Stellingen

behorende bij het proefschrift

Tissue manipulation in laparoscopic surgery

Eveline Heijnsdijk

1. Een knijpkrachtbegrenzer op een paktang vergroot niet de veiligheid vanwege de grote individuele verschillen in weefselsterkte, de grote invloed van trekkracht en het feit dat onbekend is welke kracht tot weefselschade leidt. *(dit proefschrift)*

2. Om weefsel goed en veilig te kunnen opspannen moeten de bekjes van paktangen een groot contactoppervlak hebben met het weefsel en een ondiep profiel. *(dit proefschrift)*

3. De mechanische efficiëntie van een paktang hoeft niet zo hoog mogelijk te zijn om weefsel veilig te kunnen vasthouden. *(dit proefschrift)*

4. Het gebrek aan krachtterugkoppeling in de huidige 'operatierobots' maakt een operatie uitgevoerd met zo'n systeem een echte kijkoperatie.

5. Dat de mechanische efficiëntie van de bestaande tangen erg laag is, blijkt uit de moeite die het werktuigbouwers heeft gekost om een tang te ontwerpen die net zo inefficiënt is.

6. In tegenstelling tot de uitdrukking 'dat slaat als een tang op een varken', kunnen laparoscopische tangen uitstekend op varkensweefsel worden getest.

7. Gezien de grote variatie in weefseleigenschappen tussen diverse organen is het opmerkelijk dat bij de verschillende modellen tangen in de catalogi van de fabrikanten meestal niet het weefsel vermeld is waarvoor de tang bedoeld is.

8. Hoewel in de chirurgie meer gebruik gemaakt kan worden van mechanica, moeten ingenieurs beseffen dat 'de patiënt' vaak niet te berekenen is.

9. De invoering van de Euro heeft bewezen dat mensen slecht kunnen rekenen met procenten, zoals nodig is bij het omrekenen van gulden naar Euro.

10. Bewegen is gezonder dan sporten.

Deze stellingen worden verdedigbaar geacht en zijn als zodanig goedgekeurd door de promotoren: prof.dr. J. Dankelman, prof.dr.ir. H.G. Stassen en prof.dr. D.J. Gouma.

Propositions

belonging to the thesis

Tissue manipulation in laparoscopic surgery

Eveline Heijnsdijk

1. A pinch force limiter on a grasper does not increase the safety, due to the large individual differences in tissue strength, the large influence of pull force and the fact that the force leading to tissue damage is unknown. *(this thesis)*

2. To stretch tissue properly and safely, the jaws of the graspers should have a large contact area with the tissue and a light profile. *(this thesis)*

3. The mechanical efficiency of a grasper does not necessarily have to be as high as possible to be able to hold tissue safely. *(this thesis)*

4. The lack of force feedback in the currently used 'operation robots' makes an operation executed with such a system a true looking-through-a-keyhole operation.

5. The fact that the mechanical efficiency of the currently used graspers is very low, can be deduced from the great effort of mechanical engineers to design a forceps just as inefficient.

6. In contrast to the Dutch statement 'dat slaat als een tang op een varken' (to fit like a forceps on a pig, meaning 'that makes no sense'), laparoscopic graspers can very well be tested on pig tissue.

7. Considering the large variation in tissue properties between various organs, it is striking that at the different models of graspers in the catalogue of the manufacturers the grasped tissue is mostly not stated.

8. Although in surgery mechanics can be used more often, engineers should realise that 'the patient' can often not be calculated.

9. The introduction of the Euro has proven that people are inaccurate in calculating with percentages, as needed to convert guilder to Euro.

10. To move is healthier than to practice a sport.

These propositions are considered defendable and as such have been approved by the supervisors: prof.dr. J. Dankelman, prof.dr.ir. H.G. Stassen en prof.dr. D.J. Gouma.

Tissue manipulation in laparoscopic surgery

Tissue manipulation in laparoscopic surgery

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

op 20 januari 2004 om 15:30 uur

door

Eveline Anna Maria HEIJNSDIJK

doctorandus in de bewegingswetenschappen
geboren te Delft

Dit proefschrift is goedgekeurd door de promotoren:
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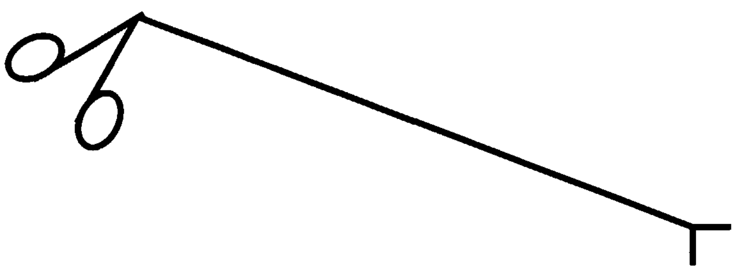
Introduction



1.1 Minimally invasive surgery

Conventional "open" surgery is performed through a generally large incision in the skin and underlying tissue, which enables the surgeon to observe and to manipulate the tissue. In contrast, minimally invasive surgery is performed by an endoscope (camera) and several long, thin instruments for tissue manipulation, introduced through a few small incisions in the skin. The view of the endoscope is projected on monitors in the operating theatre (Fig. 1.1).

Figure 1.1 An overview of the operating theatre during a laparoscopic procedure. The surgeon uses instruments to manipulate tissue and a monitor to observe tissue.

Laparoscopic surgery (minimally invasive surgery in the abdominal cavity) is generally accepted and can be used for removal of the gallbladder, bowel resection, appendectomy, donor renal transplant procedure, splenectomy or hernia repair. The advantages for the patient are reduced trauma to healthy tissue, reduced pain, better cosmetic result and lower risk of wound infections. The patient's recovery is faster and the hospital stay is shorter.

The laparoscopic procedure, however, demands more of the surgeon, due to the indirect way of manipulating and observing tissue [6,9,28,29]. Since the rigid instruments are placed in the abdomen through fixed incision points, the movements of the instruments are restricted. Furthermore, the movements of the instrument tip are mirrored to the movements of the hands. The movements are also scaled: Depending on the ratio between the length of the shaft inside and outside the abdomen the movements of the instrument tip are amplified or reduced with respect to the movements of the hands.

The indirect observation of the abdominal cavity also causes problems. The three dimensional movements are translated into a two dimensional view on the monitor. Misorientation is caused by the difference between the endoscope's line-of-sight and the surgeon's natural line-of-sight when looking directly into the abdomen. As a result, the instruments on the monitor move in a different direction than expected [7,34].

Due to the disordered hand-eye coordination and the interposition of instruments, the duration of operations performed laparoscopically is longer than operations performed in open surgery, resulting in a longer duration of anaesthesia. In addition, the surgeon needs more training to learn a particular procedure [1,26,35].

1.2 Incidence and consequences of laparoscopically induced injury

Since the movements and the view of the surgeon are impaired during minimally invasive procedures, the instruments can accidentally damage or even perforate tissue. During laparoscopic cholecystectomy, the incidence of perforation of the gallbladder is 10% to 30% [18,25]. Although this incidence is high, few complications caused by perforation of the gallbladder arise [18].

For bowel injury, the results are different. According to a literature review, the incidence of bowel injury during laparoscopic surgery is 0.13% [32]. Bowel injury can recover spontaneously or can lead to a perforation a couple of days later. When the bowel is perforated, the contents can leak into the abdominal cavity, potentially causing peritonitis. Subsequently, it can lead to abdominal sepsis and even death. In total, the mortality rate of bowel injury was 3.6% [32].

Almost half of the reported bowel injuries was caused by the insertion of a trocar or Veress needle, which is seldom missed during surgery and therefore could be treated immediately. The remaining injuries were caused by coagulators or lasers, grasping forceps, scissors or other instruments. In these cases, the exact cause is often unclear, because the injury is frequently hidden from the surgeon's view and is discovered only after a few days. Although the coagulator is often blamed for causing perforations, histological examination revealed that a part of these perforations could also have been caused by the grasping forceps [19].

Presently a small number of bowel resections is performed laparoscopically. In the Netherlands, only 182 of the 10306 (1.8%) bowel resections in 2001 were performed laparoscopically [22]. When the safety and ergonomics of the instruments will be improved, it might influence general acceptance of laparoscopic bowel surgery.

In contrast to the considerable amount of studies performed to the safety of trocars and coagulators, limited research has been performed to analyze the safety of the grasping forceps. An interview with surgeons, however, revealed that the grasping forceps is considered as one of the most dangerous instruments [5]. Therefore, one of the projects of the MISIT (Minimally Invasive Surgery and Interventional Techniques) program of the Delft University of Technology is aimed at the improvement of laparoscopic grasping forceps [33].

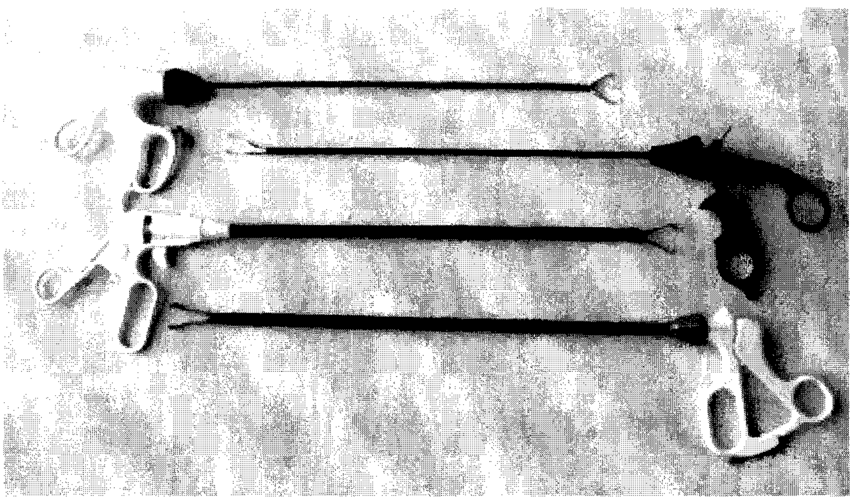


Figure 1.2 A collection of Babcock graspers to manipulate bowel tissue. From top to bottom: Ethicon (∅ 5 mm), Aesculap (∅ 5 mm), AutoSuture (∅ 10 mm) and Ethicon (∅ 10 mm). The total length is about 40 cm. All forceps are provided with a ratchet on the handle which enables the surgeon to fixate the jaws when holding tissue aside.

1.3 Laparoscopic grasping forceps

When performing open procedures, the surgeon generally uses his hands to hold tissue aside and to stretch tissue for dissection. In addition, he can palpate tissue to feel the pulsation of blood vessels and the location of tumors, stones and lymph nodes. Due to the limited access to the abdomen during laparoscopic surgery, these functions have to be fulfilled by instruments with a small diameter. Most dissection actions are performed using the scissors or coagulator in one hand, while holding or stretching the tissue with the grasping forceps in the other hand. Therefore, the grasping forceps is one of the most frequently used instruments during laparoscopic procedures (Figs. 1.2 and 1.3).

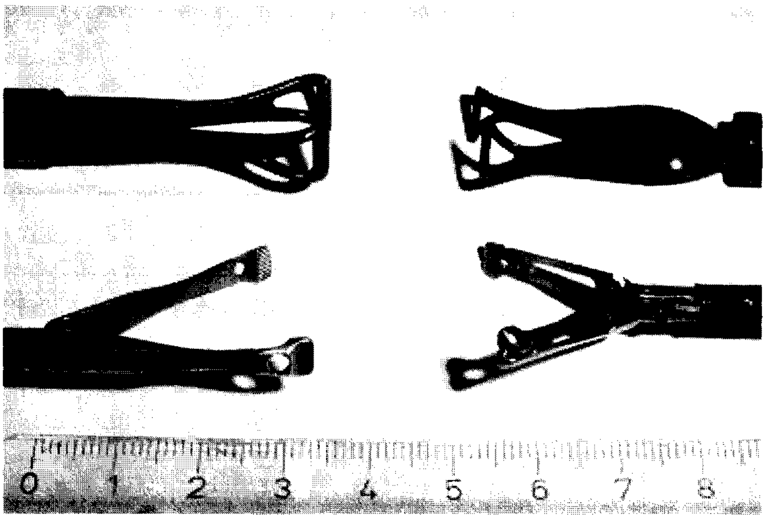


Figure 1.3 The jaws of the forceps shown in Figure 1.2. Just a small area is in contact with the tissue. The jaws have windows and have mostly a profile to improve the grip on the tissue.

Manufactures have developed a lot of different grasping forceps which should be able to safely grasp various tissue. However, compared with the human hand, it is much more difficult to manipulate tissue using these grasping forceps. The information about the grasping force applied to the tissue is transmitted via the jaws and the mechanism in the shaft to the handgrip. This force feedback is low due to considerable friction and backlash in the mechanism. During one cycle of opening and closing of the jaws, more than 70% of the energy is lost, leading to a mechanical efficiency of only 30% [27]. It was demonstrated that the pulsation of a blood vessel is much more difficult to feel using forceps instead of bare hands [4]. As a consequence, palpation of the tissue to determine the stiffness will be almost impossible [15,23].

In addition to this limited force feedback, the surgeon lacks visual feedback when the jaws of the forceps are out of the laparoscopic view. Consequently, it is difficult to apply the suitable force. Applying an inappropriate force could result in delay of the operation due to slip of the tissue out of the forceps or even in tissue injury and perforation [16].

Next to the impaired force feedback and visual feedback, the interaction with the tissue is also altered. Using the fingers of the human hand, it is possible to grasp around the bowel and to distribute the pressure for each finger and phalanx. In contrary, the jaws of graspers are short (about 20-30 mm), due to the restricted working space in the abdomen. With these short, stiff jaws it is impossible to grasp around the bowel as generally performed by the hands of the surgeon and the bowel should entirely be grasped through friction. Hence, to prevent slipping of tissue out of the jaws, the pinch force has to be large (Fig. 1.4).

Figure 1.4 The differences of grasping tissue using hands and using a laparoscopic forceps. The contact area of the jaws is much smaller and the local pressure on the tissue is higher using forceps. Due to the short jaws, it is impossible to grasp around the colon.

Besides the limited length of the jaws, also the width of the jaws is restricted, since the grasper has to be introduced through a trocar with a diameter of 5 or 10 mm. Consequently, the contact area between jaws and tissue is small, leading to high pressures on the tissue [8]. Furthermore, the jaws of presently used forceps are often sharp to ensure grip on the tissue. Even the jaws of the so-called "atraumatic" forceps have very sharp ridges (Fig. 1.5). Due to these sharp ridges, low grasping forces are already enough to damage the tissue.

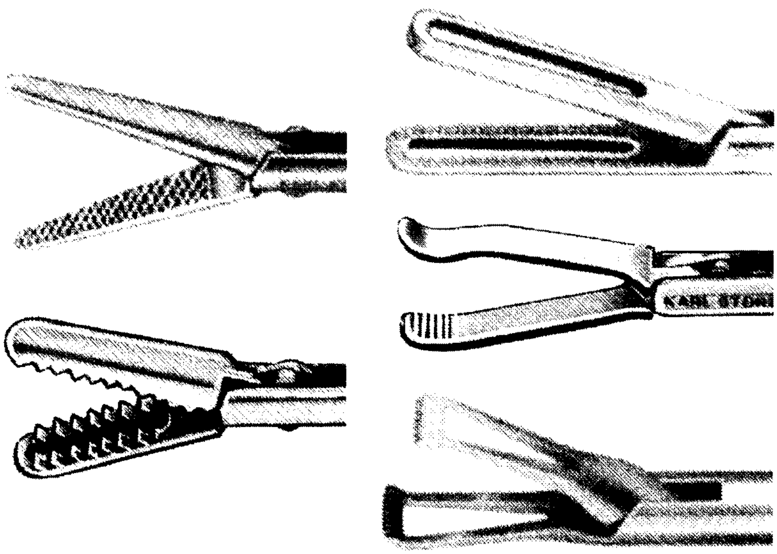


Figure 1.5 Jaws classified as "atraumatic". All these jaws are made by the same manufacturer (Storz). Clearly, no consensus about the word "atraumatic" exists.

1.4 Improving the grasping forceps

In order to improve grasping forceps, research can concentrate on three different aspects: the handle, the mechanism and the jaws of the forceps [6]. Due to the poor ergonomic design most handles cause discomfort, especially pressure on the thumb and fingers and extreme positions of the wrist, leading to fatigue and cramp [3,30,31]. Various alternative designs have been proposed but are not yet introduced in general practice [11,14,31].

The mechanism of opening and closing the forceps causes friction which diminishes the mechanical efficiency and thereby the force feedback. The mechanical efficiency can be improved from 30% to more than 90% by changing the mechanism of the forceps [2,13,21], resulting in relative simple and robust instruments. In theory, the mechanical efficiency can also be improved using electromechanical master-slave systems. The hand movements of the surgeon are measured and transformed into electronic signals, which are transmitted to the arms holding the instruments. Such systems can also reflect the forces on the jaws to the surgeon's fingertips via tactile displays [17]. Additional advantages are that the distribution of the force can be obtained and that the degrees of freedom of the instruments can be increased by adding a wrist-joint. Moreover, the effects of scaling and mirroring can be neutralized and tremor can be suppressed. Disadvantages are the high production and maintenance costs and the large size and in addition, the safety, reliability and the complexity of using the equipment. In practice, the manipulation systems used do not possess force feedback yet.

Despite the considerable amount of available jaws, little research has been performed to the design of the jaws. Changes in profile and shape show large changes in damage and slip properties [20]. It has been shown that simple adjustments in shape, such as rounding the edges can already lead to large improvements [24]. More complex designs introduced are a tip with an increased number of fingers, higher flexibility of jaws and segmented jaws [2,10,12]. However, the suitability and safety of the jaws can not be compared, since no studies have been performed to obtain the minimally required and maximally allowed pressure on the tissue.

Various aspects of the forceps can be improved. It is difficult to predict which aspect is the most important. The safety of tissue manipulation is not only dependent on the forceps itself, but also on the damage and slip properties of the grasped tissue, how the surgeon uses the forceps and if the surgeon relies on visual or on force feedback. For example, improving the mechanical efficiency is not very useful if the surgeon remains relying completely on visual information. Correspondingly, enhancing the friction between jaws and tissue is unfavorable if it is accompanied by increased tissue damage.

1.5 Research aim

A useful grasping forceps allows manipulation of tissue without slip or damage. The effect of a grasping action depends on the forces the surgeon exerts on the handle, the design of the jaws and the strength and friction properties of the grasped tissue. The force the surgeon exerts depends on the available force feedback and visual feedback.

The aim of this research is to evaluate factors influencing safe manipulation of tissue. The minimally required and maximally allowable forces during safe manipulation of bowel tissue will be obtained. These forces depend on the properties of the grasped tissue, the tissue-instrument interaction, the instruments used, and the surgeon who applies the forces. Finally, the results should lead to guidelines for the design of grasping forceps by engineers and the use of grasping forceps by surgeons.

This thesis concentrates mainly on the effect of grasping in bowel surgery, since bowel tissue is considered as the most delicate tissue and the consequences of complications after laparoscopically induced bowel injury are severe. Moreover, it is expected that forceps, which can be used safely on bowel tissue, might also be suitable for comparable tissue. For other organs or tissue at least the research method as described and used in this thesis can be followed to find suitable grasping forceps.

1.6 Outline of the thesis

In this thesis several aspects of the grasping of tissue are investigated. The thesis concentrates on tissue properties, jaw-tissue interaction and the application of the appropriate force by surgeons. For this purpose, several experiments and analyses have been performed.

Chapter 2 is a literature review of laparoscopic-induced bowel injury. The review evaluates the data on the incidence, location, time of diagnosis, the causing instruments, presence of adhesions, management and mortality of bowel injury caused during various laparoscopic procedures.

In Chapter 3 the clinical use of the grasping forceps during laparoscopic cholecystectomy and colectomy is evaluated. The amount of grasping actions resulting in slip or damage of tissue is quantified by video analyses. In addition, the duration that tissue is grasped is measured.

Chapters 4 and 5 describe experiments performed to investigate the properties of bowel tissue. In Chapter 4 the influence of pull and pinch forces on pig colon damage are measured, since the main forces during tissue manipulation are a pull and pinch force. Forceps tested on pig bowel should also be suitable for various human bowels. Therefore, in Chapter 5 the intra- and inter-individual variability in perforation forces on bowels is described. Also, the difference in perforation force between small and large bowel and between pig and human bowel tissue is investigated.

Chapter 6 describes the interaction between instrument and tissue. Several jaws are compared on slip and damage properties of pig bowel tissue, leading to guidelines of jaw design.

Chapters 7 and 8 investigate how surgeons succeed in applying the appropriate pinch force. In Chapter 7 the influence of force feedback and visual feedback and laparoscopic experience of the surgeon are investigated. Chapter 8 describes several experiments to determine the optimal mechanical efficiency of the forceps.

In Chapter 9 the research approach and findings are discussed and guidelines for the design and use of a laparoscopic grasper are presented. Finally, recommendations for future research are provided.

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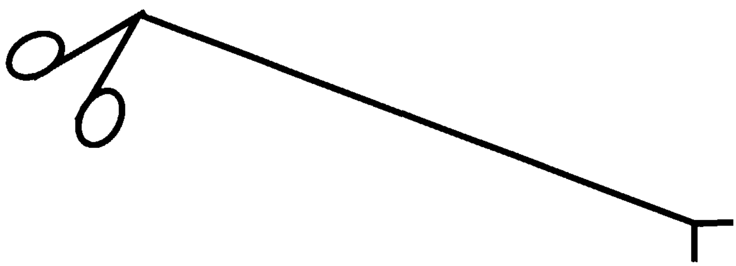
Chapter 2

A review of bowel injury as a complication of laparoscopy



M. van der Voort, E.A.M. Heijnsdijk, D.J. Gouma
Submitted.

Abstract

Background: Bowel injury is a rare but serious complication of laparoscopic surgery. This review evaluates the data on the incidence, location, time of diagnosis, the causing instruments, presence of adhesions, management and mortality of laparoscopic-induced bowel injury.

Methods: A review of the published data was carried out by using the MeSH browser within Pubmed. The keywords used were 'laparoscopy/adverse effects' and 'bowel perforation'. Additionally, articles were found by references used by the studies found in the Pubmed search.

Results: The reported incidence for laparoscopic-induced bowel injury was 0.13% (430/329924) and for bowel perforation it was 0.22% (66/29521). The small intestine was most frequently injured during laparoscopy (55.8%) followed by the large intestine (38.6%). In at least 66.8% of the cases of bowel injury the diagnosis was made during the laparoscopy or within 24 hours postoperatively. The trocar or Veress needle inflicted the most bowel injuries (41.8%), followed by thermal lesions caused by the coagulator or laser (25.6%). Adhesions seem to increase the risk of bowel injury, since adhesions or previous laparotomy were present in 68.9%. Laparoscopic-induced bowel injury is mainly managed by laparotomy (78.6%), where suturing is most often used. The mortality rate of laparoscopic induced bowel injury was 3.6%.

Conclusion: In 0.13% a laparoscopy is complicated by a bowel injury. Mainly it is caused by a trocar or Veress needle and discovered during the operation. Laparoscopic-induced bowel injury has a high mortality of 3.6%.

2.1 Introduction

The use of laparoscopic surgery has increased extensively since its introduction, and is still expanding. The great advantage of laparoscopy over traditional open surgery is shortened hospital stay, a reduction in the scar and decrease in wound infection and postoperative complications. Although laparoscopy has important advantages, also some disadvantages exist. The time of procedure is prolonged [1,2] and a few complications are specific and unique for this type of surgery. One of these complications is bowel perforation during surgery [3-8]. Although injury to the bowel is a major complication with a high morbidity and mortality rate [9], little is known about the real incidence of bowel perforation during laparoscopy [10].

The overall incidence of laparoscopic-induced bowel perforation alone does not give information about the risk of each laparoscopic procedure separately. Therefore the incidence rate should by split up along type of operation.

In addition, it is of significance at what time most laparoscopic-induced bowel perforations are recognized. Early perforation develops during or directly after surgery, whereas late perforation arises a couple of days later. Late perforation is caused by local inflammation as a reaction to damage inflicted by laparoscopy.

Another issue is which parts of the gastrointestinal tract are most vulnerable to bowel injury, and which types of laparoscopic instruments are most likely to induce bowel injuries. Knowledge about the type of instruments that cause most frequently bowel injuries is important because it may help engineers to develop better instruments [10]. Another important issue is to obtain knowledge about which patients are at risk, for example the presence of adhesions or previous laparotomy. Finally, attention should be given to the treatment and mortality of bowel injury.

Therefore the aim of this study is to review the literature on bowel perforation as a complication of laparoscopy. The aspects that are enlightened are incidence, location, time of diagnosis, the causing instruments, presence of adhesions, management and mortality.

2.2 Methods

The database Pubmed was used to collect studies on bowel injury induced by laparoscopic surgery. Within Pubmed, the MeSH Browser was used by entering the key words 'laparoscopy/adverse effects' and 'bowel perforation' and 'intestinal perforation'. The abstracts of the studies found in the Pubmed search were analyzed to judge the relevance of the study, and subsequent selection. Case reports and studies that did not state the numbers needed for this review were removed. Analyzing the references of these papers, a number of articles referred to studies that were not found in the Pubmed search, and those studies were added to the review as well. Papers reporting the same data in different articles were selected and the report with the most detailed information was included.

Many studies used only the term 'bowel injury,' no distinction was made between a full perforation and partial lesion. The definition of bowel injury used in the present study therefore also includes serosal burning lesions caused by coagulator and other non-transmural damages. These burning spots might be of great importance because they can lead to bowel perforation in due time.

The gastrointestinal tract will be divided into three parts, namely, stomach, small intestine (including duodenum) and large intestine. Where possible, this three-part division will be used to establish the location of the intestinal injury. In order to be able to make a distinction between early and late bowel injury, a division was made as follows. A 'late perforation' was defined as symptoms that developed 48 or more hours after surgery, because early traumatic perforation symptoms usually occur within 48 hours [5].

Overall, 28 studies mentioning the number of laparoscopy-induced bowel injuries as well as the number of laparoscopies performed were included. Three studies evaluated the number of bowel injuries, but did not state the total number of laparoscopies. These studies were still included in the review as well, except for the calculations of incidence rate.

2.3 Results

The incidence of bowel injury and bowel perforation found in the 28 independent studies is presented in Table 2.1. A total of 329924 laparoscopic procedures were evaluated in these studies. Bowel injury was reported in 430 procedures as a complication, leading to an overall incidence rate of 0.13% (0 - 9.62%). In only 17 of the 28 studies the nature of bowel injury was specified. Unfortunately, especially a number of large studies failed to indicate what type of bowel injury occurred. Therefore, the calculation of the incidence of bowel perforation could only be analyzed on a considerably smaller number of operations (n=29521). The incidence rate of bowel perforation was 0.22%.

A more specific procedure related incidence can be found when the data included in Table 2.1 are split up according to the type of operation, which was possible for a subset of studies (Table 2.2). Gynecologic laparoscopies, including sterilizations, had an average incidence rate of bowel injury of 0.10%. Cholecystectomy had a slightly higher rate (0.16%). The lowest rate was found for diagnostic laparoscopy (0.07%). Interestingly, the latter incidence rate was higher when the diagnostic laparoscopy was executed for surgical or gastro-enterologic reasons, namely 0.75% (8/1061) [22,27,30], whereas for diagnostic laparoscopy performed for gynecologic reasons (so-called pelvisscopy) the incidence rate was 0.06% (26/45829) [10,14,17,19,22].

Table 2.1 Incidence of laparoscopy-induced bowel injury and bowel perforation

Reference*	Laparoscopies (n)	Bowel injuries (n)	Incidence of bowel injury (%)	Bowel perforations (n)	Incidence of bowel perforation (%)
1	52	5	9.62	4	7.69
12	23540	40	0.17		
13	14243	10	0.07		
14	32205	24	0.07		
15	2100	4	0.19	4	0.19
16	915	8	0.87	2	0.22
17	29966	44	0.15		
4	90	1	1.11	1	1.11
18	13833	15	0.11		
10	25764	29	0.11		
19	70607	44	0.06		
20	9054	29	0.32	12	0.13
21	2324	8	0.34	6	0.26
22	4672	10	0.21	9	0.19
2	104	4	3.85	3	2.88
23	506	2	0.40	2	0.40
24	758	6	0.79	6	0.79
9	170	1	0.59	1	0.59
6	527	2	0.38	2	0.38
25	77604	109	0.14		
26	283	0	0.0		
8	1518	4	0.26		
7	10840	6	0.06		
27	603	4	0.66	4	0.66
28	2757	2	0.07	2	0.07
29	1000	7	0.70	1	0.10
30	300	1	0.33	1	0.33
31	3600	11	0.31	6	0.17
Total	**329924**	**430**	**0.13**		
	29521**			**66**	**0.22**

* In order of date of publication

** Total number of operations investigated on bowel perforation

A small number of laparoscopic bowel resections was evaluated in two studies. This procedure had the highest complication rate for bowel injury: 6.52% (6/52) [1,22].

The incidence rate for urologic laparoscopy was 0.87% (98/915) [16], but only one study was included. Laparoscopic treatment for gastro-reflux disease had an incidence rate of 0.79% (6/758) [24].

Table 2.2 Incidence of laparoscopy-induced bowel injury per type of procedure

Type of procedure	Laparoscopies (n)	Bowel injuries (n)	Incidence (%)	References
Gynecologic laparoscopy	132599	135	0.10	2,4,7,10,14,17,19, 22,28,31
Cholecystectomy	107285	169	0.16	6,8,9,15,20,22,23, 25,26
Diagnostic laparoscopy*	46890	34	0.07	10,14,17,19,22,27, 30

* Includes surgical and gynecologic diagnostic laparoscopies

Location

The location of the injuries was analyzed for 407 cases of bowel injury; only in 7 of these 407 cases it was impossible to establish the exact location of injury (Table 2.3). The small intestine was most frequently affected (n=227, 55.8%). Of these 227 small intestine injuries, at least 38 involved the duodenum. All duodenum injuries were complications due to laparoscopic cholecystectomy. The large intestine was damaged in 157 cases (38.6%). For 40 of these large bowel injuries the exact location was mentioned: one involved the ascending colon, one the hepatic flexure, 13 the transverse/descending colon, and 25 the rectosigmoid. Stomach injury was a rare complication that was found in only 16 cases (3.9%). Five of these stomach injuries occurred during laparoscopic treatment of gastro-esophageal reflux disease [24]. Of the remaining 11 stomach injuries, 5 were inflicted by insertion of the Veress needle, 1 by insertion of a trocar and in 5 cases the cause was not mentioned.

Table 2.3 Location of laparoscopy-induced bowel injuries

Total*	Location of injury			
	Stomach	Small intestine	Large intestine	Unknown
407	16 (3.9 %)	227 (55.8 %)	157 (38.6 %)	7 (1.7 %)

* References 2,4,6,8,9,12,13,14,15,16,17,18,19,20,21,22,23,24,25,27,28,30,31,32,33,34

Time of diagnosis

The time of diagnosis was reported for 250 cases of bowel injury (Table 2.4). In 66.8% (n=167) of these cases the lesions were discovered early. Of these 167 early diagnosed bowel injuries, 154 were recognized during surgery, whereas 13 were recognized within 48 hours after laparoscopy. For 57 cases diagnosed postoperatively, the number of hours elapsed since surgery was not reported. Of the 26 (10.4%) late-diagnosed bowel injuries, at least 8 were discovered on the third postoperative day, whereas the remaining cases were recognized later. The latter group included 3 patients in which the diagnosis was made during autopsy (1 of these patients died on the fourth and 2 on the seventh day after surgery).

Table 2.4 Time of diagnosis of laparoscopy-induced bowel injuries

Total*	Time of diagnosis		
	Early	Late**	Miscellaneous***
250	167 (66.8 %)	26 (10.4 %)	57 (22.8 %)

* References 1,2,4,6,7,9,12,13,14,15,16,17,18,20,21,22,23,29,31,32

** 3 patients died before diagnosis was made

*** bowel injuries were postoperatively recognized, but the time elapsed since surgery was not stated

Instruments involved

The laparoscopic instruments that caused bowel injury are summarized in Table 2.5. Bowel injuries occurred most frequently (41.8%) during the access phase of laparoscopy, inflicted by the insertion of the Veress needle or a trocar. During surgery thermal injuries occurred most frequently; only in a few instances bowel injury resulted from the use of grasping forceps or a scissors. In 60 cases of the rest group (n=84) the causing instrument was not mentioned; at least 35 of these 60 cases were not access-related and in 25 cases the injury occurred during blunt or sharp dissection. In 13 cases included in the rest group the instrument involved was either a scissors or a grasping forceps but it was unclear which of the two instruments was responsible for the injury inflicted. In one case a clip damaged the bowel during sterilization and in one case there was a closure perforation. Of the remaining 9 bowel injuries in the rest group the cause of injury remained unclear.

Table 2.5 Instruments causing bowel injury during laparoscopy

Bowel injury*	Trocar/ Veress needle	Coagulator/ Laser	Grasping forceps	Scissors	Rest
273	114 (41.8%)	70 (25.6%)	3 (1.1%)	2 (0.7%)	84 (30.8%)

* References 6,8,10,12,14,16,17,19,20,22,28,29,31,32

Adhesions

For 151 bowel injuries the studies indicated whether or not there were adhesions present and/or whether the patient experienced previous laparotomy (Table 2.6). In almost 69% of the cases (n=104) in which bowel injury occurred adhesions were present. The adhesions varied from extended adhesions caused by generalized peritonitis to adhesions of the gallbladder after cholecystitis.

Table 2.6 Presence of adhesions or previous laparotomy

Bowel injury	Adhesions or previous laparotomy	References
151	104 (68.9%)	2,4,6,9,12,15,21,22,23,24, 27,32,35

Management

The management of laparoscopy-induced bowel injuries has been split up into laparoscopic, laparotomy and conservative treatment (Table 2.7). Laparotomy includes conversion of the initial laparoscopy to open surgery. Deziel et al. [25] only stated that 85 of the 109 bowel injuries were treated with a laparotomy and in the remaining 24 patients treatment was unspecified. As a result, 24 non-laparotomy treatments are missing in Table 2.7.

A laparotomy was most frequently performed to manage the laparoscopy-induced bowel injury (78.6%). Conservative (7.6%) and laparoscopic (7.5%) treatment were applied considerably less frequently. Conservative management comprised percutaneous drainage of abcesses, antibiotics or expectantly treatment. In two cases a relaparoscopy was performed before repair of the bowel injury by laparotomy was done; these are both included in the laparotomy in Table 2.7. In 97 of the 282 laparotomies a more detailed description was available. Suturing was the management most often performed at laparotomy 62.9% (n=61), followed by bowel resection with reanastomoses 25.8%

(n=25). A diverting stoma was required in 11.3% (n=11) of the laparotomies. A suture to oversewn a lesion was mainly performed on serosal damages or burning spots and on immediately discovered perforations.

Table 2.7 Management of laparoscopy-induced bowel injury

Bowel injury*	Laparoscopy	Laparotomy**	Conservative	Other
359	27 (7.5%)	282 (78.6%)	25 (7.6 %)	1*** (0.3 %)

* References 1,2,4,6,9,10,12,14,15,16,19,20,21,22,24,25,28,30,31,32,36
** 28 treatments were assumed to be laparotomy, but it was not clearly stated [20].
*** serosal patch

Mortality
Of the 450 patients whose laparoscopy was complicated by a bowel injury 16 died. The overall mortality rate of this complication was therefore 3.6% [1,2,4,6-10,12-22,24-33].

2.4 Discussion

The incidence found for bowel injury as a complication of laparoscopy was 0.13%, whereas the rate for bowel perforation was 0.22%. Curiously, the incidence rate for perforation was larger than that for bowel injury. One would expect the opposite because, by definition, bowel perforations are a subset of bowel injury. Most studies that mentioned bowel perforations provided a more detailed report of bowel injury and thus employed a more accurate method of documentation. Therefore, it seems reasonable to assume that the incidence of bowel injuries has been underestimated. One possible reason for underestimation is that most of the studies were retrospective, a type of study that is likely to underestimate complication rates [10,27]. Especially complications that can also occur after leaving the hospital are easily overlooked in a retrospective study [12]. A second reason for underestimation is that intra-operative complications that did not have clinical consequences for the patients, might be neglected in some studies, like a serosal damage that had immediately been repaired [12,18]. Although the rate of laparoscopy-induced bowel injury could be underestimated, it should give a good estimation of the actual incidence because it was based on large numbers of laparoscopies.

It should be noted that the incidence of laparoscopy-induced bowel injury seems to be related to the degree of difficulty of the operation performed [10,12,14,19,21]. According to the present study, laparoscopic cholecystectomy was two times more likely to be complicated by a bowel injury compared with diagnostic or gynecologic laparoscopies. However, it would be incorrect to conclude that gynecologic and diagnostic laparoscopies are hardly at risk bowel injury. Especially in gynecologic laparoscopic surgery there is a great variety in the type of procedures and associated difficulty, as it varies from sterilization to highly advanced operative procedures like hysterectomy. The latter procedures are far more likely to lead to complications [10,14].

Two studies deserve special attention since they reported extremely high incidence rates in comparison with the other studies [1,2]. In both studies patients were at higher risk for bowel injury, because in one study they suffered from gynecologic cancer and underwent previous laparotomy, whereas in the other study the majority of patients had inflammatory bowel disease with a high dose of steroids. Above that the latter patients underwent an advanced and challenging procedure, namely laparoscopic total colectomy and proctocolectomy. This type of surgery was relatively new and could be characterized by a steep learning curve [37,38].

The small bowel was most frequently affected (55.8%). Small bowel injuries mainly occurred on the antimesenteric border of the intestine [29,31,39]. Its vulnerability could partly be due to adhesions to the anterior peritoneum. Moreover, small bowel movements can hide an injury and thus be overlooked during the operation. Therefore, the small bowel is predisposed for late perforation [13]. It has also been reported that the terminal ileum is particularly susceptible to electrical damages by the coagulator during sterilization [29,31,40].

Recognition of laparoscopic-induced bowel injury occurred in the majority of the patients during surgery and thus could be immediately repaired. About 10% of the bowel injuries were diagnosed after 48 hours. This percentage might be slightly higher, because there was a high number of cases diagnosed postoperatively (22.8%) for which the time elapsed since surgery was not stated. All patients with delayed diagnosed bowel injuries suffered from bowel perforations, as might be expected because that will lead to clinical symptoms. Those late perforations were generally due to thermal damages of the bowel [5,15,16,19,29,32,39,40-42]. In the course of time necrosis of the bowel wall and subsequent full thickness perforation can occur. The diagnosis of thermal injury is generally delayed between 48 hours till 2 weeks [13,15,16,19,29,32,39-43]. The delay of diagnosis was longer for large bowel injury than small bowel laesions [16,19].

Except for the access related injuries, the instruments that caused bowel injury during laparoscopic surgery were poorly reported. Around 40% of injuries were caused by insertion of a trocar or Veress needle. This percentage is probably quite accurate, because penetration of the bowel by a trocar or Veress needle is seldom missed during surgery. However, Veress needle injuries are sometimes self-limiting [5,44]. It was more difficult to identify the instruments that cause bowel injuries intra-operatively, because this damage frequently occurred outside the surgeon's view [15,31,36,42]. Careful and precise information about potentially harmful instruments may enable engineers to improve these instruments. When a bowel resection is performed as a treatment of bowel perforation histological examination should be done, since Levy et al. [44] have noted that it is possible to differentiate between different types of bowel injury through histological examination. About 26% of the bowel injuries were thermal injuries. The coagulator is a well-known cause of injuries. However, the use of bipolar instead of monopolar coagulators may decrease the occurrence of thermal lesions [44]. To prevent bowel injuries equipment should be checked on a regular basis. Movements of the coagulator and sharp instruments should be well followed by the camera to avoid damage occurring out of view of the camera [7,16,36]. There are three ways to create a pneumoperitoneum: (a) Veress needle insufflation; (b) direct trocar insertion; and (c) Hasson's open procedure. It has been suggested that the open procedure might be slightly safer, however this difference has never been confirmed [7,45].

Adhesions were found in 104 of 151 cases of bowel injury (58.9%). There are in general two mechanisms that lead to an injury; either insertion of a trocar or Veress needle into a bowel loop adherent to the anterior abdominal wall or dissection of adhesions [4,7,9]. It has been suggested to perform mechanical bowel preparation in patients who are suspected to have adhesions [2,12], but there is no supporting evidence.

Most bowel injuries (80%) were treated with either a conversion or a laparotomy. Laparoscopic suturing is more and more frequently applied, and will become increasingly the treatment of choice in the future, because laparoscopic repair offers the same advantages as regular use of laparoscopy [3,5]. However, bowel perforations that are delayed diagnosed are still mostly treated with a laparotomy in order to evaluate the entire abdomen [3,16]. It has been suggested that burning spots and other serosal damages should be treated immediately to avoid serious morbidity as leakage and subsequent peritonitis and sepsis or even death [16,32,40].

The mortality rate found for laparoscopy-induced bowel injury was still 3.6%. Only a full thickness perforation will lead to sepsis and multi-organ failure and eventually to death. Therefore the real mortality rate of bowel perforation might be higher. Together with vascular injury, bowel injury is the most lethal complication of laparoscopic cholecystectomy [25] and therefore prevention is of major importance.

2.5 References

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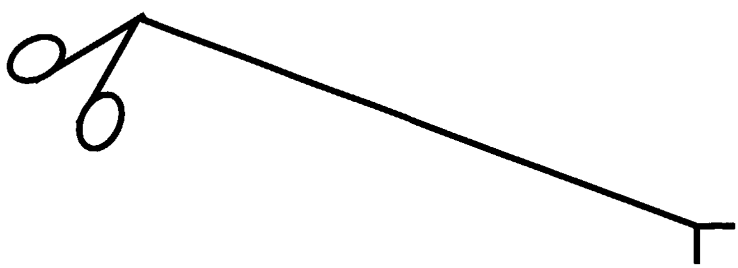
Chapter 3

Effectiveness of grasping and duration of clamping using laparoscopic graspers



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Abstract

Background: Manipulating tissue with laparoscopic forceps is more difficult than using the hands. This study investigates the effectiveness of grasping and the duration of tissue-clamping using laparoscopic forceps.

Methods: Video recordings of 10 laparoscopic colectomies and 15 cholecystectomies were analyzed using time-action analysis.

Results: The results indicated that 62% of the grasping actions were successful: the tissue was clamped sufficiently to perform an action. Of all the clamping actions on the colon, 10% were repeated actions. On the gallbladder 7% were repeated actions. The bowel slipped out of the grasper in 7% of the clamping actions, whereas the gallbladder slipped in 17%. In 89%, the colon was clamped less than 1 min. The maximum clamping time was 7 min for the colon, and 55 min for the gallbladder.

Conclusion: The low percentage of successful grasping actions indicates that the design of laparoscopic graspers is not optimal.

3.1 Introduction

During laparoscopic surgery, long rigid graspers with limited force feedback are used [2]. Therefore, it is difficult to position the jaws on the tissue in the desired way, and the surgeon may apply an inappropriate amount of force on the tissue. Because the tips of laparoscopic graspers are small, high pressures can be generated locally on the tissue [3], resulting in damage or even perforation. Too little force results in the tissue slipping out of the forceps, leading to procedure delay. In a study analyzing surgical errors during laparoscopic cholecystectomy, most of the errors in using graspers involved dropping and tearing the gallbladder [6].

To design new, safer graspers, the problems with currently used graspers should be evaluated in more detail. Evaluation of phenomena such as tissue damage with these new graspers will require insight into the usage of graspers and the duration for which tissue is clamped during laparoscopic procedures.

The purpose of this study was to evaluate the general use of laparoscopic graspers by determining the frequency and duration of clamping and the outcome of grasping actions. Two different procedures, laparoscopic colectomy and cholecystectomy, were analyzed using time-action analysis. Colectomies were chosen because in this type of procedure a large part of the colon needs to be dissected, and therefore, the colon frequently is manipulated. Cholecystectomies were analyzed because with this procedure, the gallbladder is held aside for a long time and is often perforated [6,7].

3.2 Materials and methods

To evaluate the use of grasping forceps, video recordings of laparoscopic procedures in 25 surgeries were analyzed. Recordings were made of 10 colectomies and 10 cholecystectomies performed by experienced surgeons in various hospitals. In addition, we recorded five cholecystectomies performed by residents with less than 1 year of experience.

The procedures were recorded with two small CCD cameras, giving an overview image of the operation theater and a close-up of the surgeon's hands, as previously described [4]. With a mixing device, the images of the cameras and the laparoscopic image were recorded simultaneously. After the operations, the procedures were analyzed. The duration of clamping, the clamped tissue, the type of grasper, and the outcome of grasping action were analyzed for each clamping action of the laparoscopic graspers. The following definitions for the outcome of grasping actions were used:

- *Successful clamping:* The tissue is clamped and manipulated in such a way that the action the surgeon wants to perform (e.g, dissecting or coagulating) is possible. After the action, the jaws are opened by the surgeon to replace the grasper and to perform the next action.

- *Repeated clamping:* The tissue is clamped for a short time. However, before the tissue is stretched, the grasper is repositioned to make it possible to pull with a higher force or in another direction.
- *Slip:* The tissue slips out of the grasper because too little clamping force is applied in relation to the pulling force.
- *Damage from clamping:* The tissue is damaged by pulling or pinching with too much force.
- *Undefined:* No definition can be given because the tissue is released from the grasper outside the image.

The frequency of the grasping actions was calculated by dividing the total number of grasping actions per procedure by the time between the insertion of the first grasper and the release of the last grasper. Differences between colectomies and cholecystectomies and differences between experienced surgeons and residents were tested for significance using a two-sided Student's t-test ($\alpha = 0.05$).

3.3 Results

The duration of the laparoscopic part of the colectomies varied between 24 and 119 min and the duration of the cholecystectomies varied between 14 and 62 min. The colon was clamped an average of 117 times per procedure, with a mean frequency of 1.9 per minute. The gallbladder was clamped an average of 26 times per procedure, with a mean frequency of 0.9 per minute (Table 3.1).

Table 3.1 The duration of the surgical procedures (mean ± sd) and the number and frequency of clamping.

	colectomies (n = 10)	cholecystectomies experienced (n = 10)	cholecystectomies residents (n = 5)
duration (min)	66 ± 30	30 ± 14 *	51 ± 6 *
number clamping (n)	117 ± 48	26 ± 14	42 ± 16
frequency (n/min)	1.9 ± 0.7	0.9 ± 0.2	0.8 ± 0.3

* significant difference between experienced surgeons and residents ($p < 0.05$)

The outcome of grasping actions for the colectomies and cholecystectomies is presented in Figure 3.1. The percentage of successful grasping was 63% and 61%, respectively. The colon was repeatedly clamped more often (10% vs 7%; $p = 0.03$), and the gallbladder slipped out of the forceps more often (17% vs 7%; $p = 0.008$). Damage occurred in 1% to 3% of all actions (for both procedures on average once per operation), and 12% to 19% of the actions were performed outside the image and therefore undefined. In five procedures, the gallbladder was perforated.

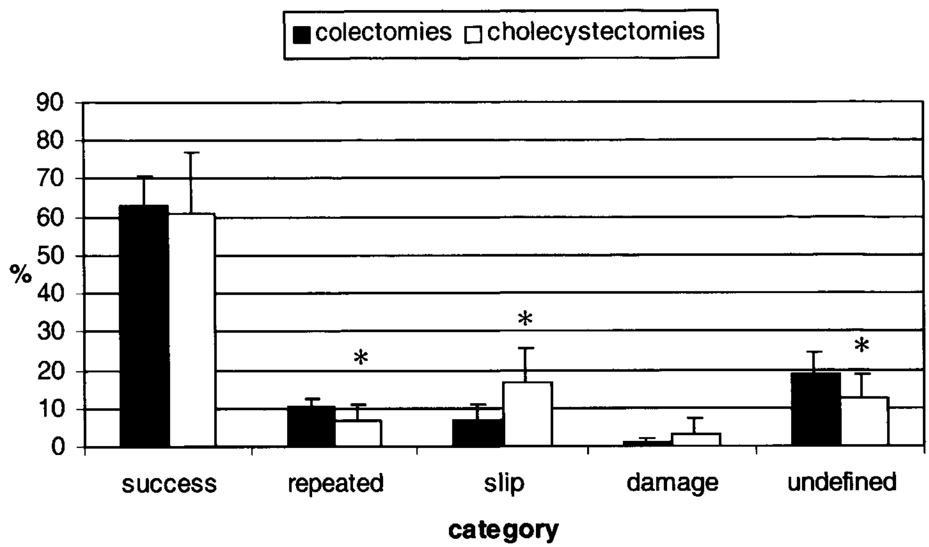

*Figure 3.1 Outcome of grasping actions during colectomies and cholecystectomies. The average percentages and standard deviations are shown. * $p < 0.05$ is significant difference between colectomies and cholecystectomies.*

The duration of clamping is presented in Figure 3.2. During the colectomies, 34 (28%) of the clamping periods were less than 1 s, and 105 (89%) were less than 60 s. An average of three times per operation, the colon was clamped longer than 3 min, upto a maximum of 7 min. Although there were fewer clamping actions on the gallbladder than on the colon, the gallbladder was clamped longer. Of all the clamping actions, 13% were shorter than 1 s, 69% shorter than 60 s, and 12% (an average of three times per operation) longer than 3 min. The maximal clamping time was 55 min.

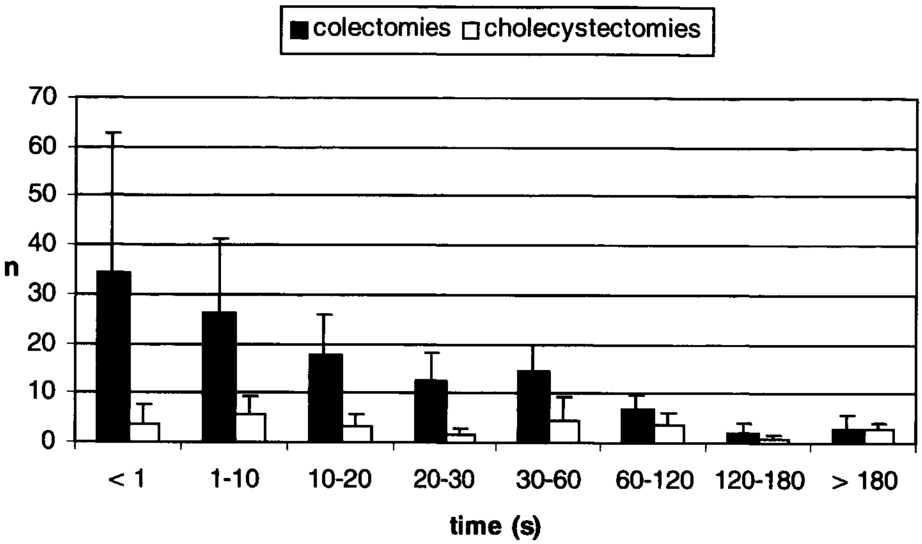

Figure 3.2 The distribution of time of clamping during colectomies and cholecystectomies. The average values and standard deviations are shown.

The duration of the cholecystectomies performed by the residents was significantly longer than the procedures performed by experienced surgeons (51 vs 30 min; $p = 0.007$). The residents did not use significantly more actions (42 vs 26; $p = 0.065$). However, relatively fewer actions were successful (45% vs 61%; $p = 0.020$). Significantly more actions with clamping times of more than 3 min were used (2.7 vs 4.8; $p = 0.010$).

3.4 Discussion

Surgical performance generally is evaluated by studying subsequent complications of the procedure and mortality. Such evaluation does not tell how well instruments have functioned. In the current study, analysis of grasper use during laparoscopic surgery has shown that, in total, 62% of the grasping actions could be defined as successful. However, actions inside the image were sometimes difficult to interpret because the intention of the surgeon was not always known.

Forceps limitations can be found by analyzing the less successful actions. Repeated clamping indicates the difficulties with positioning the long, stiff forceps on the desired location, and in the desired direction. Visible tissue damage indicates that inappropriate forces have been used, possibly caused by the forceps limited force feedback. Slip indicates too little applied force or a low friction between forceps and tissue. Because forceps were used to pull tissue out of the camera image, 17% of all grasping actions could not be defined. However, it can be expected that it is difficult to apply the appropriate force when visual feedback is not provided because the force feedback of the forceps is low.

We found differences between the grasping actions during colectomies and those during cholecystectomies. During the colectomies, the colon was frequently repeatedly clamped for short periods of time using atraumatic babcocks because the surgeon wanted to grasp the colon very carefully to prevent perforation. Damage leading to a delayed perforation after 5 to 7 days must be prevented also, because it leads to high morbidity and mortality rates [10]. Even perforation of a colon segment that will be removed may lead to contamination of the abdomen.

During the cholecystectomies, the gallbladder often slipped out of the grasper. This occurred even though the gallbladder generally was grasped with a sharp profile grasper or one that even had teeth. Possibly, the small opening of the grasper's short jaws makes it difficult successfully to grasp the large volume of the distended gallbladder. In addition, greater force is necessary to pull the gallbladder. An adequate forceps for grasping the gallbladder has yet to be designed [9]. The gallbladder was clamped for longer periods than the colon. More traumatic forceps were used on the gallbladder. Surgeons are less concerned with injuring the gallbladder because it will be removed and because perforation of the gallbladder generally does not increase postoperative complications [7].

Because experienced surgeons have adapted to the limitations of forceps, the consequences of the limitations are more obvious when residents perform the actions. Residents performed fewer successful actions and used longer clamping times. The results indicate that residents have more difficulty applying the appropriate amount of force, resulting in less successful actions. After training, their use of graspers will become more effective.

This study was performed to get insight in the use and limitations of graspers. Therefore, the outcome of grasping actions and the duration of tissue clamping were determined. An ideal forceps provides enough grip on the tissue and yet prevents damage. To determine the optimal design of forceps' jaws, both the manipulation forces surgeons use and the maximum forces allowable should be obtained in an experimental setting. In addition, experiments should be performed to determine the histologic damage after clamping. Although visible damage hardly occurred, it can be expected that tissue is microscopically damaged after clamping. Histologic damage was found after clamping of the gallbladder [8] and bowel [1,5]. However, in the studies concerning bowel graspers, clamping periods of 20 min to 1 h were used, whereas the duration of clamping during the colectomies exceeded 3 min in only 2.7% of all actions. Hence, studies into histologic damage caused by laparoscopic bowel graspers must concentrate on short clamping periods.

In conclusion, to improve laparoscopic forceps, the design of the jaws should be improved to achieve more grip and less damage to the tissue. Furthermore, force feedback should be provided to achieve less slipping and tearing of tissue. The results of this study will be used in experimental settings to obtain design criteria for laparoscopic graspers.

Acknowledgements
The authors thank the surgeons who performed the analyzed procedures at the Academic Medical Center Amsterdam, Catharina Hospital and Diaconessenhuis Eindhoven, Kennemer Hospital Haarlem, Reinier de Graaf Hospital Delft and St Antonius Hospital Nieuwegein.

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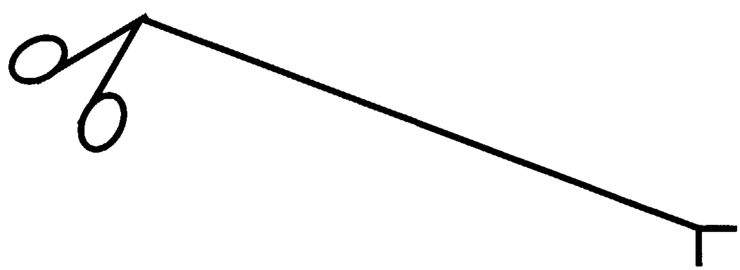
Chapter 4

The influence of pinch and pull forces on colon damage during laparoscopy



E.A.M. Heijnsdijk, H. de Visser, J. Dankelman, D.J. Gouma
Submitted.

Abstract

Background: During laparoscopic procedures, the bowel is frequently manipulated using instruments with small jaws. These small jaws can generate high pressures on the tissue, which can cause local damage or a bowel perforation. To design safer laparoscopic graspers, the influence of pinch and pull forces on bowel damage should be determined.

Methods: Pig colon (n=7) was pinched with forces of 7-16 N between two hemispheres with a diameter of 2 mm. In addition to the pinch forces, pull forces in the range 0-5 N were applied. After one minute of clamping, damage was classified as no damage, imprint or perforation of tissue.

Results: The number of imprints and the number of perforations increased significantly by increasing pinch force as well as increasing pull force. At the lowest combination of forces no perforations or imprints were found. The highest forces resulted in an imprint or perforation for all samples.

Conclusion: High peak pressures in particular in combination with large pull forces should be avoided to manipulate the bowel safely.

4.1 Introduction

Although laparoscopic surgery causes less damage to healthy tissue than open surgery, the graspers used to manipulate tissue can injure the tissue at the clamping site. Injury to bowel tissue caused by laparoscopic instruments has been reported in 0.07 to 0.7% of the bowel operations [1,12] and perforation of the gallbladder in 40 to 75% during cholecystectomy [7,8,14]. Due to limited force feedback, surgeons often apply an inadequate level of force to the tissue. Furthermore, when tissue is pulled out of the laparoscopic view, the surgeon may not notice if sharp tips and ridges perforate the tissue. It has been demonstrated by Carter et al. that with the sharp tip of a scalpel, pinch forces as small as 0.29 to 0.53 N are large enough to puncture the liver and spleen of sheep and pigs [2].

With currently used graspers high peak pressures are generated at the tip of the instruments as shown by Cartmill et al. [3]. The same research group also showed that by rounding the edges of a jaw, a reduction of 40% in peak pressure could be reached [13]. Marucci et al. [10] studied the effect of seven different jaw designs on grip and trauma properties. Jaws with small triangular teeth showed a larger grip security, but also increased tissue trauma compared to wave pattern teeth. Besides improving the jaw design, another possibility to improve the safety of the forceps would be to equip the forceps with a device that limits the forces that can be exerted without causing damage on the tissue. For the design of a new jaw and a force-limiting device, the maximal force that can be exerted on the tissue has to be known.

To determine the influence of pinch and pull forces on tissue damage, the combinations of pinch and pull forces on bowel tissue leading to imprints or perforations are measured in this study.

4.2 Methods

The experiment was performed on the cecum of seven healthy pigs (weighing 20-25 kg). The pigs were used for experimental heart surgery (approved for by the Animal Research Committee) and just after death the abdominal cavity was opened to expose the colon. The cecum was clamped between two hemispheres with a diameter of 2 mm (Fig. 4.1), placed at the ends of a lever. On top of the lever a load was placed to exert a pinch force on the tissue. At the back of the lever a pull force was applied using a spring balance (Fig. 4.2).

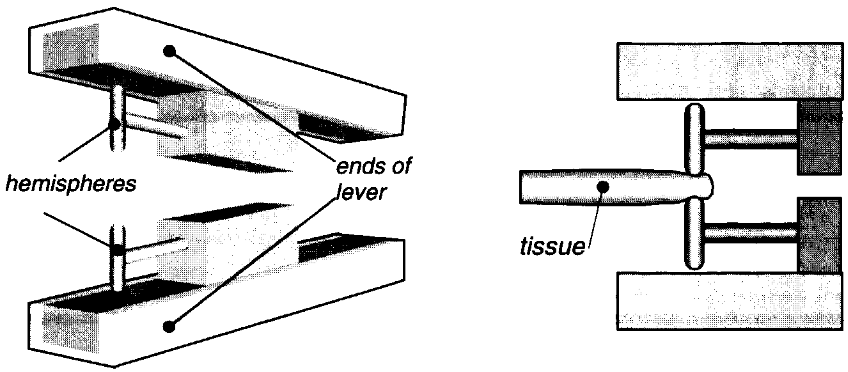


Figure 4.1 Left: The hemispheres with a diameter of 2 mm at the ends of the lever. Right: A side view of the ends of the lever, with the tissue clamped between the hemispheres.

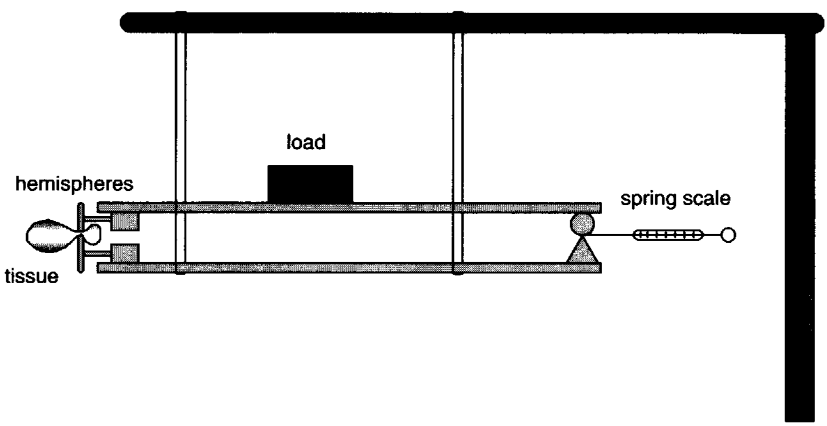


Figure 4.2 The set-up of the experiment. Tissue was clamped between the hemispheres at the end of a lever. The pinch force was applied by a load. The distance between load and tissue determined the pinch force. The pull force was applied using a spring scale. The lever was hanging from cords to apply the pull force without friction. Constant pinch and pull forces were applied for one minute.

Various combinations of pinch and pull forces were applied in a random order. The pinch force was varied between 7, 10, 13 and 16 N, whereas for the pull force values of 0, 2.5 and 5 N were chosen, representing no pull force, average pull force and maximal pull force surgeons use to manipulate tissue as shown previously [16]. The applied forces were held constant for one minute. Then, the hemispheres were removed and the damage at the clamping site of the cecum was classified by two observers, and scored for no imprint, light imprint (disappearing within a few seconds), imprint (remaining imprint) and one-sided or two-sided perforation. On every pig the effect of each of the 12 combinations of forces was measured twice. For each measurement a new location of the cecum was used.

The effect of pinch and pull force on the percentages of perforations and imprints was tested with analysis of variance (ANOVA), repeated measures [15]. A p-value less than 0.05 was considered significant.

4.3 Results

The total number of perforations of the cecum of the pigs is shown in Table 4.1. The number of perforations increased significantly with increasing pinch force ($p = 0.035$) as well as increasing pull force ($p = 0.002$). The number of perforations of the 14 measurements increased from zero at the lowest forces to 6 (43%) at the highest forces.

Table 4.1 Total number of perforations of pig cecum, n=14 (=max).

	pinch force			
	7 N	10 N	13 N	16 N
pull force				
0 N	0	0	0	2
2.5 N	0	0	1	3
5 N	3	2	2	6

Table 4.2 presents the visible damage (in terms of imprints and perforation). Visible damage increased significantly with increasing pinch forces ($p = 0.002$) as well as increasing pull forces ($p < 0.001$). The damage increased from zero at the lowest forces to the maximum of 14 (100%) at the highest forces.

Table 4.2 Total number of imprints and perforations of pig cecum, n=14 (=max).

	pinch force			
	7 N	10 N	13 N	16 N
pull force				
0 N	0	3	5	6
2.5 N	6	9	9	11
5 N	9	13	14	14

The differences between the pigs were large. In one pig no perforations were observed, whereas in another pig 6 perforations were found. In 50% of all measurements, the second measurement within a pig with a certain combination of forces resulted in the same level of damage as the first measurement with that combination of forces. In 16%, the second measurement resulted in a large difference in damage.

4.4 Discussion

In the present study it was shown that the number of imprints and perforations increased with increasing forces. Therefore, in particular the combination of pinch and pull force causes damage to the tissue. With increasing pinch force the local pressure on the tissue increases, leading to more damage. With increasing pull force the tension in the tissue increases, reducing the allowable peak pressures on the tissue. Therefore, in the design of a new forceps, for instance with a force-limiting device, both the pull force and the pinch force have to be taken into account.

An estimation of the pinch pressure leading to perforation can be made by dividing the measured pinch force by the estimated contact area of hemisphere and tissue. Mathematical approximation shows that the effective contact area of a hemisphere roughly equals 2/3 of the area of a disc with the same diameter as the hemisphere. Then, the calculated perforation pressure (at 7 N pinch force and a contact area of 2.1 mm^2) is in the order of 3000 kPa. Cartmill et al. demonstrated that laparoscopic graspers generated peak pressures of 54 to 848 kPa [3]. Despite this large difference, it cannot be concluded that laparoscopic graspers can be used safely. In general practice, the pressure peaks can be larger, because the height of the pressure peaks depends on the distribution of the pinch force, which in turn depends on the material that is being pinched and the amount and direction of the forces used. In the study of Cartmill et al., the minimal pinch force required to hold a leather strap in a uniplanar orientation with a pull force of 2.5 N was used [3]. However, in general practice the peak pressures are expected to be higher, because well-lubricated tissue offers less friction between tissue and instrument and consequently the pinch force has to be higher. In addition, surgeons will often apply a higher pinch force than the minimally required force and also a higher pull force than 2.5 N. In a previous study it was measured that surgeons used average pull forces of 2.4 N to manipulate the cecum [16], with a maximum of 4.7 N. Finally, Cartmill et al. [3] showed that an angle between tissue and instrument increased the peak pressures significantly. The same effect can be expected from a rotation around the longitudinal axis of the instrument. Therefore, the exerted pinch and pull force and direction of the force can lead to higher local pressure peaks on the tissue than provided by Cartmill [3].

The level of acceptable damage after tissue manipulation using graspers is difficult to indicate. Tissue damage is generally measured by using histology preparation of the bowel. Histological damage after clamping with laparoscopic forceps has been reported for bowel [5] and gallbladder [11]. It was shown that after clamping shearing, loss of mucosa and submucosa, muscle compression, focal thinning of gallbladder wall, epithelial loss and bleedings could be found. However, since the preparation of tissue for observation under light microscope can also cause damage to the tissue [9] and since histological damage is difficult to quantify and interpret, we chose to qualify damage in terms of perforation of tissue. Furthermore, perforation can be interpreted as the most serious tissue damage, since perforation of the bowel often causes peritonitis, which leads to high mortality and morbidity rates [1,12]. Contrary, tissue can already be damaged with pressures lower than the perforation pressure, leading to local necrosis and subsequently a delayed perforation after a few days. In a study conducted on pigs, it was shown that the risk of delayed perforation was 16% when the size of the lesion was more than 10 mm in combination with the presence of visible serosal damage and palpable mural defect [6]. In the present study the size of the lesions was less than 10 mm and instead of serosa, often more inner layers were injured. Therefore, it is expected that only a small percentage of the lesions classified as imprints would eventually have led to a perforation.

It is known that the mechanical properties of tissue change after termination, when the blood circulation stops and the tissue dehydrates [17,18]. All measurements were performed within one hour after death and the tissue was maintained wet, therefore it is not likely that the tissue properties changed significantly due to dehydration but it cannot be fully excluded. Moreover, no systematic difference was found between the repeated measurements at each combination of forces in terms of increased damage after longer interval between termination and test. A clamping duration of one minute was chosen, because from an analysis of laparoscopic colectomies we found that approximately 90% of all clamping actions during laparoscopic colectomy is less than one minute [4]. In addition, a perforation was nearly always found in the first seconds of the measurement. In pilot experiments, comparable results were found with clamping times of three minutes (unpublished data).

In conclusion, high pinch peak pressures in particular in combination with the unavoidable large pull forces should be prevented to manipulate the bowel safely. This can be achieved by changing the jaw design or by applying a device on the forceps that limits the pinch force that can be applied.

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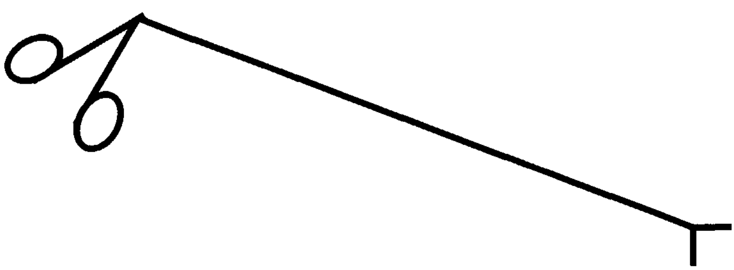
Chapter 5

Inter- and intra-individual variabilities of perforation forces of human and pig bowel tissue



E.A.M. Heijnsdijk, M. van der Voort, H. de Visser,
J. Dankelman, D.J. Gouma
Surgical Endoscopy, in press.

Abstract

Background: A laparoscopic bowel grasper should be suitable for safely grasping the bowel in a wide variety of patients. Therefore, the inter- and intraindividual variabilities in the strength of bowel tissue to resist perforation force should be analyzed.

Methods: The large and small bowels of pigs (n = 14) and the human small bowel (n = 7) were clamped between two hemispheres 1.5 mm in diameter. The pinch force was increased until the tissue was perforated.

Results: The perforation force for the pig large bowel was higher than for the small bowel (13.5 ± 3.7 vs 11.0 ± 2.5 N; $p = 0.014$). No difference was found between the human and pig small bowel (10.3 ± 2.9 vs 11.0 ± 2.5 N). The intercoefficient of variation varied between 22% and 28%, and the intracoefficient of variation varied between 14% and 18%.

Conclusions: The strength of the pig bowel is approximately comparable to the strength of the human bowel, and, therefore, testing of graspers on pig bowel is justified. However, due to the large interindividual variation, large safety margins should be taken into account.

5.1 Introduction

One of the most severe complications of laparoscopic surgery is the occurrence of a bowel perforation caused by the laparoscopic instruments. Although the incidence is relatively low (0.07-0.7%), morbidity and mortality rates of this complication are high, having been reported up to 20% [1,8]. A perforation can be caused by a trocar, a Veress needle, a coagulation hook, a grasping forceps or scissors. Grasping forceps are considered especially to be dangerous due to the lack of force feedback and the small size and sharp edges of the jaws [2]. It was found that forceps with sharp edges generate high local pressures on the tissue [4].

A safe grasper avoids damage, in particular, a perforation of bowel tissue. Because the safety of a bowel grasper is determined by the "weakest bowel", the variability in bowel strength should be carefully examined. In the literature, only studies on tensile strength or burst strength of bowel can be found [11,14]. In these studies, the bowel is cut in rings and extended until rupture. Therefore, these results are difficult to compare with local tissue strength to withstand pinching using a grasper.

Human tissue is hardly available for experiments. Therefore, most experiments are performed on pig tissue. The bowel of the pig is assumed to have a good resemblance to the human bowel in size and shape. To determine whether the results obtained from experiments on pig tissue can be extrapolated to human tissue, the exact difference in bowel strength should be investigated. Using the data from this investigation safety margins can be predicted to guarantee that a forceps approved for pig bowel can also be safely applied or at least investigated for use on the human bowel. Laparoscopic forceps are used to manipulate both the small and the large bowel. Therefore, the tests should be conducted upon both.

The purpose of this study was to determine the inter- and intraindividual variabilities of perforation forces of bowel tissue. In addition, the differences in perforation forces between small and large bowel tissue, and between pig and human tissue, are obtained. With these results, safety margins for the use of laparoscopic forceps can be obtained.

5.2 Materials and methods

The animal experiments were conducted upon the large bowel (cecum) and the small bowel of 14 healthy pigs (weighing 19 to 45 kg), which had just been killed after experimental heart or liver surgery. The bowel was clamped between two metal hemispheres with a diameter of 1.5 mm. Between the hemispheres, a potential difference of 1.5 V was applied and the electrical resistance was measured. The hemispheres were placed at the ends of a lever (Fig. 5.1).

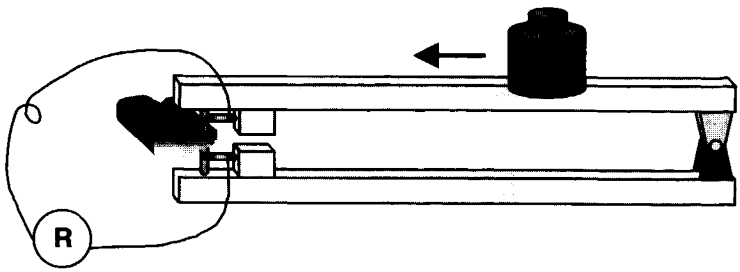


Figure 5.1 The experimental setup. Bowel tissue was pinched between the hemispheres at the ends of a lever. Between the hemipsheres, the electrical resistance (R) was measured. On top of the lever, the pinch force was applied using a load. By moving the load toward the tissue, the pinch force was increased until the resistance declined to zero, and therefore a perforation was reached.

On top of the lever a load was applied to exert a pinch force. By shifting the load manually toward the hemispheres, the pinch force could be increased. The pinch force was first set on 5.7 N, then increased by 0.8 N/s until a perforation occurred, as measured by the decline of the electrical resistance to zero. The measurements were repeated seven times on both the small and the large bowel tissues. When the highest applied perforation force (24.5 N) did not cause a perforation, the measurement was discarded, and an extra measurement was conducted to complete seven perforation forces per condition. The whole experiment was performed within 1 h after a pig was killed.

In addition, to compare the bowels of pigs and humans, the same experiment was also performed on surgically removed human tissue. Seven segments of duodenum/first part of the jejunum were used. The segments had been removed during a pancreatico-duodenectomy procedure. The patients had a mean age of 55 years (range 42-67 years) and varying diagnoses. The study protocol was approved by the local ethics committee.

The differences in perforation forces between the pig small and large bowel, and between the pig and human small bowel, were tested using a Student's *t*-test. The difference between individual pig and human tissue was tested using one-way analysis of variance. A p value less than 0.05 was considered to be significant. The inter- and intra-individual variabilities were determined by calculating the coefficient of variation, which equals: $\frac{\text{standard deviation}}{\text{mean}} * 100\%$.

5.3 Results

The mean perforation force for the pig large bowel (13.5 ± 3.7 N) was significantly higher than for the pig small bowel (11.0 ± 2.5 N; p = 0.014, Table 5.1). The mean intra-individual variability was 18% for the large bowel and 14% for the small bowel. The interindividual variability was larger, 27% and 22%, respectively.

Table 5.1 The mean perforation force, standard deviation and inter- and intracoefficients of variation (cv) for pig and human bowel.

Tissue	Perforation force (N) mean ± sd	cv inter (%)	cv intra (%)
Pig, large bowel	13.5 ± 3.7 *	27	18
Pig, small bowel	11.0 ± 2.5 *	22	14
Human, small bowel	10.3 ± 2.9	28	17

* significant difference ($p < 0.05$)

The perforation forces for the pig bowel tissue of all animals are shown in Figure 5.2. A few pigs showed a significantly higher perforation force than the other pigs. For both the large and the small bowel, there was no correlation between the pigs' weight and the perforation force, and no correlation between perforation forces for the large and small bowel.

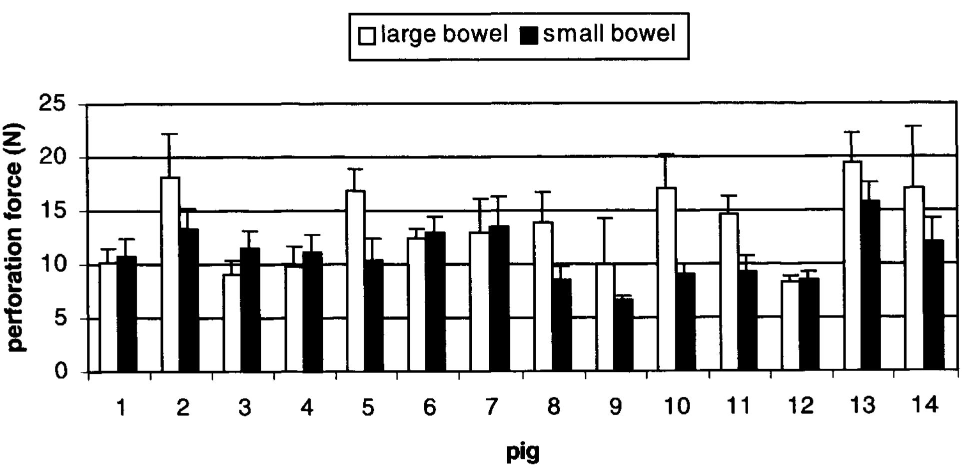


Figure 5.2 Perforation forces of pig large bowel (cecum) and small bowel (mean ± sd).

The perforation forces for the human small bowel are presented in Figure 5.3. The mean perforation force of human small bowel was not significantly different from that of the pig small bowel (10.3 ± 2.9 N vs 11.0 ± 2.5 N; $p = 0.57$). The intra- and interindividual variabilities of the human bowel were comparable with those of the pig bowel (17% and 28%, respectively). No significant correlation could be found between perforation forces and weight, age, or diagnosis.

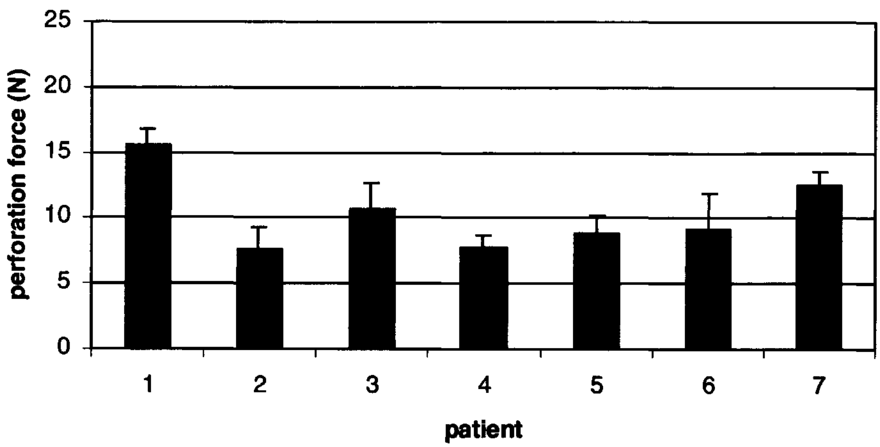


Figure 5.3 Perforation forces of human small bowel (mean ± sd).

5.4 Discussion

The results of the current study show especially that the interindividual variability in perforation forces is large. It was found that bowel strength could differ by a factor of two between the patients. Also, within patients, the highest perforation force usually was twice as large as the lowest perforation force. Because of this large variation in bowel strength, forces that can be safely applied to one patient may cause a perforation in another patient.

Despite the fact that perforation forces and other mechanical properties of soft tissue are important for the design of instruments and surgical simulation models, only a few studies on perforation forces using surgical instruments have been performed. The puncture forces for pig and sheep liver and spleen using a scalpel [3] and the puncture forces for sheep skin and tendon using suture needles [5] have been measured. In both studies, a large intraindividual variability was found, whereas interindividual variability was not measured.

The reliability of the measurement setup was tested on simulation tissue made of silicone 0.4 mm thick. The coefficient of variation was less than 6%, which indicates that the instrument caused low variability and that the measured variation in perforation forces is merely caused by the variation in tissue strength.

Variation in tissue strength can be caused by differences in bowel wall thickness and constitution, and by differences in age, weight, health status, nutrition, and medication. In our study, young healthy pigs of an equal nutritional state were used. No correlation was found between weight and perforation forces in pigs. Therefore, it is likely that the interindividual variability is caused largely by variation in bowel wall thickness and constitution. In contrast, the patients differed in age, weight, diagnosis, and medication. However, the interindividual variation in perforation forces was equal to that of the pig tissue. Also, no correlations were found between age and perforation force, or between weight and perforation force. Therefore, for human bowel, the variation is also likely caused by variation in bowel wall thickness and constitution. Using ultrasound, a large variation in wall thickness was found between healthy subjects [6]. The mean variation in thickness of the colon ascendens is 37% [12]. Health also probably has an influence on the properties of the bowel. The wall thickness is, for example, increased in patients with Crohn's disease [7].

An alternative cause of intravariation could be the presence of post-mortem muscle activity. Because the experiments were performed within 1 h of death, some peristaltic movement was still present. Muscle contraction causes local thickening of the bowel wall, thereby possibly influencing the strength of the tissue.

Although the small and large bowel differ in thickness and constitution, only a small difference in perforation forces was found. It is likely that the strength-determining layer has the same thickness in both the large and the small bowel. In a pilot experiment, the perforation force of intact pig small bowel was 12.0 N. Subsequently, the bowel was stripped, and the perforation forces of the outer layers and inner layers were measured separately. Using histology, the content of the layers was determined. The perforation force for submucosa and mucosa was significantly higher (8.2 ± 1.1 N) than the perforation force for serosa and muscle layers (6.2 ± 1.1 N; $p = 0.004$). Therefore, probably the submucosa has the largest resistance to perforation, because of its large collagen content [9,10,13].

In less than 10% of the measurements, the perforation force was out of the range of the measurement setup (higher than 24.5 N). This may be caused by local thickness of the bowel or, more likely, by an obstacle inside the bowel. Because these measurements were discarded, the perforation force and the variation may be slightly underestimated. However, the relative differences between the large and small bowel tissue and between the pig and human bowel tissue are not affected because these measurements occurred in equal amounts regardless of the origins of the different tissues.

Several additional factors influencing the variation in perforation forces have not been addressed in this study. First, in our study, the human bowels were practically empty, whereas under normal operative conditions, the bowel may be more distended and consequently perforated at lower forces. This variation in bowel contents will increase the variability in perforation forces. Also, in this study, the only force exerted was a pinch force, whereas in operative conditions, the pinch force mostly will be accompanied by a pull force. This combination of forces will decrease the perforation force. However, it is expected that the variation in perforation force will be the same when the same pull force is applied. Because of these simplifications, the absolute value of the perforation force cannot be used to predict the safety of forceps. In contrast, the relative value is a reasonable prediction of the variation in perforation force, although, under operative conditions the perforation forces may vary even more than predicted in this study.

In conclusion, the inter- and intraindividual variabilities in tissue strength are large. Surgeons should take these differences into account when applying forces to the tissue. Large safety margins should be used. Perforation forces for pig and human small bowel tissue were found to be similar. There are no reasons to assume that these results would be different for large bowel tissue. Therefore, it seems justified to perform experiments on the safety of forceps on pig bowel tissue, and to extrapolate the results to human bowel.

Acknowledgements
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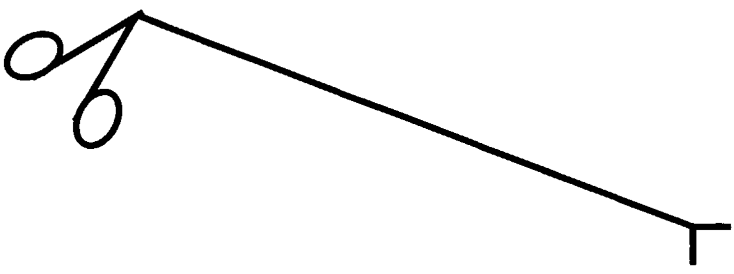
Chapter 6

Slip and damage properties of jaws of laparoscopic graspers



E.A.M. Heijnsdijk, H. de Visser, J. Dankelman, D.J. Gouma
Submitted.

Abstract

Background: The optimal jaws of laparoscopic graspers can be used to manipulate the tissue properly with minimal damage. The criteria jaws should satisfy are investigated.

Methods: The cecum of pigs was clamped between 13 pairs of jaws differing in size and profile. Various pinch and pull forces were applied. At 5 N pull force, the minimally required pinch force to prevent slip (Fslip) and the pinch force that is maximally allowable without causing damage (Fdamage) were obtained. The damage-slip ratio of the jaws was calculated by dividing Fdamage by Fslip.

Results: The slip forces varied between 2.4 and 22.0 N, whereas the tissue was damaged between 8.4 and 37.2 N. A rectangle with a diamond-shaped profile provided a significantly higher damage-slip ratio (9.4±2.3) than a smooth rectangle of the same size (0.9±0.6, $p<0.001$).

Conclusion: An optimal jaw possesses a large contact area to prevent tissue damage and a slight profile to prevent slip.

6.1 Introduction

Jaws of laparoscopic bowel forceps generally have sharp edges and ridges to provide sufficient grip on the tissue. The presence of sharp edges reduces the effective contact area between jaws and tissue. These small contact areas can cause high local pressures [1], potentially leading to tissue damage. For improving grip and preventing damage, the interaction between instrument and tissue should be investigated. Marucci et al. [6] studied the effect of seven different jaw designs on grip and trauma properties. Constant pinch forces were applied and the sheep stomach tissue was pulled until it slipped out of the forceps or tore. Jaws with sharp teeth showed a larger grip security, but also increased tissue trauma compared to wave pattern teeth. In this research high pull forces up to 50 N were applied; however, the forces required during surgery are probably much lower than that. To design optimal jaws, the forces involved in stretching and dissection of tissue during surgical use should be taken into account.

When dissecting tissue, surgeons exert a combination of pinch and pull forces. Dependent on the relative magnitude of exerted forces, the tissue will slip, will be damaged or will be grasped successfully (Fig. 6.1).

Figure 6.1 A theoretical model of the combination of pinch force and pull force leading to slip (grey), damage (black) or safe manipulation (white) of tissue.

When the pull force is high compared to the pinch force, the tissue slips out of the forceps, whereas when both pull and pinch forces are high, the tissue can be damaged. Even a high pinch force without pull force can already cause damage. Consequently, only with a correct combination of exerted forces, the tissue can be grasped successfully. The pull force is independent of the forceps and has been measured in a previous study [8]. The average pull force surgeons used to provide enough tension to the bowel was 2.5 N and the maximal force was just below 5 N. With optimal jaws, the minimal pinch force to prevent slip at a certain pull force is low and the maximal pinch force the surgeon can exert without causing damage is high. Therefore, a logical way to compare jaws is by using the damage-slip ratio, which is defined as the maximally allowable pinch force divided by the minimally required pinch force at 5 N pull force [9]. The higher this damage-slip ratio is, the more suitable the jaws are.

Manufactures offer several solutions to safely manipulate delicate bowel tissue. Various 'atraumatic' forceps are developed, differing in shape, size and profile. However, the effect of shape, size and profile of the jaws on slip and damage of tissue was hardly investigated. The aim of this study is to measure the slip and damage properties of various standardized jaws to determine which jaw has the best damage-slip ratio at 5 N pull force. Especially the influence of the size of the contact area and the height of the profile is studied.

6.2 Methods

Experimental setup

The experiments were conducted on the cecum of 23 just-sacrificed young pigs (weighing 19-58 kg) after liver or heart surgery. The cecum was clamped between exchangeable jaws, placed parallel at the ends of a lever (Fig. 6.2). The lever was hanging from three cords, perpendicular to the tissue. Two springs between the arms of the lever provided the pinch force. This force could be increased by moving the springs towards the tissue. At the back of the lever pull forces were applied using a spring scale. Just enough tissue was clamped in the jaws to prevent curling of the tissue around the jaws. During the experiment, the tissue was kept wet.

Jaws

The jaws used were stainless steel rectangles of 10 mm width. Rounding was applied to avoid extreme effects at the edges of the rectangles, which reduced the width of the contact area from 10 to 8 mm. Five series of jaws were tested. The jaws within a series were tested on the same five or seven pigs.

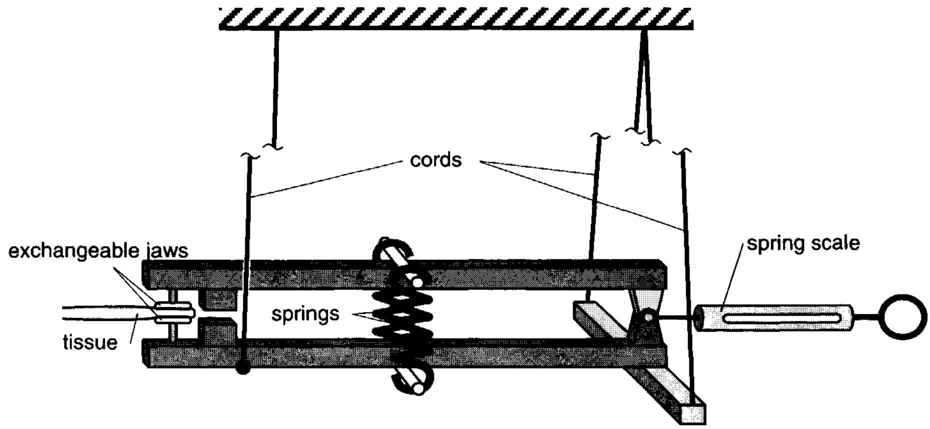


Figure 6.2 The experimental setup. The lever is suspended from three cords, each about half a metre long, allowing for frictionless movement in the longitudinal direction of the lever. Tissue is clamped between the exchangable jaws. The springs provided the pinch force and the spring scale the pull force.

Series 1: The jaws consisted of three flat rectangles with width 8 and lengths of 4, 8 and 16 mm, referred to as rect4, rect8 and rect16, respectively (Fig. 6.3a).

Series 2: The flat rectangle of 8 by 8 mm was compared to rectangles of the same size with protruding hemispheres with diameters of 2 mm. The upper jaw contained 4 hemispheres and the lower jaw 5 hemispheres in such configuration the hemispheres fell in between eachother (Fig. 6.3b). The hemispheres protruded 0.25, 0.5 or 1.0 mm from the surface. The jaws are referred to as 4x5, with the amount of mm protruding

Series 3: The flat rectangle of 8 by 8 mm was compared to two equal rectangles with 5 hemispheres, causing the hemispheres falling on eachother (Fig. 6.3c). The hemispheres also protruded 0.25, 0.5 or 1.0 mm from the surface. The jaws are referred to as 5x5, with the amount of mm protruding.

Series 4: Rect8 was compared to rectangles with a diamond-shaped profile (diam.3) and a ribbed (rib.3) profile, protruding 0.3 mm from the surface (Fig. 6.3d and 6.3e). The profiles were the same as commonly used in current forceps, except that the edges of the jaws were rounded.

Series 5: Rect8 was compared to three rectangles of the same size with a diamond-shaped profile. The profile protruded 0.15 (diam.15), 0.3 (diam.3) and 0.6 (diam.6) mm from the surface (Fig. 6.3e).

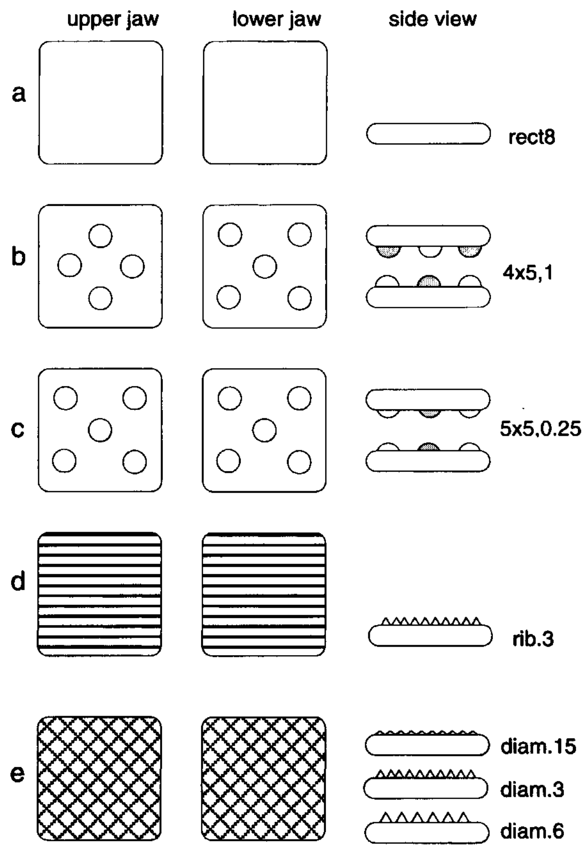


Figure 6.3 Top and side view of the various jaws used in the experiment.

Definitions

The slip force (Fslip) was defined as the pinch force, minimally required to prevent slip, while pulling with 5 N. To measure Fslip, pinch forces in the range of 2 to 27 N were applied to the tissue. The pull force was increased with about 1 N/s until the tissue slipped out of the forceps entirely. The measurements were repeated five times for at least two different pinch forces. The pinch forces were plotted against the pull forces. A 2^{nd}-order polynomial was fitted through these data points and the origin, representing the slip line. Fslip was determined by the pinch force at 5 N pull force on the slip line.

The damage force (Fdamage) was defined as the maximal pinch force, which can be exerted without damage, while pulling with 5 N. Damage to the tissue was determined using a pull force of 5 N and various pinch forces (ranging from 4 to 50 N). After one minute of clamping, the damage to the tissue was judged by the same observer. This time period was based upon a video analysis [3], which showed that during manipulation in about 90% of the cases the tissue is held for less than one minute each time. Damage was defined as a visible tear in one of the layers of the bowel wall. When no damage was found, the measurement was repeated on a new location using a higher pinch force. In contrary, when damage was found, the measurement was repeated using a lower pinch force, until the difference between damage force and no damage force was about 10%. Fdamage was defined as the mean of these two pinch forces.

The damage-slip ratio was calculated by dividing Fdamage by Fslip. The average damage-slip ratio was calculated by averaging the damage-slip ratios over the pigs. Occasionally, no damage-slip ratio could be determined because the pinch force to prevent slip already caused damage. Then, the damage-slip ratio was set on 0.5.

Statistics

Differences between the various jaws within the series were tested with the use of analysis of variance (ANOVA) repeated measurements. Differences between the damage-slip ratios were tested using a chi-square (Friedman) test. Significance was set at the 5% level.

6.3 Results

Series 1: The series of flat rectangles with increasing sizes showed that with increasing size the slip force increased significantly (Fig. 6.4).

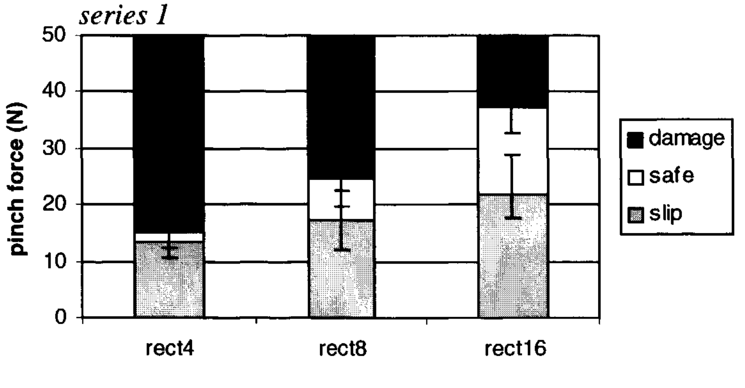


Figure 6.4 The slip and damage forces of the rectangles (series 1). The grey bars represent the slip force, the white bars the safe pinch force and the black bars the damage force (mean and std).

The damage force could not be determined in one or two pigs, since the lowest pinch force to prevent slip already caused damage. For the other pigs, the damage force increased significantly with increasing size ($p < 0.01$). Increasing the contact area had a stronger effect on the damage force (from 15 N to 37 N) than on the slip force (from 13 N to 22 N). There was no significant difference in damage-slip ratio (Fig. 6.7). The damage-slip ratio was just above 1, which means that a pinch force a little large than needed to prevent slip, can already cause damage.

Series 2 and 3: The jaws with hemispheres showed that both Fslip and Fdamage decreased with increasing protrusion (Fig. 6.5). The damage-slip ratio was 2 to 4 for all jaws with hemispheres (Fig. 6.7).

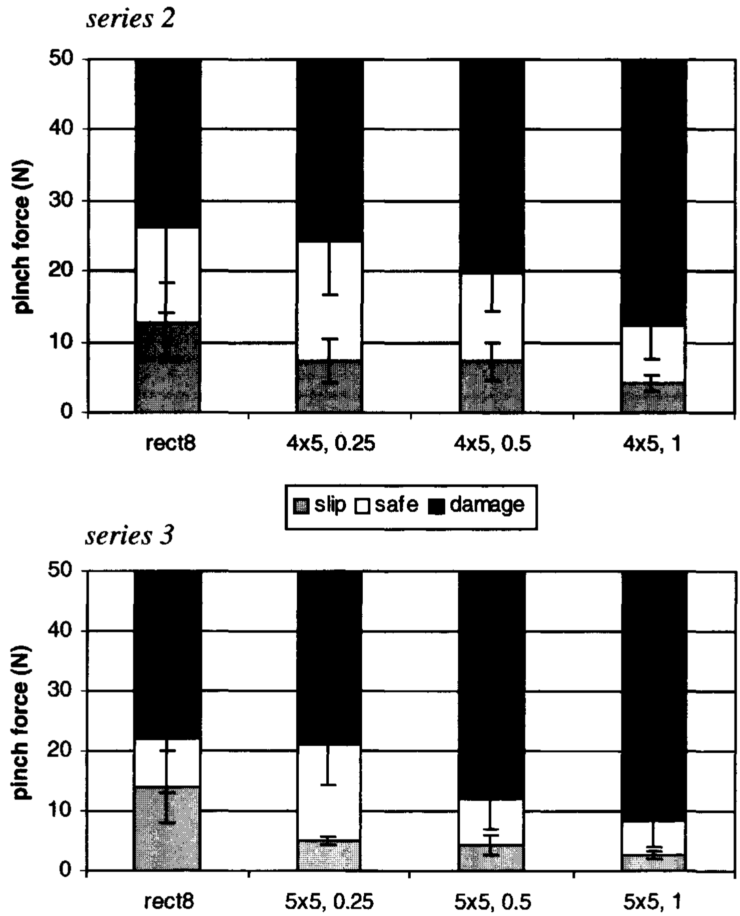


Figure 6.5 The slip and damage forces of the rectangles with 4 on 5 (series 2) and 5 on 5 (series 3) hemispheres.

Series 4 and 5: Compared to the flat jaws, the profiles decreased the slip force significantly from 22 N to approximately 3 N (Fig. 6.6). The damage force remained about the same (28 N), resulting in a slip-damage ratio about 9 times larger. The slip force was significantly higher ($p = 0.024$) for the profile protruding 0.15 mm, compared with the profile protruding 0.6 mm, due to the small standard deviations. No effects of the height of the profile were found for the damage forces and for the damage-slip ratio (Fig. 6.7).

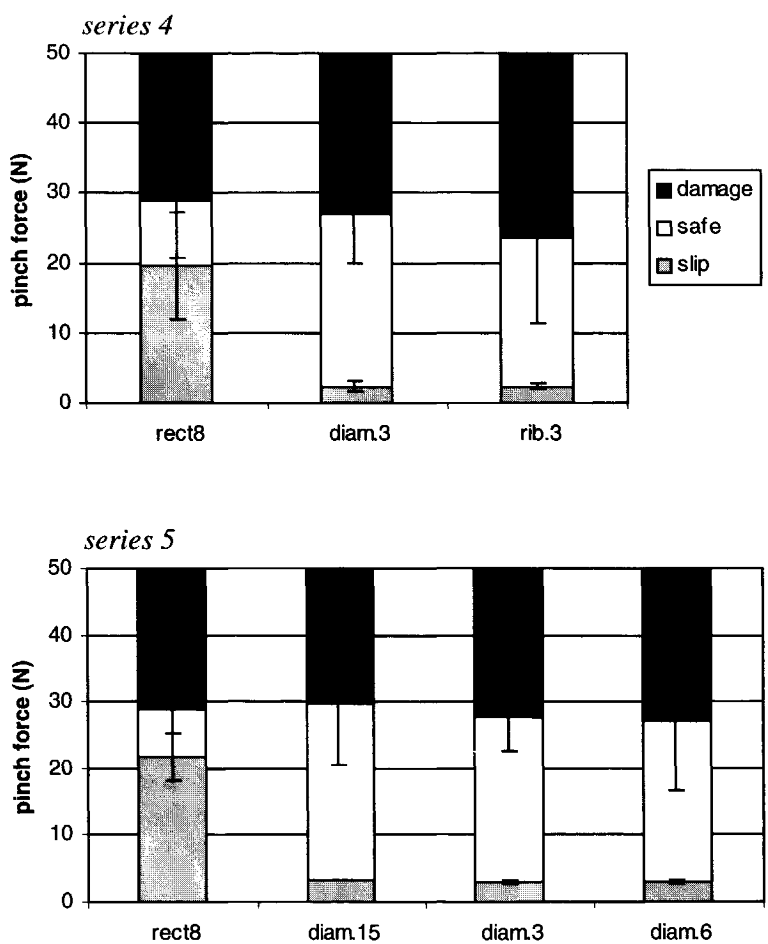


Figure 6.6 The slip and damage forces of the rectangles with different profiles (series 4) and various depths of the profile (series 5).

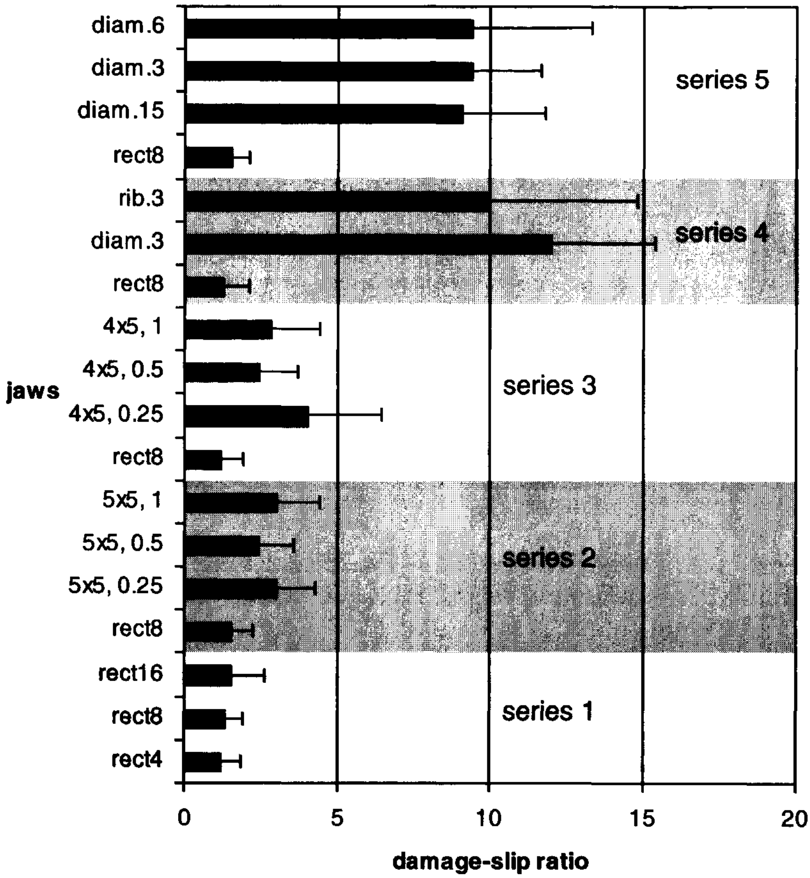


Figure 6.7 The damage-slip ratio of the jaws (mean and std).

6.4 Discussion

No guidelines exist about which criteria laparoscopic jaws should fulfil. The jaws of presently used forceps are difficult to compare, since they differ in many properties. Therefore, in this experiment the influence of the size of the contact area, the type of profile and the depth of the profile on the safety and usefulness of the jaws are investigated. Using the damage-slip ratio large differences between the jaws were found. The jaws with a diamond shaped profile provided a damage-slip ratio of 9, which implies that at a pull force of 5 N, the surgeon can safely exert a pinch force 9 times larger than is necessary to prevent slip. Contrary, a ratio of 0.9, found for the flat jaws, indicates that it is impossible to pull the tissue with 5 N without damaging the tissue.

The series of flat rectangles with increasing sizes showed that with increasing contact area both Fslip and Fdamage increase. This can be explained by the fact that with increasing size, a certain pinch force leads to a lower pressure on the tissue. Consequently, more force is needed to prevent slip but also more force can be exerted without causing damage. Increasing the contact area has a stronger effect on Fdamage than on Fslip, therefore the damage-slip ratio increase.

A large contact area results in a favorable high damage force but also in an unfavorable high slip force. Fslip can be decreased by reducing the effective contact area, and by enclosure of tissue. These aspects have been investigated using the rectangles with protruding hemispheres. Because the tissue that is grasped is very deformable, the effective contact area increases with increasing pinch force. When the pinch force is low, only the tips of the protruding hemispheres are in contact with the tissue, but when the pinch force is high, the entire jaw is in contact. The results showed that both Fslip and Fdamage decreased with increasing protrusion (Fig. 6.5). The best damage-slip ratio was found for the hemispheres protruding 0.25 mm. When comparing the 4 on 5 with the 5 on 5 hemispheres little differences were found, possibly because the distance between the protruding hemispheres was relatively large.

The effect of a profile is tested using existing ribbed and diamond-shaped profiles of various depths. Compared to the flat jaws, jaws with a profile decreased Fslip, whereas Fdamage remained about the same, consequently the slip-damage ratio was larger. The damage-slip ratio of the profiled jaws was also larger than that of the rectangles with hemispheres. In commonly used forceps, next to a diamond-shaped profile, a ribbed profile is generally used. The advantage of a diamond-shaped profile is that the profile is also suitable when forces are exerted in other directions than in the length of the forceps.

The effect of depth of the profiles was studied in the last series. Compared to flat rectangles, the profiles increased the damage-slip ratio significantly by decreasing the slip force. Even a slight profile of 0.15 mm is already enough to improve the slip force, without effects on damage force.

Occasionally, (especially for the smooth rectangles) the damage force could not be determined, since the damage force was lower than the slip force. Therefore, the damage-slip ratio was less than 1, but the exact value could not be determined; it was only known to be somewhere between 0 and 1. In these cases, it was rather arbitrary chosen to set the ratio at 0.5, being the mathematically best estimate. The best estimate from a safety point of view would be to set the ratio at 0, to exclude the possibility of overestimating the safety of the jaws. However, since the conclusions are mostly based on the differences between the jaws, instead of the exact value of the damage-slip ratios, the mathematically best estimate is more appropriate than the safe estimate.

Differences in damage were found between the various jaws. The flat jaws with a large contact area usually caused mucosal damage, whereas the jaws with a profile more often caused both mucosal and serosal damage. The long term effect of tissue damage is difficult to predict. The risk of secondary perforation is likely to increase when a serosal defect or a palpable mural defect can be found [5], whereas damage to the mucosa can recover very fast [7]. In the present study it was observed that damage was not caused by clamping exclusively, since also slip sometimes caused damage. Jaws with a profile could cause serosal damage after slip, whereas the flat jaws more often showed mucosal injury after slip. Therefore, it is necessary that the jaws of laparoscopic forceps prevent slip, both to make the surgical procedure faster and, more importantly, to avoid tissue damage.

The friction coefficients can be calculated by dividing the 5 N pull force by the slip force. In this study, the friction coefficients varied between 0.2 and 1.7. Similar results of 0.2 for plain metal surface to 1.9 for pins protruding 0.9 mm were reported on pig small bowel [2]. A friction coefficient between 0.6 and 0.9 was suggested for a bowel clamp. In present study, the most favorable jaw showed a comparable friction coefficient of 1.7. Thanks to this high friction coefficient, the pinch force can be low, when the bowel is pulled by the forceps.

The sometimes large differences in damage and slip forces of the same jaws tested in various series (rect8 and diam.3) show that jaws tested on different pigs can not be compared, due to the variation in bowel tissue between the pigs. The damage-slip ratios determined on these healthy pigs can only be extrapolated to human tissue using large safety margins. Although in a previous study no differences were found between the perforation forces of healthy pig and human tissue [4], the strength of severely affected human tissue is unknown. The used definition of damage has been chosen to be able to compare all jaws, but the long term effect of this kind of damage is unknown. In addition, only forces perpendicular to the tissue have been applied. Forces in other directions, as frequently applied during surgery, are expected to be more damaging and need to be investigated further [1]. However, it is assumed that the differences in damage-slip ratio found are a reliable indication for the relative safety of the jaws.

Concluding, the shape and profile of the jaws of a laparoscopic forceps influence to a large extent the forces leading to slip and damage of tissue. A large contact area with a slight profile seems to be favorable, since it lowers the slip force and enhances the damage force, leading to a large damage-slip ratio. In future experiments the effect of enclosure and rounding will be further investigated.

Acknowledgements

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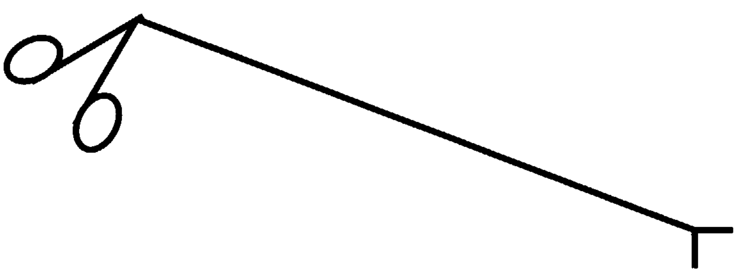
Chapter 7

The influence of force feedback and visual feedback in grasping tissue laparoscopically



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D.J. Gouma
Submitted.

Abstract

Background: Due to the limited force feedback provided by laparoscopic instruments, it is expected that surgeons may have difficulties in applying the appropriate force on tissue. The influence of force feedback and visual feedback on the exerted pinch force is determined.

Methods: A grasper with a force sensor in the jaws was developed. Subjects with and without laparoscopic experience grasped and pulled pig bowel with a force of 5N. The applied pinch force was measured during tasks of one second and one minute. Visual feedback was provided in half the measurements. Force feedback was adjusted by changing the mechanical efficiency of the forceps from 30% to 90%.

Results: The mean pinch force applied was 6.8N (±0.5), whereas the force to prevent slip was 3.0N (±0.4). Improving the mechanical efficiency had no effect on the pinch force for the one-second measurements. The amount of excessive pinch force when holding tissue for one minute was lower at 30% mechanical efficiency compared with 90% (105% vs 131%, p=0.04). The tissue slipped more often without visual feedback (2% vs 8%, p=0.02).

Conclusion: Force feedback as well as visual feedback play a more limited role than expected in grasping tissue with laparoscopic forceps.

7.1 Introduction

Force feedback of presently used laparoscopic forceps is very low, due to friction in the transmission mechanism. Therefore, the mechanical efficiency of presently used forceps is only 8-42 % [11]. Several studies revealed that tasks such as the estimation of stiffness or shape and surface structure of objects could be performed best by using bare hands, then by using instruments for open surgery and then by using laparoscopic instruments [2,3,9]. In addition, video-analyses showed that during laparoscopic procedures surgeons have difficulties in applying the appropriate grasping force to the tissue, resulting in slipping or damaging of tissue [5,7].

When performing a laparoscopic procedure, the surgeon can obtain information about the applied force via visual feedback and force feedback. Visual feedback is provided via the laparoscope and monitor. Probably this visual feedback consists of changes in shape and color of the grasped tissue. Force feedback is provided by the handle of the forceps that exerts a pressure on the surgeon's hand, detected by pressure sensors in the skin. In addition, Golgi tendon organs and muscle spindles provide information about the applied muscle force and opening angle of the hand. When dissecting bowel tissue, the surgeon grasps the tissue in view of the laparoscope and frequently pulls the tissue out of the view, to perform dissection with other instruments. Therefore, when grasping tissue the surgeon has limited use of both force feedback and visual feedback. In contrast, when the tissue in the forceps is held out of view, the surgeon has to rely completely on force feedback.

Presently, much effort is made to improve force feedback of laparoscopic instruments. Also in the field of robotic surgery systems, an important complaint is the lack of force feedback [10]. Several actuators and sensors have been developed that measure and transmit the pinch force on the jaws electronically to the surgeon's hands [e.g. 6,9]. Another solution is to improve the mechanical construction and thereby the mechanical efficiency of the forceps [1,4,8]. It has been shown that an enhanced mechanical efficiency improves the feeling of pulsation of blood vessels [3], but the amount of mechanical efficiency necessary to grasp and hold tissue safely has not been quantified yet. Experienced surgeons seem to be able to operate without complications using forceps with low force feedback or even using robotic systems without any force feedback at all. Therefore, other factors such as visual feedback and experience of the surgeon may be more important than the amount of force feedback.

The aim of this study is to determine the influence of visual feedback, force feedback and experience of the surgeon both on grasping tissue and on holding tissue for longer times. At 5 N pull force, which is the maximal pull force needed to stretch tissue [12], the differences between the applied pinch force and the minimal required pinch force will be determined.

7.2 Methods

Subjects

Twenty-one subjects participated in the experiment. Nine subjects were surgeons who had performed at least 50 laparoscopic procedures. The other twelve subjects had no laparoscopic experience and were researchers experienced in animal experimental (open) surgery.

Measurement set-up

A custom-made grasper with a built-in load cell is developed for measuring the pinch force (Fig. 7.1). The length of the forceps shaft, the ergonomic dimensions of the handgrip and the opening angle of the handle are made as much as possible similar to commercially available grasping forceps, since these parts of the instrument constitute the interface with the surgeon. Six ball bearings are used to gain a high mechanical efficiency. On the transmission mechanism two spring-loaded friction bars with friction discs are placed. By changing the position of the springs along the instrument's axis, the mechanical efficiency is adjustable. When the bars are not in contact with the mechanism, the mechanical efficiency is maximal. By placing the bars against the mechanism and moving the springs towards the jaws of the forceps, the mechanical efficiency can be decreased.

Prior and in between the experiments the mechanical efficiency was measured with the springs in three different positions using a standard protocol as previously described [11]. The mechanical efficiency ranged from 92% (± 1%) without contact of the friction bars to 63% (± 3%) and 34% (± 1%) with the springs placed in two different positions.

The forceps consists of an extended lever mechanism. The arms of the lever are large (240 mm) to allow the jaws to close in parallel, thereby maintaining a constant pinch force independent of the position of the tissue in the jaws. The jaws of the forceps are exchangeable and are made of stainless steel rectangles of 10x10 mm with a diamond-shaped profile protruding 0.3 mm. Rounding is applied to avoid tissue damage at the edges of the rectangles, which reduces the size of the contact area from 10x10 to 8x8 mm.

In the lower jaw, a load cell is placed to measure the pinch force (RDP electronics USA, model 31 load cell, 10 lbs.). The load cell signal is amplified by a transducer amplifier (RDP electronics USA, type S7DC) and is measured using a multimeter (Dynatek, 6080RS), which is connected via the RS232 port to a computer. Using this set-up, the pinch force can be measured with an error of less than 0.02 N, within a range of 0 to 16 N and a sample frequency of 3 Hz.

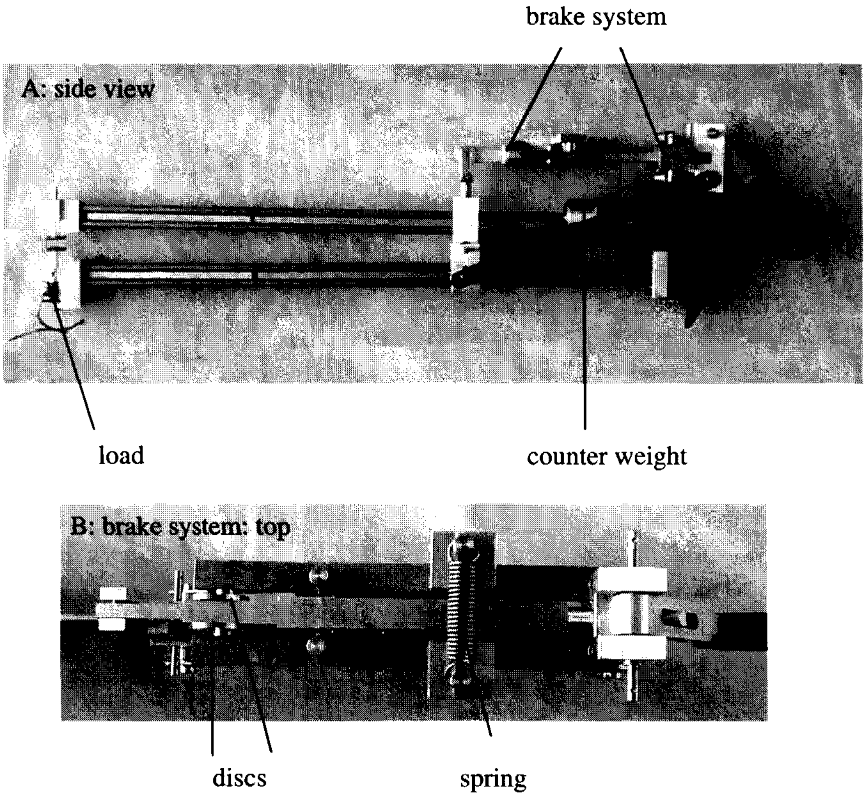

Figure 7.1 A: A side view of the forceps with the load cell in the jaws and the brake system to adjust the mechanical efficiency. The counter weight is used to keep the jaws slightly open when no force is exerted on the handle. B: A top view of the brake system. The springs push two bars against discs on the mechanism. By moving the springs to the left, the force on the discs is increased, leading to increased friction, a lower mechanical efficiency and therefore less force feedback.

A counter weight at the end of the lever is used to compensate for the weight of the upper jaw and arm. When no force is exerted on the handle, no pinch force is exerted on the load cell. To keep the total weight as low as possible, the handles are made of PVC and the other parts are mostly made of aluminium. The total weight of the forceps is approximately 500 g. By hanging the forceps from four cords, this weight did not disturb the subjects and a pull force could easily be applied. The force transmission ratio of the forceps is about 1:1, which means that the force exerted on the handle is the same as exerted on the tissue. Tissue was clamped between two grippers, also hanging from four cords. The pull force was measured using a spring scale with a resolution of 0.1 N.

To simulate the laparoscopic environment, direct sight on the jaws holding the tissue was prevented. A miniature camera with a telephoto lens (Panasonic wv-KS152) and a monitor, placed next to the table, were used to provide visual feedback to the subjects.

Measurement procedure

The experiments were conducted on pig bowel tissue. Small bowels of 9 pigs (mean weight of 44 kg) were collected, after the animals had been sacrificed for other research (approved for by the Animal Research Committee). The bowel of each pig was used for one to four subjects. Prior to the measurements by the subjects, the minimal pinch force required to prevent slip, whilst pulling with 5 N, was measured. This force was defined as the slip force (Fslip). The slip force was measured by grasping the tissue while increasing the pull force to 5 N, then the pinch force was decreased slowly until the tissue slipped out of the jaws. The slip force was calculated as the mean of 10 measurements.

The subjects performed two experiments. First they were asked to place the forceps in their non-dominant hand (the hand generally used for grasping tissue) on the edge of the tissue and to increase the pull force to 5 N, while using minimal pinch force. In half of the measurements, visual feedback was provided until the pull force reached a value of about 2 N, since then the jaws of the forceps disappeared out of the camera view. In the other measurements, the jaws were always in the camera view. At 5 N, the subjects were asked to hold the same forces for about two seconds. The measurement was repeated until the tissue was grasped eight times without slip. Each series of eight correct measurements was performed with a mechanical efficiency setting of the forceps of about 30% and 90%, and with and without visual feedback leading to 32 (4 * 8) measurements for each subject. The four conditions were randomly applied.

In the second experiment, the subjects held the tissue six times for one minute, randomly using a mechanical efficiency of about 30%, 60% and 90% and with and without visual feedback. The measurement was repeated when the tissue slipped. The duration of the entire experiment was about 30 minutes.

Prior to the experiment and after completion of the experiment, the subjects filled in a questionnaire. The subjects were asked to score the importance of information they used to estimate the pinch force on a scale of 1 to 5 (from not important to very important).

Data analysis

For each one-second measurement, the mean exerted pinch force of the last second recorded (Fpinch) was calculated. The amount of excessive pinch force was calculated as the relative deviation of the force needed to prevent slip by: $\frac{\text{Fpinch} - \text{Fslip}}{\text{Fslip}} * 100\%$.

The mean pinch force and the amount of excessive pinch force of the one-minute measurements were calculated and additionally a straight line was fit through all data points to obtain the trend in force over one minute.

The differences between the conditions and between experienced and inexperienced subjects were analyzed statistically using analysis of variance (ANOVA), repeated measurements. The scores on the questionnaire and the amount of times tissue slipped were tested using a Friedman test. α was set to 0.05.

7.3 Results

The pinch force necessary to prevent slip at a pull force of 5 N was on average 3.0 N. The variation between the pigs bowels was 2.6 to 3.3 N and the mean standard deviation of the 10 measurements within the pigs was 0.4 N. The highest slip force measured was 4.3 N. The mean pinch force the subjects applied was 6.8 N which is more than twice as much as needed to prevent slip. The tissue slipped out of the jaws in 7% of the measurements. Two of the twelve inexperienced subjects were excluded, because they exerted on all measurements the maximal measurable pinch force (16 N).

An example of the exerted pinch forces is shown in Figure 7.2. In Figure 7.3 the mean percentage of excessive pinch forces while holding tissue for one second are shown. No significant differences were found between the various levels of mechanical efficiency. Also there was no difference in excessive pinch force between the measurements with and without visual feedback. Finally, there was no effect of laparoscopic experience. The amount of times tissue slipped out of the jaws was significantly higher without vision (2% with vision, 8% without vision, $p = 0.02$).

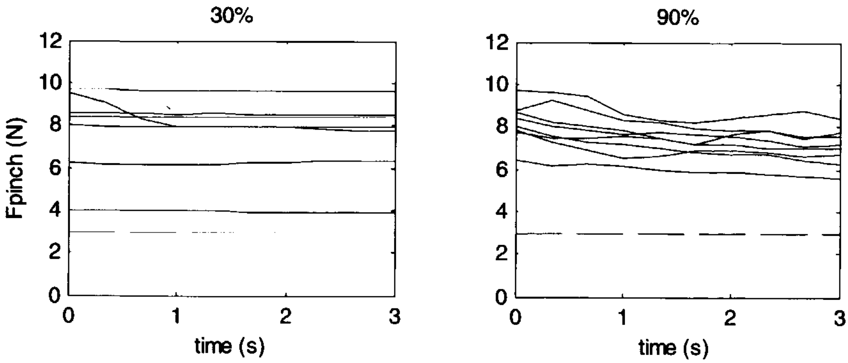

Figure 7.2 An example of the pinch force exerted by one of the subjects during grasping tissue and holding it for one second. All eight measurements with a mechanical efficiency of 30% and 90%, both with visual feedback are shown. The lowest (dashed) line is the minimal pinch force needed to prevent slip.

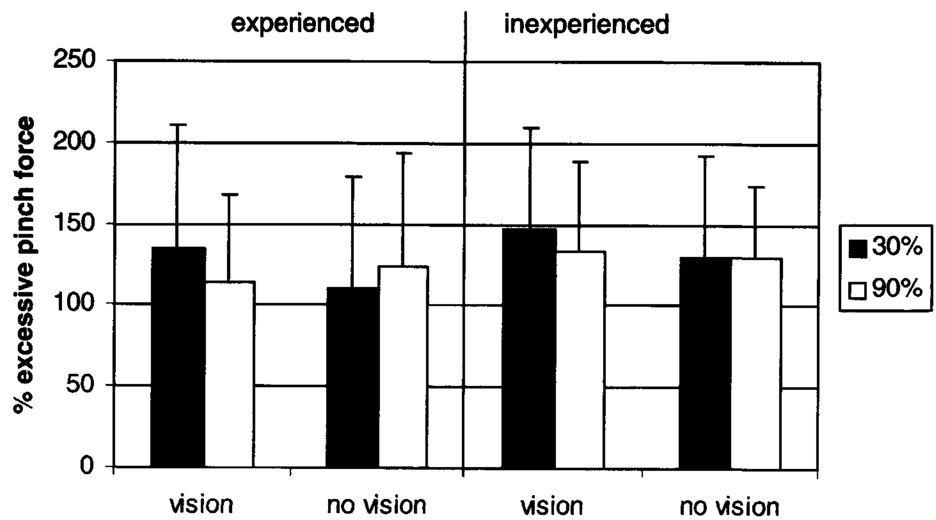

Figure 7.3 The mean percentage of excessive pinch force (and std) while holding tissue for one second for experienced surgeons and inexperienced subjects.

Figure 7.4 shows the mean percentage of excessive pinch forces while holding tissue for one minute. With a mechanical efficiency of 30% the subjects used a significantly lower amount of excessive pinch force compared to 90% (105% vs 135%, $p = 0.04$). No effect of vision and laparoscopic experience were found. No differences were found in the amount of times that tissue had slipped. In 86% of the measurements, the gradient of the fitted straight line was negative. The pinch force declined significantly (16.2%, $p < 0.001$), while holding tissue for a minute.

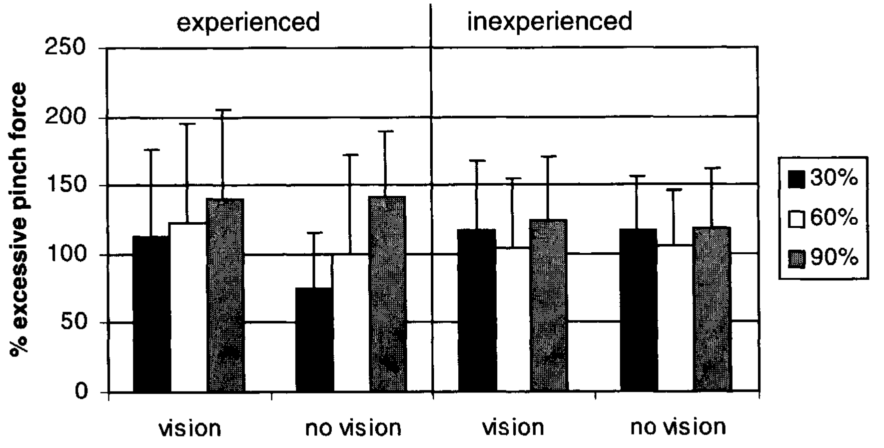

Figure 7.4 The mean percentage of excessive pinch force (and std) while holding tissue for one minute for experienced surgeons and inexperienced subjects.

The results of the questionnaire after completion of the experiment are shown in Figure 7.5. According to the subjects all aspects mentioned in the questionnaire play a certain role. The most important indicated aspects during manipulating tissue are the vision and feeling of tissue slip, the muscle force of the hand and the pressure of the handle on the hand (score > 3.5). The opening angles of the jaws or hand are assumed less useful. There were no differences in scores between the experienced and inexperienced subjects. Prior to the experiment, changes in color and shape of tissue and the angle of the jaws were assumed more important than after the experiment, whereas the muscle force of the hand was first classified as less important.

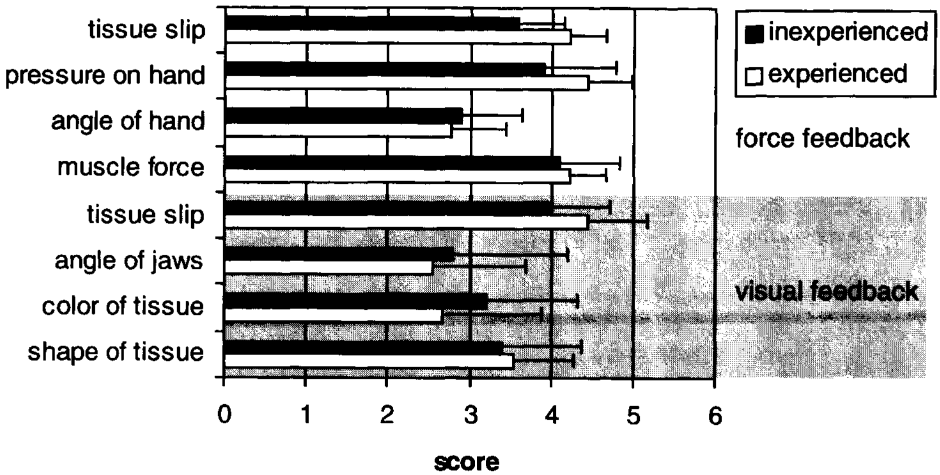

Figure 7.5 The results of the questionnaire after completion of the experiment (mean and std). The answers were given on a scale of 1 (not important at all) to 5 (extremely important).

7.4 Discussion

In the present study it was shown that the exerted pinch force on the tissue was not influenced either by mechanical efficiency of the forceps, visual feedback or laparoscopic experience. These results were contrary to previous experiments [3,6,9], in which the performance, perceiving pulsations in tissue or perceiving changes of stiffness, improved when force feedback was increased.

This difference can be explained by the relationship between the force of the hand on the handle and the force of the jaws on the tissue (Fig. 7.6). Due to energy losses the force transmission is different for opening and closing the forceps and for a different level of mechanical efficiency. At a mechanical efficiency of 90%, the force transmission between handle and jaws is about the same for opening and closing the forceps. However, at a mechanical efficiency of 30%, due to the large amount of friction, the force on the handle needs to be higher to produce the same force on the tissue. When the pinch force of the hand is decreased, the force of the jaws will remain nearly constant, until the lower curve is reached. Then the jaws will open and the force exerted by the jaws will decrease according to the lower curve.

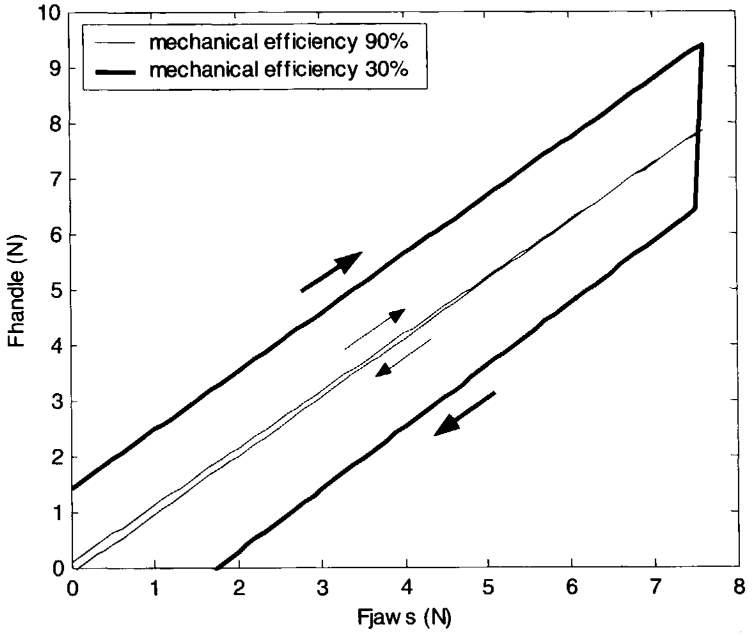

Figure 7.6 The transmission force of the hand on the handle (Fhandle) to the force of the jaws on the tissue (Fjaws) with a mechanical efficiency of 90% (thin line) and 30% (bold line). At a mechanical efficiency of 90%, opening and closing the forceps result in about the same force transmission. At a mechanical efficiency of 30%, the force transmission during closing the jaws is according to the upper curve, the force transmission during opening the jaws is according to the lower curve.

Consequently, with a certain amount of friction it is easier to apply a constant pinch force on the tissue, since small variations in the force of the hand are not transmitted to the jaws. With a mechanical efficiency of 30% the variation in pinch force can be as high as 3 N without changing the forces on the tissue and with a mechanical efficiency of 60%, this variation is 0.7 N. This lower variation in pinch force of the jaws with low mechanical efficiency was also observed in the applied pinch forces (Fig. 7.2). Obviously, the pinch force at the tissue is more constant with a mechanical efficiency of 30% than with 90%. It is assumed that with a constant pinch force the risks on tissue slip and tissue damage are lower. Some subjects preferred a mechanical efficiency of 60%, reporting that they had less difficulty to establish a constant pinch force than at a mechanical efficiency of 90%.

Therefore, a suitable mechanical efficiency for laparoscopic forceps probably will depend on the tasks that are performed. For tasks requiring movement of the jaws for dynamic gripping or to feel the tissue, as in previous experiments [3,6,9], a high mechanical efficiency of the forceps would be recommended, since the exerted force on the handle results in the same force on the tissue. Conversely, for tasks requiring a constant pinch force on the tissue, as holding tissue described in this experiment, a certain amount of friction in the mechanism of the forceps can be useful, since variations in force on the handle are not transmitted to the tissue.

The influence of visual feedback in this experiment was less than expected. Some of the subjects applied even more pinch force when visual feedback was available which indicates that they were distracted by visual feedback. The subjects seemed to establish the pinch force during grasping of tissue with the use of visual feedback and subsequently held the pinch force constant during pulling. Since in this experiment the tissue did not visibly change much in shape or color when the pinch force was increased, it can be assumed that visual feedback was of limited importance in applying the pinch force. Perhaps, during surgery visual feedback is more important in establishing the pull force by observing the tension in the tissue, since the perception of pull force is impaired by the friction in the trocar. The influence of visual feedback and force feedback on the pull force should be measured in future experiments.

Laparoscopic experience showed no influence on the applied pinch force. The task of pulling firmly, while pinching carefully was difficult, especially for the inexperienced subjects. Some experienced surgeons indicated that they would normally use lower pull forces (approximately 1 N) and consequently lower pinch forces. At lower pull forces, it is expected that the differences in exerted pinch forces will be even smaller.

Since visual and force feedback did not improve the performance, the question remains which cues the subjects used when manipulating soft tissue. In the questionnaire the subjects indicate to rely more on force feedback, since the pressure of the handle on the hand and the muscle force of the hand are indicated to be more important. Furthermore, slip of tissue could be perceived with both visual and force feedback, however, during surgery, perceiving of slip of tissue will be more difficult due to the friction in the trocar.

Although the pinch force used was often at least twice as high as needed, the pinch force is still much less than the pinch force of 27 N causing visual tissue damage in a previous experiment [13]. In real procedures, however, the attention will probably be paid more to the other instrument in the dominant hand. Moreover, the forceps can rotate on its longitudinal axis, causing higher local pressures on the tissue. Additionally, at lower pinch forces the tissue can be damaged without visual signs, still causing a perforation after several days. Therefore applying the minimally required pinch force is always necessary.

In conclusion, force feedback, visual feedback and laparoscopic experience are less important than expected in the particular task of holding tissue. The optimal mechanical efficiency of laparoscopic forceps probably depends on the tasks performed with the forceps. This will be investigated in a future experiment.

Acknowledgements
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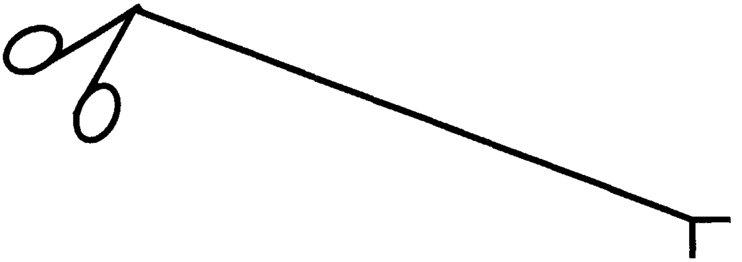
Chapter 8

The optimal mechanical efficiency of laparoscopic forceps



E.A.M. Heijnsdijk, A. Pasdeloup, J. Dankelman,
D.J. Gouma
Submitted.

Abstract

Background: Currently used laparoscopic forceps have a large amount of friction in the mechanism, leading to a limited mechanical efficiency, which impairs the force feedback. The advantage of a little amount of friction is that it is easier to maintain a constant pinch force on the tissue. Therefore, to obtain the optimal mechanical efficiency of the forceps, the influence of mechanical efficiency on the performance of several static and dynamic operative tasks such as grasping tissue and estimating pressure is quantified.

Study design: A grasper with adjustable mechanical efficiency and a load cell to measure the pinch force on the tissue was developed. Using this grasper, subjects performed several tasks on pig bowel tissue and simulation tissue. The tasks existed of grasping tissue, reproducing a requested static and dynamic force and estimating the pressure in a tube.

Results: With increasing mechanical efficiency a dynamic force could be reproduced more accurately (deviation from the requested force decreased from 34.4% to 24.9%, $p=0.016$). The performance on the tasks grasping tissue, reproducing a static force and estimating pressure did not improve with increased mechanical efficiency.

Conclusions: The optimal mechanical efficiency of laparoscopic forceps is dependent on the task that is performed. For tasks requiring little movement of the forceps such as grasping and holding tissue a low mechanical efficiency is sufficient, whereas for tasks requiring repeated movement of the forceps to feel tissue a high mechanical efficiency is required.

8.1 Introduction

Manipulation of tissue using laparoscopic instruments requires special demands [1]. Besides the problems in moving the instrument to the operative field, there are also problems in the transformation of grasping movements of the hand in grasping movements of the jaws of the instrument. Due to friction in the construction of the forceps, the feedback of the pinch force to the surgeon's hand is poor [2,3,4]. It was shown that the mechanical efficiency of common forceps is about 30%, which means that 70% of the energy is lost during opening and closing of the jaws [5].

Using a forceps with improved mechanical efficiency, an increased perception of pulsation of blood vessels was found [6]. In addition, increased performance in estimating stiffness and localizing tumors was found with improved force feedback [7,8]. In contrast, in a previous study improved mechanical efficiency did not show an increasing performance on a tissue grasping task [9]. In this previous study, the subjects had to grasp and hold tissue, using the minimal required pinch force. The exerted pinch force was more than twice as high as needed, independent of the mechanical efficiency of the forceps.

These differences in the influence of mechanical efficiency are probably due to different tasks to be performed. In tasks requiring movement of the jaws to perceive tissue properties, the forceps is repeatedly moving against the friction in the mechanism and therefore the mechanical efficiency will be more important than in tasks requiring no movement as in holding tissue (Table 8.1). Also there can be a difference in active moving the handle and jaws (for example to apply a pinch force) versus passive feeling of force (for example to feel pulsations). Therefore, the need for improved mechanical efficiency will be strongly dependent on the tasks that are performed with the forceps.

The purpose of this study is to define tasks for which improved mechanical efficiency of the forceps is useful. Four experiments were performed to measure the effect of improved mechanical efficiency.

Table 8.1 Tasks performed using laparoscopic forceps

	active handling	passive handling
repeated movement of forceps	* estimating stiffness of tissue	* perceiving pulsation of blood vessels
one-time movement of forceps	* applying pinch force	* holding tissue

8.2 Methods

Subjects

Ten subjects with surgical experience but without laparoscopic experience participated in the first two experiments. In the third and fourth experiment 31 subjects participated with and without laparoscopic or surgical experience (13 surgeons, 11 researchers and 7 medical students).

Measurement set-up

A custom-made grasper with built-in load cell was developed for measuring the pinch force exerted on the tissue. In addition, the mechanical efficiency of the grasper was adjustable from 30% to 90%. The jaws used were stainless steel rectangles of 8 by 8 mm with a diamond-shaped profile. The grasper has been described in detail previously [9].

The grasper was hanging from four cords. Tissue or simulation material was clamped between two grippers, also hanging from four cords. The pull force was measured using a spring scale with an accuracy of 0.1 N.

Experiment 1: Holding tissue

These measurements were conducted upon pig bowel tissue. Small bowels of 5 pigs (mean weight 50 kg) were collected, after the animals had been sacrificed for other research (approved for by the Animal Research Committee). The bowel of each pig was used for one to three subjects. Prior to the measurements with the subjects, the minimal pinch force required to prevent slip was measured, while pulling with a pull force of 5 N [10]. This pinch force was defined as the slip force (Fslip). The slip force was measured by grasping the tissue with enough pinch force to withstand a pull force of 5 N, and then decreasing the pinch force slowly until the tissue slipped out of the jaws. The slip force was calculated as the mean of 10 measurements.

The subjects placed the forceps on the edge of the tissue using their left hands and increased the pull force to 5 N, while exerting minimal pinch forces. At 5 N, the subjects held the same forces for about two seconds. The measurement was repeated eight times. Each series of eight measurements was performed using a mechanical efficiency of 30%, 60% and 90%. The three conditions were randomly applied. For each measurement, the exerted pinch force was calculated as the mean of the 8 pinch forces (Fpinch) of the last second recorded. The amount of excessive pinch force was calculated as the percentage of the force needed to prevent slip by: $\frac{\text{Fpinch} - \text{Fslip}}{\text{Fslip}} * 100\%$.

Experiment 2: Reproducing pinch force one-time

This experiment was performed immediately after experiment 1 on the same tissue. The subjects had to apply a force of 1, 2, 4 or 6 N, while the exerted force was shown. Then the subjects had to reproduce the requested force three times without the display of the exerted force. Between each measurement the forceps had to be released and grasped again. The measurements were repeated for the four pinch forces and with mechanical efficiencies of 30%, 60% and 90%. The absolute deviation in percentage of the requested force was calculated.

Experiment 3: Reproducing pinch forces repeatedly

A strip of silicon with a thickness of 1.5 mm was used to represent tissue. The subjects were asked to apply three series of forces of 3 N, 6 N, 3 N, 6 N, 3 N using the forceps with their left hand. Each force was held for four seconds. The subjects practiced with the exerted force displayed and then performed the experiment without displaying the exerted force. Between the measurements the subjects could practice with display of the exerted force. These three measurements were performed with a mechanical efficiency of 30%, 60% and 90%. The absolute deviation in percentage of the requested force was calculated for the last two of each four seconds.

Experiment 4: Perceiving pressure in a tube

This experiment was performed immediately after Experiment 3. A thin silicon tube with a diameter of 11 mm was filled with air under 5 different pressures from 25 kPa to 125 kPa outside the view of the subjects. Prior to the experiment the subjects could feel the difference between all pressures. Before each measurement the subjects could feel the mean pressure of 75 kPa (reference pressure). Then the pressure was changed and the subjects had to estimate if the new pressure was one or two steps higher or lower or the same. The highest and lowest pressures were presented once, the other pressures twice in random order. The experiment was performed first by the left hand and then repeated randomly with the forceps with a mechanical efficiency of 30% and 90% in the left hand. The number of errors was defined as the number of steps from the estimated pressure to the actual pressure.

Statistics

The differences between the conditions were statistically analyzed using analysis of variance (ANOVA), repeated measurements. α was set to 0.05.

8.3 Results

Force transmission

The transmission of force from the handle to the jaws was different for the various levels of mechanical efficiency (Fig. 8.1). With decreasing mechanical efficiency, the difference between opening and closing the forceps is larger, leading to more uncertainty about the pinch force exerted on the tissue.

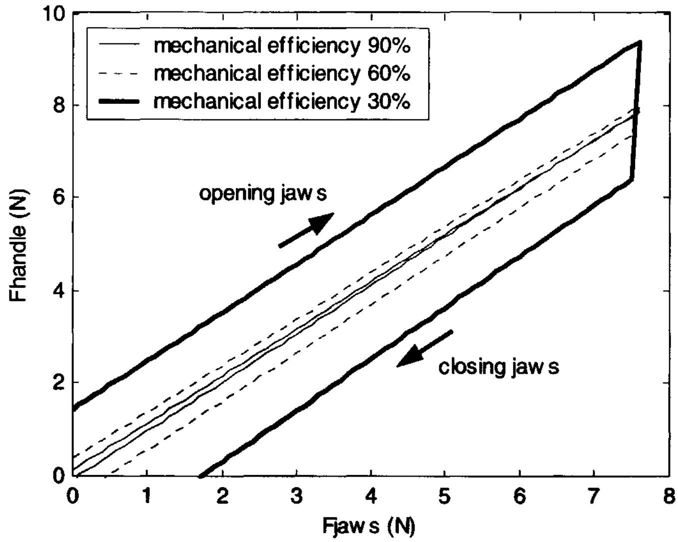


Figure 8.1 The transmission force of the handle (Fhandle) to the jaws (Fjaws) with a mechanical efficiency of 90% (thin line), 60% (dotted line) and 30% (bold line). At a mechanical efficiency of 90% opening and closing the forceps results in about the same force transmission. At a mechanical efficiency of 30%, the force transmission during closing the jaws is according to the upper curve, the force transmission during opening the jaws is according to the lower curve.

Experiment 1: Holding tissue

The pinch force necessary to prevent slip at a pull force of 5 N was on average 3.0 N (2.7 to 3.3 N averaged per pig). The mean pinch force the subjects applied was 6.1 N, which is about twice as much as needed to prevent slip. The tissue slipped out of the forceps in 4% of the measurements. In Figure 8.2, the mean percentages of excessive pinch force while holding tissue are shown. No differences were found between the various levels of mechanical efficiency.

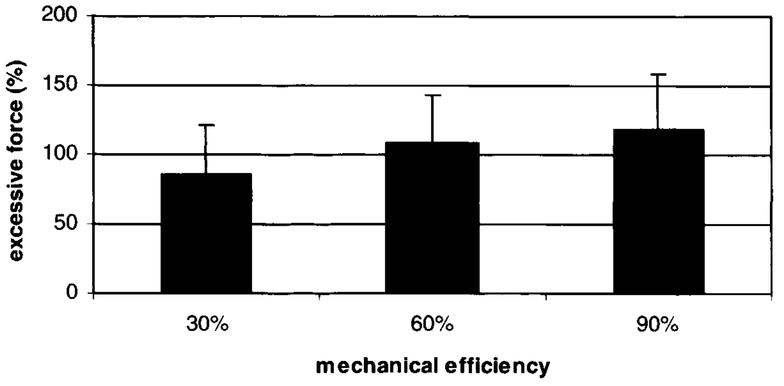


Figure 8.2 The mean amount of excessive pinch force (and std) used while holding tissue using a pull force of 5 N. The measurements were performed at a mechanical efficiency of 30%, 60% and 90%. No differences in amount of excessive pinch force were found for the various levels of mechanical efficiency.

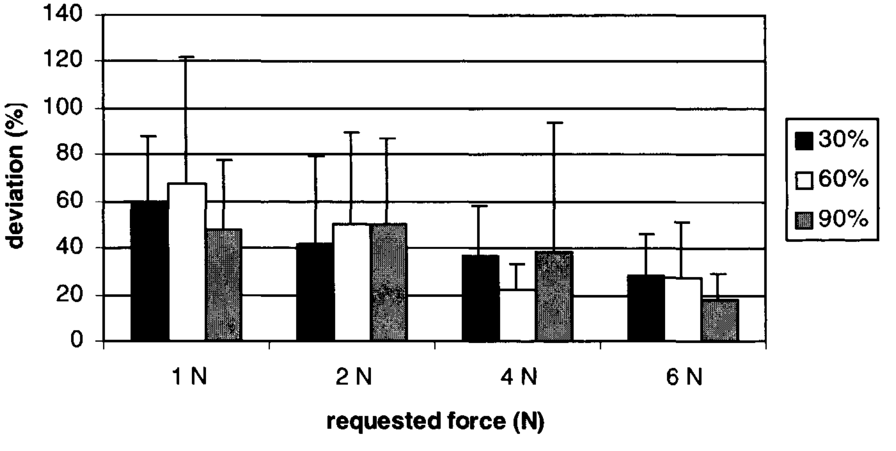


Figure 8.3 The absolute deviation (and std) of the requested force for the various levels of mechanical efficiency during reproducing a pinch force one-time. The deviation decreased significantly with increasing force. No differences in deviation were found between the levels of mechanical efficiency.

Experiment 2: Reproducing pinch force one-time

For the three levels of mechanical efficiency, the mean absolute deviations in percentage of the requested force are shown in Figure 8.3. Improving the mechanical efficiency showed no effect on the deviation. The deviation was significantly smaller when higher forces were requested ($p < 0.001$, Fig. 8.3). The performance decreased significantly for the three measurements within one condition ($p = 0.02$, Fig. 8.4).

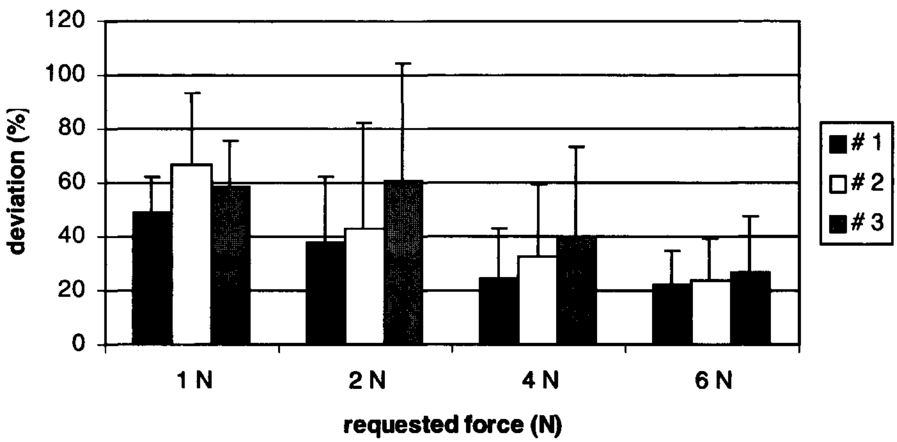


Figure 8.4 The absolute deviation (and std) of the requested force for the three subsequent measurements during reproducing a pinch force one-time. The deviation increased significantly during the three measurements.

Experiment 3: Reproducing pinch forces repeatedly

The forces applied to the simulation tissue showed a different pattern for the various levels of mechanical efficiency (Fig. 8.5). At a mechanical efficiency of 30% the exerted force was more constant. The absolute deviation with the requested force was significantly smaller at a mechanical efficiency of both 60% and 90%, compared with 30% (27.4 and 24.9 respectively vs 34.4, $p = 0.033$ and $p = 0.016$, Fig. 8.6). No effect of surgical experience on the performance was found.

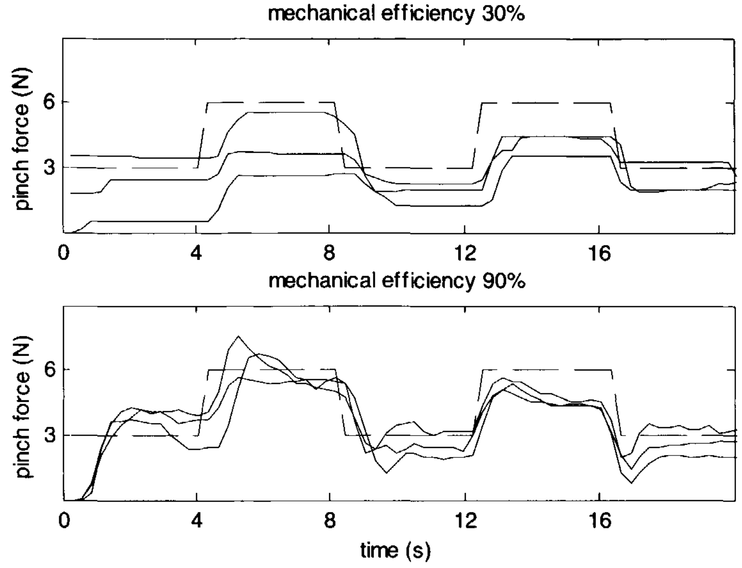


Figure 8.5 An example of the applied pinch force at a mechanical efficiency of 30% (top) and 90% (bottom). The dashed line is the requested force, the three solid lines are the applied forces. The force is more constant at a mechanical efficiency of 30%, although the deviation with the requested force is larger.

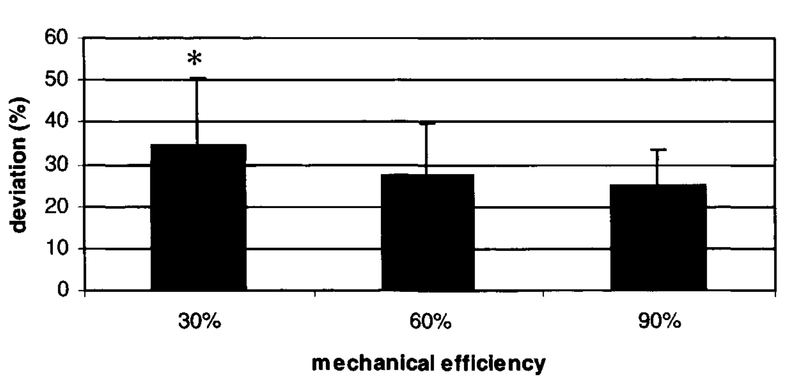


Figure 8.6 The absolute deviation (and std) of the requested force for the various levels of mechanical efficiency during repeatedly reproducing a pinch force. The deviation is significantly smaller at a mechanical efficiency of 60% and 90% compared to 30%. $p < 0.05$.*

Experiment 4: Perceiving pressure in a tube

There were large differences between the subjects in manually estimating the pressure (0 to 9 errors, mean of 4.1 errors). Using the forceps 1 to 14 errors were made. The number of errors was significantly larger for the forceps than manually (6.7 (30%) and 7.1 (90%) vs 4.1, $p < 0.001$, Fig. 8.7). No differences between the levels of mechanical efficiency and between the level of surgical experience were found.

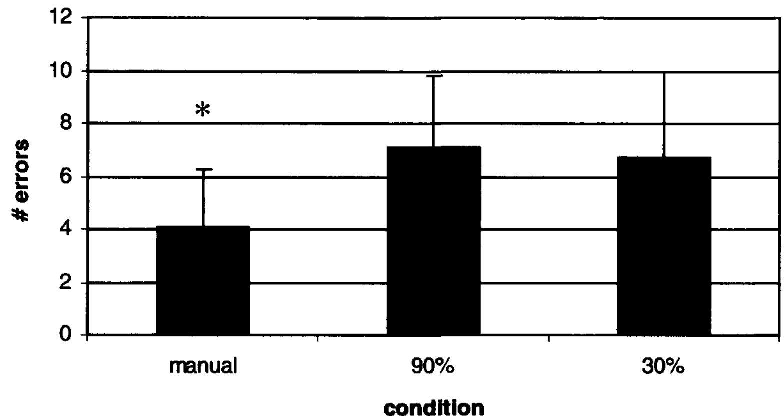


Figure 8.7 The number of errors made after estimating the pressure in a tube manually and with the forceps at a mechanical efficiency of 30% and 90%. The number of errors is significantly smaller when feeling manually than using the forceps. * $p < 0.05$.

8.4 Discussion

In this study, four different tasks were performed to define tasks for which an improved mechanical efficiency improves performance. The results show that improvement of the mechanical efficiency was only useful for reproducing a dynamic force.

The task in the first experiment of grasping tissue was one-time actively closing of the forceps. The second experiment (reproducing a force) required also one-time active closing. Contrarily, Experiments 3 (reproducing pinch forces repeatedly) and 4 (perceiving pressure in a tube) contained tasks requiring repetitively actively opening and closing the jaws. Therefore, the force transmission shifted frequently between the upper and lower curves in Figure 8.1, which leads to confusion of the actual force exerted on the tissue. In Experiment 3 the force was reproduced more accurately at higher mechanical efficiency, indicating that an improved mechanical efficiency can be useful for such tasks. However, in Experiment 4, no differences were found in estimating the pressure, although all subjects indicated they had more difficulties in estimating the pressure at a mechanical efficiency of 30% and often had to guess. In other studies a positive effect of improved force feedback on estimating stiffness was found [7,8].

According to these results, the mechanical efficiency of a forceps should be high for tasks requiring repetitively opening and closing the forceps. With a high mechanical efficiency the transmission of force between handle and jaws is equal for opening and closing the forceps and therefore the force applied can be estimated more accurately. Movement of the jaws, for example caused by pulsating blood vessels, can be perceived more easily, since it is not damped out by friction in the mechanism. In contrast, for tasks demanding a constant force on the tissue, for example pulling and holding tissue out of the laparoscopic view, a lower mechanical efficiency is sufficient. The force on the tissue is more constant, since variations in the force on the handle are not transmitted to the tissue. When exerting constant forces, the risks on tissue slip and tissue damage are expected to be lower. Therefore, the mechanical efficiency of a dissection forceps, used to palpate tissue should probably be higher than the mechanical efficiency of a grasping forceps, used for holding tissue.

A second design criterion for laparoscopic forceps can be derived from Experiment 2 (reproducing pinch force one-time). Since the error in reproducing a force decreases when the requested force increases, a small force on the tissue is easier to reproduce when a larger force on the handle can be exerted. The moment ratio between handle and jaws of currently available graspers is about 3:1 [5]. When a ratio in length of handle and jaws of 2:1 is taken into account, the transmission of force between handle and jaws will be about 1.5:1. Probably, with a force transmission of 2.5:1 or 3:1, small forces on the tissue can be exerted more accurately. The decrease in performance during the three successive measurements shows that the memory the exerted force is inaccurate.

In conclusion, an improved mechanical efficiency of laparoscopic forceps showed increased performance on tasks demanding repetitively actively opening and closing the forceps. For tasks demanding one-time opening and closing the forceps the performance did not improve with improved mechanical efficiency. Therefore, the optimal mechanical efficiency of laparoscopic forceps is dependent on the task performed with the forceps.

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8.5 References

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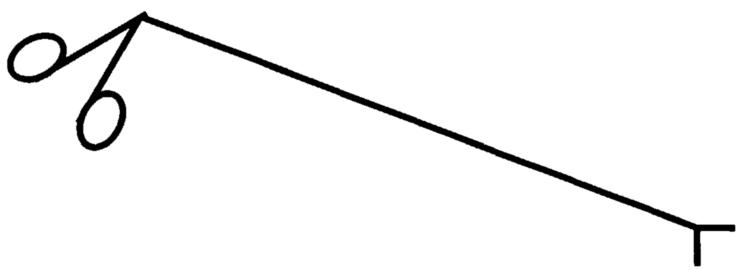
Chapter 9

Discussion



9.1 Introduction

Little research has been performed to the safety of laparoscopic forceps. This is probably mainly due to the fact that little is known about the properties of soft tissue. Especially, the dynamic behaviour of bowel tissue is very complex, since it exists of five different layers in a wet environment. Although finite element modelling of soft tissue is rapidly developing, no models are able to simulate accurately large deformations and slip [11]. In addition, the forces leading to tissue damage are unknown, since the long-term consequences of mechanical tissue damage are difficult to predict.

The chapters in this thesis describe a first attempt to get insight in these issues in an experimental way. The current use of laparoscopic forceps and the incidence of tissue damage are explored. In addition, the factors influencing safe tissue manipulation are evaluated. Tissue properties, such as the strength of tissue and the variation in strength are determined experimentally. Also, the interaction between jaws and tissue and the interaction between surgeon and forceps are studied, leading to guidelines for the design of forceps and for the use of forceps. Following this experimental method to determine intrument-tissue interaction, no optimal guidelines can be given. However, the results can be used as input for further (model) studies.

9.2 Laparoscopic manipulation of tissue

Laparoscopic graspers are mainly used to pull tissue aside or to stretch tissue to facilitate dissection with another instrument. The tissue should be grasped and pulled aside properly without causing damage. From the video analyses in Chapter 3, it has been derived that tissue manipulation using laparoscopic graspers is not efficient. Slip and damage of bowel tissue sometimes occur, possibly leading to perforation. Although in Chapter 2 the reported incidence of bowel injury caused by the grasping forceps is low, this incidence is probably underestimated, since injury is sometimes incorrectly attributed to other instruments [4]. The relatively low implementation of advanced laparoscopic procedures such as colectomy might be influenced by the absence of safe instruments. Moreover, with improved forceps the procedures can be performed faster and easier.

The research described in this thesis is focused on the safety of forceps. The safety of forceps can be studied by taking the forces on the tissue into account. When dissecting tissue using forceps, surgeons need both a pinch force and a pull force. For properly stretching the tissue, a maximal pull force of 5 N is needed [9]. In Chapter 6 a model for tissue grasping is presented (Fig. 9.1).

The experiments described in Chapters 4 and 6 showed that when the pull force on the tissue increases, a larger pinch force is necessary to prevent slip of tissue, but the pinch force causing tissue damage is lower. When an appropriate combination of pinch force and pull force is exerted, the tissue is grasped successfully and safely. An incorrect combination of forces leads to tissue slip or tissue damage. The size of the safe area is determined by the tissue properties, the tissue-instrument interaction and the surgeon-instrument interaction. The influence of these aspects will be discussed below.

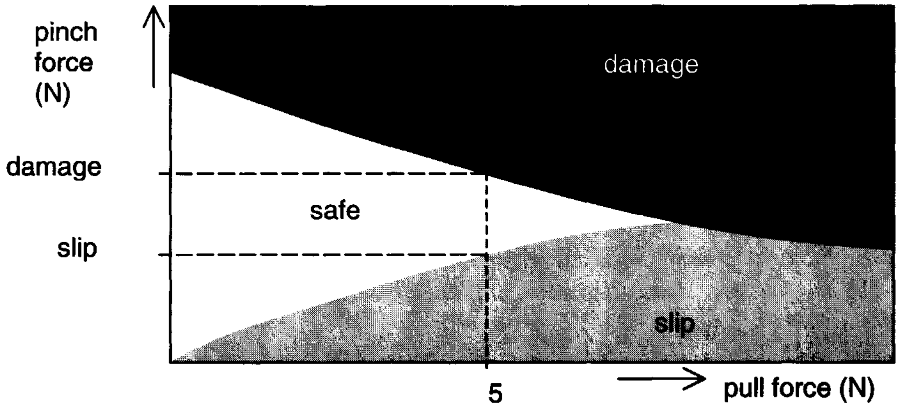


Figure 9.1 The model for the result of grasping actions. At a pull force of 5 N, the tissue slips out of the grasper when a low pinch force is applied (grey area) and it is damaged when a high pinch force is applied (black area). Consequently, only in the safe (white) area, the tissue can be grasped safely.

9.3 Tissue properties

In spite of the difficulties in manipulating the gallbladder shown in Chapter 3, it was chosen to concentrate the research performed in this thesis on bowel tissue. Bowel tissue is considered to be very delicate and the consequences of a bowel perforation, ranging from local peritonitis to death due to severe abdominal sepsis, are very severe in contrast to the mild consequences of a gallbladder perforation. However, using the same measurement set-ups as described in this thesis, it should be possible to find guidelines for suitable forceps for grasping the gallbladder with a limited chance of perforation. Tissue properties that affect the quality and safety of grasping are the slippery surface, the strength and recovery of tissue.

Tissue slip

Tissue has a well-lubricated, slippery surface and therefore may easily slip out of the jaws of the grasper. Modeling of tissue slip is difficult, since the dynamic behaviour is very complex. For example, the law of Coulomb friction, which is valid for linear-elastic materials, states that friction depends on the normal force and is independent of the size of the contact area. The results in Chapter 6 show that this law should not be used for bowel tissue, since the friction force was also dependent on the contact area. However, the slip force can be measured easily and reproducibly by exerting a known pinch force on the tissue and by increasing the pull force until the tissue slips out of the grasper. Almost without exception, there was a linear relation between the pinch and pull force leading to slip. Therefore, to predict the slip force, just a few measurements are needed.

Tissue strength

Little is known about mechanical properties of living, human tissue. This is mostly due to the difficulties in finding suitable test material. Although it is assumed that pig bowel corresponds to human tissue in anatomy and physiology, it was unknown if it also corresponds in mechanical properties like strength. In Chapter 5 it was found that the perforation force (as a measure of strength) of healthy human and pig small bowel is about the same, whereas pig large bowel has a slightly larger perforation force. The difference in perforation force between subjects of one species could be as large as a factor two. Considering this resemblance in perforation force between healthy pig and human bowel tissue, all subsequent experiments described were performed on pig tissue. Nevertheless, it should be kept in mind that measuring the strength of tissue does not determine the safety of grasping forceps, since the forceps should also be suitable to grasp affected human tissue. Furthermore, the recovery of all grades of tissue damage should be known.

Causes and consequences of tissue damage

Contrary to slip of tissue, damage of tissue other than perforation is difficult to measure and to interpret due to the unpredictability of long term effects of mechanical tissue damage. The perforation force can be measured very accurately, but with forces lower than the perforation force, the tissue can already be severely damaged, leading to a delayed perforation several days after the surgical procedure. In Chapter 4, damage was found to increase by increasing pinch force and increasing pull force. A theoretical distinction was made between no damage, light (disappearing) imprint, (remaining) imprint and perforation. However, since it is unknown which tissue damage will recover spontaneously and which tissue damage will lead to delayed perforation, the level of allowable damage is difficult to predict.

An attempt was made to quantify the histological damage after clamping the bowel with various forceps. In this experiment the tips of laparoscopic forceps were placed on pig colon tissue for 1, 2 and 5 minutes. A constant pull force of 2 N was applied, whereas the pinch force was set on a level at which the colon still could be grasped without slipping out of the forceps. Biopsies were collected, cut in sections of 5 μm and observed under a light microscope. The histological results showed vascular congestion, high numbers of white blood cells, some bleedings and disruption of epithelial layer (Fig. 9.2).

Similar results, however, were found in control experiments in which the bowel was either not clamped or clamped with maximal force. Since all control biopsies showed the same results, it can be concluded that mechanical damage to the tissue was also caused by the treatment of the tissue while preparing biopsies and not by the instruments alone. Moreover, this short term histological damage does still not predict the long term result. Therefore, it was concluded that it is not possible to quantify short term damage with the use of histology. For the design of safe graspers the long term result of tissue damage is an essential issue that should be studied further in more detail.

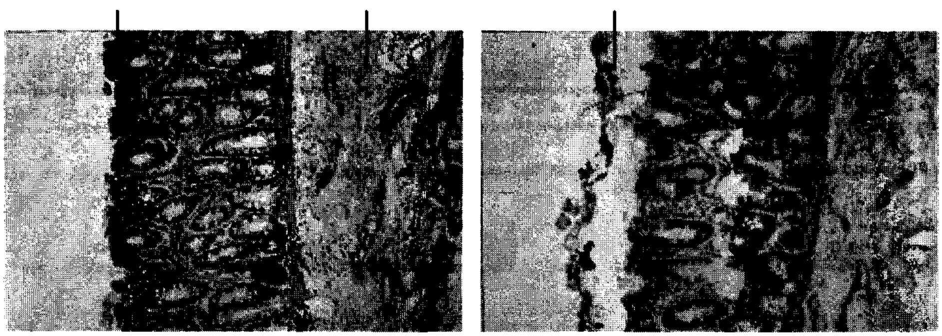


Figure 9.2 Photomicrographs of colon biopsy sections, both after clamping with preparation forceps. In the left picture the epithelial layer is hardly damaged. The right picture shows large disruption of the epithelial layer (lifting of apical epithelium). There is no vascular congestion in the submucosa (light tissue at the right). Colored with Haematoxylin-Eosin (H&E) stain (10x enlarged).

9.4 Tissue-instrument interaction

Currently used laparoscopic forceps show a large variation in shape of the jaws. Just measuring which jaws have the largest damage force is not enough to determine the suitability of jaws, because it is also important how well the jaws succeed in preventing slip of tissue. In Chapter 6, the safety and suitability of jaws was determined by measuring the damage-slip ratio. This ratio indicates the amount of extra pinch force that can be exerted without damaging the tissue above the force needed to prevent slip of the tissue. As a result, both slip and damage properties are taken into account.

Although the local pressure on the tissue determines the result of a grasping action, it was chosen to measure pinch force instead of pressure. The local pressure is difficult to measure or calculate, since it is dependent on the distribution of force over the contact area. This distribution of force is dependent on the placing of the forceps on the tissue, on the shape of the jaw and also on the shape of the jaw at the other side of the tissue. Since the pinch force the surgeon applies on the handle results in a pinch force of the jaws on the tissue, it was chosen to compare the pinch forces on the tissue.

Current forceps designed for grasping bowel tissue all have jaws with windows. The windows are located either close to the tip of the jaws or just behind a small flat contact area. Possibly, when the tissue is bulging into the windows the pinch force needed to prevent slip will be lower. However, simultaneously the contact area between jaws and tissue will be reduced, leading to higher pressures and a lower damage force. A study was performed to compare these effects [3]. Jaws with round windows with a diameter of 3 and 6 mm in and behind a flat contact area were used (Fig. 9.3). The windows were rounded off and also the edges were rounded of with a radius of 0.5 mm.

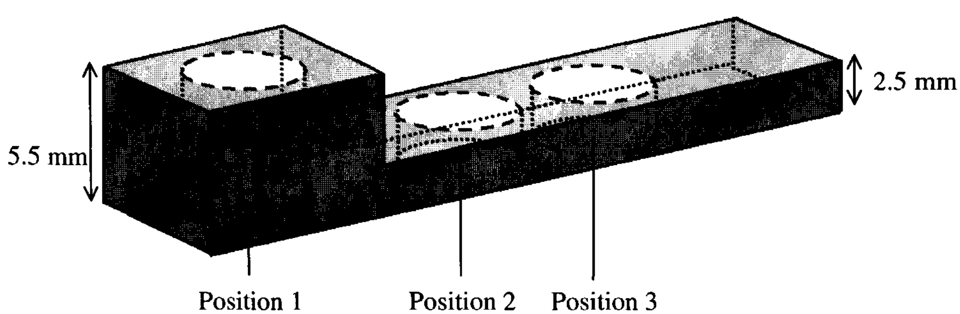


Figure 9.3 The jaws used in the experiment. Only the lower jaw is shown. The windows were located at one of the three positions. The total length was 40 mm, the contact area (left) was 100 mm².

The jaws with a window were compared to jaws of the same size without a window. The slip and damage forces were measured at a pull force of 0, 2.5, 4, and 5 N, using a measurement set-up and protocol comparable to the set-up and methods described in Chapter 6. The results showed that at all positions, a window decreased the damage force, whereas no significant effect was found on the slip force. The damage forces and slip forces of the windows at Position 2 are shown in Figure 9.4.

In total, the damage-slip ratio decreased significantly ($p = 0.013$) with increasing window size. Bulging of tissue in the windows was hardly observed. Concluding, the reduced contact area caused by the windows leads to increased tissue damage without a positive effect on tissue slip. Therefore, to reduce slip of tissue, profiled jaws seem more effective than a window in the jaws and for bowel graspers the application of windows should be abolished.

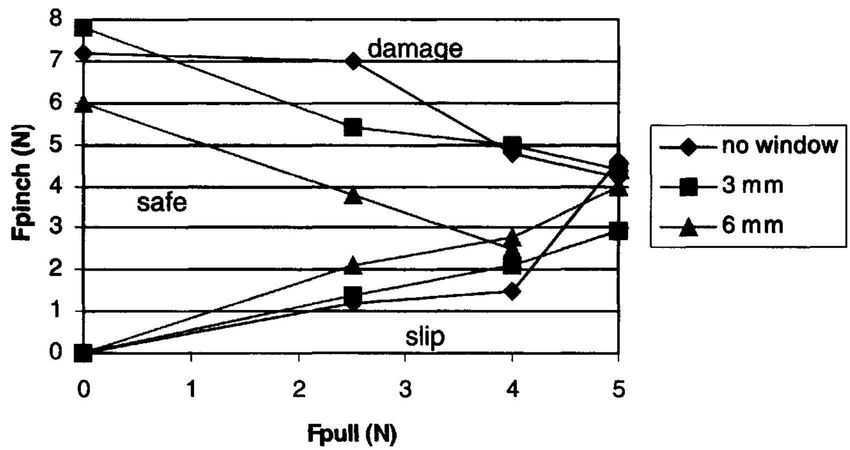


Figure 9.4 The effect of windows just behind the contact area (Position 2) on the slip force (three bottom lines) and the damage force (three top lines). The results show that a window has no effect on the slip force, whereas the damage force decreases compared to jaws without windows (except at 5 N pull force). At 5 N pull force the damage force of the window of 6 mm was lower than the slip force and therefore could not be measured.

9.5 Surgeon-instrument interaction

The instruments are the interface between tissue and surgeon. The jaws interact between forceps and tissue and the handle interacts between forceps and surgeon. Two properties determine the quality of the forceps; the force transmission between handle and jaws and the pinch force feedback. Presently, the force transmission varies between forceps, which may cause confusion, since the same force exerted on the handle can result in different forces on the tissue [7]. The force transmission can be adjusted to a suitable value. Most grasping actions can be performed with low pinch forces, probably less than 3 N. From Chapter 8 it can be derived that larger forces can be reproduced more accurately than small forces. Therefore, the ideal force transmission can be larger than 1:1. With a force transmission of 3:1, a force of 6 N on the handle results in a force of 2 N on the tissue. This force on the tissue can be reproduced with only a small deviation of 0.5 N. The force transmission should not exceed 3:1, since constantly exerting forces on the handle larger than 9 N causes fatigue of the hands [8,11].

In currently used forceps the friction in the mechanism of the forceps causes a low mechanical efficiency of less than 50%. Due to the low mechanical efficiency, the surgeon has little pinch force feedback. Improved designs lead to mechanical efficiencies higher than 90% [1,5]. Other solutions to improve the mechanical efficiency can be found in the field of robotics [2,6]. By measuring the forces in the tip of the instrument, and coupling these forces back to the handle, it should be possible to provide the surgeon with an accurate force feedback. These systems, however, are not yet available and will be very expensive. Force feedback can also be displayed on for example a monitor, representing the level of force. A disadvantage of this method is that the surgeon has an extra variable to monitor. A more simple mechanical solution is a forceps equipped with a device to limit the pinch force. However, taking the variation between patients into account, this device should be adjustable for each patient and the damage force should be known.

In Chapters 7 and 8, experiments are described with a grasper with improved mechanical efficiency. For just holding tissue, enhanced mechanical efficiency did not improve the performance, since the pinch force exerted on the tissue was still twice as high as needed. Moreover, the use of a grasper with a lower mechanical efficiency of 30% resulted in a more constant pinch force on the tissue. Contrary, for tasks involving repeatedly moving of the jaws, when reproducing a dynamic force, an improved mechanical efficiency improved the performance. Therefore, the optimal mechanical efficiency of laparoscopic forceps depends on the task to perform.

The findings of the experiments described in this thesis as tissue strength, jaw design and optimal efficiency, lead to guidelines both for engineers for the design of forceps and for surgeons for the use of grasping forceps for bowel tissue.

9.6 Guidelines for the design of laparoscopic forceps

From the experiments described in Chapter 6, it can be derived that two properties of jaws are important for safe manipulation: the size of the contact area which should be as large as possible with a laparoscopic approach, and the jaws should possess a profile. In addition, it was suggested that the jaws should provide enclosure [10]. When the jaws grasp partially around the tissue, the pinch force to prevent slip can be lower, since the tissue is not entirely held by friction.

The size of the jaws is restricted both in width and length, since the forceps is introduced to the abdomen through trocars with a diameter of 5 or 10 mm and since the workspace between abdominal wall and colon is limited. Nevertheless, the contact area with the tissue should be as large as possible. When more tissue is in contact with the jaws, the pressure on the tissue is lower, which means that more force can be exerted on the tissue before it is damaged. Small curvatures of the jaws generate locally increased pressures on the tissue and thus should be avoided. In contrast, entirely flat jaws do not provide enough grip on the tissue. Therefore, a profile is necessary to improve the grip.

Compared to flat jaws a profile enhances the grip on the tissue, whereas the damage force remains the same. The profile should not be too sharp or protruding too much. In the experiments a diamond-shaped profile protruding 0.3 mm provided the best damage-slip ratio. Possibly a lower profile may be as effective. Jaws with a ribbed profile of the same depth showed approximately the same results. Still, a diamond-shaped profile can be preferred to a ribbed profile, since a diamond-shaped profile is also functional for forces exerted in directions other than in line with the instrument.

When the tissue can be grasped by partial enclosure instead of entirely by friction, the exerted pinch force can be lower. Jaws with windows allow grasping of tissue using enclosure. These windows, however, strongly reduce the contact area of the jaws, thereby decreasing the force causing damage. A more suitable method to allow enclosure seems protruding of tissue at the back of the jaws, combining a large contact area with the effect of enclosure. For enclosure long jaws are needed. The advantage of long jaws is that the tip of the jaws closes more in parallel, leading to a more even distribution of pressure compared to short jaws.

As mentioned in Chapter 8, the optimal mechanical efficiency depends on the main task performed with the forceps. When tissue is just pulled aside, a little amount of friction in the forceps provides a more stable grasp. When structures on the tissue should be perceived, the mechanical efficiency should be as high as possible.

The transmission of the force from handle to tissue can be larger than 1:1. A suitable force transmission seems 3:1, since larger forces can be applied to the handle, leading to small, accurate forces on the tissue.

9.7 Guidelines for the use of laparoscopic forceps

Manipulation of tissue can only be safe when the surgeon has enough experience in handling laparoscopic instruments.

Choice of forceps

First of all, from the large amount of available laparoscopic grasping forceps, the most suitable forceps to manipulate delicate bowel tissue should be chosen. Additional to the properties of the jaws mentioned in the previous section, the forceps should possess an ergonomic handle and an, for the task performed, optimal mechanical efficiency. Such a forceps will allow optimal force transmission and will prevent unnecessary high pressures on the tissue.

Use of forceps

Surgeons should always be aware to exert the lowest possible forces to avoid tissue damage and at the same time to avoid slip of the tissue. Due to the large intervariability in bowel strength between patients, these minimal and maximal forces will be different for each individual patient.

Next to applying the minimal pinch and pull forces, the direction of the forces should be taken into account. Rotation of the forceps can cause high local pressures on the side or tip of the jaws and therefore should be avoided. An optimal placement of the trocars and of the forceps on the tissue facilitates grasping of tissue. The use of a ratchet to fixate the tip of the forceps should be used with caution, since the forceps still can rotate and thereby inadvertently damage the tissue. Slip of tissue out of the grasper should be prevented. Besides delaying the surgical procedure, slip may also lead to tissue damage.

Stretching tissue for a long time during dissection of the bowel is a difficult task. Especially during colon surgery, the forceps is frequently pulled outside the laparoscopic view and therefore not only the force feedback but also visual feedback is limited. Although it was found that visual feedback is of limited importance in applying the pinch force, it probably will be more important in applying the pull force, since force feedback of this pull force is impaired by the friction in the trocar. To prevent damage, the forceps with the tissue should be in view whenever possible.

9.8 Conclusions

Although little research has been performed on safe grasping forceps, many problems exist when manipulating tissue. The forceps can be optimised by changing the design of the jaws and the mechanism. Jaws should have a large contact area with the tissue to reduce tissue damage. Jaws should possess a slight profile to limit tissue slip. The mechanism should be optimised for the main task performed with the forceps. A high mechanical efficiency is needed when changes in tissue stiffness have to be perceived and for dynamic gripping tasks. The mechanical efficiency can be lower when the tissue is only pulled aside, which can even be helpful to keep the force on the tissue more constant.

The forceps should always be used with caution, preferably under vision. Minimal pinch and pull forces should be applied to avoid tissue damage, taking differences in tissue strength between individual patients into account. Since pig bowel tissue is comparable with human bowel tissue, the safety of forceps can be tested on pig bowel tissue.

9.9 Recommendations for future research

In addition to the guidelines, several recommendations for future research on tissue grasping can be given.

To begin with, mechanical properties of soft tissue should be studied further. Simulation models of the complex dynamic behaviour of tissue (Finite Element Models) should be made. With these models, the effects of pinching and pulling with new instrument designs can be predicted using less animals for experiments and without the large variation in results found in animal experiments. Other organs, such as the gallbladder, which are also grasped laparoscopically should be investigated. A comparison in tissue strength and recovery should be made between healthy tissue and affected tissue, since during the surgical procedure, the forceps should sometimes also grasp affected tissue. One of the greatest challenges is to quantify tissue damage and to predict the long term effect of this tissue damage.

On the field of jaw design the optimal depth of the profile should be studied further to find the optimal profile. The material of the jaws can be changed from stainless steel to a material having more grip on the tissue and causing less damage. It might well be that materials as silicone or more porous material have these properties. Clearly, it should be kept in mind that the material should withstand sterilisation at least one time. Additionally, more revolutionary ideas of jaws with multiple fingers or grasping tissue using vacuum can be studied. Instead of grasping based on force, grasping based on shape of the grasped organ can be investigated, leading to lower pinch forces on the tissue.

The mechanical efficiency of the forceps should be adapted to the tasks performed with the forceps. Therefore the optimal mechanical efficiency for each tasks should be obtained. The force transmission should be optimised by constructing the mechanism of the forceps in such way that when the surgeon exert a safe force on the tissue, the surgeon feels an easily reproducible force at he handle. However, care should be taken to maintain the same force transmission for all forceps, since the surgeon frequently changes instruments during a surgical procedure. An interesting research topic might be to investigate if the force transmission function should be constant throughout the full circle of opening and closing the forceps. In presently used forceps this force transmission function is far from constant, leading to different forces on the tissue dependent on the opening angle of the jaws.

The knowledge of all aspects of safe tissue manipulation should result in improved, reliable instruments. New instruments might contribute to the laparoscopic performance of more complex procedures, which are now being performed open. The development of new instruments should always involve an intensive collaboration of the technical and medical field.

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Appendix A

Forceps with adjustable mechanical efficiency

In Chapters 7 and 8, experiments are described using a grasper with a load cell and an adjustable mechanical efficiency (Fig. A.1). The grasper is designed and constructed at the section of Man-Machine Systems. Since the grasper is used in experimental, open surgery, no restrictions for size or weight are made. Nevertheless, the parts that constitute the interface with the surgeon are made as similar as possible to currently used laparoscopic forceps. Therefore, the total length of the forceps is 350 mm. Special attention is paid to the size and material of the handle. According to current handles, the openings in the handle are 45 by 22 mm for the fingers and 30 by 22 mm for the thumb and the edges are rounded. The opening angles of the handle are 33 degrees with closed jaws and 48 degrees with fully opened jaws. The handle is made of PVC.

To minimize the total weight, most parts are made of aluminium, except for the parts that adjusted the friction, which are made of steel. The weight of the upper arm is counterbalanced by a weight at the end of the upper arm. In total, the weight of the forceps is 520 g, five times larger than the weight of current forceps. This weight, however, did not disturb the subjects, since the forceps was hanging from cords.

The long arms close parallel. In this way the pinch force on the tissue is independent of the position and thickness of the tissue. The hinges consist of six ball bearings with diameters of 7 and 9 mm. The friction in these ball bearings is low enough to obtain a mechanical efficiency of 90%. By pushing two spring-loaded bars against the friction discs, the amount of friction can be adjusted and increased by moving the springs towards the jaws of the forceps. With increasing friction, the mechanical efficiency of the forceps decreases. The force transmission between handle and jaws is about 1:1, which means that without friction, a certain force on the handle results in the same force of the jaws on the tissue.

Although this method of introducing friction seems different from the friction of currently used instruments, the principle is the same. The friction is caused by steel on steel contact of various parts, resulting in the same characteristcs. The friction is mainly caused by the arms contacting the discs on the mechanism, whereas the friction in currently used forceps is caused by the slide bearings and possibly the shaft. However, this difference in friction can not be perceived by the subjects, since in both cases it is the friction between handle and jaws.

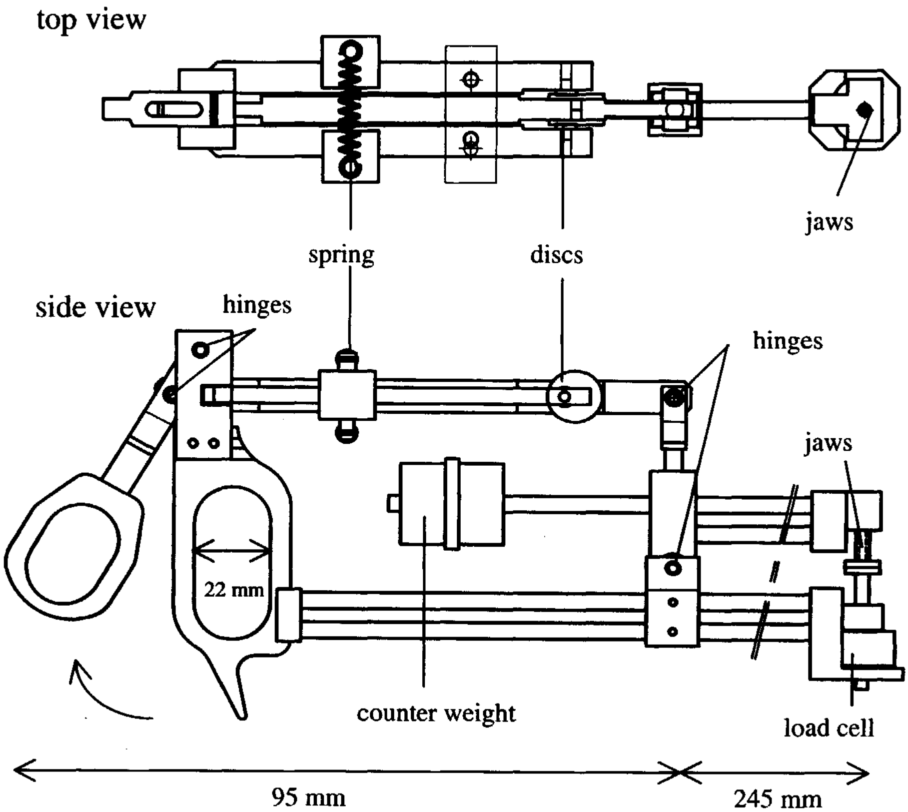

Figure A.1 Top and side schematic view of the forceps. The arms at the right side are shortened for the drawing. The brake system to introduce the friction and the four hinges are indicated. The counter weight compensates for the weight of the upper jaw. When the handle for the thumb (left) is moved to the left, the jaws are opened.

Appendix B

Measuring the mechanical efficiency of forceps

Friction in the mechanism of the forceps during a cycle of opening and closing of the jaws causes energy dissipation. The ratio between input and output energy is the mechanical efficiency. The mechanical efficiency was assessed by using the test set-up schematically shown in Figure B.1. The forceps was clamped in a vice and 3 N was placed on the upper jaw, representing a pinch force. The handle of the forceps was connected via a thread to the load cell, which was placed on a positioning table. To exclude the effect of elasticity of the thread, a double thread, as short as possible, was used.

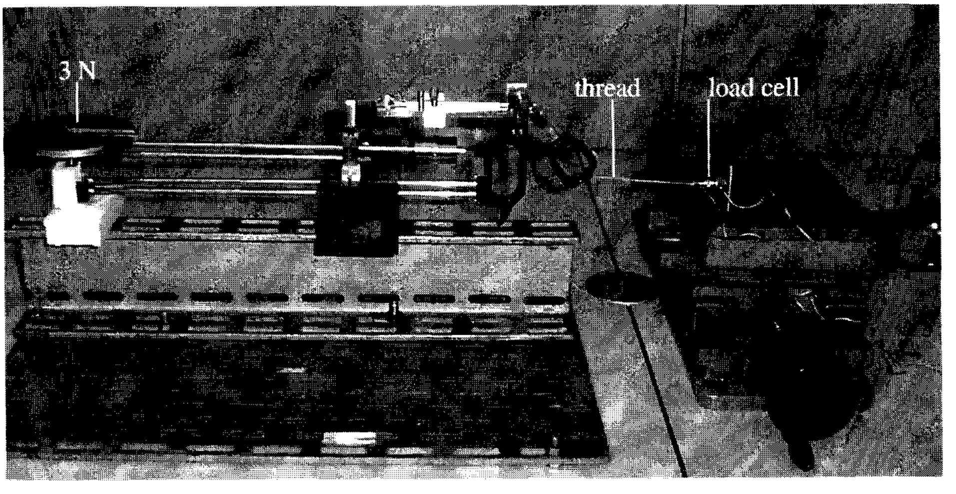

Figure B.1 The test set-up used to measure the mechanical efficiency. The handle of the forceps was opened and closed, while the force was measured by the load cell and the displacement by the positioning table.

The measurement started when the jaw was closed and the thread was without tension. Then, the handle was opened using the positioning table manually with a constant velocity of approximately 8 mm/min. When the jaws were entirely opened, at a displacement of the handle of 10 mm, the jaws were closed with the same velocity. During the measurement, the force was registered each 0.5 mm.

Force-displacement functions are shown in Figures B.2 and B.3. A 6th order polynomial was fit through these data points and the areas below the upper and lower curves were calculated numerically. The mechanical efficiency was defined as the percentage of area below the lower curve from the area below the upper curve. The mechanical efficiency could be measured with a standard error of less than 1%.

The measurements were repeated with the friction mechanism on the forceps in several positions, until the positions resulting in a mechanical efficiency of 30% and 60% were found.

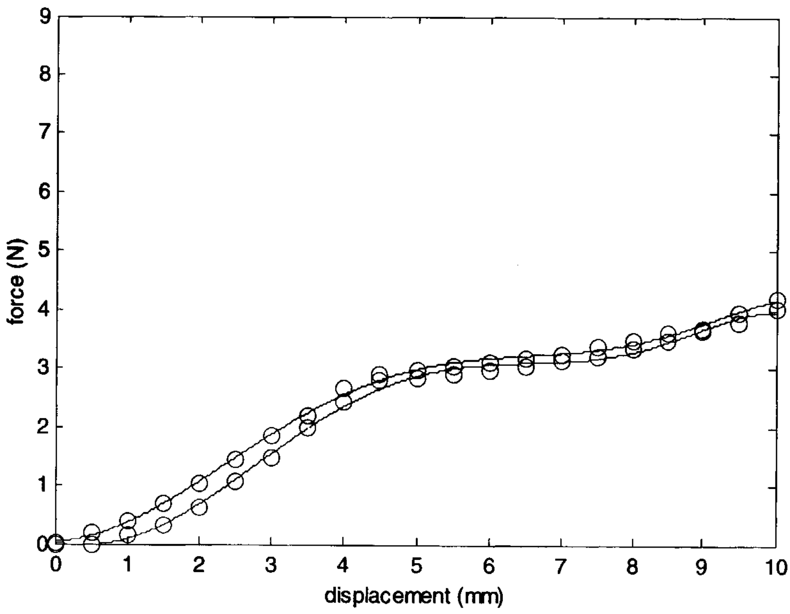

Figure B.2 The force-displacement curve of the forceps without the friction mechanism. At a displacement of 0 mm, the jaws were closed, at 10 mm the jaws were entirely opened. The upper curve represents opening of the jaws, the lower curve closing of the jaws. The area between the curves is the energy loss. The mechanical efficiency is about 92%.

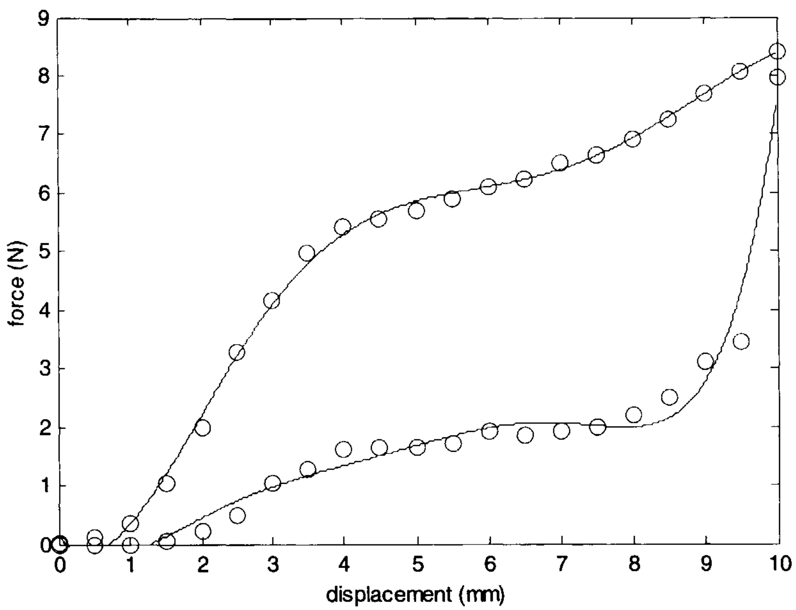

Figure B.3 The force-displacement curve of the forceps using the friction mechanism. The area between the curves is much larger than in Figure B.2. Consequently, the mechanical efficiency is only about 34%.

Summary

Tissue manipulation in laparoscopic surgery

Laparoscopic surgery is a relatively new method to perform operations in the abdomen. The procedure is performed through small incisions with the use of special instruments and an endoscope. The benefits for the patients are reduced tissue damage, leading to improved cosmetics, less pain and a shorter hospital stay. These advantages are accompanied by difficulties for the surgeon. Hand-eye coordination is impaired and the tissue can only be manipulated with long, rigid instruments. Especially when performing a colectomy, the bowel tissue is frequently stretched by the grasping forceps in one hand, while performing the dissection action with the instrument in the other hand. Since the quality of these grasping forceps is not optimal, surgeons have difficulty in applying the appropriate forces to the tissue, which can lead to slip of tissue out of the forceps, tissue damage, or even bowel perforation.

In this thesis, the factors related to manipulation of bowel tissue were evaluated. The minimally required forces and the maximally allowable forces during safe manipulation of bowel tissue are obtained. Special attention is paid to the influence of tissue properties, jaws of the forceps and of perceptive information that the surgeon needs to manipulate tissue.

An evaluation of the use of forceps while manipulating the bowel was made. From video analyses it was derived that the bowel is manipulated on average more than 100 times during a colectomy. In only 63% of the grasping actions, the bowel is grasped without slip or damage and held in the laparoscopic view. The duration tissue is grasped is obtained and used in the experiments.

The tissue properties and the local forces on the tissue influence the probability of tissue damage. Since tissue damage is difficult to quantify, it has been chosen to compare the macroscopically visible damage in terms of imprints in the tissue and in terms of perforations. With this method it was demonstrated that at low forces no imprints were found, whereas at higher forces the imprints became clearly observable. At very high forces also perforations in the tissue were found. When manipulating tissue, a combination of pinch and pull force is necessary. It was found that both an increase in the pull force and an increase in the pinch force enlarge tissue damage significantly.

To determine the safety of graspers, pig bowel tissue was used in all experiments. Measuring the electrical resistance between the jaws was a reliable method to measure perforation forces. It was found that the perforation forces of pig and human bowel tissue are comparable. Therefore, the safety of a grasper can be measured on pig bowel.

However, particularly the inter-individual variation in perforation forces was large. Considering this large variation in tissue strength, forceps should be used with caution on various patients.

The safety and suitability of various jaws were compared using a model of tissue slip and tissue damage. At a high pull force, the minimally required pinch force to prevent slip and the maximally allowed pinch force without causing damage were measured for 13 different jaws. The highest damage-slip ratio was found for jaws with a large contact area, rounded edges and a slight diamond-shaped profile. Using these jaws, the pinch forces resulting in tissue damage were 9 times higher than the pinch forces necessary to prevent tissue slip.

Friction in the mechanism of the forceps reduces the mechanical efficiency and thereby the force feedback. To test the influence of force feedback and visual feedback during grasping tissue, a grasper with a load cell in the tip and a mechanism to adjust the mechanical efficiency was developed. The pinch force that subjects exerted on bowel tissue was measured. The results showed that the applied pinch force on the tissue was generally twice as high as needed. No effect on the exerted pinch force was found of mechanical efficiency, visual feedback and laparoscopic experience. A little amount of friction in the forceps appeared useful when a constant pinch force on the tissue was required.

Several experiments were performed to determine the optimal mechanical efficiency for laparoscopic forceps. Reproducing a dynamic pinch force was performed more accurately with higher mechanical efficiency, whereas the performance in reproducing a static pinch force was not increased with increased mechanical efficiency. It is concluded that tasks requiring movement of the jaws to feel tissue can best be performed using forceps with high mechanical efficiency, whereas tasks requiring a constant pinch force can best be performed using forceps with lower mechanical efficiency. Therefore, the optimal mechanical efficiency of laparoscopic forceps depends on the tasks to be performed.

In conclusion, the results of the experiments described in this thesis have led to insight in which factors are involved in manipulation of tissue. Tissue properties, shape of the jaws and mechanical efficiency of the forceps have been investigated.

Eveline Heijnsdijk, 2004

Samenvatting

Weefselmanipulatie tijdens laparoscopische chirurgie

Laparoscopie is een relatief nieuwe methode voor het uitvoeren van operaties in de buikholte. De operatie wordt uitgevoerd door kleine sneden met behulp van speciale instrumenten en een endoscoop. Het voordeel voor de patiënt is minder weefselschade, met als gevolg minder littekens, minder pijn en een korter ziekenhuisverblijf. Deze voordelen gaan vergezeld met moeilijkheden voor de chirurg. De oog-handcoördinatie is verstoord en het weefsel kan alleen worden gemanipuleerd met lange, stijve instrumenten. Met name tijdens het uitvoeren van een colectomie wordt het darmweefsel vaak opgespannen met een paktang in de ene hand, terwijl de dissectie wordt uitgevoerd met het instrument in de andere hand. Omdat de kwaliteit van deze paktangen niet optimaal is, heeft de chirurg problemen om de juiste kracht op het weefsel uit te oefenen, wat kan leiden tot het uit de tang slippen van weefsel, schade aan het weefsel of zelfs een darmperforatie.

In dit proefschrift worden de factoren die een rol spelen tijdens het manipuleren van darmweefsel geëvalueerd. De minimaal-benodigde en de maximaal-toegestane krachten voor het veilig manipuleren van darmweefsel zijn bepaald. Er is vooral gekeken naar de invloed van weefseleigenschappen, de rol van de bekjes van de tang en de informatie die de chirurg nodig heeft voor weefselmanipulatie.

Het gebruik van de tang tijdens het manipuleren van darmweefsel is geëvalueerd. Uit videoanalyses is gebleken dat de darm gemiddeld meer dan 100 keer per operatie wordt vastgepakt. In slechts 63% van deze pakacties is de darm gepakt zonder uit de tang te slippen of te worden beschadigd en in zicht van de laparoscoop. De tijdsduur dat het weefsel wordt vastgehouden is bepaald en werd gebruikt in de experimenten.

De weefseleigenschappen en de locale krachten op het weefsel beïnvloeden de kans op weefselschade. Omdat weefselschade moeilijk te kwantificeren is, is er voor gekozen om de macroscopische schade zoals afdrukken in het weefsel en perforaties te vergelijken. Met deze methode is aangetoond dat er bij lage krachten geen afdrukken gevonden worden, terwijl bij hogere krachten de afdrukken duidelijk zichtbaar worden. Bij zeer hoge krachten ontstaan er ook perforaties in het weefsel. Als weefsel gemanipuleerd wordt, is een combinatie van knijpkracht en trekkracht nodig. Er is aangetoond dat zowel een toename in trekkracht als een toename in knijpkracht de weefselschade significant vergroot.

In alle experimenten werd darmweefsel van varkens gebruikt om de veiligheid van paktangen te bepalen. Het meten van de elektrische weerstand tussen de bekjes van de tang bleek een betrouwbare methode om perforaties te meten. Er werd gevonden dat de perforatiekrachten van varkensweefsel en humaan weefsel vergelijkbaar zijn. Daarom is varkensdarmweefsel geschikt om de veiligheid van een paktang te bepalen. Echter, vooral de inter-individuele variatie in perforatiekrachten was groot. Gezien deze grote variatie in weefselsterkte, moeten de tangen bij patiënten zo voorzichtig mogelijk worden gebruikt.

De veiligheid en bruikbaarheid van de bekjes van de tangen werden vergeleken met behulp van een model voor weefselslip en weefselschade. Met een relatief hoge trekkracht werden de minimaal-benodigde knijpkracht om slip te voorkomen en de maximaal-toelaatbare knijpkracht gemeten met 13 verschillende bekjes. De hoogste schade-slip ratio werd gevonden voor bekjes met een groot contactoppervlak, afgeronde randen en een ondiep, ruitvormig profiel. Voor deze bekjes was de knijpkracht die schade veroorzaakte 9 maal hoger dan de knijpkracht die nodig was om slip van het weefsel te voorkomen.

Wrijving in het mechanisme van de paktang vermindert de mechanische efficiëntie en daarmee de krachtterugkoppeling. Om de invloed van krachtterugkoppeling en visuele terugkoppeling te meten is een paktang met een krachtsensor in de tip gemaakt. De knijpkracht die proefpersonen op darmweefsel uitoefenden werd gemeten. De resultaten lieten zien dat de uitgeoefende knijpkracht op het weefsel meestal twee maal hoger was dan nodig. Er werd geen effect van mechanische efficiëntie, visuele terugkoppeling en laparoscopie-ervaring op de gebruikte knijpkracht gevonden. Een beetje wrijving in de tang bleek nuttig om een constante knijpkracht op het weefsel te houden.

Verschillende experimenten werden uitgevoerd om de optimale mechanische efficiëntie van laparoscopische tangen te bepalen. Een dynamische knijpkracht kon nauwkeuriger gereproduceerd worden met een hogere mechanische efficiëntie, terwijl de prestatie bij het reproduceren van een statische knijpkracht niet verbeterd werd met een hogere mechanische efficiëntie. Geconcludeerd werd dat de taken waarvoor beweging van de bekjes nodig is om weefsel te voelen het best kunnen worden uitgevoerd met een hoge mechanische efficiëntie, terwijl taken waarvoor een constante knijpkracht nodig is het best kunnen worden uitgevoerd met een lagere mechanische efficiëntie. Daarom is de optimale mechanische efficiëntie van een laparoscopische tang afhankelijk van de taken die ermee gedaan worden.

Concluderend kan gesteld worden dat de resultaten van de experimenten die in dit proefschrift beschreven zijn, inzicht hebben gegeven in de factoren die een rol spelen tijdens het manipuleren van weefsel. Weefseleigenschappen, het ontwerp van de bekjes en de mechanische efficiëntie van de tangen zijn daarbij onderzocht.

Eveline Heijnsdijk, 2004

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Als bewegingswetenschapper viel het soms niet mee tussen twee nieuwe werelden (de technische en de medische) te werken. Gelukkig waren overal mensen bereid mee te denken en te helpen.

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Curriculum Vitae

23/2/1976	Born in Delft
1988-1994	Gymnasium at Sint-Stanislascollege in Delft
1994-1999	MSc-study Human Movement Sciences at the Vrije Universiteit, Amsterdam. Specialisation in exercise physiology and biomechanics, with a study on the mechanical efficiency of the klapskate
2000-2004	PhD-study at the Delft University of Technology, department of Mechanical Engineering and Marine Technology, section Man-Machine Systems and Control. The project was embedded in the MISIT (Minimally Invasive Surgery and Interventional Techniques) program, in cooperation with the Academic Medical Center Amsterdam.