colon. On each of the mentioned locations the following procedure was repeated three times (except for the first surgeon: he did five repetitions, but this number was then lowered to three, to shorten the experiment time).

The surgeon was asked to place two clamps on the colon in a way that he thought to be adequate for sufficient stretching of the attached mesocolon. The clamps (Fig. 3.2) were modified to give a constant and reproducible pinch force. The pinch force was set to the lowest possible force that still prevented slipping. Spring scales were attached to the clamps. The surgeon was asked to apply, via these spring scales, enough force to the bowel to stretch the mesocolon. The magnitude of the forces was read from the spring scales with an accuracy of 0.1 N. Using the "Palpator", a 3D-position measuring device (van der Helm et al. 1991), the co-ordinates of the top and bottom ends of both spring scales were registered with an accuracy of 1 mm. From these data, the magnitude, direction and application points of the forces on the colon could be calculated. In order to be able to determine the displacements required for stretching, the positions of the clamps were also registered before the surgeon applied the pull forces. The set-up of the experiment is shown in Fig. 3.3.

Force determination

The magnitude, direction and application points of the forces on the colon were calculated as shown in Fig. 3.4. The co-ordinates of points P and Q were recorded with the "Palpator", as shown in Fig. 3.3. With the co-ordinates of these two points, the force F_{hand} read from the spring scale, the known length of the clamp and the known weight W of the clamp, the co-ordinates of point R and the magnitude and direction of force F_{pull} can be calculated by assuming static force and moment equilibrium.

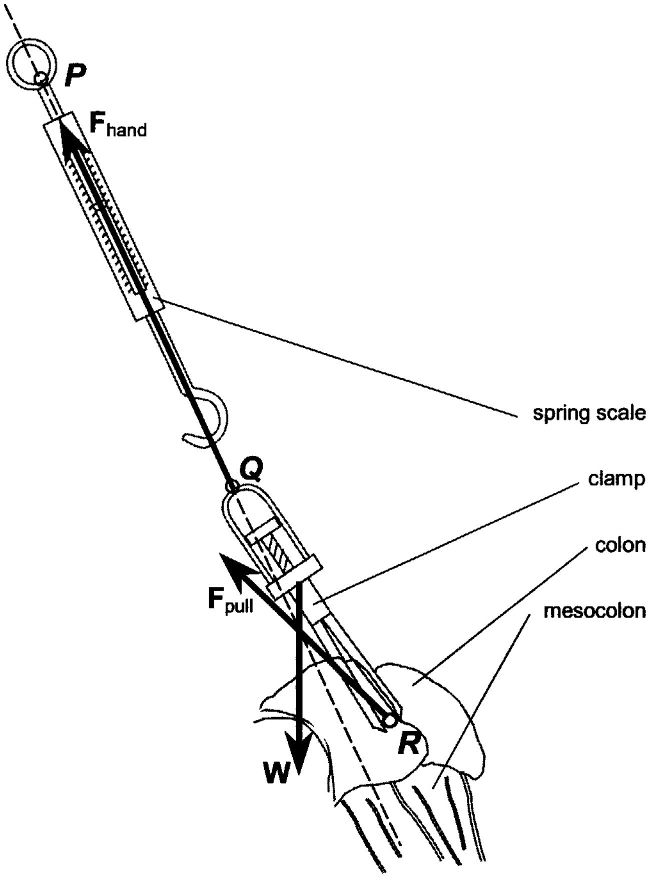


Figure 3.4. Determination of the pull force.
The pull force F_{pull} and its application point R can be calculated when the points P and Q and the forces F_{hand} and W (the weight of the clamp) are known.

Results

The results are presented in three graphs: one with the forces required to stretch the part of the mesocolon that is attached to the cecum, one with the forces required to stretch the part of the mesocolon that is attached to the sigmoid, and one with the displacements required for stretching.

Unless indicated otherwise, all values are given as an average value and a standard deviation, for example 2.4 ± 1.1. All forces are given in Newtons (N), all angles in degrees (°) and all displacements in millimetres (mm). All directions are defined by two angles, γ and ϕ (Fig. 3.5). For all measurements the total averages of all surgeons and the separate averages per surgeon are given.

The average pull force (per clamp) to stretch the mesocolon connected to the cecum for all surgeons combined was 2.4 ± 1.1 N. The maximum pull force measured was 4.7 N. In Fig. 3.6 the average magnitudes and directions of the pull forces applied by the left (F_L) and right hand (F_R) are shown for all surgeons combined (T) and for each surgeon

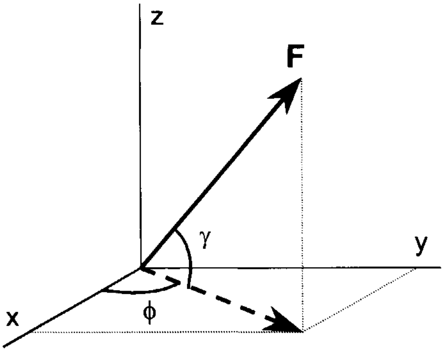


Figure 3.5. Definition of the direction of a force F.
γ is the angle between F and the horizontal xy-plane. ϕ is the angle between the dashed projection of F on the xy-plane and the x-axis. The x-axis points in the transverse direction, the y-axis towards the pig's tail.

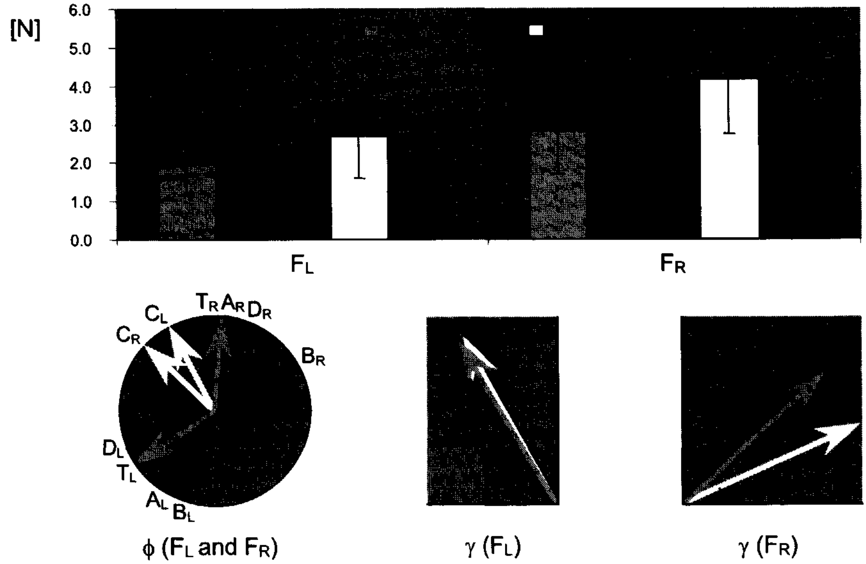
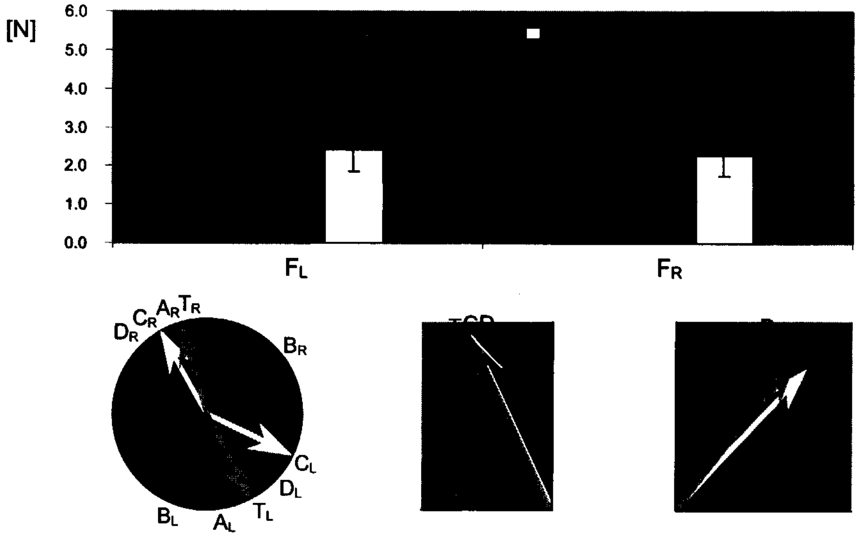


Figure 3.6. Forces on the cecum.
Top figure: magnitude of the pull forces applied to the cecum by the left (F_L) and right hand (F_R). The total averages for the left and right hand are given, as well as the averages per surgeon (A, B, C, D). Bottom figures: directions ϕ and γ (see Fig. 3.5) of the pull forces applied to the cecum by the left (F_L) and right hand (F_R). The total averages for the left (T_L) and right (T_R) hand are given, as well as the averages per surgeon for the left hand (A_L, B_L, C_L, D_L) and the right hand (A_R, B_R, C_R, D_R).

separately (A,B,C,D). A and B are the experienced laparoscopic surgeons, C and D are the surgical residents.

For the sigmoid the average pull force (per clamp) for all surgeons combined was 1.9 ± 0.6 N. The maximum pull force measured was 3.1 N. Fig. 3.7 gives the average pull forces per hand (F_L and F_R) for the sigmoid. From Figs 3.6 and 3.7 it can be seen that the two experienced surgeons (A and B) applied approximately the same forces. One resident (C) applied slightly higher forces whereas the other resident (D) used forces that were considerably lower.

Fig. 3.8 gives for cecum and sigmoid the displacements of the tip (point R in Fig. 3.4) of the left (d_L) and the right (d_R) clamp required for stretching. It also shows the distance (D_{LR}) between the application points of the pull forces F_L and F_R, i.e. the distance between the tips of the two clamps. The average displacement for the cecum was 44 mm, for the sigmoid 33 mm. The average distance between the clamps was quite similar: 80 mm for the cecum and 86 mm for the sigmoid.



ϕ (F_L and F_R) γ (F_L) γ (F_R)

Figure 3.7. Forces on the sigmoid.

Top figure: magnitude of the pull forces applied to the sigmoid by the left (F_L) and right hand (F_R). The total averages for the left and right hand are given, as well as the averages per surgeon (A, B, C, D). Bottom figures: directions ϕ and γ (see Fig. 3.5) of the pull forces applied to the sigmoid by the left (F_L) and right hand (F_R). The total averages for the left (T_L) and right (T_R) hand are given, as well as the averages per surgeon for the left hand (A_L, B_L, C_L, D_L) and the right hand (A_R, B_R, C_R, D_R).

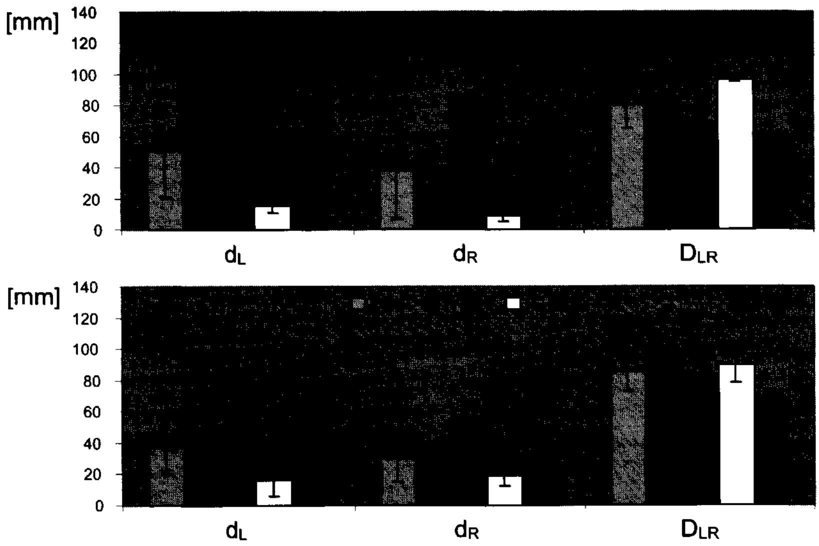


Figure 3.8. Displacements.
The displacements of the tip of the left (d_L) and right (d_R) clamp (point R in Fig. 3.4) during stretching and the distance between the tip of the clamps when the mesocolon is stretched (D_{LR}). The total averages of all surgeons are given, as well as the averages per surgeon (A, B, C, D).
Top figure: cecum, bottom figure: sigmoid.

Discussion

In the study of Toledo et al. (1999) the forces at the end of a laparoscopic instrument during the performance of several tasks were calculated. A pull force of 9.3 N was reported. This is nearly four times the average and nearly twice the maximum force found in the experiments presented here, which can be explained as follows:

Firstly, in Toledo's study it was not mentioned which organs were pulled. As mentioned earlier, the weight of the organ can have a large influence on the magnitude of the force required to manipulate it. Secondly, both force feedback and visual feedback are much less impaired in the open set-up used than in a laparoscopic setting (Breedveld et al. 1999; den Boer et al. 1999a). It is therefore assumed that in the open set-up the surgeons will be better able to minimise the required forces than in a laparoscopic set-up. Thirdly, in the presented experiments no movement limitations were present. This allowed the surgeons to ideally place the clamps and apply the forces. And finally, it appears that in Toledo's study a single instrument was used, whereas in the presented experiments always two graspers were used. An estimation of the required pull force when only one instrument would have been used for stretching might be obtained by adding up the two pull forces F_L and F_R. However, it should be realised that if only one grasper would have been used, the used force might not be as high as the calculated estimation because it is likely that the surgeon would choose to stretch only a smaller part of the mesocolon each time.

To stretch the mesocolon connected to the sigmoid, all surgeons used a lower force than for the cecum. An explanation for this is that, in order to stretch the mesocolon, the colon is partly lifted and pulled. Therefore the force measured also includes the weight of that colon part. If the sigmoid is smaller and lighter than the cecum, the pull force will also be smaller.

The highest force measured was mentioned to be 4.7 N. In fact one surgeon once used a slightly higher force than that, but claimed not to be actively using that hand for stretching of the mesocolon at that time. It was therefore classified as not being a 'required force'.

Besides the pull forces, required to stretch the mesocolon, the 'unstretched' forces were also recorded. These were the forces required to lift the colon, such that the clamps were no longer resting on the other organs, but not yet stretch the mesocolon. The intention was to use the calculated force increase and displacements required for stretching to calculate an estimation for the tissue's stiffness, being the difference between the 'unstretched' and the 'stretched' force divided by the displacement from 'unstretched' to 'stretched'. However, a large variation in the 'unstretched' forces was observed, possibly indicating that this task was not clearly enough explained. Whereas surgeons B and D hardly raised the clamps for the 'unstretched' measurements, surgeon C used much larger forces, already slightly stretching the mesocolon. This explains the differences in the displacements shown in Fig. 3.8: surgeons B and D needed large displacements to get from 'unstretched' to 'stretched', whereas surgeon C only needed small displacements to do this.

Figs 3.6 and 3.7 show that the two pull forces F_L and F_R usually are at an angle of 40 to 70° to the horizontal plane. From the directions of these forces the angle between them can be calculated. It turns out that this angle is virtually the same for both locations (cecum: 60 ± 14°, sigmoid: 62 ± 12°). Fig. 3.8 shows that the distance between the application points of the two pull forces is also virtually equal for both locations (cecum: 80 ± 16 mm, sigmoid: 86 ± 12 mm). For laparoscopic surgery this suggests that for an ideal force application with minimised loads on the tissue, the trocars should be placed such that the grasping instruments reach the operation area at an angle of about 40 to 70° and approximately 60° relative to each other, with about 80 mm distance between the instrument tips. Hanna et al. (1997) reported virtually the same angles to be optimal for endoscopic intracorporal knotting.

Conclusions

This study showed that surgeons apply with each clamp a force of approximately 2.5 N on average and 5 N maximal to the colon to stretch the mesocolon sufficiently for dissection. It is therefore concluded that a safe laparoscopic grasper should be able to transmit at least a pull force of 5 N, without damaging the tissue or having the tissue slip out of the grasper.

In a set-up where no movement limitations are present, the pull forces measured are at an angle of about 40 to 70° relative to the horizontal plane, approximately 60° relative to each other, and about 80 mm apart. These values should be taken into account when placing the trocars, since an optimal placement of the instruments will reduce the forces used.

3.4 Required and allowable pinch forces

To be able to handle the colon safely, clearly the pinch force that is minimally required to transmit the pull force should be lower than the pinch force that is maximally allowable without causing damage to the colon. If the pinch force used is lower than the minimally required pinch force, the tissue will slip out of the grasper. Therefore, from here on the minimally required pinch force will be referred to as the slip-preventing force, or simply the 'slip force'. Following a similar reasoning the maximally allowable pinch force will simply be called the 'damage force'. Both the slip force and the damage force are influenced by the magnitude of the pull force and by the design of the grasper jaws.

Influence of the pull force

The slip force will increase as the pull force increases. For force transmission purely based on friction this is obvious because there is by definition a positive relationship between the pinch force F_p and the resulting friction force F_f. For linear-elastic materials, like metals, this relationship is linear: $F_f = f \cdot F_p$, in which f is the coefficient of friction. For poro-viscoelastic materials, like organic tissue, the relationship usually is non-linear, but nevertheless positive. For force transmission through full enclosure the pinch and pull force are independent, and thus the slip force would be zero. However, as the jaws do not grab fully around the colon, but onto it, the transmission of the pull force is only partially based on enclosure; the remainder is transmitted via friction. The larger the pinch force, the larger are both the friction force and the enclosure, and thus the larger the pull force must be to let the colon slip out of the jaws. Therefore, the positive relationship between slip force and pull force also applies when transmitting force through (partial) enclosure.

The influence of the pull force on the damage force may not be as obvious as its influence on the slip force, therefore an experiment was set up in which the pinch forces leading to perforation were determined with different pull forces present, when pinching the tissue between two hemispheres with a diameter of 2 mm (Heijnsdijk et al. 2001). For this experiment the same set-up was used as for the experiments described later on in Chapter 5. In the experiment pinch forces of either 7, 10, 13 or 16 N were applied together with pull forces of either 0, 2.5 or 5 N. These pull forces were chosen based upon the results of the experiment described in Sect. 3.3. The pinch forces were chosen after a few tests to determine the range in which perforations would occur, but slip would not. All measurements were done on the cecums of 7 different pigs, all weighing between 19 and 25 kg, who were terminated about 15 to 45 minutes prior to the experiment. Each time the

Table 3.1. Number of perforations.
The number of perforations caused by the 2 mm hemispheres, given as a function of the pinch and pull forces used. In total 18 perforations were observed. 168 measurements were done, 24 on each pig.

16 N	*2*	*3*	*6*
13 N	*0*	*1*	*1*
10 N	*0*	*0*	*2*
7 N	*0*	*0*	*3*
	0 N	*2.5 N*	*5 N*

combination of pinch and pull force was applied for one minute. This time period was based upon a video analysis by Heijnsdijk et al. (2002), which revealed that in 90 % of all cases the surgeon holds the colon for less than one minute. Table 3.1 gives an overview of the number of perforations as a function of the pinch and pull forces. It shows that the percentage of perforations significantly increases with increasing pull force (p=0.002) as well as with increasing pinch force (p=0.035). It is thus concluded that the damage force decreases when the pull force increases. Therefore the damage force must always be determined with respect to a predetermined and appropriate pull force. Based upon Sect. 3.3 this pull force is set at 5 N. From here on, the 'damage force' will always refer to the pinch force that is maximally allowable to the tissue without causing a certain set level of damage, while transmitting a 5 N pull force; unless otherwise indicated.

A confirmation for the observation that increasing pull force decreases the maximally allowable pinch force is the fact that the pull force is used for the stretching of the mesocolon, which eases the cutting of it. The same holds true for the colon itself, but in that case it is an negative side effect: the pull force causes tension in the colon which

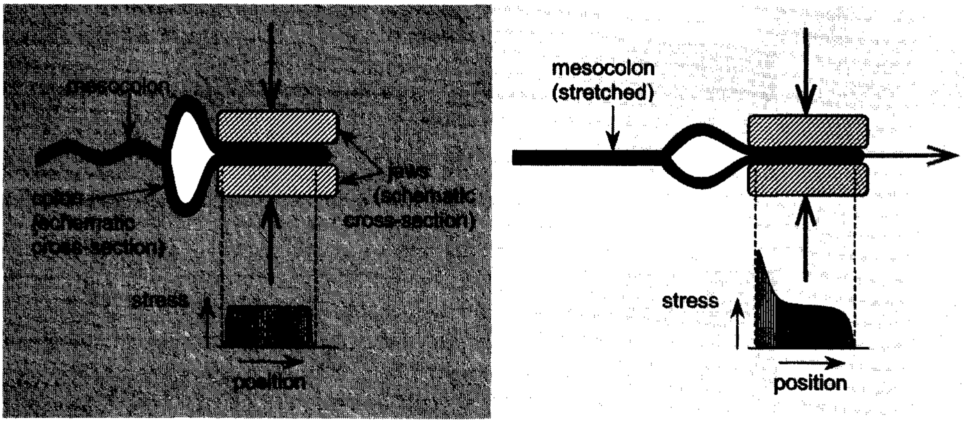


Figure 3.9. Influence of pull force on the stress in the tissue.
The left figure shows an estimation of the stress (pressure) in the tissue when only a pinch force is applied to the tissue. The right figure shows an estimation, obtained from a finite-element simulation, of the total stress in the tissue when a pull force is added. Sharp points or profiles on the jaws may increase this effect even further.

makes it easier to (involuntary) damage or cut it. Fig. 3.9 shows how the presence of a pull force increases the stress in the tissue. As a consequence, the local stress at the left side might exceed the maximally allowable stress in which case the tissue will be damaged.

The effect of the pull force on the slip and damage force can be summarised schematically in a single graph, as first done by Kemner (1999) and shown in Fig. 3.10. Below the 'slip line' the pinch force is too low to prevent slipping. Above the 'damage line' the combination of pinch and pull force will cause damage to the tissue. Combinations of pinch and pull forces in the area to the right of the crossing point of the slip and damage lines will cause the tissue to get damaged even though it still slips out of the grasper's jaws. At the top left of the graph there is a point where the pinch force is so high that it will damage the tissue even without any pull force present. Clearly, the safe working area is the area below the damage line and above the slip line, the grey area in Fig. 3.10.

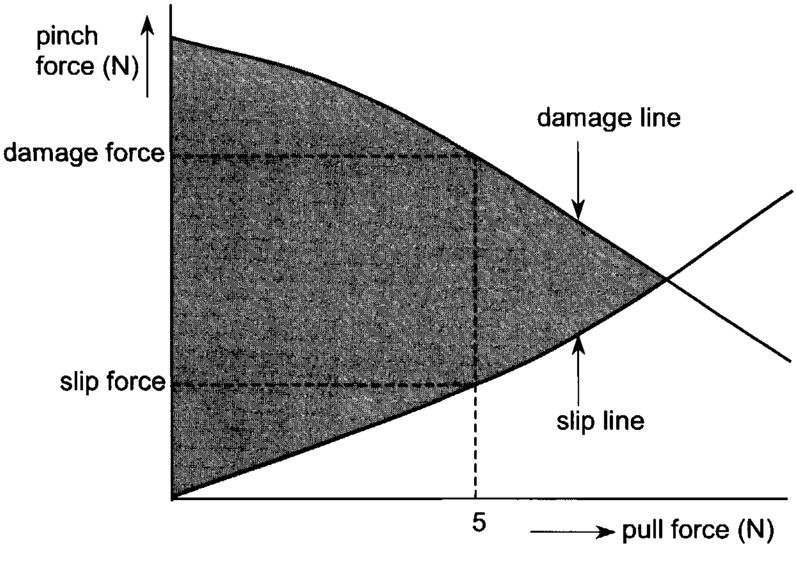


Figure 3.10. Slip and damage forces.

Generalised slip and damage behaviour as a function of the pinch and pull forces. The damage line is an estimation of the damage limit: any combination of pinch and pull force above the damage line will cause an unacceptable level of damage. Based upon the results presented in Table 1, the damage line is expected to decline. The slip line is an estimation of the slip limit: any combination of pull and pinch force below the slip line will not be able to prevent the tissue from slipping out of the jaws. The grey area between the slip line and the damage line is the safe working area. The directions of the slip line and the damage line depend on the jaw shape used. For example, a smooth flat jaw is expected to have a steep slip line, as a lot of pinch force will be required to prevent slip, and a declining damage line starting high on the vertical axis. A sharp pointy jaw is expected to have a rather flat slip line, as not much pinch force will be needed to prevent slip, and a declining damage line that starts low on the vertical axis, as already a small pinch force may cause unacceptable damage. The dashed lines indicate how the 'slip force' and the 'damage force' are defined.

Influence of the jaw design

The design of the jaws also influences the slip and damage forces. E.g. putting a sharp pointy profile on the jaws will lower the slip force, but it will also lower the damage force, whereas smooth jaws will have both a high slip force and a high damage force.

Assuming the material of all jaws is equal, the slip forces of the different jaws are determined by either the type of profile or the type of enclosure created when the jaws grab the tissue, and possibly by the size of the contact area between jaws and tissue. Although the size of the contact area has no influence on the friction between two linear-elastic materials, this is not self-evident for biological materials.

In contrast, the damage force is certainly influenced by the size of the (effective) contact area, which is the part of the jaw's surface that actually comes in contact with the tissue, and by the distribution of the pinch force over that contact area, as shown in Fig. 3.11. As the pressure at which the tissue gets damaged is a material property and therefore presumably constant, any decrease in the contact area will decrease the damage force. An uneven distribution of pinch force, e.g. caused by protrusions such as the pyramid on the left in Fig. 3.11, will also lower the damage force. From the results of the mentioned experiment with the 2 mm hemispheres it was calculated (Appendix A) that the pressure leading to tissue damage usually is in the range of 0.9 to 3.3 N/mm^2 (= 0.9 to 3.3 MPa). Clearly, when a jaw possesses sharp edges or points, for example in its profile, the contact area will be (severely) reduced and hence also the damage force. With a pull force present, the distribution of the pinch force will be even more uneven, as shown in Fig. 3.9, and the damage force will be reduced even further, but so may the slip force. Thus the design of the jaw has a significant influence on the damage force as well as the slip force.

Chapter 4 will discuss a method for judging the quality of a jaw design based upon the slip force and the damage force.

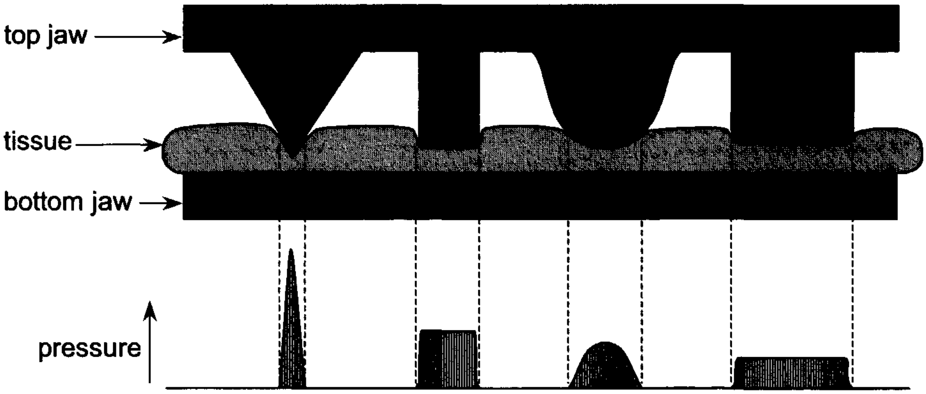


Figure 3.11. Influence of the jaw surface profile on the pressure on the tissue.
Estimations of the pressure on the tissue caused by different jaw surface profiles. Sharp points on the jaws may lead to lower slip forces, but also to a smaller contact area between tissue and jaw, and consequently to higher pressure on the tissue (if the pinch force does not change). The higher the pressure on the tissue resulting from a certain pinch force, the lower the damage force.

4 Design Criteria

Finding a way to compare grasper designs

4.1 Introduction

Quantifying the grip quality

To determine whether new designs of grasper jaws are actually improvements compared to existing ones, some kind of quantification of the quality of jaws is required. The quality of the jaws is mainly determined by the quality of the grip that the jaws provide on the tissue. Key factors herein are the slip and damage behaviour.

The mechanical properties and behaviour of the organic tissues, with which the grasper will be dealing, are not well known in detail. Finding the optimal shape for interaction with such tissues, or even just improving existing shapes will likely require a considerable number of intermediate steps, because the influence of many parameters on the quality of the grip needs to be investigated. Therefore, to enable quick comparison and judgement of new jaw designs with regard to their slip and damage behaviour, an easily assessable combination of parameters needs to be found, which can serve as an objective quantification of the grip quality.

Several different types of parameters could be chosen for the "criterion of grip quality" and usually each one requires a specific way of testing. For testing in a computer simulation, it is likely that another grip quality criterion will be used than for testing on animals. For example, with computer modelling it might be possible to calculate exactly how high the pressure peaks on the tissue will be, and this pressure could be used as the grip quality criterion. When testing on animals, it will be difficult to determine the exact pressure on the tissue, but the consequences of the pressure peaks may be visible on the tissue. In such a case, some quantification of observed tissue damage might be used as the grip quality parameter. It is therefore necessary to first determine on which material the instruments will be tested, before establishing a quality criterion for comparison of jaw shapes. Since the instrument will be used on living and often diseased human tissue, and in particular the human colon, this would be the best material to test on. Evidently, this is usually very difficult. Alternative materials are either virtual (computer simulations), synthetic or organic. Once the material has been determined, the properties that need to be incorporated in the criterion have to be chosen, before the final criterion of (grip) quality can be established.

Sect. 4.2 describes the potential materials upon which the experiments may be performed. In Sect. 4.3 the parameters that need to be included in the criterion are identified, while Sect. 4.4 describes the ways in which these parameters are defined and determined. The final criterion of quality is determined in Sect. 4.5.

4.2 Materials

This section will give an overview of possible materials to test on, and their influence on the choice of a criterion of quality for judging grasper designs.

4.2.1 Virtual materials

Putting both tissue and instrument in a computer model would have the large benefit that the effects of changes to the instrument design could be tested easily and rapidly, once a reliable model of the tissue is obtained. Pressure peaks in the (virtual) tissue, occurring as a result of a certain combination of pinch and pull force, could easily be observed and examined, and could be used as a criterion of quality in judging the jaw designs. However, the condition that the tissue model has to be reliable turned out to be a major obstacle.

An attempt was made to create a Finite Element Model (FEM) to simulate the interaction between instruments and tissue, using a computer programme called Algor (version 12.08, www.algor.com). Stress and strain properties of the colon were obtained

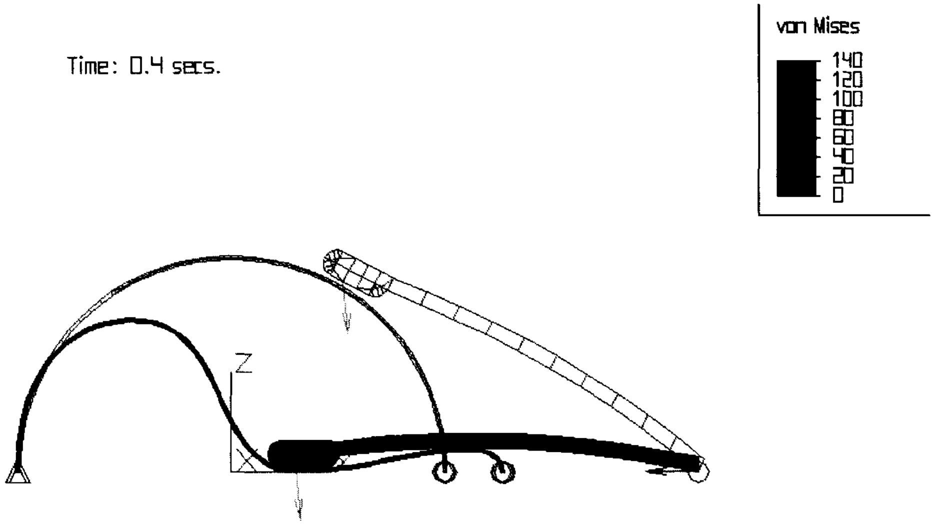


Figure 4.1. Finite Element Model of a colon being pinched.
Because the colon cross-section and the grasper are symmetrical, only half of them need to be modelled, which reduces calculation time. The see-through shapes show the starting situation, the solid shapes depict the situation after the pinch force is applied. To simplify the calculation, the left side of the (semi)colon has been fixated, whereas the right side can slide freely in the horizontal direction.

from several sources in literature (Yamada 1970, Duck 1990, Fung 1993, Maass 1999, Brouwer et al. 2001) and entered into the programme. The programme fitted a curve on this data to obtain a so-called Mooney-Rivlin model of the tissue. Mooney-Rivlin is a model type used for materials that undergo large deformations and exhibit non-linear stress-strain-behaviour, such as rubber. Unfortunately, no tissue model could be found that led to a converging simulation. Therefore, further simulations were done with the standard Mooney-Rivlin model for rubber to first determine whether the programme could cope with large deformations in combination with friction between materials sliding over each other, before developing the tissue model further.

Fig. 4.1 shows that the large deformations that occur during tissue manipulation proved to be no problem. A two-dimensional finite element model was made of a tube with a 50 mm diameter, symbolising the colon, being pinched by flat jaws. This simulation was successful and was extended by applying a pull force to the tissue. The results from that simulation were not satisfying, due to the poor simulation of dynamic (or *sliding*) friction within the programme. Some simple models of situations with dynamic friction without large deformations revealed that the simulation of dynamic friction is very complex and that each model would require many complex adjustments of all kinds of model parameters before the computer simulations would converge to a solution. Therefore, it was decided that the used programme was not likely to provide an efficient method for tissue modelling. Following steps, such as modelling in three instead of two dimensions and improving the tissue model, were not taken and further use of this design method was omitted.

When looking at literature and congress proceedings it becomes clear that finite element modelling of biological structures is rapidly developing, but it is yet producing little usable material. Several research groups are working on finite element models of blood vessels but the results so far do not show this method to be a sound alternative for the traditional method of testing on animal tissue. The colon is even more complex than a blood vessel, as it consists of five different layers instead of three. It is thus not surprising that no references of successful finite element models of the colon could be found in literature. Developing such a model will require several years at least, and this is clearly not feasible within this research project in which it was only intended to be used as a (supporting) design tool.

4.2.2 Synthetic materials

Synthetic materials basically suffer from the same drawbacks as virtual materials. It is difficult, if not impossible, to find a material that has the same complex behaviour of organic tissue without the material variability that makes testing on organic material so tedious. Several materials or combinations of materials have been tried. Often, a synthetic material combination would quite accurately mimic the slip and damage behaviour of the (porcine) colon when manipulated with a certain type of the grasper jaws, but when manipulated with another type of jaws, the behaviour would be far from accurate. No material combination was found that could properly function as a model for the colon when being manipulated with a large variety of jaw shapes. Hence, a synthetic model can only be used to examine jaw shapes that differ only slightly, and another group of jaw shapes will require a different synthetic tissue model. Furthermore, the reliability of the results remains questionable and further tests and validation on more representative (organic) material remains necessary.

4.2.3 Organic materials

To test the effect of graspers on diseased living human colon tissue, the most reliable results would be obtained from tests on such tissue itself, directly after it has been removed from the patient. Unfortunately, such material is rarely available and that would turn this study, in which a large number of jaw shapes needs to be tested, developed, tested again etc., into a very time consuming and expensive project. The next closest possible model would be a healthy living human colon, but obviously neither volunteers nor ethical approval will be found for this. Human cadaver colons are considered to be less reliable for representing the living colon, because it is known that the mechanical properties of muscle tissue, of which the colon wall mainly consists, change after the blood circulation has ceased (Watters et al. 1985), but it is unknown how much and how fast they change. Consequently, the reliability of obtained results will always be questionable to a certain extent. However, this argument is valid for any model. Traditionally, animals, in particular pigs, have been the objects of use in studying the effects of instruments, drugs, etc. on human (colon) tissue. Pigs are often used as test animals because of the good resemblance with human organs in size and shape. Concerning the colon, the resemblance is particularly true for the cecum and sigmoid. Since the main focus of this study is on the cecum as this is regarded the most vulnerable part of the colon, and since pigs are available in reasonable numbers at laboratories for experimental surgery, the pig colon has been the main model of choice in this study. The validity and reliability of this material model will be discussed later on in this thesis, in Chapter 6.

There are basically two ways of doing experiments with animal material at a surgical laboratory: using living animals or using dead ones. When using living animals the material best resembles human colon tissue, but the high costs of pigs, personnel and operating room usage make this a very expensive method. Using an animal that has first been used by other researchers can reduce the costs strongly, but it still requires personnel to check and maintain the anaesthetics and an experimental surgeon to supervise the experiment. There are fewer requirements, and thus fewer costs, for experiments on animals that have first been used by other researchers and are then terminated just before the start of the experiments. The latter has therefore been the method mainly used in this study, as it was anticipated that a large number of experiments might be needed. The variations in material properties due to the treatment prior to or during the experiments will be discussed in Chapter 6.

Besides living pigs and just-terminated pigs, organ material from the abattoir can be used. Advantages are the large available quantities and the low costs. Main disadvantages are that the time since the animal's death and the treatment of the organ part (stretching etc.) are unknown. Therefore, this method was only used in some pilot studies.

4.3 Required parameters of the criterion of quality

The material on which the grasper jaws are going to be tested will be organic tissue. Therefore, probably the most simple and intuitive method to judge graspers would be to call one grasper better than another grasper if it would cause less damage to the tissue, assuming that the same pinch force has been applied to the handles of both the graspers. This definition is insufficient for two reasons.

Firstly, since the force transfer ratio is different in each grasper, equal forces on the handles will not result in equal pinch forces on the tissue. Furthermore, all graspers possess internal friction in the shaft and hinges. Existing graspers have an efficiency of only 10 to 40 percent (Sjoerdsma et al. 1997). This means that most of the force on the handle gets lost due to friction, which severely obscures the relationship between the force on the handle and the resulting pinch force on the tissue. For example, assume that graspers A and B are completely equal, except A has more internal friction than B. With an equal force on the handle, the pinch force on the tissue will be lower for grasper A, since more force gets lost in friction. Grasper A will produce less force on the tissue and thus seemingly cause less damage. However, to obtain the same amount of grip on the tissue as grasper B, a larger force on the handle of grasper A is required, due to the larger friction. In practice, most surgeons will actually prefer grasper B because it provides better force feedback. Therefore, for a fair comparison of the jaw shapes one should not look at what happens when a certain force is applied to the handle of the grasper, but to what happens when a certain force is exerted onto the tissue by the grasper.

Secondly, in the definition above, the prevention of slip is not taken into account. If, for example, a grasper X has a very high damage force, whereas a grasper Y has a slightly lower damage force, then normally grasper X would be preferred. However, if grasper X also has a very high slip force (i.e. slip-preventing pinch force), while grasper Y only requires a very small pinch force to prevent slip, then in total grasper Y might be the safer choice.

Consequently, not only the pinch force that is maximally allowable on the tissue, the so-called damage force, should be taken into account, but also the pinch force that is minimally required to prevent the tissue from slipping out of the jaws, the so-called slip force.

Another property of the jaws that may need to be incorporated in the criterion of quality is the mechanical reliability of the jaws. As this research is limited to the part of the grasper that comes in contact with the tissue, the reliability of the hinge system that transmits the force from the rod in the instrument shaft to the jaws is not an issue here. Focus will be purely on the reliability of the jaws themselves, which basically limits the issue to potential mechanical failure of the material used. In the research presented here, the choice of material is limited to stainless steel. Considering the forces involved are not very high and assuming all jaws are properly designed, the chance of parts breaking off the jaws is negligible and thus the mechanical reliability will not be a major concern.

In conclusion, the criterion of quality for jaw comparison should contain information about both the damage force and the slip force. Information about the reliability may be omitted.

4.4 Defining and determining slip and damage

Slip is defined as the event in which the tissue slides completely out of the grasper's jaws, so no contact between instrument and tissue remains. In Chapter 3 the slip force was defined as the pinch force required to prevent slip when a certain pull force is being applied.

The slip force needs to be determined while a pull force of 5 N is being applied to the tissue. This is the magnitude of the maximum pull force that surgeons use when they need to stretch tissue structures connected to the colon for dissection. This magnitude was determined in the experiments described in Sect. 3.3 (de Visser et al. 2002).

The damage force, defined in Sect. 3.4 as the pinch force that is maximally allowable without causing a certain level of damage, obviously is not defined without a clear definition of damage. Damage will first occur on a microscopic level. When the forces on the tissue increase, macroscopically observable damage in the different layers of the colon will occur and eventually the colon will be perforated. A perforation of the colon usually is easily noticed during surgery. Such a level of damage is obviously unacceptable. However, sometimes the colon is only slightly damaged. This level of damage may low enough for the human body to be able to repair it, but it may also be so severe that the damage will progress into a perforation, which does not emerge until several days after surgery (Schrenk et al. 1996, Bishoff et al. 1999). Although Johansson et al. (1984) presented a few criteria that may indicate which lesions have an increased risk of progressing to perforations, it is still not exactly known what kind of damage can still be repaired by the body, and what damage will eventually lead to perforation.

It is thus impossible to determine the exact limit of which pinch force is still acceptable. Therefore one will just have to choose a certain type of damage, preferably an easily observable one, and assume that to be the limit. In the experiments presented in this thesis, the limit was set at a visible tear in one of the layers of the colon wall. For relative use (comparison of jaw designs) this is assumed to be acceptable, but use of the absolute values should be done with extreme precaution, because the accuracy of the absolute values of the damage forces obviously depends on the accuracy of the chosen damage limit. In the experiment described in Sect. 3.4 (Heijnsdijk et al. 2001) it was noticed that the magnitude of the pull force influences the damage force, decreasing it as the pull force increases. Therefore, the damage force should be determined with a representative pull force present. Similar to the determination of the slip force, the magnitude of the pull force should be 5 N, based on the results of the experiments described in Sect. 3.3.

4.5 Choosing the final criterion of quality

Damage-slip-ratio with 'robustness correction'

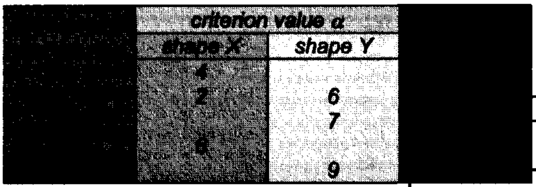
Damage-slip-ratio

The damage force F_{damage} and the slip force F_{slip} form the upper and lower limit of the working range in which the surgeon can adequately and safely grasp the tissue. The two most logical ways to put these two values into a criterion would be either to subtract the lower form the higher (F_{damage} - F_{slip}) or to divide the higher by the lower (F_{damage} / F_{slip}). Subtraction would result in an absolute value, being the size of the working range in Newton. Division will result in a ratio, which indicates how many times the minimally required pinch force the surgeon can apply before he will cause damage to the tissue. When a surgeon wants to pinch harder, he is not likely to reason in absolute values like "let's apply 10 N extra pinch force", but in a relative manner like "let's pinch twice as hard". Therefore, it is the author's opinion that the damage-slip-ratio $\frac{F_{damage}}{F_{slip}}$ *(4.1)*
will be a good way to judge different grasper designs, because it is easily interpretable. When the ratio is below 1 the grasper is useless, since the pinch force on the tissue that is minimally required to prevent slipping will already cause tissue damage. The larger the ratio is, the larger is the relative working range in which the surgeon can adequately grasp the tissue without damage, and thus the safer the instrument. An alternative for the damage-slip-ratio $\frac{F_{damage}}{F_{slip}}$ would be $\frac{F_{damage} - F_{slip}}{F_{slip}}$ which can be rewritten as: $\frac{F_{damage}}{F_{slip}} - 1$ *(4.2)*
This 'shifted' damage-slip-ratio, or 'working range'-slip-ratio, is negative for useless instruments and positive for useful ones (the higher the ratio, the better the instrument), which is preferable in some calculations, as will be explained later in this section.

Robustness

In pilot experiments it was noticed that there were large variations in the material properties of the porcine colons upon which the experiments were conducted. These material variations caused variations in the observed damage-slip-ratios. These variations in the ratios were much larger for some jaw shapes than for other shapes. Clearly, if two graspers have the same average damage-slip-ratio, but grasper A has smaller variations in its ratio than grasper B, then grasper A should be preferred, because its performance is more reliable. This sensitivity to material variation should be added to the two parameters, damage force and slip force, that make up the grip quality criterion. Therefore, a new parameter is introduced: *Robustness*. It is defined as the insensitivity of the grip quality of a jaw design to variations in the (mechanical) properties of the tissue that is being pinched.

Determining or quantifying this robustness and incorporating it in the criterion of quality in the shape of a (mathematical) formula is not straight-forward. The easiest way to incorporate the robustness in the criterion seems to be to first determine a criterion of quality based only on the slip and damage forces, i.e. the damage-slip-ratio, and then apply a correction to that criterion based on the robustness. The best way to quantify the robustness seems to be the following: Test a certain jaw shape on several different tissue specimens (read: 'different colons'). Determine of each specimen the criterion value, i.e. the damage-slip-ratio, and a certain material property that will serve as an indicator of the tissue strength. The robustness is then defined as the insensitivity of (the damage-slip-ratio of) the jaw shapes to variations in (the chosen material property of) the tissue. The robustness is calculated by dividing the standard deviation of the material property (given as a percentage of the average) by the standard deviation of the criterion values (also as a percentage). Fig. 4.2 gives an example of how the robustness is determined.



criterion value α	
shape X	shape Y
4	
2	6
	7
6	
	9

Shape X:

$$average\ (\alpha_X) = \frac{4+2+6}{3} = 4$$

$$\sigma(\alpha_X) = \sqrt{\frac{3(4^2+2^2+6^2)-(4+2+6)^2}{3(3-1)}} = 2$$

$$\sigma_{\%}(\alpha_X) = \frac{2}{4} \times 100\,\% = 50\,\%$$

$$average\ (\beta_{pigs\ 1,2,4}) = \frac{7+4+5}{3} = 5.3$$

$$\sigma(\beta_{pigs\ 1,2,4}) = 1.5$$

$$\sigma_{\%}(\beta_{pigs\ 1,2,4}) = \frac{1.5}{5.3} \times 100\,\% = 29\,\%$$

$$Robustness\ (Shape\ X) = \frac{29}{50} = 0.58$$

Shape Y:

$$average\ (\alpha_Y) = 7.3$$

$$\sigma(\alpha_Y) = 1.5$$

$$\sigma_{\%}(\alpha_Y) = 21\,\%$$

$$average\ (\beta_{pigs\ 2,3,5}) = 6$$

$$\sigma(\beta_{pigs\ 2,3,5}) = 2$$

$$\sigma_{\%}(\beta_{pigs\ 2,3,5}) = 33\,\%$$

$$Robustness\ (Shape\ Y) = 1.6$$

Figure 4.2. Determining the robustness.

In this example the robustness of two grasper shapes, X and Y, is determined using data obtained from 5 different pigs. However, each shape is only tested on 3 of the 5 pigs. The criterion value α (the damage-slip-ratio) for shape X has been determined on pigs 1, 2 and 4, and has an average of 4 and a standard deviation of 2, which means that its relative standard deviation is 50%. To determine the robustness of shape X, a certain material property β has been determined on pigs 1, 2 and 4. It has an average of 5.3 and a standard deviation of 1.5, resulting in a relative standard deviation of 29%. Dividing those two percentages gives a robustness of 0.58. A similar calculation for shape Y yields a robustness of 1.6. The higher robustness of shape Y indicates that shape Y is much less sensitive to variations in the tissue properties than shape X.

For the mentioned material property an easily obtainable parameter should be chosen. The damage force of a certain jaw shape, the 2 mm hemispheres, seems to be a good choice, as already experience with this shape was obtained in the preliminary experiment described in Sect. 3.4. The robustness of a certain jaw shape X would then be the (relative) standard deviation of the measured damage forces of the 2 mm hemispheres divided by the (relative) standard deviation of the measured damage forces of jaw shape X:

$$\frac{\sigma_{\%}(F_{damage,\ 2mm})_{x_i,\ x_j \ldots x_n}\ (\%)}{\sigma_{\%}(F_{damage,\ shape\ X})\ \ (\%)} \tag{4.3}$$

In this equation the standard deviations $\sigma_{\%}$ are given as percentages of the averages:

$$\sigma_{\%}(F) = \frac{\sigma(F)}{\overline{F}} * 100\ \% \tag{4.4}$$

in which $\overline{F}$ is the average of all F's (see also Fig. 4.2). Such a relative standard variation is also known as the *coefficient of variance*. The indices x_i, $x_j \ldots x_n$ indicate that the standard deviation of the measured damage forces of the 2 mm hemispheres should be calculated using only the damage forces of the 2 mm hemispheres obtained from the specimens on which jaw shape X was tested, i.e. pigs *i, j ... n*. It is virtually impossible to test all shapes on the same specimen, i.e. the same pig cecum, because of three reasons. Firstly, per jaw shape a large number of measurements is required, due to the large variations in the tissue. Secondly, there is a considerable number of different shapes to be tested. And thirdly, the biological material on which the tests are done deteriorates rapidly. Therefore, on each pig only some of the jaw shapes can be tested, as was already indicated in Fig. 4.2. Only the 2 mm hemispheres are tested on all specimens, because their damage force is used as the 'material property' in the determination of the robustness.

Combining Damage-slip-ratio and Robustness

When combining the damage-slip-ratio and the robustness factor into the final criterion of quality by multiplying them, it is preferable to use the 'shifted' damage-slip-ratio instead of the 'normal' damage-slip-ratio. If it would be impossible to properly grab tissue without causing damage with a certain jaw shape, it would be useless, even though it might be very robust. It would have a (normal) damage-slip-ratio lower than 1 but a high robustness factor, and the final criterion of quality, being the product of the two, might be above 1, suggesting it is a safe instrument when in fact it is not. With the shifted damage-slip-ratio, the final criterion of quality will always remain negative for useless instruments, no matter how high the robustness factor. Consequently, the final criterion of quality for rating grasper jaw designs is the product of Eqs (4.2) and (4.3):

$$\left[\frac{F_{\text{damage, shape X}}}{F_{\text{slip, shape X}}} - 1\right] * \frac{\sigma_{\%}(F_{damage,\ 2mm})_{x_i,\ x_j \ldots x_n}}{\sigma_{\%}(F_{damage,\ shape\ X})} \tag{4.5}$$

In the next chapter the results of experiments done with a variety of different jaw shapes will be presented and the damage-slip-ratio and the robustness, introduced in this chapter, will be used to judge the quality of the grip of these jaw shapes.

5 Design process

The experimental path to improved jaw shapes

5.1 Introduction

When looking at existing graspers, a large variety of jaw designs can be noticed. Fig. 5.1 shows a collection of grasper jaws used for several different tasks. All these graspers are produced by the same manufacturer, and all are categorised as being atraumatic. From this variety it can be deduced that several strategies can be followed to obtain a safe and reliable grip on tissue. Some shapes possess features that aim to reduce the slip force, so that only a small pinch force is required. Other shapes aim to achieve a high damage

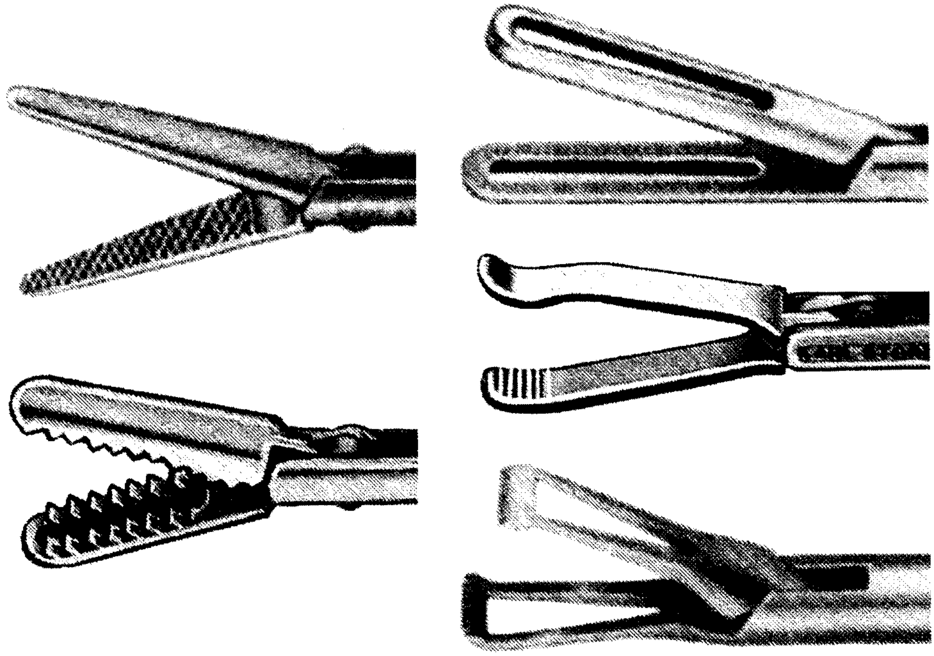


Figure 5.1. Collection of 'atraumatic' grasper jaws.
All the jaw shapes shown here are produced by the same manufacturer (Storz). Despite the clearly visible differences, all of these shapes are classified as being atraumatic. This indicates that there is no clear consensus as to when a grasper truly is atraumatic.

force, so even a large pinch force will not harm the tissue. And sometimes both objectives are combined by incorporating several design features: some to lower the slip force and some to raise the damage force. However, it is not clear to which extent each feature of a certain jaw design contributes to, or opposes, the realisation of these two objectives. The fact that most existing jaw shapes contain several design features and the often unknown influence of each separate design feature can easily turn the determination of the ideal jaw shape into a search for a needle in a haystack. Therefore an approach has been chosen in which one aims to create better jaw shapes by obtaining more understanding of the mechanics of tissue grasping. Instead of investigating existing jaw shapes, series of elementary shapes have been designed. In each of these series the influence of one design feature on the damage-slip-ratio and the robustness of the jaws has been investigated. These elementary shapes were then combined to create more complex shapes, which may look more like the shapes of existing jaws. The results of these complex shapes were then evaluated to draw up guidelines for the design of jaw shape with which delicate organs can be handled safely.

The next section describes the methods used to perform the experiments. In Sect. 5.3 the results of the experiments with the elementary shapes are presented. Sect. 5.4 describes how the elementary shapes were combined into complex shapes. This is followed by the results from measurements with these complex shapes (Sect. 5.5). In Sect. 5.6 the results of the experiments mentioned so far are interpreted and combined into guidelines for new jaw shapes. These guidelines are summarised in Sect. 5.7.

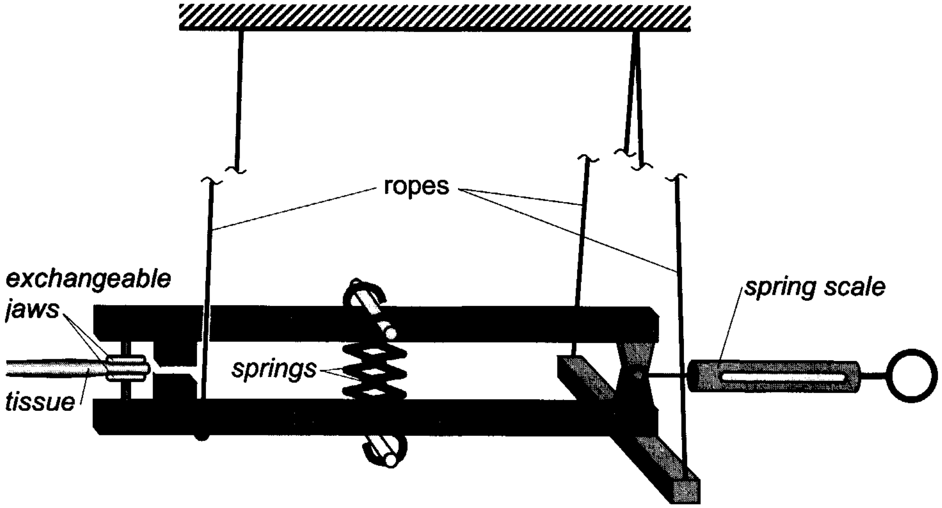


Figure 5.2. Experimental set-up.
The experiments were conducted using a lever that is suspended from three ropes, each about half a metre long. This suspension allows for frictionless movement in the longitudinal direction of the lever, but it also introduces a pendulum effect. The length of the ropes is much larger than the size of the movement in the horizontal direction, therefore the unwanted vertical movement caused by the pendulum effect is negligible. The jaws under investigation are mounted in the tips of the arms of the lever. Springs between the two arms provide the pinch force. Alternatively, a mass placed on the top arm can be used instead of the springs. The pull force is applied to the rear end of the lever via a spring scale.

5.2 Methods

Testing how a large number of jaw shapes interacts with delicate biological material, creates a number of conditions for the set-up used in the experiments, as well as for the procedure followed during the experiments, for the materials used and for the way data is gathered and processed.

5.2.1 Set-up

Since the experiments were performed in several locations, the set-up had to be easy to transport and to install. It should fit on or above an operating table, in such a way that the jaw shapes could be tested on the pig's colon during in situ experiments. Furthermore, the exchange of the different jaw shapes has to be quick and easy, as time is an important factor because of the rapid deterioration of the biological material on which the tests were performed. It should be possible to apply a variable and measurable pinch force to the tissue, and to apply a constant pull force of 5 N (de Visser et al. 2002) via the jaws onto the tissue.

Fig. 5.2 shows the set-up that was used in the experiments. A lever mechanism is hanging from three ropes. Exchangeable jaws can be mounted in the tips of its arms. Springs between the two arms of the lever - or a mass on the top arm of the lever - produce the adjustable pinch force. The pull force is applied via a spring scale at the back end of the lever. All these features will now be discussed in detail.

The lever mechanism has been chosen instead of e.g. a piston-cylinder or a parallelogram mechanism because of its simplicity. The jaws of existing graspers also make a lever motion, but the length of the arms is much shorter than in this set-up. An often mentioned problem of existing graspers is the scissors-like way in which they close. When grasping tissue, the tissue at the base of the jaw near the hinges is squeezed very hard whereas the tissue near the tip of the jaws is hardly pinched at all. This effect decreases when the length of the jaws increases, because the jaws will be more parallel to each other when they come into contact with the tissue, and the distribution of the pinch force on the tissue will be more homogeneous. Because closing mechanism of the jaws is a property of the grasper design, and this research focuses only on the jaw design, it has been decided to have the jaws close in an more or less optimal way by making the lever arms very long (245 mm from the centre of the hinge to the centre of the jaws). Consequently the jaws will close virtually parallel.

All jaw shapes are equipped with 2 mm rods that fit in the holes in the tips of the lever. Each shape is secured by tightening a small screw, so to exchange a set of jaws, only two screws have to be loosened. Fig. 5.3 shows the tips of the lever in detail. In conformance with existing graspers, all jaw shapes are made of stainless steel and all are limited in width to 10 mm.

A variable pinch force is achieved easily by placing springs between the two lever arms. The pinch force is increased by moving the springs towards the tip of the lever. This force can be calculated easily using moment equilibrium, assuming there is no friction in the hinge of the lever. Alternatively, the variable pinch force can be achieved by placing a mass on the top arm of the lever, while the bottom arm is supported by the three ropes. Positioning the mass closer to the tips increases the pinch force. However, when high pinch forces are needed, the mass has to be rather big, which can be inconvenient. In that case, it is easier to use the springs between the two lever arms, but this method is slightly less accurate than using a mass. This is because the spring force depends on the length of the springs, which depends on the opening of the jaws. In practice this unwanted variation in the resulting pinch force is limited to only a few percent.

The pull force of 5 N is applied to the back of the lever, simply by pulling via a spring scale. The pull force is always applied in the longitudinal direction of the lever. If the lever would slide over a table, friction would disturb the transmission of the pull force; therefore a frictionless support of the lever is required. By hanging the lever on ropes, the motion in horizontal direction is hardly disturbed. As long as the ratio between the horizontal motion and the length of the ropes is small, the pull force transmission is virtually unaffected.

5.2.2 Procedure

Per jaw shape three properties need to be determined: the slip force, the damage force and the robustness.

The slip force, defined as the pinch force required to prevent slip while pulling with 5 N, is determined indirectly in the following way. A certain pinch force is applied by placing either a mass or the springs on the lever. Then the pull force, starting at zero, is increased until the jaws slip off the tissue. This is repeated five times, after which the pinch force is changed. If the average pull force in the first set was below 5 N, the pinch force is increased, otherwise it is lowered. Then a second set of 5 measurements is done. All measured pull forces are plotted in a graph against the respective pinch forces and a

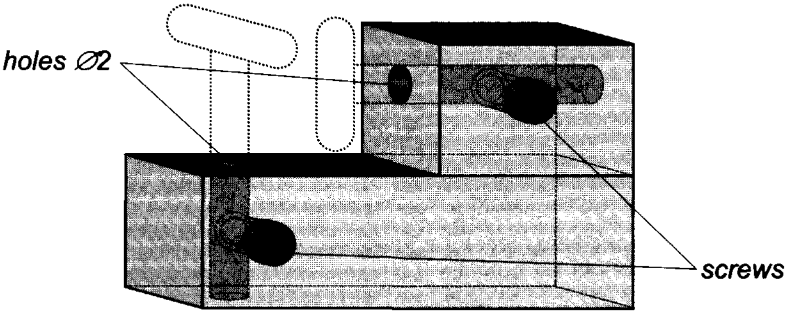


Figure 5.3. The tip of the bottom arm of the lever in detail.
All jaw shapes are equipped with 2 mm rods that fit in the holes in the tips of the lever. By tightening the small screws the shapes are secured, so that they cannot move relative to the lever. There are horizontal and vertical holes in the tips of the lever. This allows for two different ways of positioning the jaw shapes, indicated by the dotted shapes (compare also Figs 5.8 and 5.10). Only the tip of the bottom arm is shown. The tip of the top arm is the mirror image of the tip of the bottom arm.

least square fit through these data points and the origin is calculated, using a second-order polynomial equation. This least square fit is taken as the slip line and the slip force is read from the graph (Fig. 5.4).

The damage force, defined as the pinch force that is maximally allowable without exceeding a certain level of damage with a 5 N pull force present, is determined subjectively. The tissue is placed between the jaws and for one minute a certain pinch force is applied together with a 5 N pull force. This time period has been chosen based upon a video analysis by Heijnsdijk et al. (2002), which showed that during manipulation in about 90% of the actions the tissue is held less than a minute per action. After one minute the lever is opened and the extent of damage inflicted upon the tissue is assessed by the observers. To minimise the number of influencing parameters this assessment is done by the same observers for all measurements. If the damage exceeds the limit of what is acceptable, a lower pinch force is chosen and the procedure is repeated. As mentioned in Sect. 4.4, this limit has been set at a visible tear in one of the layers of the colon wall. If the damage is below the limit, the pinch force is increased and the procedure is repeated. This process of repetitions is continued until the damage force is determined within an

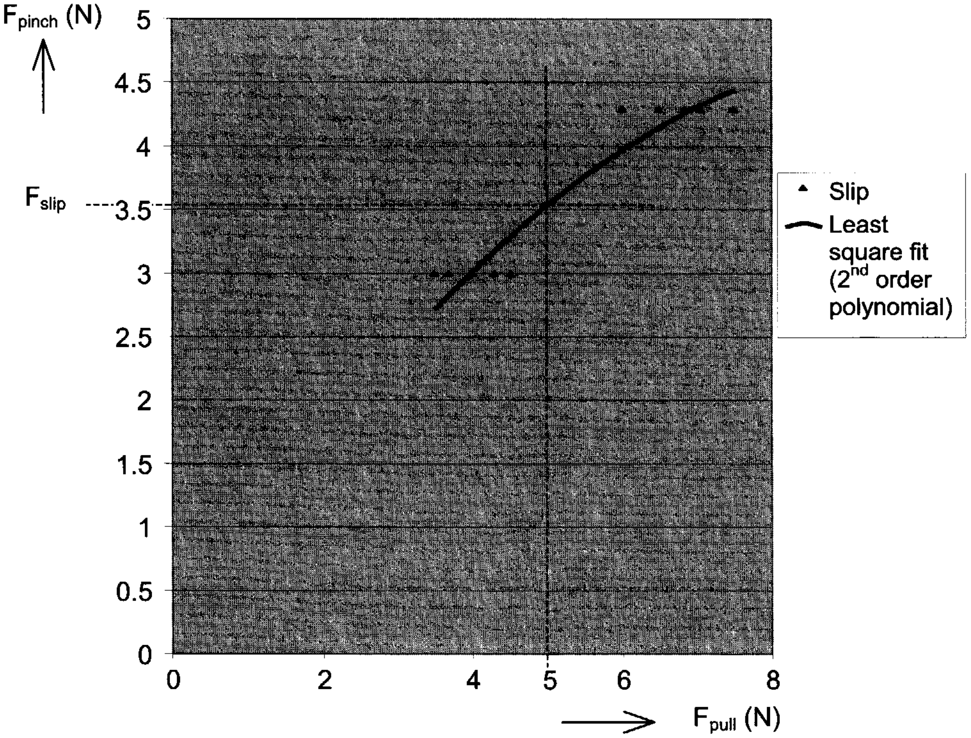


Figure 5.4. Determination of the slip force.

For two different pinch forces (in this example 3 N and 4.3 N) the pull force required to let the tissue slip out of the jaws is measured 5 times. A least square fit through these data points and through zero is calculated. The fitted line is called the slip line. The slip force, defined as the pinch force required to prevent slip when a 5 N pull force is applied, is then determined using the obtained slip line.

error margin of approximately 10%. The damage force is then taken to be the average of the highest measured pinch force that does not yet result in unacceptable damage and the next, higher pinch force that does cause unacceptable damage (Fig. 5.5).

The robustness can be determined without any additional measurements. As described in Sect. 4.5, the calculation of the robustness of a jaw shape requires a certain parameter for the strength of the colon wall. The damage force of one particular jaw shape, the 2 mm hemisphere, is used as this parameter. Therefore, this jaw shape is tested upon all pigs, whereas the other shapes can only be tested on some of the pigs, for reasons described also in Sect. 4.5.

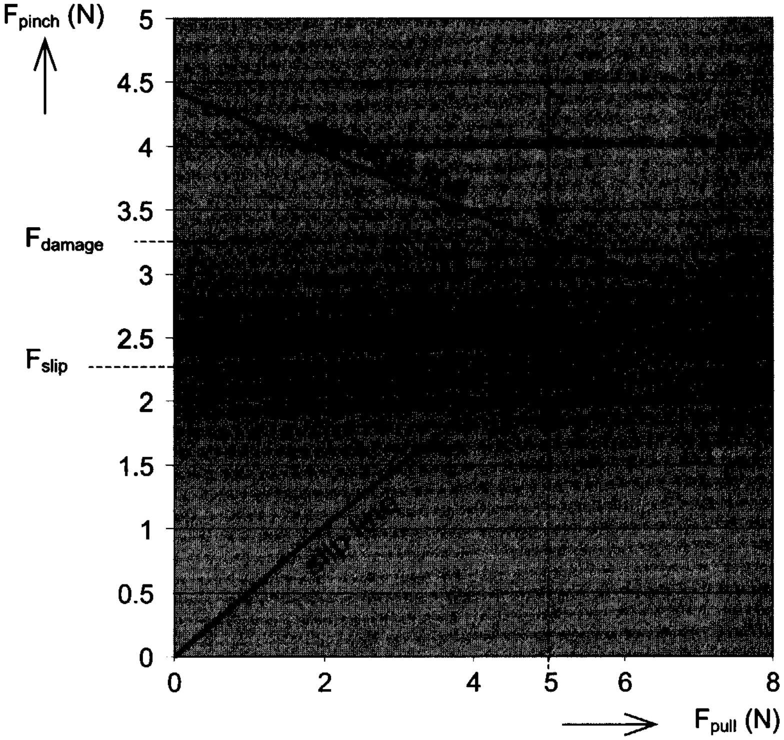


Figure 5.5. Determination of the damage force.
The damage force is obtained as follows: The tissue is subjected to a combination of a certain pinch force and a 5 N pull force for one minute. If the combination of pinch and pull force has caused unacceptable damage to the tissue (e.g. the combination indicated with a square), the pinch force is lowered and the new combination is again applied for one minute. If the combination of pinch and pull force has not caused unacceptable damage to the tissue (e.g. the combination indicated with a triangle), or caused the tissue to slip out of the jaws (e.g. the combination indicated with a dot) the pinch force is raised. This process is repeated until the difference between the lowest unacceptable pinch force and the highest acceptable pinch force is less than 10 % (e.g. the combinations indicated with a square and a diamond). The average of these two pinch forces is then taken as the damage force.

5.2.3 Material

All measurements were done in situ on pig's cecum: the first part of the colon. All pigs were terminated 15 to 60 minutes before the start of the experiment. Of approximately half of the pigs most of the blood had been drained prior to the experiment. The colon tissue was kept wet during the entire experiment. The jaws were always positioned in the same way: perpendicular to the longitudinal direction of the cecum. For each damage measurement a normal, unaffected part of the cecum was used. Consequently, the number of measurements per pig was limited not only by time, but also by the size of the cecum. A total number of 47 pigs was used during the experiments. The weight of the animals varied between 18 and 80 kg, with an average of 31 kg and a median of 25 kg.

5.2.4 Data gathering and processing

For all series, only those measurements were included, which were done on pigs on which at least two of the shapes from that series were tested, unless otherwise indicated.

On some pigs, either only the slip force or only the damage force of a certain jaw shape was determined. In these cases the damage-slip-ratio obviously could not be calculated. However, this measured slip or damage force was included in the calculation of the average slip or damage force.

The average damage-slip-ratio is calculated by averaging all the determined damage-slip-ratios of a certain shape, nòt by dividing the average damage force by the average slip force. There are occasions in which the slip force (the pinch force required to prevent slip) will already cause damage. There are also occasions in which the slip force does not damage the tissue, but any pinch force higher than the slip force dòes cause unacceptable damage. In all of these cases the damage force (the pinch force that is maximally allowable without causing unacceptable damage) is lower than the slip force and is very difficult, or even impossible, to determine (Fig. 5.6). Consequently, the damage-slip-ratio cannot be determined either. It is only known that the ratio will be less than 1. Such occasions are not included in the calculations of the average damage force and the average damage-slip-ratio of a certain shape. However, for each shape, a second, adjusted value for the average damage-slip-ratio is given. The adjustment concerns those occasions in which the ratio has been lower than 1. The *adjusted (average) damage-slip-ratio* is calculated using all ratios, also the ratios that are lower than 1 and thus unknown. In the calculation the unknown ratios are assumed to be 0.5. This way, it is avoided that a shape that occasionally has a ratio below 1 still scores a seemingly good average damage-slip-ratio, just because all its bad scores are not included in the calculation of its average damage-slip-ratio. The value of 0.5 has been chosen because it is halfway between 0 and 1. Any value between 0 and 1 could have been chosen, but 0.5 gives the mathematically best estimation. When looking at the interpretation of the absolute values of the damage-slip-ratios, a value of 0 would provide a safer estimate. However, in the series that will be presented, most conclusions will be drawn from the relative differences in the ratios of the jaw shapes, not from absolute values. Therefore, it was decided to use the *mathematically best* estimate instead of the *safest* estimate.

The robustness of a shape is calculated by dividing the variation in the tissue on which the shape is tested (material property β in Fig. 4.2) by the variation in the *adjusted* damage-slip-ratios of the shape (criterion value α in Fig. 4.2), as discussed in Sect. 4.5.

All statistical analyses are done using a two-tailed paired Student's t-Test, unless otherwise indicated.

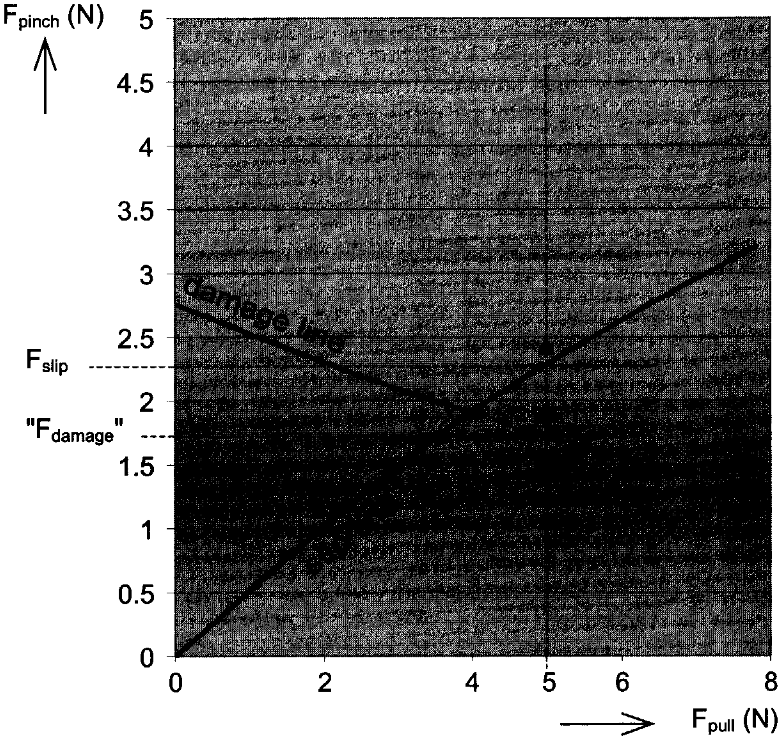


Figure 5.6. Determination of the damage force.

For jaws with a damage line similar to the one shown here, the damage force is difficult, if not impossible, to determine. It is not possible with these jaws to pull with 5 N, without causing unacceptable damage (the combination of forces indicated by the triangle) or letting the tissue slip out of the jaws (square), or sometimes even both (dot).

5.3 Results (I)

Elementary shapes

Looking at the grasper jaws in Fig. 5.1, several design features can be identified. Some jaws possess sharp edges or windows, which provide a more enclosure-based force transmission. The aim of such edges or windows is to obtain a low slip force, but at the same time their presence may decrease the damage force. Other jaws have a large contact area to reduce the pressure on the tissue resulting from a certain pinch force. This may yield a high damage force, but as the force transmission is mostly based on friction, the slip force may be high as well. In this section the influence of several basic design features has been examined. Three series of elementary shapes are discussed. The first series are flat rectangular shapes. In this series the influence of the size of the contact area has been examined. In the second series, the influence of the diameter of cylindrical shapes has been determined. The third series are hemispherical shapes. In this series, again the influence of the diameter has been examined. In Fig. 5.7 a photo of the elementary shapes is shown. Details of all the shapes are given in the relevant subsections.

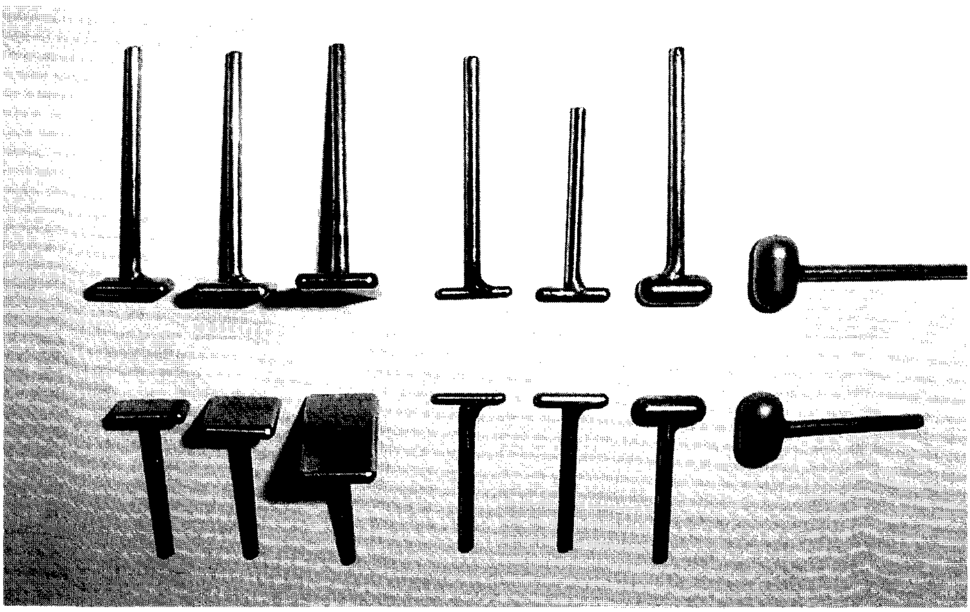


Figure 5.7. Elementary shapes.
The three pairs on the left are the rectangular shapes. The four pairs on the right are the hemispheres (when positioned like the pair on the right) and cylinders (when positioned like the fourth, fifth and sixth pair from the left). For the rectangles and the cylinders, the pull force is directed perpendicular to the plane of view; for the hemispheres it is directed to the right.

5.3.1 Rectangles

To determine the influence of the size of the contact area, three pairs of rectangular shaped jaws have been made. All are 10 mm wide. The edges of the rectangles have been rounded off to avoid extreme effects. The rounding reduces the width of the smooth flat contact area from 10 to 8 mm. The lengths of the 3 pairs, excluding the rounding, are 4 mm, 8 mm and 16 mm, as shown in Fig. 5.8. The three shapes will be referred to as *Rect4*, *Rect8* and *Rect16*, respectively.

In Fig. 5.9 the measured slip forces, damage forces and damage-slip-ratios of the three rectangular pairs are shown. The individual measurements are presented as well as the averages plus standard deviations. The damage force could not always be determined, because sometimes every pinch force above the slip force would already cause damage, as described in Fig. 5.6 and in Sect. 5.2.4. This occurred once for *Rect4* and *Rect8*, and twice for *Rect16*. These occasions are shown in Fig. 5.9 as dark triangles. They indicate the lowest pinch force that could be measured above the slip force, but that would still cause damage. The average damage-slip-ratios are adjusted for the mentioned occasions as described in Sect. 5.2.4. These adjusted ratios are indicated in Fig. 5.9 by asterisks (*). In Table 5.1 the results are summarised and the robustness of the three rectangles is given.

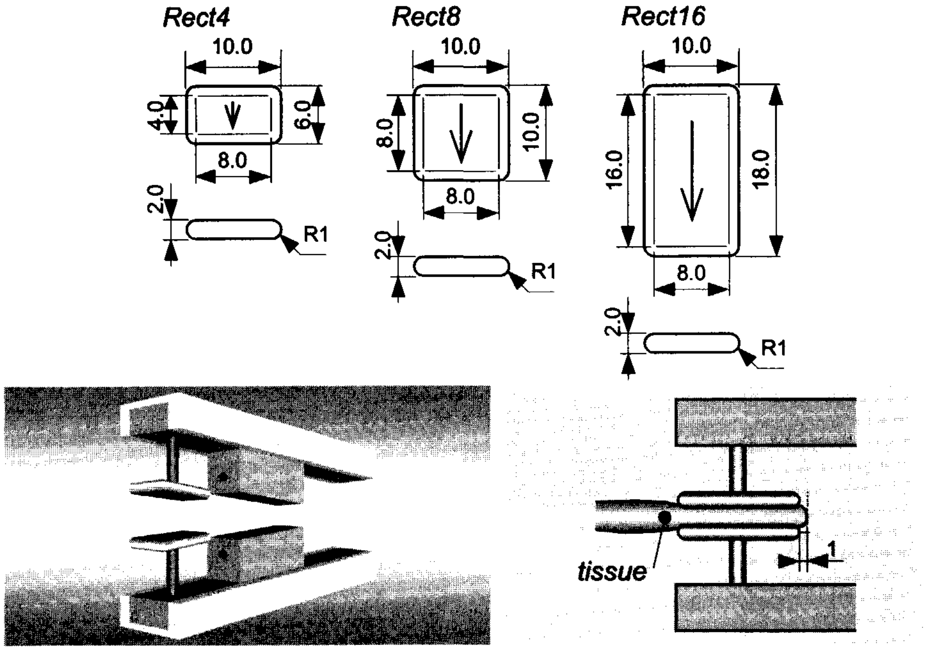


Figure 5.8. Rectangular shapes.

Top figures: Top and side views of the rectangles. The arrows on the top views indicate the direction of the pull force. All dimensions are in millimetres. Bottom left figure: A three-dimensional impression of the positioning of the jaw shapes in the ends of the lever. Bottom right figure: Side view of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside (i.e. at the right side in the picture) of the jaw shapes.

Table 5.1. Overview of the results of the rectangles.
In the top table the results of each shape are given. The bottom tables show the p-values of the differences in slip forces and in damage forces between the shapes. All differences with a p-value smaller than 0.05 are considered significant.

shape	Rect4	*n*	Rect8	*n*	Rect16	*n*
F_{slip} (N)	13.3 ± 4.3	7	17.1 ± 5.3	7	22.0 ± 6.7	7
F_{damage} (N)	**15.1 ± 2.8**	**6**	**24.8 ± 5.0**	**6**	**37.2 ± 4.5**	**5**
damage-slip-ratio	1.3 ± 0.6	6	1.5 ± 0.5	6	1.9 ± 1.0	5
$F_{damage} < F_{slip}$	**1 out of 7**		**1 out of 7**		**2 out of 7**	
adjusted damage-slip-ratio	1.2 ± 0.6	7	1.3 ± 0.6	7	1.5 ± 1.1	7
robustness	**0.59**		**0.73**		**0.44**	

Differences in slip forces (p values)	Rect8	Rect16
Rect4	0.03	0.0009
Rect8		**0.02**

Differences in damage forces (p values)	Rect8	Rect16
Rect4	0.0004	0.0001
Rect8		**0.0009**

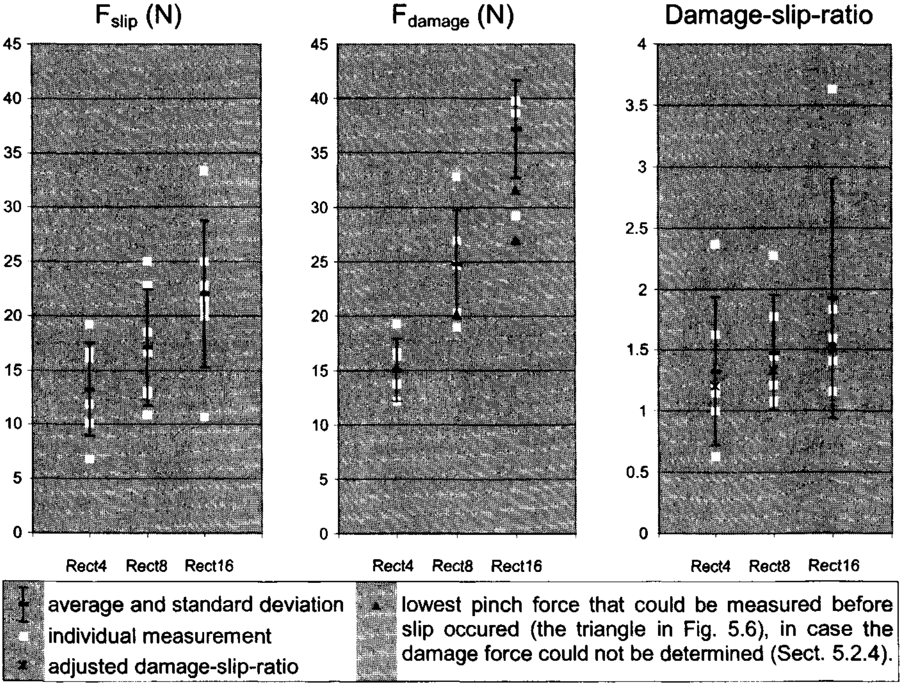


Figure 5.9. Results of the rectangles.
The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the rectanglular shapes. In each figure the results of three shapes are presented: Rect4, Rect8 and Rect16.

5.3.2 Cylinders

The shape of several existing jaws can be approximated by combining several cylindrical shapes. In this subsection such cylindrical shapes have been examined. The influence of the diameter of a cylinder on its slip and damage behaviour has been determined. Four pairs of cylinders have been made, all 10 mm long and with diameters increasing from 1.5 mm to 6 mm. The ends of each cylinder have been rounded off with the same diameter as the cylinder itself to avoid local extreme effects. Fig. 5.10 shows the exact dimensions of the cylinders. The cylinders will be referred to as *Cyl1.5*, *Cyl2*, *Cyl4* and *Cyl6*, where the number indicates the cylinder's diameter.

Fig. 5.11 shows the measured slip forces, damage forces and damage-slip-ratios of the cylinders. Also shown are the occasions in which the damage force was lower than the slip force and could not be determined for reasons described in Sect. 5.2.4 (dark triangles), and the average damage-slip-ratios adjusted for these occasions (asterisks). In Table 5.2 the mentioned results are summarised and the robustness of the shapes is given.

The number of measured damage-slip-ratios has been very low for all the cylinders: n=2. This is due to the relatively large number of cases in which the ratio could not be determined because the damage force was lower than the slip force, and a few cases in which only the damage force but not the slip force has been determined. Therefore the individual measurements have been given instead of the averages. All of these ratios have been determined using the same two pigs, except for the first mentioned ratio of *Cyl1.5*.

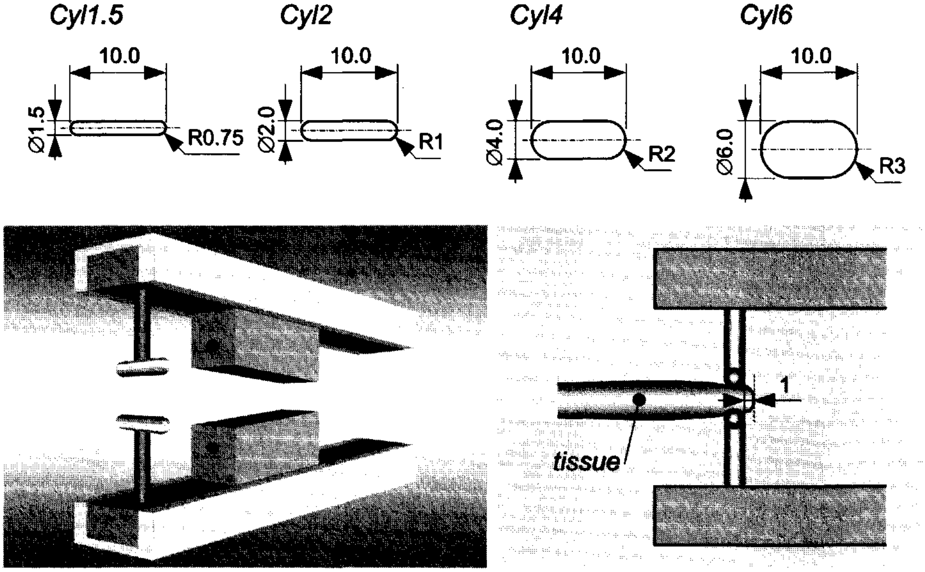


Figure 5.10. Cylindrical shapes.

Top figures: Side views of the cylinders. All dimensions are in millimetres. Bottom left figure: A three-dimensional impression of the positioning of the jaw shapes in the ends of the lever. Bottom right figure: Side view of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside (i.e. at the right side in the picture) of the jaw shapes.

Table 5.2. Overview of the results of the cylinders.
In the top table the results of each shape are given. For the damage-slip-ratios the individual measurements are given instead of the averages, because of the low number of successful measurements (n=2, for all shapes). The bottom tables show that none of the differences in slip forces and in damage forces between the shapes was significant.

shape	Cyl1.5	*n*	Cyl2	*n*	Cyl4	*n*	Cyl6	*n*
F_{slip} (N)	2.7 ± 0.4	4	3.0 ± 0.8	5	4.7 ± 0.7	5	4.6 ± 0.4	4
F_{damage} (N)	**12.8 ± 9.5**	**3**	**14.2 ± 8.9**	**5**	**16.2 ±10.4**	**4**	**17.2 ± 8.1**	**4**
damage-slip-ratio	1.2; 6.8	2	2.2; 6.5	2	1.2; 5.0	2	1.2; 5.7	2
$F_{damage} < F_{slip}$	**2 out of 5**		**3 out of 8**		**3 out of 7**		**4 out of 8**	
adjusted damage-slip-ratio	2.2 ± 3.0	4	2.0 ± 2.6	5	1.5 ± 2.0	5	1.5 ± 2.1	6
robustness	**0.24**		**0.39**		**0.38**		**0.34**	

Differences in slip forces (p values)	Cyl2	Cyl4	Cyl6
Cyl1.5	ns	ns	ns
Cyl2		**ns**	**ns**
Cyl4			ns

Differences in damage forces (p values)	Cyl2	Cyl4	Cyl6
Cyl1.5	ns	ns	ns
Cyl2		**ns**	**ns**
Cyl4			ns

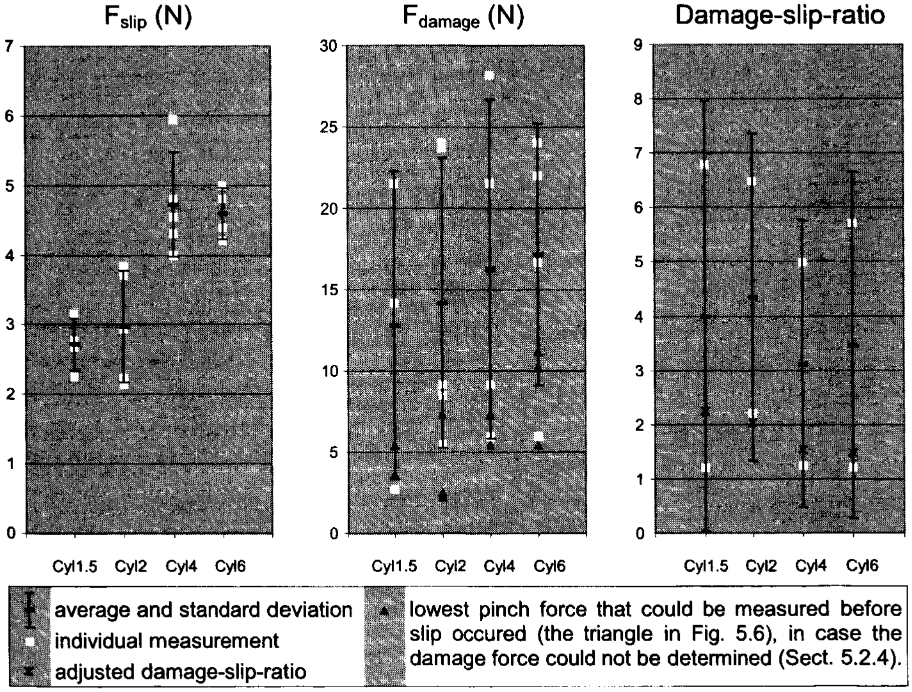


Figure 5.11. Results of the cylinders.
The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the cylindrical shapes. In each figure the results of four shapes are presented: Cyl1.5, Cyl2, Cyl4 and Cyl6.

5.3.3 Hemispheres

The last of the elementary shapes studied are the hemispheres. Just like in the series of the cylinders, the diameter has been the parameter under investigation. Four pairs of hemispheres have been tested. Similar to the cylinders, the diameters of the hemispheres are 1.5, 2, 4 and 6 mm. They will be referred to as *Hemi1.5*, *Hemi2*, *Hemi4* and *Hemi6* (Fig. 5.12).

In Fig. 5.13 the measured slip forces, damage forces and damage-slip-ratios of the hemispheres are shown. Fig. 5.13 also shows the occasions in which the damage force was lower than the slip force and could not be determined for reasons described in Sect. 5.2.4 (dark triangles), and the average damage-slip-ratios adjusted for these occasions (asterisks). In Table 5.3 all results are summarised and the robustness of the shapes is given.

For *Hemi1.5* the individual measurements of the damage forces and the damage-slip-ratios are given in Table 5.3 instead of the averages, because there were only two successful measurements. In three other cases the damage force was lower than the slip force and could therefore not be determined.

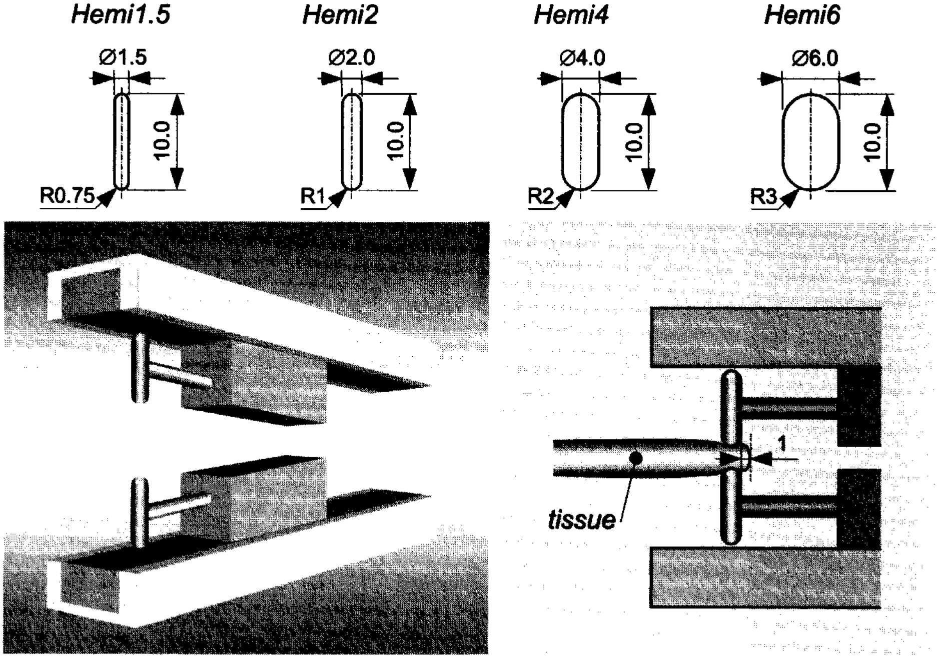


Figure 5.12. Hemispherical shapes.
Top figures: Side views of the hemispherical shapes. All dimensions are in millimetres. Bottom left figure: A three-dimensional impression of the positioning of the jaw shapes in the ends of the lever. Bottom right figure: Side view of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside (i.e. at the right side in the picture) of the jaw shapes.

Table 5.3. Overview of the results of the hemispheres.
In the top table the results of each shape are given. For Hemi1.5 the individual measurements of the damage force and the damage-slip-ratio are given instead of the averages, because of the low number of successful measurements (n=2). The bottom tables show that, except for the difference in damage force between Hemi2 and Hemi4, none of the differences was significant.

shape	Hemi1.5	*n*	Hemi2	*n*	Hemi4	*n*	Hemi6	*n*
F_{slip} (N)	3.8 ± 0.8	5	3.9 ± 0.5	4	4.4 ± 0.1	3	4.2 ± 0.1	5
F_{damage} (N)	5.0; 6.0	2	6.5 ± 2.8	5	7.0 ± 3.2	5	8.3 ± 3.2	5
damage-slip-ratio	1.2; 1.6	2	1.9 ± 0.5	3	1.8 ± 0.7	3	2.2 ± 0.6	4
$F_{damage} < F_{slip}$	3 out of 5		2 out of 7		0 out of 5		1 out of 6	
adjusted damage-slip-ratio	0.9 ± 0.5	5	1.3 ± 0.8	5	1.8 ± 0.7	3	1.9 ± 0.9	5
robustness	0.91		0.89		1.32		1.29	

Differences in slip forces (p values)	Hemi2	Hemi4	Hemi6
Hemi1.5	ns	ns	ns
Hemi2		ns	ns
Hemi4			ns

Differences in damage forces (p values)	Hemi2	Hemi4	Hemi6
Hemi1.5	ns	ns	ns
Hemi2		0.004	ns
Hemi4			ns

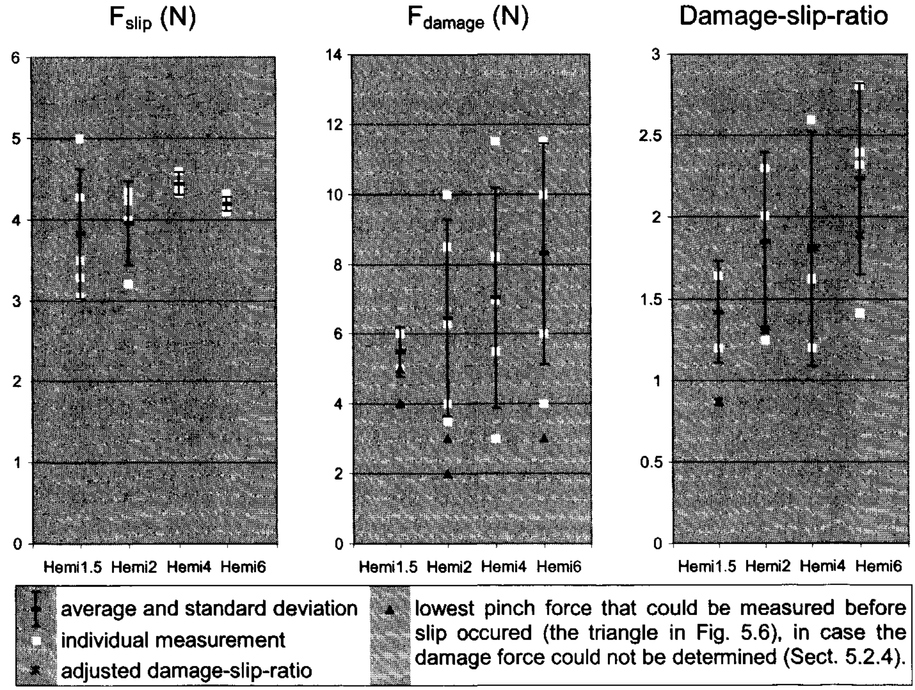


Figure 5.13. Results of the hemispheres.
The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the hemispherical shapes. In each figure the results of four shapes are presented: Hemi1.5, Hemi2, Hemi4 and Hemi6. For Hemi4 the adjusted damage-slip-ratio equals the normal damage-slip-ratio, indicating that there were no occasions in which the damage force of Hemi4 was lower than the slip force.

5.4 Evaluation & Interpretation (I)

From elementary to complex shapes

In this section the three series of elementary shapes are evaluated. From these evaluations some general conclusions are drawn. Based on these conclusions, series of more complex jaw shapes have been designed.

5.4.1 Rectangles

When looking at the results of the series of rectangles, it is noticed that there are clear relations between the size of the contact area and both slip force and damage force. The slip force increases significantly when the size of the contact area increases. In Sect. 3.4 the assumption was made that the law of friction ("friction force equals friction coefficient times normal force"), which is true for linear-elastic materials, may not be valid for biological materials. The results of the series of rectangles confirm this assumption, as they clearly show that the friction depends not only on the normal force, but also on the size of the contact area.

It was noticed that the slip line of the rectangles, as defined in Fig. 3.10 and determined as described in Sect. 5.2, usually was not a straight line. Within the range of pull forces under investigation (i.e. around 5 N; usually 0-10 N), the slip line had a slightly curved shape: For higher pinch forces a relatively large pull force could be applied before slip would occur. For all of the other series, including all series of complex shapes, the second-order interpolation, described in Sect. 5.2, usually yielded a more or less straight slip line.

The damage force of the rectangles also increases significantly when the size of the contact area increases. This increase is logical, because if the pinch force is distributed over a larger contact area, it takes a higher pinch force to exceed the maximally allowable pressure on the tissue.

Increasing the contact area has a stronger effect on the damage force than on the slip force. This can be deducted from the fact that the damage-slip-ratios are increasing with the contact area. Mostly due to the large variations in the slip force, the variations in the ratios are rather big and in several occasions the ratio is lower than 1. This results in a rather low robustness for all the rectangles, which indicates that even though the ratios of all rectangles are sufficient, these shapes are quite often not suitable for the job. In most cases this is caused by the poor slip-preventing qualities of the smooth-surfaced rectangles.

5.4.2 Cylinders

The series of cylinders presents a remarkable slip behaviour. *Cyl1.5* and *Cyl2* have a nearly equal slip force, and so do *Cyl4* and *Cyl6*. The average slip force of *Cyl4* is nearly

60 % lower than that of *Cyl2*. However, this difference is not significant, due to the low number of corresponding pigs upon which both the shapes have been tested. Nevertheless, the slip force seems to increase when a larger cylinder is used. Theoretically speaking, if the tissue would be non-deformable, the contact area between the tissue and a cylinder would be a line and a larger cylinder would have a smaller contact area, because of the larger rounding at the sides. However, the tissue clearly is very deformable and therefore it is assumed that the size of the contact area is in fact larger for larger cylinders. However, the size of the effective contact area cannot be determined exactly, therefore it is not known whether the influence of the contact area is stronger or weaker than the effect of enclosure (the bulging of tissue at the backside of the cylinders), which is expected to lower the slip force for smaller cylinders.

The damage forces of the cylinders also show a trend of increasing with increasing diameter, but none of the differences between the damage forces is significant, due to the large variations. A possible cause for these large variations might be uncertainty of the observer. It is very difficult to detect damage in the inner layers of the bowel wall when the contact area is not much more than a thin line. There were two pigs on which all cylinders score exceptionally high damage forces. This shows in Fig. 5.11 as all cylinders have two points that are distinctively higher than the other damage forces. However, the reference measurements with *Hemi2*, which are required for the determination of the robustness, showed that these two pigs were only of average strength. This indicates that another factor has caused the two exceptionally high damage forces of each shape. This factor might have been an inadequate damage detection by the observer, because in later series when the observers were more experienced, such large variations were not observed. However, when looking at the individual results *per pig*, the increasing trend in the damage force remains apparent in most of them. The rate at which the damage force in the series of cylinders increases is much lower than that in the series of rectangles. This indicates that the increase in effective contact area is not as large in the series of cylinders as it is in the series of rectangles.

The damage-slip-ratios of the two small cylinder pairs, *Cyl1.5* and *Cyl2*, seem larger than the damage-slip-ratios of the larger cylinder pairs, which indicates that the effect of the slip force is stronger than that of the damage force. The increase in the slip force as the cylinders become larger has been attributed to both the increasing contact area and the decreasing influence of enclosure. The increase in the damage force is assumed to be caused mainly by the increase in the contact area, as enclosure is not expected to have as much influence on the damage force as it does on the slip force. In the series of rectangles, in which the size of the contact area is the only influencing factor, the effect of the slip force was weaker than the effect of the damage force, leading to an inclining trend in the damage-slip-ratio. The fact that this trend is the opposite in the series of cylinders suggests that enclosure plays an important role in the slip behaviour of cylinders, because it clearly reduces the slip force for smaller cylinders.

The higher damage-slip-ratios of the smaller cylinders suggest that the smaller cylinders are better than the larger ones, but this is not necessarily true. For example, if the jaws are moved in a direction other than the longitudinal direction of the instrument, the shape of the contact area between tissue and jaws may change from a thick line into a pointy shape. In that case, the new situation may bare closer resemblance to grasping with the hemispheres, than with the cylinders; and the smaller hemispheres score much worse than both the larger hemispheres and the small cylinders. Furthermore, the robustness of all cylinders is very low. This is caused by the large variations in the observed ratios. Sometimes the ratios of all the cylinders are relatively high, but for these same cylinders up to 50% of the damage forces could not be determined, because they were lower than the slip forces. This low robustness indicates that even though their damage-slip-ratios may appear to be sufficient, the cylinders by themselves are not reliable enough to be used as atraumatic grasping jaws.

5.4.3 Hemispheres

The slip force of the hemispheres hardly seems to increase as the diameter of the hemisphere increases. A slightly increasing trend might be recognised, but none of the differences in slip forces are statistically significant, because of the small differences between them and because of the relatively large variations in the slip forces of *Hemi1.5* and *Hemi2*. In conclusion, the effects of a slight increase in the size of the contact area and a slight decrease in the effect of enclosure as the diameter increases do not seem to result in a significant increase in the slip force.

The damage force shows an increasing trend. Although it does not seem obvious because of their large variations, the difference between *Hemi2* and *Hemi4* actually is significant, because in all (4) occasions the damage force of *Hemi4* is clearly higher than that of *Hemi2*. The increase in the damage forces is similar in rate to that of the cylinders, but less than that of the rectangles. This indicates that the increase in effective contact area in the series of hemispheres is similar to that in the series of cylinders, but lower to that in the series of rectangles. In the latter, the size of the contact area increases roughly with a factor 2 when comparing either *Rect4* and *Rect8* or *Rect8* and *Rect16*, and the damage force increases with a factor of approximately 1.6 in both cases. In the series of hemispheres, the increase in damage force when going from one hemisphere to the next one in size is no more than a factor 1.1 to 1.2. This suggests that the increase in the size of the effective contact area will be a factor of 1.4 to 1.5, when comparing one hemisphere to the next one in size.

The increasing trend in the damage-slip-ratios shows that the increase in the damage forces is stronger than the increase in the slip forces. This is similar to the situation of the rectangles, but opposite to that of the cylinders, suggesting that enclosure does not have as much influence on the slip forces of the hemispheres as it does on the slip forces of the cylinders. When looking at the adjusted ratios (which include the occasions in which the damage-slip-ratios are lower than 1), the performance of the smaller hemispheres turns out to be rather poor. *Hemi1.5* even has an adjusted damage-slip-ratio lower than 1, which indicates that it is not suitable for the task of transmitting a 5 N pull force onto colon tissue. The robustness of all hemispheres is reasonable, being above 1 for *Hemi4* and *Hemi6*, and just below 1 for *Hemi1.5* and *Hemi2*. This means that the performance of the hemispheres is stable. Nevertheless, the smaller hemispheres remain unsuitable because of the fact that their damage-slip-ratios are quite often below 1.

5.4.4 Conclusions

A large contact area is required to achieve a high damage force. However, simply using a smooth flat rectangle is not sufficient, because it has a very high slip force, resulting in a low damage-slip-ratio.

There seem to be two ways to decrease the slip force: reducing the contact area, and increasing the enclosure. The first way seems to contradict the requirement for a high damage force, but this is not entirely true. Because the tissue that is grasped is very deformable, so is the contact area. It is possible to have a small contact area when the pinch force is low, and a large contact area when the pinch force is high.

5.4.5 Designing complex shapes

A very clear way to achieve enclosure and a small contact area is by placing several cylinders behind each other. The resulting slip force is expected to be low, but as the contact area does not change and remains small, the damage force is also expected to be rather low, compared to a flat rectangle.

A varying contact area can be achieved by adding protruding hemispheres to a flat rectangle. In fact, the hemispheres will also introduce the effects of enclosure, thus both mentioned strategies to decrease the slip force are actually used in this shape. It is expected that the balance between these two strategies mainly depends on the height to which the hemispheres protrude. Hemispheres that protrude very far may strengthen the effect of enclosure, but they may still be reducing the effective contact area when the pinch force reaches the level of causing unacceptable damage.

If the size of the protruding hemispherical elements is decreased, their numbers increased, and their shapes altered, jaw shapes emerge that resemble the profiles that are used on a variety of existing surgical instruments. Similar to the flat square with protruding hemispheres, these profiled shapes are expected to have a varying contact area and a certain amount of enclosure, which should result in low slip forces. Again, the height of the profile may influence both slip force and damage force, and so may the shape of the protruding elements.

All of the shapes suggested in this subsection have been made and tested to determine which shape provides the best combination of slip force and damage force, expressed in the damage-slip-ratio.

5.5 Results (II)

Complex shapes

Several series of complex shapes have been investigated. In the first series, the effect of enclosure has been examined using two pairs of cylinders side-by-side. Two variations have been tested: one where the top jaw and bottom jaw are in line, and one where the bottom jaw is shifted relative to the top jaw. In the second and third series flat squares with protruding hemispheres have been investigated. In the first variant, the top and bottom jaws are equal. In the second variant, the hemispheres of the top jaw will rest in between the hemispheres of the bottom jaw, when the jaws are closed. In both series, the parameter under investigation has been the height of the protrusion. In the fourth series, two types of profiles have been tested: a diamond-shaped profile and a ribbed profile. In the fifth series, the influence of the height of the (diamond-shaped) profile has been investigated. In the last series, the effects of two restrictions applied to all shapes have been investigated. These restrictions are the rounding, which has been applied to most shapes, and the protrusion of tissue at the backside of the jaws.

In Fig. 5.14 photos of all the complex shapes are shown. Details of all the shapes are given in the relevant subsections.

5.5.1 Double cylinders

The first series of the complex shapes are the double pairs of cylinders. Two types of enclosure have been investigated: symmetrical and asymmetrical enclosure. Symmetrical enclosure implies that the tissue bulges in a window in the jaws or at the backside of the jaws. Asymmetrical enclosure implies a 'wave pattern'. Fig. 5.15 shows the dimensions of the shapes used to obtain enclosure. Symmetrical enclosure is achieved by positioning the two cylinders of the top jaw right above the two cylinders of the bottom jaw, such that when the jaws are closed the cylinders of the top jaw will rest *on* the cylinders of the bottom jaw (Fig. 5.15, top right). It mimics the effect of having windows in the jaws. Asymmetrical enclosure is achieved by shifting one of the jaws, such that when the jaws are closed the cylinders of the top jaw rest *in* between the cylinders of the bottom jaw (Fig. 5.15, bottom right). This way, the tissue is forced into a wave shape when it is pinched. The two variations will be referred to as *2on2* and *2in2*, respectively.

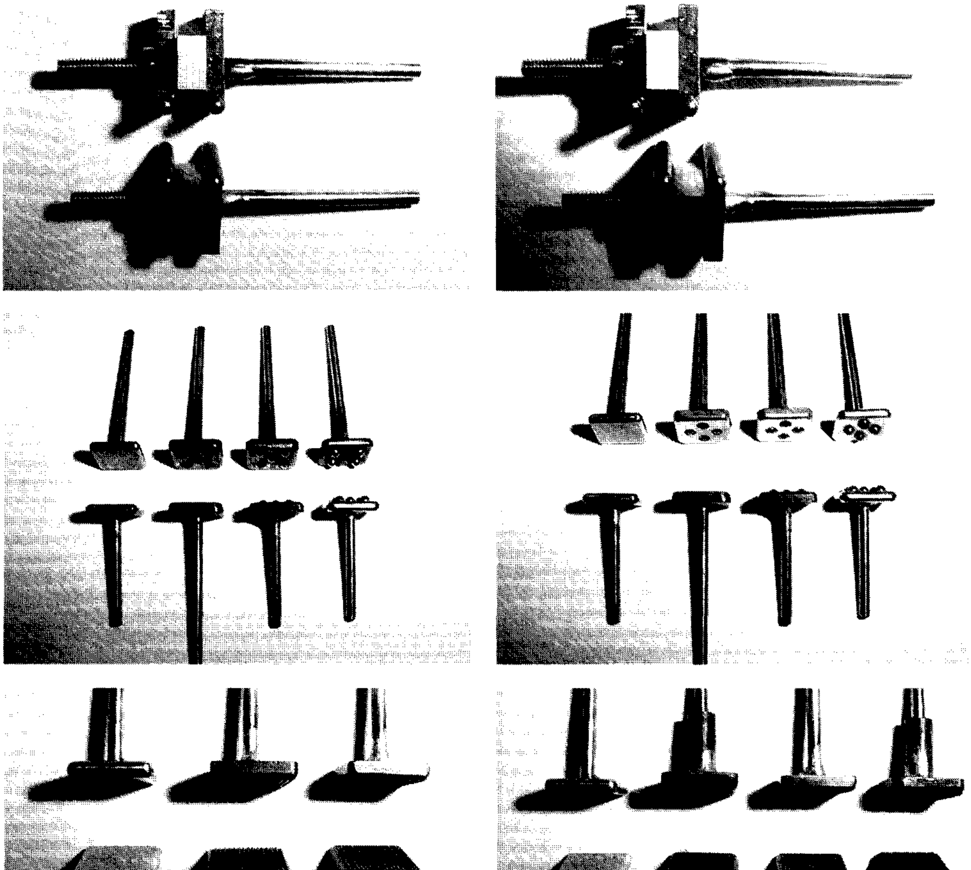


Figure 5.14. Complex shapes.

The top two photos show the double cylinders in two configurations: with the top and bottow jaw in line (top left; Sect. 5.5.1) and with the bottom jaw shifted (top right; Sect. 5.5.1). The middle two photos show the flat squares with protruding hemispheres. There are two variations: a series with equal top and bottom jaws (middle left; Sect. 5.5.2) and a series with interlocking top and bottom jaws (middle right; Sect. 5.5.3). In the bottom two photos the profiled shapes are shown. In the first series of profiled shapes different profile shapes have been compared (bottom left; Sect. 5.5.4). In the second series of profiled shapes different profile heights have been compared (bottom right; Sect. 5.5.5).

In Fig. 5.16 the measured slip forces, damage forces and damage-slip-ratios of the double cylinders are shown. Fig. 5.16 also shows the occasions in which the damage force was lower than the slip force and could not be determined for reasons described in Sect. 5.2.4 (dark triangles), and the average damage-slip-ratios adjusted for these occasions (asterisks). In Table 5.4 all results are summarised and the robustness of the shapes is given.

The slip forces are measured with the tissue being clamped as shown in Fig. 5.15. In the case of *2on2*, when the tissue slips out from between the first pair of cylinders, but is still clamped between the second pair, the event is not classified as slip. Only when the tissue has completely slipped out of the jaws, the event is classified as slip.

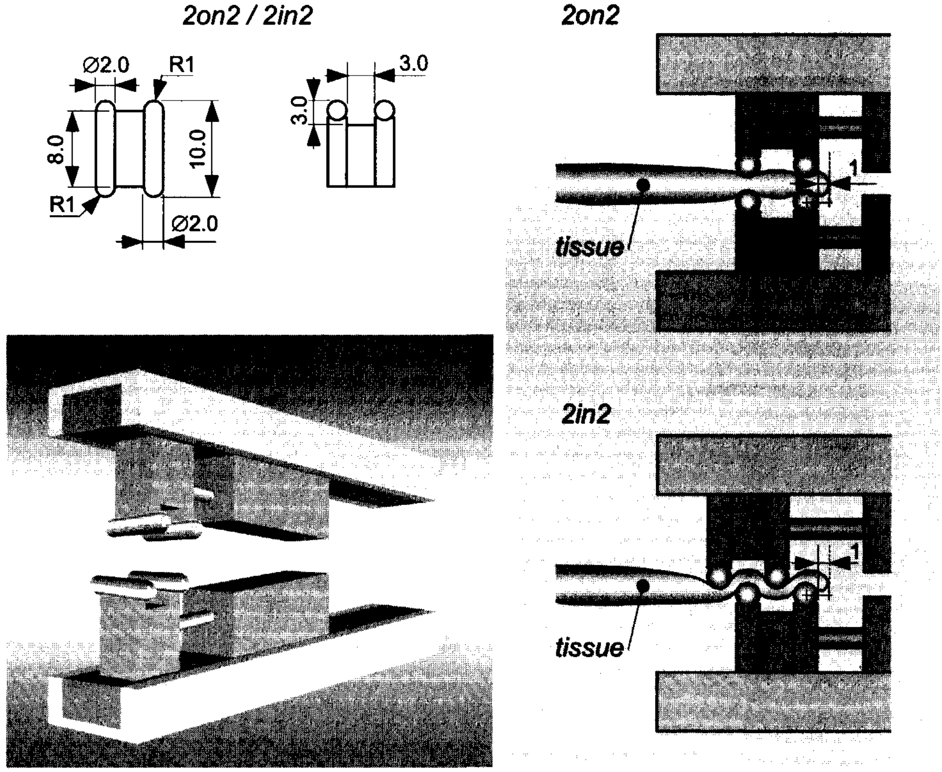


Figure 5.15. Double cylinders.
Top left figures: Top and side views of the double cylinders. All dimensions are in millimetres. Bottom left figure: A three-dimensional impression of the positioning of the 2in2 jaw shapes in the ends of the lever. Right figures: Side views of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside (i.e. at the right side in the picture) of the jaw shapes. Top right: 2on2; bottom right: 2in2.

Table 5.4. Overview of the results of the double cylinders.
For both shapes the results are presented including the robustness. The differences in slip forces and in damage forces between the two shapes were not significant.

shape	2on2	*n*	2in2	*n*
	2.8 ± 0.6	5	2.4 ± 0.3	5
F_{damage} (N)	**4.5 ± 1.4**	**6**	**5.2 ± 0.9**	**5**
damage-slip-ratio	1.7 ± 0.6	4	1.9 ± 0.3	3
$F_{damage} < F_{slip}$	**1 out of 7**		**2 out of 7**	
adjusted damage-slip-ratio	1.5 ± 0.8	5	1.3 ± 0.8	5
robustness	**0.79**		**0.71**	

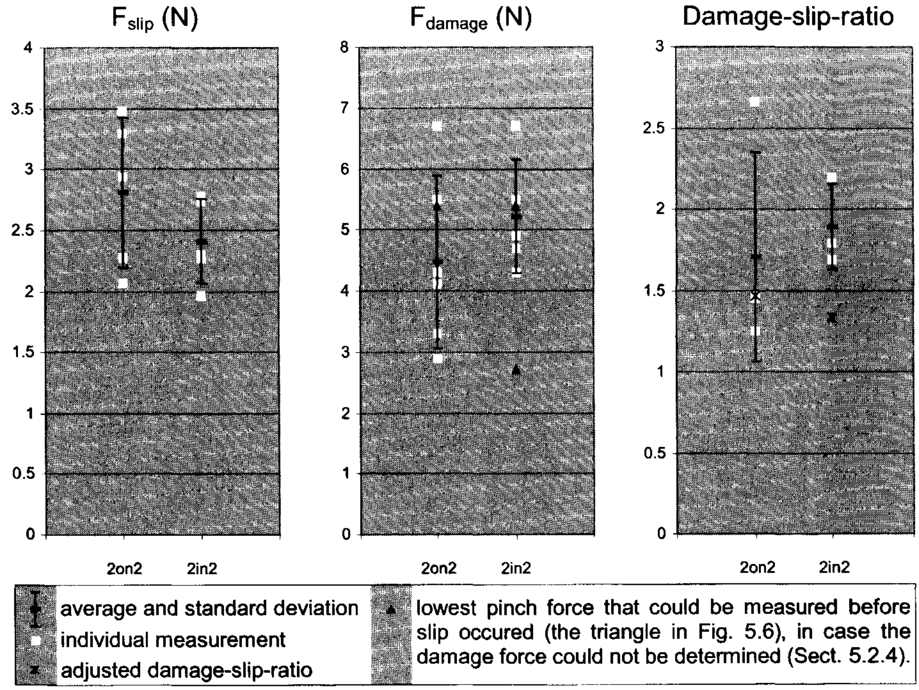


Figure 5.16. Results of the double cylinders.
The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the two variations of the double cylinders: 2on2 and 2in2.

5.5.2 Flat square with 5 on 5 protruding hemispheres

The slip force of the flat rectangles presented in Sect. 5.3 can be reduced by placing protruding elements on the flat surface. However, such protruding elements may also affect the damage force. The protruding elements under investigation in this subsection were hemispheres and the investigated parameter was the extent of the protrusion of these hemispheres. The jaws contain 5 hemispheres, positioned like the 5 eyes on a dice (Fig. 5.17). The top jaw and the bottom jaw are equal, so when the jaws are closed, the hemispheres of the top jaw rest on those of the bottom jaw. Just like the edges of the rectangular shapes, the edges of these shapes have been rounded off to avoid extreme effects. The three pairs of shapes will be referred to as *5x5,1/4*, *5x5,1/2* and *5x5,1*, where the number behind the comma indicates how far the hemispheres protrude, in millimetres. A flat rectangle with the same dimensions (*Rect8*) was also included in this series.

Fig. 5.18 depicts the measured slip forces, damage forces and damage-slip-ratios of the *5x5* shapes. Also shown are the occasions in which the damage force was lower than the slip force and could not be determined for reasons described in Sect. 5.2.4 (dark triangles), and the average damage-slip-ratios adjusted for these occasions (asterisks). In Table 5.5 all results are summarised and the robustness of the shapes is given.

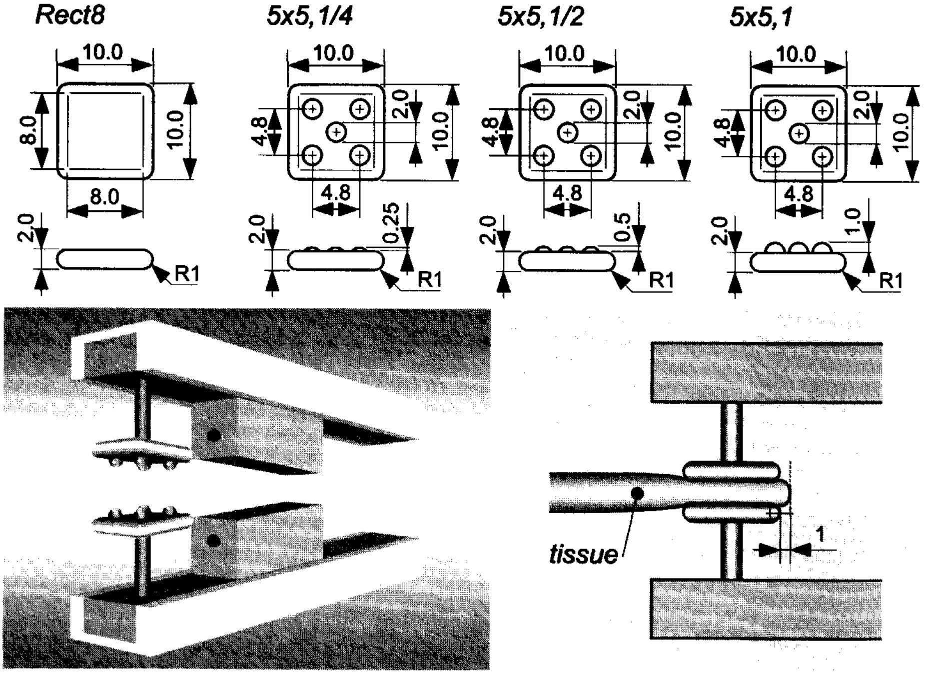


Figure 5.17. Flat square with 5 on 5 protruding hemispheres.
Top figures: Top and side views of the 5x5 shapes. All dimensions are in millimetres. Bottom left figure: A three-dimensional impression of the positioning of the jaw shapes in the ends of the lever. Bottom right figure: Side view of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside (i.e. at the right side in the picture) of the jaw shapes.

Table 5.5. Overview of the results of the flat squares with 5 on 5 protruding hemispheres.
In the top table for each shape all results are shown, including the robustness. The bottom tables show the p-values of the differences in slip forces and in damage forces between the shapes. All differences with a p-value smaller than 0.05 are considered significant.

shape	Rect8	*n*	5x5,1/4	*n*	5x5,1/2	*n*	5x5,1	*n*
	14.0 ± 6.0	9	5.1 ± 0.7	5	4.4 ± 1.7	6	2.8 ± 0.7	6
F_{damage} (N)	22.1 ± 9.0	10	21.0 ± 6.6	7	12.1 ± 5.2	7	8.4 ± 4.3	8
damage-slip-ratio	1.7 ± 0.6	6	3.0 ± 1.3	3	2.8 ± 0.7	4	3.0 ± 1.4	5
$F_{damage} < F_{slip}$	1 out of 11		0 out of 7		1 out of 8		0 out of 8	
adjusted damage-slip-ratio	1.5 ± 0.7	7	3.0 ± 1.3	3	2.4 ± 1.2	5	3.0 ± 1.4	5
robustness	1.28		1.56		1.07		1.38	

Differences in slip forces (p values)	5x5,1/4	5x5,1/2	5x5,1
Rect8	0.01	0.02	0.01
		0.01	ns
			ns

Differences in damage forces (p values)	5x5,1/4	5x5,1/2	5x5,1
Rect8	ns	0.01	0.03
		ns	0.01
			0.03

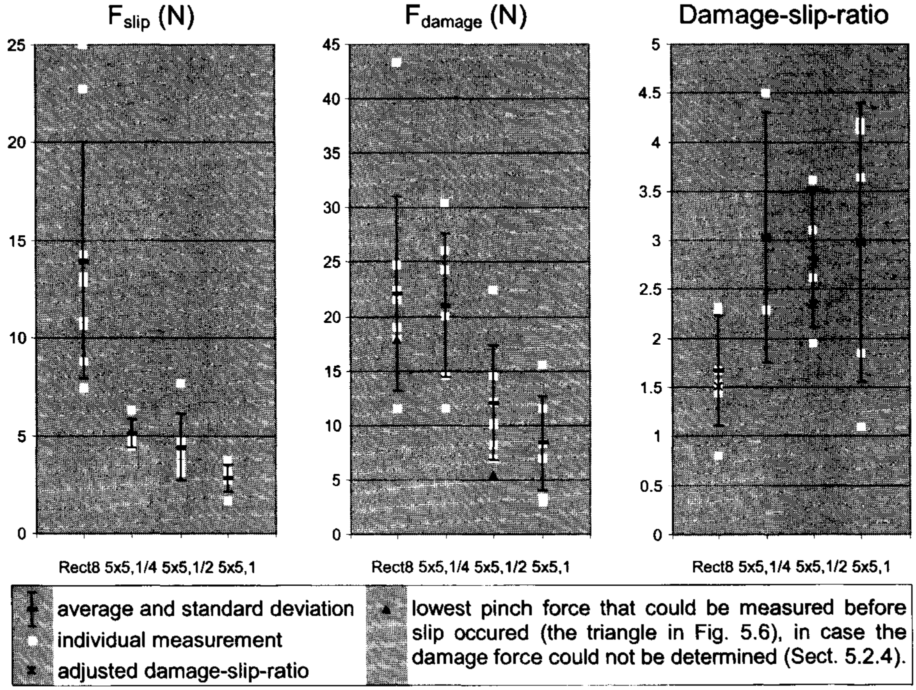


Figure 5.18. Results of the squares with 5 on 5 protruding hemispheres.
The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the 5x5 shapes. In each figure the results of four shapes are presented: Rect8, 5x5,1/4, 5x5,1/2 and 5x5,1. For 5x5,1/4 and 5x5,1 there were no occasions in which the damage force was lower than the slip force.

5.5.3 Flat square with 4 on 5 protruding hemispheres

The shapes presented in this subsection are equal to those from the previous subsection, except that the top jaw now contains only 4 hemispheres, and they are positioned differently, as shown in Fig. 5.19. When the jaws are closed, the hemispheres of the top jaw rest in between those of the bottom jaw, whereas in the previous subsection, the hemispheres of the top jaw rested on the hemispheres of the bottom jaw. The three pairs of shapes will be referred to as *4x5,1/4*, *4x5,1/2* and *4x5,1*, where the number behind the comma indicates how far the hemispheres protrude. Again, a rectangle with the same dimensions (*Rect8*) has been included in this series.

In Fig. 5.20 the measured slip forces, damage forces and damage-slip-ratios of the *4x5* series are presented. Fig. 5.20 also shows the occasions in which the damage force was lower than the slip force and could not be determined for reasons described in Sect. 5.2.4 (dark triangles), and the average damage-slip-ratios adjusted for these occasions (asterisks). Table 5.6 summarises all results and also shows the robustness of the shapes.

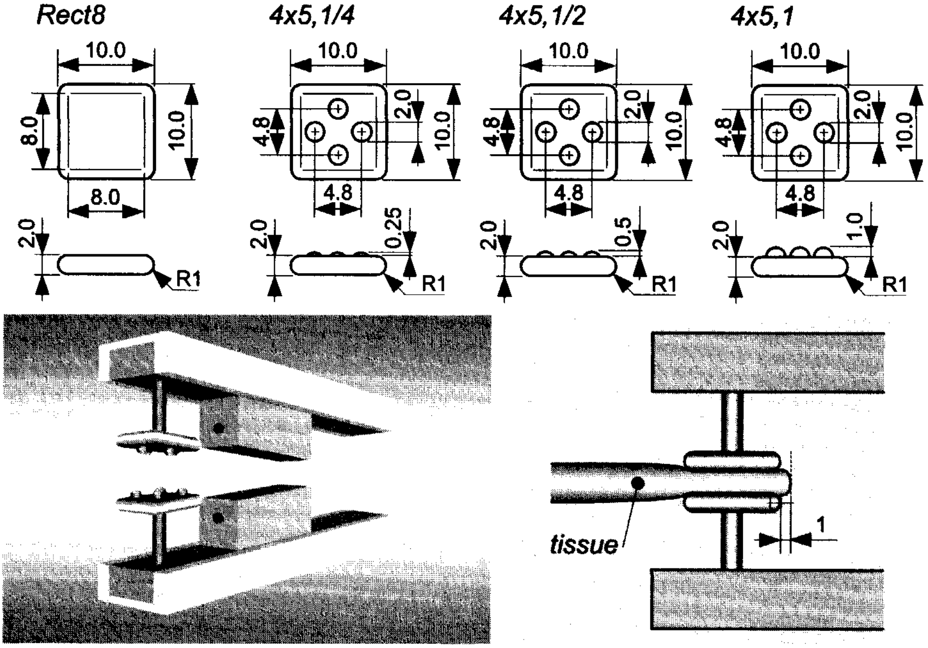


Figure 5.19. Flat square with 4 on 5 protruding hemispheres.
Top figures: Top and side views of the top jaws of the 4x5 shapes. The bottom jaws are equal to the 5x5 shapes shown in Fig. 5.17. All dimensions are in millimetres. Bottom left figure: A three-dimensional impression of the positioning of the jaw shapes in the ends of the lever. Bottom right figure: Side view of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside (i.e. at the right side in the picture) of the jaw shapes.

Table 5.6. Overview of the results of the flat squares with 4 on 5 protruding hemispheres.
In the top table the results of each shape are given. The bottom tables show the p-values of the differences in slip forces and in damage forces between the shapes. All differences with a p-value smaller than 0.05 are considered significant. For the differences in slip forces between Rect8 and 4x5,1/4 and between Rect8 and 4x5,1/2 no p-values could be determined, because in both cases there was only one pig upon which the slip force of both shapes was determined.

shape	Rect8	*n*	4x5.1/4	*n*	4x5.1/2	*n*	4x5.1	*n*
	12.8 ± 5.5	6	7.2 ± 3.1	5	7.3 ± 2.7	5	4.3 ± 1.2	6
F_{damage} (N)	**26.2 ± 12.1**	**8**	**24.2 ± 7.3**	**7**	**19.8 ± 5.3**	**5**	**12.3 ± 4.6**	**10**
damage-slip-ratio	1.6 ± 0.6	4	4.0 ± 2.4	5	2.8 ± 0.9	4	3.2 ± 1.3	5
$F_{damage} < F_{slip}$	**2 out of 10**		**0 out of 7**		**1 out of 6**		**1 out of 11**	
adjusted damage-slip-ratio	1.2 ± 0.7	6	4.0 ± 2.4	5	2.4 ± 1.3	5	2.8 ± 1.6	6
robustness	**0.97**		**0.71**		**0.30**		**0.90**	

Differences in slip forces (p values)	4x5,1/4	4x5,1/2	4x5,1
Rect8	-	-	0.02
		ns	**ns**
			ns

Differences in damage forces (p values)	4x5,1/4	4x5,1/2	4x5,1
Rect8	ns	0.01	0.04
		ns	**ns**
			ns

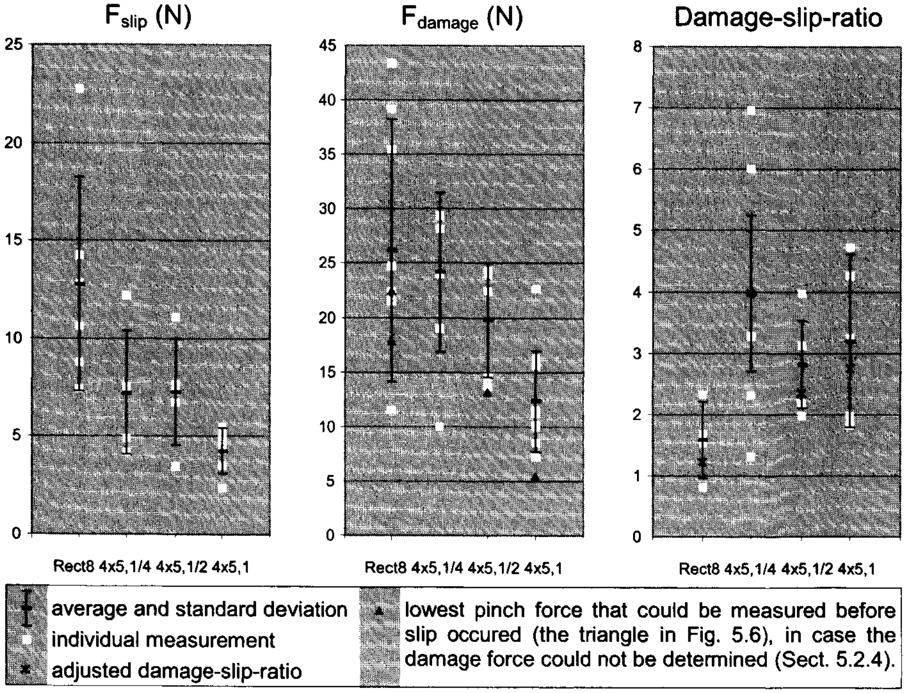


Figure 5.20. Results of the squares with 4 on 5 protruding hemispheres.
The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the 4x5 shapes. In each figure the results of four shapes are presented: Rect8, 4x5,1/4, 4x5,1/2 and 4x5,1. For 4x5,1/4 there is no difference between the normal and the adjusted damage-slip-ratio, because for this shape there were no occasions in which the damage force was lower than the slip force.

5.5.4 Profiles

Another way of reducing the slip force of the flat rectangles is providing the surfaces with a profile. Basically, such a profile can be interpreted as a collection of protruding elements, just like in the previous two subsections, only the size of the elements is smaller and the number is higher. Two types of profiles have been compared. The first pair of jaws has a profile made up of diamond-shaped elements and will be referred to as *Diam.3*. The second pair has a ribbed profile and will be referred to as *Rib.3*. The number indicates the height of the profile, i.e. 0.3 mm. The investigation into the influence of the height of the profile will be described in the next subsection. The types of profiles used here are commonly used in existing laparoscopic instruments. The main difference with existing graspers is the fact that the edges of the jaws have been rounded off. Fig. 5.21 shows the exact dimensions of both pairs of profiled jaws. The profiled shapes will be compared to a flat rectangle with the same dimensions (*Rect8*).

In Fig. 5.22 the measured slip forces, damage forces and damage-slip-ratios of the profiled shapes are shown. Fig. 5.22 also shows the occasions in which the damage force was lower than the slip force and could not be determined for reasons described in Sect. 5.2.4 (dark triangles), and the average damage-slip-ratios adjusted for these occasions (asterisks). In Table 5.7 all results are summarised and the robustness of the shapes is given.

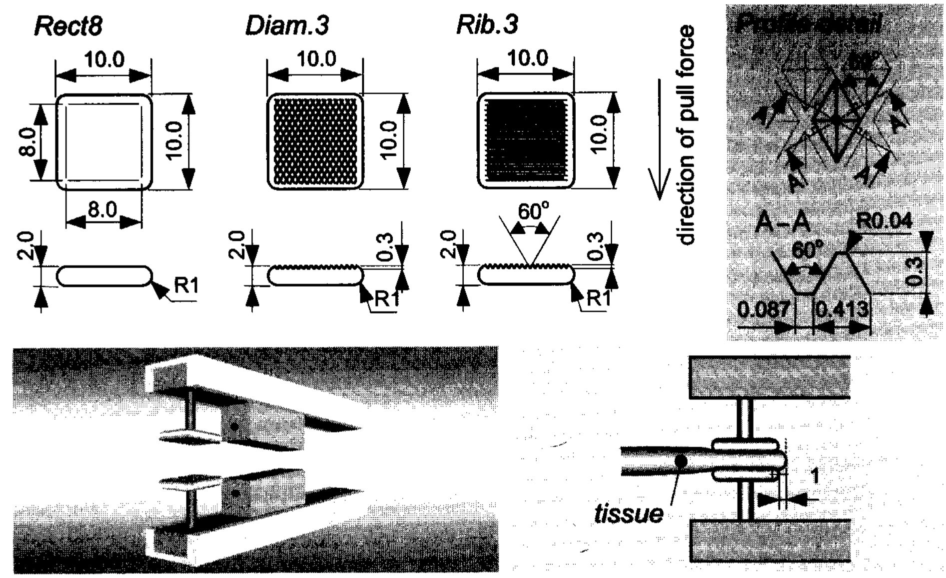


Figure 5.21. Profiled shapes.
Top left figures: Top and side views of the flat shape Rect8 and the two profiled shapes Diam.3 and Rib.3. All dimensions are in millimetres. Top right figure: A single profile element of Diam.3 in detail. A top view of a single profile element is given, as well as a cross-section (A-A). The profile elements of Rib.3 have virtually the same cross-section. Bottom left figure: A three-dimensional impression of the positioning of the jaw shapes in the ends of the lever. Bottom right figure: Side view of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside of the jaws.

Table 5.7. Overview of the results of the profiled shapes.

The top table shows the results of the profiled shapes. The bottom tables show the p-values of the differences in slip forces and in damage forces between the shapes. All differences with a p-value smaller than 0.05 are considered significant.

shape	Rect8	*n*	Diam.3	*n*	Rib.3	*n*
	19.4 ± 7.7	3	2.4 ± 0.7	6	2.4 ± 0.4	6
F_{damage} (N)	28.9 ± 9.1	5	27.0 ± 7.0	6	23.7 ± 12.2	6
damage-slip-ratio	1.5 ± 0.7	3	12.0 ± 3.4	6	10.0 ± 4.8	6
$F_{damage} < F_{slip}$	1 out of 6		0 out of 6		0 out of 6	
adjusted damage-slip-ratio	1.2 ± 0.8	4	12.0 ± 3.4	6	10.0 ± 4.8	6
robustness	0.77		1.66		0.99	

Differences in slip forces (p values)	Diam.3	Rib.3
Rect8	0.05	0.05
Diam.3		ns

Differences in damage forces (p values)	Diam.3	Rib.3
Rect8	ns	ns
Diam.3		ns

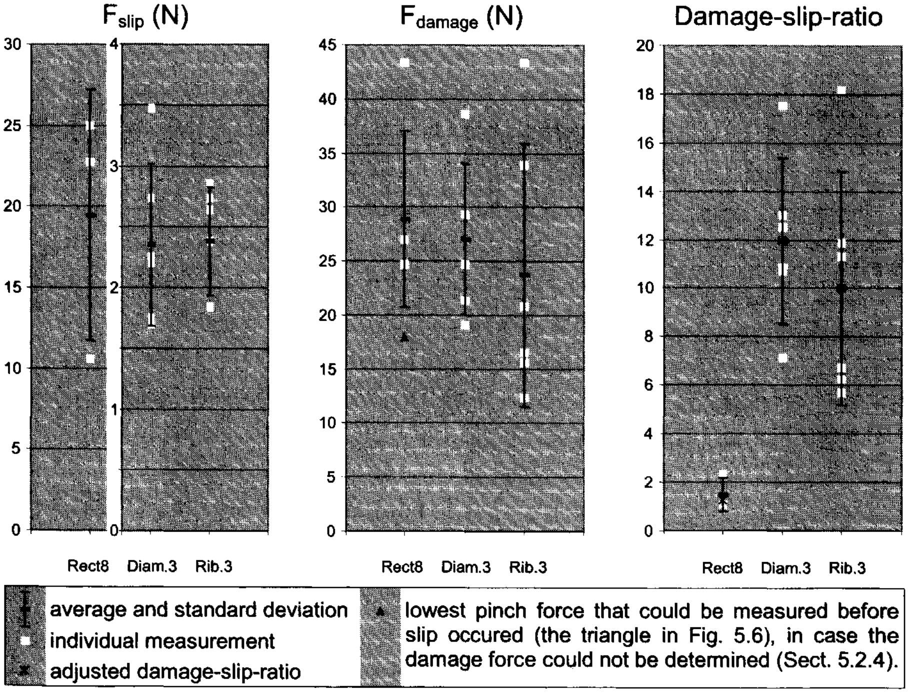


Figure 5.22. Results of the profiled shapes.

The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the profiled shapes. In each figure the results of three shapes are presented: Rect8, Diam.3 and Rib.3. The differences in slip forces between Rect8 and Diam.3 and Rib.3 were so large that two different scales had to be used in the graph of the slip forces. For Diam.3 and Rib.3 the damage-slip-ratios do not change, because for these shape there were no occasions in which the damage force was lower than the slip force.

5.5.5 Diamond-shaped profiles with varying heights

It was expected that the performance of the profiled shapes would be influenced by the height of the profiles, just like in the series of flat squares with protruding hemispheres. Therefore, three shapes, with profile heights of 0.15, 0.3 and 0.6 mm, have been compared. They will be referred to as *Diam.15*, *Diam.3* and *Diam.6*, respectively (Fig. 5.23). The diamond-shaped profile has been used instead of the ribbed profile, because of its slightly better performance in both ratio and robustness, as shown in the previous subsection. Just like all previous shapes, the edges of these profiled shapes have been rounded off to avoid extreme effects. A flat rectangle with the same dimensions (*Rect8*) has also been included in this series.

Fig. 5.24 presents the measured slip forces, damage forces and damage-slip-ratios of the diamond-shaped profiles. Also shown are the occasions in which the damage force was lower than the slip force and could not be determined for reasons described in Sect. 5.2.4 (dark triangles), and the average damage-slip-ratios adjusted for these occasions (asterisks). For the three profiled shapes, there were no such occasions. In Table 5.8 all results are summarised and the robustness of the shapes is given.

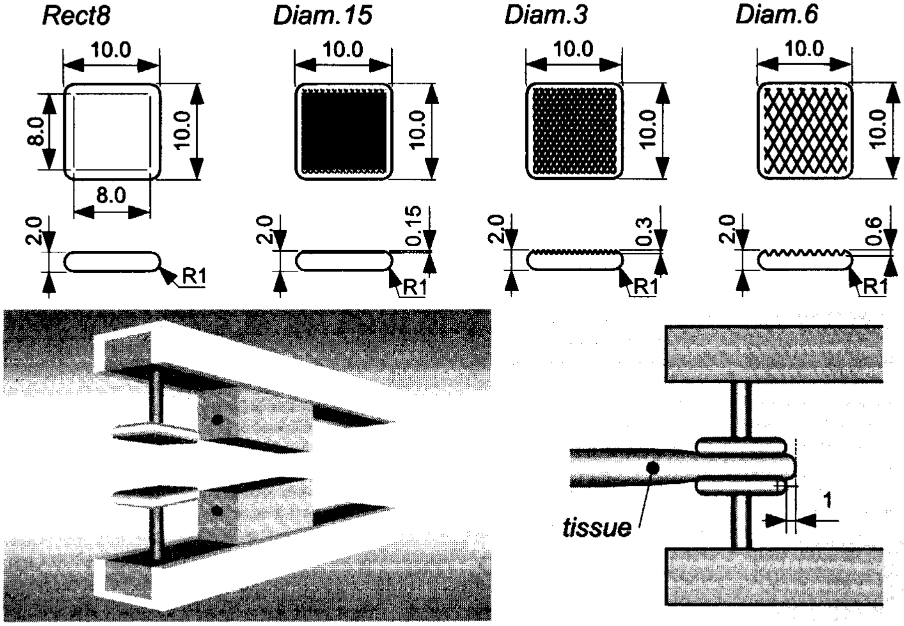


Figure 5.23. Diamond-shaped profiles with varying height.

Top figures: Top and side views of the diamond-shaped profiles. All dimensions are in millimetres. In Fig. 5.21 the shape of the elements of the profile of Diam.3 is shown in detail. The profiles of Diam.15 and Diam.6 are identical in shape to the profile of Diam.3, but half, respectively double in all dimensions, except for the groove between the profile elements. This groove is 0.087 mm wide for all three shapes. Bottom left figure: A three-dimensional impression of the positioning of the jaw shapes in the ends of the lever. Bottom right figure: Side view of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside of the jaw shapes.

Table 5.8. Overview of the results of the diamond-shaped profiles.
In the top table the results for each shape are presented. The bottom tables show the p-values of the differences in slip forces and in damage forces between the shapes.

shape	Rect8	*n*	Diam.15	*n*	Diam.3	*n*	Diam.6	*n*
	21.8 ± 3.6	7	3.3 ± 0.1	7	3.0 ± 0.3	7	2.9 ± 0.3	7
F_{damage} (N)	28.9 ± 3.6	3	29.7 ± 9.1	7	27.7 ± 5.0	7	27.0 ± 10.3	7
damage-slip-ratio	1.5 ± 0.3	3	9.1 ± 2.7	7	9.4 ± 2.3	7	9.4 ± 3.9	7
$F_{damage} < F_{slip}$	4 out of 7		0 out of 7		0 out of 7		0 out of 7	
adjusted damage-slip-ratio	0.9 ± 0.6	7	9.1 ± 2.7	7	9.4 ± 2.3	7	9.4 ± 3.9	7
robustness	0.61		1.28		1.55		0.92	

Differences in slip forces (p values)	Diam.15	Diam.3	Diam.6
Rect8	<1e-5	<1e-5	<1e-5
Diam.15		0.01	0.004
Diam.3			ns

Differences in damage forces (p values)	Diam.15	Diam.3	Diam.6
Rect8	ns	ns	ns
Diam.15		ns	ns
Diam.3			ns

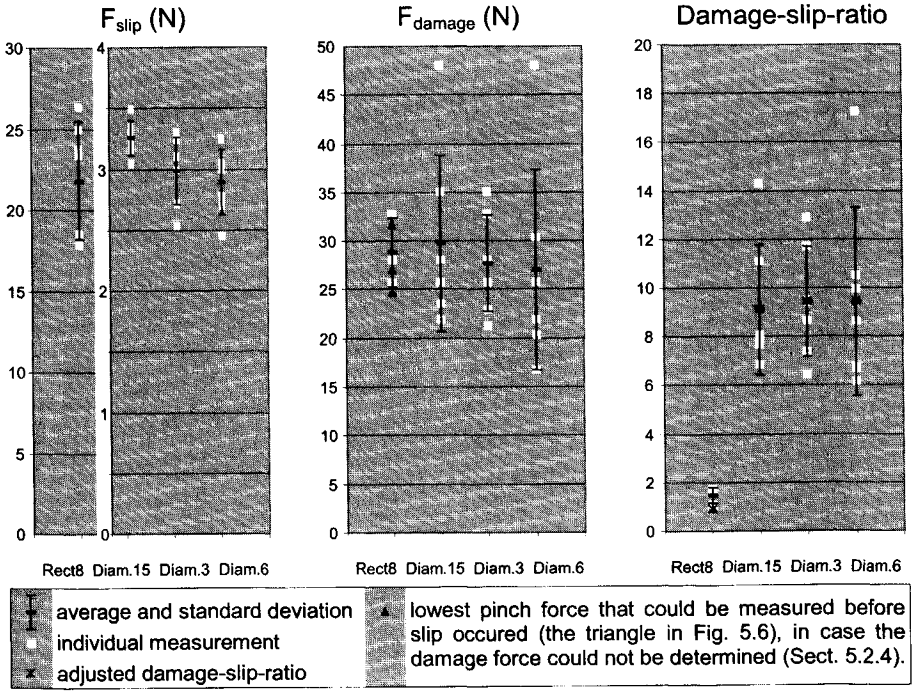


Figure 5.24. Results of the diamond-shaped profiles.
The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of the diamond-shaped profiles. In each figure the results of four shapes are presented: Rect8, Diam.15, Diam.3 and Diam.6. The differences in slip forces between Rect8 and the other shapes were so large that two different scales had to be used in the graph of the slip forces. For Diam.15, Diam.3 and Diam.6 the damage force was never lower than the slip force.

5.5.6 Tissue protrusion and rounding

In all series except the double cylinders, it has been the intention to investigate the effects of changes in the surface of the jaw shapes on the damage and slip forces. To ensure that any observed effects are caused only by those surface changes under investigation, and not by any other design parameters, two restrictions have been given to all series. Firstly, the tissue has not been allowed to protrude more than 1 mm at the backside of all jaws. Secondly, the edges of all shapes have been rounded off to avoid that any misalignment of tissue and jaws might result in extreme local pressure on the tissue at the edges of the jaws. The effects of these two restrictions are investigated in this subsection.

To determine the influence of rounding, the flat square with rounding (*Rect8*) has been compared to a shape of the same size (10 x 10 mm), but without any rounding or

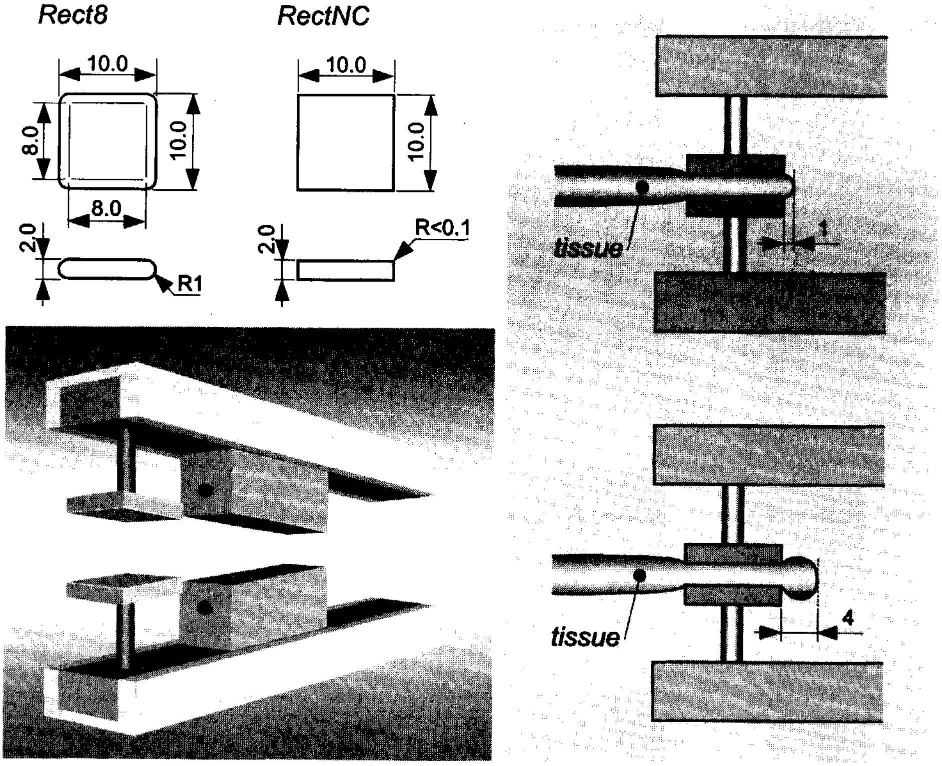


Figure 5.25. Rounding and tissue protrusion.
Top left figures: Top and side views of the flat square with and without rounding (Rect8 and RectNC respectively). The edges of RectNC are not perfectly sharp. However, any rounding or chamfering of RectNC is negligible compared to that of Rect8. All dimensions are in millimetres. Bottom left figure: A three-dimensional impression of the positioning of the flat squares without chamfering in the ends of the lever. Right figures: Side views of the ends of the lever, with an indication of how far the tissue was allowed to protrude at the backside of the jaw shapes (shown for RectNC). Top right: no tissue protrusion (i.e. protruding no more than 1 mm); bottom right: tissue protruding approximately 4 mm.

chamfering (Fig. 5.25). This shape will be referred to as *RectNC* (Rectangle with No Chamfering). All measured forces and ratios of *Rect8* and *RectNC* are shown in Fig. 5.26. In each of the three graphs, the results of *RectNC* are the first from the left (*RectNC w/o*); the results of *Rect8* are the third from the left (*Rect8 w/o*). The differences in the slip forces and in the damage forces between the two shapes were not significant. All results, including the robustness, are summarised in Table 5.9.

To investigate the influence of tissue protrusion at the backside of the jaws, the damage and slip forces of three shapes have been tested in two ways: with the tissue sticking out no more than 1 mm, and with the tissue sticking out approximately 4 mm, as shown in Fig. 5.25. The three shapes used are *Rect8*, *RectNC* and *Diam.3*. All measurements are shown in Fig. 5.26 and Table 5.9. The average slip force of *Rect8* measured with the tissue sticking out 4 mm was about 33 % lower (i.e. better) than the average slip force measured with the tissue sticking out in the normal way. For *RectNC* the slip force decreased 78 % when tissue protrusion was allowed. For *Diam.3* the slip force decreased 12 %. None of the damage forces changed significantly.

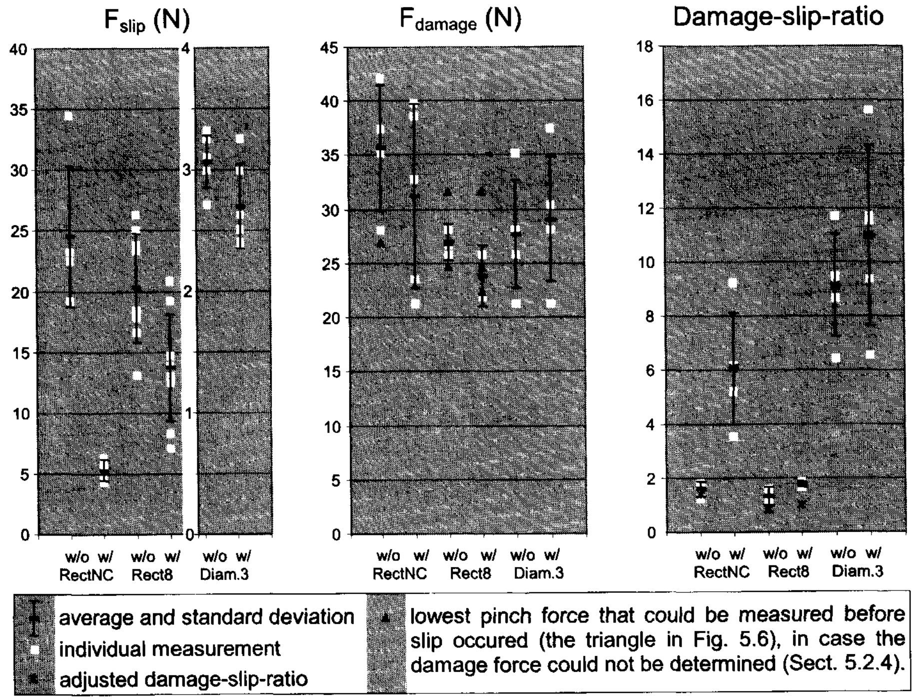


Figure 5.26. Results of the shapes with and without tissue protrusion and the shape with and without rounding.

The slip forces (left), damage forces (middle) and damage-slip-ratios (right) of three shapes (RectNC, Rect8 and Diam.3) without tissue protrusion (w/o) - i.e. protrusion of less than 1 mm - and with tissue protrusion of approximately 4 mm (w/). For the graph with the slip forces two different scales have been used, because of the large differences in slip forces between the different shapes. The flat squares without and with rounding are the first and third shape in each graph (RectNC w/o and Rect8 w/o, respectively).

Table 5.9. Overview of the results of one shape with and without rounding (Rect8 vs. RectNC) and of three shapes (RectNC, Rect8 and Diam.3) without (w/o) and with (w/) tissue protrusion. *In the top table the results for each shape are presented. The bottom tables show the p-values of the differences in slip forces and in damage forces between the shapes with and without tissue protrusion. All differences with a p-value smaller than 0.05 are considered significant. The differences in slip force and in damage force between the shape with rounding and the shape without rounding were not significant.*

shape	Rect8	*n*	RectNC	*n*	RectNC w/o	*n*	RectNC w/	*n*
F_{slip} (N)	21.6 ± 3.4	5	24.5 ± 5.8	5	24.5 ± 5.8	5	5.3 ± 0.9	5
F_{damage} (N)	27.0 ± 1.6	2	35.7 ± 5.8	4	35.7 ± 5.8	4	31.2 ± 8.5	6
damage-slip-ratio	1.3 ± 0.3	2	1.6 ± 0.3	4	1.6 ± 0.3	4	6.1 ± 2.1	5
$F_{damage} < F_{slip}$	3 out of 5		1 out of 5		1 out of 5		0 out of 5	
adjusted damage-slip-ratio	0.8 ± 0.5	5	1.4 ± 0.6	5	1.4 ± 0.6	5	6.1 ± 2.1	5
Robustness	0.59		0.87		0.87		1.81	

shape	Rect8 w/o	*n*	Rect8 w/	*n*	Diam.3 w/o	*n*	Diam.3 w/	*n*
F_{slip} (N)	20.3 ± 4.5	9	13.7 ± 4.4	9	3.1 ± 0.2	6	2.7 ± 0.3	6
F_{damage} (N)	27.0 ± 1.6	2	23.9 ± 2.8	2	27.7 ± 5.0	6	29.7 ± 6.8	5
damage-slip-ratio	1.3 ± 0.3	2	1.8 ± 0.1	2	9.1 ± 1.9	5	11.0 ± 3.3	5
$F_{damage} < F_{slip}$	3 out of 5		3 out of 5		0 out of 5		0 out of 5	
adjusted damage-slip-ratio	0.8 ± 0.5	5	1.0 ± 0.7	5	9.1 ± 1.9	5	11.0 ± 3.3	5
robustness	0.59		0.69		1.00		1.14	

Differences in slip forces (p values)	RectNC w/	Rect8 w/	Diam.3 w/
RectNC w/o	0.002		
Rect8 w/o		[illegible]	
Diam.3 w/o			0.008

Differences in damage forces (p values)	RectNC w/	Rect8 w/	Diam.3 w/
RectNC w/o	ns		
Rect8 w/o		[illegible]	
Diam.3 w/o			ns

5.6 Evaluation & Interpretation (II)

From elementary and complex shapes to guidelines for new designs

In this section the results of each of the series of complex shapes are evaluated. General conclusions are drawn from these individual evaluations, and from comparison of all series with each other. Based on these conclusions, guidelines for the design of new atraumatic jaw shapes are derived and summarised in Sect. 5.7. An overview of the results of all shapes is given in Fig. 5.27.

5.6.1 Double cylinders

The slip forces of the two variations of double cylinders, *2on2* and *2in2*, are quite similar, with the slip force of *2on2* being slightly, but not significantly higher. In comparison to a single pair of cylinders, *Cyl2*, the addition of the second cylinder has not improved the slip force much. The slip force of *2on2* is almost equal to that of *Cyl2* and the slip force of *2in2* is a bit lower (20%). However, *Cyl2* has not been tested on the same pigs as *2on2* and *2in2* and therefore statistical significance could not be determined with a two-tailed paired Student's T-test.

When comparing the damage forces, *2in2* again scores slightly better than *2on2*, but the difference is not significant. However, in two occasions the damage force of *2in2* was lower than the slip force, whereas for *2on2*, this occurred in only one occasion. The average damage force of *Cyl2*, shown in Sect. 5.3.2, is higher than that of *2on2* and *2in2*. The high average of *Cyl2* has been caused mainly by two measurements that were well above 20 N, whereas all the others were below 10 N. This may have been caused by inaccurate observation, as explained in Sect. 5.4. Based on the strong relationship between the size of the contact area and the damage force noticed in other series, it is expected that if *Cyl2* would be tested on the same pigs as *2on2* and *2in2*, its damage force would be lower than that of both *2on2* and *2in2*, because those shapes both have a contact area that is potentially twice as large as that of *Cyl2*.

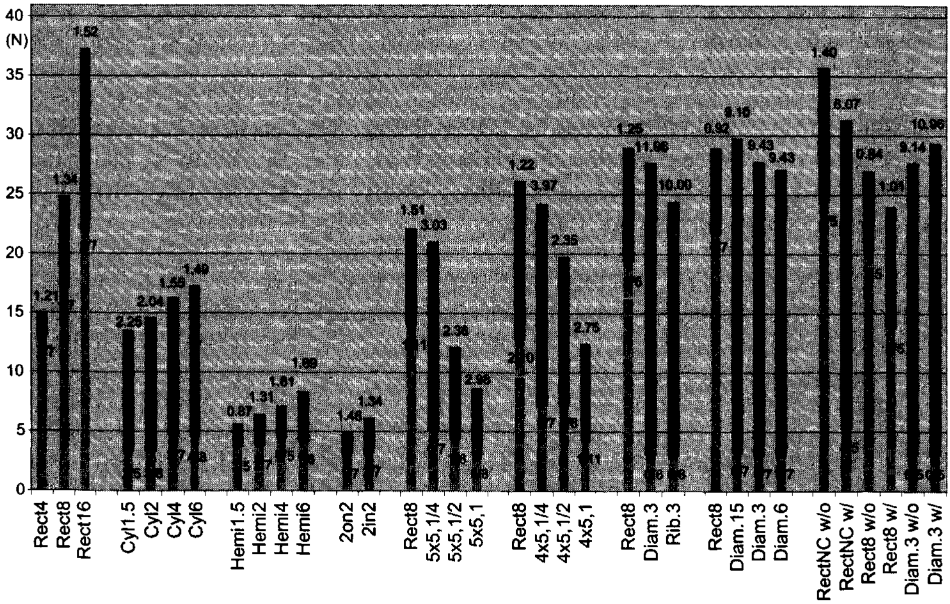


Figure 5.27. Overview of all the results.

This graph shows the 'working range' of all the shapes. The bottom limit of this working range is the slip force, the top limit is the damage force. Above each working range, the adjusted damage-slip-ratio is shown. Below each working range, the number of times that the damage force has been lower than the slip force is shown as a fraction of the total number of measurements of the damage force.

No significant difference between the average damage-slip-ratios of *2on2* and *2in2* has been observed. If the ratios below 1 are not included in the averages, *2in2* has the slightly higher average ratio. If those ratios below 1 are included, the average of *2on2* becomes slightly higher than that of *2in2*. The robustness of both shapes is reasonable and approximately equal, indicating that both shapes have a reasonably stable performance. However, their average ratios are quite close to 1, and both shapes occasionally have had a ratio of less than 1.

Whether additional pairs of cylinders will bring any improvement cannot be determined yet. When comparing *2on2* and *2in2* to *Cyl2*, the addition of a pair of cylinders has improved the slip force only marginally. The damage force is expected to improve by adding more cylinder pairs, but there is insufficient data to support this statement. It seems that stimulating the effect of enclosure to provide a low slip force is only useful when there is a contact area large enough to ensure a reasonable damage force.

5.6.2 Flat square with 5 on 5 protruding hemispheres

Observation of the slip forces of the *5x5* series shows that even only slightly protruding elements already cause a large improvement (i.e. decrease) of the slip force. The slip force of the flat square, *Rect8*, is significantly higher than that of all the shapes with 5 on 5 protruding hemispheres. The slip force decreases clearly as the hemispheres protrude further, although not all differences between any two shapes are significant, due to the small physical difference between the shapes and the low number of pigs on which both shapes have been tested.

The damage force is significantly reduced when the hemispheres protrude more than a quarter of a millimetre. The difference in damage force between *Rect8* and *5x5,1/4* is very small (5%) and not significant, which indicates that the effective contact area is hardly reduced when only slightly protruding hemispheres are added to the flat surface. All other differences, except the difference between *5x5,1/4* and *5x5,1/2* (p=0.06), are significant.

When combining the results of the slip forces and the damage forces, an optimum in the damage-slip-ratio is expected for the shape with the slightly protruding hemispheres, *5x5,1/4*. However, the ratio of *5x5,1/4* is only slightly better (20%) than the (adjusted) ratio of *5x5,1/2*, and the ratios of *5x5,1/4* and *5x5,1* are nearly equal. The latter is mainly due to the low number of pigs on which both shapes have been tested (n=2). When looking at the *estimated* damage-slip-ratios (i.e. the average damage force divided by the average slip force) *5x5,1/4* scores nearly 40% better than *5x5,1*, which confirms a preference for *5x5,1/4*. Both *Rect8* and *5x5,1/2* have had one occasion in which the damage-slip-ratio was lower than 1. This reflects in the robustness as both *Rect8* and *5x5,1/2* have a robustness lower than that of the other two. Nevertheless, all shapes have a robustness above 1, which shows that the performance of all shapes is stable.

In conclusion, the protruding hemispheres clearly improve the slip force and if the hemispheres protrude only slightly, the damage force is hardly affected. As a result the damage-slip-ratio seems to have an optimum for the shape with the 0.25 mm protruding hemispheres, *5x5,1/4*.

5.6.3 Flat square with 4 on 5 protruding hemispheres

Just like in the *5x5* series, the slip force clearly decreases as the hemispheres protrude further, although the differences in the *4x5* series are not as big as in the *5x5* series. Only the difference in slip force between *Rect8* and *4x5,1* is significant.

The damage forces also show a decreasing trend as the hemispheres protrude further, but the decline is not as steep as in the *5x5* series. The difference between *Rect8* and *4x5,1/4* is only very small (8%), but the differences between *Rect8* and *4x5,1/2* and *4x5,1* are significant. The differences in damage forces between *4x5,1* and both *4x5,1/4* and *4x5,1/2* are not significant, due to the low number of corresponding pigs, i.e. pigs upon which both shapes have been tested. (The differences àre significant when using the so-called unequal variance Student's T-test, in which all data is used, instead of only the data obtained from corresponding pigs).

Similar to the *5x5* series, an optimum is expected for the shapes with slightly protruding hemispheres, when the results of the slip forces and the damage forces are combined. Indeed, the damage-slip-ratio of *4x5,1/4* is the highest in this series, being over 40% higher than the (adjusted) ratio of *4x5,1*. The ratio of *4x5,1/2* is lower than that of *4x5,1*. This is mainly due to the remarkably high slip force of *4x5,1/2*. The ratio has been below 1 twice for *Rect8* and once for *4x5,1/2* and *4x5,1*, but this does not reflect much in the robustness. Both *Rect8* and *4x5,1* have a good robustness near 1, whereas *4x5,1/4* only has a reasonable robustness (0.7), even though its ratio has always been above 1. The robustness of *4x5,1/2* is low, which indicates that the performance of this shape is quite sensitive for variations in the bowel tissue.

When comparing the *4x5* series to the *5x5* series, it is noticed that both slip force and damage force are on average higher for the *4x5* shapes. However, the resulting damage-slip-ratios are quite similar, and on average the robustness is better in the *5x5* series. In both groups, the shape with the hemispheres protruding 1/4 mm seems to be the best choice.

5.6.4 Profiles

In comparison to the other shapes, the profiled shapes score very well. *Diam.3* and *Rib.3* have virtually equal slip forces that are lower than that of any of the previous shapes. The slip forces of both shapes are over 8 times lower than that of *Rect8*. Still, these differences are not yet statistically significant ($p=0.05$ for both) due to the low number ($n=3$) of corresponding pigs on which all three shapes have been tested. (To minimise the influence of *interporcine* variation, the slip forces can be normalised by dividing all the slip forces obtained from a certain pig by the average of all the slip forces obtained from that pig. After such a normalisation, the differences in slip forces between *Rect8* and both *Diam.3* and *Rib.3* are significant.)

Both profiled shapes have a damage force that is slightly lower than that of *Rect8*. The difference in damage forces between *Rect8* and *Diam.3* is only 7%. Between *Rect8* and *Rib.3* the difference is about 22%. These differences are not statistically significant and neither is the difference between *Diam.3* and *Rib.3*.

Clearly, the damage-slip-ratios of both profiled shapes are much better than that of *Rect8*, thanks to the extreme improvements in the slip forces. Neither of the profiled shapes had any occasions in which the ratio has been lower than 1, whereas there has been one such occasion for *Rect8*. As a result, the robustness of *Rect8* is only reasonable, while that of both *Diam.3* and *Rib.3* is good. The robustness of *Diam.3* can even be called very good, as it is nearly 70% higher than that of *Rib.3*. This indicates that the ribbed profile is much more sensitive to variations in the tissue than the diamond-shaped profile. Nevertheless, the performance of both shapes is very good.

When looking at the height of the protruding elements, *Diam.3* and *Rib.3* with their 0.3 mm high profiles can best be compared with *5x5,1/4* and *4x5,1/4*. In all cases the protruding elements decrease the damage force only slightly (5-22%), compared to a completely flat surface (*Rect8*). The slip force is decreased with a factor between 1.8 (*4x5,1/4*) and 8.3 (*Diam.3*). This shows that an increase in the number of protruding elements (per unit area) clearly improves the slip force without affecting the damage force, even though the protruding elements of *Diam.3* are rather sharp compared to the hemispheres of *4x5,1/4* and *5x5,1/4*.

5.6.5 Diamond-shaped profiles with varying heights

When comparing the profiled shapes, it was noticed that *Diam.3* scored slightly better than *Rib.3*. Therefore the diamond-shaped profile has been chosen for further investigation with two additional shapes: *Diam.15* and *Diam.6*.

The slip forces of all three jaw shapes with diamond-shaped profiles are significantly better (i.e. lower) than the slip force of the flat rectangle. The slip force initially improves clearly as the profile elements become bigger: The slip force of *Diam.15* is significantly higher, and thus worse, than the slip forces of *Diam.3* and *Diam.6*. Further increase in the size of the profile elements from *Diam.3* to *Diam.6* brings no significant improvement.

The damage forces of all the shapes are virtually equal, whereas a slight decline in damage force was expected when the profile height increases. It is believed that the difference in the profiles is too subtle to show significant differences in the limited number of experiments. Furthermore, the type of imprint that *Diam.6* causes on the tissue, makes it very difficult to recognise a potential tear in the inner layers of the colon. Therefore, the determination of the damage forces of *Diam.6* may be less reliable and the recorded values may sometimes be higher than the damage forces really are. This assumption is confirmed by the fact that *Diam.6* has a lower robustness than the other two diamond-shaped profiles.

The damage-slip-ratios of all three shapes with diamond-shaped profiles are high and relatively close to each other (9.1, 9.4 and 9.4). The numbers suggest a slight preference for *Diam.3* and *Diam.6*, but the differences are very small. Obviously, more measurements are required before a clear distinction may be detected. The robustness of the three shapes is good, above 1 for *Diam.15* and *Diam.3* and just below 1 for *Diam.6*.

Based upon the damage-slip-ratio, no clear preference can be given to one of the shapes, but when looking at the robustness, *Diam.3* scores best (1.55 versus 1.28 for *Diam.15* and 0.92 for *Diam.6*) and may therefore be preferred.

5.6.6 Tissue protrusion and rounding

Allowing the tissue to protrude at the backside of the jaws clearly improves the slip force. For all three pairs of jaw shapes (*Rect8*, *RectNC* and *Diam.3*) the decrease in the slip force is significantly. The effect is strongest for *RectNC*: its slip force decreases nearly 80 %. In comparison, the slip force of *Rect8* decreases only 33 %. This difference is mainly caused by the rounding. Although a similar amount of tissue bulges at the backside of the jaws, the effect of enclosure is much weaker for *Rect8*, because the bulged tissue is easily guided in between the two jaws due to the rounding. It is believed that in the case of *RectNC* the force transmission is almost purely based on enclosure and the pinch force is mainly needed to prevent the distance between the jaws from becoming so big that the bulged but deformable tissue can slip through. In the case of *Rect8*, it is believed that the pinch force mainly serves to create enough friction to prevent the tissue from slipping through the jaws, as the rounding causes an easy conduction of the bulged tissue and therefore reduces the effect of enclosure. For *Diam.3* the effect of tissue protrusion is even less. Its slip force decreases only 12 %, but it is nevertheless a statistically significant improvement. It is believed that the limitation of the effect is mainly due to the fact that the profile already causes so much micro-enclosure, evidenced by the already very low slip force of *Diam.3*, that the enclosure caused by the protrusion is only a relatively small addition.

The damage forces are not significantly affected by the tissue protrusion. The damage forces of both *Rect8* and *RectNC* decrease slightly, but not significantly. The damage force of *Diam.3* even increases slightly, but this difference is also not significant.

The clear improvements in the slip forces and the hardly affected damage forces result in better damage-slip-ratios for the cases where tissue was allowed to protrude at the backside of the jaws. The improvements in the *adjusted* damage-slip-ratios of *Rect8* and *Diam.3* are about 20 %; for *RectNC* the improvement is very large: over 400 %. The robustness of the rectangles does not change much: a 15 % decrease for *Rect8* and a similar increase for *RectNC*. The robustness of *Diam.3* is affected considerably: Due to larger variations in both slip force and damage force it decreases over 30 %, but nevertheless it remains above 1. In conclusion, tissue protrusion provides a good way to improve the damage-slip-ratio.

Rounding has been applied to almost all the jaw shapes, to avoid extreme effects near the edges of the jaw shape. However, such extreme effects hardly occurred in the experiments, because the jaws were always positioned in the same way: perpendicular to the colon. Consequently, there are no remarkable differences between the results of the rectangles with rounding (*Rect8*) and those without rounding (*RectNC*). Because of the rounding, the effective contact area of *Rect8* is smaller than that of *RectNC*. In the series of rectangles it was noticed that an increase in the size of the contact area results in an increase in the slip force and a relatively stronger increase in the damage force. This corresponds with the results of *Rect8* and *RectNC*. The slip force of *RectNC* is about 13 % higher than that of *Rect8*, while the damage force of *RectNC* is about 32 % higher than that of *Rect8*. Consequently, the damage-slip-ratio of *RectNC* is approximately 21 % better and the adjusted ratio even 67 %. The robustness of *RectNC* is also better than that of *Rect8*, nearly 50 %. In conclusion, the reduction in size of the contact area due to the rounding is not compensated in any way when the positioning of the jaws on the tissue is ideal, as was the case in the experiments. Therefore, rounding or chamfering is not required in these ideal circumstances. However, in the reality of the operating room, instrument positioning will hardly ever be ideal. In such cases, rounding will be important, as shown by Shakeshaft et al. (2001, Marucci et al. 2002). Which extent of rounding is the best for non-ideal circumstances, remains to be investigated.

5.6.7 Conclusions

From the results of the elementary shapes it was concluded that a high damage force is achieved by ensuring a large contact area and a low slip force is achieved by reducing the contact area or by increasing the enclosure.

The effect of enclosure has been investigated further in the series of double cylinders. There seems to be no clear preference as far as the type of enclosure is concerned. Two types of enclosure have been investigated: *symmetrical* and *asymmetrical enclosure*. Symmetrical enclosure is achieved by clamping the tissue between two pairs of cylinders and having it bulge in between the pairs of cylinders (*2on2*). Asymmetrical enclosure is obtained by having the tissue wave in between alternating cylinders (*2in2*). Both types have lead to almost equal results. When the double cylinders, *2on2* and *2in2*, are compared to *Cyl2*, it is noticed that the addition of a pair of cylinders has not improved the slip force much. This suggests that addition of enclosure does not improve the slip force as much as expected. However, the slip tests with tissue protrusion, mentioned in Sect. 5.5.6, suggest otherwise. In a few occasions, the slip forces of three shapes (*Rect8*, *RectNC* and *Diam.3*) have been tested in two ways: with the tissue protruding no more than 1 mm, as shown in Fig. 5.25 (top right), and with the tissue protruding approximately 4 mm (Fig. 5.25, bottom right). The slip forces measured with the tissue protruding 4 mm were significantly lower than the slip force measured with the tissue protruding in the normal way (≤ 1 mm). This indicates that enclosure can provide a significant improvement. However, the low damage forces of *2on2* and *2in2* show that stimulating the effect of enclosure to provide a low slip force is only useful when there is also a large enough contact area to ensure a reasonable damage force. Therefore it seems to be better to design the jaws in such a way that tissue protrusion at the backside is possible, rather than to introduce windows in the jaws, because although such windows allow for bulging of the tissue and in that way create the effect of enclosure, they also reduce the contact area.

The two types of enclosure are also recognised in the series of flat shapes with protruding hemispheres. The *5x5* shapes provide symmetrical enclosure; the *4x5* shapes provide asymmetrical enclosure. When comparing these two series, it is noticed that corresponding shapes have virtually equal damage-slip-ratios, except for *4x5,1/4*, whose ratio is about 30% higher than that of *5x5,1/4*. Similar to the comparison of *2on2* and *2in2*, comparison of the damage-slip-ratios of the *5x5* series and the *4x5* series suggests that there is no clear preference for one type of enclosure over the other. However, when looking at the robustness, symmetrical enclosure (*5x5* series, *2on2*) always seems to score better than asymmetrical enclosure (*4x5* series, *2in2*). The difference between *2on2* and *2in2* is negligible, but the differences in robustness between the corresponding shapes from the *5x5* and the *4x5* series are quite clear. The larger variations in the slip forces of the *4x5* series compared to those of the *5x5* series seem to be the principal cause for the lower robustness in the *4x5* series. However, a preference for symmetrical enclosure just because of its better robustness cannot be justified, because the number of pigs on which both series together have been tested is too low.

A way to use the effect of enclosure to improve the slip force is to allow the tissue to protrude at the backside of the jaws. Such a protrusion produces a significant decrease in the slip force, in particular for smooth shapes such as the rounded-off rectangle *Rect8* and the unchamfered *RectNC*.

Both profiled shapes, *Diam.3* and *Rib.3*, score exceptionally well compared to the other shapes, with the diamond-shaped profile, *Diam.3*, scoring slightly better than the ribbed profile, *Rib.3*. They show that the addition of a profile to a flat surface dramatically improves the slip force, without much affection of the good damage force of the flat surface. The added profile can be interpreted as microscopic asymmetric enclosure. From that point of view, *Rib.3* can be considered to be similar to *2in2*, but with smaller, sharper and more ridges. *Rib.3* has much better scores than *2in2* for both slip force and damage force. This shows that a "wave pattern" can be successful, as long as the waves are not too long and high. *Diam.3* can best be compared to *4x5,1/4*. They have similar damage forces that are not significantly lower than that of a flat surface with the same dimensions (*Rect8*), but the slip force of *Diam.3* is approximately three times lower, and therefore better, than that of *4x5,1/4*. In comparison to *4x5,1/4*, *Diam.3* has sharper protruding elements, i.e. diamond-shaped instead of hemispherical, and more protruding elements per unit area. These changes clearly improve the slip force, without affecting the damage force. The height of the profile does not seem to have a strong influence, at least not within the series of diamond-shaped profiles tested. The damage force does decrease as the profile elements become bigger, but not excessively. Judging from the very small difference in slip forces between *Diam.*3 and *Diam.6*, the slip force does not seem to improve much beyond a certain profile height. This indicates an optimal profile height somewhere between 0.3 and 0.6 mm. As the robustness of *Diam.*3 is considerably better than that of *Diam.*6 (1.55 versus 0.92), a profile height of 0.3 mm seems to be the preferred choice.

Comparison of the results of the rounded-off rectangle *Rect8* and the unchamfered rectangle *RectNC* shows that rounding or chamfering is not necessary in case of ideal instrument positioning. However, such an ideal instrument positioning is only possible in an experimental set-up, not in the operating room. Which extent of rounding is best for instruments used in realistic rather than ideal circumstances, is yet to be investigated.

In literature, except for Marucci et al. (2000), nothing could be found on the design of grasper jaws with regard to the damage-causing and slip-preventing properties. Marucci et al. focused on the way in which the grip on tissue can fail. They clamped pieces of fresh sheep stomach between jaws with a constant pinch force of 24, 48 or 72 N and increased the pull force until tissue either slipped or tore. Unfortunately, their approach differed too much from the approach presented in this thesis to provide a meaningful comparison.

5.7 Conclusion

Guidelines for new jaw shapes

Basically, the first aim is a damage-slip-ratio as high as possible. This is achieved by keeping the damage force as high, and the slip force as low as possible. Clearly, features that increase the damage force should not be incorporated if they cause a relatively larger increase in the slip force, unless other features are available to counteract this unwanted side effect. Visa versa, features intending to lower the slip force are only useful if they do not affect the damage force too much. The second aim is a constant, reliable performance. The achievement of this is expressed in the robustness. In this chapter, a strategy has been followed to concentrate on the first aim, while keeping an eye on the second.

To keep the damage force as high as possible, the effective contact area must be as large as possible. Elements that protrude far from the surface will reduce the effective contact area and should be avoided. If any sharp edges exist, the effective contact area may reduce to a thin line along such an edge, as soon as the positioning of the grasper relative to the tissue is anything less than perfect. Rounding or chamfering removes these sharp edges, but it also reduces the potential contact area. The ideal extent of rounding or chamfering is not yet known.

To lower the slip force as far as possible, a profiled surface is necessary. The profile should consist of a large number of small protruding elements. They should not protrude too far, otherwise the damage force gets affected too much. Diamond-shaped elements with a height of 0.3 mm are the preferred choice. The slip force can be lowered further by applying enclosure. An easy way to do this is by designing the jaw shapes in such a way that protrusion of the tissue at the backside of the jaws is possible. This is preferable over the application of windows in the jaws, because such windows will reduce the contact area and thus the damage force.

6 Discussion

6.1 Introduction

When a research project addresses a relatively unknown area, each discovered answer is bound to raise a dozen more questions. Consequently, there are many possible paths to choose from. This chapter discusses many of the choices made during this project. In Sect. 6.2 the variations observed in the data are analysed and discussed. Sect. 6.3 addresses the relevancy of the obtained results, which includes discussions on the choice of the material used and on the definitions of damage, robustness and the adjusted damage-slip-ratio. In Sect. 6.4 the project as a whole and in particular the choices made in the initial phase will be discussed.

6.2 Variations in the obtained data

In Chapter 5 a large amount of data has been presented. Occasionally, large standard deviations have been observed, which makes it more difficult to objectively drawn conclusions from the results from different jaw shapes. These variations in the measurements have several different causes. The three most important causes that contribute to the variation observed in a single series of measurements are:

- variations in the used material: porcine colon *tissue*,
- inaccuracies of the *observer*,
- inaccuracies in the *instruments*: the set-up and the measurement devices.

In the following subsections each of these three causes will be analysed and quantified, and the measures taken to minimise these variations are discussed.

6.2.1 Tissue variations

Variations in the porcine colon tissue can be categorised in three main groups. First of all, there is the so-called *intraporcine* variation: the tissue variation within a single pig. The damage force depends on the strength of the colon wall, so if the strength of the colon wall varies for different locations, so does the damage force. The local strength of the colon wall depends on its thickness, its structure and the presence of elements such as arteries and folds, the so-called plicae semilunaris (Fig. 6.1). The thickness and structure of the colon wall depends on its function. More distally, more water has been absorbed from the faeces and therefore the more difficult it becomes to move the faeces through the colon. Consequently, the structure, and thus the strength, of the colon changes over its course from the proximal cecum to the distal rectum. The presence of arteries, folds and irregularities also contributes to the variation in the damage force. The extent of the variations depends partially on the shape of the jaws used, as shown in Fig. 6.2. The presence of such elements also influences the slip force, because it can increase the effect of enclosure, as shown in Fig. 6.3. Again, some jaw shapes are more sensitive to these variations in the colon wall than others.

The second type of animal tissue variation is *interporcine*: variation between pigs. The strength and slipperiness, and therefore the damage force and the slip force, of the colon are likely to depend on a number of factors, such as: age, weight, diet and administered drugs (anaesthetics). Besides the variations caused by these factors, there will also be a natural variation for which there is no explanation.

The last cause of animal tissue variation is the treatment of the tissue before and during the experiment. The properties of the tissue can change severely over time. When deprived from the circulation of essential fluids and nutrients, the colon will deteriorate

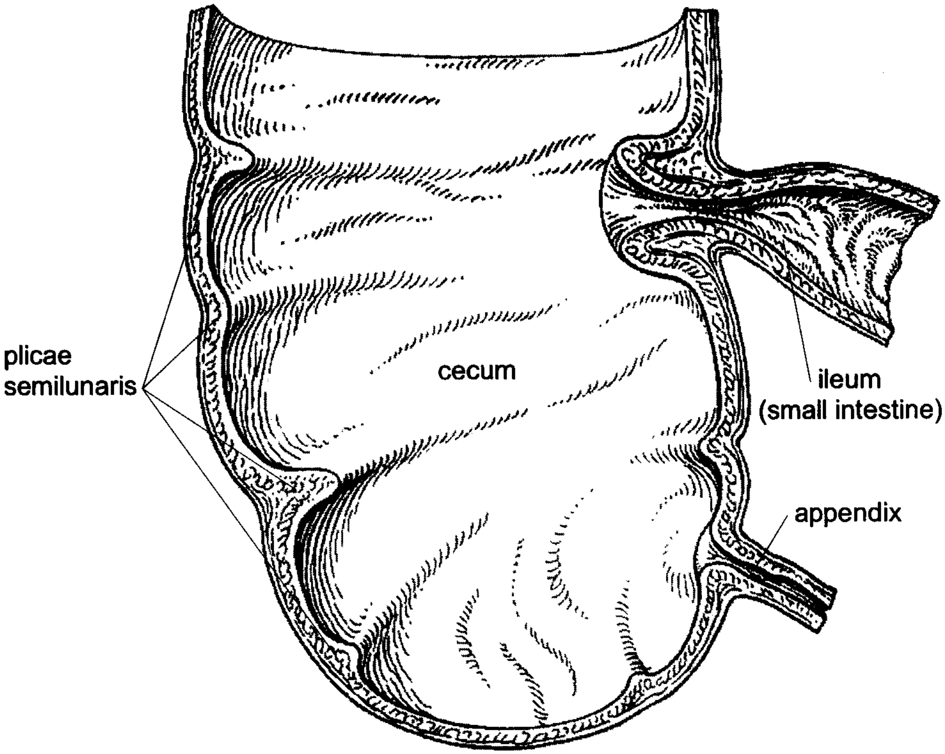


Figure 6.1. Cross-section of the cecum.
The figure shows that the thickness of the colon wall varies quite significantly, especially near the folds in the wall, the so-called plicae semilunaris. This variation in the wall thickness causes variation in the strength of the wall, which in turn can cause variation in the measured damage forces. (Picture adapted from: Sesam Atlas van de anatomie, Deel 2 Inwendige organen).

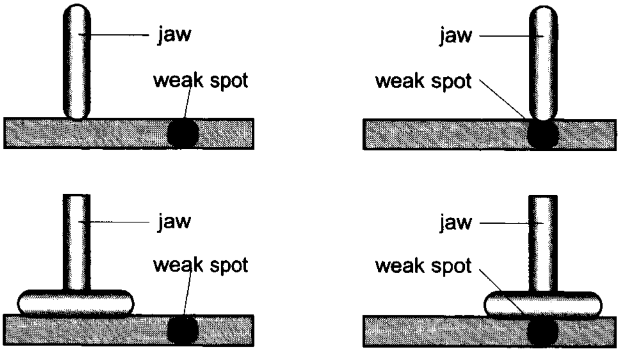


Figure 6.2. Influence of the shape of the jaw on the variations in the damage force.
The shape of the jaw can influence the extent of the variations in the damage force. For example, assume that there is a weak spot present in the material that is being pinched. This weak spot may cause variations in the damage force: if the jaw is positioned right on the weak spot (the dark-grey area), as in the figures on the right, the damage force will be lower than when the jaw is positioned on a normal part of the material (the light-grey area), like in the left figures. How large the difference in the damage forces between the left figures and the right figures is, depends on the size and shape of the used jaw. If the size of the jaw is similar to the size of the weak spot (top figures), the variations in the damage force will be much larger than when the jaw is so large that it completely spans over the weak spot (bottom figures).

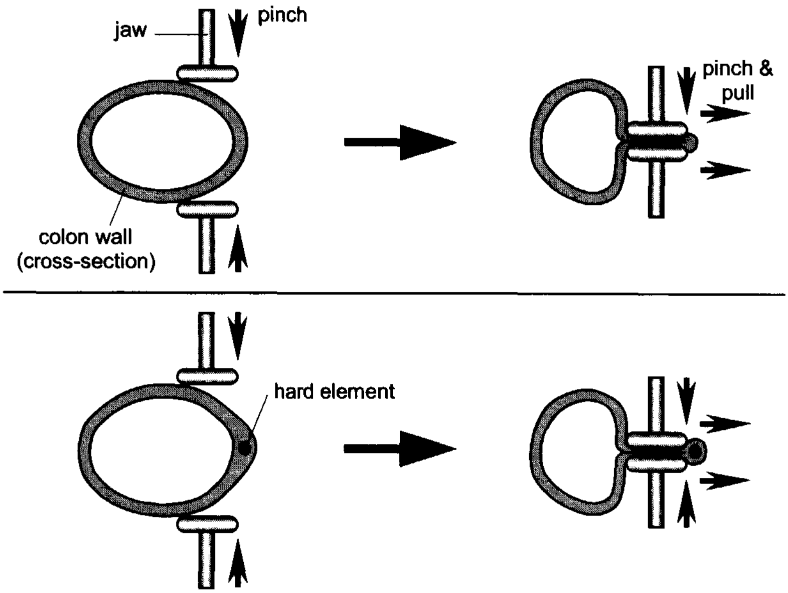


Figure 6.3. Influence of variations in the colon wall structure and thickness on the slip force.
The presence of deviant elements in the colon wall, e.g. arteries, can influence the slip force. Imagine two colons, one with a homogeneous wall structure (top left figure) and one with a harder element, such as an artery, in its wall (bottom left figure). Both colons are being pinched (right figures). Now when the jaws are pulled to the right, the colon in the top figure will slip out of the jaws much easier than the colon in the bottom figure. This is because the hard element in the wall of the colon in the bottom figure increases the effect of enclosure. Consequently, in the bottom situation less pinch force is needed to prevent slip, or in other words, the slip force is lower.

rapidly (Watters et al. 1985, Yamada 1970). Consequently, the damage force will decrease. Key factors that influence the rate of deterioration are: how long it has been since the pig has been terminated; whether the vascular system has been flushed; how long the colon has been exposed to the open air and whether or not the colon has been kept wet during the experiment. It was sensed that in the experiments in which the blood had been drained, the deterioration of the colon might be faster. However, this phenomenon has not been investigated. Exposure to open air has the same effect. The deterioration, and consequently the affection of the damage force, is slowed down by keeping the colon wet. The slip force is also influenced by dehydration. When the colon gets dryer, it will slip less easy, and therefore the slip force will become lower. A different element of treatment that influences the variation in the measured forces, is how long it has been since the pig has been fed. It was noticed that hard particles in the intestinal lumen occasionally have the same effect as irregularities in the colon wall, causing variations in both damage force and slip force.

To examine the magnitude of the animal tissue variations several additional experiments with the set-up shown in Chapter 5 have been performed (Heijnsdijk et al. 2003). In these experiments the observed average intraporcine coefficient of variation (i.e. standard deviation divided by average) in the perforations forces using 1.5 mm hemispheres was 18 %; the interporcine coefficient of variation in these perforation forces was 27 % for a total of 14 pigs. This indicates that variations in the tissue may cause variations in the observed damage forces of up to 50 %. It should be noticed that this concerns the coefficient of variation. The difference between the obtained maximum and minimum values can be even bigger.

To minimise the variations in damage forces and slip forces caused by animal tissue variations, the tissue variations themselves should be minimised. To do this, in the experiments all circumstances have been kept as constant as possible. The intraporcine variations were minimised in the following way. The jaws were always placed on the same part of the colon, namely the cecum. The jaws were nearly always placed on a smooth part of the colon wall, not on an artery, fold or hard particle in the lumen. And finally, the jaws were always positioned perpendicular to the longitudinal direction of the cecum. Interporcine variation has been difficult to avoid, because the pigs used were all pigs that first had been used in other experiments and therefore selected and prepared for those experiments. It is assumed that preoperative diet, haemodynamic circumstances and anaesthetics were more or less the same for all pigs. Age and weight are strongly related. The weight of the pigs did not vary much: the majority of the animals weighed between 18 and 27 kg. Variations caused by treatment were avoided by keeping the circumstances during the experiments as constant as possible. Whether or not the vascular system was flushed depended on the prior experiment and could therefore not be influenced. However, the humidity of the tissue was kept as constant as possible by regularly pouring water over the cecum.

The influence of tissue variations has been minimised further by increasing the number of measurements, and by varying the order in which the shapes were tested. This means that the order in which the shapes of a certain series are tested, has been different for each pig.

In conclusion, as the experiments mentioned indicated, when working with animal tissue large variations should be expected, which can never be fully avoided.

6.2.2 Observer-caused variations

There are three main types of observer-caused inaccuracies that may have lead to increased variations in the measured slip forces and damage forces: 1) inaccuracy in the definition of damage and slip, 2) inaccuracy in the recognition of damage and slip and 3) inaccuracy in the execution of the experiment.

Concerning the slip force, definition and recognition of slip are believed to cause hardly any variations, because the definition of slip has been straightforward: any occasion in which the tissue slipped out of the jaws completely, was classified as slip. If the tissue slipped out only partially (e.g. in the *5x5* series, when the tissue slipped past the first two of three hemispheres, but was still kept by the others), the pull force was increased further until it slipped out completely. In a few rare occasions, the tissue slipped out almost completely, but then got stuck on a tiny corner of the jaws. In these cases, the measurement was aborted and redone from the start. Observer-caused variations in the slip force are mainly caused by inaccuracies in the experiment execution. These inaccuracies include: inaccurate positioning of the weight or the springs that provide the pinch force, inaccurate placing of the tissue in the jaws, inaccurate reading of the magnitude of the pull force from the spring scale, non-perpendicular positioning of the lever relative to the tissue and non-parallel positioning of the jaws in the lever. Because the protocol is straightforward, inaccuracies in the execution should be limited. Nevertheless, it is noticed that in the early stages of the experiments lack of experience may have caused some inaccuracies, in particular in the placing of the tissue in the jaws and in the treatment of the tissue: Tissue may have protruded too far at the backside of the jaws, and it may not have been kept wet enough. Occurrence of such inaccuracies is indicated by the change in the average slip force of *Rect8*. In the first two series (chronologically) in which *Rect8* was included, the *4x5* and the *5x5* series, the slip force of *Rect8* has been lower than in later series. It is believed that inadequate placing of the tissue in the jaws and inadequate moisturising of the tissue, due to inexperience, may have caused these lower measured values. These values have not been excluded because the other shapes in these series showed similarly lower slip forces in these occasions and therefore the relationships within the series are assumed to be virtually unaffected.

Concerning the damage force, the same inaccuracies in the experiment execution may occur as the ones mentioned before. But, compared to the variations in the slip forces, in the variations in the damage forces definition and recognition play a much more important role. Variation of the definition of damage causes variation in the measured damage force. Originally, damage was defined as a sustaining imprint on the tissue. This definition left too much room for error, as some "sustaining" imprints would disappear after rubbing over the tissue or waiting for a long time, whereas others remained. Therefore, a more objective definition of damage has been chosen: Any occurrence of a tear in one of the layers of the colon wall, visible with the naked eye, has been classified as damage. Still, inaccuracies can occur when a tear in one of the layers is not recognised. In particular, small tears in the inner layer of the colon wall, caused by small protruding elements such as the hemispheres, can be overlooked occasionally. In such a case, the measured damage force will be too high. In contrast, the flat rectangles sometimes leave a large imprint that looks like a large window in the colon wall, which is easily mistaken for a tear in the inner layer. However, these "windows" usually disappear after a while, whereas a tear remains. If such a window is mistakenly identified as a tear, the recorded damage force will be too low.

Evidently, observer-caused variation is difficult to measure properly. In particular in the series performed earliest (hemispheres and cylinders) large variations have been observed, which cannot be ascribed to tissue variations and instrument inaccuracies alone. It is believed that at least part of these large variations may have been caused by inexperience of the observers, who initially had some difficulty recognising damage accurately.

Observer-caused variations should be minimised. Variations in the measured forces caused by variations in the definition of damage have been avoided, because all measurements done with the old definition of damage ('sustaining imprint') have been excluded. Inaccuracies in the recognition of damage will be limited by experience. Therefore, it is expected that such inaccuracies in the recognition of damage will mainly have occurred in the earliest series (i.e. the hemispheres and cylinders), and probably also in the series of shapes that potentially cause very small tears (i.e. shapes with small protruding elements, such as the series of hemispheres, the *4x5* series and the *5x5* series). Further ways that have been used to minimise observer-caused variations are the fact that damage has always been judged by the same observers, and increase in the number of measurements.

6.2.3 Instrument-caused variations

In the instruments there are two sources of variations in the measured forces: inaccuracies in the experimental set-up and irregularities in the measurement devices.

The first kind of inaccuracy in the set-up is caused by friction in the hinges. However, in comparison to the pinch forces the friction forces are so small (less than 1 %) that this type of inaccuracy can be neglected. The second kind of inaccuracy in the set-up is caused by variation in the length of the springs that provide the pinch force. This is explained in Appendix B. This kind of inaccuracy is also limited (less than 2.5 %). Inaccuracies in the set-up only affect the pinch force, not the pull force.

The only measurement device used in the experiments is the spring scale at the rear end of the lever, so any inaccuracies in the measurement device will only concern the pull force. Two spring scales have been used in the experiments. Both are calibrated and are proved to have only a very small inaccuracy (less than 1 %). Therefore, any variations in the measured forces caused by inaccuracy in the spring scales will be small enough to be neglected.

The experiments of Heijnsdijk et al. (2003) confirmed that the instrument-caused variations were small. In these experiments the instrument-caused variations were found to be less than 6 %.

Instrument-caused variations are smaller than the two previously mentioned types of variation. Nevertheless, the relative impact of inaccuracies of the instruments can still be limited further, by increasing the number of measurements.

6.3 Relevancy of the obtained results

The relevancy of the obtained results depends on several factors:

- How accurate is the chosen material, pig's colon, as a model for the human colon?
- How accurate is the definition of damage, used in the experiments?
- How relevant is the so-called robustness?
- How appropriate is the adjustment of the damage-slip-ratio in the occasions when the damage force could not be determined?
- How optimal will new jaw shapes be that are based on guidelines, which are derived from experiments on only a limited number of different jaw shapes?

These questions will be discussed in more detail.

6.3.1 Choice of material

All results have been obtained using healthy pigs' colons as a model for the human colon. To determine whether this model provides relevant results another experiment has been conducted (Heijnsdijk et al. 2003). Perforation tests with the 1.5 mm hemispheres have been done on healthy small intestines (ileum and jejunum) of 14 pigs and compared with findings from healthy small intestines (duodenum) of 7 humans. The measurements done on the porcine intestines have been performed in situ, similar to the experiment described before (Sect. 5.2). The measurements done on the human intestines have been performed in vitro. The samples from the human intestines have been obtained during so-called pancreatico duodenectomies. In these procedures, the head of the pancreas is resected and during this resection the duodenum is also partially removed. The tests showed no significant difference in perforation forces between the porcine intestines and the human intestines. However, it should be borne in mind that healthy human duodenum has been tested, not diseased human colon. The results of the tests show that healthy porcine intestine is a good model for healthy human intestine, which suggests that the healthy porcine colon may also be a good model for the healthy human colon. However, laparoscopic graspers will also be used on the diseased human colon. Furthermore, the perforation tests have only been performed with the 1.5 mm hemispheres, so to which extent the results can be extrapolated to other jaw shapes and to other human intestinal material remains unknown. Therefore, the results obtained in Chapter 5 cannot be extrapolated to other situations without a large safety margin. This consideration particularly concerns the presented damage-slip-ratios. A jaw shape with a ratio slightly above 1 is only just safe enough to handle a healthy porcine colon. It cannot be guaranteed that it will also handle a diseased human colon safely. Nevertheless, assuming the same safety margin will be applied to all shapes, the conclusions from Chapter 5 remain relevant, because the safety margin does not change the relative differences between the different shapes and virtually all of the presented conclusions are drawn particularly from these relative comparisons within each series. Therefore, the guidelines derived should still lead to the development of the safest possible jaw shapes for handling colons, at least in comparison to the other shapes presented in Chapter 5. Whether or not they will eventually be safe enough to manipulate diseased human colons is beyond the scope of this thesis.

The determination of the required pull force in Sect. 3.3 has also been done on porcine colons, instead of human colons. Consequently, the obtained pull force cannot be extrapolated without a safety margin. Therefore, the pull force (5 N) used in the experiments of Chapter 5 is not based on the average required pull force (2.4 N) determined in the experiments described in Sect. 3.3, but on the maximum pull force (4.7 N) measured in these experiments, rounded upward.

Considering the substantial variations observed in the results from the tests on porcine colon, and the limited relevancy of the porcine colon as a model for the human colon, it could be argued that other models for the human colon might be more suitable. However, as discussed before (Sect. 4.2), it is believed that alternative models, such as computer models or synthetic materials, will simplify the complexity of the human colon to an unacceptably large extent. Consequently, even though results from such models may show less variation than the porcine model, they are expected to be less accurate and thus less relevant than the porcine model.

6.3.2 Definition of damage

Another issue that is of great importance for the relevancy of the results, is the definition of damage used throughout the experiments. The damage force has been defined as the highest pinch force that is maximally allowable (to transmit a pull force of 5 N) without causing a visible tear in one of the layers of the colon wall. However, it is not known whether or not this kind of damage is indeed unacceptable. If the human body is always able to repair such a tear without complications, the acceptable level of damage might be higher than used in the definition of the damage force. This means that the actual damage-slip-ratio would be higher than the damage-slip-ratio calculated with the value of the damage force defined as mentioned. However, if the human body is unable to spontaneously repair a level of damage lower than the one mentioned in the definition of the damage force, the acceptable level of damage is actually lower than the one used. This means that the actual damage-slip-ratio will be lower than the damage-slip-ratio calculated with the defined damage force. Therefore, certain safety margins should be applied when using any obtained damage-slip-ratio. Further research is needed to bring clarity to the acceptable level of damage. However, even though a change in the definition of damage will alter the absolute values of the damage forces, the relative differences between the shapes are not expected to change much, because all shapes are judged using the same definition of damage. As most conclusions have been based on relative differences, they are not expected to change remarkably if a change in the definition of damage would occur.

6.3.3 Robustness

Another matter of discussion is the relevancy of the so-called robustness. The robustness is defined as the insensitivity of a jaw shape to variations in the tissue. In the calculation of the robustness, these tissue variations are quantified as the coefficient of variation (i.e. the standard deviation divided by the average) in the damage forces of a reference shape: the 2 mm hemispheres. It could be argued that a choice for another reference shape in the quantification of the tissue variations might lead to different values for the robustness. Similarity in shape is likely to imply a similarity in damage behaviour. Therefore, jaw shapes that are similar in shape to the reference shape may have an advantage, because they are likely to show the same variations in their damage forces as the reference shape, and consequently they may automatically end up with a robustness around 1. Indeed, it has been shown that all shapes in the series of hemispheres score a robustness close to 1. Although this may be a coincidence, it could indicate that the robustness scores of the hemispheres should be used with precaution. Nevertheless, the manner of calculation of the robustness is used for all the experiments, because it is believed that the difference in shape between the 2 mm hemispheres and all the other series, as well as likely new designs, is large enough not to cause an advantage for any particular series of shapes.

6.3.4 Adjusted damage-slip-ratio

In the processing and interpretation of the results of the experiments, one aspect in particular may be considered controversial. It is the method used in cases when the damage force cannot be determined because it is lower than the slip force. In these cases the damage force is not known and therefore not included in the calculation of the average damage force of a certain jaw shape. However, it is known that the damage-slip-ratio in these cases is lower than 1, but its exact value is unknown. To account for these occasions, besides the normal average damage-slip-ratio, the adjusted average damage-slip-ratio has been determined. In the calculation of the *normal* average damage-slip-ratio the unknown damage-slip-ratios are not included. In case of the *adjusted* average damage-slip-ratio these unknown damage-slip-ratios are estimated to be 0.5, and are included in the calculation. The value of 0.5 has been chosen because the value of the unknown damage-slip-ratios must be between 0 and 1. It could be argued that 0 would be a better choice, because it would be safer to get an estimate for the average damage-slip-ratio that is too low than an estimate that is too high, because that would suggest that the shape is safer than it really is. However, it has already been mentioned that most of the conclusions drawn are based on the relationships between the shapes within each series. For these relationships, the absolute value of the average damage-slip-ratio is less important than its value in comparison to the values of the average ratios of the other shapes within that series. In this case of relative comparison, it is more important to obtain an estimate for the average damage-slip-ratio as accurate as possible, than an estimate as safe as possible. Nevertheless, as a safety check, the adjusted average damage-slip-ratios have also been calculated with the unknown ratios estimated to be 0. These alternative calculations (data not provided) yielded some changes in the relations between the different shapes, but the overall outcome and conclusions remained the same.

6.3.5 Optimal jaw shapes?

It should be noticed that because of the limited number of series of shapes tested in this study, the presented guidelines may only lead to a so-called local optimum in the design of new jaw shapes, instead of the best, so-called global optimum. Further improvement of the guidelines can only be achieved by further experiments and research, for example into the optimisation of the chamfering and into the use of materials other than (stainless) steel.

6.4 Evaluation of the entire project

At the initial stage of the project, safety in laparoscopic colon surgery was selected to be the key issue for further research. The choice for this particular topic out of a range of potential topics (Sect. 2.3) was based mainly on extensive discussions with the co-operating surgeons. The surgeons considered several of the presented topics to be of importance, but in particular, safety in laparoscopic colon surgery was broadly recognised as an important issue. It is believed that the lack of safe instruments for the manipulation of the colon, combined with the dramatic consequences of colon damage, in particular the occurrence of perforations, causes amongst many surgeons certain reluctance to perform colectomies laparoscopically. Obviously there was a great enthusiasm for any research that would provide more insight in how instrument safety could be improved. Therefore this important topic was selected as the principal subject for this project.

To improve the safety of laparoscopic colon graspers, a fundamental approach was chosen in which the influence of basic elements of the design of grasper jaws on the safety was investigated. The fundamental approach might not lead to spectacular improvements, but certainly to more insight, which in turn might lead to structural, economically feasible improvements. Therefore, this fundamental approach was preferred over the development of more exotic ideas, like the ones shown in Fig. 2.4, of which many have already been tried and have led to interesting prototypes and patents, which usually were too exotic to be economically feasible.

In the next chapter, future steps that may follow from this project are presented.

7 Future steps

7.1 Introduction

In this chapter several steps beyond the scope of this project are discussed. Sect. 7.2 focuses on future research, as it presents a number of recommendations, based on the limitations observed in this project. Sections 7.3 and 7.4 focus more on the practical use of the findings of this project. Sect. 7.3 summarises the guidelines for the development of new jaw shapes, which were drawn from the results presented in Chapter 5. In Sect. 7.4 a suggestion for a protocol for the safety assessment of new atraumatic graspers is given. Such a qualification may aid in the confidence of surgeons in their instruments, as it provides an objective measure for the safety of graspers.

7.2 Recommendations for future research

During this project several limitations were encountered, as well as several unexplored possibilities. Most of them are interesting subjects for further research and will be discussed in some detail.

Jaw material

All the jaws used in the experiments were made of stainless steel. No other materials were used. Recently, graspers have been introduced to the market that possess silicon cushions embedded in the traditional surgical stainless steel, for example Aesculap's A-Trac (www.aesculap.com). To investigate the influence of using silicone instead of stainless steel, a pilot experiment has been performed with the set-up used in Chapter 5 (Henstra and Janson 2002). Two shapes made from silicone were compared to the same two shapes made traditionally from stainless steel. The two shapes were a flat square with rounded-off edges (*Rect8*) and a flat square with rounded-off edges and hemispheres protruding 1 mm from the surface (*4x5,1*). Significant differences in performance were observed between the silicone shapes and the stainless steel shapes. This indicates that further research into the use of alternative materials will definitely be useful.

Rounding

Almost all shapes in the experiments were given a rounding of 1 mm to avoid extreme effects at the edges, but the results of the only shape without this rounding, *RectNC*, showed that the used rounding may have been exaggerated. The ideal extent of rounding remains to be investigated, in particular under circumstances in which the positioning of the jaws relative to the tissue is unfavourable.

Definition of acceptable damage

It is unknown if the chosen limit of acceptable damage is accurate. In the experiments a visible tear in one of the layers of the colon wall was classified as unacceptable damage. It is unknown whether such a tear indeed will evolve into a perforation or whether it can be repaired by the human body. For comparison of jaw shapes within a series, such an uncertainty in the validity of the definition of damage may not have severe consequences, as it is expected that all measured damage forces within a series are affected more or less in the same way. However, for the absolute values of the damage forces, and thus the damage-slip-ratios, an appropriate definition of acceptable damage is crucial. Therefore, further research into the ability of the human body and in particular the colon to recover from certain damage to the colon wall is extremely important.

Accuracy of the porcine model

All experiments were performed on healthy porcine colons. Additional experiments showed no significant differences between the healthy *porcine* small intestine and the healthy *human* small intestine and between the porcine *small intestine* and the porcine *colon*. This suggests that the healthy porcine colon may be a good model for the healthy human colon, but this is not certain. Furthermore, laparoscopic graspers will be used not only on the healthy human colon, but also on the diseased human colon. It remains to be investigated how accurate the healthy porcine colon models the diseased human colon.

Alternative tissue models

In this project, computer simulations and synthetic models of the colon were found to be too inaccurate to be useful. However, in particular the field of computer modelling of biological tissue is rapidly developing. Putting both tissue and instrument in a computer model would have the large benefit that the effects of changes to the instrument design could be tested easily and rapidly, once a reliable model of the tissue is obtained. Pressure peaks in the (virtual) tissue, occurring as a result of a certain combination of pinch and pull force, could easily be observed and examined for numerous different jaw designs, without the large variations inherent to testing on animal tissue. This could reduce the numbers of required test animals considerably. Because of these large benefits, further development of these alternative soft tissue models is very important.

Damage caused by slip

Only two types of failure have been studied in the experiments: damage, caused by a too high pinch force, and slip, caused by a too low pinch force. However, occasionally it has been observed that tissue got damaged when it slipped out of the jaws, although it did not get damaged when it was successfully held with a higher pinch force. This means that an annoying but not fatal failure (slip) could turn into a fatal failure (damage). This phenomenon may have severe consequences for the definition of the damage force and should therefore be investigated further.

Positioning of the jaws on the tissue

In the experiments the positioning of the jaws relative to the tissue has virtually always been ideal, with the instrument perpendicular to the tissue and the pull forces perfectly in line with the instrument. During laparoscopic surgery however, the positioning of the instruments will in many circumstances not be ideal. The influence on the damage and slip forces of different positioning of the jaws on the tissue and of varying directions of the pull force should be investigated, in particular in relation to the used rounding.

Movement of the jaws when closing

In the experiment the top and bottom jaws closed virtually parallel, which provided an ideal distribution of the pinch force over the contact area. In practically all existing instruments the jaws close in a scissors-like manner, which can cause high local pressure on the tissue. Therefore, the influence of the various types of closure on the damage force and the slip force of the different jaw shapes should be investigated.

7.3 Guidelines for the design of new jaw shapes

This section summarises some basic guidelines for the design of the jaws of atraumatic graspers, based on the findings presented in Chapter 5.

To prevent tissue damage during the manipulation of the colon, it should be avoided that the grasper jaws cause local pressure peaks on the tissue. This can be avoided by ensuring that the effective contact area between the jaws and the tissue is as large as possible and that the distribution of the pinch force over the contact area is as constant as possible. Therefore, a number of prerequisites should be made:

- Elements (e.g. profiles) that protrude more than 0.6 mm from the main contact surface should be avoided.

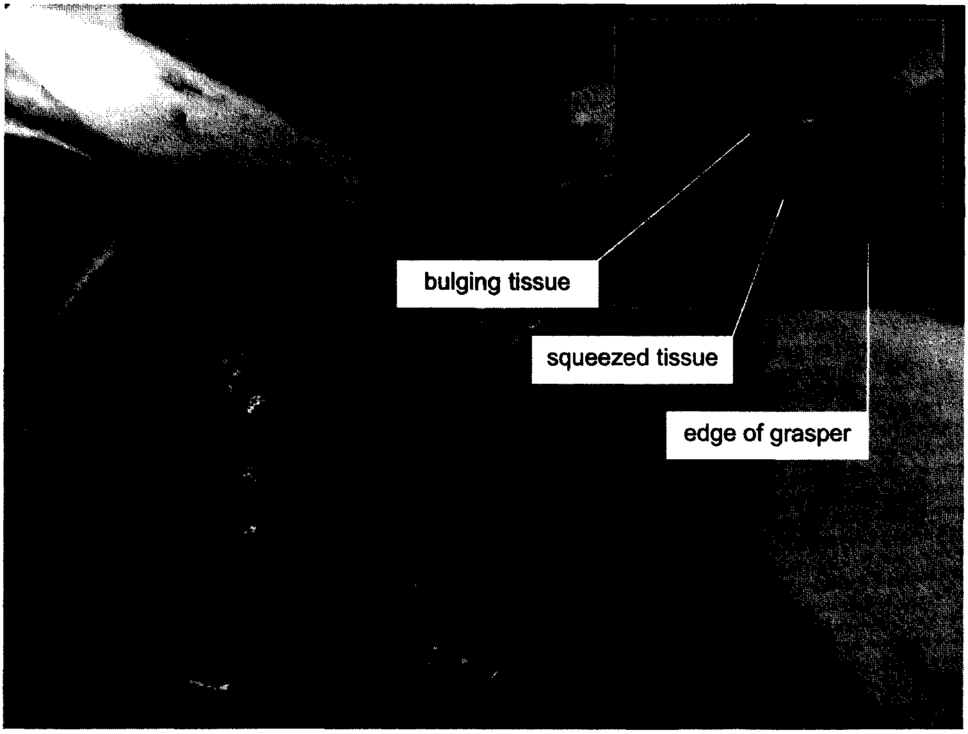


Figure 7.1. Grasping a bowel with a Babcock.
Example of an existing grasper with a small contact area. Because the contact area of the grasper is very small, tissue is easily damaged with this grasper. The enlargement at the top right of the figure shows how part of the tissue bulges in the window. In between the bulging part and the edge of the grasper a bit of tissue is visible that obviously has been squeezed to a severe extent. The sharp transition from the bulging tissue to the tissue just below it, suggests that the inner layer of the bowel might be torn at that location.

- Shapes that consist of a single element only with a small potential contact area, or of a combination of elements, each with small potential contact areas, should be avoided. For example, cylindrical shapes have a potential contact area that is not much more than a line. Therefore, a jaw shape should not consist of a combination of only cylindrical shapes. An example of an existing grasper with a small contact area is shown in Fig. 7.1.
- The presence of sharp edges should be prevented. When the directions of the pull force and the pinch force are not perpendicular, presence of sharp edges may cause large pressure peaks, as shown by Cartmill et al. (1999) and illustrated in Fig. 7.2.
- Windows in the jaws should not be so big that the remaining edge around the window is very narrow, because this would result in a small remaining contact area.

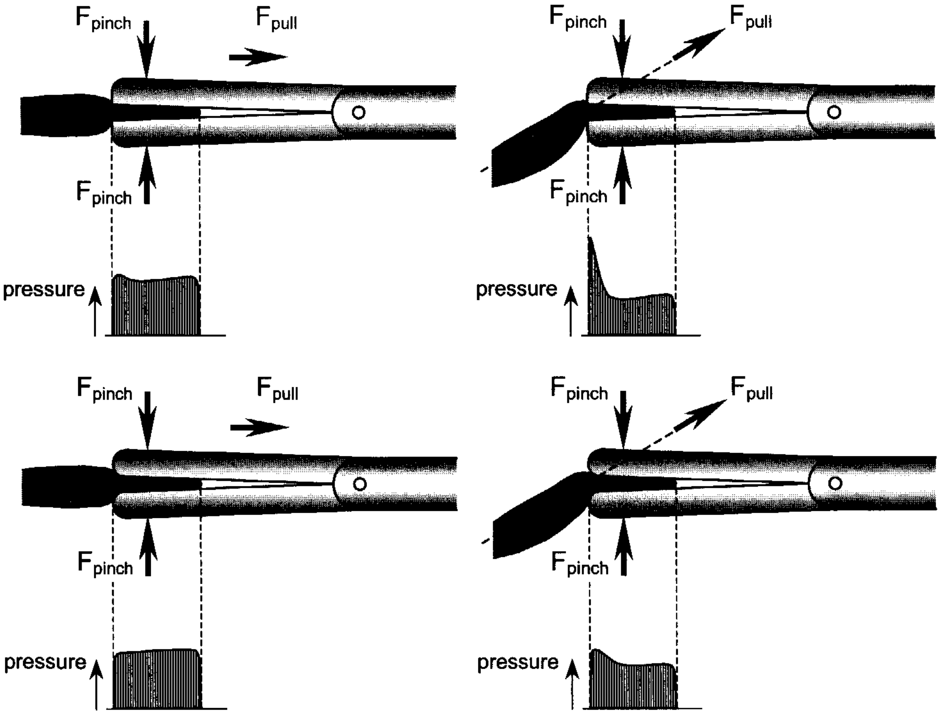


Figure 7.2. Pressure peaks caused by sharp edges in combination with a not ideally directed pull force.

Sharp edges do not necessarily cause dangerously high pressure peaks. It is in particular the combination with a not optimally directed pull force that may have dramatic consequences. If the pull force is in line with the instrument, the sharp edges will not cause large pressure peaks (top left figure), but when the pull force is not in line with the instrument, large pressure peaks occur (top right figure). They are partially based on the results from Cartmill et al. (1999), who showed that the height of the pressure peaks increases when the angle between the pull force direction and the longitudinal axis of the instrument increases. Rounding of the sharp edges reduces the pressure peaks (Shakeshaft et al. 2001, Marucci et al. 2002), as shown in the bottom figures. All the pressure graphs shown are estimations only and are not necessarily to scale.

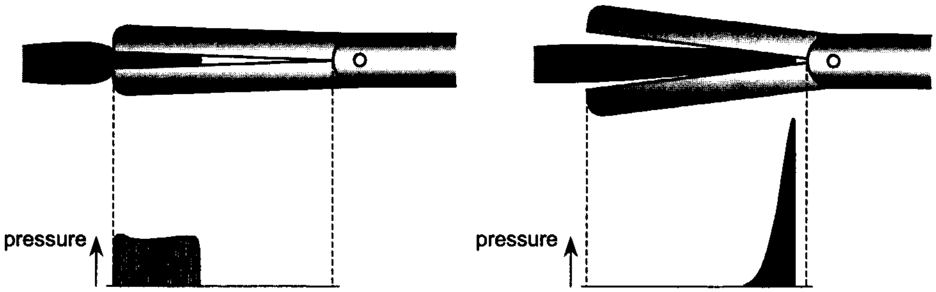


Figure 7.3. Pressure peaks because the tissue is too close to the hinges.
The graphs show estimations of the pressure on the tissue, when it is grasped with the ends of the jaws (left figure), and when it is grasped with the beginning of the jaws, near the hinge (right figure). Both pressure graphs shown are estimations only and are not necessarily to scale.

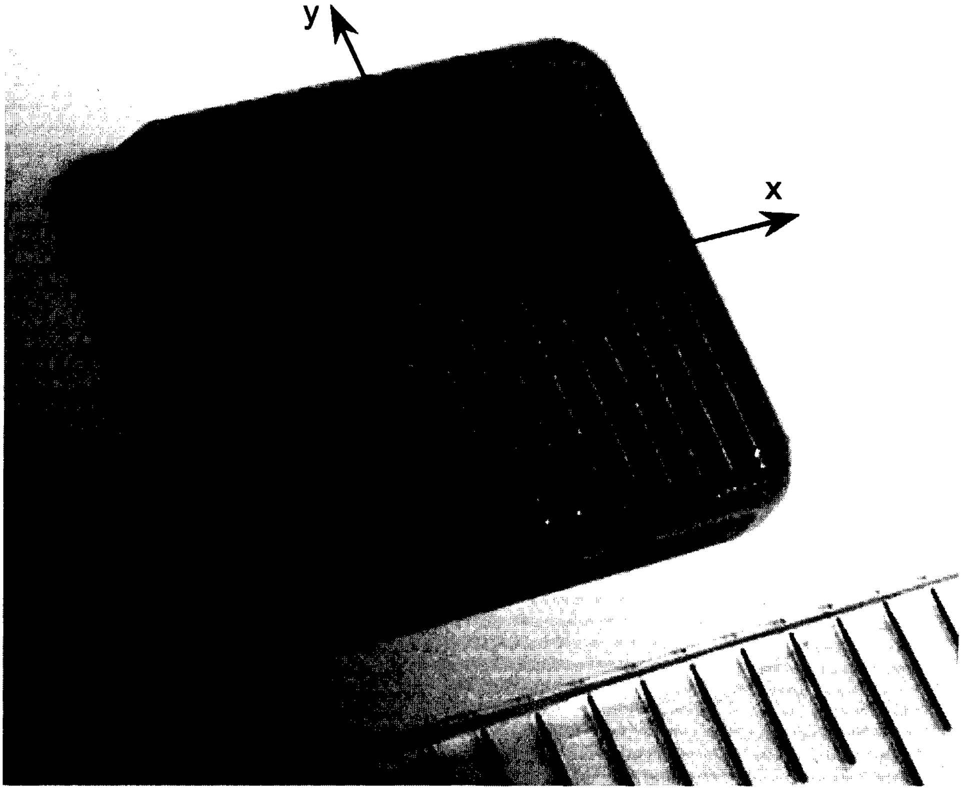


Figure 7.4. Direction-dependency of the slip behaviour.
A ribbed profile, like Rib.3 shown here, works well if the pull force is directed perpendicular to the ribs, i.e. in the direction of the x-axis, but it will not prevent slip very well when the pull force is directed along the ribs, i.e. in the direction of the y-axis. If the shape of the profile elements is equal in the x-direction and the y-direction, e.g. diamond-shaped, the slip force does not depend on the direction of the pull force.

- Contact between the tissue and the jaws close to the hinges should be avoided. If the jaws are closed, tissue close to the hinges will already be squeezed, whereas the rest of the tissue is not even in contact with the jaws. As a result, the tissue close to the hinges may be subjected to unacceptably high local pressure (Fig. 7.3).

To prevent the tissue from slipping out of the grasper jaws, the surface of the jaws should be equipped with a profile and the effect of enclosure, i.e. grasping partially around the tissue instead of pinching only directly on the tissue to provide friction (Fig. 3.1), should be stimulated. The profile should have the following features:

- The profile should consist of a large number of protruding elements. Too much distance between the profile elements deteriorates the slip prevention.
- The height of the profile elements should be within a range of 0.2 to 0.6 mm to prevent the tissue on the one hand from slipping out of the jaws too easily and on the other hand from getting damaged too easily.
- The shape of the profile should be similar in longitudinal direction and transverse direction. For example, a ribbed profile, like *Rib.3*, will function adequately if the pull force is directed perpendicular to the ribs, but it will not prevent slip very well when the pull force is directed along the ribs (Fig. 7.4). In contrast to the ribbed profile, diamond-shaped profile elements are virtually direction-independent.

Enclosure can be provided in several ways:

- A window in the jaws, in which the tissue can bulge, increases the effect of enclosure. However, as mentioned before, the window(s) should not be too large, otherwise the damage-preventing behaviour is affected.
- The jaws should be designed in such a way that the tissue can protrude at the backside of the jaws. This way, the tissue can bulge without reduction of the contact area. When tissue is allowed to protrude at the backside of the jaws, care should be taken to prevent the tissue from getting to close to the hinges.
- Providing the top and bottom jaw with an interlocking wave pattern (Fig. 7.5) also stimulates the effect of enclosure. Such a wave pattern can be interpreted as a profile with large smooth elements. By itself, a wave pattern is not expected to provide a very good slip prevention, but if a profile, with small elements as described earlier, would be applied on top of such a wave pattern, the resulting combination may yield a better slip prevention than what the profile would provide just by itself.

Clearly, features that improve the damage-preventing behaviour should not be incorporated if they cause a relatively larger degradation of the slip-preventing behaviour, unless other features are available to counteract this negative side effect. Visa versa, features intending to improve the slip behaviour are only useful if they do not affect the damage behaviour too much.

Fig. 7.6 gives an impression of a grasper with jaws that are in accordance with the presented guidelines, based on the jaw shapes that scored best in the experiments presented in this thesis (*Diam.3*).

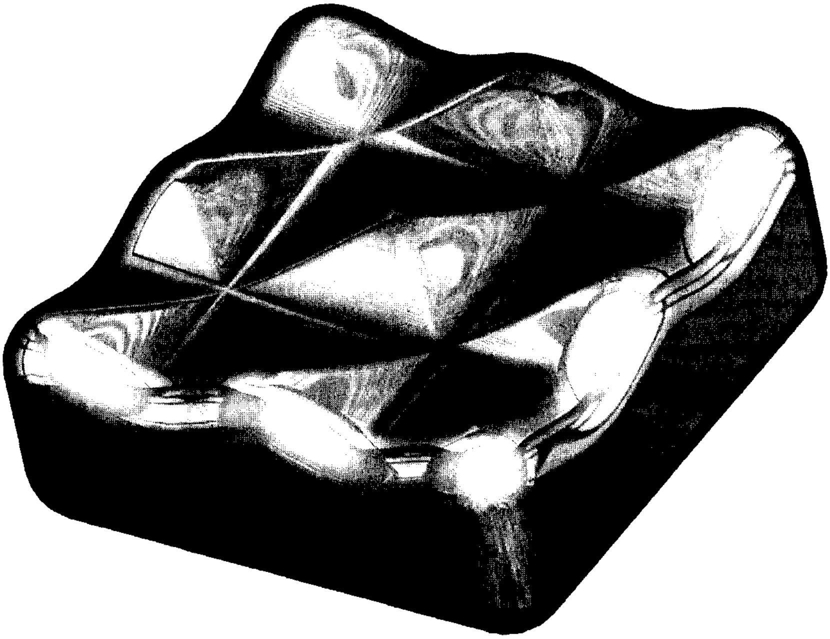


Figure 7.5. Jaw with a wave pattern.
Impression of a jaw shape with a wave pattern to increase the effect of enclosure.

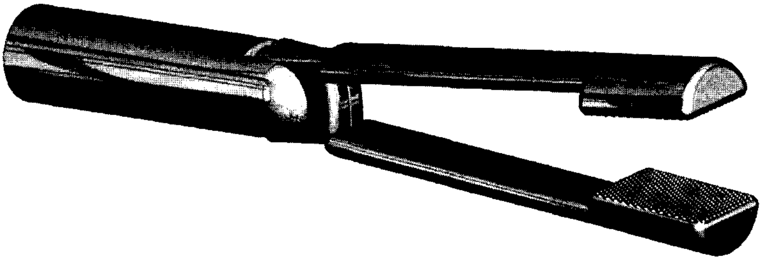


Figure 7.6. Example of a grasper with jaws according to the given guidelines.
Impression of the tip of a grasper with jaws according to the presented guidelines, based on the jaw shapes that scored best in the experiments of Chapter 5: Diam.3.

7.4 Protocol for the safety assessment of atraumatic graspers

In The Netherlands less than 2 percent of all bowel resections is performed laparoscopically (Prismant 2001). In other Western European countries, the percentage of laparoscopically performed bowel resections is much higher (11 to 36 %). It is believed that many surgeons prefer not to handle an organ that is so easily damaged with instruments that provide hardly any tactile feedback (den Boer et al. 1999a) and an operation method that has severely reduced visual feedback compared to traditional open surgery. It is believed that improvement of non-traumatic grasping and presenting of organs should help to overcome the surgeons' reluctance to perform colectomies laparoscopically. A system for assessment of the safety of presumably atraumatic instruments may help the surgeons to have more confidence in the instruments they are using and may help to select the right instruments. The protocol presented in this section aims to provide such a quantification of the safety of atraumatic laparoscopic graspers. The protocol does not focus on the design of the grasper itself, but only on the jaws of the grasper, as those are the parts that actually come in contact with the tissue. The quantification is based on two properties of the jaws: their ability to prevent slip and their damage-causing behaviour. The resulting 'grade' should provide the surgeon with an indication of how traumatic or atraumatic the grasper is. This protocol does not claim to be a complete assessment system. It is merely a rough impression of the author of what such an assessment system should include. The protocol is mainly based on the experiences gained during the performance of the experiments presented in this thesis and on some of the recommendations made in the previous section. Consequently, it is mostly summarising procedures that have already been presented before.

Material

The grasper jaws should be tested on representative material. At this moment, animal colon, preferably that of a pig, seems to be the best choice, as synthetic materials lack the complexity of the structure of the human colon wall. The measurements should preferably be done on the cecum, as this is assumed to be the weakest part of the colon, because the wall of the cecum is very thin.

Required data

In the presented project, a grasper has been defined as safe when it has a large working range, within which the tissue can be manipulated without being damaged. The working range is quantified by the so-called damage-slip-ratio, which is the upper limit of the working range, the so-called damage force, dividing by its lower limit, the so-called slip force. The slip force is defined as the pinch force that is minimally required to prevent the (moist) tissue from slipping out of the jaws when the surgeon pulls at the tissue with 5 N (de Visser et al. 2002). The pinch force is the force on the jaws that is imposed upon the tissue, not the force on the handle of the instrument. The damage force is defined as the pinch force that is maximally allowable without causing an unacceptable level of damage, while the surgeons pulls at the tissue with 5 N. In the presented project, this damage limit was set at a visible tear in one of the layers of the colon wall. A tear in the inner layer of the colon wall is sometimes hard to recognise. For example, if the imprint left by the jaws has a quite homogeneous dark colour and the transition from light to dark is not very sharp, it is expected that the imprint will fade over time. However, if there is a part within the imprint that is clearly darker than the rest, with a sharp edge, than this is almost certainly a tear in the inner layer, unless it is a bit of faeces stuck on the inside of the colon wall. One can distinguish between a tear and a bit of faeces by rubbing the colon between ones fingers, as the position of a tear will not change much, whereas that of a bit of faeces usually will.

The slip force and damage force of the jaws under investigation should be measured on several different pigs, because there are large variations within and between the pigs. The proper number of measurements still needs to be investigated, but for the moment it is suggested to do at least 7 measurements for each force and if possible more.

To be able to compare the results of the jaws under investigation with the results of other jaw shapes obtained in other experiments, the slip force and damage force of a reference jaw shape should be determined on the same (7 or more) pigs as the jaw shape under investigation. A suggested reference shape, based on the experiences gained from the experiments presented in this thesis, is shown in Fig. 7.7.

In the everyday practice of the operating room, the jaws will be placed upon the tissue in many different orientations and consequently the pull force will usually not be in line with the instrument, as shown in Fig. 7.2. To take this into account, the above procedure should be repeated (on the same pigs) for several different directions of the pull force. The appropriate directions are yet to be determined.

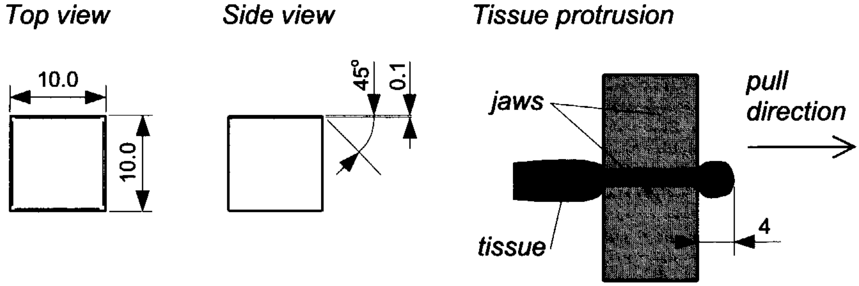


Figure 7.7. Suggested reference jaw shape.
The suggested shape to be used as a reference for new jaw designs is a 10 mm cube with a slight chamfering as indicated. The two jaws should close parallel, even if the jaws under investigation close in a scissors-like manner. Tissue should be allowed to protrude at the backside of the reference jaws as indicated.

Data processing

For each pig, the value of the damage force of the jaw shape under investigation should be divided by the value of the slip force, to obtain the damage-slip-ratio. The average and standard deviation of the (7 or more) damage-slip-ratios should be calculated. The same should be done for the reference shape.

It should also be investigated how insensitive the jaws are to variations in the tissue that is being grasped. This insensitivity is quantified by the so-called robustness. It is determined by dividing the coefficient of variation (i.e. the standard deviation divided by the average) of the damage-slip-ratio of the reference shape by the coefficient of variation of the damage-slip-ratio of the jaw shape under investigation. The larger the robustness, the more reliable is the performance of the grasper, as it is less sensitive to tissue variations.

Grading the jaw shapes

The average damage-slip-ratio is the main indicator for the safety of the grasper under investigation. The larger it is, the safer is the instrument. If the damage-slip-ratio is lower than 1, it is impossible to prevent the tissue from slipping out of the jaws without damaging the tissue, and the instrument is useless. The robustness provides a measure for how reliable the obtained damage-slip-ratio is. The robustness and the average damage-slip-ratio can be combined into a single grade by subtracting 1 from the ratio and then multiplying it with the robustness. However, it is suggested that they are reported separately as well, together with the damage-slip-ratio of the reference shape, in order to provide clear insight in how the grade was accomplished and how well the new shape performs in relation to the standard reference shape.

Conclusion

During laparoscopic surgery, it is important how a grasper performs on a colon of average strength, but in particular how safely it can handle a diseased, weak colon. Therefore, an average damage-slip-ratio should always be used with a large safety margin.

Once more, it should be stressed that the presented protocol is far from complete. It is a mere suggestion for what a safety assessment protocol might look like. Further research into the proper damage limit and into the appropriate directions of the pull force are needed before a more detailed safety assessment system can be derived.

8 Conclusion

General overview of the project

The project described in this thesis can be divided into two parts.

In the initial part a general exploration of technical aspects of instruments used during laparoscopy was performed. The aim of this exploration was described as 'the identification of a key problem in laparoscopy', to be used as the main research area for this project. 'Safe manipulation of the intestines' was chosen from a number of important problems in laparoscopy, which had been identified using a clinically driven approach. This approach implies that the engineer establishes a continuing interaction with surgeons through discussions, brainstorming sessions and regular visits to the operating room. From this interaction, several genuine problems experienced by the surgeons emerged. The importance of each of these problems was determined in another brainstorming session with the surgeons. Within the selected research area, the followed approach was not to create an exotic new instrument for safe manipulation of the intestines, but to improve existing grasping instruments. It was decided to focus specifically on the parts of a grasper that will have direct contact with the tissue of the bowel (large intestine): the jaws.

The second part was the core of this project. The aim was to improve existing grasper jaws and to determine which jaw shape provides the best grip on bowel tissue. Instead of an optimal jaw shape, the most important outcome of this project has been a set of guidelines for the design of safe, minimally traumatic grasper jaws. According to these guidelines (Sect. 7.3) tissue damage is best prevented by ensuring a large contact area between the grasper and the bowel tissue. Slip of the tissue is best prevented by providing the jaw shapes with a profile, preferable with profile elements of limited height and diamond-shaped. Slip can be prevented further by allowing the tissue to bulge at the backside of the jaws, such that when the tissue is pulled, the jaws transmit the pull force not only on friction, but also by pushing against the backside of the tissue. In the experiments leading to the guidelines, a preference was found for jaw shapes that have a diamond-shaped profile with a height of 0.3 mm. However, it would be premature to call these jaw shapes the best possible shapes to obtain a safe grip on bowel tissue, because the number of different shapes tested has been limited. Besides the guidelines, a suggestion has been presented for a protocol (Sect. 7.4) for the assessment of the safety of newly developed 'atraumatic' graspers.

The guidelines and protocol were derived from the results of a large number of experiments. In the first experiments (on pigs) the functional requirements of a bowel grasper were assessed. It was determined that a bowel grasper should be able to pull at the bowel with 5 N, without causing the tissue to slip out of the grasper and without causing damage that will eventually lead to clinical complications in humans. These limitations on slip and damage behaviour of the grasper have been quantified in the damage-slip-ratio: the ratio of the maximum pinch force that will not cause too much damage and the minimum pinch force required to prevent slip. The insensitivity of the grasper to variations in the bowel tissue within subjects and between subjects has been quantified in the so-called robustness: the variation in the material properties divided by the variation in the performance of the grasper. Together, the damage-slip-ratio and the robustness formed the criteria that were used in the comparison of different jaw shapes. The examination of the performance of different jaw shapes was divided in two parts: using elementary shapes and using complex shapes. In series of elementary shapes each time the influence of a single design feature on the slip and damage behaviour was investigated. It was concluded that a large contact area is required to prevent damage, but for avoiding slip the contact area should be small. These requirements are not necessarily contradicting, because not the entire jaw needs to be in contact with the tissue when the pinch force is applied that is minimally required to avoid slip. If not the entire jaw will be in contact with the tissue, the contact area will be smaller and the requirement for avoiding slip will be met. It was found that the slip-preventing pinch force could be lowered by applying so-called enclosure. Enclosure implies that the pull force is transmitted directly onto the tissue by pushing against the backside of it, rather than via friction. Two ways to apply the principle of enclosure were investigated: Macroscopic enclosure is obtained by grasping partially or completely around the tissue. Microscopic enclosure can be obtained by applying a profile to the contact surface. These findings were investigated further in more complex jaw shapes. From these investigations, the guidelines and protocol mentioned were derived. In the future, further research into the optimal extent of chamfering or rounding and into alternative materials for the jaws should supplement these guidelines.

A good understanding of what 'safety' and 'atraumatic' imply is indispensable for the design of instruments with which delicate organs are handled. The presented research and the resulting guidelines and protocol are intended as a first step in the design and validation of such instruments. It is believed that the availability of safer, better and more reliable instruments, in which the surgeon has high confidence of safety, may contribute to the future acceptance of sophisticated laparoscopic procedures like the colectomy as probably well accepted alternatives to the traditional open procedures.

Appendix A:
Pressure leading to tissue damage

An estimation of the magnitude of the pressure that will cause tissue damage is obtained using the results from several experiments in which colon tissue was pinched between two hemispheres with a diameter of 2 mm (referred to as *Hemi2*, Fig. 5.11).

In experiments it was found that the damage force, the pinch force that is maximally allowable without causing unacceptable damage, of *Hemi2* usually lies within the range of 2 to 7 N. Because of the hemispherical shape, this pinch force is not uniformly distributed over the area of contact between the hemispheres and the tissue, which makes the calculation of the maximally occurring local pressure less straightforward. However, it can be estimated easily as follows.

Imagine a cylinder, with a flat top (in contrast to the cylinders mentioned in Chapter 5) and the same diameter as the hemisphere, is pinched into the tissue with its topside. The pinch force F will cause an impression with a depth dy and an average pressure $p_{average}$ on the tissue, which equals F/A, in which A is the cross-sectional area of the cylinder: $\pi * r^2$. As the pinch force is equally distributed over the contact area, the local pressure will be the same everywhere. Using the hemisphere, the same pinch force F will cause the same average pressure on the tissue, but the local pressure will vary. This is because the local pressure is directly related to the local depth of the impression, which is obviously not constant due to the hemispherical shape. The maximum local pressure can be obtained using the fact that the ratio between the maximum local pressure p_{max} and the average pressure $p_{average}$ (which equals the average pressure of the cylinder) is equal to the ratio between the maximum depth of the impression dy_{max} and the average depth of the impression dy (equal to dy of the cylinder): $\frac{dy_{max}}{dy_{average}} = \frac{p_{max}}{p_{average}}$

If the tissue is assumed to be homogeneous, the pinch force F will cause compression of the same volume of tissue for both shapes. Equalling the volume of a cylinder and the volume of a hemisphere yields the following: $h \pi r^2 = \frac{1}{2}\frac{4}{3}\pi r^3$

$$h = \frac{2}{3} r$$

This means that pushing a cylinder into tissue to a depth of $h = 2/3\ r$ requires the same force as pushing a hemisphere into the tissue to a (maximum) depth of r. In other words, the maximum depth of impression of a hemisphere is 3/2 times the maximum (=average) depth of impression of a cylinder, which in turn means that the maximum (local) pressure on the tissue is 3/2 times the average pressure on the tissue.

As the average pressure on the tissue equals F/A, the maximum pressure on the tissue equals $3/2 * F/A$. The damage-causing pinch force F was mentioned to lie between 2 and 7 N and $A = \pi * r^2$, with $r = 1$ (mm). Consequently, the pressure that will lead to unacceptable tissue damage lies between 0.9 and 3.3 N/mm^2, which equals 0.9 - 3.3 MPa.

Appendix B:

Influence of the length of the springs on the magnitude of the pinch force

Variation in the length of the springs causes inaccuracy in the pinch force, but the following analysis shows that the magnitude of this inaccuracy is limited.

The pinch force that the jaws impose upon the tissue depends on the length L of the springs (Fig. B.1) and on their position $x2$. In the experiments the length of the springs is assumed constant and the pinch force is calculated by multiplying the (constant) spring force by $x2/x1$. In reality, the length of the springs, and thus the spring force, is not constant, because when the lever opens over a distance y, the length of the springs changes to $L+dL$. The change in spring length dL depends on y and the relative position $x2/x1$ of the springs on the lever: $dL = y * x2/x1$. The spring elongation dL causes a variation $dF_{spring} = c * dL$ in the spring force, where c is the spring constant. This spring force variation dF_{spring} causes a variation dF_{pinch} in the pinch force: $dF_{pinch} = dF_{spring} * x2/x1 = c * dL * x2/x1 = c * y * x2/x1 * x2/x1 = c * y * (x2/x1)^2$. By definition, c is constant (in this case: $c = 1.38$ N/mm) and $x2/x1$ is smaller than 1. The opening y depends on the thickness and stiffness of the tissue that is being pinched. The opening y is shown strongly exaggerated in the figure. The opening y is usually around 1 mm or less for low pinch forces and decreases to only a few tenths of a millimetre for high pinch forces. For low pinch forces y is relatively large, but the springs are placed near the hinge and therefore $x2/x1$ is small. For large pinch forces y is relatively small, but the springs are placed near the jaws and therefore $x2/x1$ is close to 1. Consequently, the product $y * (x2/x1)^2$ is in practice never higher than approximately 0.25. Therefore, the maximal variation in the pinch force due to variations in the spring length is approximately 0.35 N, which is less than 2.5 % for pinch forces above 15 N. Lower pinches are usually created using a mass on the top arm of the lever instead of using springs.

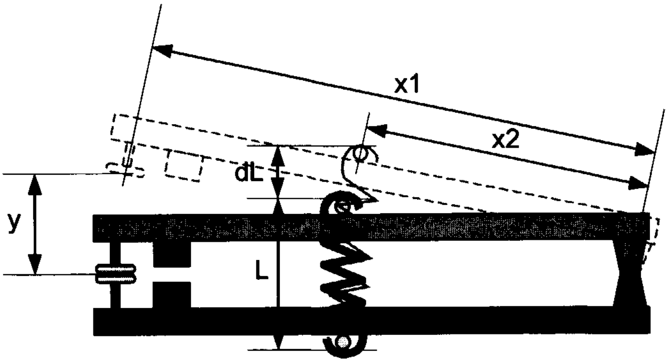


Figure B.1. Variation in the length of the springs.

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Note: Surnames with prefixes are listed under the first letter of the name, not the prefix; e.g. "den Boer" is listed under "B".

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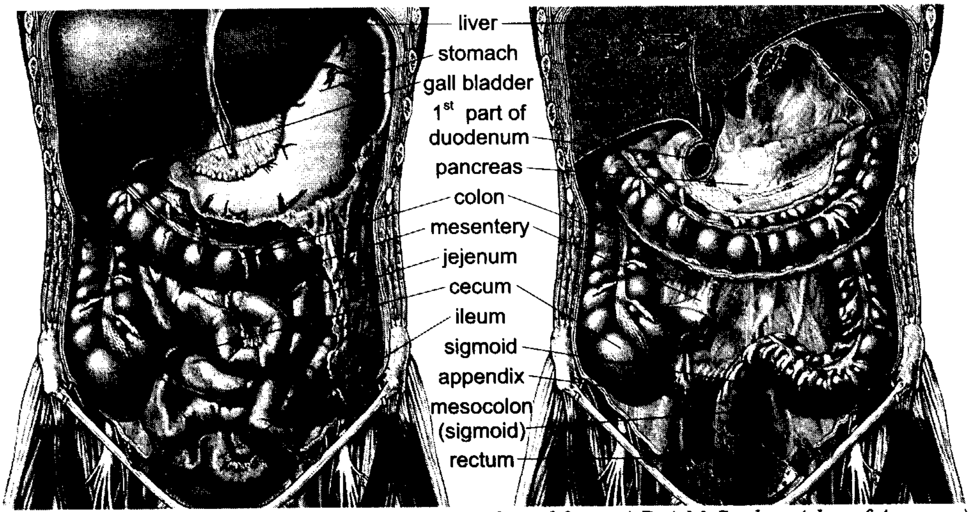
Glossary



(Adapted from: A.D.A.M. Student Atlas of Anatomy)

anastomosis	connection of two organ parts
Babcock	laparoscopic grasper for large delicate organs (Fig. 2.2)
cecum	first (proximal) part of the large intestine
colectomy	removal of (part of) the colon
colon	large intestine, bowel
damage force	pinch force that is maximally allowable to transmit a pull force of 5N without exceeding a certain set level of damage to the tissue
distal	away from the centre of the body, towards the end
duodenum	first (proximal) part of the small intestine
dysphagia	difficulty or inability to swallow
enclosure	grasping (partially) around the tissue, such that force transmission is (partially) done by pushing against the back of part of the tissue, instead of solely by friction (Fig. 3.1)
endoscopy	surgery through small incision under camera vision, *keyhole surgery*
extracorporal	outside the body
FE(M)	finite element (modelling)
fundus	top part of the stomach
gastroesophageal	of the stomach and oesophagus
haemo-	blood-
ileostomy	surgical procedure in which the bottom of the ileum is attached to a stoma
ileum	last (distal) part of the small intestine

interporcine	between pigs
intracorporal	inside the body
intraporcine	within a pig
jejunum	middle part of the small intestine
laparoscopy	endoscopic surgery in the abdomen
laparotomy	traditional open abdominal surgery
mesentery	membrane containing the blood vessels of the small intestine
mesocolon	membrane containing the blood vessels of the large intestine
metastasis	spreading of an infection or disease to other organs
pancreatico duodenectomy	surgical procedure in which (part of) the pancreas and the duodenum are resected
peritoneum	membrane covering most of the inside of the abdominal cavity
peritonitis	infection / inflammation of the peritoneum
pressure	(pinch) force per unit area
porcine	(from/of a) pig
proximal	towards / close(r) to the centre of the body / the beginning
ratchet	mechanism to lock the position of the jaws of a grasper (Fig. 1.2)
rectum	last (distal) part of the large intestine before the anus
sigmoid	curved section of the large intestine, proximal to the rectum
slip force	pinch force that is minimally required to transmit a pull force of 5 N without letting the tissue slip out of the grasper jaws
stress	force per unit area
tension	(pull) force per unit area
trocar	device used in laparoscopic surgery, which functions as an entry portals in the abdominal wall, through which the laparoscopic instruments and camera are inserted

Curriculum Vitae

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1986-1992	Atheneum (high school) at the Veenlanden College in Mijdrecht.
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