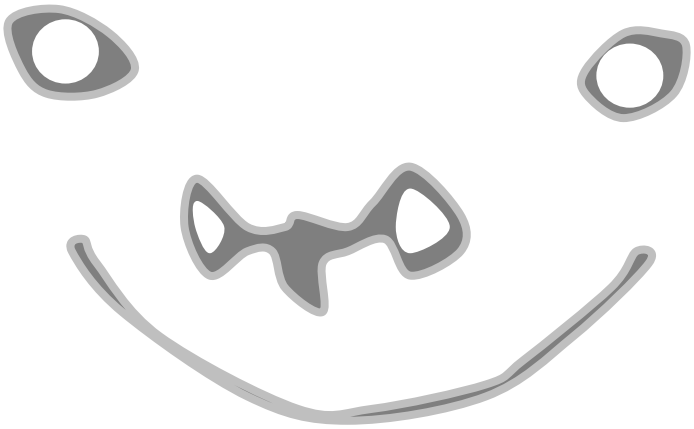
The feasibility of vacuum technique in minimal invasive surgery

Improving the patient safety through instrument design



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Content

Chapter 1.

General Introduction

Context

Current operating rooms are filled with an enormous scala of devices and instruments. Some devices are big and some are small. Some devices utilize electronics and software while some are manually controlled and function mechanically. These devices share a purpose to positively contribute to the surgical procedure and not to compromise the patient safety. A specific element of the surgical procedure is the grasping and holding of organs. Grasping, handling and manipulation of soft organs and tissue has always been conducted by means of so called conventional grasping. Conventional grasping is characterized by applying a pinch force to the organ in order to grasp it [1]. Such instruments are among other things characterized by a pair of grasper jaws. There are many types of grasper jaws to grasp the organ. Conventional grasping has its origins in the primary functions of hands, namely to obtain a better 'grip' on the surroundings. Basically the human hand itself was and still is the first grasper jaw, all other types of jaws are derived from thereon. The grasp instrument is basically an extension of the hand and is more precise and robust.

In contrary to the surgical field, a variety of grasp techniques are applied in industry for all sorts of applications. Examples of other types of grasp and hold forms which are frequently utilized outside the surgical field are, magnetics, Velcro, vacuum (pressure), knots (rope), hooks and clasps, fasteners and glue.

The grasp types as described above can be linked to minimal invasive surgery (MIS) as follows. Magnetic grasping (retraction) is being investigated regarding their potential as grasp technique in a surgical setting [2]. Velcro is not utilized as grasp technique in the surgical field. Vacuum has been studied as grasp technique however is not applied as such in today's operating room [3, 4, 5]. Knots, being suturing, hooks and clasps are common grasp and hold techniques concerning surgical products and procedures. Fasteners such as click fasteners and tie wraps are used but less common (gastric band). A different type of grasping can be found in muco-adhesives which is being studied [6].

The medical context of this thesis is minimal invasive surgery (MIS), more specifically laparoscopic surgery. MIS characterizes itself by the small incisions (5 to 12 mm) made through which so called trocars are fixed. Long thin instruments and an endoscope are inserted through the trocar. The surgeon visualises the procedure by means of the scope and a monitor. The benefits of MIS are summed up as, less physical discomfort for the patient, shorter recovery time and improvement of the aesthetic aspect concerning the patient [7, 8]. Disadvantages, for the surgeon, are poor eye-hand coordination due to visualization of the procedure through monitors, limitations in the degree of freedom of instrument

use, the requirement to translate a 2D image on a screen to the 3D situation of the procedure, and instrumentation which is not optimally designed [7, 9].

Grasping in MIS is conducted with so called laparoscopic graspers. These graspers are generally derivatives of instruments used in open surgery[1] [10]. The performance of these graspers depends on the technical and medical functionality, the skills and experience of the user, the surgeon, and the comfort of use related to the instrument [7, 9].

The foremost characteristic required for any grasp instrument in grasping soft organs and tissue is the so called 'safe grip'. The technical and medical functionality of any grasp instrument depends on this property. In the safe grip two aspects are important. The first aspect is the grip on the tissue which must be sufficient to ensure the manipulation of an organ. The second aspect concerns the prevention of potential tissue damage caused by the act of grasping. The combination of sufficient grip and a damage-free grip translate into the safe grip, or a safe instrument-tissue interaction [11, 12]. A safe grip adds to the prevention of adverse events and therefore it enhances the patient safety during a surgical procedure for as far as the safe handling of organs is concerned.

The more skilled and experienced the surgeon the better the performance with the instrument. However, not every surgeon is that skilled and experienced which suggests that the performance with the grasp instruments is not a constant. It is desired that the performance actually should be a constant regardless of the skills and experience of the user (a goal that is the central theme of this thesis). This leads to the question whether an instrument can be developed which performance does not depend for such a great part on the users competences and limitations.

Another aspect of a safe grip can be found in the comfort of use of the grasp instrument. The instrument may provide sufficient grip and cause no damage what so ever, however, when the surgeon experiences discomfort due to the use of the device, the instrument is nonetheless useless and potential harmful since discomfort in the usage of the instrument may induce physical pain to the surgeon and abusive use of the device [13].

Patient safety

The patient safety during a hospital stay, between arrival and departure, depends on many factors. Concerning the surgical procedure the patient safety is closely related to and dependent on the skills and experience of the surgeon, the state of mind of the surgeon and the adequacy of the equipment and

[1] Conventional open surgery is a type of surgery where a relatively large incision compared to minimal invasive surgery is made in order for the surgeon to insert the instruments. The surgeon visualizes the procedure through the incision.

instruments [9, 13]. The patient safety then, during a surgical procedure, is defined as the completion of a procedure throughout which no adverse events take place which compromise the physical (and also mental) wellbeing of a patient. The focus of this thesis is on the usage of the instruments, more specifically on grasp instruments. As stated before, the performance of these grasp instruments depend largely on the skills and experience of the surgeon though it is noted that the performance, and therefore patient safety, may also be compromised if the instrument is inadequate. Adequacy in this context means that the instrument functions according to its description. Nevertheless the surgeon remains responsible during the whole surgical procedure and responsible with regard to the result of the procedure even though sometimes the instruments can be inadequate. Therefore it is of great importance that the (grasp) instruments function optimally according their description and intended use.

Research subject

Vacuum technique as grasping technique for MIS was chosen as research subject for this thesis. There were three main reasons for this choice. First, vacuum technique is a widely applied grasp technique in industry. It is used in automatized industrial settings as well as manually operated devices. All sorts of objects are grasps using vacuum force, objects with smooth surfaces and rough surfaces, objects which are very heavy and very light, robust and delicate, hard and soft and all kinds of sizes. This enormous variety in application leads to the presumption that vacuum technique has potential to be used in a laparoscopic setting in order to grasp soft organs. In medicine vacuum technique is also used, however, the applications are far less numerous as it is in industry. A few examples of vacuum applications in the medical field are, a vacuum pump for baby delivery, vacuum assisted wound closure, the vacuum connection in the operating room, laboratory applications and a beating heart stabilizing system [14]. Second, the potential induced by its variety of applications in industry, vacuum technique, as grasp technique for MIS, has been studied concerning its potential [3, 4]. These studies underline the potential of vacuum technique however, the findings were not translated to actual applications in MIS nor was any knowledge provided concerning the conditions or requirements in relation to vacuum grasping which ensure a safe grip. The third aspect of vacuum technique is its physical principles. Vacuum grasping is a very controlled and homogenous way of grasping. When an object is grasped by means of vacuum, the forces are equally distributed over the grasped area. The nozzle of a vacuum grasper also does not contain any moving parts which depend on the mechanical soundness of the device. In that sense, the vacuum technique appears to be, at least for a part, independent of the user.

The ‘object’ type which will be grasped by means of vacuum is the bowel. The bowel is an organ which is frequently grasped during MIS procedures. It is a very delicate and easily damaged. Bowel damage can have serious consequences for the patient [15, 16, 17]. Concerning the current used graspers extensive research has been conducted concerning to grasping the bowel. With regard to grasping the bowel no research has yet been conducted concerning different types of grasp techniques. Therefore it is interesting to investigate whether vacuum technique can be utilised as grasp technique for MIS.

Problem definition

In today’s technology overloaded operating room, it is of the upmost importance that the equipment and instruments work properly and are tuned to one another. Despite incredible improvements and innovations in the surgical field, the workload increases and the procedures must be conducted faster, more efficient and safer, which applies also to grasp instruments. This induces a strong push toward optimisation and new developments in the field of grasp instruments [1, 10, 12, 18, 19]. Nevertheless how clever and innovative these new concepts and products are, their performance depends largely on the user. One can have the best racing car in the world and yet not be able to drive it. Instrument and user must be complementary to each other.

The surgeon relies primary on his skills and experience concerning the effective and safe use of grasp instruments [9]. The ideal grasp instrument matches these skills and experience. Therefore the instrument should also be recognisable as grasp instrument for the surgeon. Such properties add to a low threshold in order to use a new developed instrument.

Current conventional graspers have been researched as to their comfort of use. Fatigue and pain in hands and lower arms are common [7]. The comfort of use of a grasp instrument, a handheld device, depends largely on the physical dimensions and properties of the instrument. These physical dimensions and properties determine the size of the handle, the weight of the device, the forces required to operate the device and, the way the instrument is held [7, 20, 21, 22]. Comfort of use is a property which is difficult to measure since it also depends on the experience, capabilities and limitations of the user. Besides these instrument properties, the comfort of use also depends on other factors which are present in the operating room. Examples of such factors are, the position of the patient, the complexity of the procedure, the use of other instruments in relation to the grasp instrument, the types of manoeuvres to be undertaken with the grasp instrument.

Another important aspect in relation to the use of a grasp instrument is the patient. The instrument must also be tuned to the patient. The current conventional mechanical graspers used in de operating room are naturally all approved medical devices. Nevertheless, it is relatively easy to damage an organ

with these conventional instruments [11, 12]. This means that a new grasp instrument must be atraumatic in its use concerning the patient. Atraumatic means, as it is used in this thesis, that the instrument does not harm the patient, more specifically it does not harm the grasped organ (bowel). In that sense the instrument adds to the patient safety. It also means that the instrument should, in itself, prevent abusive or undesired use. To illustrate this in relation to the currently used mechanical grasper instruments, the instrument could have incorporated a system which signals the user when he exceeds the amount of acceptable force applied to the bowel or, the instrument could be in itself atraumatic by principle (this thesis) [12]. And yet even when such a system is incorporated, the surgeon can still exceed the maximum allowable force. Limiting the grasp force also does not increase the atraumatic quality of the instrument [11]. Therefore conventional mechanical graspers cannot be truly atraumatic.

As described in the previous paragraph, bowels are delicate and easily damaged. Bowel damage can have serious consequences and therefore it is important that reliable and safe grasper instruments are developed. Outside the medical field vacuum technique is frequently utilized due to the level of precision and control. Vacuum is therefore a promising technique which can be used to grasp the bowel. Roughly vacuum technique can be applied in two ways, automatic and manual. When applying automatic vacuum in the operating room either the vacuum connection or the pressure connection is used to generate vacuum. Considering a manually operated instrument, vacuum is generated by the surgeon most likely by hand force.

Research methods

Design Inclusive Research (DIR) was applied as the methodological tool concerning this project [23, 24]. DIR is characterized by the incorporation of design activities which support and provide as input for the research activities. This particular method was chosen due to the intention and necessity of developing vacuum grasp instruments on behalf of the research activities.

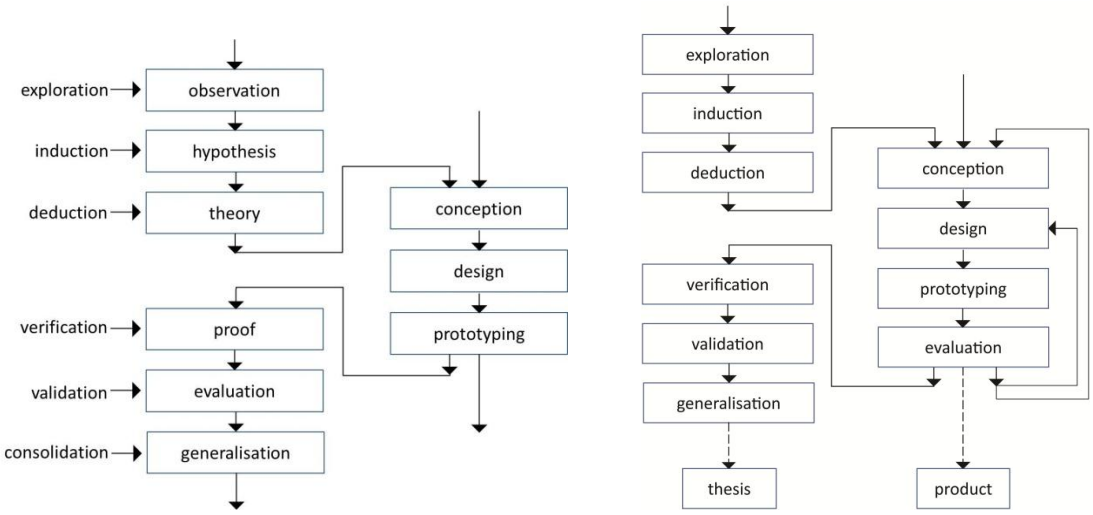

Figure 1.1. Schematic view of design inclusive research (DIR) on the left and the modified version incorporating an iterative basic design cycle on the right. [23, 24]

DIR exists roughly of three phases, an explorative research phase, a creative design phase and an evaluative research phase. The creative design phase as described in the model by Horvath (Figure 1.1, left) was modified (Figure 1.1, right) [23, 24]. An additional evaluation step was added to the creative design phase. This choice was made in order to have the possibility to evaluate the design activities also in the creative design phase. This makes it easier to repeat certain design steps or start from a few steps earlier in order to bring the design up to a satisfying level of development before entering the evaluative research phase. The creative design phase was approached as described in the basic design cycle by Roozenburg and Eekels [25]. Figure 1.1 shows the schematic view of DIR and the modified version of it. Chapter 8, methodological aspects, emphasises on the applied method with respect to its content.

Research question and focus

This thesis focusses on the feasibility of vacuum technique as grasp technique for MIS. This is based on the premise that we strive to a constant performance regardless of the skills and experience of the user. This translates to the research question as:

—*Is vacuum technique feasible as grasping technique for minimal invasive surgery?*—

This feasibility can be interpreted as the feasibility of a vacuum grasp instrument. The performance is determined by the technical and medical functionality of the instrument, the skills and experience of the surgeon and the comfort of use. This leads to three focus areas. The first to focus points are related to the technical and medical functionality. The third focus point is derived from the skills and experience of the surgeon and comfort of use.

First the grip on the bowel by means of vacuum. This relates to the technical functionality of a vacuum grasp instrument. The emphasis is on determining the conditions to obtain an optimal grip on the bowel. Grip is the property which determines level of effort which is required to grasp the bowel. Effort in this context can be explained as, how much vacuum force is to be applied in order to manipulate (stretching, pulling, lifting) the bowel in a MIS setting. The vacuum force (vacuum level) also depends on the dimensions of the grasp-element with which the bowels are grasped. The grip, noted as the applied vacuum force and dimensions of the grasp-element, is expressed in measurable variables.

Then the damage to the bowel caused by vacuum. This relates to the medical functionality of a vacuum grasper instrument. The emphasis is on determining the conditions which determine a safe grasp area in order to grasp the bowel. These conditions can be expressed, like the grip, in measurable variables. The variables which express the grip on the bowels are used as input to determine the 'safe' conditions concerning bowel grasping by means of vacuum. The conditions for both, grip on the bowel and damage to the bowel are determined in relation to vacuum grasping in MIS.

The third focus point is the comfort of use of a vacuum grasp instrument. This relates to the comfort of use of a vacuum grasp instrument. The emphasis is on functional and usage validation of (a) functional model(s) and product(s) which determine(s) the usability and comfort of use of a vacuum grasper instrument. Through these usability aspects the focus areas concerning grip on the bowel and damage to the bowel are connected and combined in an application.

The composed proposition is defined as:

—If vacuum technique provides sufficient grip on the bowel and, if vacuum technique does not cause any damage to the bowel and, if a surgeon can successfully use a laparoscopic vacuum instrument without experiencing discomfort, then vacuum technique can be regarded as feasible as grasp technique for minimal invasive surgery—

Then the so called intended use of a vacuum instrument can be defined. The intended use determines the exact functionality of a vacuum instrument, the user and the environment, and, considering it is a medical device, the intended use also determines in relation to whom the instrument is used. The purpose of the intended use in relation to this project is twofold. First, the intended use positions the idea or concept of a vacuum instrument as a (potential) medical device which leads to a preliminary set of requirements concerning the device. Second, it confirms the comprehensiveness of the described focus areas. The intended use was defined as:

—A laparoscopic vacuum grasper is a device which safely grasps the bowel by means of vacuum. The device is used by surgeons throughout minimal invasive surgery procedures during which the bowel needs to be manipulated—

Thesis layout

This thesis consists of 1o chapters including general introduction and summery. Chapters 2-7 form the central part of this thesis. The outline of this thesis can be described as follows.

Chapter 1 describes the context of the research, the research subject, research question and focus areas.

Chapter 2 describes a preliminary assessment of the feasibility of vacuum technique as grasp technique in MIS. Two functional models with specific nozzle types are used to manipulate pig bowels in an open in-vivo setting. The bowels are macroscopically assessed for tissue (bowel) damage. The physical principles of vacuum technique are explained. In addition to the conducted tests the functional models are also used to grasp the liver, gallbladder and spleen.

In chapter 3 two nozzle types are compared concerning their grip on the bowel. The nozzle type which was used for the assessment described in chapter 1, is further defined and compared with a standard nozzle. The standard nozzle is defined as a basic cylindrical shape. The aim of this chapter is to determine the conditions and dimensions which ensure a sufficient grip on the (pig) bowel. This chapter relates to the focus point, grip on the bowel (technical functionality).

Chapter 4 relates to the focus point, damage to the bowel (medical functionality). The most optimal nozzle shape as was determined in Chapter 3, is used for a series of damage tests. Pig bowels are grasped at different vacuum levels in an open in-vivo setting. The harvested bowel samples are microscopically assessed for tissue damage. The aim of this chapter is to determine the boundaries which determine a safe grasp area to grasp the bowels by means of vacuum.

Chapter 5 describes the technical performance of vacuum grasp instrument, a laparoscopic vacuum grasper (LVG). The LVG combines the results of chapters 2, 3 and 4. The technical specifications (capabilities and limitations) are determined and recommendations are provided concerning the improvement of the LVG.

The results of the usage validation of the LVG can be found in chapter 6. The instrument is used in the medical context of an training-laboratory (Skillslab) and used in a box trainer simulating a laparoscopic gastric bypass procedure. In addition this simulation was also conducted on life pigs. Concerning its use the LVG is characterized by short manipulations, the usage is dynamic. The aim of this chapter is to determine the feasibility of a manually operated vacuum instrument in relation to the three previously determined focus areas.

Chapter 7 describes the development of another vacuum grasp instrument, a laparoscopic vacuum retractor (LVR). Three functional models are evaluated in an in-vivo laparoscopic setting. The LVR is also evaluated concerning the three focus areas from the composed proposition. Concerning its use the LVR is characterized by grasping the bowel for relative long periods of time, the usage is dynamic.

The general discussion can be found in chapter 8. The aim of this chapter is to evaluate the research results. The results are recapitulated and explained in relation to the research question and the constructed theory. Then the impact of the results is discussed with regard to the implications for the medical field and patient safety, the limitations and recommendations toward future research and design activities concerning vacuum technique as grasp technique.

The methodological aspects related to this thesis are described and discussed in chapter 9. This chapter explains the steps taken which lead to the results as they are described and discussed in this thesis. This chapter closes with a discussion concerning the applied DIR method and the challenges it induced. Chapter 10 contains the summery of the thesis in Dutch as well as in English.

This thesis exists of a series of articles, some published and some submitted bundled together. Since each article is required to be an independent piece of work, the reader will experience some repetition amongst the thesis chapters. The author hopes that this does not hinder the reader in any way. Each chapter ends with a number of references instead of a reference list at the end of the thesis. The author finds this way of presenting the references more convenient to the reader. Due to this way of presenting the references, there is some redundancy amongst the reference lists between the chapters.

Figure 1.2 shows a schematic view of the chapters as they can be positioned in the modified DIR model of Figure 1.1.

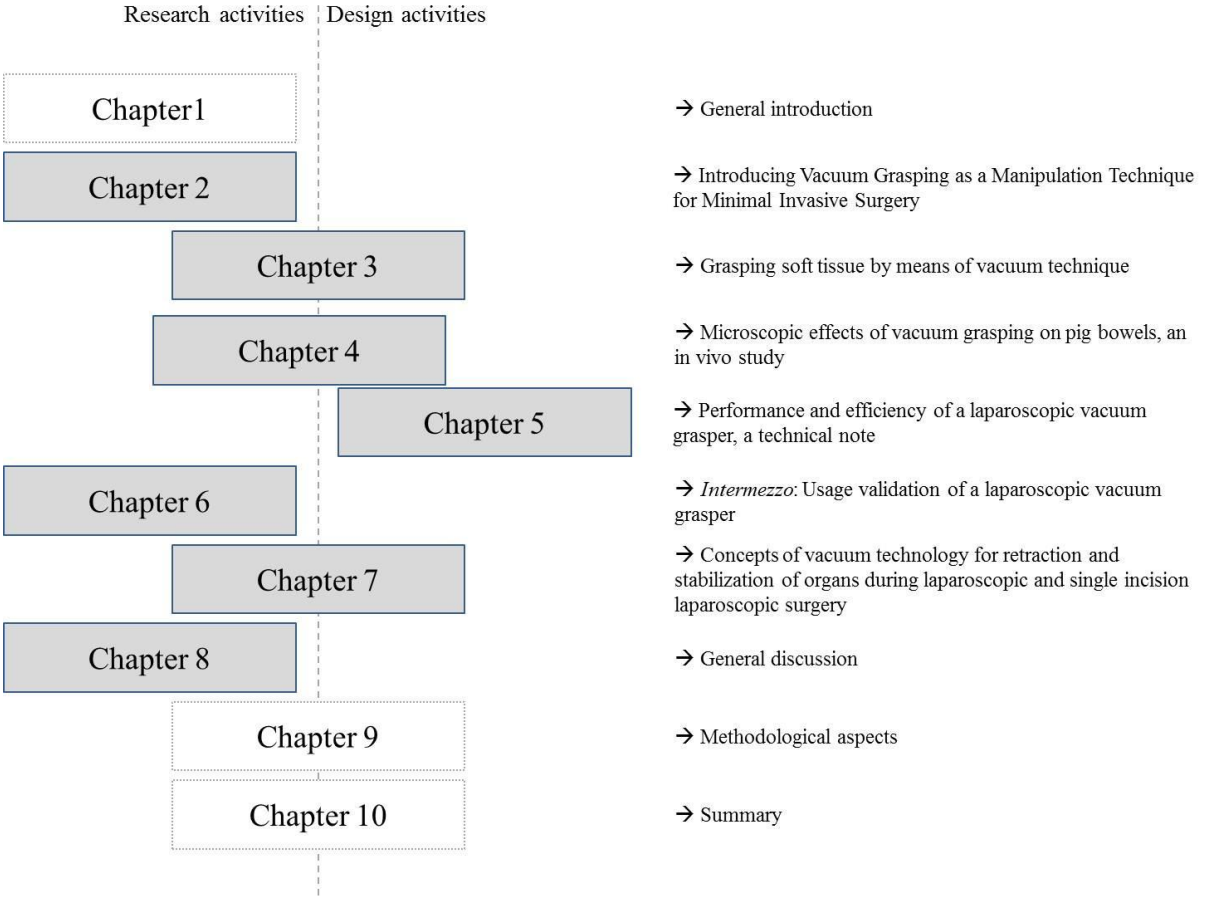

Figure 1.2. schematic view of the outline of the thesis chapters.

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Chapter 2.

Introducing Vacuum Grasping as a Manipulation Technique for Minimal Invasive Surgery

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Abstract

Background: Laparoscopic surgery requires special designed instruments. Bowel tissue damage is considered one of the most serious forms of lesion specifically the perforation of the bowel.

Materials: An experimental setting is used to manipulate healthy pig bowel tissue by means of two vacuum instruments. During the experiments two simple manipulations are carried out for both prototypes by two experienced surgeons. Each manipulation is repeated, 20 times for each prototype at a vacuum level of 60 kPa and, 20 times for each prototype at a vacuum level of 20 kPa. All manipulations are macroscopically assessed by two experienced surgeons regarding tissue damage the bowel.

Results: From the total of 160 observations, 63 ecchymoses were observed. All 63 ecchymoses were classified as not relevant and negligible. No serosa and/or seromuscular damages and no perforations were observed.

Conclusion: Vacuum instruments, such as the tested prototypes, have the potential to be used as grasper instruments for e.g. minimally invasive surgery (MIS).

Introduction

Laparoscopic surgery requires special designed instruments in order to manipulate the internal organs in a safe manner [e.g. 1 - 17]. Bowel tissue damage is considered one of the most serious forms of lesions [1, 18, 19, and 20] and perforation of the bowel causes peritonitis, which leads to high morbidity and mortality rates [18]. It is also possible to damage the tissue without immediate perforation. This may lead to local tissue necrosis, causing a delayed perforation of the bowel and resulting in serious complications for the patient [18, 21, 22, and 23].

In industrial applications, vacuum is a common and successful grasping technique especially when accuracy and delicacy is required. Some studies also show that vacuum technique can be used as a safe stabilizing and positioning technique during a surgical procedure [24, 25, 26, and 27].

In a joint project, Karl Storz and Delft University of Technology, two vacuum technique based grasper prototypes were developed (Patent No. NL2000796).

The aim of this study is to introduce vacuum technique as a technique for laparoscopic bowel manipulation by testing the of two vacuum grasper prototypes for bowel damage. In addition the prototypes are used to explore their performance regarding tissue damage on the liver, the spleen, and the gallbladder.

Materials and methods

An experimental setting is used to manipulate healthy pig bowel tissue by means of two vacuum instruments (prototype A and B, see Figure 2.1 and 2.2). The prototypes are constructed on the same technical principle and are constructed in such a way that both prototypes fit through a 12 mm trocar (Patent No. 2000796). Both prototypes are connected to a vacuum pump (Leybold, Germany). The vacuum pump generates a preset vacuum level (60 kPa and 20 kPa, where 100 kPa is the atmosphere and 0 kPa is the absolute minimum) measured by a vacuum transducer (Econtronic, Germany) and a calibrated vacuum reader with digital output (from 100 to 0 kPa). Both prototypes have two control options, grasping tissue and releasing tissue. In order to grasp tissue, the nozzle of the prototype is placed on the tissue surface and the opening of the shaft is closed off by means of a finger. The tissue is sucked into the nozzle. The nozzle of prototype A has an inlet diameter of 7.5 mm and a grasp volume of 0.66 ml. The nozzle of prototype B has an inlet diameter of 8.0 mm a grasp volume of 1.33 ml. Prototype A uses a one-way suction system and prototype B a two-way suction system (Figure 2.2). The suction systems determine the outer shape of both nozzles. The angle of the chamfered tip of prototype A is arbitrary chosen, therefore the chamfer has no intentional function. Both nozzles use strainers to prevent the tissue from bulging into the instrument. In order to release the grasped tissue, the finger is lifted up from the opening on the shaft to create a leak, which decreases the vacuum level causing the tissue to slip out of the nozzle.

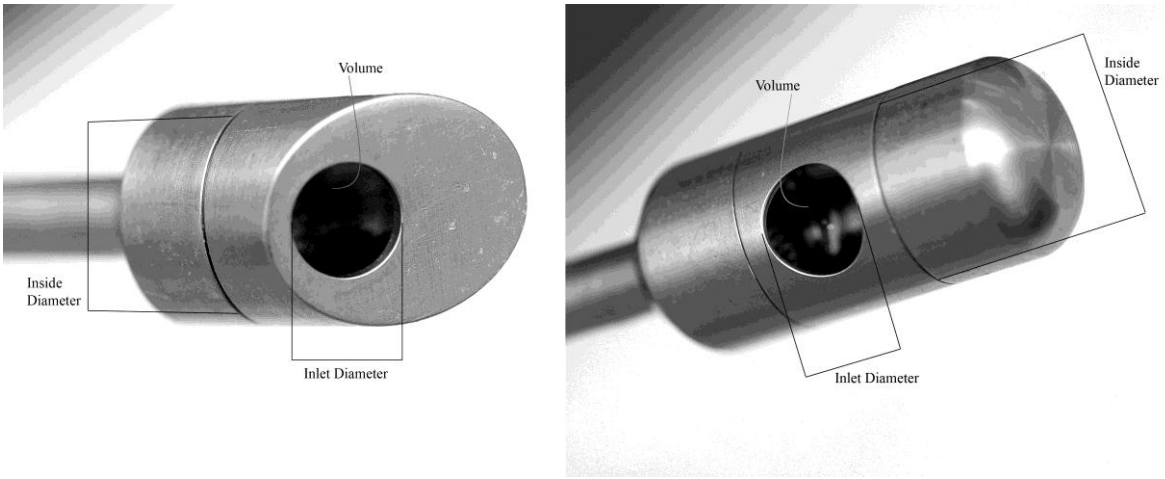

Figure 2.1. Prototypes A (left) and B (right)

During laparoscopic procedures, segments of the bowel often need to be moved and repositioned. Such manipulations require a firm grip on the delicate bowel. Two simple manipulations are carried out for both prototypes by two experienced surgeons to simulate such manipulations. For the first manipulation, the tissue is grasped and lifted 90° upwards 15 cm (Figure 2.4). For the second

manipulation, the tissue is grasped and pulled horizontally 20 cm (Figure 2.4a and 2.4b). Each manipulation is repeated, 20 times for each prototype at a vacuum level of 60 kPa and, 20 times for each prototype at a vacuum level of 20 kPa. 160 manipulations are assessed. In addition, the bowel is grasped at a level of 20 kPa for 60 seconds, once for each prototype. All effects of the manipulations are macroscopically assessed by two experienced surgeons regarding tissue damage. 15 minutes after the assessment of the 160 manipulations, both surgeons examine the small bowel for tissue damage as a final check-up. The tissue damages are categorized in five levels of visible damage: no damage at all, bruise or ecchymoses (tissue layers intact), serosa damage, seromuscular damage and perforation of the bowel. As an additional test, the liver and the spleen are lifted 90° upwards 10 cm and the gallbladder is grasped and elevated. All manipulations during this test are repeated 10 times at a vacuum level of 20 kPa. Prototype B is used for these additional tests. Tissue damage regarding the liver, spleen and gallbladder is also assessed macroscopically and described.

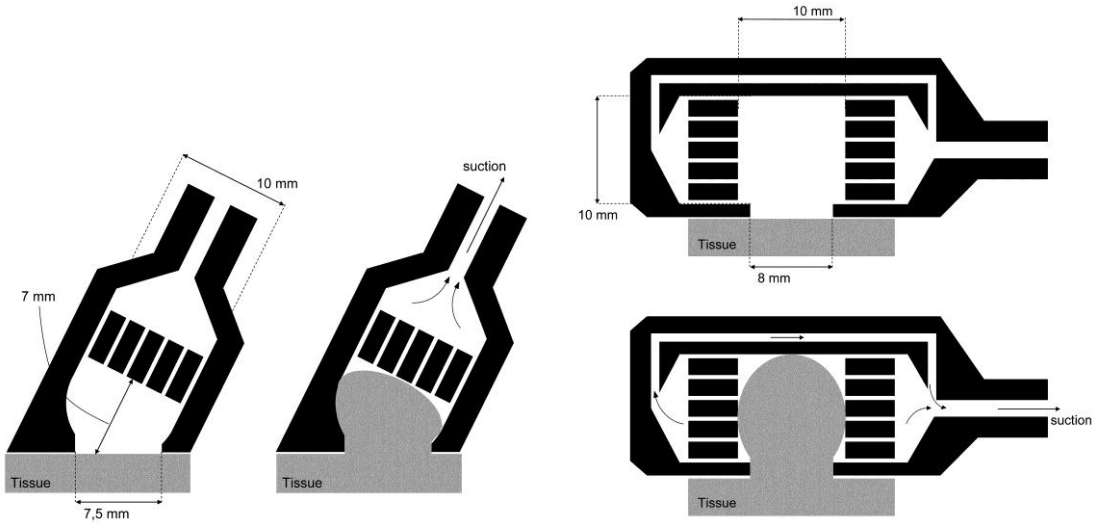

Figure 2.2. Schematic views of prototypes A (left) and B (right)

All bowel manipulations are assessed for successful grasping and unsuccessful grasping. Successful grasping is defined as; when the tissue is instantly grasped and lifted or pulled up the prescribed distance before it is released. Deviations from this definition will be assessed as unsuccessful. Both Prototypes grasp the tissue in a rather complex manner due to the deformation of the tissue as it bulges into the nozzle (Figure 2.1 and 2.2). The tension and stresses exerted on the tissue cannot be determined with the available data. Therefore no comparison is and can be made to existing laparoscopic graspers regarding these aspects. For the experiments an anaesthetized healthy female pig, weight 34 kg, is used. The experiment took place at the department of experimental surgery of the Amsterdam Medical Center.

Figure 2.3. Lifting the bowel upwards

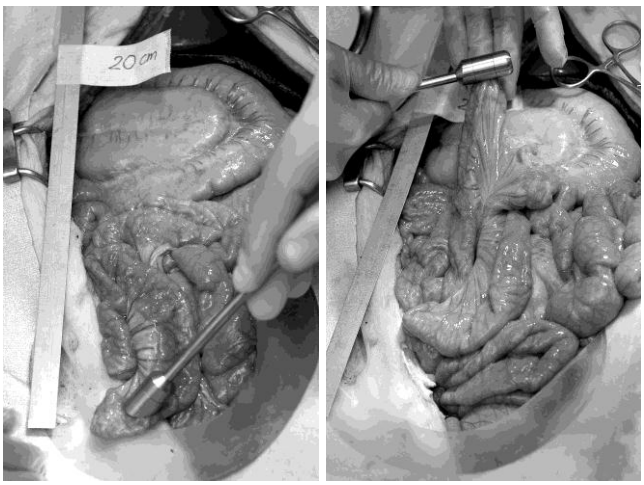

Figure 2.4 a). Pulling the bowel sideways (start) b). Pulling the bowel sideways (end)

Results

The results regarding tissue damage for both vacuum levels, 60 kPa and 20 kPa, and for both prototypes are shown in Table 1. When the grasped bowel tissue is lifted 90° upwards 15 cm, 14 small ecchymoses were observed (out of 40 manipulations assessed) at a vacuum level of 60 kPa. In 2 cases the manipulations were unsuccessful. Both unsuccessful manipulations were conducted with prototype B. At a vacuum level of 20 kPa, 24 small ecchymoses (Examples are shown in Figure 2.5 and 2.6) were observed (out of 40 manipulations assessed). In 1 case the manipulation was unsuccessful. The unsuccessful manipulation was conducted with prototype A. When the grasped bowel is pulled horizontally for 20 cm at a vacuum level of 60 kPa, 7 small ecchymoses were observed (out of 40 manipulations assessed). In 1 case the manipulation was unsuccessful. The unsuccessful manipulation was conducted with prototype A. When the grasped bowel tissue is pulled horizontally for 20 cm at a vacuum level of 20 kPa, 18 small ecchymoses were observed (out of 40 manipulations assessed). For both prototypes, no damages occurred during the unsuccessful manipulations. The unsuccessful manipulation at a vacuum level of 20 kPa was caused by an inaccuracy of one of the surgeons, the manipulation started before the tissue was properly sucked into the nozzle. The unsuccessful manipulation at a vacuum level of 60 kPa was caused by leakage due to tissue variations and/or lack of grip.

60 kPa	Upwards	Sideways	**Total**
manipulations (n)	40	40	**80**
successful manipulations, no damage (n)	26	33	**59**
successful manipulations, non-consequential damage (n)	14	7	**21**
successful manipulations, consequential damage (n)	0	0	**0**
unsuccessful manipulations, no damage (n)	2	1	**3**
unsuccessful manipulations, non-consequential damage (n)	0	0	**0**
unsuccessful manipulations, consequential damage (n)	0	0	**0**

20 kPa	Upwards	Sideways	**Total**
manipulations (n)	40	40	**80**
successful manipulations, no damage (n)	16	22	**38**
successful manipulations, non-consequential damage (n)	24	18	**42**
successful manipulations, consequential damage (n)	0	0	**0**
unsuccessful manipulations, no damage (n)	1	0	**1**
unsuccessful manipulations, non-consequential damage (n)	0	0	**0**
unsuccessful manipulations, consequential damage (n)	0	0	**0**

(n): number of

Table 2.1. Results of the observations regarding tissue damage at a vacuum level of 60 kPa and 20 kPa

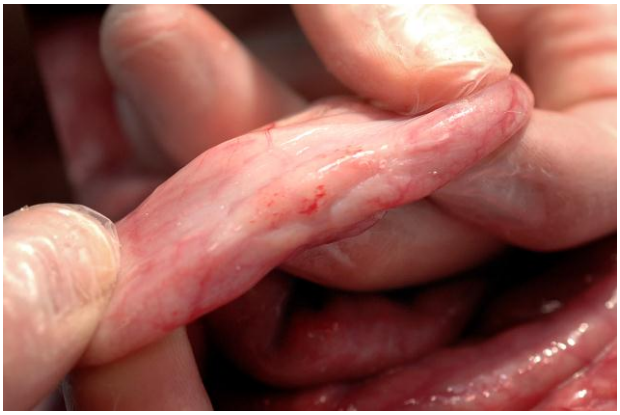

Figure 2.5. Example of ecchymoses (1)

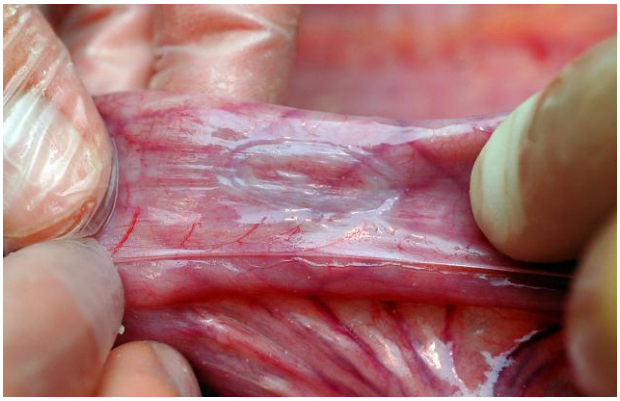

Figure 2.6. Example of ecchymoses (2)

Between the two prototypes (A and B) there is no evident noticeable difference regarding tissue damage. For prototype B the bowel is not automatically released, for both vacuum levels, when the surgeon lifts his finger from the opening on the shaft. For both prototypes it is easier to release the tissue at a vacuum level of 60 kPa as it is at a vacuum level of 20 kPa. This seems normal since the vacuum forces are lower at a lower vacuum level. A number of times the opening of the nozzle caused an imprint on the tissue surface. The serosa was still intact and the imprint disappeared after a few minutes. In addition to the conducted experiments, the tissue was grasped with a vacuum level of 20 kPa for 60 seconds, once for each prototype. The tissue was assessed in both cases by both surgeons. The ecchymoses caused by the vacuum forces disappeared after a few minutes. With regard to tissue damage of the liver, spleen and gallbladder at a vacuum level of 20 kPa for prototype B, the results can be described as follows. The manipulations on the liver resulted in no visible tissue damages and after 10 minutes the nozzle prints on the surface of the liver caused by the nozzle disappeared. With regard to the manipulations on the spleen, these also resulted in no visible tissue damages but the nozzle

prints remained visible after 10 minutes. Finally, the manipulations on the gallbladder, as on the liver and spleen, resulted in no visible tissue damages.

Discussion

The physical principles of the vacuum prototypes allow pig bowel tissue to be safely grasped, up to a vacuum level of 20 kPa. From the total of 160 manipulations, 63 ecchymoses were observed and classified as not relevant and negligible. No torn tissue layers and/ or tissue perforations were observed. The surgeons agreed in more than 99% of all manipulations assessed. Ecchymoses and serosa damage are considered non-consequential, these types of damages have no consequences what so ever. Seromuscular damage is considered potentially consequential and may lead to consequential damage — perforation of the bowel, adhesions, and scars. The small bowel was as healthy before as after the final check-up 15 minutes after the primary assessment. Pig bowel tissue was used for the experiments. The use of pig bowel tissue for testing the vacuum grasper is justified since the strength of pig bowel tissue is approximately comparable to human bowel tissue [7].

A vacuum instrument has a number of interesting characteristics regarding the handling of the bowel. These characteristics lie within the physical principles of a vacuum instrument and can be described as follows. When tissue is grasped firmly by means of the tested prototypes, the inlet diameter (Figures 2.1 and 2.2) of the nozzle is sealed off by the tissue. A vacuum instrument therefore automatically uses its entire surface area in order to grasp and hold the tissue. The forces that are applied to the grasped tissue remain practically constant and can be preset at a safe level.

The vacuum level inside the nozzle is closed off from the outside atmosphere by means of the grasped tissue. When a leak occurs the outside atmosphere starts to level with the vacuum level inside the nozzle. This causes the vacuum forces (grasp forces) to decrease and hence the tissue starts to slip. To conclude, the chance for tissue damage due to slip is minimal since the forces applied to the tissue become minimal.

A vacuum instrument seems less sensitive to variations within the tissue. It is presumed that since the tissue is not compressed in order to firmly grasp it, a vacuum instrument is less sensitive to variations in wall thickness, tissue folds and bowel mesentery. It is also presumed that the vascularization of the tissue is less compromised by a vacuum instrument. The fact that during the experiment no relevant damages were observed and 4 of the 160 manipulations assessed as unsuccessful, underline this presumption.

The nozzle has no moving parts that are controlled by the user. The forces which grasp and hold the tissue are determined by the level of vacuum which is preset at a constant level independent of the surgeon. Therefore, when using a vacuum instrument, a novice surgeon applies the same forces in order to grasp and hold the tissue as an expert surgeon which adds to the patient safety during surgical procedures.

The main causes of unsuccessful grasping are: the exerted vacuum forces are not strong enough to provide a firm grip; inaccuracy from the user such as moving the tissue before it is properly grasped; and leakage between nozzle and the grasped tissue due to the variations within the tissue such as wall thickness and tissue folds.

In addition to the conducted tests on pig bowel tissue, a number of manipulations were conducted on the liver, the spleen, and the gallbladder. Prototype B was used for these additional tests. The manipulations on all three types of tissue resulted in no visible organ damages. These tests indicate that a vacuum instrument can be used to grasp the spleen, liver or gallbladder, without causing damage to these types of tissue. Other studies regarding a laparoscopic splenectomy [25] and a laparoscopic adrenalectomy [26] underline this finding.

Vacuum instruments, such as the tested prototypes, have the potential to be used as grasper instruments for e.g. minimally invasive surgery (MIS). The question rises whether a vacuum instrument can be used for stabilizing tissue where the tissue is held for longer periods of time. On-going further tests are conducted to evaluate the use of a vacuum instrument in relation to soft tissue characteristics. It is also noted that when leakage occurs the continuous suction flow of the vacuum pump would compromise the aero-peritoneum if the prototypes were to be used in a laparoscopic setting. A manually operated vacuum instrument may solve this potential problem. In comparison to the aero-peritoneum, a manually operated vacuum instrument uses a very small volume to generate the vacuum (grasp forces). Manually generated vacuum is also non-continuous which means that air leakage is not bypassed as when using a vacuum pump. For conventional mechanical grasping the user generates manually the grasp forces. Therefore, in order to conduct a fair comparative test between vacuum grasping and conventional mechanical grasping in a laparoscopic setting, manually operated vacuum instruments (prototypes) must be developed. Further tests are conducted to evaluate both vacuum grasping (manually) and mechanical grasping.

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Chapter 3.

Grasping soft tissue by means of vacuum technique

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Abstract

Introduction. A notable characteristic of bariatric surgery is the frequent manipulation of the bowel. The bowel is large, delicate, flexible, and has a natural lubricant on the tissue surface. Therefore the bowel is difficult to grasp and manipulate. Vacuum technique is commonly used in industry for all types of grasping and manipulation. Two types of nozzles that differed slightly in geometry (NT1 & NT2), were reviewed in an experimental set up for pull tests on pig bowels.

Materials and Method. An experimental set-up was used to conduct a series of pull tests on pig bowel tissue. The basic principle of the measurements was a Newton's force balance; $F_{p\ \max} = \Delta p * A$. Student t-tests, two-way ANOVA and Wilcoxon signed rank tests were conducted for the statistical analysis of NT1 and NT2 with regard to the maximum pull force ($F_{p\ \max}$).

Results. Concerning NT1 the Newton's force balance could not be confirmed. Concerning NT2 the Newton's force balance could partly be confirmed. For both nozzle types the effect of Δp on $F_{p\ \max}$ was significant. $F_{p\ \max}$ increases linear in proportion as Δp increases. This relation between $F_{p\ \max}$ and Δp was confirmed by the Newton's force balance.

Discussion. The results confirm that vacuum technique can be used as a grasp technique for soft organs, particularly the bowels. By means of a clever design of the nozzle a firm grip can be obtained on the bowel segments. Therefore vacuum technique should be studied for further development of instruments, graspers and retractors, to be used in the abdominal cavity.

Introduction

Laparoscopic surgery is a type of minimal invasive surgery where long thin instruments and a scope or camera are used to perform the procedure. The instruments and scope are introduced into the abdominal cavity through small portholes, so-called trocars. Workspace is created inside the abdominal cavity by means of carbon dioxide gas.

Since the first laparoscopic removal of the gall bladder in 1985 [1], the number of laparoscopic procedures has increased dramatically. This is especially true for a specific type of laparoscopic surgery called bariatric surgery, also known as weight loss surgery. Bariatric surgery is performed on patients who are dangerously overweight [2]. A notable characteristic of bariatric surgery is the frequent manipulation of the bowel.

The bowel is large, delicate, and flexible, and has a natural lubricant on the tissue surface, making it difficult to grasp and manipulate. Instruments that are used to grasp and manipulate the bowel must provide a firm and safe grip.

Vacuum technique is commonly used in industry for all types of grasping and manipulation. In the medical field, it is a less commonly used grasp and manipulation technique although it is applied in a few applications [3, 4]. A number of studies found in literature also show that vacuum technique has the potential to be used for laparoscopic surgery [5, 6, 7, 8]. In a recent in vivo study where pig bowels were manipulated using vacuum, the authors showed that this kind of bowel grasping is safe for relatively short manipulations at low and medium high vacuum levels [9] (Chapter 2).

Two types of nozzles were reviewed in an experimental set up for pull tests on pig bowels. Vacuum force was utilised to grasp the segments of the pig bowels that were used for the pull tests. The aim of this study was to determine the feasibility of vacuum technique for grasping soft organs such as the bowel, and specifically to determine the conditions of a firm grip.

Materials and Method

An experiment was set up to conduct a series of pull tests on pig bowel tissue (Figure 3.1). It was constructed as follows: a tensile testing machine ((1) Mark 10, US), a vacuum pump ((2) Leybold, Germany), a digital force gauge ((3) Aikoh, Japan), an analogue vacuum control ((4) Carl Roth, Germany), a digitally calibrated vacuum reader (5), and a laptop (6).

Figure 3.1. Experimental set-up

Among the standard equipment of the tensile testing machine was a set of two mechanical clamps which were used to fixate a specimen. The lower clamp was positioned on the base plate, while an electrical motor allowed the upper clamp, which was attached to the force gauge, to travel up and down at a constant speed. For this study the upper clamp was replaced by a vacuum system (Figure 3.1). This system consisted of a nozzle (7), a connector (8), a filter (9), and an air tube (10). Two types of nozzle with varying geometrical dimensions were used to grasp the bowel specimens by means of vacuum (Figure 3.2).

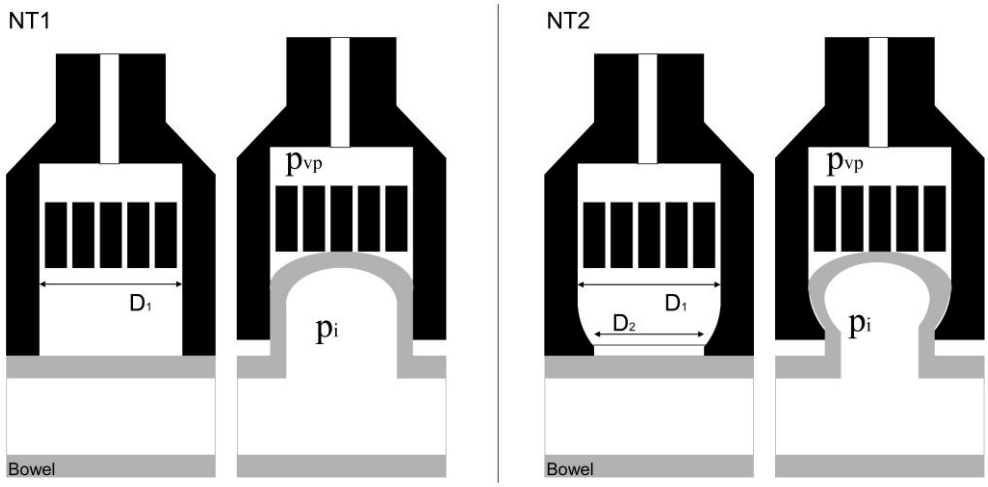

Figure 3.2. Schematic view of NT1 and NT2

The first nozzle type (NT1) was characterised by a cylindrical shape. NT1 had two variable parameters, the inner diameter D_1 and the vacuum level Δp. The second nozzle type (NT2) was characterised by the narrowed inlet and had three variable parameters, the inner diameter D_1, the inlet diameter D_2, and the vacuum level Δp. As the area of focus is minimal invasive surgery, the outer diameter of the nozzle was restricted by the opening of a porthole or trocar, namely a diameter of 12 mm.

The pig bowels were prepared to specimens of 30 cm with 5 cm of mesentery still attached. Physiological salt was used to keep the specimens moist. The bowel specimens were harvested from 20 healthy pigs that had been terminated within the last 12 hours.

Figure 3.3 shows schematically how the specimens were positioned and fixed in the tensile testing machine. The lower clamp was used to grasp the bowel specimen on the mesentery. The mesentery is a membrane attached to the bowel which connects it to the posterior wall of the abdomen. The specimen was pulled upward at a constant speed (300 mm/min) stretching the specimen until it slipped out of the nozzle. The digital force gauge measured the maximum pull force $F_{P\max}$ which was entered in a laptop computer. The accuracy of the digital force gauge was 0.1 N. Each of the specimens was grasped 5 times by a specific nozzle combination, 5 cm between each grasp. A nozzle combination was determined by D_1 and Δp for NT1 and by D_1, D_2 and Δp for NT2 (e.g. NT1: D_1 = 9 mm and Δp = 60 kPa; NT2: D_1 = 10 mm, D_2 = 7 mm and Δp 80 kPa). $F_{P\max}$ was determined for all nozzle combinations as the mean value of each set of 25 pull tests.

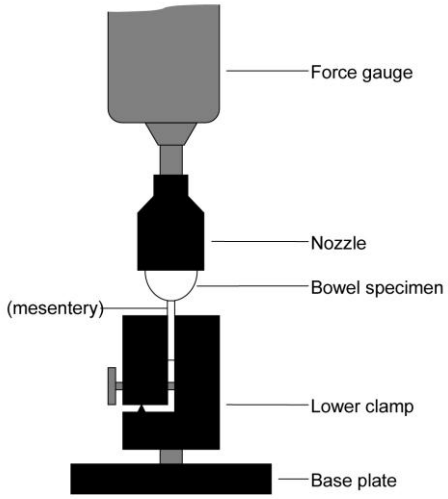

Figure 3.3. Clamping the bowel

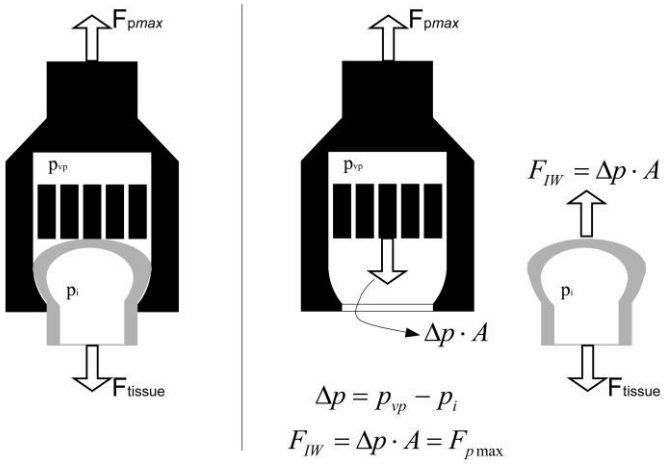

Figure 3.4. General free body diagram of a nozzle, applies to both nozzles

Physical model

The basic principle of the measurements was a Newton's force balance (Figure 3.4):

$$F_{IW} = \Delta p \cdot A \qquad (1).$$

F_{IW} represented the force applied to the intestinal wall by the vacuum. Δp was the pressure difference between the vacuum generated by the vacuum pump p_{vp} and the atmosphere inside the intestinal wall p_i. Cross section A was determined by the inner diameter D_1 of both nozzles (Figure 3.2). It was presumed that A was equal to the surface area of the bowel specimen grasped by the vacuum forces F_{IW}.

The pressure difference Δp acted as a chain linkage between the nozzle and the grasped bowel specimen. The strength of this linkage was determined by a combination of Δp and A (Figure 3.4). The measured maximum pull force $F_{P\max}$, as the force applied to the intestinal wall by the vacuum F_{IW}, therefore depended on Δp and on A. It was expected that the Newton's force balance that applies to this particular situation could be written as follows:

$$F_{IW} = \Delta p \cdot A = F_{p\max} \qquad (2).$$

This meant that F_{IW} represented the expected outcome of the maximum pull force. Air leakage occurs when the bowel specimen fails to close the inner wall of the nozzle. When this happens, Δp cannot be maintained as a constant and will decrease. As a consequence, F_{IW} decreases and hence $F_{P\max}$ also decreases. The narrowed inlet of NT2 was designed to prevent air leakage and allow for a firmer grip on the bowel specimen, compared to NT1. This implied that, according to this model, the pull tests resulted in a significantly larger $F_{P\max}$ for NT2, compared to NT1.

For nozzle NT1, we varied the vacuum levels and the inner diameter D_1, and for each combination we obtained 25 measurements of the maximum pull force. Table 1a summarises the possible combinations and lists the corresponding expected maximum pull force based on Newton's force balance (1).

D_1 (mm)	8			9			10		
Δp (kPa)	40	60	80	40	60	80	40	60	80
Expected max. pull force (N)	2.01	3.02	4.02	2.55	3.82	5.09	3.14	4.71	6.28
number of measurements (n)	25 measurements for each nozzle combination								

1a

D_2 (mm)	7								
D_1 (mm)	8			9			10		
Δp (kPa)	40	60	80	40	60	80	40	60	80
Expected max. pull force (N)	2.01	3.02	4.02	2.55	3.82	5.09	3.14	4.71	6.28
number of measurements (n)	25 measurements for each nozzle combination								

1b

D_1 (mm)	10								
D_2 (mm)	8			7			6		
Δp (kPa)	40	60	80	40	60	80	40	60	80
Expected max. pull force (N)	3.14	4.71	6.28	3.14	4.71	6.28	3.14	4.71	6.28
number of measurements (n)	25 measurements for each nozzle combination								

1c

Table 3.1, 3.1a) Expected maximum pull force for nozzle NT1, keeping D2 fixed. 3.1b) Expected maximum pull force for nozzle NT2, keeping D2 fixed. 3.1c) Expected maximum pull force for nozzle NT2, keeping D1 fixed.

For nozzle NT2, we varied the vacuum levels and the inner diameter D_1 while keeping the inlet diameter D_2 fixed at 7 mm. For each combination we obtained 25 measurements of the maximum pull force. Table 1b summarises the possible combinations and lists the corresponding expected maximum pull force.

For nozzle NT2, we also varied the vacuum levels and the inlet diameter D_2 while keeping the inner diameter D_1 fixed at 10 mm. For each combination we obtained 25 measurements of the maximum pull force. Table 1c summarises the possible combinations and lists the corresponding expected maximum pull force. Note that for each variation of D_2 at each of the three vacuum levels Δp, the expected value of $F_{P\max}$ is the same (Table 3.1c). This is due to the fact that it is D_1 that determines A in the Newton's force balance.

The acquired data was statistically analysed as follows.

A student's t-test for a mean value was used to evaluate $F_{P\max}$ for each nozzle combination of both nozzle types in relation to the expected outcome of the maximum pull force (F_{IW}). This test shows to what extent the obtained $F_{P\max}$ deviated from F_{IW} .

The variable parameters D_1, D_2 and Δp were then evaluated within groups of the two nozzle types. The impact of each variable parameter on $F_{P\max}$ in relation to each other for both NT1 and NT2 was statistically determined. A student's t-test for mean values was conducted to evaluate D_1 & Δp regarding NT1. A one-way ANOVA was used to evaluate D_1, D_2 and Δp in relation to NT2.

Finally, a two-way ANOVA between groups was performed to evaluate $F_{P\max}$ regarding NT1 and NT2. The two independent variables, or factors, in the ANOVA were defined as nozzle combination and pressure difference.

The level of significance for the t-tests and the two-way ANOVA is $\alpha = 0,05$. Wilcoxon signed rank tests were conducted alongside the t-tests and two-way ANOVA.

Results

Table 3.2 shows the measured $F_{P\max}$ for NT1 and the corresponding 95% confidence intervals for the different combinations of D_1 and Δp. As can already be seen from the data, the confidence intervals lie above the expected maximum pull force $F_{P\max}$. For every combination, the average measured $F_{P\max}$ was found to differ significantly from its value obtained from the Newton's force balance (1).

Δp (kPa)	D_1 (mm)	$F_{P\max}$ Expected	Measured	Confidence Interval		p-value t-test	Wilcox
40	8	2.01	0.884	0.79	0.98	<0.0000	<0.0000
60		3.02	1.508	1.39	1.62		
80		4.02	2.156	2.00	2.31		
40	9	2.55	1.064	1.02	1.10		
60		3.82	1.632	1.56	1.71		
80		5.09	2.228	2.10	2.36		
40	10	3.14	1.044	0.96	1.13		
60		4.71	1.468	1.28	1.66		
80		6.28	2.008	1.86	2.16		

Table 3.2. Results of maximum pull force for NT1

Student *t*-tests yield *p*-values below 0.0001 and the Wilcoxon signed rank tests also give *p*-values below 0.0001.

For the different combinations of D_1 and Δp of NT1, a one-way ANOVA confirms a clear effect of Δp on the maximum pull force $F_{P\max}$ ($p < 0,0001$). The effect of the inner diameter D_1 was found not to be statistically significant ($p = 0,9182$). An interaction effect between D_1 and Δp was observed ($p = 0,0114$).

The results regarding NT2 are as follows. First, $F_{P\max}$ was measured for each combination of D_1 and Δp while the inlet diameter D_2 was kept fixed (Figure 3.2). The effect of Δp is evident ($p < 0,0001$). Also, the effect of the inner diameter D_1 was found to be highly significant ($p < 0,0001$), as was the interaction effect between D_1 and Δp ($p < 0,0001$).

Table 3.3 shows the measured $F_{P\max}$ and the 95% confidence intervals for the different combinations of D_1 and Δp, together with the expected $F_{P\max}$. For $D_1 = 8mm$, all expected outcomes of $F_{P\max}$ are within the confidence intervals.

Δp (kPa)	$D_1 (D_2)$ (mm)	$F_{P\max}$ Expected	Average	Confidence Interval		*p*-value *t*-test	Wilcox
40	8 (7)	2.01	2.104	1.94	2.27	0.2592	0.1485
60		3.02	2.944	2.76	3.13	0.4087	0.4578
80		4.02	3.900	3.74	4.06	0.1261	0.1135
40	9 (7)	2.55	2.608	2.45	2.77	0.4696	0.3254
60		3.82	3.620	3.45	3.79	0.0253	0.0342
80		5.09	4.928	4.78	5.08	0.0328	0.0626
40	10 (7)	3.14	2.992	2.88	3.11	0.0130	0.0118
60		4.71	4.148	4.00	4.29	<0.0000	<0.0000
80		6.28	5.612	5.49	5.73	<0.0000	<0.0000

Table 3.3. Results of maximum pull force for NT2 concerning D1

Neither student *t*-tests nor Wilcoxon signed rank tests indicate any significant differences between the measured outcomes of $F_{P\max}$ and the expected outcomes. Regarding $D_1 = 10mm$, the measured outcomes of $F_{P\max}$ all differ significantly from their expected outcomes with student *t*-test *p*-values, varying from $p = 0,013$ ($\Delta p = 40kPa$) to $p < 0,0001$ ($\Delta p = 80kPa$). The results for $D_1 = 9mm$ are somewhere between those for $D_1 = 8mm \,\&\, D_1 = 10mm$. For $D_1 = 9mm$, the student *t*-test *p*-values vary between $p = 0,4696$ ($\Delta p = 40kPa$) and $p < 0,033$ ($\Delta p = 80kPa$).

Second, D_1 was kept fixed and $F_{P\max}$ was measured for each combination of D_2 and Δp (Figure 3.2). Table 3.4 shows the measured $F_{P\max}$ and the 95% confidence intervals for the different combinations of D_2 and Δp, together with the expected $F_{P\max}$.

Δp (kPa)	$D_1 (D_2)$ (mm)	$F_{P\max}$ Expected	Average	Confidence Interval		p-value t-test	Wilcox
40	8 (10)	3.14	1.748	1.54	1.95	<0.0000	<0.0000
60		4.71	2.848	2.66	3.03		
80		6.28	3.840	3.57	4.11		
40	7 (10)	3.14	2.992	2.84	3.15	<0.0000	0.0108
60		4.71	4.148	3.95	4.34	<0.0000	<0.0000
80		6.28	5.612	5.45	5.77		
40	6 (10)	3.14	2.192	1.98	2.41		
60		4.71	3.516	3.21	3.82		
80		6.28	4.456	4.14	4.77		

Table 3.4. Results of maximum pull force for NT2 concerning D2

At all three vacuum levels, the measured $F_{P\max}$ decreased for $D_2 = 6mm$ compared to the measured $F_{P\max}$ for $D_2 = 7mm$. The main effects of vacuum level Δp and inlet diameter D_2 were found to be highly significant; no interaction effect was observed.

For all combinations, the difference between the observed average pull force and its expected value on the basis of Newton's force balance (1) was found to be highly significant.

Discussion

Aim of the study

The aim of the study is to determine the feasibility of vacuum technique as a grasp technique for soft organs. On the one hand this is determined by the grip on the tissue and, on the other, whether the tissue is grasped safely. This study focuses on the grip part of vacuum grasping. The grip was defined as the maximum pull force applicable by means of the tested nozzle types. With regard to grasping the tissue without causing damage, a previously conducted study shows that pig bowels can be grasped safely [9] (Chapter 2).

Results demonstrated

The first thing to note is that for NT1 the expected pull force cannot be attained, and secondly, that NT2 gets quite close to the expected pull force (Tables 3.2, 3.3 and 3.4). Vacuum grasping seems feasible with regard to NT2, but impossible regarding NT1.

The results for NT1 show that the effect of Δp on $F_{P\max}$ was significant. $F_{P\max}$ increases linearly in proportion as Δp increases. This relationship between $F_{P\max}$ and Δp was confirmed by the Newton's force balance (1) and (2). For D_1, the Newton's force balance cannot be confirmed. The values for D_1 ($D_1 = 8,9,10mm$) that were tested in this study have no effect on $F_{P\max}$ in relation to each other. At first sight this is odd, as the dimensional variable D_1 determines A. D_1, according to the Newton's force balance, should therefore have a positive and proportional effect on $F_{P\max}$. The measured $F_{P\max}$ for NT1 is twice as low as the expected pull force. This low value of $F_{P\max}$ and the *non-effectiveness* of D_1 regarding NT1 are the result of early air leakage when a bowel segment is pulled by means of the nozzle and the tensile testing machine. When the bowel segment is sucked into the nozzle it sticks to the inner wall due to the vacuum. The bowel segment is then stretched and the tension in the bowel wall pulls the bowel segment of the inner wall of the nozzle (Figure 3.5). A possible explanation for this event can be described as follows.

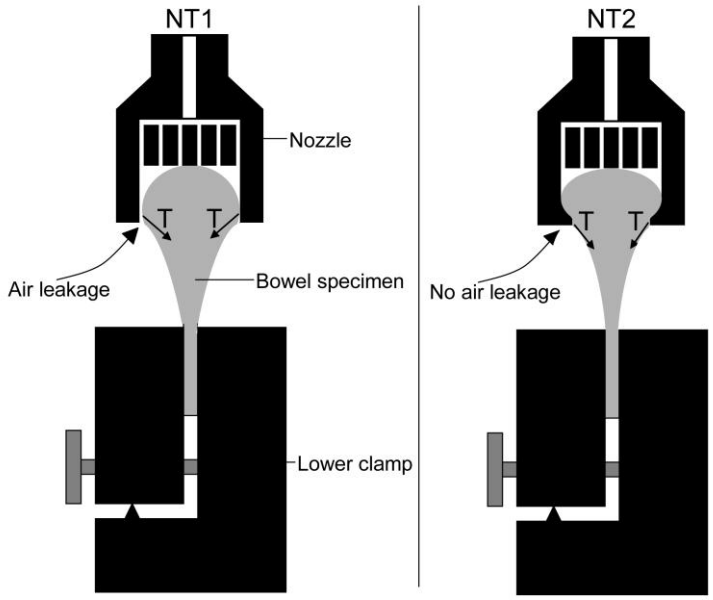

Figure 5. Occurrence of air leakage (left view), and how to prevent it (right view)

It is first necessary to describe the bowel in simple terms as if it were a static object. The bowel surface is smooth. It has the shape of a tube and its average diameter and wall thickness are such that tissue folds are caused. There is a membrane attached to the bowel (mesentery) which holds the bowel in position. This membrane was used to position the bowel segment in the tensile testing machine, but without any account being taken with regard to the grip on the bowel. The bowel segment is grasped by the nozzle as illustrated in Figure 3.2. It is then is stretched and pulled while being grasped by vacuum forces. It is the opinion of the authors that as the bowel segment is being stretched, the bowel characteristics such as the diameter, wall thickness and tissue folds largely determine whether air leakage occurs or not. In other words, the shape and dimensions of the bowel are of great importance. The inside of nozzle NT1 has the shape of a cylinder, which is not sufficient for grasping the bowel segment in line with its dimensions or for closing off the vacuum to achieve the expected pull force. The results for NT2 confirm this phenomenon.

NT2 was specifically designed to prevent air leakage (Figure 3.2 and 3.4). The results for NT2 show, similarly to NT1, that the effect of Δp on $F_{P\max}$ is significant and $F_{P\max}$ increases linearly in proportion as Δp increases. This is obvious, and is due to the same reasons as for NT1. Regarding D_1, the Newton's force balance is largely confirmed (Table 3.3). The narrowed inlet D_2 closes off the vacuum, which allows the expected pull force to be realised. This means that D_1, as far as Newton's force balance is concerned, depends on the performance of D_2. When $D_1 = 10mm$, the Newton's force balance is not confirmed (Table 3.3 and 3.4). If D_1 increases, more tissue is sucked into the nozzle. One explanation is that too much tissue is sucked into the nozzle while the bowel segment has a

limited diameter size, resulting in premature air leakage. D_1 has an optimum at which the bowel is most firmly grasped. This, however, is an assumption and although it seems probable, it has not been proven.

D_2 is an independent variable and as stated, for each variation of D_2 at each of the three vacuum levels Δp, the expected value of $F_{P\max}$ is the same. This is due to the fact that it is D_1 that determines A in the Newton's force balance (Table 3.4). D_2 is not part of equations (1) and (2). Nevertheless, D_2 is of great importance as it is the factor that prevents air leakage. Table 3.4 shows that variations in D_2 have an undeniable effect on $F_{P\max}$. However, this effect is not significant with regard to realising the expected maximum pull force.

The effect of D_2 can be explained as follows. When the narrowed inlet D_2 is not integrated in the nozzle, air leakage occurs and the tissue slips as was shown for NT1. A relatively large D_2 has an effect but it is too small to realise the expected pull force (Table 3.4). In that case, NT2 shows a closer resemblance to NT1. A relatively small D_2 has a negative effect, as the inlet becomes too small for the bowel segment to be sucked into the nozzle. The inlet has a minimum size which still allows the bowel segment to enter the nozzle and a maximum size where the inlet ceases to function. Like D_1, D_2 has an optimum at which the right amount of tissue is sucked into the nozzle where the tissue can still be sufficiently closed off to prevent air leakage. Tables 3.3 and 3.4 confirm this. Choosing exactly the right value for D_2 is the criterion that determines whether D_1 functions according to the Newton's force balance — to realise the expected pull force.

It is notable that although NT2 comes fairly close to the Newton's force balance, the data obtained also show that the results are sometimes close, but not significant. This shows that bowel tissue has varying characteristics and is difficult to model.

Implications

The results confirm that vacuum technique can be used as a grasp technique for soft organs, particularly the bowels. By means of a clever design of the nozzle, a firm grip can be obtained on the bowel segments. Vacuum technique should therefore be studied for further development of instruments, graspers and retractors, to be used in the abdominal cavity. Organs such as the colon, liver, gall bladder, spleen, and adrenal glands could be subject of further research regarding vacuum grasping [5, 6, 7]. The nozzles that were tested for this study were designed specifically for minimal invasive surgery. Nevertheless, it is conceivable that vacuum technique could also be applied to for

general open surgery and other types of surgery such as single port surgery [10, 11], NOTES [12, 13], and robotic surgery [14, 15, 16].

Correspondence to other literature

The grip on the bowel is at an optimum when the nozzle has just the right dimensions, as explained above. In order to determine the feasibility of vacuum grasping, a nozzle must also be able to exert a pull force of 5 N on the bowel [17, 18]. Tables 3 and 4 confirm that this is possible at a Δp of 80 kPa. Three studies found in literature also show that vacuum technique allows for organs to be grasped sufficiently firmly for a period of time without causing any damage [5, 6, 7].

Limitations of the study

The optimum of the nozzle at which a safe grip can be obtained applies only for the type of nozzle used in this study. The results of this study apply to potential applications in minimal invasive surgery. It is likely that the results can be translated to other types of surgery, but this will take more research and study of the subject. Moreover, NT2 can be used on bowels and probably also on the colon. However, for organs with evidently different material characteristics, such as the liver or spleen, NT2 may not be adequate. It seems probable that each type of organ or tissue requires a different type of nozzle.

The bowels used were those of recently terminated pigs. It is clear that dead tissue responds differently to life tissue. If the results are to be translated to the design of a vacuum grasper instrument, it is important to test this instrument thoroughly regarding its grip and applicable pull force on live pig bowels. In vivo studies concerning vacuum grasping are currently being conducted.

Conclusion

The bowels can be firmly and safely grasped by means of vacuum. This offers the opportunity to use a vacuum grasper as an alternative, not a substitute, to the conventional mechanical grasper. The results can be initiated into instrument design. The real optimum is not necessarily one of the tested variations of NT2. The actual optimal dimensions of the nozzle should be determined by further tests, and the results can be the starting point of an instrument design. The nozzle is the element that actually interacts with the grasped tissue and is predetermined by its optimal dimensions. This implies that the design effort should be focused on the control part of the instrument. The control of such an instrument could be either manual or machine-operated.

Further developments concerning the designing and testing of a vacuum instrument, whether manually driven or by vacuum pump, are being conducted to evaluate their feasibility.

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Chapter 4.

Microscopic effects of vacuum grasping on pig bowels, an in vivo study

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Abstract

Introduction: Vacuum technique has a number of advantages: the forces are homogenous distributed over the grasped area of the tissue; there are no moving parts and/or sharp edges in a suction cup or nozzle which can harm the tissue; when the tissue slips out of the suction cup or nozzle no peak forces are applied to the tissue; and finally, a suction cup or nozzle is not sensitive to tissue variations such as tissue folds, wall thickness and mesentery. The aim of this study was to examine the microscopic effects by means of histological examination of vacuum grasping on pig bowels using a life porcine model.

Method: A functional model of a laparoscopic vacuum (grasp) system (LVS) was developed in a joint project with Karl Storz GmbH and Delft University of Technology. Th LVS was used in-vivo to grasp pig bowel. First, a blinded general histological examination was performed on hematoxylin and eosin stained coupes of the bowel samples. Second, an ordered multinomial logit model was used to determine the relation between the level of Δp and the type of damage assessed.

Results: The layers of the bowel wall were intact for all samples. Severe hemorrhages, crush artifacts, ruptures or perforations were not assessed in any case in the samples. The only type of damage found is subserosal and/or intra muscular haemorrhage.

Discussion: The results indicate that vacuum technique can be safely applied in the clinical setting provided the safe range $|0, \Delta p_{da} = 97\rangle$ (kPa) is considered and the time limit of 15 minutes is not exceeded.

Introduction

Grasping soft tissue during Minimal Invasive surgery (MAS) procedures such as the bowel is a delicate matter and requires great skill and experience of the physician [1-20]. The current grasp technique of mechanical grasping, is as old as surgery itself. It is interesting to explore whether other grasp techniques as the mechanical one, have potential to be used in the operating room. Previous study showed that the bowels can be grasped in a safe manner and with a firm grip by means of vacuum [21, 22] (Chapter 2 and 3). Vacuum technique has a number of advantages: the forces are homogenous distributed over the grasped area of the tissue; there are no moving parts and/or sharp edges in a suction cup or nozzle which can harm the tissue; when the tissue slips out of the suction cup or nozzle no peak forces are applied to the tissue; and finally, a suction cup or nozzle is not sensitive to tissue variations such as tissue folds, wall thickness and mesentery. This high level of control concerning vacuum technique is underlined by a several studies [23, 24, 25].

These studies relate to macroscopic effects of vacuum grasping and the assessment was conducted in a qualitative manner. The authors could find no literature on studies concerning the consequences of grasping soft tissue by means of vacuum at a microscopic level. Tissue damage caused by vacuum is thus far determined as visual detectable damage. Histological examination is likely to bring about valuable insight concerning vacuum grasping of soft tissue. One can speculate that due to the 'suction' forces hemorrhages and hypoxia may occur resulting in local bleeding and eventually rupture of the upper tissue layers. It is interesting to determine the range (in vacuum level) in which vacuum grasping can be considered as safe in respect to its potentiality to be used in MIS. Concerning conventional mechanical grasping several studies report on both macroscopic and microscopic assessment in regard to tissue damage [1, 6, 7, 26-29].

This study focused on bowel tissue. Bowel tissue is considered very delicate and easy to damage. A porcine model was used to conduct *in vivo* experiments. A functional model of a laparoscopic vacuum (grasp) system was developed in a joint project with Karl Storz GmbH and Delft University of Technology. This vacuum system (LVS) was used to grasp a pig bowel for a fixed period of time at

preset vacuum levels. In addition to the grasping conducted by means of vacuum, the bowel was also grasped using the conventional technique of mechanical grasping using a laparoscopic mechanical grasp system (LMG). This additional experiment was conducted to explore possible relation and/or differences between vacuum grasping and mechanical grasping in terms of microscopic effects.

The aim of this study was to examine the microscopic effects by means of histological examination of vacuum grasping on pig bowels using a life porcine model. The bowel was grasped for 15 minutes, which is a relative long period of time. The LVS was used to determine a safe range in which vacuum technique can be used or applied as grasping technique in MIS.

Materials and Method

The experimental set up can be described as follows. The vacuum pump (Leybold, Germany) that was used for the experiments concerning the Laparoscopic Vacuum System (LVS) could be preset at vacuum levels within the range of low and medium vacuum. Low vacuum ranges from 100 kPa – 3 kPa where 100 kPa is the atmospheric pressure and 0 kPa the absolute minimum (National Physical Laboratory (NPL), UK). For this study the range of low vacuum was chosen as the target range. Low vacuum can be generated by any none complex device and is perfectly applicable for manually driven instruments and devices that can use the pressure system of the operating room without using special equipment. The vacuum levels at which the vacuum pump was preset can be found in Table 4.1. The vacuum levels will be referred to as pressure difference Δp (in kPa) in relation to the atmospheric pressure. A vacuum level of e.g. 30 kPa can be written as: Δp = 70 kPa (100 kPa – 30 kPa). An analog vacuum control (Carl Roth, Germany) and a digital calibrated vacuum reader were used to determine and control the required pressure differences.

LVS				LMG		
p (kPa)	Δp (kPa)	number of samples (n)	number of controls (s)	p_c (kPa)	number of samples (n)	number of controls (s)
50	50	10	10	–	–	10
40	60	10		60	10	
30	70	10		–	–	
20	80	10		80	10	
10	90	10		–	–	
3	97	10		–	–	

Table 4.1. Vacuum levels and compression stress levels of LVS and LMG where 100 kPa is the atmospheric pressure.

The LVS itself existed out of a chain of 5 nozzles (Figure 4.1). These nozzles were connected in series by means of flexible tubes and plastic tube connectors. The design of the nozzle was based on a previous study where two types of nozzles were tested to determine which nozzle type provided a more efficient and firm grip on the bowel [22] (Chapter 3). The surface area *A* of the nozzles was $6.4x10^{-5}$ m^2. Two filters were used to prevent debris from entering the vacuum control, vacuum reader and vacuum pump. The filters were designed not to obstruct the vacuum flow of the LVS.

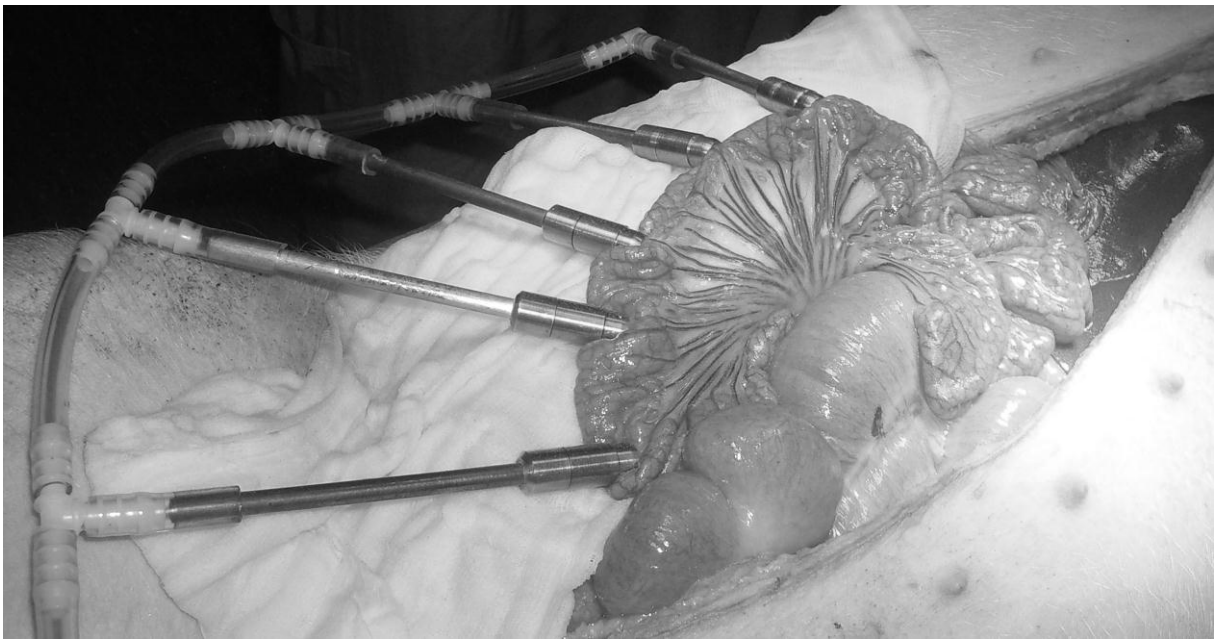

Figure 4.1. The laparoscopic vacuum system (LVS).

The grasping of the bowel with the LVS can be described as follows. The nozzles were simultaneously positioned on a section of the bowel when the vacuum pump was turned on. The nozzles were positioned with sufficient distance between each two nozzles to ensure blood circulation in the bowel and between the bowel and the mesentery. This distance was determined on site and varied between 40 mm and 50 mm (Figure 4.1). The LVS was used to grasp the bowel a fixed period of time hence simulating stabilization of the bowel during the procedure of a bowel anastomoses. A bowel anastomoses is a procedure where two bowel segments are reconnected in order to re-establish the bowel function [30]. The duration in which to perform a bowel anastomoses is well within 15 minutes. Therefore the time period the bowel was grasped by the LVS was set at 15 minutes. After this given time period had passed the vacuum pump was shut off, releasing the bowel and allowing the samples to be harvested and placed in a formalin solution. Table 4.1 shows the number of samples taken at each vacuum level plus the number of controls.

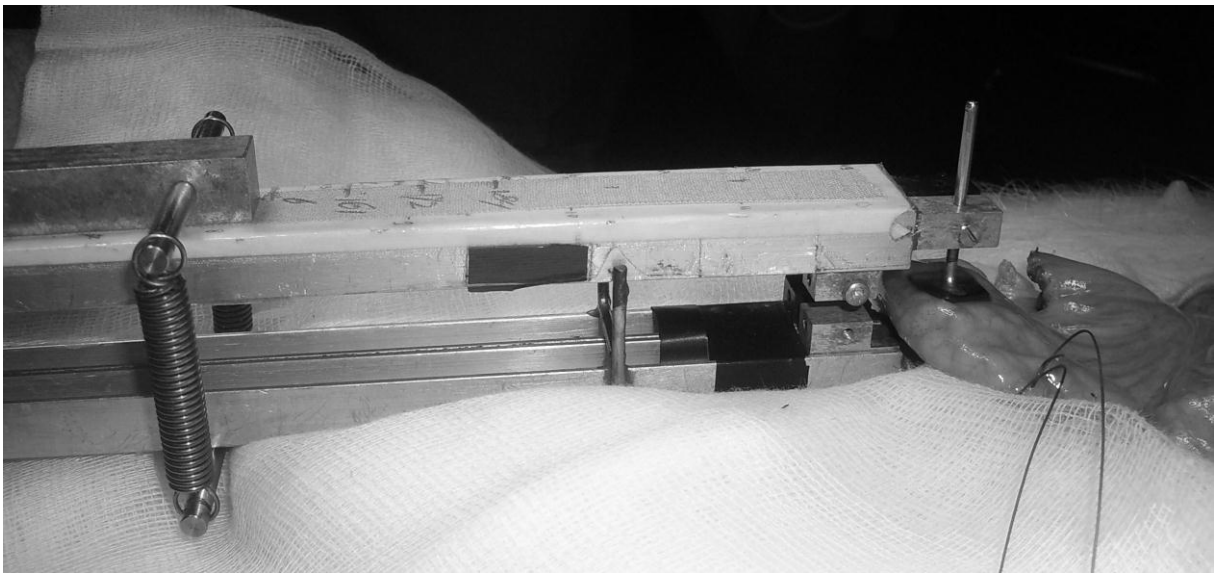

Figure 4.2. The laparoscopic mechanical grasper (LMG).

Additional to the experiments conducted with the LVS, a functional model of a laparoscopic mechanical grasper LMG (Figure 4.2 and 4.3) was also used to grasp and hold the bowel for 15 minutes. The LMG can be described as follows. A clamp existing out of two levers with at its distal end two sockets which can be used to clamp a set of grasper jaws, and at the proximal end a pivot allowing the LMG to grasp the bowel.

The pinch force was obtained by means of two stainless steel springs which can be positioned on the lever arms [1, 6]. The spring-constant was determined at 0.57 N/mm using a Mark 10 (US) tensile testing machine. The equation of the spring force was determined as:

$$F_s = (0.57)l_s + 4.3 \quad (1)$$

where F_s: Spring force of both springs combined in Newton and l_s : Spring length in mm (Figure 3).

The position (p_s) of the springs was determined by the basic torque principle:

$$(p_c \cdot A_{jaw}) \cdot a = F_s \cdot p_s \quad (2)$$

where p_c : compression stress level at the grasp jaws in Pa, A_{jaw}: surface area in m², a: lever length in mm, and p_s : spring position in mm (Figure 3).

In order to determine the correct position of the springs, one must compensate for the bowel thickness (b_t). The bowel thickness was measured as follows. The distance between the two sockets of the LMG was 31 mm. Then the LMG was positioned to grasp the bowel without using the springs. The upper jaw exerted a force of 0.32N lightly squeezing the bowel between upper and lower jaw (Figure 3). The distance between the sockets when grasping the bowel as described above was measured using a digital caliper (Mitutoyo, Japan). This resulted in a bowel thickness (b_t) of 1.65 mm ± 0.11 mm. The spring length (l_s) and hence the spring force (F_s) was compensated using the tangent of the lever and the position of the spring (p_s).

With this set up the variations in p_c are limited and acceptable [1]. The grasper jaws that were used for the LMG resembled the profile of a Babcock grasper with a surface area *A* of 1.0×10^{-4} m^2.

It was considered that in a real life condition, an LVS will be used at pressure differences Δp ranging from 60 kPa to 80 kPa. Therefore the compression stress levels p_c (compression stresses) of 60 kPa and 80 kPa were chosen as opposite values to the LVS to be applied in the experiments concerning the LMG. This is also shown in Table 4.1.

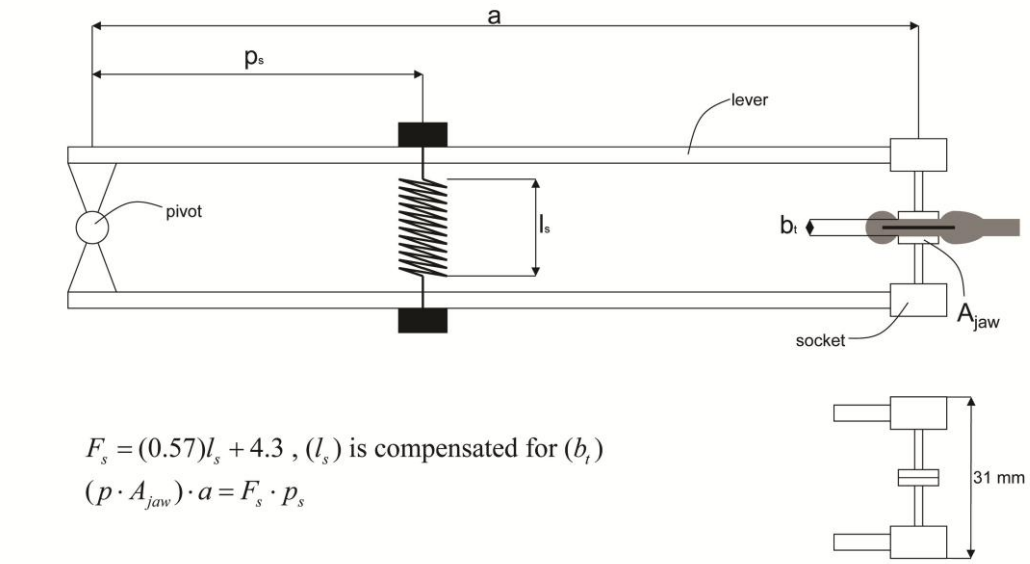

Figure 4.3. schematic view of the LMG

For this study two anesthetized healthy female pigs were used, each 6 months old and weighing between 35 and 50 kg. The experiments were conducted under the official approved protocol concerning experiments on large animals of the Academic Medical Center of Amsterdam, the Netherlands.

The samples obtained from the experiments with the LVS and LMG were examined by a pathologist. Blinded general histological examination was performed on hematoxylin and eosin stained slides of the bowel samples. The samples were examined for mechanical damage which was determined as: no damage, hemorrhage, crush artifacts (one or more crushed cells due to compression.), ruptures and perforations. Hemorrhage was categorized in a three-tiered system; small, moderate or severe. For this study the distance between the types of bowel damage concerning their clinical significance was

considered ordered and equal where small hemorrhages are least clinical relevant and perforations most urgent. The three levels of hemorrhage were based on the surface area of the hemorrhage which was arbitrary assessed. Small and moderate hemorrhages were considered to be none consequential damage and hence as not clinically relevant. Severe hemorrhages, crush artifacts, ruptures, and perforations were considered to be (potentially) consequential damage and therefore as clinically relevant.

Histological examination was performed for the whole bowel sample from mucosa till serosa. The assessment was conducted according blind protocol, without prescience of the applied grasp technique nor pressure and vacuum levels.

The acquired data was analysed as follows. By means of histological examination a range of safe vacuum grasping was determined given the maximum time span of 15 minutes in which the bowel was grasped. The safe vacuum range was defined as the atmospheric pressure, which corresponds to a pressure difference Δp of 0 kPa, up to a so called Δp-damage (Δp_{da}) where at least in one observation a clinically relevant damage would be assessed. This can be described as $\left|0, \Delta p_{da}\right\rangle$ in kPa. This means that it is presumed that up to a certain Δp no damage will occur and that chance for clinically relevant damage increases when Δp increases. This also means that when clinically relevant damage is assessed in a more random fashion throughout the harvested samples at different levels of Δp, vacuum grasping should be discarded as a safe grasping technique for the time being.

An *ordered multinomial logit model* was used to determine the relation between the level of Δp and the type of damage assessed. The model with two independent variables and interaction can be described as follows. A none observable variable ξ is linear dependent on the two independent variables X_1 and X_2 plus a measuring error ε. X_1 was defined as the absolute applied pressure difference when using the LVS either the LMG. X_2 was defined as the grasp method (LVS: vacuum = 0, LMG: compression = 1).

$$\xi = \beta_1 \cdot X_1 + \beta_2 \cdot X_2 + \gamma \cdot X_1 \cdot X_2 + \varepsilon \qquad (3)$$

The dependable variable Y (1 = no damage, 2 = small hemorrhage, 3 = moderate hemorrhage, 4 = severe hemorrhage, 5 = crush artifacts, 6 = ruptures, 7 = perforations) relates to ξ as follows.

$$Y = \begin{cases} 1 \text{ if } \xi \le \alpha_1 \\ 2 \text{ if } \alpha_1 < \xi \le \alpha_2 \\ 3 \text{ if } \alpha_2 < \xi \le \alpha_3 \\ 4 \text{ if } \alpha_3 < \xi \le \alpha_4 \\ 5 \text{ if } \alpha_4 < \xi \le \alpha_5 \\ 6 \text{ if } \alpha_5 < \xi \le \alpha_6 \\ 7 \text{ if } \alpha_6 < \xi \end{cases},$$

where $-\infty = \alpha_0 < \alpha_1 < \alpha_2 < \alpha_3 < \alpha_4 < \alpha_5 < \alpha_6 < \alpha_7 = \infty$ are the unknown parameters which define the borders of the categories of Y. The *ordered multinomial logit model* suggests a logistic distribution concerning ε. Therefore the relation between the dependent variable Y and the independent variables X_1 and X_2 is:

$$P(Y \le j) = \frac{e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}{1 + e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}} \text{ , } (j = 1, ..., 7) \qquad (4)$$

Concerning the marginal probabilities per category this means:

$$\pi_j = P(Y = j) = \frac{e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}{1 + e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}} - \frac{e^{\alpha_{j-1} - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}{1 + e^{\alpha_{j-1} - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}, \text{ where } (j = 1, ..., 7) \qquad (5)$$

Within this model the following hypotheses were examined.

1. $H_0 : \beta_1 = 0$, the variable X_1 (absolute applied pressure difference) does not affect bowel damage.
2. $H_0 : \beta_2 = 0$, the variable X_2 (grasp method) does not affect bowel damage.
3. $H_0 : \gamma = 0$, the interaction between X_1 and X_2 does not affect bowel damage.

First the number of categories concerning the dependable variable Y are determined. The number of categories is determined by the most serious type of damage that was assessed. The data was statistically computed with *R* (http://www.r-project.org/).

Results

Table 4.2 shows the results concerning the LVS where the bowel was grasped for 15 minutes at 6 different pressure differences *Δp*. Table 4.3 shows the results concerning the LMG where the bowel was grasped also for 15 minutes at two compression stress levels (pinch force). 10 grasps were conducted at each vacuum and compression stress level. Severe hemorrhages, crush artifacts, ruptures or perforations were not assessed in any case in the samples. The only type of damage found is subserosal and/or hemorrhage in the muscularis propria.

Δp (kPa)	no deviations	small hemorrhage	Moderate hemorrhage	total number of samples
(Controls)	10	0	0	10
50 kPa	5	2	3	10
60 kPa	7	3	0	10
70 kPa	4	4	2	10
80 kPa	6	2	2	10
90 kPa	6	2	2	10
97 kPa	7	2	1	10

Table 4.2. Results concerning vacuum grasping per pressure difference *Δp*. The table only shows the actual observed damage types.

p_c (kPa)	no deviations	small hemorrhage	Moderate hemorrhage	total number of samples
(Controls)	10	0	0	10
60 kPa	8	2	0	10
80 kPa	9	1	0	10

Table 4.3. Results concerning mechanical grasping per compression stress level p_c. The table only shows the actual observed damage types.

The layers of the bowel wall were intact for all samples (mucosa, muscularis mucosae, submucosa, muscularis propria, subserosa and serosa). Other deviations are not found. Figure 4.4 shows an example of a moderate hemorrhage.

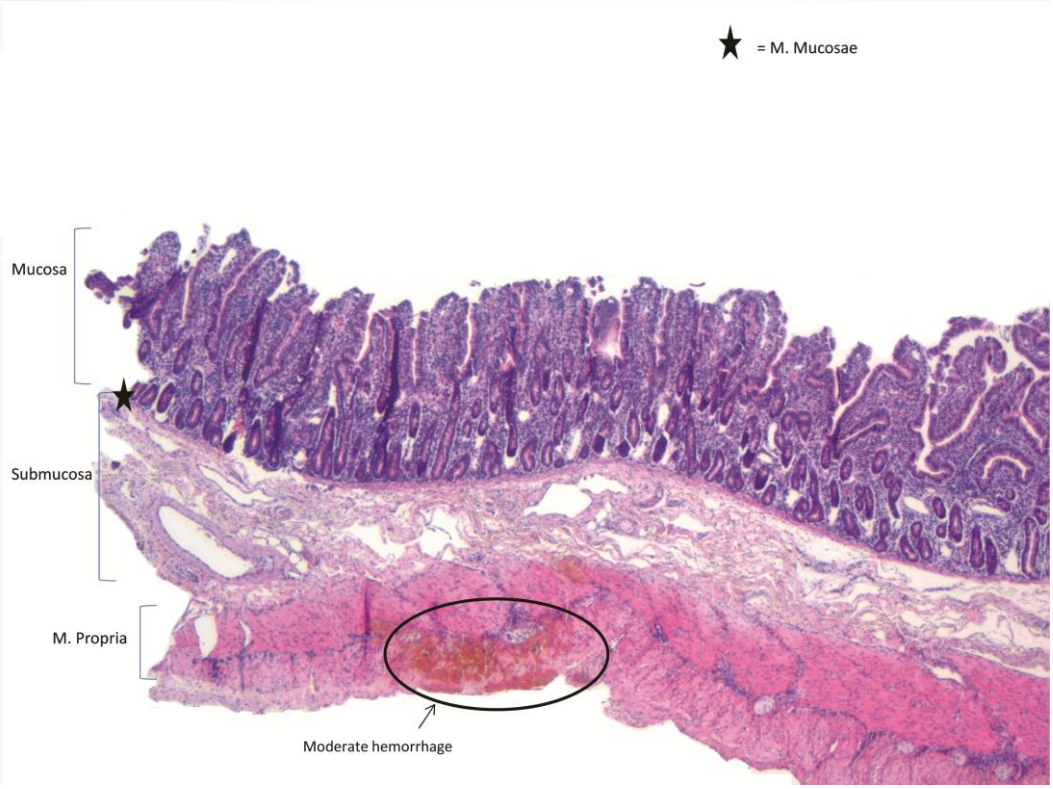

Figure 4.4. close up of moderate hemorrhage.

The number of categories concerning the dependent variable Y was reduced to 3 since the most serious type of damage assessed was moderate hemorrhage. The latter four categories were not excluded however, those categories do not add any significance to the analyses. The categories are: 1 = no damage, 2 = small hemorrhage, 3 = moderate hemorrhage. Then Y relates to ξ as follows.

$$Y = \begin{cases} 1 \text{ if } \xi \le \alpha_1 \\ 2 \text{ if } \alpha_1 < \xi \le \alpha_2 \\ 3 \text{ if } \alpha_2 < \xi \end{cases}.$$

Therefore the relation between Y and the independent variables X_1 and X_2 was adjusted to:

$$P(Y \le j) = \frac{e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}{1 + e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}} \text{ , } (j = 1,2,3) \quad (6)$$

And hence concerning the marginal probabilities per category:

$$\pi_j = P(Y = j) = \frac{e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}{1 + e^{\alpha_j - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}} - \frac{e^{\alpha_{j-1} - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}{1 + e^{\alpha_{j-1} - \beta_1 \cdot X_1 - \beta_2 \cdot X_2 - \gamma \cdot X_1 \cdot X_2}}, \text{ where } (j = 1,2,3) \quad (7)$$

Within this model the following hypotheses were examined.

The model was fitted to the data as follows.

Coefficients	Value	Std. Error	t-value	p-value
β_1	–0.0094	0.0153	–0.6108	0.5432
β_2	1.0197	4.6275	0.2204	0.8262
γ	–0.0342	0.0677	–0.5056	0.6146

,

and

Intercepts	Value	Std. Error	t-value
α_1	–0.3205	1.1589	–0.2765
α_2	0.3264	1.1598	0.2814

.

The p-value was provided under the assumption that β_1, β_2, and γ are normal distributed. This implies that the hypotheses $H_0 : \beta_1 = 0$, $H_0 : \beta_2 = 0$ and, $H_0 : \gamma = 0$ cannot be rejected. To

summarize; the *absolute applied pressure difference* (X_1) does not affect bowel damage, the *grasp method* (X_2) does not affect bowel damage and, the interaction effect between X_1 and X_2 cannot be confirmed. The safe vacuum range can be described as $\left|0, \Delta p_{da} = 97\right\rangle$ in kPa with a time limit of 15 minutes.

Discussion

Aim of the study

The aim of this study was to examine the microscopic effects of vacuum grasping on pig bowels in order to determine a safe range in which vacuum technique can be used or applied as grasping technique in MIS. More specifically, this study focuses on the safety part of vacuum grasping. In addition, vacuum grasping (LVS) is in limited extend compared to mechanical grasping (LMG).

Results demonstrated

Two aspects concerning the results attract attention. First, grasping the bowel where the pressure difference Δp increases from 50 kPa to 97 kPa has no effect on the seriousness of the damage, i.e. there is no serious damage . Second, no clinically relevant damage was assessed at all.
This can be explained as follows. Mechanically, the grasped bowel segment shapes into the nozzle in the same manner at each Δp. The vacuum forces are evenly distributed and the stretch over the grasped bowel tissue is homogeneous [21-24] (Chapter 2 and 3). It is probable that a so called safe limit can be determined concerning vacuum grasping. Beyond this, yet to be obtained safety limit, the occurring bowel damage becomes more serious as Δp increases.

The physiology of grasping the bowel by means of vacuum (LVS) as conducted in this study can be described as follows. The vacuum forces stretch the tissue causing the blood vessels to be saturated during a period of 15 minutes. The stretch or flexibility of the blood vessels was in most cases not exceeded. Then when the vacuum is released from the bowel the blood vessels empty and relax without being damaged. Occasionally they did break which caused small and moderate hemorrhages. This phenomenon is known as extravasation of erythrocytes. Damage caused by hypoxy was not assessed because microscopic changes caused by hopoxia occur after several hours to days. Therefore the study should be conducted in a survival experiment concerning the pigs. When the nozzle was released from the bowel an imprint was visible in some cases.

Concerning mechanical grasping the blood vessels break due to compression causing small and moderate hemorrhages. Just small hemorrhages were observed at the relatively low compression stresses applied during the experiments. Compression stresses at higher magnitudes can result in clinically relevant damage [28, 29].

In several samples fibrinopurulent exudate is present at the serosal side. This is a sign of acute peritonitis and is caused by lengthy and testing in a none sterile environment. These changes are not related to vacuum grasping since it was also present in the control samples.

Limitations of the study

The tests with the LVS and LMG were conducted in a static fashion. This means that a vacuum force or a compression force was applied to the bowel without an additional pull force. Adding a pull force has an effect on the potential bowel damage concerning the LMG due to slipping of the tissue [1]. Regarding vacuum it is not probable that an added pull force will increase the chance for bowel damage [21, 22, 23] (Chapter 2 and 3). Nevertheless further tests should be conducted to exclude this.
The tests were conducted on pigs. Although pig bowel resemble human bowel, it is not recommended to extrapolate the results of this study to the clinical setting [6]. The results are a strong indication though that vacuum technique can be safely used on human bowels.
Sometimes delayed bowel damage can occur, therefore it is recommended as stated above to conduct a survival experiment [31, 32]. Concerning this study that means the pigs should survive for at least 24 hours before the bowel samples are harvested to be microscopically examined. It is presumed that no delayed damages will occur since the assessed damages were very mild in nature.
Grasping by means of vacuum differs from mechanical grasping. Vacuum stretches the bowel while mechanical grasping the bowel compresses. Crush artefacts are therefore more likely to be found regarding mechanical grasping as vacuum grasping. Further testing at stronger levels of Δ p and higher levels of compression forces encompass the possibility that for both grasp techniques different types of damage will occur. That makes it difficult to compare vacuum grasping and mechanical grasping.

Conclusion

The results indicate that vacuum technique can be safely applied on pig bowels and potentially in the clinical setting provided the safe range $\left|0, \Delta p_{da} = 97\right\rangle$ (kPa) is considered and the time limit of 15 minutes is not exceeded.

Recommendations

As mentioned further tests must be conducted including a pull force on the bowel combined with a vacuum force and a survival experiment to examine potential delayed bowel damage. Also tests concerning other types of tissue must be conducted.

Furthermore the development of vacuum instruments suitable for laparoscopic procedures should be initiated. Such instruments can be researched in vivo on pigs simulating laparoscopic procedures. Examples of such studies are; positioning the bowel to facilitate an anastomoses, or retraction of the liver during a cholecystectomy.

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Chapter 5.

Performance and efficiency of a laparoscopic vacuum grasper, a technical note

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Abstract

Introduction. a so called laparoscopische vacuum grasper (LVG) was developed (Delft University of Technology & Karl Storz, KS02253). The LVG is a reusable manually operated medical device that can be used in the clinical area of an operating room. The device is used by an expert to grasp the bowel or small intestine without causing clinically relevant damages to the grasped tissue or organ.

Materials and methods. The LVG uses vacuum force to grasp the bowel. This vacuum is generated manually by means of a cylinder-piston. The instrument exists out of two parts, a front handle integrated with the cylinder, shaft and nozzle, and a back handle integrated with a piston and spring. The pressure levels were obtained in two ways, the expected pressure and the measured pressure, both based on increase in start volume.

Results. The pressure level of the LVG was obtained by calculation and then verified by measurements. The LVG generates a maximum pressure difference of 60 kPa (performance) which allows for a grasp force on the bowel of 4 N. The energy loss due to friction is 30 % (efficiency).

Discussion. The performance of the LVG depends on how well the vacuum system as a total operates. There are three main factors influencing the performance which are the friction force $F_{friction}$, the spring force F_s, and the start volume V_0. These factors can be optimised to improve the performance of the LVG. The LVG has potential to be used as a grasping device for laparoscopic surgery.

Nomenclature

A_{cs} = cross section area of the cylinder in m^2

C_s = spring constant in $N \cdot mm^{-1}$

F_s = spring force in N

F_v = vacuum force in N

l = travel length of the spring in m^2

M_{eff} = mechanical efficiency in %

n = amount of gas in *moles*

p = pressure in *kPa*

p_a = atmospheric pressure in *kPa*

p_d = decreased pressure in *kPa*

p_e = expected pressure in *kPa*

p_m = measured pressure in *kPa*

Δp = pressure difference in *kPa*

R = universal gas constant $8,314472\ J \cdot mol^{-1} \cdot K^{-1}$

T = temperature in K

V = volume in m^3

V_0 = start volume LVG in m^3

V_{LVG} = increased volume LVG in m^3

Introduction

In order to safely grasp the human bowel, so called atraumatic graspers are frequently used during laparoscopic procedures. The term atraumatic refers to the notion that an instrument grasps the bowel firmly without causing damage, i.e. the instrument grasps with a *safe grip*. Keeping in mind the fact that laparoscopic surgery requires professional skill and since the number of laparoscopic procedures is increasing, this is a sensible development. In literature several studies were found concerning atraumatic grasping where potential improvements and solutions were described in conventional and non-conventional approaches [1-10]. Two previously conducted studies by the authors show that vacuum technique can be utilised as an atraumatic grasping technique [6, 7] (Chapter 2 and 3). Based on these two studies a so called laparoscopische vacuum grasper (LVG) was developed (Delft University of Technology & Karl Storz, KS02253). The LVG is a reusable manually operated medical device that can be used in the clinical area of an operating room. The device is used by an expert to grasp the bowel or small intestine without causing clinically relevant damages to the grasped tissue or organ [6] (Chapter 2). The aim of this technical note is to determine the performance and efficiency of a manual vacuum instrument (LVG). instrument.

Materials and methods

Vacuum principles of the LVG

The LVG uses vacuum force to grasp the bowel. This vacuum is generated manually by means of a cylinder-piston. The instrument exists out of two parts, a front handle integrated with the cylinder, shaft and nozzle [7] (Chapter 3), and a back handle integrated with a piston and spring (Figure 5.1). The basic principle to generate vacuum is based on the Ideal Gas Law.

Figure 5.1. The laparoscopic grasper (LVG)

The Ideal Gas Law states:

$$p \cdot V = n \cdot R \cdot T \qquad (1)$$

Where p is the pressure of the gas in Pa, V the volume measured in m³, n the amount of gas in moles, R the universal gas constant, and T the temperature in K. With regard to the conducted calculations, pressure is described in magnitudes of kPa.

More specifically Boyles Law can be applied to the vacuum system of the LVG. Boyles Law is a special version of the Ideal Gas law where T and n are constants in a closed system. Then the pressure and volume are reversibly proportional related. Boyles Law states:

$$p \cdot V = C \tag{2}$$

Where C is a constant. This means that in a closed system where Boyles Law applies, an decrease in pressure p can be obtained by increasing volume V . Therefore p and V in can be calculated as follows

$$p_1 \cdot V_1 = p_2 \cdot V_2 \tag{3a}$$

where p_1 and V_1 are the pressure and volume in the *before situation* and p_2 and V_2 are the pressure and volume in the *after situation*. Concerning the LVG, p_1 and V_1 are the atmospheric pressure p_a (100 kPa) and start volume V_0 , and p_2 and V_2 are the obtained decreased pressure p_d (kPa) and increased volume V_{LVG} (m^3).

$$p_a \cdot V_0 = p_d \cdot V_{LVG} \tag{3b}$$

It is noted that V_0 has not a fixed magnitude, rather V_0 has a minimum of $3.0 \cdot 10^{-6}$ m^3 since that is the start volume of the LVG when the handle is fully compressed. V_0 depends on how well the cylinder-piston system is closed. The volume of the LVG can be calculated as follows

$$V_{LVG} = A_{cs} \cdot l + V_0 \tag{4}$$

Where A_{cs} is the cross section area of the cylinder in m^2 and l is the travel length of the spring in m.

Generating vacuum

The conical pressure spring that is used for the LVG has the following specifications.

- Unloaded length of 38.1 mm
- Block length 2.8 mm
- Force at block length 56.76 N

- Spring constant (C_s) of 1.61 N/mm

The vacuum is generated as follows. The handle of the LVG is entirely compressed and simultaneously the inlet of the nozzle is sealed off (by the grasped tissue). When the handle is released the spring force F_s (*N*) starts to relax and pushes the piston out of the cylinder which causes the increase in volume and hence a the pressure decreases. F_s decreases when it starts to relax its magnitude decreases while p_d increases. This means that at a certain travel length a state of static equilibrium is reached between F_s , the vacuum force F_v (*N*) and the friction force $F_{friction}$ (Figure 5.2). F_s and F_v can be calculated as follows.

$$F_s = ((38.1 - 2.8) - l) \cdot C_s \quad (5)$$

$$F_v = \Delta p \cdot A_{cs} \quad (6)$$

where Δp is the pressure difference in kPa obtained from p_d

$$\Delta p = 100 - p_d \quad (7)$$

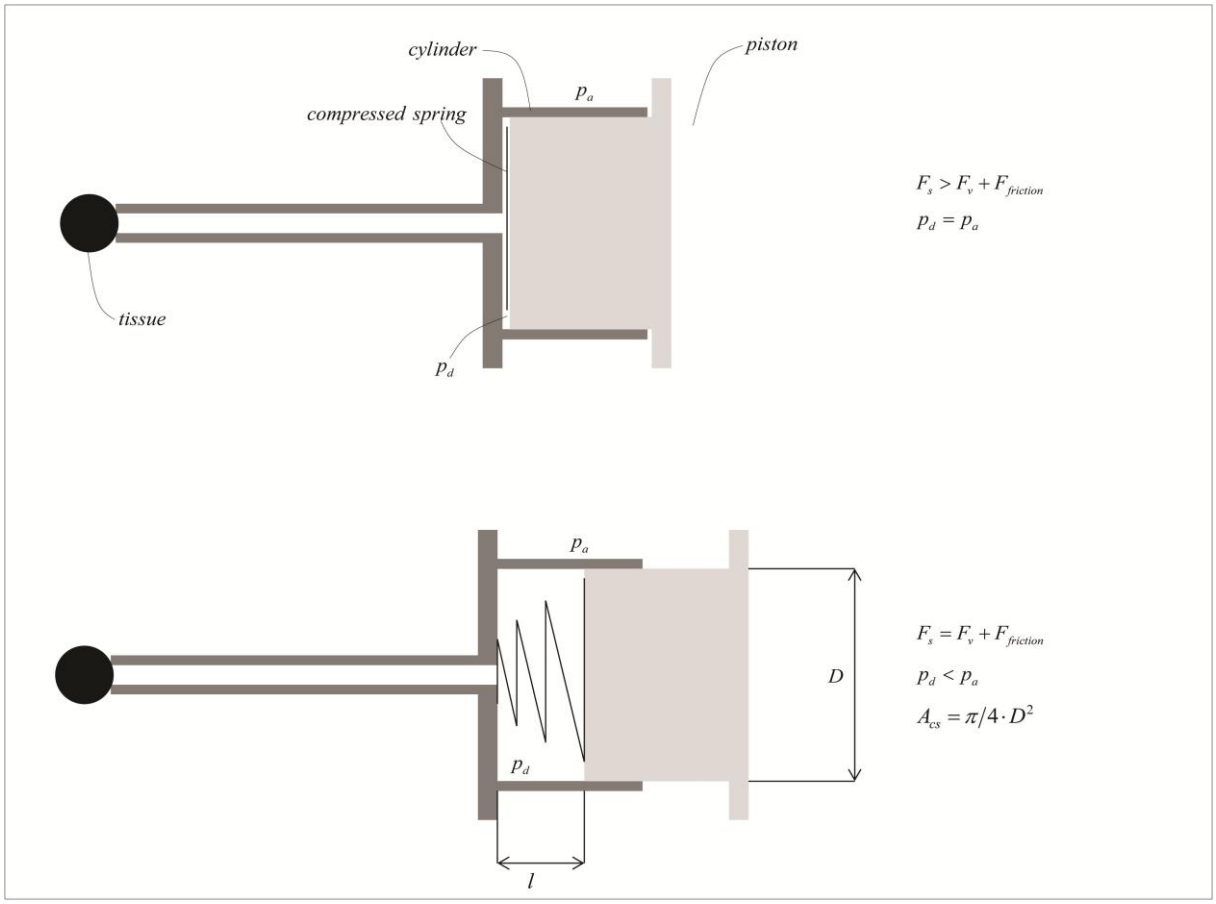

Figure 5.2. Schematic view of the LVG concerning the vacuum force and spring force. The upper view shows the LVG in the state where the handle was just released and the spring just starts to relax. The lower view shows the LVG in the state of static equilibrium.

F_s and F_v are in linear proportion to one another. It was presumed that F_v is lower in magnitude compared to F_s due to energy loss caused by friction in the cylinder-piston system. In terms of energy in- and output of the vacuum system, F_s is considered the input and the F_v output. This means that the mechanical efficiency M_{eff} of the LVG can be calculated as follows:

$$\frac{F_v}{F_s} \cdot 100\% = M_{eff} \tag{8}$$

and

$$F_s = F_v + F_{friction} \quad (9)$$

Calculations concerning the LVG

The pressure level p_d generated by the LVG was determined and calculated in two different ways, the expected pressure p_e and the measured pressure p_m.

A valve of a pressure transducer was adapted with variable volume and connected to the LVG. V_0 was pre-set at three different start volumes, $3.0 \cdot 10^6$ m^3, $4.0 \cdot 10^6$ m^3 and $7.2 \cdot 10^6$ m^3. While the LVG was connected to the valve, the travel length l was measured at each V_0 when pressure was generated. p_e was obtained from equations (4) and (5), where l is the average travel length and p_d resembles p_e.

Then the valve was connected to both the nozzle of the LVG and a digital vacuum (pressure) reader. When pressure was generated, p_m was noted as the measured output from the digital vacuum reader. As with p_e, p_m was obtained from equations (3b) and (4), where l is the average travel length and p_d resembles p_m.

In addition to these calculations, F_s was determined based on the travel length. The performance of the LVG was defined as the output F_v of the vacuum system which was determined based on p_e and p_m using equation (6) and (7). The mechanical efficiency M_{eff} of the LVG was determined using equation (8)

Ergonomic considerations

The dimensions of the handle of the LVG was designed according ergonomic guidelines concerning a so called *power grip* or *clubbing grip* [11, 12]. A power grip is obtained when one utilises the whole hand to grasp an object, in this case a handle of a surgical instrument. The handle span, the length and width of the handle parts, and the magnitude of the compression spring were determined in relation to the power grip principles.

The handle span of the handle when it is opened and when it is closed was set at 80 mm and 45 mm respectively. Concerning precision tasks the handle should be fully open between 60 - 80 mm [13]. Both men and woman are strongest at a handle span of 45 – 55 mm [14].

The length & width of the front and back handle parts were set at 80 mm & 30 mm and 65 & 18 mm respectively [13].

The maximum force of the spring was determined at 30% of the maximum gripping force a P5 woman, age 50 - 54 years, is capable of inducing which is 201 N [14, 15]. The handle when compressed had a handle span of 45 mm and induced a force of 56.8 N ±0.1 N to the users hand. The P5 woman was taken as point of reference concerning F_s to ensure a large user group.

Results:

Table 5.1 shows the results related the conducted calculations and measurements concerning the LVG. The travel length (l) and the measured pressure (p_m) are average measured values. The spring force (F_s), vacuum force (F_v [p_e & p_m]), expected pressure (p_e) and mechanical efficiency (M_{eff} [p_e & p_m]) are calculated values.

V_0 (10^{-6}m³)	3.0	4.0	7,2
l (10^{-3}m)	8.1 ± 0.1	9.3 ± 0.3	11.7 ± 0.1
Fs (N)	43.9	42.9	38.1
Fv (N) [*pe*]	31.2	29.3	24.6
Fv (N) [*pm*]	32.0	30.8	26.6
pe (kPa)	41.2	44.9	53.6
pm (kPa)	39.7 ± 0.6	42.1 ± 0.5	49.9 ± 0.3
Meff (%) [*pe*]	71.1	68.3	64.6
Meff (%) [*pm*]	72.9	71.8	69.8

Table 5.1. Results concerning the conducted tests with the LVG.

Figure 5.3 shows the results concerning the generated pressure in relation to the start volume. p_e and p_m resulted in comparable values and confirm the accuracy of the calculations and measurements.

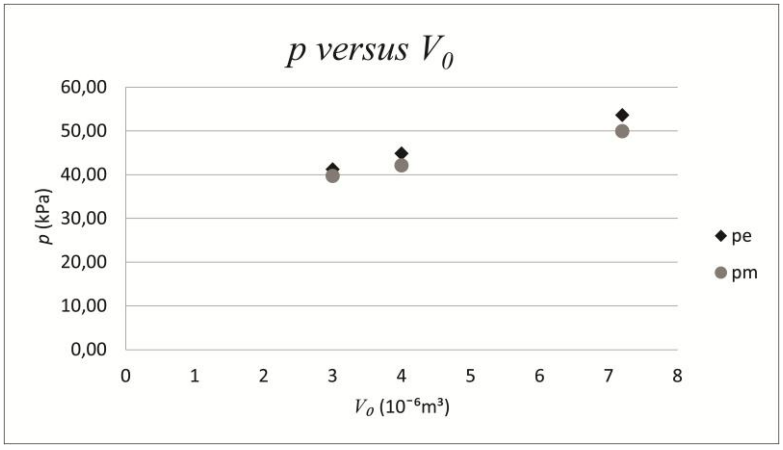

Figure 5.3. Generated pressure by the LVG in relation to the start volume.

Figure 5.4 shows the spring force (F_s) and vacuum force (F_v) in relation to the travel length (l). F_{v1} , F_{v2} and F_{v3} represent the vacuum force in relation to l at $V_0 = 3.0 \cdot 10^{-6} m^3$, $4.0 \cdot 10^{-6} m^3$ and $7.2 \cdot 10^{-6} m^3$ respectively. As described in the materials and methods section, F_s , F_v and $F_{friction}$ are in a state of static equilibrium where the friction compensates the loss in energy of the spring.

Figure 5.4 also shows the states of equilibrium E_1 , E_2 and E_3 where the gap between these points and the F_s line represents the friction force which is 30% of F_s . The vacuum force concerning each of the three start volumes is represented in F_{v1},F_{v2} and F_{v3} where $V_0 = V1 = 3.0 \cdot 10^6$ m^3, $V_0 = V2 = 4.0 \cdot 10^6$ m^3 and $V_0 = V3 = 7.2 \cdot 10^6$. Figure 4 also shows that F_v decreases when V_0 decreases (dotted lines).

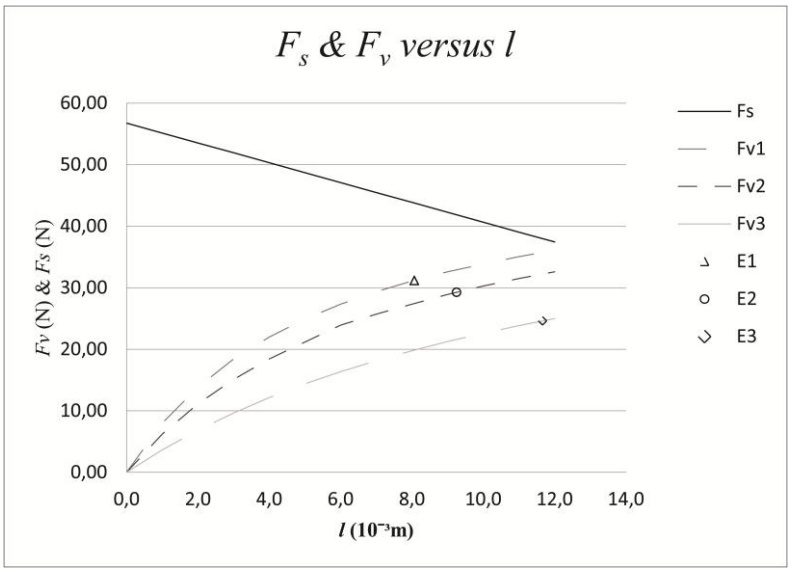

Figure 5.4. Spring force and vacuum force in relation to the travel length.

Discussion

The performance of the LVG was determined as the vacuum force F_v. The higher F_v, the better the performance. The pressure levels p_d were obtained in two ways (p_e and p_m), both based on increase in start volume. First the pressure level was obtained by calculation and then verified by measurements. This method provides a reliable result since both, calculations and measurements, confirm one another.

The performance of the LVG depends on how well the vacuum system as a total operates. There are three main factors influencing the performance. These factors are the friction force $F_{friction}$, the spring force F_s, and the start volume V_0. The following explains how these three factors can be optimised in relation to the performance of the LVG.

The mechanical efficiency of the LVG is 70% (Table 5.1 & Figure 5.4). That means an energy loss of 30% due to friction. This loss of energy can be reduced by eliminating friction.

A hypothetical graph is used to illustrate the increase in vacuum force F_v when the friction force were to be eliminated (Figure 5.5a). The start volume $V_{0/1}$ and the spring force F_{s1} remain unchanged. The elimination of friction means a loss of energy of 0%. Therefore the increase in vacuum force is where the lines of F_{s1} and $F_{v(V_{0/1})}$ meet ($a \rightarrow b$). As l increases, F_v also increases however at an increasingly lower rate. This means that the handle span of the LVG concerning this example is becoming rapidly larger which may compromise comfort of use if it exceeds the margin of 80 mm [13]. Eleminating the friction is impossible, although a reduction of it may be accomplished by using different materials and/or coatings with regard to the cylinder-piston system. Reduction of friction

enhances the performance of the LVG within its current dimensions, however it is a rather limited solution.

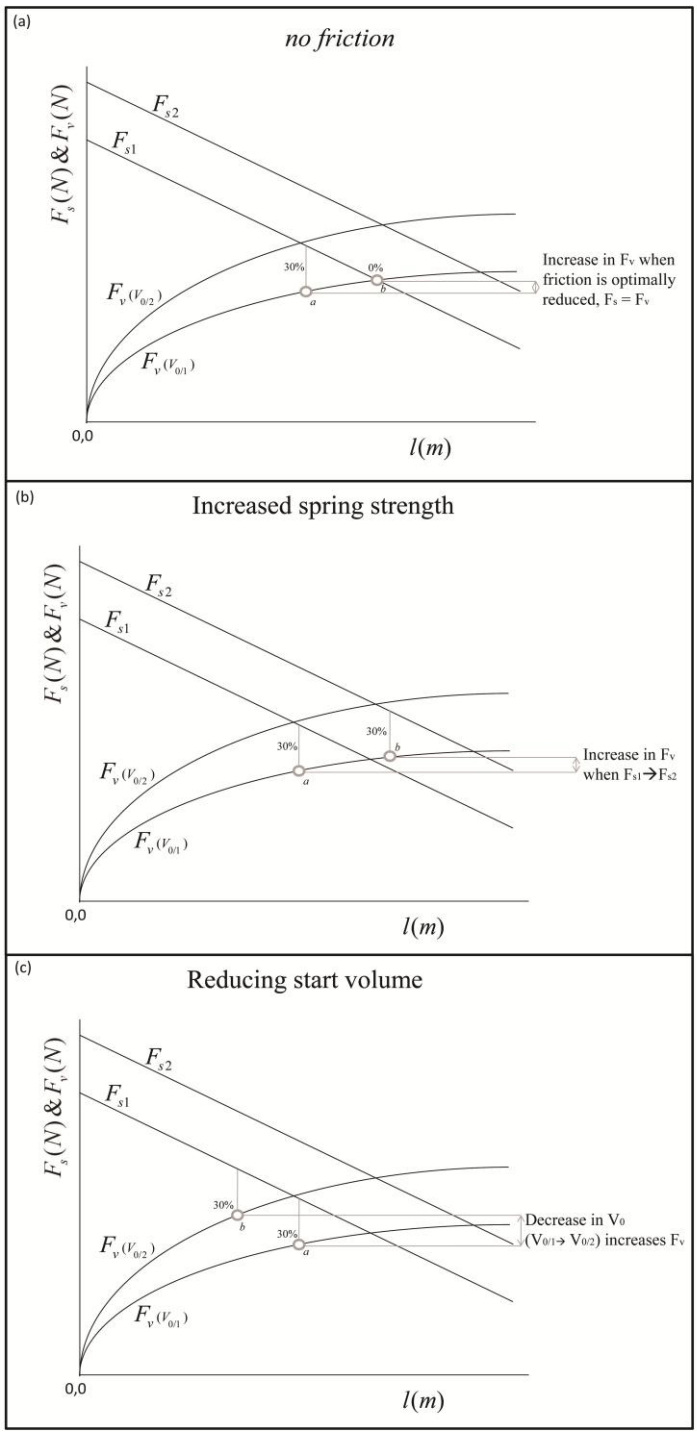

Figure 5.5. Increase the vacuum force due to (a) elimination of friction, (b) increase in spring strength, and (c) reduction of start volume.

Then the strength of the spring force can be increased. A hypothetical graph is used to illustrate the increase in vacuum force F_v when the strength of the spring is increased (Figure 5.5b). The start volume $V_{0/1}$ remains unchanged and the friction causes an energy loss of 30 %. The results concerning this example are similar to the results elimination of friction.

The disadvantage of a stronger spring is that it exceeds the 30% of the maximum gripping force of a P5 woman [14, 15]. The number of potential users of the LVG is then reduced. It is questionable whether such a solution is desirable since the gain in vacuum force is minimal.

A stronger spring may also mean a longer spring. A longer spring has the advantage that when it is compressed over the same length as a short spring, it loses less energy relatively spoken. The disadvantage of this is that it results in a larger handle casing which in turn leads to a larger start volume.

And third, the start volume can be reduced. A hypothetical graph is used to illustrate the increase in vacuum force F_v when the start volume is reduced (Figure 5.5c). The spring force F_{s1} remains unchanged and the friction causes an energy loss of 30 %. The results confirm that a smaller startvolume ($V_{0/2}$) generates a lower pressure level (p_d) which leads to a higher pressure difference (Δp) and hence a higher vacuum force (F_v). When V_0 is minimalised, an increase in V_{LVG} by a factor two ($\Delta p = 50kPa$) is reached at a much lower l ($a \rightarrow b$).

This means that F_v increases more rapidly in relation to l and the state of equilibrium is reached at a higher F_s (less energy loss). Therefore, V_0 should be as small as possible. By reducing V_0 the performance of the LVG is optimised within the current dimensions of the handle which are ergonomically sound.

A larger cylinder diameter (A_{cs}) may also help to reduce the travel length (Figure 5.2). In terms of the physical principles, increasing A_{cs} is similar to decreasing V_0 since the ratio between V_0 and V_{LVG} determines p_d . The travel length l decreases, therefore the spring force F_s loses less energy which results in a higher vacuum force F_v .

The increase of A_{cs} is limited and may also induce the need for a stronger spring and altering the handle dimensions may result in discomfort of use [11-16].

Both, the elimination of friction and a stronger spring force result in a large travel length and hence a wide handle span of the LVG. This is largely due to the dimensions of the LVG which were determined by the applied ergonomic guidelines. These guidelines enhance the comfort of use of the LVG and yet these anthropomorphic guidelines also limit the vacuum system in its performance. From the hypothetical graphs in Figure 5.6 it can be concluded that the best option to optimise the performance of the LVG, is to reduce the start volume as much as possible. Perhaps also increase A_{cs} provided that the comfort of use is not compromised. Then a friction reduction and an increase in spring force can be used as additional modifications to enhance the performance even further. It is noted that the data presented in this study is specifically applicable for the LVG.

Concerning the nozzle, the LVG generates a potential pull force of 4 N to manipulate the bowel ($\Delta p = 60kPa$) [7] (Chapter 3). This is sufficient for basic handling and manipulation of the bowel. However, with regard to ‘presenting for an anastomoses’ or ‘positioning for incision’ a 5 N pull force is desired [1, 17]. The LVG is capable of doing these latter tasks however, the chance that the grasped tissue will slip at 4 N maximum pull force is more probable as it is at a pull force of 5 N. It is recommended that the performance of the LVG is optimised to ensure a maximum pull force of 5 N. It

is also recommended that the LVG is to be tested in an in vivo setting to determine its comfort of use and performance according an realistic user test.

The LVG has potential to be used as a grasping device for laparoscopic surgery. The performance of the LVG can be improved. A next version of the LVG which generates the required pull force is being developed.

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Chapter 6.

Intermezzo: **Usage validation of a laparoscopic vacuum grasper**

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This intermezzo can be interpreted as a pre-study to obtain insight in the functional and medical usage of the laparoscopic vacuum grasper. The obtained insights are to be used for further development of the device and as a pilot study to start up a clinical validation of the laparoscopic vacuum grasper.

Introduction

Minimal invasive laparoscopic surgery is a type of minimal invasive surgery (MIS) that focusses on the abdominal cavity where the bowel or small intestine is often manipulated (e.g. gastric bypass and bowel resections). So called laparoscopic grasper instruments are generally used to grasp and manipulate the bowel. This type of grasping can be referred to as conventional mechanical grasping.

These conventional grasper instruments can be characterised as follows. The grasper instrument exists out of three basic parts; the handle, the shaft, and the grasper jaw. The mechanical movement of the handle is converted into movement of the grasper jaw by means of the connecting rod between handle and grasper jaw. The movement of the handle is relatively large compared to resulting movement of the grasper jaw. The effectiveness of the grasper instruments is largely determined by its mechanical efficiency [1, 2].

These characteristics make it challenging for the surgeon to sense how firm the bowel is actually grasped. The surgeon may grasp the bowel with too much force or not enough force due to his interpretation of the image on the monitor and the tactile feedback in the handle [2, 3, 4]. Both grasping with excessive force or not enough force may cause bowel damage [5] (Chapter 2). Therefore, expert skill and training is required to use these grasper instruments safely during laparoscopic procedures. Many studies have been conducted concerning conventional mechanical grasping. These studies deal with tissue damage, functionality, ergonomics and comfort of use, and training models (Chapter 1 and 2).

The question arises whether it may be possible to introduce an instrument which requires less expert skill and less training to use, and which simply grasps safely. In a joint project Karl Storz GmbH and Delft University of Technology a laparoscopic vacuum grasper (LVG, KS02253) was developed

(Chapter 5). This device was specifically designed to be used in order to grasp and manipulate bowel tissue. The LVG was used in a series of usage trials on harvested and life pig bowels.

A previous study shows that a vacuum grasper is safe within the margins of low vacuum and a maximum time of 15 minutes (Chapter 4). Other studies underline the conclusions of this study (Chapter 2 and 4).

The aim of this study is to determine the feasibility and usability of the laparoscopic vacuum grasper (LVG). The basic functioning of the device, comfort and ease of use, and concerns related to bowel damage and patient safety were assessed.

Materials and Methods

A laparoscopic vacuum grasper (LVG) was used in a box trainer on pig bowels by 6 surgeons, four male and two female. The bowels were harvested within 12 hours before testing. Additional to this test on harvested pig bowels the LVG was tested in a life porcine model by two of these surgeons.

The LVG is a reusable device and uses vacuum force to grasp the bowel. Instead of a set of jaws, a nozzle grasps the bowel . The shape of the nozzle was described in a previous study (Chapter 2, 3 and 5). The vacuum is manually generated by using a piston-cylinder system. This means that the vacuum force is generated by creating a difference in volume as with a syringe. Generating vacuum with the LVG can be described as follows. When the handle is compressed, the piston travels into the cylinder causing a pressure spring to tension and by doing so the piston reduces the start volume inside the LVG. When the handle is released the piston starts to relax. The pressure spring pushes the piston outwards of the cylinder which creates an increase in volume and hence a vacuum (Chapter 5). This principle can be described as reversed handling, relax to obtain grip on the bowel and squeeze to release the bowel. The LVG was used in combination with a 10 mm trocar.

The laparoscopic gastric bypass simulations were conducted according standard protocol. This means that for this study there was no adjustments in the number of trocars used, the types of instruments that were used, nor adjustments in the protocol of the actual procedure. The use of the LVG was combined with the standard procedure of the gastric bypass as part of the procedure. This means that the operative/test time was not lengthened due to the use of the LVG.

The LVG was used during the procedure of a laparoscopic gastric bypass simulation in a box trainer. These events can be described as follows. As it was designed, the LVG was strictly and only used to grasp the bowel.

The bowel was macroscopically assessed by the surgeons. A validation protocol was used to conduct the assessment which consisted of two parts. First a critical evaluation by means of a questionnaire was conducted. This questionnaire was used to assess the surgeons opinions concerning the usage and functionality of the LVG (Figure 6.1a).. The second part of the assessment consisted of a checklist to

assess the medical functioning of the LVG (Figure 6.1b). The checklist scored the grip on the bowel, the level of atraumatic grasping, and the comfort of use of the LVG in terms of bad, moderate and good. This scale was arbitrary chosen A bad score concerning grip was given when the LVG was incapable of providing sufficient grip on the bowel. A moderate score meant that the LVG provided overall a sufficient grip on the bowel, and a good score was given when the grip was continuously sufficient.

A bad score concerning atraumatic grasping meant that clear visible damage was visible, serosa damage, seromuscular damage and perforations. A moderate score meant a bruise or ecchymoses (tissue layers intact). A good score was given when there was no damage observed at all (Chapter 2).

A bad score in terms of comfort of use was given when the participant experienced physical pain. A moderate score meant that the participant felt that he was obstructed to perform his task without experiencing physical pain. A good score was given when the participant was capable of performing his task comfortably.

In addition to this study two surgeons were asked test the LVG on a life porcine model and give their comments on the device concerning its usability. The aim of this additional test was to get an impression of the functioning of the LVG on life pig bowels. No gastric bypass procedure was simulated during this test. The studies on the box trainer and on the life porcine model took place at the Catharina Hospital Eindhoven, The Netherlands and at the Academic Medical Centre in Amsterdam, The Netherlands, respectively.

Validation protocol (Questionnaire)

Was the function of the device clear to you (first time usage)?
Yes / no
because,…….

Was it clear that the instrument has an upper and lower halve which determine how to position the instrument in your hand?
Yes / no
because,……..

Did this influence the usage in any way?
Yes / no
because,…….….

Did you succeed to correctly position the inlet of the nozzle in order to grasp the bowel?
Yes / no
because,……..

Did you fully squeeze the handle each time in order to grasp the bowel?
Yes / no
because,……..

In order to obtain an optimal grip on the bowel you should wait for 1 second after grasping the bowel before manoeuvring. Did you do this?
Yes / no
Because,……..

When you position the device in order to grasp the bowel you are required to use force. When the Bowel is grasped you can relax your hand. How did you experience this?
……

Could you comment on releasing the bowel (squeezing the handle in order to release)
……

Did you experience any physical discomfort during the usage of the instrument (posture, arms, hands)
Yes / no
Namely……....

Figure 6.1 a). Validation protocol concerning the questionnaire.

Validation protocol (checklist)

Measuring the bowel

Grip:

Bad Moderate good

Atraumatic grasping:

Bad Moderate good

Comfort:

Bad Moderate good

Remarks:……
……...

Presenting when opening the bowel

Grip:

Bad Moderate good

Atraumatic grasping:

Bad Moderate good

Comfort:

Bad Moderate good

Remarks:……
……...

Presenting the bowel to the stapler

Grip:

Bad Moderate good

Atraumatic grasping

Bad Moderate good

Comfort:

Bad Moderate good

Remarks:……
……...

Holding, stabilizing the bowel during suturing

Grip:

Bad Moderate good

Atraumatic grasping:

Bad Moderate good

Comfort:

Bad Moderate good

Remarks:……
……...

Comfort of use

The amount of force that is required to operate the instrument:

Bad Moderate Good

Remarks:……

The handle rotates in your hand according to your movements. Could you comment on that?

Bad Moderate Good

Remarks: ……..

Figure 6.1 b). Validation protocol concerning the checklist.

Results

First a description explaining the outcomes of the questionairre, then the assessment of the LVG with regard to the checklist.

Concerning the questionnaire (Figure 6.1a): (Question (Q) 1) The basic function of grasping tissue was clear for all participants. The reversed-handling principle of the LVG was not clear for all participants. For two participants the working of the LVG had to be explained..

(Q 2 and 3) None of the participants noticed that the LVG has and upper halve and a lower halve. The instrument was found to be symmetrical. Four of the participants used the LVG in its upside down position however, after being notified of this fact, they did not experience any discomfort from this.

(Q 4, 7 and 8) Positioning the nozzle correctly on the bowel and subsequently grasping the bowel required some practice from all participants. The handle should be fully closed while positioning the nozzle on the bowel. This usage aspect of the LVG was considered by two participants as discomforting. The principle of reversed handling was overall not experienced as discomforting however it did took some time getting used to. One of the participants did regard the reversed handling as none-intuitive. Releasing the bowel was experienced as successful for all participants.

(Q 5 and 6) Four of the participants consequently did not fully close the handle in order to grasp the bowel. Therefore the level of vacuum the LVG generated was not entirely sufficient. This caused the bowel to accidentally release itself from the nozzle more often compared to the two participants who did fully close the handle. It was advised to wait for a second after the bowel was grasped before actually manipulating the bowel in order to allow the spring in the handle to generate sufficient vacuum (Chapter 5). None of the participants took this into account.

(Q 9) Overall handling of the LVG was considered as comfortable by all participants. Nevertheless, the general opinion was also that the LVG required more hand force to operate compared to a conventional mechanical grasper.

Concerning the checklist (Figure 6.1b): The grip on the bowel during *measuring* the bowel was assessed as ‘good’ by two participants and as ‘moderate’ by four participants. *Measuring* the bowel was assessed as ‘moderate’ considering the comfort of use. The grip on the bowel during *presenting, holding*, and *stabilizing* the bowel was assessed as ‘moderate’ by all participants. The experienced comfort of use during *presenting, holding*, and *stabilizing* the bowel was also assessed as ‘moderate’ by all participants (Figure 6.1b). The overall comfort of use was assessed as ‘moderate’ by four participants and as ‘good’ by two participants. It was suggested that users with small hands may sooner experience discomfort in handling the LVG.

No bowel damage what so ever was observed by any of the participants, in both the box trainer simulation and the life porcine model, hence atraumatic grasping was overall assessed as ‘good’. No difference in performance, atraumatic grasping and comfort of use was observed when using the LVG in a life porcine model.

Discussion

The aim of this study was to validate the usage of a laparoscopic vacuum grasper in terms of its technical and medical functioning.

The overall comment on the LVG is that it takes some time to get acquainted to it. After some practice the LVG performed quite well. There seems to be a learning curve. The main difference when compared to a conventional mechanical grasper, besides the difference in generating grasp force, is the reversed handling of the LVG. This reversed way of handling could be considered as none intuitive since the surgeons are used to a different way of handling a grasper instrument. Two participants squeezed the handle expecting the LVG to grasp the bowel. This was confusing to these participants and it required instruction. This indicates that the working of the LVG should be clearly explained before usage. Nevertheless the basic working of the device, a grasp instrument, was clear to all participants.

Another important aspect concerning the functioning of the LVG is that the handle should be fully squeezed in order to generate sufficient vacuum force. And it is advised to wait for approximately 1 second for the spring to generate the maximum amount of vacuum force. Both aspects, to fully squeeze the handle and to wait for a moment, were hardly considered by the participants. The main reason for this was that they were not used to perform these actions when using conventional mechanical graspers. This shows that the surgeons preferred the way of handling that they were already used to.

None of the participants experienced the use of the LVG as discomforting. The handle was not too big or too small. The amount of force required to squeeze the handle was assessed as comfortable. Nevertheless, the participants did experienced some challenge when positioning the LVG on the bowel for the first time. The participant was required to squeeze the handle and position the LVG at the same time before grasping the bowel. This was also considered as none intuitive.

When *presenting*, *holding*, and *stabilizing* the bowel, the participant could relax his hand (reversed handling). This was considered comfortable since the spring also functioned as a ratchet without locking the handle. This characteristic of the LVG is interesting when using the LVG to hold or stabilize the bowel for a longer period of time, hence using the LVG as a retractor device.

Releasing was a successful task for each participant. No visible damage was assessed by any of the participants as well as on the harvested as on the life pig bowels. This is supported by previous studies [refs] (Chapters 2 and 4). This underlines that vacuum technique in principle is a safe grasping technique to be used in minimal invasive surgery (MIS).

A limitation of this study is that the tests were not conducted in the clinical setting. It is likely that the actual clinical setting provides more insight in the technical and medical functioning of the LVG. The tests were conducted by experienced surgeons, who have specific preferences regarding the usage of the instruments, it is interesting to run the tests also with novice surgeons to observe the difference in usage. A novice surgeon does not yet have a preference regarding the usage of a grasper instrument.

Conclusion

This study supports the findings of previous studies that vacuum technique can be safely used to grasp and manipulate the bowel. The LVG should be further developed in order to generate a higher vacuum force which would increase its performance (Chapter 5). Another important aspect is whether the aspect of 'reversed handling' is appropriate and effective or whether the handling of the LVG should be more intuitive as a conventional mechanical grasper. The LVG is specifically designed for grasping the bowel, it should be investigated whether the same type of nozzle could also grasp different types of organs. It is also advised to conduct clinical validation with the tested LVG, or with a next generation LVG.

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Chapter 7.

Concepts of vacuum technology for retraction and stabilization of organs during laparoscopic and single incision laparoscopic surgery

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Abstract

Introduction. In the past decade research and new developments on MIS were focused mainly on minimizing operation trauma, reducing postoperative pain and improving cosmetic results. To achieve these targets surgeons strove to reduce the number and size of access ports. Furthermore, concepts of single incision laparoscopic surgery were developed.

Materials And Methods. Three functional models of a so called laparoscopic vacuum retractor (LVR) were assessed using laparoscopic porcine models. Two female pigs weighing between 35 kg and 50 kg were used for this study. An LVR is used to manipulate the bowel during a minimal invasive surgery (MIS) procedure. The LVR is introduced into the abdominal cavity through a trocar and subsequently fixed to the abdominal wall. The bowel or a segment of the bowel is then stabilized by the LVR.

Results. No bowel damage as well as damage to the abdominal wall was assessed for neither one of the LVR types. Successful bowel anastomoses were performed with three different LVR types. Though differences in performance and comfort of use were assessed.

Discussion. Vacuum retraction has potential to be used in MIS, conventional laparoscopic surgery and single portal laparoscopic surgery (SPLS). An LVR is comfortable in its use providing it retracts the organ with a safe grip.

Introduction

In the past decade research and new developments on MIS were focused mainly on minimizing operation trauma, reducing postoperative pain and improving cosmetic results. To achieve these targets surgeons strove to reduce the number and size of access ports. Furthermore, concepts of single incision laparoscopic surgery were developed.

Reduction of the number of ports and the port size used in the course of advanced laparoscopic procedures does reduce trauma of the abdominal wall and improves cosmetic results. Downside is however that retracting and stabilization becomes difficult and challenging.

Single port laparoscopic surgery (SPLS) offers improved cosmetics results since the scar is hidden in the natural scar of the umbilicus. Furthermore, it potentially offers a reduction of postoperative pain. Success outcomes of SPLS for colonic surgery are reported [10, 11, 12, 13, 14]. The procedure is however technically difficult and challenging with regard to the number of instruments that can be used trough one port. It necessitates intense training to be able to perform the procedure swiftly [1]. In spite of its technical difficulties SPLS became increasingly used for procedures as appendectomy, cholecystectomy [2 - 14] as well as for advanced laparoscopic procedures. SPLS is also feasible for bariatric surgery although it is even more challenging for surgeons as manipulation, retraction, stabilization and suturing of the bowel is needed [15, 16, 17].

For this study three functional models of a vacuum retractor system were developed in a joint project between Delft University of Technology and Karl Storz GmbH. The function of retractors was to safely grasp and hold the bowel during the advanced laparoscopic, particularly when the bowel anastomoses has to be performed, thus eliminating the use of additional access ports and/or assistance. The retractors were tested in vivo in several laparoscopic porcine models and may as well be used for retracting organs such as the gallbladder, liver and stomach.

Main aim of the study was to determine the feasibility of a stand-alone vacuum retractor facilitating bowel anastomoses. Assessment was focused on the usage and functionality of the device. Finally, potential use of the device in other surgical procedures is discussed.

Materials & Methods

Three functional models of a so called laparoscopic vacuum retractor (LVR) were assessed using laparoscopic porcine models. Two female pigs weighing between 35 kg and 50 kg were used for this study. The pigs were healthy and anaesthetized. First, a general description concerning the retractor is provided followed by a description of each retractor type. Then the analysis as conducted is explained.

General functionality of a laparoscopic vacuum retractor

An LVR is used to manipulate the bowel during a minimal invasive surgery (MIS) procedure. The LVR is introduced into the abdominal cavity through a trocar and subsequently fixed to the abdominal wall. The bowel or a segment of the bowel is then stabilized by the LVR. The LVR utilizes vacuum force to grasp and hold the bowel. When the surgical task, e.g. a bowel anastomoses, is successfully completed the LVR is extracted from the abdominal cavity through the trocar. Concerning this study the LVR was assessed as a stabilization device to facilitate a bowel anastomoses.

Laparoscopic vacuum retractor type 1A

The functional model of laparoscopic vacuum retractor type 1A (R1A) is shown in Figure 7.1a. The nozzle, which grasps the bowel, was mounted at the distal end of the retractor cannula. At the tip of the retractor cannula a removable sharpened tip was placed. The sharpened tip allowed R1A to be pierced through the abdominal wall from inside the abdominal cavity outwards. Small ribs were formed onto the retractor cannula at the proximal end. These ribs allowed R1A to be introduced into the abdominal cavity by means of a laparoscopic fenestrated grasper (Karl Storz, KS33300). The trocar size that was used for introduction of R1A was 12 mm. A control gap was integrated at the proximal end of the nozzle which allowed R1A to be manoeuvred and positioned inside the abdominal cavity by means of a Babcock grasper (Karl Storz, KS33500). Figure 1a also shows the clamp that was used to secure R1A to the abdominal wall ones it was positioned. When the sharpened tip was removed, a vacuum tube was connected to the cannula which connected R1A to the vacuum system. At this stage R1A was installed and ready to grasp and hold the bowel. The foremost alternation concerning the surgical protocol of the bowel anastomoses was that R1A had to be pierced through the abdominal wall which embodied a risk of tissue damage. In potential up to three retractors could be used to position the bowel. It was noted that each R1A added caused a small incision of 4 mm into the abdominal wall. A concern of possible organ damage during introduction and manipulation with R1A within the abdominal cavity, necessitates changes in the construction and manipulation of the device. Therefore LVR type 1B was developed and tested.

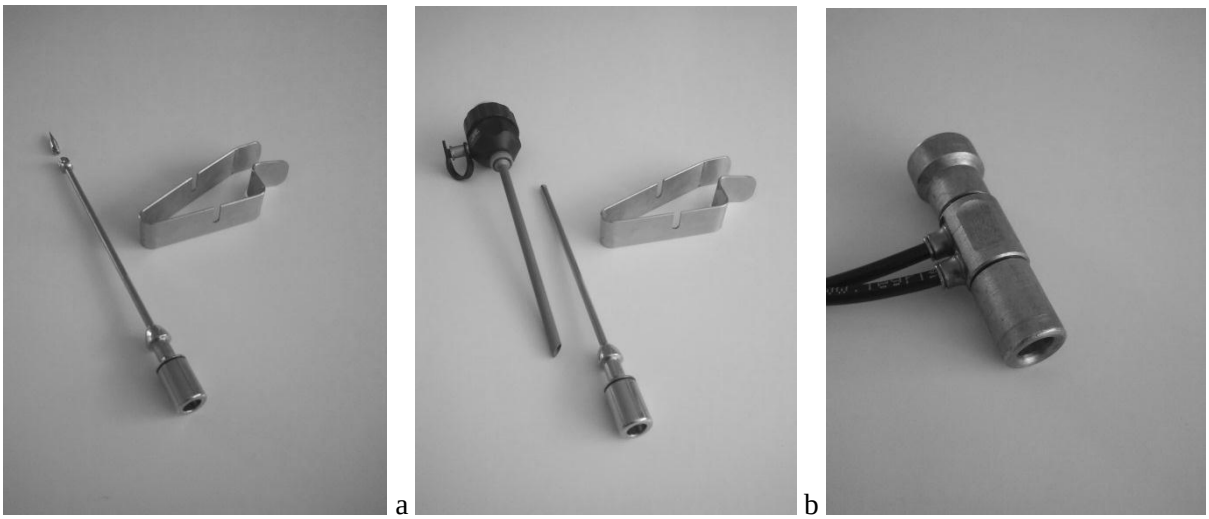

Figure 7.1. the retractor types. 7.1a) LVR type 1A (R1A). 7.1b) LVR type 1B (R1B). 7.1c) LVR type 2 (R2).

Laparoscopic vacuum retractor type 1B

Figure 7.b1 shows the functional model of laparoscopic vacuum retractor type 1B (R1B). R1B was a redesign of R1A and basically the same in design and dimensions excluded the sharpened tip. R1b utilised a 3.9 mm trocar (Karl Storz, 30117GP) to be pierced through and positioned to the abdominal wall. The 3.9 mm trocar was positioned and pierced through the abdominal wall into the abdominal cavity. R1B was inserted into the trocar from the inside the abdominal cavity. Then the trocar was removed and hence R1B was fixed. As with R1A, R1B was manoeuvred and handled by means of a laparoscopic fenestrated grasper and a Babcock grasper. R1B is also secured with the same clamp as was used for R1A. Concerning the surgical protocol, the alternations caused by R1B are comparable to those of R1A except for the risk factor related to the use of a sharpened tip on top of the retractor cannula. To avoid the use of a 3.9 mm trocar which necessitates an additional 3 mm incision, LVR type 2 was developed.

Laparoscopic vacuum retractor type 2

The functional model of laparoscopic vacuum retractor type 2 (R2) is shown in Figure 7.1c. R2 consists of two nozzles which are connected to each other with the functional nozzle inlet in opposite direction. R2 contained a nozzle to grasp the bowel and a nozzle to fix itself to the abdominal wall. Two separate vacuum connectors, one for each nozzle, were connected by means of flexible tubing to the vacuum system. R2 was handled by means of a Babcock grasper and was hand assisted inserted into the abdominal cavity because the vacuum connectors could not fit through a 12 mm trocar. The order in which positioning of the R2 and grasping the bowel was conducted was up to the surgeon.

With the exception of using an additional instrument, the surgical protocol concerning a bowel anastomoses remained unchanged since R2 does not invade tissue or organs.

The nozzle (NT2) that was used to retract the bowel of all three retractor types and the nozzle (NT1) of R2 that was used to fix itself to the abdominal wall, were based on the nozzle designs of a previous conducted study [18, 19] (Chapter 2 and 3). The experiments were conducted by two experienced surgeons under officially approved protocol of the Academic Medical Centre of Amsterdam, the Netherlands regarding experiments on large animals.

The vacuum system

The vacuum system can be described as follows. The vacuum was generated by means of a vacuum pump (Leybold, Germany) and was preset at 20 kPa (Δp = 80 kPa), where 100 Kpa is the atmospheric pressure and 0 kPa absolute vacuum. The vacuum level was controlled by means of an analogue vacuum control (Carl Roth, Germany) and a calibrated digital vacuum reader. Two filters were positioned between the LVR types and the vacuum system in order to prevent tissue debris to enter the vacuum system. R1A and R1B required one vacuum pump and R2 two vacuum pumps.

Data analysis

Facilitating a bowel anastomoses by means of a laparoscopic vacuum retractor was assessed using a validation protocol by two experienced surgeons (Figure 7.2). The validation protocol exists out of four main parts. The duration from each of the conducted anastomoses was registered. The duration that the bowel (and peritoneum) were grasped until the bowel (and peritoneum) were released. This was assessed by the surgeons conducting the experiment whether the total time it took to perform the anastomoses was acceptable or not.

The anastomoses were conducted using surgical suturing material. The second part of the validation protocol was the assessment of the quality of the sutures. The quality of the suture line and anastomoses were assessed by the experienced surgeons according standard operating procedures (V-Lock 180, Covidien).

Then the comfort of use was assessed by using a so called '*think aloud*' technique [20]. When using *think aloud* the user is asked to speak his mind during the usage of the LVR. The surgeon can score the comfort of use as poor, acceptable and good. When the surgeon is not capable of performing his task or is annoyed due to the use of the LVR the score was defined as poor. The score regarding grip on the bowel and peritoneum is considered poor when the LVR loses its grip more than ones during the whole anastomoses procedure. Losing the grip on the bowel or peritoneum one time was considered acceptable. When the surgeon was capable of performing his task without interruptions

(e.g. losing grip more than ones, requiring to reposition the LVR) the score was acceptable. When no interruptions occurred, the grip endured throughout the whole procedure and the surgeon felt that the retractors added to his performance, the score was good.

In the final part of validation protocol the bowel damage was macroscopically assessed [18] (Chapter 2). In addition to this also potential collateral damage to other type of tissue and organs were assessed. Figure 2 shows the assessed tissue damage types. The results of the assessment were discussed according the validation protocol.

Validation protocol

Retractor type: R1A R1B R2

Duration:
From grasping until releasing the bowel ……. min

Quality anastomoses:
Quality of the sutures Bad / Good

Comfort of use concerning:
(1) Introduction retractor into the abdominal area
Poor acceptable Good
(2) Positioning/fixing the retractor to the abdominal wall
Poor acceptable Good
(3) Attaching the bowel to the retractor
Poor acceptable Good
(4) Performing the anastomoses
Poor acceptable Good
(5) Grip of the retractor
(a) Concerning the bowel:
Poor acceptable Good
(b) Concerning the abdominal wall
Poor acceptable Good
(6) Releasing the retractor
(a) Concerning the bowel:
Poor acceptable Good
(b) Concerning the abdominal wall
Poor acceptable Good
(7) Extracting the retractor from the abdominal area
Poor acceptable Good

Bowel damage:

Type of damage	Occurrence
no damage	……
ecchymoses	…… times
serosa damage	…… times
seromuscular damage	…… times
perforation	…… times

Collateral Tissue Damage:

Type of tissue	Type of damage	Occurrence
…….....	……..	……times
…….	……..	……times
…….	……..	……times
…….	……..	……times
…….	……..	……times
…….	……..	……times

Figure 7.2. Validation protocol concerning the assessment of the retractor types R1A, R1B and R2.

Results

The results concerning the usage of all three retractors is shown in Figures 7.3 and 7.4. Figure 7.3 shows per LVR type the time period in which the anastomoses was performed. The average time with regard to R1A was 19.0 minutes whereby the longest time was 27 minutes and the shortest 12 minutes. The average time period of R1B was 18.6 minutes whereby the longest time was 25 minutes and the shortest 14 minutes. The average time of R2 was 21.5 minutes with time periods of 26 and 17 minutes. There was no difference in quality of the sutures between the LVR types. The suture quality was assessed as good.

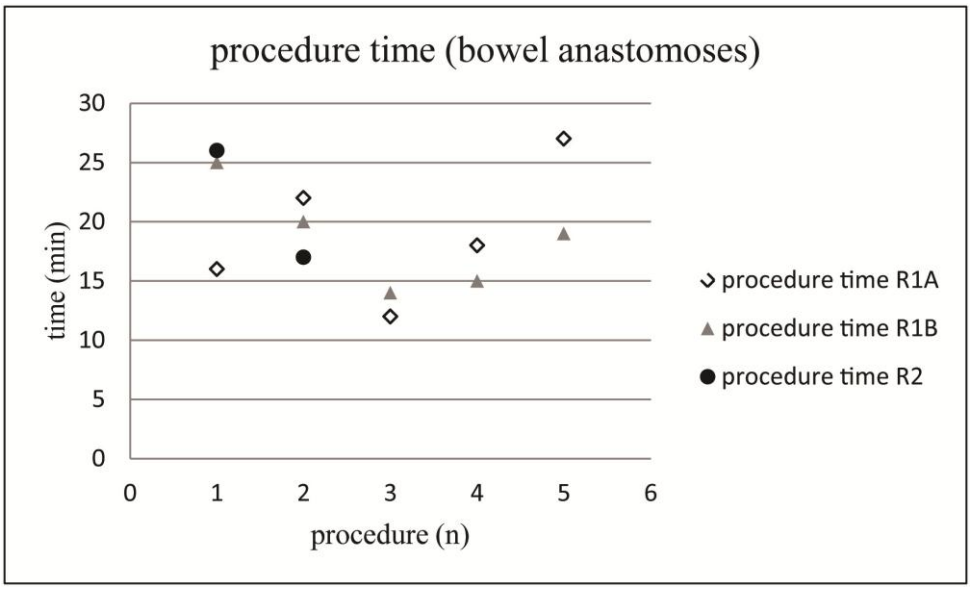

Figure 7.3. procedure time in relation to each LVR type.

Figure 7.4 shows the comfort of use score for three retractor types. Introducing the LVR into the abdominal cavity was assessed as acceptable for R1B and poor with regard to R1A and R2. The sharpened tip of R1A was experienced as a risk factor as to organ and tissue damage. Introducing R2 into the abdominal cavity was experienced as challenging due to the vacuum connectors and tubes attached to it.

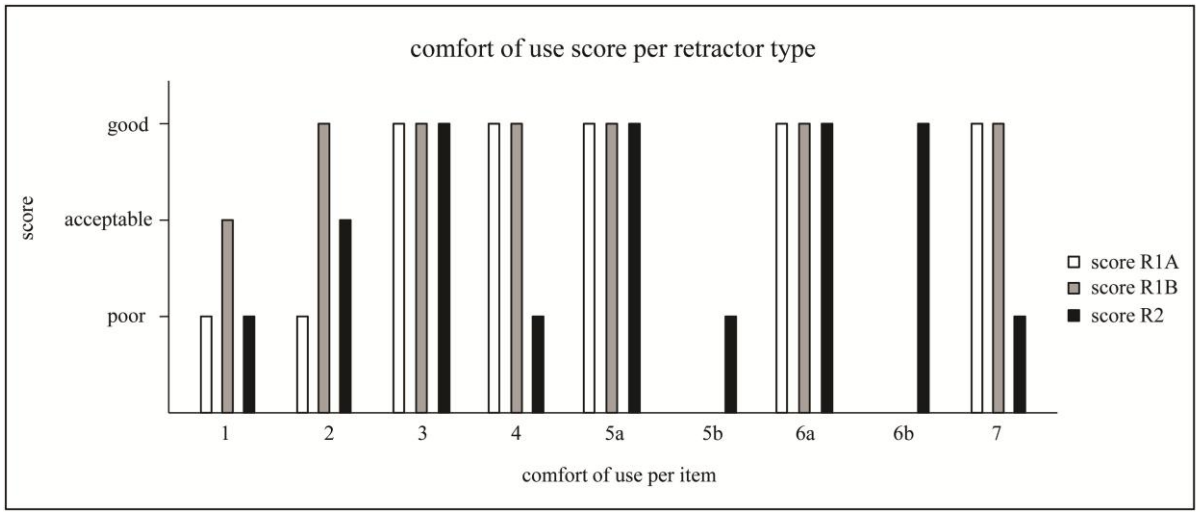

Figure 7.4. The score concerning the comfort of use for each LVR type in relation to the comfort of use aspects.

R1A was assessed as poor with regard to fixating it to the abdominal wall. It was a rather difficult task to pierce R1A through the abdominal wall. R1B was assessed as good. R2 was assessed as acceptable yet it required some practice to handle R2 in order to fixate it to the abdominal wall. All three LVR types performed very well in grasping the bowel in order to stabilize a bowel segment. The bowel was attached to the nozzle by means of a laparoscopic fenestrated grasper after the LVR was fixed to the abdominal wall.

Performing the anastomoses was assessed as good for types R1A and R1B. All three retractors did not obstruct the surgeons view on the work space. Extra work space was created by lifting the bowel segment which allowed easy access to perform the anastomoses. R2 was nevertheless assessed as poor due the insufficient grip on the abdominal wall.

The grip on the bowel during the procedure of conducting the anastomoses was assessed as good for all LVR types. Sufficient stretch and torque could be applied to the grasped bowel segment. Of all the conducted anastomoses, the bowel slipped ones out of the nozzle (R2). The suture was sucked into the nozzle which created an air leakage.

The grip on the abdominal wall applied exclusively to R2. This grip was assessed as very fragile and hence as poor. Due to continuous releasing of the nozzle from the abdominal wall, 3 attempts were conducted to perform an anastomoses as opposed to 4 and 5 performances with R1A and R1B respectively. The first attempt was successful in the sense that the anastomoses was completed. However, the nozzle released itself from the abdominal wall nine times. The second attempt the procedure was discontinued after the 5th time the nozzle released itself. During the final attempt the focus was mainly on maintaining the grip on the abdominal wall. The anastomoses was successfully completed, the nozzle released itself one time.

Releasing the bowel was assessed as good for each LVR type. In some cases the bowel slipped out of the nozzle when the vacuum was disconnected. In other cases a fenestrated grasper was used to gently pull the bowel segment out of the nozzle. Releasing the abdominal wall was easily conducted by manoeuvring R2 slightly in an angle in relation to the abdominal wall (which often occurred unintentionally during the procedure).

Finally, concerning the comfort of use, extracting the LVR from the abdominal cavity. R1A and R1B were both assessed as good. Extracting R2 was, similar to introducing it into the abdominal cavity, challenging and assessed as poor.

No bowel damage as well as damage to the abdominal wall was assessed for neither one of the LVR types. When the bowel was released a bulge on the bowel was visible on which disappeared after some time. The nozzle of R2 resulted in mild ecchymoses to the abdominal wall which also disappeared after some time. R1A caused damage to the liver when it was manoeuvred inside the abdominal cavity. The sharpened tip pierced through the liver which caused a mild bleeding, nevertheless clinically relevant. This adverse event occurred one time.

General discussion

Aim of the study

The aim of the study was to evaluate a vacuum retractor system applicable for MIS. The study was conducted according an iterative case study whereby the bowels were stabilized in order to facilitate a bowel anastomoses. The focus of the study was quite broad and encompassed the general usage of a vacuum retractor. Three retractor types, iterations, were evaluated and assessed in an in vivo laparoscopic setting. Possible damage inflicted to the bowel or other organs was macroscopically assessed.

Results demonstrated

The conducted procedures can be divided in three components. The first 3 aspects of comfort of use refer to the component of, (1) preparation (Figure 7.2, materials and methods). Aspects 4 and 5 relate to the component of, (2) conducting the anastomoses and aspects 6 and 7 refer to the component of, (3) completing the procedure. Safety, functionality and comfort of use are the determining factors of the procedure.

1) Preparing the procedure

The performance of R1B exceeded those of the other two retractors as to the preparation of the procedure. Introducing the retractor into the abdominal cavity is easiest with R1B. This retractor was easy to control by means of a Babcock grasper and had no sharpened tip as R1A to take into account while manoeuvring the retractor. The utilization of a 3.9 mm trocar to fix R1B to the abdominal wall also increased the level of control.

The surgeon did not need to apply force to pierce the retractor through the abdominal wall which is required for R1A since this retractor utilized a sharpened tip. Despite the sharpness of the tip, the surgeons commented that relative much force was necessary to pierce R1A through the abdominal wall. Another aspect of R1A was that the sharp tip may not only injure the internal organs but the surgeon may also hurt himself when piercing through the abdominal wall. Such an adverse event would compromise the sterile environment and hence the patient safety.

A disadvantage of both R1A and R1B was that the surgeon was required to assess the ideal fixation point of the retractor on the abdominal wall. Therefore, the correct fixation point of such a retractor should be determined according protocol as part of the standard operating procedure since it is

undesirable to relocate the retractor ones fixed. R1A was fixed from the inside out (using the sharpened tip) while a trocar was used from the outside to fix R1B. The surgeons preferred the method of R1B since it was common (experience) to them to locate and fix a trocar at the correct location to the abdominal wall.

The fixation of R1A and R1B to the abdominal wall was very robust. The retractors were secured with a clamp outside the abdominal cavity (Figure 7.1a and 7.1b). The vacuum connection of these two retractor types was also outside the abdominal cavity. Because R2 utilized vacuum force to fix itself to the abdominal wall it could be relocated to the preference of the surgeon. A disadvantage of R2 was that it had no control gap to handle and manoeuvre the retractor as with R1A and R1B (Figure 7.1). The distance between the abdominal wall and the retracted bowel should be as small as possible in order to create as much work space as possible. Therefore R2 had to be as small as possible which compromised the control gap. An R2 with a diameter of 5 mm should be easier to handle however, technically more complex considering the nozzles require a diameter size of 10 or 12 mm [18 19, 21, 22] (chapter 2, 3, 4). This reduction in size would also match with the trend of minimization in minimal invasive surgery e.g. single incision laparoscopic surgery (from 10 mm to 5 mm and from 5 mm to 3 mm in diameter).

2) Conducting the anastomoses

Conducting the anastomoses using R1A and R1B was then experienced as comfortable while conducting the anastomoses using R2 was qualified as uncomfortable. The crux is fixing the retractor to the abdominal wall. R1A and R1B were firmly fixed to the abdominal wall. The fixation of R2 was much less robust. The nozzle itself was the cause of this. The abdominal wall is more solid and less flexible as the bowel and cannot be sucked into the nozzle as is the case concerning the bowel [19] (Chapter 3). Therefore this nozzle must have an inlet which has a large surface area to ensure sufficient grasp force to fix R2 to the abdominal wall ($F = p \cdot A$) [19] (Chapter 3). As was mentioned in the materials and methods section, nozzle type 1(NT1) was used to fix the retractor to the abdominal wall. When R2 was fixed and a bowel segment was retracted the situation was in principle stable. If the forces applied to the retractor were more or less in line with the suction forces, the grip on the abdominal wall was sufficient. This working method however proved to be far from optimal since it required from the surgeon to focus much of his attention on the retractor instead of performing the anastomoses. When however the forces applied to the retractor were not parallel to the suction force, air leakage occurred which caused R2 to release itself from the abdominal wall (Figure 7.5). Figure 7.6 shows a possible solution. The neck of the nozzle which is fixed to the abdominal wall could be made flexible. Then the retractor is less rigid and can be pulled outside the line of the suction

forces without releasing itself. Whether the nozzle itself should also be flexible should be investigated. It is preferred that the nozzle matches the grasped object.

All three retractor types performed well in retracting the bowel. The bowel released itself one time from R2 due to the fact that the suturing material was sucked into the nozzle which caused loss of vacuum (air leakage).

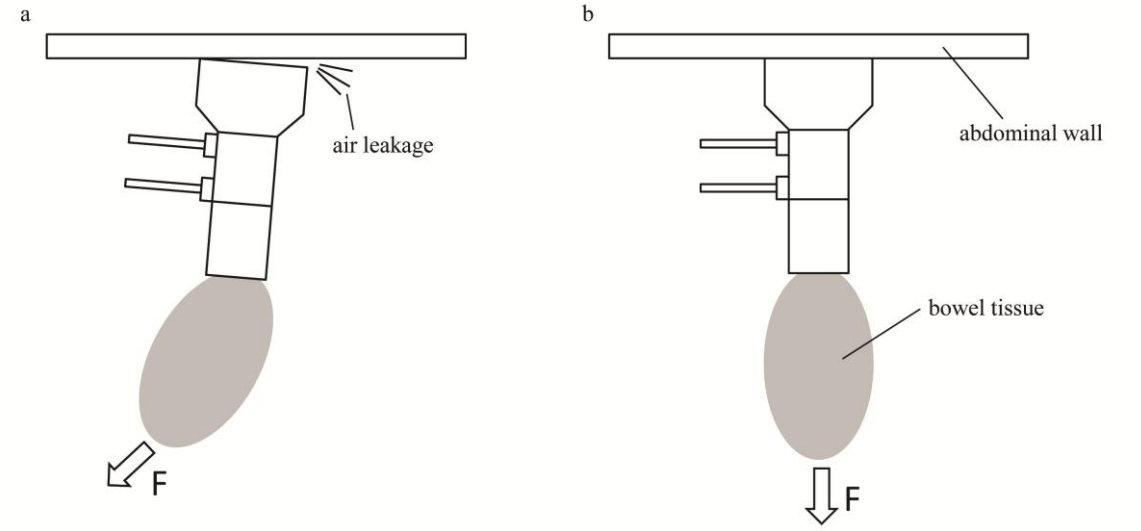

Figure 7.5.7.5a) R2 releases itself from the abdominal wall when the applied forces are not in line with the suction force. 7.5b) the fixation of R2 is stable when the applied forces are parallel to the suction forces.

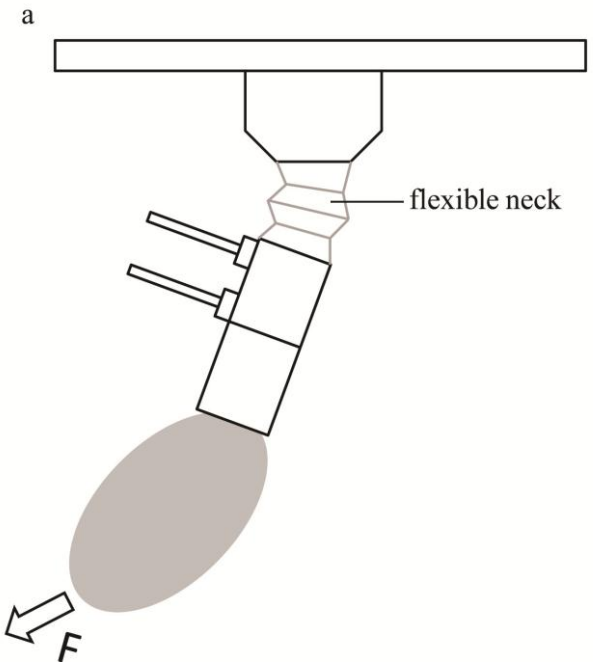

Figure 7.6. A laparoscopic vacuum retractor utilizing two vacuum connections and a flexible neck.

3) Completing the procedure

Releasing the bowel, and concerning R2 releasing the abdominal wall, went well for all retractor types. R1A and R1B were easily extracted from the abdominal cavity. The vacuum was disconnected and by means of a Babcock grasper the retractors were presented into a 12 mm trocar and then removed. When R1A was extracted, the sharpened tip was no longer fixed to the retractor cannula since it was removed in order to connect the vacuum before conducting the anastomoses. Because of its dimensions R2 was difficult to manoeuvre which hinders introduction as well as extraction of the instrument. Summarizing, R1B scores highest on all elements mentioned in the validation protocol, safety, functionality and comfort of use. The principal disadvantage of R1B is that it necessitates an additional trocar which requires an incision to the abdominal wall, although minimal.

Additional remarks

A vacuum retractor finds its application in the field of minimal invasive surgery (MIS), more specific laparoscopic surgery (this study) and potentially single port laparoscopic surgery (SPLS). Performing a bowel anastomoses in a laparoscopic setting utilizing a laparoscopic vacuum retractor (LVR) was successful which was for a part due to the experience of the surgeon. An LVR could be used during SPLS procedures. Challenges of SPLS procedures are e.g. instruments obstructing one another, limited view on the work space due to the instruments, therefore it is difficult to retract tissue or an organ [23]. These challenges could be faced by the utilization of an instrument such as the LVR. The LVR has the potential to create sufficient workspace without obstructing the other instruments. Examples are retracting the gallbladder during a single portal cholecystectomy, retracting the bowel during a single port gastric bypass, and retracting the spleen during a single portal splenectomy [24, 25, 26, 27]. R2 seems to be the most probable retractor type to be applied in SPLS since it does not necessitate an additional incision provided it can be sufficiently fixed to the abdominal wall. R1A and R1B require an additional incision which refers to ‘assisted’ SPLS. Basically there are three potential ways of applying an LVR in SPLS. The key aspect is fixing the retractor to the abdominal wall. First a compromise between all three retractor types. Fixing the LVR can be obtained by using a hook or a clamp [23]. Such a system can be firmly fixed to the abdominal wall. A disadvantage of such a system is the increased risk for tissue damage due to the hook or clamp. A second option is to utilize suturing material as fixation. This would simplify the LVR in its construction however it would as be laborious to relocate the retractor if necessary. A final option is develop a nozzle specifically to fix itself to the abdominal wall. R2 was equipped with two tubes however these can be replaced by one tube with two separate channels.

The tubes connected to R2 did not obstruct the procedure in any way. Not in any case were the tubes pulled or pushed since they ran high and close to the abdominal wall. A possible alternative could be a manually operated LVR with no tubes. Such a retractor would induce its own technical and medical challenges which were not researched for this study.

The duration of performing the anastomoses was experienced by the surgeons as acceptable though the differences were relatively large. The shortest operating time (to complete the anastomoses) was 13 minutes and the longest 27 minutes. A previous conducted study shows that at the microscopic level no bowel damage occurs up to a time limit of 15 minutes and a vacuum level of 3 kPa [28] (Chapter 4). Macroscopic assessment conducted for this study showed that also up to 27 minutes and a vacuum level of 20 kPa no damage what so ever occurs. During the performance of the anastomoses the grasped bowel segment was pulled and stretched in all directions. It is fair to state that also at the microscopic level no bowel damage had occurred.

Limitations of the study and recommendations

Two vacuum pumps were used to conduct the tests. The usage of the vacuum pump was not part of the study. The vacuum pumps were operated at the surgeons command. It is probable that the suction system present in the operating room would be used to generate vacuum. Investigating the possibility to use this suction system and how it should be operated in relation to the LVR is recommended.

This study solely focussed on facilitating a bowel anastomoses. It is advised to investigate vacuum retracting concerning other soft organs in order to study different types of surgical procedures (MIS, SPLS) during which these organs are retracted. The success of the LVR depends on how well the nozzles grasp the organ. Therefore it is recommended that nozzles will be developed which are excellent in grasping for instance the abdominal wall, the gallbladder, the liver and the spleen.

The functional models (R1A, R1B and R2) that were used, were in an early stage of development. Though this study shows the potential of an LVR and provides insight in it usage, it is advised to develop the LVR up to the stage of a sufficient prototype which is medically approved (CE-mark).

Conclusion

Vacuum retraction has potential to be used in MIS, conventional laparoscopic surgery and single portal laparoscopic surgery (SPLS). An LVR is comfortable in its use providing it retracts the organ with a safe grip. Laparoscopic vacuum retraction seems particularly suitable for advanced minimal invasive surgery such as SPLS since it is meets the challenge to create sufficient workspace to stabilize an organ without obstructing the surgical procedure in any way.

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Chapter 8.

General discussion

Aim of the study

The aim of this thesis was to determine the feasibility of vacuum technique as grasp technique for minimal invasive surgery procedures. From this aim a study was designed which had the characteristic of an elaborate design case. The reason for this is the fact that no instruments were available which enable to manipulate tissue by means of vacuum technique. In order to focus even further, vacuum technique was evaluated grasping the bowel. Three conditions or requirements were predetermined, a sufficient grip on the bowel, not to damage the bowel in any way and the instrument must be useful.

Conclusions summarized

Vacuum technique as grasp technique has potential, no damage to the bowel was encountered either at the macroscopic or at the microscopic level (Chapter 2 and 4). A try-out towards grasping other types of tissue shows that vacuum also has potential to safely grasp the liver, gallbladder and spleen (Chapter 2 and 7). From a technical view point vacuum technique offers a number of benefits concerning the physical principle of vacuum grasping (Chapter 2). It is a very constant and controllable way of grasping which provides sufficient grip on the bowel (Chapter 3 and 5). Vacuum technique does not compress the tissue and seems none sensitive to variations in the tissue such as differences in wall thickness and tissue folds which adds to the safe way of grasping (Chapter 2 and 4). The nozzles of the instruments have no moving parts and the vacuum is limited. Therefore it makes no difference whether the instruments are used by an expert or a novice (Chapter 2, 6 and 7). And this the performance on this aspect is constant regardless of the skills and experience of the user. The overall conclusion is that basically vacuum technique is a safe and useful technique to grasp the bowel.

General remarks

The general notion which lies behind this thesis is the desire to be able to grasp and manipulate the soft organs in the abdominal cavity is a safe and secure way. During MIS procedures and specifically during laparoscopic procedures these soft organs are frequently manipulated. The purpose of a grasp instrument that is used for manipulation is to safely grasp an organ, perform the task, manoeuvre or handle effectively and then release the organ. An instrument which does not harm the organ or tissue and yet grasps it firmly and is comfortable in use, is ideal. Unfortunately such instruments do not exist though many studies have been conducted to define and determine ways to meet this ideal (see also Chapters 1, 2, 5, and 7). These studies focussed mainly on conventional mechanical grasping.

This optimal picture of a grasp instrument or of grasping organs and tissue in general is described in the three focus areas of this thesis. The first two focus areas, which are crucial characteristics, grip on the bowel and damage to the bowel (Chapter 3 and 4), could be defined as the interaction between the instrument and the tissue. When this instrument-tissue interaction is optimal, the instrument can be considered as safe and effective. The third focus area can be defined as the interaction between the user and the instrument. This user-instrument interaction is considered optimal when the surgeon can use the instrument without experiencing any adverse or unexpected effects. These three focus areas encompass all requirements of a grasper instrument to ensure safe and comfortable tissue grasping. In a sense there are two types of interaction, the instrument-tissue interaction (focus area 1 and 2) and the user-instrument interaction (focus area 3). The interaction between instrument and tissue is considered passive since the patient is not actively involved in the interaction. The interaction between the user and instrument is naturally characterized as active. .

This thesis presents an opportunity to optimise the interaction between the grasp instrument and the grasped tissue. Chapter 3 shows that the grip on the bowel by means of vacuum depends strongly on the shape of the nozzle. In this chapter two types of nozzle were compared in relation to their grasp performance. The shape of the nozzle should allow a firm grip on the bowel at a relative low vacuum level (a low vacuum means less effort in order to generate it). The nozzle that was used in Chapter 3 (NT2) as the absolute optimal shape nevertheless it is a very capable option to grasp the bowel sufficiently at a relative low vacuum level by preventing loss of vacuum (air leakage). More details concerning these aspects on grip can be found in Chapter 3. A disadvantage of the nozzle (NT2) is that it is difficult to manufacture. The tests to determine the grip on the bowel were conducted using a tensile testing machine and a vacuum pomp which is a linear and rather static way of pulling the tissue. The design of NT2 was implemented into a laparoscopic vacuum grasper (LVG) and a laparoscopic vacuum retractor (LVR). The LVG is characterized by the dynamic way of grasping and utilized manual generated vacuum. The LVR is static in its use and requires a vacuum pump or system.

Despite that the same nozzle type is used for both instruments to grasp the bowel, the bowel is expected to slip more readily out of the nozzle with regard to the LVG. This is due to the fact that the vacuum of the LVG is manually generated. There are two principle at work here, one related to the user, the surgeon, and the other one is inherent to manually generated vacuum. The first principle relates to the fact that the generated vacuum of the LVG has a maximum. Whether this maximum is reached, and therefore whether sufficient grip is generated, depends on the surgeon. The second principle which is inherent to manually generated vacuum, is that loss of vacuum (air leakage) is not compensated by a vacuum pump (Chapter 2, 6 and 7). This means that loss of vacuum is likely to result in slipping of the tissue. Therefore, generating not enough vacuum, not enough grip, may also

induce more readily the slipping of the tissue. Concerning the LVR (retractor) grasping is more static and the vacuum pump compensates loss of vacuum.

This thesis makes a modest comparison to conventional mechanical graspers (chapter 4 and 6). The main reason for this was that vacuum grasping differs in principle from conventional mechanical grasping in terms of grip and damage. Mechanical grasping utilises a grasper jaw to grasp the tissue. This means that the bowel is grasped between an upper and a lower jaw. Therefore the grasp forces are practically perpendicular to the pull direction of the grasped tissue [1, 2] (Chapter 3). Concerning vacuum grasping the grasp forces are in line with the pull direction of the grasped tissue. The pull direction is also in most cases the direction in which the tissue slips out of the grasper jaw or nozzle. The way the tissue is grasped and the relation between the forces are quite different for both grasp forms. Comparison in relation to tissue damage is discussed further on this paragraph. Nevertheless a few remarks can be made on mechanical grasping in relation to vacuum grasping. The focus is on the application of both grasp techniques. The grip of a conventional mechanical grasper is not limited unlike the LVG. It could be stated that the bowel is more easily damage by mechanical grasping because the user can exceed the allowable grasp force. On the other hand it could also be stated that a mechanical grasper is always capable to grasp the bowel in a firm yet safe manner providing that the surgeon acts with caution. This is a matter of careful applying the grasp forces which is a skill that can be trained [24]. A potential disadvantage of the LVG is that the maximum vacuum force which can be generated is also the required force to grasp the bowel. It is preferred that the user generates the maximum vacuum force at all times. This is a property of the LVG as it was designed. The LVG can generate a grasp force of 4 N, potentially a grasp force of 5 N. Generating a larger grasp force than 5 N is unlikely since the vacuum is generated manually (Chapter 5 and 6). Compared to a mechanical grasper, this means that the LVG is always capable of grasping the bowel safely however, the surgeon must always use full force (generate the maximum vacuum force) in order to generate sufficient grip.

Chapter 4 shows that it is possible to guarantee safe grasping by means of vacuum for as long as the vacuum forces remain within certain boundaries $\langle 0, \Delta p_{da} = 97(kPa) \rangle$ and a time limit of 15 minutes. The nozzle used in this chapter is the nozzle which provided the most sufficient grip in the previous chapter (Chapter 3). The study shows that within the boundaries of low vacuum the bowel can be safely grasped. Concerning its application as grasp technique for MIS this is more than sufficient (Chapter 4). From the results of this chapter it could also be stated that the actual boundaries extend to a larger area (beyond low vacuum) than the determined boundaries. Up to a time limit of 15 minutes and a vacuum limit of 97 kPa (pressure difference) no damage what so ever was encountered. To determine the actual boundaries, the time limit per vacuum level should be determined where the vacuum level is increased up to the point where it damages the bowel instantly. It should be noted though that beyond the area of low (and medium) vacuum the application of vacuum instruments as

grasp instruments is not probable since the effort to generate higher levels of vacuum than low and medium vacuum requires special equipment.

Another aspect concerning safe grasping is potential delayed damage (chapter 2 and 4). To determine whether this phenomenon plays a part in vacuum grasping survival experiments should be conducted (Chapter 4). Such a study is rather complex since it requires to grasp the bowel a certain period of time and at a certain vacuum level. Each grasp then should be marked. Nevertheless a survival study should at least be conducted concerning the upper boundaries of the application area as it was determined in Chapter 4.

A few remarks in relation to conventional mechanical grasping. With regard to vacuum grasping the bowel and is stretched while being compressed during mechanical grasping. The bowel responds differently to both grasp techniques. When the blood vessels are stretched (vacuum) the circulation remains intact and when the bowels are compressed (mechanical) the circulation is compromised. This principle difference illustrates the difficulty to compare both grasp techniques. It can be concluded though that both grasp techniques may cause severe damage to the bowel when it is grasped with too much force and /or when the grasp force is applied for too long.

The usage validation of the LVG and the study conducted with the LVR, both focussing on the subjective or active interaction between user and instrument, show that vacuum technique is usable in a minimal invasive setting (Chapter 6 and 7). Both instruments are safe in use, they cause no harm to the bowel. There are differences though with regard to the grip on the bowel. As described above, the grip provided by the LVG is not as secure as the grip of the LVR. The LVR and LVG differ from each other on three levels which are of importance for the comfort of use. These differences are, a manually controlled LVG as opposed to an automatized LVR, the LVG which is operated by hand outside the abdominal cavity while the LVR is fixated inside the abdominal cavity and, the short manipulations of the LVG as opposed to the relative long term grasps of the LVR.

The LVG probably would benefit from the usage of a vacuum pump concerning the grip on the bowel. Moreover the handling of the LVG may also improve since the vacuum would no longer generated manually. The surgeon can keep his had relaxed during the usage of the instrument. A disadvantage would be the necessity to use tubes to link the LVG to a vacuum pump or suction system present in the operating room. The tube may limit the usage of the LVG in the already overcrowded operating field. Nevertheless it would be interesting to investigate the option of an automatized LVG (grasper).

The handle of the LVG (grasper) was based on a set of ergonomic guidelines relating to hand size and grip strength (Chapter 5). The implementation of these guidelines ensure that a large group of users can use the LVG comfortably. The design of the LVG is capable of generating a pressure difference of 60 kPa which in turn translates to a grasp force of 4 N (Chapter 5). In order to increase the grasp force

the handle of the LVG is likely to be adjusted. Such adjustments should not compromise the comfort of use obtained from the ergonomic guidelines. If the LVG cannot generate up to 80 kPa of pressure difference without compromising the comfort of use, the quality of the functionality would be lessened. A different type of handle which is more intuitive might generate more than 80 kPa, this should be further investigated. The LVG is used dynamically through different access ports (trocars) and held in different positions. Therefore it is also interesting to investigate the possibilities of an LVG which utilises a vacuum pump or suction system.

An additional remark concerning the LVG. The mechanical functionality of the instrument is directly linked to the ergonomic soundness of the instrument. This means that the mechanism through which the LVG generates vacuum is dependent, is shaped, by the ergonomic requirements (Chapter 5). Though the overall functionality should be clear, both the mechanical elements and the ergonomical aspects determine the shape and function of the instrument. To illustrate this, the spring must be strong enough to generate sufficient vacuum and yet may not compromise the comfort of use. This is typical for applied technology in user products.

A manually controlled LVR (retractor) could also be an interesting alternative although it seems that the tubes are not disturbing the surgical procedure. The LVR remains fixed at one position and therefore the tubes may remain in the same location. A manually controlled LVR also induces complexity to its usage. If for instance the vacuum system of such an instrument would also be a cylinder-piston system similar to the LVG, the piston must either be pre-tensioned outside the body or inside the body (Chapter 5). Another option could be to develop an LVR which utilises mechanical generated vacuum. This means that the start volume of the LVR would practically be nihil (Chapter 5). Then a small increase in volume generates a strong vacuum. Such a vacuum system can be compared to the suspension vacuum system of a car navigation device which is mounted to the windshield.

The LVR is controlled by other instruments. Conventional mechanical graspers are required in order to introduce and extract the LVR from the abdominal cavity. During its usage when fixed to the abdominal wall, the LVR is not actively used by the surgeon, it has a supporting function.

Limitations

This thesis presents the potential of vacuum technique in minimal invasive surgery. A few limitations concerning the conducted studies should be mentioned. Each chapter discusses the more specific limitations to the conducted studies. Most of the tests were conducted on pig bowels, on life and cadaver tissue. The pig bowels were harvested shortly before testing (Chapter 3). Literature states that pig bowels have comparable properties to human bowels [4]. These studies were conducted using conventional mechanical graspers. The tests to determine the optimal grip of the nozzles were

conducted on cadaver pig bowel tissue. Cadaver tissue reacts and behaves different compared to life tissue. From the studies where life tissue was used the grip of the nozzles was sufficient. Nevertheless a linear comparison between the studies using cadaver tissue and life tissue cannot be entirely justified.

No other type of tissue then pig bowels were used during the studies, except a small try-out on liver, gallbladder and spleen in Chapter 2. The outcome of the tests on other organs indicate that vacuum also has potential to be used on those types of tissue and other. It seems probable that vacuum technique can also be safely used on the colon since it is comparable to the small bowel in terms of mechanical properties [5].

The nozzle which was used for the LVG and LVR was specifically designed for grasping the bowel. Other types of organs/tissue with other properties most likely require other types of nozzles. The nozzles used for this thesis were shaped in such a way that the bowel was literally sucked into the nozzle. This way of grasping is not possible when grasping the liver or the spleen since the liver and spleen are solid organs with different tissue characteristics and cannot be sucked into the nozzle. Different nozzle shapes are required. Chapter 7 illustrates this when the LVR was fixed to the abdominal wall. The nozzle which was used to fix the LVR to the abdominal wall was of a different shape as the nozzle which grasped the bowel (NT1, Chapter 3).

The nozzles, functional models and instruments which were used for this thesis, are suitable for a laparoscopic setting providing 10 and 12 mm trocars are used. The trend in laparoscopic surgery is toward instruments with a diameter of 5 mm in size. This implies that the nozzle should be further developed in order to embrace this trend. Such nozzle could be composed of part steel part silicon. On the other hand, many instruments used during advanced laparoscopic procedures require 10 or 12 mm trocars and therefore such new developments should not be rushed. Many instruments used for tissue approximation such as clipping and stapling devices are 10 to 12 mm in diameter.

Despite the fact that the LVG was carefully designed and that the handle complies to the ergonomic requirements, the usage study (Chapter 6) concerning the LVG has certain limitations. The LVG necessitates a different way of use than the conventional mechanical grasper. The handle must be compressed to tension the spring before the bowel is grasped and the handle must be released in order to grasp the bowel. To release the bowel the handle must again be compressed. The handle clearly also has a different shape compared to today's mechanical graspers (Chapter 6).

Overall implications

This thesis has several implications which are related to research, design and MIS. The implications regarding MIS relate to, skill independence and patient safety and novel surgical techniques. The patient safety during a surgical procedure was defined in Chapter 1 as, the completion of a procedure throughout which no adverse events take place which compromise the physical (and potential mental) wellbeing of a patient. The patient safety can be improved by a system approach (safety and quality in surgery). The surgeon, the surgical team, must be well trained and should uphold their skills [3, 6]. Protocols/standard operating procedures must be maintained to monitor the procedure [7]. Another effective way to improve the patient safety is to develop instruments and medical equipment in such a way that they function adequately. Adequate in the context of this thesis means that the instrument functions according its description and causes no harm what so ever to the patient when used according the user instruction, as described in Chapter 1.

Although the assessed grasp instruments (functional models) represent a relative small part of the total surgical armamentarium and settings, they encompass an interesting concept. This concept implicates that instruments and equipment can be developed and designed in such a way that it makes no difference whether they are used by a very experienced or a less experienced user. The result and performance of the instrument is always the same and therefore predictable. This predictability includes a high level of control which is a desirable property for any surgical instrument especially in relation to patient safety. In case of the LVG and LVR this means that the bowel is simply not damaged regardless the skill and experience of the surgeon. It is presumed that if the LVG and LVR are used, the surgeon can focus his attention on performing procedure. He does not need to consider whether he is grasping the bowel safely, he just is. This is likely to have added value especially for the novice surgeon. This however is not a statement that the LVG and LVR can be used carelessly, utmost alertness remains a requirement during the completion of the surgical procedure.

With regard to novel surgical techniques, robotic surgery and single port surgery seem interesting application fields of vacuum technique. If used during robotic surgery vacuum would be generated by means of a vacuum pump or a suction system available in the operating room. as stated before, the nozzle is not sensitive to tissue variations and up to a pressure difference of 97 kPa and a time limit of 15 minutes vacuum can grasp the bowel firm yet safe. Other types of tissue such as the liver and spleen can possibly be grasped by means of vacuum. Providing a specific nozzle for robotic surgery is developed, no haptic or tactile feedback is required to ensure safe handling and manipulation. Current robotic systems do not provide any feedback at all. Such a nozzle would keep the grasp system simple and add to the effectiveness and safety of the robotic grasper.

The LVR could find an application in Single Incision Laparoscopic Surgery (SPLS). Retracting the gallbladder during a cholecystectomy during a SPLS procedure is not an easy task since all instruments enter the abdominal cavity from the same location [8-11]. The LVR could be used to

retract the gallbladder. The LVR would be even more interesting for SPLS if it could be designed to generate mechanical vacuum as described above. An LVR which has the size of a matchstick and requires no tubes promises to be a very helpful additional (assisting) instrument also for MIS.

The implications with regard to research and design relate solely to the applied method or research approach. This research outline of this thesis was based on design inclusive research (DIR). This means that the research activities were supported and nourished so to speak by design activities. The support of the design activities was vital in order to generate new knowledge. As to the design activities a well-known design method was used, the basic design cycle of Roozenburg and Eekels [12]. This iterative approach was successfully adapted into the DIR approach or method. The correlation between the research and design elements is what makes this project extraordinary. The DIR approach is rather novel and is far from crystallized. This thesis adds to the potential of DIR. Chapter 10 emphasises further on the research and design aspects.

Future research

For this thesis, the focus was strict on grasping, retracting and stabilizing the bowel. To broaden the fundament of vacuum technique in MIS it is required to evaluate and assess vacuum technique as grasp technique for other organs with different tissue characteristics such as, liver, spleen, omentum, abdominal wall and adrenal glands. The safe grip could be specified for these different organs concerning vacuum level and time. Next to this the shape of each nozzle which provides the most optimal safe grip must be defined. Specific nozzle types are required.

The material of the nozzles that were evaluated and assessed was steel. It is recommended that other materials, which can be utilized into new nozzle designs, are researched. As mentioned silicon rubber is a potential alternative material to investigate and even be used in combination with steel.

Concerning the LVG and LVR, it is recommended to investigate the possibilities and potential of mechanical vacuum. If mechanical vacuum can be successfully applied, the instruments can be miniaturised which makes vacuum technique more applicable for e.g. SPLS.

The concept of *skill independence*, should be further evaluated. The supposed necessity of skill independence suggests that the surgeon is impaired (to an extend). In context of this thesis the impairment means that the surgeon is cannot ensure that he grasps the bowel in a safe way. From practise it shows that an experienced surgeon is in practically all cases very well capable of grasping the bowel safely using conventional mechanical graspers. Therefore the less experienced surgeon is likely to benefit the most of the LVG (grasper). Nevertheless an instrument such as the LVR (retractor) can be a valuable addition to MIS procedures regardless of the skill and experience of the surgeon. It is recommended that the usage of the LVG is compared to the usage of a conventional laparoscopic grasper concerning less experienced surgeons. In addition it is advised that the LVG and

LVR are thoroughly evaluated in user trials to investigate whether the use of such *skill independent* instruments indeed allow surgeons to better focus on the procedure itself. Both recommendations, user trials with novices and the increase in focus of the surgeon, are of importance since if both are confirmed, the patient safety in relation to the vacuum instruments is even more specified and guaranteed.

Finally the potentials of vacuum technique in relation to novel surgical techniques should be researched and evaluated as well as technological as in terms of future applicability.

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Chapter 9.

Methodological considerations

Two case examples of a modified DIR approach

Introduction

This chapter emphasises on the research and design structures and processes of this project. Since the research conducted was greatly based on the design decisions made concerning the subject of this project, a thorough understanding of the combined research and design approach was vital to ensure the progress of the project. First the context of the project is explained. Then the applied methodology is elaborated on followed by an over view of the whole project and how it fits with regard to each research and design phase in the methodology. The advantages and disadvantages specifically concerning this project are explained.

Structures and processes

The method that was applied concerning the research and design activities of this project is known as Design Inclusive Research (DIR) [1, 2]. DIR supposes that the new knowledge is obtained through supporting design activities and cannot be obtained otherwise. The design activities may refer to an artefact, software, service, phenomenon and other. With regard to DIR, the function of the research means are determined by internal (gathering of data) and external goals (social context, experience). DIR consists of three phases, an explorative research phase, a creative design phase, and an evaluative phase (Figure 9.1).

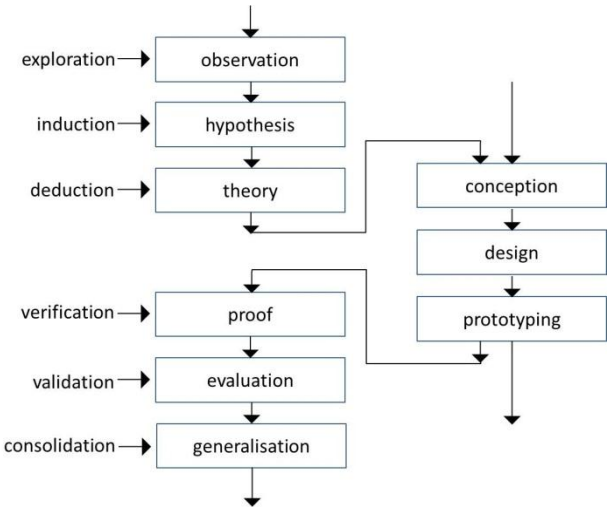


Figure 9.1. schematic view of design inclusive research (DIR) [1, 2]

The explorative research phase is characterized by knowledge gathering related to the research subject among which the research problem, surrounding factors and the current criticized state of affairs. This gathered knowledge leads to a new constructed theory in relation to the research subject. Which in term leads to the formulation of the research question, the hypothesis is defined and the aims of the design activities are determined [1, 2].

The creative design phase consists of the development of ideas, concepts, functional models, and methods. The ideas and concepts are transformed in order to be tested and experienced. The design activities add vital knowledge to the understanding of the research subject [1, 2].

The evaluative research phase is characterized by the verification of the design activities and the hypothesis through which the constructed theory can be proved. The findings of the conducted research and the methods used are validated. The results of the study are discussed in relation to the current understanding of the research subject [1, 2].

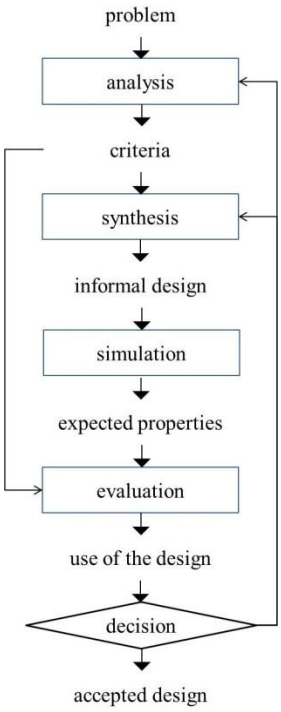


Figure 9.2. Iterative basic design cycle [3].

The research method as shown in Figure 9.1 was modified in relation to the design activities of this research project. An iterative design method according the basic design cycle of Roozenburg and Eekels was applied to the design activities [3]. Figure 9.2 shows the schematic view of this design process. The schematic view of Figure 9.2 indicates an additional evaluation to the design activities in the creative design phase. This additional design iteration induces the possibility to reanalyse the design problem and start a second creative design phase. This modification was built into the research method in order to increase the potential value of the design activities (Figure 9.3). The aim concerning the design activities was an approved (i.e. CE marking) medical product (see discussion).

The design evaluation includes the steps *evaluation*, *use of the design*, and *decision* of the basic design cycle of Roozenburg and Eekels (Figure 9.2).

It is noted that DIR as a research method is in a development state (under construction) and the complexity of it is not explained nor emphasised in this chapter. As is described, applied and understood as written above, the method and structure of this project was based on the insights thus far known concerning DIR.

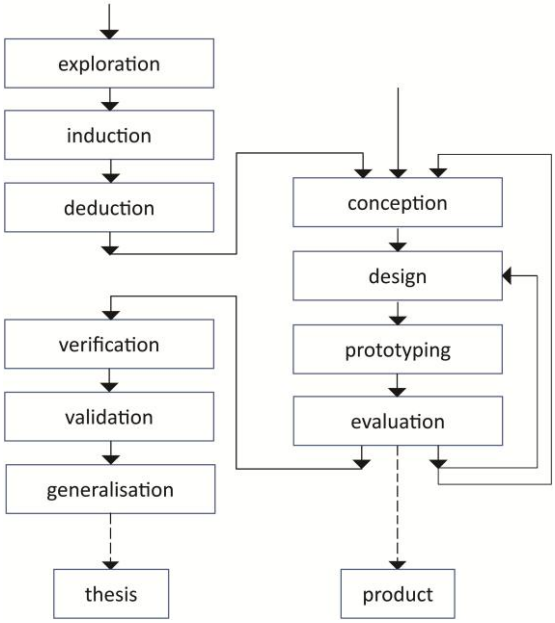


Figure 9.3. Schematic view of design inclusive research incorporating an iterative basic design cycle.

The research phases illustrated

Explorative research

Exploration

During this step the main issues of the research subject (vacuum technique in laparoscopic surgery) were explored. First the current methods of manipulation during laparoscopic procedures and its short comings in relation to the patient safety were explored. Second, the manipulation or grasp technique itself was investigated. The focus concerning the second part was on the potential of vacuum technique.

Both issues were explored using literature study and expert interviews. The literature provides an objective view of the current knowledge in relation to the research subject and the expert interviews offer a subjective insight in the application of the current knowledge. This combination of gathering objective and subjective knowledge with regard to the research subject leads to valuable information concerning the theoretical and practical side of the research/design problem. In order to determine the potential usefulness of vacuum technique, it was necessary to compare both forms of knowledge. Literature showed that vacuum technique had potential however it was unknown by experts as grasp technique [4, 5, 6]. Therefore it was essential to verify its potential and validate its usefulness.

Induction

The research area was outlined and specified. Herewith the focus of this project was determined. The research question was formulated as a conclusion from the exploration of the research subject. From there the aims and requirements concerning the creative design phase were determined. To recapitulate, the research question was formulated as follows. *Is vacuum technique feasible as grasp technique for minimal invasive surgery?* The research question leads to a composed proposition from which three focus areas were defined. In short, these focus areas were, grip on the bowel by means of vacuum, damage to the bowel caused by vacuum, and the handling of a vacuum instrument (grip on the bowel, damage to the bowel, handling).

Deduction

As described above, the research question was used to define a model or constructed theory which served as initial concept and basic assumption for the creative design phase. The three focus areas outlined three initial outcomes. The first outcome described the grip of vacuum technique on the bowel based on existing physical models (Chapter 3). The second outcome, which was based on the first outcome plus existing knowledge on bowel damage, described the potential bowel damage caused by vacuum technique (Chapter 4). The first two outcomes then were used to recommend two design proposals, a laparoscopic vacuum grasper (LVG) and a laparoscopic vacuum retractor (LVR) ((Chapters 5, 6, 7)). During this stage of the project the pragmatic character of the creative design phase was determined which lead to the modified DIR model (Figure 9.3).

Creative design

Conception

The first issue in the creative design phase was to define the so called *intended use* (Chapter 2). In context of medical instrument design and European regulations (CE marking) this is a logical and necessary first step towards a design proposal. Considering this project the intended use was defined as follows. The intended use determines the exact functionality of the device, the user and the environment, and, considering it is a medical device, the intended use also determines in relation to whom the device is used. The purpose of the intended use in context of this project was twofold. First, the intended use positions the design proposals as a (potential) medical devices. Second, it confirms the comprehensiveness of the described focus areas (partly taken from Chapter 1).

A preliminary list of requirements was determined in relation to the grip on the bowel, damage to the bowel and handling. Herewith the three focus areas were converged to a solid point of reference from which the design activities were initiated.

Design

This step of the creative design phase was characterized by the design decisions made in relation to the focus areas. As to grip on the bowel and damage to the bowel, the specifications were determined regarding the experimental set-ups which were used to study these issues.

The handling part concerning the LVG was divided three chronological phases. The first phase focussed on the basic function of the LVG, generating enough vacuum to ensure sufficient grip on the bowel. Three concepts were proposed which differed from each other in respect to their technical solution concerning the basic function of the LVG (Figure 9.5a, 9.5b, 9.5c). The next phase was focussed on the comfort of use of the LVG which lead to one concept (Figure 9.5d). Finally the concept propositions concerning the basic function and comfort of use were merged into a final concept proposal (Figure 9.5e and 9.5f).

The handling part concerning the LVR consists of two chronological phases. The focus of the first phase was the basic function of the LVR which resulted in one concept (Figure 9.6a). Then comfort of use was included into the design of the LVR. This resulted in two concepts to be tested and evaluated by the user (Figure 9.6b, 9.6c).

Prototyping

The design activities of the previous step resulted in the realization of the experimental set-ups and functional models of the LVG and LVR (Figures 9.4, 9.5, 9.6). Two experimental set-ups were constructed to gather data with regard to the grip on the bowel and damage to the bowel. Five functional models were manufactured concerning the LVG and three functional models concerning the LVR. All of the constructing and manufacturing took place within the university (Delft University of Technology). This ensured a high level of control with regard to the quality of the set-ups and functional models.

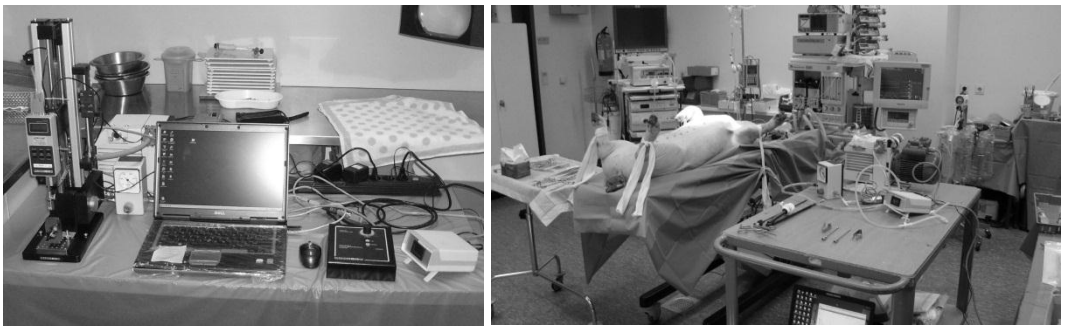


Figure 9.4. Experimental set-ups concerning the grip on the bowel and damage to the bowel.

Evaluation

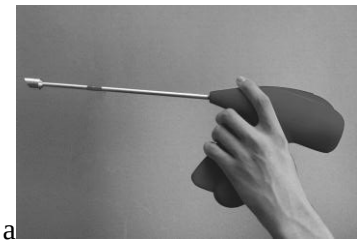
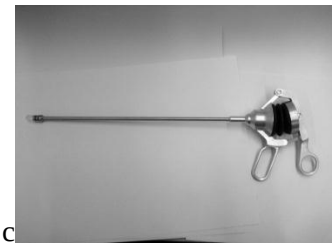
The aim of this additional step to the creative design phase was to evaluate the experimentel set-ups and functional models according the design requirements and specifications.

The experimental set-ups were verified and evaluated through conducting pilot tests. These pilot tests were conducted under exactly the same conditions and in the exact same location as the actual tests. These tests were conducted on cadaver and life pig bowels. The experiments on life pig bowels were conducted under the official approved protocol concerning experiments on large animals of the Academic Medical Center of Amsterdam, the Netherlands.

Concerning the LVG, three design iterations took place. These iterations were partly supported by separate design projects[2] (Appendix A). Functional models 9.5b and 9.5c and the actual product 9.5f as shown in Figure 9.5, were not supported by a design project. All of the functional models including the actual product, were evaluated during a simulation of a laparoscopic setting/procedure (Figure 9.7). Each of the functional models was evaluated and assessed by expert surgeons. These separate evaluations and assessments provided valuable insight in the functionality and comfort of use of the LVG. This translated the concept and functional model of the LVG into an actual medical approved

[2] 1st project: Project Advanced Products, Faculty of Industrial design, Delft University of Technology, 2009, *designing a vacuum pump handle for laparoscopic surgery*, *N. Nuri, C. He, T. Elfering, B. Waumans, I. Sorgendal*
2nd project: Graduation Project, faculty of Industrial Design, Delft University of technology, 2010, *Design of a new handle for a Vacuum Grasper*, *N. Nuri*
3rd project: Project Advanced Products, Faculty of Industrial design, Delft University of Technology, 2010, *Laparoscopic vacuum grasper*, *O. Klaas, R. Rosenbrand S. Wolswinkel, D. Epema, T. Martens*

device[3] (Chapter 5). The surgeons participated to the design process from the start of each project. An important part of their input was the feedback they provided with regard to each evaluation and assessment which in turn was used as new knowledge (input) for the next project.

a  b  c 

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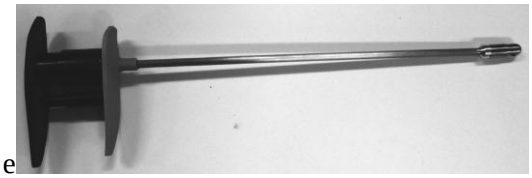
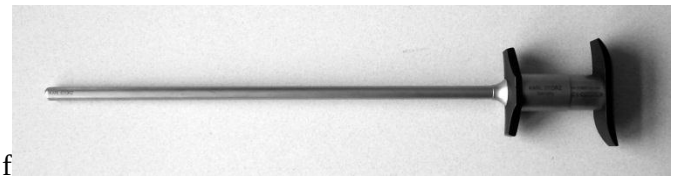
e  f 

Figure 9.5. Overview of all the functional models of the LVG. 9.5a) Vacuum is generated in a closed system. When the handle is compressed, the vacuum is generated. 9.5b) Vacuum is generated in a closed system. The vacuum is generated after the compressed handle is released. 9.5c) Vacuum is generated in a closed system, the start volume is minimized using an almost solid shaft. 9.5d) Vacuum is generated by means of a cylinder-piston system. 9.5e) Final version of the laparoscopic vacuum grasper (LVG). 9.5f) The actual product.

[3] Medical product: In this context, a CE approved medical device which meets the essential principles for safety and performance of medical devices and the requirements of the following EC council directive(s).

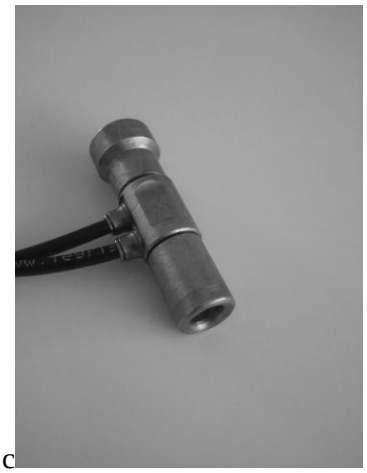
a  b  c 

Figure 9.6. overview of the functional models of the LVR. 9.6a) The retractor utilizes a sharpened tip and clamp to fix itself to the abdominal wall. 9.6b) The retractor utilizes an additional trocar and clamp to fix itself to the abdominal wall. 9.6c) The retractor utilizes vacuum to fix itself to the abdominal wall.

The functional models of the LVR were also evaluated in a laparoscopic setting. As with the LVG, the LVR was partly supported by a design project[4] (Chapter 7). Functional models 9.6b and 9.6c as shown in Figure 9.6 were not the result of a supporting design project.

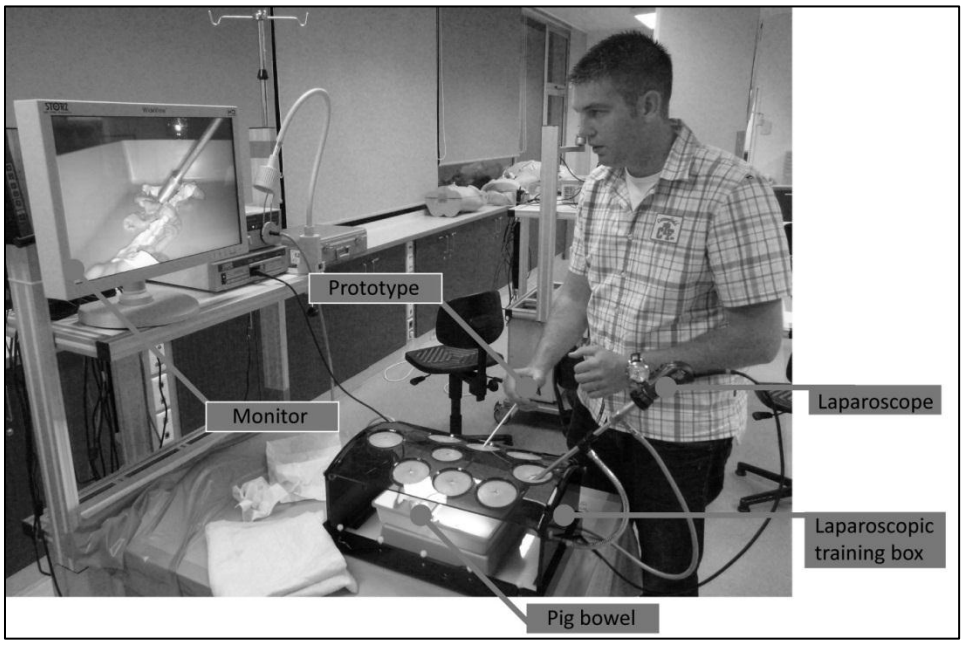


Figure 9.7. laparoscopic set-up to evaluate each of the functional models and the actual product.

[4] Project Advanced Products, Faculty of Industrial design, Delft University of Technology, 2011, *support system for bariatric surgery, F. Henny, J. Zhao, T. Nedkov. O. Kampinga, R. Kassels*

Evaluative research

Verification

The verification of the constructed theory as formulated in the general introduction induced three (three focus areas) related studies which resulted in the preceding chapters of this thesis. Two studies concentrated more on the fundamental aspects and support the constructed theory. Those are the studies concerning grip on the bowel and damage to the bowel. These studies were characterized by the inward focus on the medical and technical context of the project. Experimental set-ups were used to gather data concerning the grip on the bowel and damage to the bowel. This data gathering took place in the confined area of a skillslab[5]. Adjacent to these studies, the handling of the LVG and LVR was verified and validated whereby medical approval (CE marking) and user tests are compulsory (Appendix B). The focus concerning the handling was aimed outward on the social context and experience of both devices. Expert surgeons evaluated and assessed the LVG and LVR through usage validation and in vivo simulation of a laparoscopic procedure respectively. Here the focus was both on the functionality of the device and the social context in which it was used.

The conducted studies in relation to the three focus areas were considered sufficient and effective to support the constructed theory and to answer the research question.

Validation (internal and external)

Internal validation of the research methods (This chapter).

Validation (external) of the research findings is foremost illustrated in the preceding chapters and general discussion of this thesis. As mentioned above, the experiments on life pig bowels were conducted under the official approved protocol concerning experiments on large animals of the Academic Medical Center of Amsterdam, the Netherlands.. The studies confirm the research question

[5] A skillslab refers to a facility in the hospital where hospital residents are trained and where the conditions are fitted to conduct scientific experiments.

and hence approve the design results. The validation concerning grip on the bowel and damage to the bowel was conducted using standardized evaluation techniques such as physical models, statistical evaluation and histological examination. With regard to the LVG and LVR the validation was based on the expert opinions of the surgeons (experience, macroscopic assessment).

Generalisation

Grip on the bowel by means of vacuum, damage to the bowel caused by vacuum, and the handling of a vacuum instrument enforce a set of conditions (composed proposition, general introduction) which were analysed using an empirical approach.

The first two conditions, a firm grip on the bowel and no damage to the bowel were used to determine whether vacuum technique could obtain a safe grip. This safe grip was considered mandatory with regard to any type of vacuum instrument. The handling part, obviously also mandatory, was more focussed on the comfort of use concerning the specific functional models and medical device which were assessed.

The study concerning grip on the bowel and damage to the bowel can be referred to as validation of the proposition in its broader sense and the study regarding the handling as validation of the proposition in a more narrow sense. In the broader sense, the potential of vacuum instruments in minimal invasive surgery was determined by the safe grip. In the narrow sense, the validated functional models and medical device provide a strong indication whether the potential of vacuum instruments can be realized.

Discussion

This project was conducted according the method and structure of DIR although modified. The approach resulted in a thesis and a medical product. In itself an extraordinary and satisfying result. The DIR method as it was applied during this project was considered sufficient and effective and has its advantages and disadvantages.

An advantage of such a research project is the involvement of the user (surgeon). This project aimed to determine the feasibility of vacuum technique as grasping technique. By answering the medical/technical questions, the feasibility of vacuum technique could be determined in that respect. The user however is required to apply this new technique and therefore the new technique must be adapted to the fit the users wants and needs. User requirements are defined to evaluate and assess the experience of the new technique. The feasibility of a practical technique is co-determined by the practitioner, the user through the user experience.

The question whether the acquired new knowledge could only be obtained by means of a combination of research and design activities, is confirmed. The technical feasibility of vacuum technique was determined through the studies regarding grip on the bowel and damage to the bowel. The feasibility concerning the usability of vacuum technique is determined through the study of an artefact (LVG, LVR). The question which can be derived from this is, whether it was required to develop the artefact up to the level of an approved medical device (LVG). This was absolutely the case, an approved medical product guarantees a certain level of applicability and sophistication which cannot be obtained otherwise. The main difference expresses itself in the fact that an approved product complies to the required medical standards. Even if a non-approved prototype would in principle comply, a certain level of doubtfulness with regard to its functionality and safety would remain.

The challenge of DIR is the communication between the research part and the design part and how to join the two into a solid body of new knowledge [1, 2]. During the project this challenge was clearly present. The research and design activities were largely separately conducted and executed. There was no clear coupling between the two. The design activity was for a great part an isolated element of the

project. This was especially true concerning the LVG and LVR due to the fact that several iterations were conducted. In between these iterations the results were not verified in relation to the research question. Instead, the design problem was redefined based on the evaluation of the previous design and hence the iteration was resumed starting from the redefined design problem. The usage validation of the LVG and the in vivo study concerning the LVR brought the design part back in line with the research part.

The studies concerning the grip on the bowel and damage to the bowel were in line with the research part. This was due to the fact that the experimental set-ups were constructed to gather data which seems a research activity in itself.

It can be concluded that, the nature of the design activity had a profound influence on the overall character of the project. The more pragmatic design approach of the LVG and LVR had the tendency to separate the design part from the research part.

A disadvantage of applying a DIR method to this project was the time-aspect of the design activities. The design activities were time consuming. The pragmatic character of the design activity also added to the time factor. Concerning this, it is presumed that valuable time can be saved by adopting a more parallel approach towards solving the design issues. Parallel means to solve the design problems alongside each other as opposed to a more pragmatic approach. This however is not always possible since the results of one solution is sometimes the start point or input of the next design issue (e.g. first determine the specifications for an optimal grip and then investigate for which conditions this optimal grip causes no tissue damage, this thesis).

An additional challenge was found in the fact that the researcher was the designer and vice versa. The linking between the two demands practice and discipline. There almost seems to be a bias in the notion that the designer and researcher is one and the same. Another aspect to consider is the fact that it is desirable that the individuals who conduct the evaluation and assessment of the functional models in the design phase or not the same individuals who conduct the usage validation. The assessors of the functional models actually participated in the design phase and are therefore potentially biased.

An external party (Karl Storz GmbH) from the medical industry was involved in this project. As a consequence the research part was characterized as open, aimed outwards, while the design part was characterized as closed, aimed inwards. In other words, the PhD-student foresees a strong thesis while the external company focusses on a commercially interesting product. From the view point of the research, information exchange with the outside world and fellow researchers and engineers was much desired. This however was obstructed to an extend due to the partly commercial or industrial character of the design part. It may be considered not to incorporate an external party or to incorporate an external party at a later stage into the research project, however the advantages of a commercial party in the design phase should not be overlooked either. Vital is that clear understanding is obtained and firm agreements are made between all parties concerning the openness of the project. An example of a potential dilemma could be described as follows. The external company decides not to further develop the prototype or product which is used as a research means. Nevertheless the companies name would still be attached to any of the publications concerning this prototype or product. Such dilemmas may proof to be sensitive and require clear understanding and agreement of all parties at the start of a research project. Needless to say that such understanding and agreement is not easily obtained since the actual content of the to be obtained new knowledge is not easily predicted.

To conclude, DIR is an effective method to tackle a research problem which encompasses design and engineering issues. DIR is not a rigorous straight jacket which should be followed step by step. It is much more a very dynamic approach which requires discipline and an open view towards research and design from the researcher. This project successfully implemented the ideas of DIR in order to study the potential of vacuum technique in minimal invasive surgery.

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[4] Gentilli S, Velardocchia M, Ferrero A, Martelli S, Donadio F. Laparoscopic splenectomy: how to make it easier using an innovative atraumatic suction grasper. Surg Endosc 1998;12:1345–1347.
[5] Gentilli S, Ferrero A, Veraldocchia M, Garavoglia M. Laparoscopic adrenalectomy: advantages of an atraumatic suction grasper. Surg Endosc 1998;8: 335–337.
[6] Frantz D. Suction-cup support for the kidney, a new aid in renal surgery (German article). Der Urologe 1967;6:173–174

Summary

Grasping in minimal invasive surgery (MIS) is conducted with so called laparoscopic graspers. These graspers are generally derivatives of instruments used in open surgery. The performance of these graspers depends on the technical and medical functionality, the skills and experience of the user, the surgeon, and the comfort of use related to the instrument. The foremost characteristic required for any grasp instrument in grasping soft organs and tissue is the so called 'safe grip'. The technical and medical functionality of any grasp instrument depends on this property.

The patient safety was defined as the completion of a procedure throughout which no adverse events take place which compromise the physical (and also mental) wellbeing of a patient.

Vacuum technique as grasping technique for MIS was chosen as research subject for this thesis. There were three main reasons for this choice. First, vacuum technique is a widely applied grasp technique in industry. Besides the potential induced by its variety of applications in industry, vacuum technique, as grasp technique for MIS, has been studied concerning its potential. These studies underline the potential of vacuum technique however, the findings were not translated to actual applications in MIS nor was any knowledge provided concerning the conditions or requirements in relation to vacuum grasping which ensure a safe grip. The third aspect of vacuum technique is its physical principles. Vacuum grasping is a very controlled and homogenous way of grasping.

The 'object' type which was grasped by means of vacuum was the bowel. The bowel is an organ which is frequently grasped during MIS procedures. It is a very delicate and easily damaged. Bowel damage can have serious consequences for the patient. With regard to grasping the bowel no research has yet been conducted concerning vacuum grasping.

Design Inclusive Research (DIR) was applied as the methodological tool concerning this project. DIR is characterized by the incorporation of design activities which support and provide as input for the research activities. This particular method was chosen due to the intention and necessity of developing vacuum grasp instruments on behalf of the research activities.

As stated above, this thesis focusses on the feasibility of vacuum technique as grasp technique for MIS. This is based on the premise that we strive to a constant performance regardless of the skills and experience of the user. The research question was defined as, is vacuum technique feasible as grasping technique for minimal invasive surgery?

This feasibility can be interpreted as the feasibility of a vacuum grasp instrument. The performance is determined by the technical aspects, the skills and experience of the surgeon and the comfort of use. This leads to three focus areas. The first two focus points are related to the technical and medical functionality (grip and damage). The third focus point is derived the comfort of use.

From this study it can be conclude that, vacuum technique as grasp technique has potential to be used in minimal invasive surgery, no damage to the bowel was encountered either at the macroscopic or at the microscopic level. A try-out towards grasping other types of tissue showed that vacuum also has potential to safely grasp the liver, gallbladder and spleen. From a technical view point vacuum technique offers a number of benefits concerning the physical principle of vacuum grasping. It is a very constant and controllable way of grasping which provides sufficient grip on the bowel. Vacuum technique does not compress the tissue and seems none sensitive to variations in the tissue such as differences in wall thickness and tissue folds which adds to the safe way of grasping. The nozzles of the instruments have no moving parts and the vacuum is limited. Therefore it makes no difference whether the instruments are used by an expert or a novice. The performance on this aspect is constant regardless of the skills and experience of the user. The overall conclusion is that basically vacuum technique is a safe and useful technique to grasp the bowel.

Samenvatting

Het vastpakken van weefsel in minimaal invasieve chirurgie wordt gedaan met behulp van zogenaamde laparoscopische grijpinstrumenten. Over het algemeen zijn deze grijpinstrumenten afgeleiden van de grijpinstrumenten die gebruikt worden voor open chirurgie. De prestaties van deze laparoscopische grijpinstrumenten hangt af van de technische en medische functionaliteit, de vaardigheid en ervaring van de chirurg en hoe comfortabel ze zijn in gebruik. Het belangrijkste aspect is de zogenaamde 'safe grip'. De technische en medische functionaliteit hangen af van deze eigenschap.

De patiënt veiligheid was gedefinieerd als het volbrengen van een chirurgische procedure zonder dat er enige 'adverse events' plaatsvinden die het fysieke en mogelijk ook mentale welzijn van de patiënt in gevaar brengen.

Het onderwerp van dit proefschrift is vacuüm techniek als grijptechniek in minimaal invasieve chirurgie. Ten eerste, vacuüm techniek wordt veelvuldig toegepast in de industrie. Daarnaast is vacuüm techniek beperkt onderzocht als grijptechniek in minimaal invasieve chirurgie. Deze studies onderstrepen de potentie van vacuüm techniek. De resultaten van deze studies hebben echter niet geleid tot werkelijke instrumenten en tevens wordt ook niet duidelijk gemaakt wat de voorwaarden zijn van de 'safe grip'. Het derde aspect van vacuüm techniek is het fysische principe ervan. Vacuüm techniek is een zeer controleerbare en homogene wijze van grijpen.

Om het vastpakken met vacuüm te onderzoeken is de dunne darm gebruikt als uitgangspunt voor deze studie. De dunne darm is een orgaan dat veelvuldig wordt vastgepakt gedurende minimaal invasieve chirurgie. Het is een erg delicate en gemakkelijk te beschadigen. Dunne darmschade kan ernstige gevolgen hebben voor de patiënt.

De onderzoeksmethode die is toegepast voor deze studie is Design Inclusive Research (DIR). DIR karakteriseert zich door een combinatie van ontwerp en onderzoeksactiviteiten waarbij de ontwerp activiteiten hoofdzakelijk als ondersteuning en input worden gebruikt voor het onderzoek. Er was specifiek gekozen voor deze onderzoeksmethode aangezien de intentie en noodzaak er lag om vacuüm grijpinstrumenten te ontwikkelen ten behoeve van het onderzoek.

Zoals hierboven vermeld is de focus van dit onderzoek op de haalbaarheid van vacuüm techniek als grijptechniek voor minimaal invasieve chirurgie. Dit is gebaseerd op de stelling dat er voortdurend gestreefd wordt naar een constante prestatie ongeacht de vaardigheid en ervaring van de chirurg. De onderzoeksvraag was gedefinieerd als, is vacuüm techniek haalbaar als grijptechniek in minimaal invasieve chirurgie?

Deze haalbaarheid kon geïnterpreteerd worden als de haalbaarheid van een vacuüm instrument. Het presteren van een dergelijk instrument wordt bepaald door de technische aspecten, de vaardigheid en ervaring van de chirurg en het gebruiksgemak. Dit leidde tot drie focus gebieden. De eerste twee focusgebieden zijn gerelateerd aan de technische en medische functionaliteit (grip en schade). Het derde focusgebied werd afgeleid van het gebruiksgemak.

Uit deze studie kan geconcludeerd worden dat vacuüm techniek potentie heft om gebruikt te worden voor minimaal invasieve chirurgie. Er was geen schade aan de darm geconstateerd, niet op macroscopisch niveau en niet op microscopisch niveau. Een try-out om andere types weefsel vast te pakken met behulp van vacuüm liet ook zien dat vacuüm techniek als grijptechniek gebruikt kan worden op de lever, galblaas en mild. Vanuit een technisch oogpunt bekeken biedt vacuüm techniek een aantal voordelen die gerelateerd zijn aan de fysische principes van vacuüm. Het is een zeer controleerbare manier van grijpen en het geeft voldoende grip op de darm. Vacuüm comprimeert de darm niet tijdens het grijpen en is niet gevoelig voor verschillen in variaties in het weefsel zoals verschillen in wanddikte en weefselvouwen. Dit draagt bij aan de veilige manier van grijpen. De zuigmonden/zuignappen van de instrumenten hebben geen bewegende delen en tevens is het gegenereerde vacuüm begrenst. Hierdoor maakt het niet uit of een beginnende of een ervaren chirurg het vacuüm instrument hanteert. Het presteren van een laparoscopische vacuüm grijper is dus niet afhankelijk van de vaardigheid en ervaring van de chirurg. De algemene conclusie luidt dan ook dat vacuüm techniek een bruikbare en veilige manier is om de darm en eventueel andere zachte organen vast te grijpen.

Appendix A (A1, A2, A3)

Design iterations of the LVG

Appendix A1

Taken from: *Project Advanced Products, Faculty of Industrial design, Delft University of Technology, 2009, designing a vacuum pump handle for laparoscopic surgery, N. Nuri, C. He, T. Elfering, B. Waumans, I. Sorgendal*

First iteration, laparoscopic vacuum grasper.

The focus during the process of this iteration was on the basic functionality of the LVG. Generating sufficient vacuum in order to grasp and manipulate the bowel safely in a laparoscopic setting.

Since the instrument had to be developed from scratch, it was also required to design the handle. Three handle designs were developed. The first handle was based on ergonomic guidelines (*Project Advanced Products,……, I Sorgendal*) (Figure A1.1 and A1.2). The next handle was a copy of the handle of a conventional laparoscopic mechanical grasper The third handle was mechanically formed according 'form follows function' philosophy (Figure A1.2).

The first handle was found most comfortable and the third handle allowed the surgeon to generate the strongest level of vacuum. The second handle was difficult to operate due to an imbalance in its weight.

The vacuum for all three handles was generated in a closed system, a bellow-spring system (Figure A1.2). The bellow-spring system worked according expectations however, it did gave some difficulties concerning sterilization. The functional models were tested in a laparoscopic setting.

Next follows an impression of this first iteration of the development of the LVG.

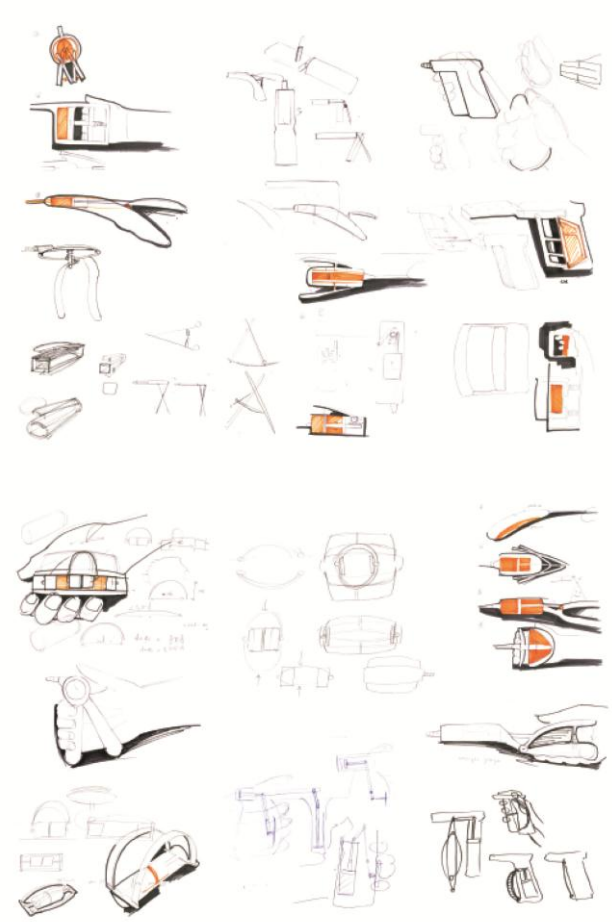

Figure A1.1. Idea sketches during the first iteration, taken from: *Project Advanced Products,……, I Sorgendal*

Figure A1.2. A1.2a) The first handle design based on ergonomic guidelines (*Project Advanced Products,……, I Sorgendal*), A1.2b) The second handle design based on a conventional laparoscopic mechanical grasper, and A1.2c) The third handle design which was design according the philosophy of 'form follows function'.

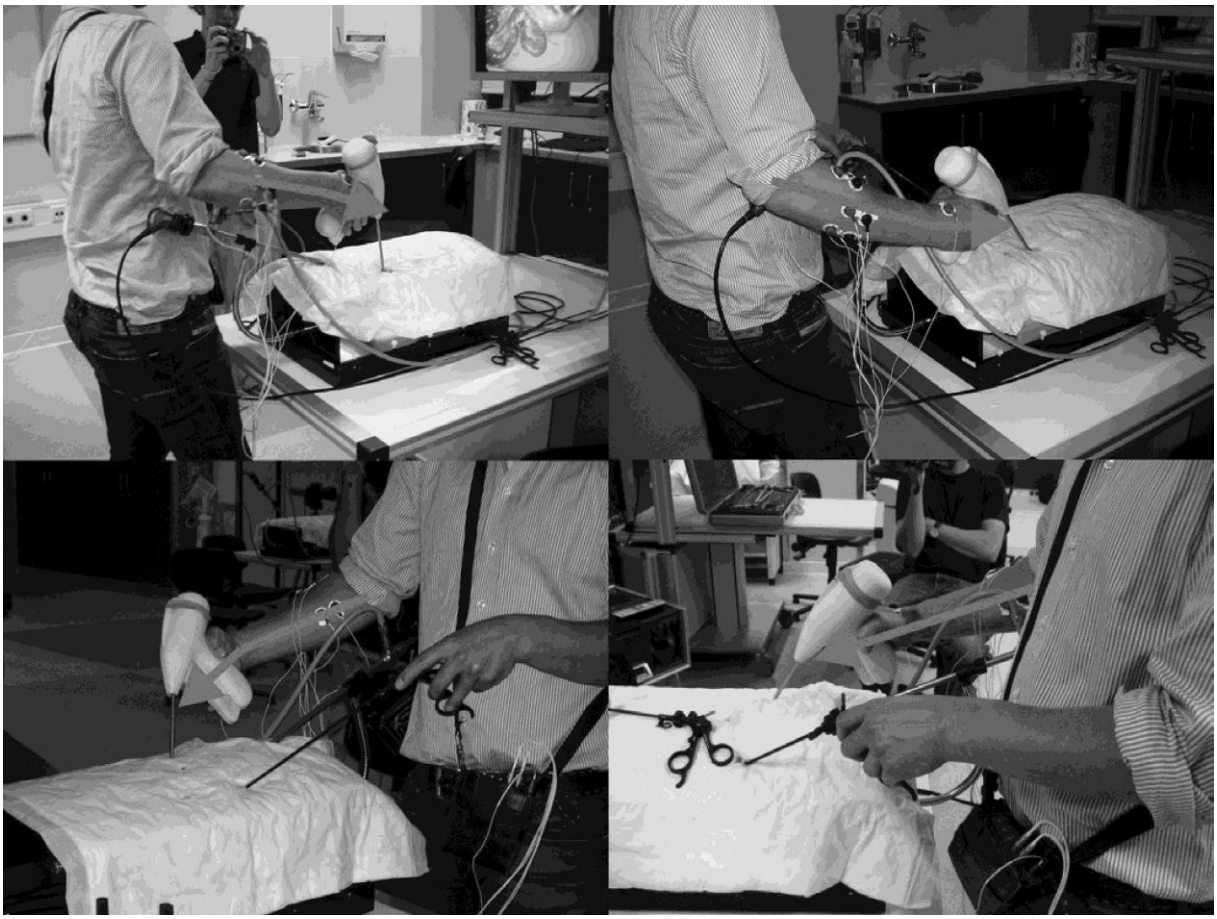

Figure A1.3. Testing the functional models in a laparoscopic setting. Each functional model was tested by experienced surgeons performing basic manipulations on pig bowels (*Project Advanced Products,……, I Sorgendal*).

Appendix A2

Taken from: *Graduation Project, faculty of Industrial Design, Delft University of technology, 2010, Design of a new handle for a Vacuum Grasper, N. Nuri*

Second iteration, laparoscopic vacuum grasper.

The focus during the process of this iteration was on the ergonomic soundness of the LVG. Ergonomic guidelines found in literature, a survey among surgeons to investigate discomfort when using laparoscopic instruments, and form studies were used to optimize the handle (Figures A2.4-A2.8) (*Graduation Project, ……, N. Nuri*).

A piston-cylinder system was utilized to generate vacuum. Such a system showed to be as effective and efficient as a bellow-spring system. An advantage of the piston-cylinder system is that is is easy to sterilize.

The piston-cylinder system was not fully optimized during this iteration. The functional model was able to generate a vacuum level of 50 kPa which is 10 kPa less as the bellow-spring system (Chapter 5).

Next follows an impression of this second iteration of the development of the LVG.

Figure A.4. many handle types and shapes provide inspiration for the handle of the LVG (*Graduation Project, ……, N. Nuri*).

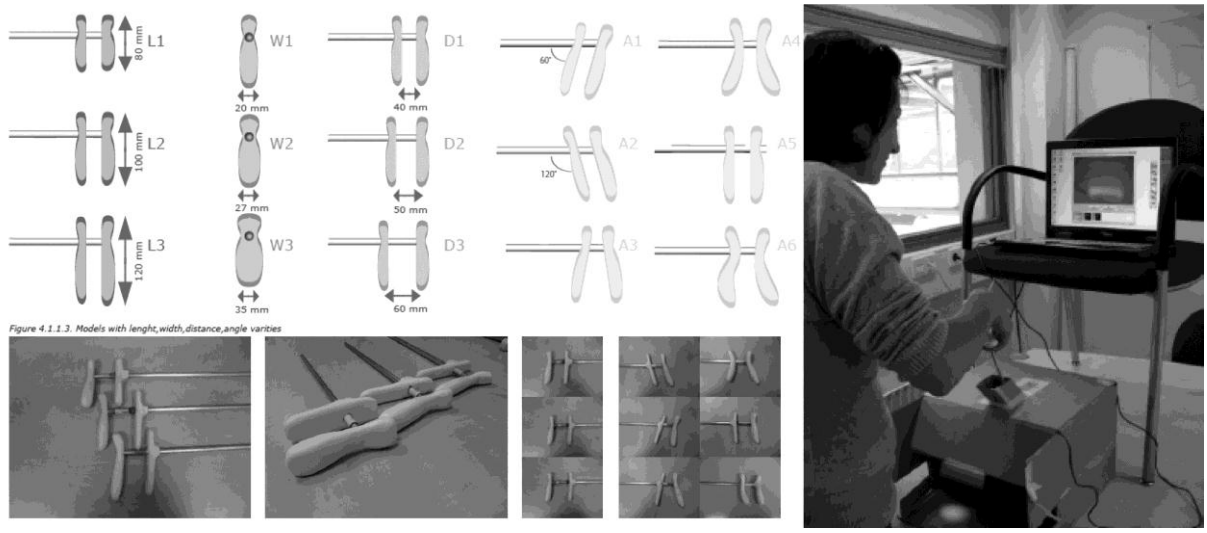

Figure A.5. Different variations of the handle were developed and researched (*Graduation Project, ……, N. Nuri*).

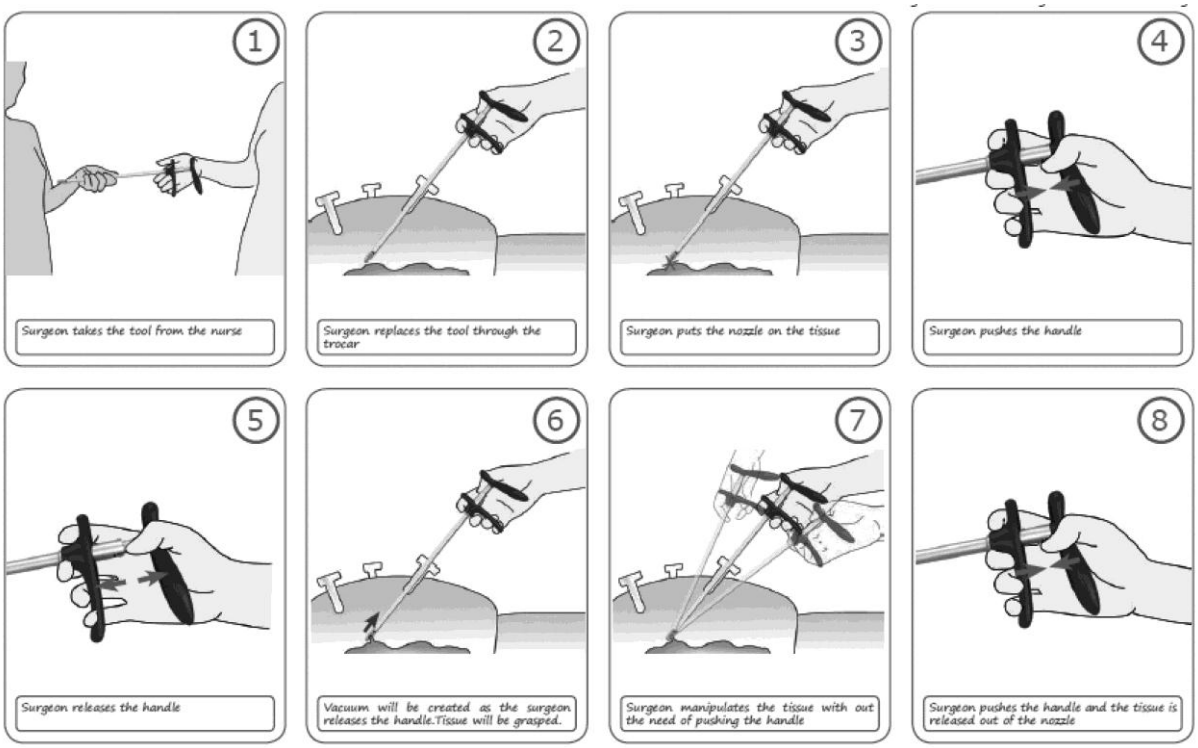

Figure A.6. Usage scenarios were determined which provide insight in how the handle is operated (*Graduation Project, ……, N. Nuri*).

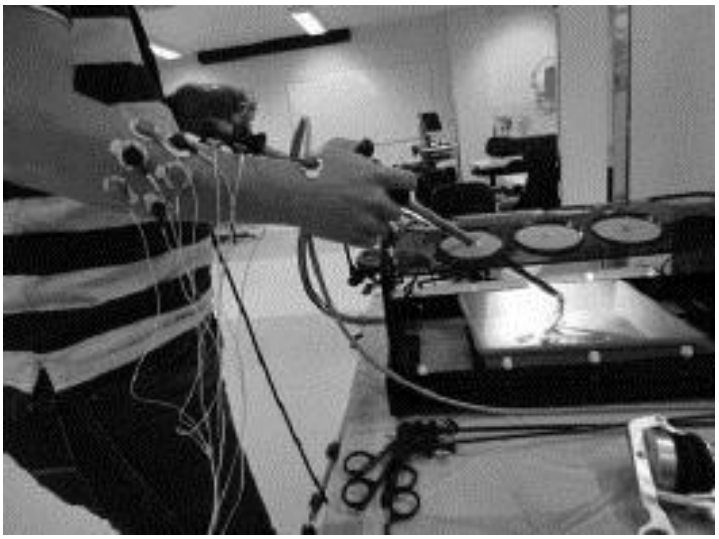

Figure A.7. EMG patches were used during the user test to determine the muscle activity during usage of the LVG.

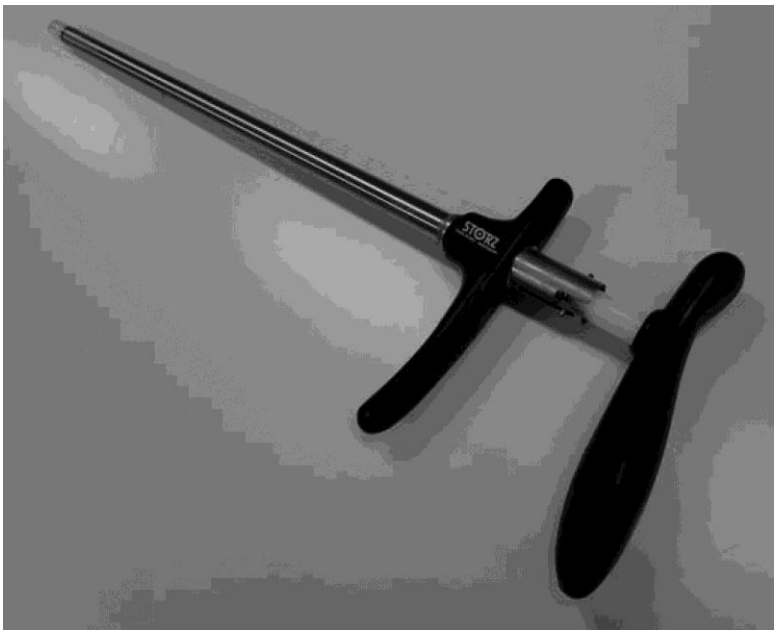

Figure A.8. The functional model of the second iteration (*Graduation Project, ……, N. Nuri*).

Appendix A3

Taken from: *Project Advanced Products, Faculty of Industrial design, Delft University of Technology, 2010, Laparoscopic vacuum grasper, O. Klaas, R. Rosenbrand S. Wolswinkel, D. Epema, T. Martens*

Third iteration, laparoscopic vacuum grasper.

The focus during the process of this final iteration was to develop a full-fledged/approved product. This was conducted in two steps. The first step was a student project (*Project Advanced Products, ……, T. Martens*). The focus of this project was to develop a functional model which should be the start point of a actually medically approved device. The piston-cylinder system was further developed and generated a vacuum level of 60 kPa.

The second step encompassed the process of classification and failure analyses to obtain a CE-mark. This process was conducted at Karl Storz GmbH. The result is a simple, robust and reusable medical product that consists of basically two parts.

Next follows an impression of this third and final iteration of the development of the LVG.

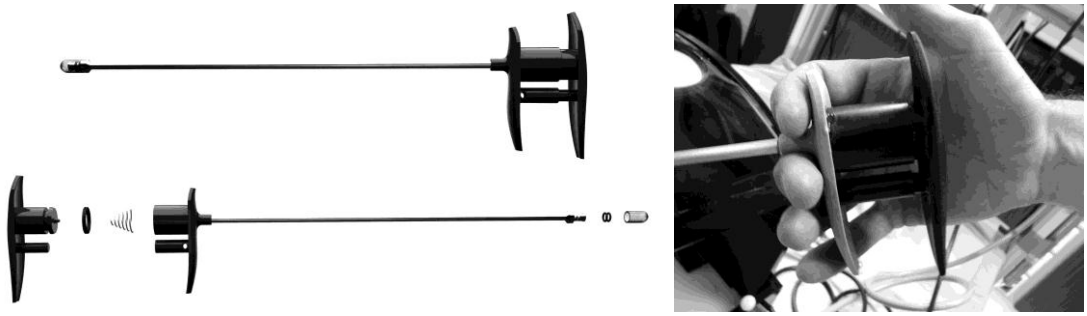

Figure A.9. Renderning of the functional model of the third iteration and a photograph of the handle (*Project Advanced Products, ……, T. Martens*).

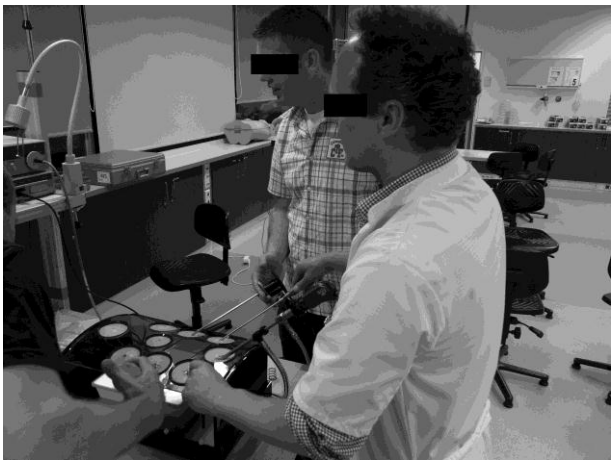

Figure A.10. testing the functional model (*Project Advanced Products, ……, T. Martens*).

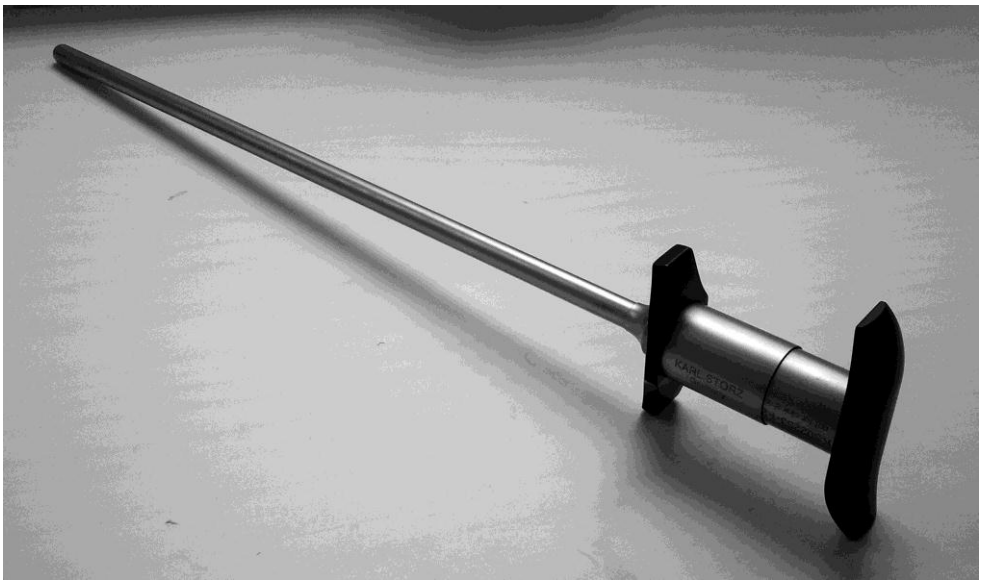

Figure A.11. The final approved medical device, a laparoscopic vacuum grasper (LVG).

Appendix B

CE conformity certificate

KARL STORZ — ENDOSKOPE

EC-DECLARATION OF CONFORMITY

Product Name:	Vacuum grapser, atraumatic, sheath, size 10 mm, length 34 cm
Model Number(s):	KS02253-1-1
Classification:	Class I per Annex IX, Rule 6 of Council Directive 93/42/EEC *-Amended by Directive 2007/47/EC-*
GMDN Code:	36293

We herewith declare under our sole responsibility that the products mentioned above meet the Essential Principles for Safety and Performance of Medical Devices (GHTF SG1/N41R9:2005) and the Requirements of the following EC Council Directive(s).

All supporting documentation is retained at the premises of the manufacturer.

This Declaration of Conformity is issued according to:

☐ Annex II Council Directive 93/42/EEC for Medical Devices of 14 June, 1993
(for class IIa, IIb and III products)
Notified Body / Registration Number:
TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München / 0123

☐ Annex II Council Directive 93/42/EEC for Medical Devices of 14 June, 1993
(for class I sterile)

Notified Body / Registration Number:
TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München / 0123

☒ Annex VII Council Directive 93/42/EEC for Medical Devices of 14 June, 1993
(for class I products)

Applied standards: N/A

Karl Storz GmbH & Co. KG
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Germany

TEST - LABORATORY - STANDARD - SERVICE - APPROVALS
STORZ
KARL STORZ - ENDOSKOPE GERMANY
Quality controlled

Tuttlingen, 07 June 2011

Carsten Keller
- Regulatory Affairs -

This declaration loses all validity if Karl Storz GmbH & Co. KG performs a product change which affects the Conformance to the Essential Requirements or an alteration of any kind not approved by Karl Storz GmbH & Co. KG was made at the device mentioned above.

Acknowledgements

First I would like to give my special gratitude and thanks to Richard Goossens and Jack Jakimowicz for their guidance and input. Dear Richard, thank you so much for all the uplifting talks and good advice and insights. Dear Jack, thank you so much for opening doors and your amazing knowledge.

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Curriculum vitae

Durandus Vonck was born in Hoogkerk, the Netherlands on April the 27th 1978. In 1995 he finished HAVO and in 1997 VWO. In 1998 he started at the faculty of industrial Design Engineering at the Delft University of Technology where he received his master degree in 2007. Durandus started his PhD-research right after receiving his master degree. The title of the research project was, *The feasibility of vacuum technique in minimal invasive surgery. Improving the patient safety through instrument design*. The PhD research was conducted in cooperation with Karl Storz GmbH. Durandus was also a finalist in the prestigious Delft design and Engineering Awards in 2009. His work was also presented in the Kunsthal Rotterdam, at the Utrecht Manifest in Utrecht and at the Dutch Design Week in Eindhoven.

Currently Durandus is employed at Lely Industries N.V., a company that develops a complete concept to automatize cattle farms. He is employed there as validation engineer.


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