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Development and evaluation of a training model for a hand-sewn duodenojejunal anastomosis technique with the Radius-Surgical-System.

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Meinen Eltern gewidmet…

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1 Background

1.1 Training Laparoscopic Surgery

1.1.1 Overview

Prior to the introduction of laparoscopic cholecystectomy in the late 1980's, surgical skills acquisition was imbedded in the traditional assistential/teaching model of the surgical residency, which had remained relatively unchanged since the late 1800's [6]. Under this model, gradual supervised learning of surgical skills and techniques are acquired by the trainee in the operating theatre directly on patients. With increasing experience, the resident progressively takes over more parts of the procedure. Objectively defined criteria are seldom determined in postgraduate medical education to guide the decision of how much a trainee is allowed or ready to do; this decision usually pertains the supervisor, is influenced by many subjective factors and has been described to be prone to bias [27,90].

The introduction of new surgical procedures or modifications to established techniques was until then largely done also within this system. It is recognized that every surgical training program has its own set of "rules" or has its own "school" regarding, for example, incisions, anastomosis technique, or preferred suturing materials among other technical details. Laparoscopic cholecystectomy was so radically different, however, that it evidenced some of the disadvantages of the established system. This procedure and the other laparoscopic techniques that followed, created special educational needs that where until then unforeseen in the surgical disciplines.

The concepts of motor skills acquisition, learning curves and performance evaluation within a surgical curriculum entered the surgical literature and interest in surgical education grew. The debate about adequate surgical skills training was further fuelled by reports of an increased incidence of serious complications after laparoscopic cholecystectomy, which was probably related to the uncontrolled manner in which this procedure was initially disseminated [74].

Patient safety became a matter of increasing concern. The questions of when a surgeon is considered proficient, and when a procedure is considered safe became central for the subsequent expansion of the laparoscopic approach.

1.1.2 Learning motor skills: „training“

As mentioned, surgical skills acquisition was not systematized before laparoscopic surgery and only few works on open suturing skills analysis were published before [80,6] Although the cognitive sciences had been investigating the process of motor skills acquisition for more than a hundred years, only at this stage did surgery as a discipline looked into the matter with deep interest [48].

Among several theoretical models of how humans learn motor skills, the three-staged model by Fitts and Posner was broadly adopted as relevant to surgical training [48]. The first stage of the model is known as the cognitive phase; the pupil acquires an understanding of the task through demonstrations and explanations by an instructor. The second step is called the associative stage, where the pupil performs the task and receives feedback from the instructor, gradually eliminating errors and deepening the understanding of the whole skill being learnt. The final step is the autonomous stage, where the trainee performs the task repeatedly without major cognitive input while depurating his or her technique [31].

This general model differs from the classic adagios “see one, do one, teach one” and “repetitio mater studiorum est”, which partially reflect the philosophy of traditional surgical training, in several matters. First, it divides the process of learning into distinct phases, which permits identify several intervention points where the learning process can be modified. Second, it implies roles and varying degrees of intervention for instructor and trainee on each of these phases, making clear that no part of the process is passive. In this respect, the importance of the instructor is highlighted, since structured feedback has been shown to be fundamental in the learning process of motor skills [59,31].

A third important difference with the traditional educational paradigm in surgery is that it demystifies the learning process and lets the trainee understand how and why is he or she learning the new tasks through critical thinking and independent learning; this is known as metacognition (i.e., “I learn HOW to learn”) [64]. These aspects give structure and objectivity to the learning process.

It must be stated, however, that being a model, it must be adapted to the specific educational goals at hand. Most of the research behind cognitive theory was done based on the acquisition of simple motor skills. A surgical procedure is an extremely complex entity, which requires the surgeon to be able to perform several overlapping and complex motor skills needed to complete each part of the procedure. Single component skills are more readily learned than a complex complete procedure, and there is correlation between improvements in performance of component skills with better performance of the whole task [51]. It is therefore useful to “deconstruct” surgical procedures into simpler component tasks that can be adapted to the model and thus better trained.

The step-by-step training of skills under this model also allows for evaluation of the trainee’s performance at different points. This permits the plotting of the corresponding learning curve, provided the training and evaluation occur within a controlled setting.

1.1.3 The Learning Curve concept in surgical training

A learning curve is a graphic depiction of the relationship between experience with a task and an outcome variable. It is a simple way of representing part of the learning process of a task, which is in itself extremely complex. The literature on laparoscopic surgical techniques saw a considerable increase in the use of “learning curves” and related concepts in recent years: it is sometimes helpful to visualize the impact of experience on clinically relevant performance characteristics such as operative time, complication rates, and mortality.

For this visualization a “trend-line” is plotted on top of a scatter or graphic with the chosen variables. This trend-line should have a good correlation ($R > 0.5$) in order for it to be valid. The logarithmic trend-line, a simple function in most statistical analysis software is the most commonly used [15].

The learning curve concept was coined by the cognitive sciences to describe the changes in human performance of industrial tasks and production. In principle it relates an independent variable –experience – with an outcome measure. In this form, it has been adopted in the surgical literature. An example of a learning curve for a novel experimental procedure developed in our department is represented in Figure 1. It broadly consists of two distinct parts. The explanation for the initial “steep” part also borrows from the cognitive sciences, which have previously established that improvement occurs more rapidly during the early experience with a task both in animals and humans. This is coincident with the associative stage of the motor skills learning process described in the previous section and broadly corresponds with the steep part at the beginning of the surgical learning curve.

When experience accumulates less improvement occurs after each repetition and the curve becomes “flatter”, roughly meaning that the learning process has entered the autonomous phase where the task is mastered by the individual and he or she may therefore be considered proficient or having “passed” the steep part of the learning curve [20]. From a theoretical perspective, motor neuron adaptation and other neurological processes should occur with continuous practice and it would take a long time before a further substantial improvement could be seen as long as no other intervention is made. Of importance here is the continuous practice, since it is known from the motor skills and general cognitive science literature that a reverse effect (un-learning or forgetting curve) is the rule [31].

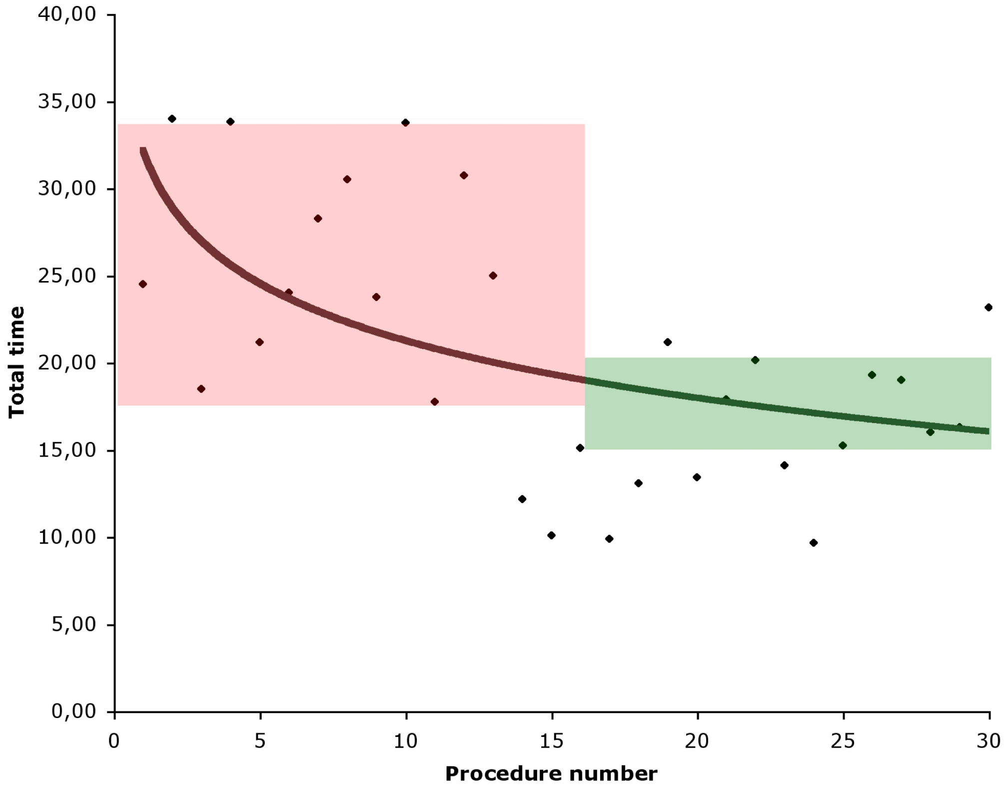

Figure 1 Learning curve for the experimental single port transvaginal cholecystectomy for one surgeon with a logarithmic trendline for interpretation. The "steep" part is highlighted in red, the "flat" part in green. Adapted from Becerra et al.

Although a useful tool, the concept of learning curve has been widely misused in the surgical literature.

The first kind of misuse relates to the application for complex tasks done by one surgeon in the clinical setting. The learning curve is more precise when depicting simpler tasks (e.g. object manipulation with laparoscopic graspers). It is more useful to identify what influences the learning process in a given individual: for example, by analyzing the results at the beginning and towards the end of the curve and knowing which educational interventions were made, one can identify which of these had a positive effect on performance.

Surgical procedures are, as discussed, complex tasks where many individuals with different proficiency levels interact. Although it is possible to depict a simple learning curve for a procedure done by one single surgeon this does not distinguish other factors that may influence the outcome variable such as the individual learning processes of the other members of the surgical team (the assistant, scrub nurse, etc.).

When starting the use of a new technique, each member of a surgical team is involved in an independent learning process that may have an effect in the outcome variable [8]. Furthermore, there are other factors, independent from the learning processes, which may influence the measured outcome. Cook and co workers have described a hierarchy of influences on individual learning of a surgical procedure, which is represented in Figure 2 [15]. The complexity of the system is evident; therefore the use of the learning curve concept in the clinical setting must be used and interpreted with caution when analyzing the results and the learning process of a new procedure.

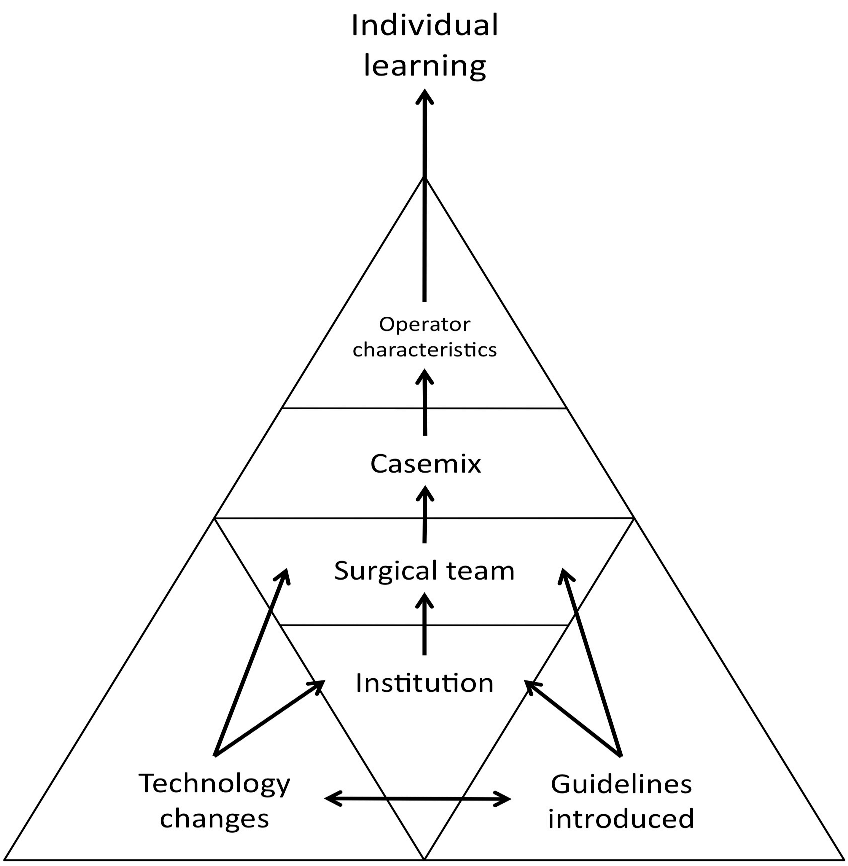

Figure 2 Factors influencing individual learning in the surgical setting (Adapted from Cook et al).

Another kind of misuse is the grouping together of learning curves of many surgeons into a single graphic. The learning process is a highly individual one.

The idea that learning occurs in a smooth fashion (hence, representing a curve) is an artefact that results from grouping the values of each individual and plotting a curve based on the mean value for each point. Each individual's learning curve has in fact a unique shape and may be influenced by different factors. Agreeably, there are instances when it may be useful to know how an individual performs with respect to a standard (group) learning curve, for example when a surgeon is evaluated for matters of certification.

A third common difficulty encountered when dealing with the learning curves of novel procedures (or those of surgeons new to an already established procedure) is the choice of outcome variable to describe the learning process. It is relatively straightforward to determine if a surgeon is capable of completing a task in a controlled environment such as a training lab. Measuring ability in actual surgical procedures, however, it is a completely different matter.

How do we know who is proficient and when? There are two types of indicator that are generally used to address this question in the clinical setting: measures of patient outcome and measures of surgical process [17]. Patient outcome measures include postoperative complications, survival, and success rates, among others. Many factors besides surgeon experience may influence these measures. Process outcomes are more convenient to collect and analyse and are therefore more commonly used; they include blood loss, operative time, and the occurrence of specific surgical complications. These, however, are only indirectly related to patient outcome and only limited conclusions can be drawn from studies reporting them.

From the previous explanation on the learning curve concept, it should be clear that several conditions should be met in order to properly analyze what influences the learning process of a new surgical procedure.

First, the task should be deconstructed and taken out of the clinical setting to allow for controlled evaluation of the process. Second, the learning process should be investigated individually and in a controlled fashion. During the learning process, every intervention such as feedback, technique modification, instrument changes and so forth, occurring during the learning process, should be annotated. Finally, but of extreme importance, is the choice of an adequate outcome variable that is relevant to the procedure, can be objectively measured, and has at least some correlation with patient outcome. This variable becomes then the performance indicator with which a surgeon can be evaluated during the learning process and afterwards [15].

1.1.4 Indicators of surgical skills acquisition and training

As mentioned in the previous section, there is no single objective measure that correlates surgical skill and optimal patient outcome. Therefore the question “who is proficient enough to operate a patient?” is a matter of intense investigation and debate.

Dagash et al. made a systematic review on learning curves of different laparoscopic procedures in order to address this question [20]. The studies included had analyzed the “learning curve” in a laparoscopic procedure using at least one of the following 4 outcome measures: operating time, conversion rate to open surgery, complication rate, and length of hospital stay. They only chose studies that established or suggested the number of procedures performed to achieve proficiency or to reach the flat part of the learning curve.

The 37 studies ultimately reviewed included reports on laparoscopic cholecystectomy, fundoplication, colectomy, herniorrhaphy, and splenectomy. Of the outcome measures used, operating time was investigated in 26 studies, conversion rate in 23, complication rates in 27 and length of hospital stay in 12. All the studies done in adults on all techniques reported a reduction of the outcome measures when comparing “initial” with “late” experience, suggesting that there is indeed a “learning curve” in laparoscopic surgery. A detailed look at the data, however, shows that none of the measures used in the different studies throw consistent results.

For cholecystectomy, the most common laparoscopic procedure, median operating time in minutes at “initial” experience was 134 (range, 44 to 216) and 78 (range, 32 to 114) at “late” experience; conversion rate decreased from 9.4% to 4.3%; complication rates equally fell from 6.2% to 1.3%. From the pooled data, the mean number of procedures a surgeon needed to perform to be considered “proficient” was 30; the range of 8 to 200 procedures among the studies, however, shows how unreliable this parameter is. Similar results are reported for the other procedures.

Regarding bariatric surgery in general, the “learning curve” has been the focus of several publications. A wide range of 75-150 procedures has been suggested as the “limit” of the learning curve for the Gastric bypass, with significant reduction in morbidity found in most studies. Across these studies, however, different criteria were used to define the end of the “learning curve”, with intervention time, hospital length of stay and complication rate used indistinctly [57,84,4,53,11].

Besides the lack of consensus on how to evaluate learning curves in surgery, there are specific disadvantages of using these measures in the clinical setting as surrogates of learning.

Total operating time fails to reliably represent a surgeon’s performance for several reasons: it is a product of the performance of every member of the surgical team (see above); it is influenced by individual patient characteristics – e.g. extent of adhesions to the gallbladder, abdominal wall thickness; it has no demonstrated correlation with patient outcome or surgeon’s proficiency, and it has been stressed that a fast surgeon is not necessarily a good surgeon [21].

Conversion rates to open surgery had relevance in the early years of laparoscopic surgery. In the absence of an experienced colleague or proctor, newly trained surgeons preferably opted for conversion when encountering difficulties. The rate of conversion was reduced, predictably, with increased individual experience. More recently, however, cumulated experience of the surgical department, established treatment guidelines, and other factors may play a role in the decision to convert to open surgery, irrespectively of the surgeon’s or resident’s level of expertise. Interestingly, the decision of NOT to convert cases until certain threshold is met may yield lower conversion rates but increased operative times in the “late” experience.

General complication rates also have several drawbacks as measures of surgeon’s performance or skill. Medical and surgical complications may arise at any moment during the perioperative period and may be related to the surgical procedure but also to the patient’s health status, ancillary measures and other factors that have no relation to the surgeon's technical performance. From a methodological point of view, a complication is a dichotomous variable, like survival, and is therefore relatively difficult to use in sound statistical analysis. Some grave complications have a relatively low incidence rate and to note any significant change during the surgeons "learning curve" would require an unrealistically high number of patients.

When procedure specific complications are considered, such as anastomosis leak rate in bariatric procedures, we encounter another disadvantage of using complications as surrogate for surgeon's proficiency: we must wait for a patient to have it in order to detect it. Under these circumstances, a surgeon could in theory be deemed unable to do the procedure *a posteriori.* In the face of current knowledge and technical advancements in surgery, this should be unacceptable.

Having an adequate measure that properly represents learning and correlates with clinical outcome may help guide the decision of when a surgeon is beyond the steep part of the learning curve for specific tasks related to a procedure and hence should be able to perform the procedure on a patient under proctorship thus minimizing the influence of human error on the outcome.

From the above discussion follows that adequate training must meet certain characteristics that do not exist in everyday surgical practice. It is also desirable that the cognitive and associative stages of motors skills learning occur before a surgeon practices a procedure new to him on a patient. The best place to learn a new surgical technique would be then, in the age of laparoscopic surgery, outside the OR.

Well-defined training steps of specific surgical tasks should be evaluated using the most adequate measures of performance within a controlled setting. For this reason, simulation based training has gained much attention in medical and surgical education worldwide. We will continue with a discussion on simulators and their role in training and development of surgical procedures.

1.2 Simulators in surgical training

A simulator is an artificial representation of reality. In this context, simulators for surgical training can be categorized into high fidelity and low fidelity, based on the level of realism that the simulator reaches. Important aspects that determine how realistic a simulator is relate to the sensory information they provide the surgeon. Visual and spatial characteristics, tactile and mechanical properties as well as level of interaction –feedback or “reaction” of the simulator to input – are particularly relevant [39].

Low fidelity simulators include training boxes or “pelvitrainers” propped with inanimate materials that provide means to train tasks of variable complexity such as orientation, object manipulation, suturing and knot tying. They have a demonstrated role in the initial acquisition of laparoscopic skills [7]. A particular advantage is that they provide some sensory feedback, which is relevant for acquiring fine motor skills.

High fidelity simulators may be computer based (“virtual reality”) or biological (live animals). Although not covered in most reviews on simulators, human cadavers [10,34], and inanimate biological models [91] such as the one proposed in this work can be considered to belong to this group. An overview of high fidelity simulator types, characteristics and advantages/disadvantages is presented in Table 1.

Table 1 High fidelity simulators. Characteristics, advantages and disadvantages.

Simulator type	Description	Advantages	Disadvantages
Virtual Reality simulators (full procedure software)	Computer generated visual environment combined with laparoscopic instrument interface	• Software usually permits objective assessment of performance • Individual learning of procedure steps possible	• Provides mainly visual information • Few models provide suboptimal tactile information • Expensive

Simulator type	Description	Advantages	Disadvantages
Animal models	Live animals (swine, dog)	• Full sensory feedback • Full procedures may be simulated	• High costs • Discrepancies in anatomic relationships with humans • Limited case/trainee ratio
Human cadavers	Preserved or unpreserved (laparoscopic autopsy) human cadavers	• Real anatomy • Full sensory feedback	• Limited availability • Logistics • High costs • Limited case/trainee ratio
Inanimate biological model (Tuebingen Trainer concept)	Preserved or unpreserved animal organs inside trainer replicating human abdominal cavity	• Full sensory feedback • Ad hoc simulation • Relatively low cost • Higher case/trainee ratio	• Logistics

Based on several sources

The ultimate purpose of training in a simulator is to acquire skills in a controlled setting, without putting patients at risk. Several studies have reviewed the effect of training on performance using different simulators. If, however, the skills acquired in a simulator actually translate to real life needs to be demonstrated. Before using a simulator as an educational tool, it must go through the process of formal validation, which will be explained in the following section.

1.2.1 Validation of surgical simulators

With the large number of simulators now available, surgeons may be exposed to a wide range of educational experiences. These are influenced mainly by the simulator itself, the tasks involved, the time and type of exposure, and the educational curricula under which the training occurs. Although common sense might suggest that repetition of tasks leads to training, the actual effect of the training experience needs to be thoroughly evaluated in order to optimise any given training module [39].

Beyond teaching and task training, the assessment of a surgeon's level of competence and the question of certification are of importance and require rigorous evaluation of the training/assessment instruments, including simulators. The ideal simulator model is that which offers such a realistic experience that performance on it after training correlates adequately with actual clinical performance later. To arrive at proof that a simulator model actually has the desired effect on surgeon's performance, the simulator model needs to be validated. Full validation of a simulator model as a training tool is a lengthy process [63]. The steps are illustrated in Table 2. It is important to note that the development of a simulation model begins before validation and is of considerable importance.

Table 2 Validation steps for surgical simulators

Validation step	Question	Method of evaluation	Result
Face validity	Does the model represent what it is intended to represent?	Usually informal evaluation by experts/non-experts: yes/no, graded score	Model is realistic
Content validity	Is the realistic model appropriate for teaching what it is intended to teach? (procedure or task specific)	Informal/formal evaluation by experts: yes/no (ideally for each task or step intended to teach), graded score	Model is appropriate Model measures performance of the task(s)
Construct and concurrent validity	Does the simulator (and its measurement of performance) distinguish experienced from unexperienced subjects?	Formal evaluation with subjects of different skill levels (construct validity) Comparison of measurements with performance on another, previously validated tool (concurrent validity)	The model is valid for evaluation of specific skills Training on the model is acceptable, pending predictive validation
Predictive validity	Does performance measured during training correlate with actual performance in real patients after training?	Requires controlled trial with objective intraoperative measurements	Training in the model is recomended

1.2.2 Simulators and development of new techniques

Simulators play an increasingly important role in the development of new techniques and technologies in many fields of surgery. From an ethical perspective it is necessary that technologies be thoroughly tested up to the point that a clinical study can be undertaken without unnecessary risk for the enrolled patients. The European Association for Endoscopic Surgery has recently published its recommendations for technologies and technique development in endoscopic surgery before clinical application [67].

Although many surgical technologies and techniques have been tested on live animals before human use, some details need not be tested on live tissue. The ideal model for testing the technology or technique should be sought on a case-to-case basis.

1.2.3 Error analysis in a simulation setting

One of the main advantages of simulation training and technology testing in simulators is the possibility of analyzing errors and adverse events with objectivity. The nature of medical error and the approach the medical profession towards it has been discussed elsewhere [73,19]. There is increasing interest in a more constructive paradigm of error management as used in the airline industry [41].

Low cost high fidelity models facilitate a non-judgmental analysis of surgeons' errors during training. This is done by subtracting the consequences a procedural error may have in a patient during a surgeon's training and by eliminating the stressful atmosphere of a real-life operating theatre, while maintaining an acceptable degree of realism relating to the procedure.

Beyond performance indicators, individual learning and specific feedback relating to errors and adverse events may be the most valuable part of the educational experience for the trainee [81].

1.2.4 The need of an organ preservation technique for advanced biological training models

Non-living biological models using organs from different animals have been used for teaching and training laparoscocpic procedures since the 1990's in the University of Tuebingen and elsewhere [91]. Training of cholecystectomy, funduplication and colorectal surgery is done regularly using either fresh or frozen-thawed organ blocks according to the training program. Porcine liver and gallbladder, as well as oesophagus and stomach withstand this handling without excessive tissue alteration allowing for trainees to have exposure to a good number of cases with consistent reality from case to case.
The small intestine, however, is a more fragile organ and although it has not been formally documented to date, it is common knowledge that it looses its biomechanical properties after a few hours from harvesting because it suffers autolysis early on, with further decomposition potentially caused by normal enteral flora. This limits its use and thus hinders adequate training of surgeons aiming to master techniques that require an intestinal anastomosis.

1.2.4.1 Freeze-thawing injury on tissues

Organs that can be collected, frozen and used when needed make inanimate biological models flexible for experimental and training use. Although freezing-thawing is viable for other organs, the small intestine is particularly sensitive to the well described mechanisms of freezing and thawing injury. When frozen, fresh tissues and organs are injured through a combination of osmotic gradient and direct ice-crystal injury, which has adeleterious effects on cells and tissue (cellular and non-cellular) architecture afther thawing [71]. This negatively affects the viscoelastic properties of the intestinal wall, resulting in unrealistic tissue consistency, altered mechanical properties and a more fragile tissue that responds inadequately to surgical manipulation.

1.2.4.2 Tissue preserving techniques

Preservation is thus desirable for two reasons: the availability of organs for training or experimentation on a shot notice and the reliability of tissue consistency.

There are numerous organ preservation techniques described in the fields of surgical anathomy, anathomopathology, organ transplantation and even food processing [37,89,43]. None of them, however focus on preserving the biomechanical characteristics of organs as much as possible while maintaining a realistic feel and look on the organs.

Some of the substances used in organ, tissue and/or cell preservation have well described mechanisms of action. Glycerol has been described as a crioprotective agent, since it displaces water from cells and has a very low freezing point, thus protecting cells from both mechanisms of freeze-injjury [37]. Alcohol also causes cell and tissue dehydration and stabilizes cell membranes as well as denatures proteins and enzymes. Formaldehyde, on its part, forms cross-links between proteins at a slow constant rate and preserves the microarchitecture of proteins and cells; nevertheless, it greatly modifies the organ or tissue macrostructure and its physical properties [43].

Our needs are different from other disciplines, where microanatomy or even protein epitope preservation is the goal. We therefore sought to find a preservation technique for the small intestine using a combination of agents that would give consistent results.

This point is crucial in this work and for further work in advanced laparoscopic surgery, since the model we propose needs to offer an objective way to measure performance and must be easily reproducible with reliable results.

Both formaldehyde and Glycerol/ethanol solutions offer, in theory, some desirable results. We theorized that through a combination process we could acquire preserved organs of reliable quality, with a realistic look and feel as well as realistic and consistent mechanical properties

1.3 Bariatric/Metabolic surgery

1.3.1 Generalities of bariatric surgery techniques

Bariatric Surgery as a whole has proved to be the most effective therapy for morbidly obese patients with or without co morbidities. Even though only few randomized controlled trials have directly compared any type of surgical treatment with conservative measures, the accumulated evidence clearly shows that for these patients only surgical treatment offers the best long-term chances of weight control. Long-term studies also show that there is a substantial reduction in mortality after bariatric surgery in obese patients with or without diabetes when compared to medical treatment cohorts, as well as complete resolution or improvement of diabetes, hyperlipidemia, hypertension and obstructive sleep apnoea in the majority of operated patients. The therapeutic effect of bariatric surgery on these other illnesses, as well as the better understanding of the actual mechanisms of this effect, prompted the recent adoption of the term “Metabolic surgery” [75].

Bariatric operations are now accepted as standard treatment for obesity. Several medical societies have reviewed its results and recommendations. As recently as 2007 a multidisciplinary panel on the treatment of obesity made the latest review of the evidence of bariatric surgical treatment and published its recommendations, including indications, and follow-up requirements. [78].

Currently, the main types of surgical procedures for the treatment of obesity are categorized into restrictive, absorption limiting techniques and combined procedures.

- Food limitation or restrictive operations
    - Vertical banded gastroplasty (VBG)
    - Gastric sleeve resection
    - Gastric banding
        - Adjustable (AGB)
        - Non-adjustable
    - Roux en-Y Gastric bypass (RYGB)
        - Proximal

        - Long-limb
- Operations that limit the absorption of nutrients and energy
    - Biliopancreatic diversion (BPD)
- Combined operations
    - Distal gastric bypass
    - Biliopancreatic diversion with duodenal switch (BPD-DS)

This description is based on the mechanism by which they, in theory, cause weight loss [75]. Nevertheless, the observed effects of bariatric surgery involve a much more complex series of physiological adaptations which include changes in recentrly discovered hormone secretion patterns such as that of ghrelin, and the incretins which have been reviewed elsewhere [94,9].

Whether restrictive or malabsortive, the procedures require modification of the normal gastrointestinal anatomy (Figure 3).

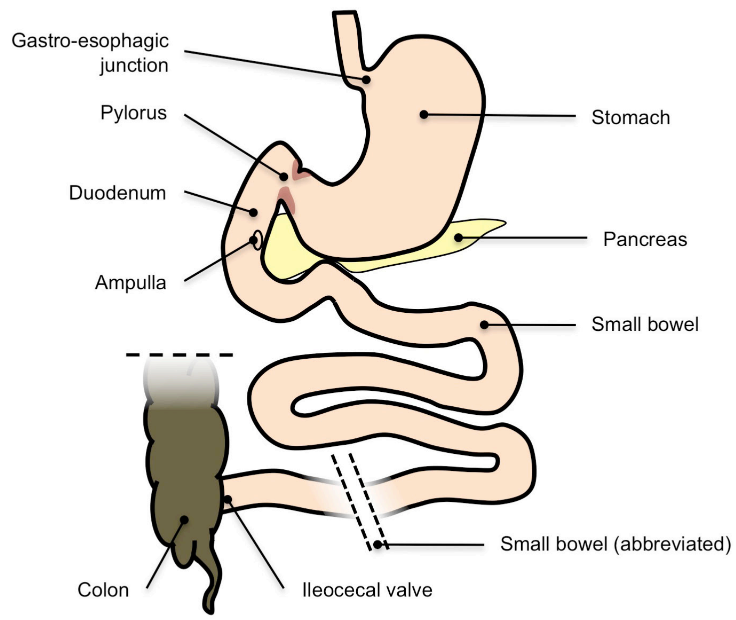

Figure 3 Normal gastrointestinal tract anatomy.

Restrictive methods focus on modifying the stomach to limit its capacity either by introducing a foreign object that forces a reduction of diameter –'band'-, surgical transection or both. Long-term gastric capacity restriction is intended to cause lower dietary intake by the patient and thus weight loss and control.

Currently, purely restrictive surgical methods include Laparoscopic Adjustable gastric band (LAGB, and vertical banded gastroplasty (VBG).

The most commonly practiced bariatric procedure is the Roux-en-Y gastric bypass (RYGB); this procedure is mostly restrictive, but since it includes a bypass of 90% of the stomach, the duodenum and a variable portion of jejunum, a malabsorptive element is also in play.

Purely malabsorptive methods are no longer in use, but this mechanism remains fundamental in the surgical treatment of obesity surgery; malabsorption is caused by bypassing variable extensions of the proximal intestinal tract to diminish the time the bolus is in contact with biliopancreatic secretions as well as to shorten the effective absorption area. This creates a limited absorptive capacity that remains even after intestinal adaptation, thus weight loss and weight control is –in theory- independent of total dietary intake. Today, the techniques that use malabsorption are all mixed procedures since they include some restrictive procedure in the stomach. Biliopancreatic diversion (BPD) with or without duodenal switch (DS) belongs in this category. It is a complex procedure that involves three main steps: sleeve gastrectomy, duodenoenterostomy and Roux en-Y reconstruction. The principles of this technique are explained in Figure 4 through Figure 6, which will serve as reference for further discussion.

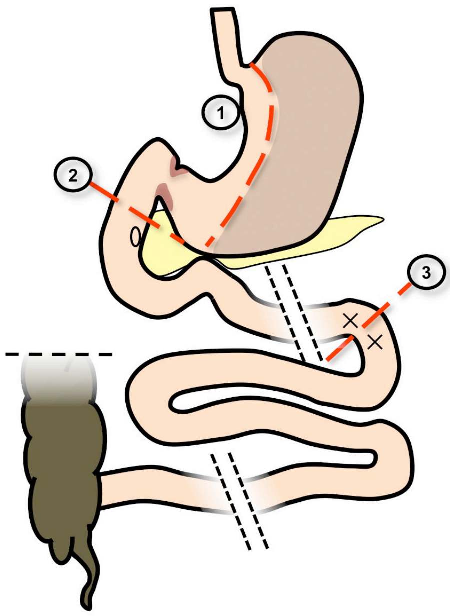

Figure 4 Duodenal switch principles I. The fundus and body of the stomach are excised (1), the duodenum is divided above the second portion (2) and the small bowel is transected distally (3).

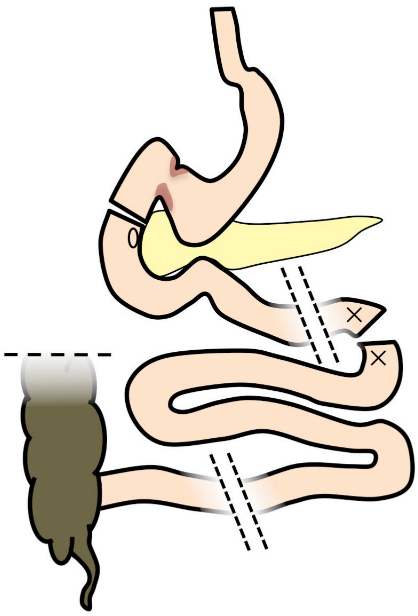

Figure 5 Duodenal switch principles II. Resulting segments prior to reconstruction. Note the original position of the proximal and distal small bowel ends (×).

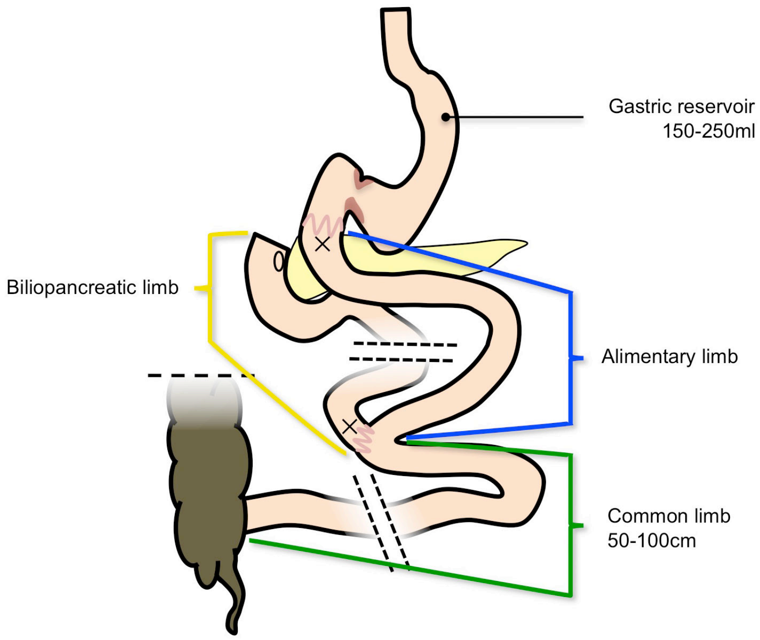

Figure 6 Duodenal switch principles III. Resulting components of the gastrointestinal tract. The long "sleeve" gastric reservoir remains after removal of the body and fundus. The pylorus and fist duodenal portion are preserved and connect directly to the distal intestine forming the alimentary limb. The biliopancreatic limb is longer than in the RYGB, excluding most of the jejunum from contact with food. The alimentary limb's length is determined by initial weight and weight goal.

However these categories help to explain the principles, the underlying mechanisms through which the mixed procedures cause weight loss and control of co morbidities are certainly more complex and may involve as yet unknown hormonal intermediaries. The intricacies of the gastrointestinal system are not completely understood and the anatomical and thus physiological modifications done through the aforementioned procedures have prompted new research into the role of the gut in metabolism and homeostasis in health and disease [95].

1.3.2 Biliopancreatic diversion with the Duodenal Switch

The BPD with *duodenal switch* is the result of a combination of techniques.
From the 1970's, Scopinaro's biliopancreatic diversion had shown the best long-term results regarding weight loss and the most dramatic effect in the control of comorbidities of obese patients. Nevertheless, the BPD was associated with a varying incidence of long-term sequelae. The risk of severe nutritional deficiencies secondary to malabsorption was high. Also the restrictive

component of this technique made for the appeareance of postgastrectomy symptoms and the Roux-en-Y reconstruction is known to be ulcerogenic. A more physiologic procedure that retained its efficacy yet reduced the difficult to treat complications was sought.

Unrelated to contemporary work in bariatric surgery, in 1988 DeMeester and his team published their experimental and clinical results of a proximal end-to-end duodenojejunostomy for pathologic duodenogastric reflux or duodenal switch [23]. Prior to this procedure, the surgical treatment for duodenogastric reflux consisted mainly of Roux-en-Y bile diversion with antrectomy and vagotomy. This interrupted the physiologic continuum of stomach-duodenum and patients were prone to postgastrectomy syndrome. Also, there was a high incidence of jejunal ulcers with the existing treatment. The DS is a more physiologic surgical procedure due mainly to three reasons:

- Preservation of the pylorus AND the antrum, which favours normal gastric pump function and emptying.
- Preservation of the first portion of the duodenum, permiting the duodenal inhibition of gastric acid secretion taking place.
- Preservation of vagal inervation to stomach and pylorus, favouring adequate gastric emptying and less disruption of gastrointestinal physiology.

Duodenojejunostomy as such was at that time increasingly common as reconstruction procedure after pancreatoduodenectomy and its effects on glucose tolerance, insulin response and gastric emptying, had been studied beforehand by Itani *et al* in an experimental setting in dogs [47]. In this study, no difference was found in gastric emptying of liquids, solids and glucose 20% solution between control and operated animals. Both glucose tolerance and insulin response showed slight differences between the groups, with a lower peak insulin level and delayed plasma glucose rise in operated dogs. The authors theorized that there should be as yet unidentified modulating factors that were produced in the jejunum and had an effect on gastric function; some of these factors have already been identified (see above).

These features were of theoretical advantage for bariatric surgery. The DS was incorporated to the BPD independently by the groups of Baltasar, Hess and Marceau, with the addition of a sleeve gastrectomy to maintain the restrictive element of the procedure. Each author published their work comparing BPD with BPD with DS in 1998 [42,60,5].

Since then, the technique involving a sleeve gastrectomy and a BPD with varying distance of the intestinal limbs, with a duodeno-jejuno or duodeno-ileal anastomosis for the alimentary limb is known as the *duodenal switch*. Before discussing the open and laparoscopic technique in detail, we will review the current indications and results of this procedure respecting obesity and diabetes mellitus.

The current accepted indications for BPD-DS are the same as for any other bariatric surgery technique. According to the latest European guidelines there is insufficient evidence to recommend a specific type of bariatric procedure to a subset of patients. Some groups use it as their main procedure since its introduction. Nevertheless, for the majority of bariatric surgery centres that practice it, it is usually reserved for the extremely obese (i.e. BMI>50). This may be because it is more surgically complex, yet it offers the most weight loss when compared to other techniques in this subset of patients [72].

The DS has been used as a “second-step” procedure on sleeve-gastrectomy patients who fail to loose sufficient weight or that regain weight [44]. It is also considered as an adequate revision procedure for LAGB patients who fail to loose sufficient weight. In these patients adhesions to the stomach may difficult the fabrication of a classic gastric bypass [42].

Importantly, the DS has been proposed and used within clinical trials, without accompanying gastric resection, as treatment for dislipidemia and DM2 in non-obese patients and in obese patients without weight loss as the main goal [68,16].

1.3.3 Surgical technique of the BPD-DS

1.3.3.1 Open technique

As mentioned previously, DeMeester described the DS for the treatment of duodenogastric reflux in the 1980’s [23]. The technique is in essence the same as needed for a BDP-DS, which was latter adopted, and also for postpyloric reconstruction after pylorus preserving pancreatoduodenectomy, which was in use many years before.

Adapted from the original description by DeMeester and the later modification for bariatric surgery by Hess and Marceau [42,60], the main steps of the procedure are described as follows.

- Upper midline incision, exposure
- Kocher manoeuvre until free access of the posterior aspect of the duodenum and head of pancreas is possible.
- Identification of the ampulla in the second duodenal portion by palpation through the duodenal wall.
- Dissection of the duodenum free of the pancreatic head at a point exactly above the ampulla, dividing the small vessels that course between the two. Particular care should be taken not to injure the pancreatic portion of the common bile duct. This dissection is continued until the index finger can be freely passed between the duodenum and pancreas.
- The duodenum is transected in the distal part of the dissection using a GIA stapler or between clamps. The distal stump is closed. Confirmation of bile flow in the distal duodenal stump may be done.
- The jejunum, at 25cm distal to the ligament of Treitz (DeMeester) or the ileum at 100 to 250cm proximal to the ileocecal valve (Hess, Marceau), is brought through the transverse mesocolon right of the midcolic vessels. A 2cm long segment is prepared free of mesentery and transacted.
- The distal jejunal (DeMeester) of ileal (Hess, Marceau) limb is anastomosed end-to-end to the proximal duodenum using a single layer suturing technique.

- The proximal jejunal limb is brought back below the mesocolon and is then anastomosed end-to-side to the distal jejunal limb at 55cm caudal to the duodenojejunal anastomosis.

1.3.3.2 Technique, laparoscopic

The recognized reduction in the stress response reduction to surgery with minimally invasive techniques and the potential reduction in cardiopulmonary and wound complications –particularly common in morbidly obese patients –, favoured the introduction of the laparoscopic approach to the already established field of bariatric surgery. The BPD-DS is considered such a complex procedure, that it was done laparoscopically relatively late. As mentioned earlier, the weight-loss results of open and laparoscopic BPD DS are comparable. The potential advantages favour the laparoscopic approach, yet the technical difficulties limit its widespread application.

The groups of Baltasar [5] and Gagner [49] have independently described their laparoscopic BPD-DS techniques in humans. Interestingly, only one work was found that describes the experimental application of the laparoscopic BPD-DS, in a live pig model, a work done by Gagner's team before their initial clinical experience [22].

This complex procedure consists of three main steps: sleeve gastrectomy, duodenal switch (dissection and anastomosis) and Roux-en-y reconstruction. All the proponents do the sleeve gastrectomy part of the procedure in a similar way. The technique for the dissection of the duodenum and its transection is common to all described methods with minimal differences. Variations on the length of the biliopancreatic, alimentary and common limbs are of minor technical importance and respond to a more complex decision process done by the surgical group in a case-to-case basis; thus, for the description of the technique a common limb of 100cm and an alimentary limb of 250cm were chosen. The duodenoenteral anastomosis is technically challenging and represents the riskiest step in the procedure. There are many different techniques described for this single step, with no consensus relating results and safety.

The standard laparoscopic BPD-DS technique is thus as follows.

- The patient is put in the supine position under general anesthesia with legs apart (French position). The surgeon takes the position between the patient's legs, with first and second assistants at each side of the patient.
- The number of laparoscopic access ports varies from five to seven, although up to nine have been used on occasions. A first 10mm –a contact view trocar is recommended –access port is made with an open technique in the supraumbilical region and the abdominal cavity is insuflated with CO2 to 15mmHg. Following insuflation and initial laparoscopy, the remaining access ports are placed. A sub-xyphoid trocar (5/10mm) is used for liver retraction. Two ports are placed at the lateral borders of the anterior rectus muscle slightly higher than the first supraumbilical port. Further working ports are placed on both sides of the abdominal wall at the subcostal margins on the midclavicular line. Variations on port placements are common, since the altered anatomy of the abdominal wall in obese patients and the displacement it suffers during insuflation does not permit an exact topographical localization of the underlying organs. Each port will serve different purposes during the procedure and the surgical team should be able to adapt to various working configurations.
- The greater curvature of the stomach along with pylorus and first portion of the duodenum are devascularized. The small vessels between the pancreatic head and the duodenum are easily controlled in this fashion. Care should be taken, however, to preserve the posterior branches of the pancreato-duodenal arcade supplying the pylorus.
- The hiatus is dissected in order to have a clear exposure of the cardias and to completely liberate the gastric fundus.
- The sleeve gastrectomy is initiated exactly proximal to the antrum with linear staplers, parallel to the lesser curvature of the stomach. The anesthesiologist introduces a 48-60f intragastric bougie, which serves as

a stent that guides the subsequent stapling actions in direction to the cardias to create the gastric tube, which will have a 150-200ml capacity.

  - The gastric staple line is oversewn with laparoscopicaly placed sutures by most authors. This has been shown to reduce gastric leaks and it also serves for haemostasis.
  - The gastric remnant is removed through one of the large ports.

- The lateral aspect of the first and second portion of the duodenum is dissected. It is not necessary to complete a Kocher's manoeuvre. It should be enough to dissect the first duodenal portion free of the retroperitoneal space to make room for the linear stapler if it is to be used. No direct visualization of the common duct, portal vein and mesenteric vessels is needed; the dissection plane should always remain superficial (i.e. adjacent to the duodenal wall). The pyloric vessels provide the necessary blood supply to the proximal duodenum.
- The duodenum is transected 2-4cm distal to the pylorus. When transecting with a linear stapler, enough room should be available on the posterior aspect of the duodenum. The identification of the second portion and the ampulla is crucial –as described in the open technique. There is no standard described method to do this laparoscopically, although adequate mobilization of the duodenum and indirect palpation with a laparoscopic instrument should be enough.
- The surgical team changes positions, and the surgeon takes place at the left of the patient. The measurement of the common limb is begun at the ileocecal valve without stretching the intestine. At 100cm, a suture mark is placed to locate the site of the future enteroentero anastomosis. Measurement is continued proximally until reaching the 250cm mark, where the intestine is transected and the mesentery is partially divided to permit mobilization of the proximal and distal intestinal limbs.
- A lateral-to-lateral intestinal anastomosis is done between the proximal –biliopancreatic- limb and the distal intestine at the previously placed 100cm mark to form the common limb. Here both stapled and hand-sewn anastomosis is viable.

- The remaining free end of jejunum-ileon is brought up, either antecolic or retrocolic, to the previously prepared duodenum to proceed with the duodenoenteral anastomosis (see next section for detailed discussion).
- The resulting mesenteric opening is closed and a final verification of the gastrointestinal tract is made. A drain may be left close to the duodenoenteral anastomosis and near the stapple-suture line of the sleeve gastrectomy.

1.4 Radius Surgical system

The limitations of conventional laparoscopic instruments for creating intestinal anastomoses have been matter of study and reviewed elsewhere [49]. Perhaps most critical is the reduction in degrees of freedom the surgeon has to confront while working with conventional laparoscopic instruments. The human hand has seven degrees of freedom –without counting the movements assisted by arm and upper body –, and the surgeon finds these reduced to four while using a conventional needle holder. While it is true that it is possible and trainable to suture with these instruments, the acquisition of a high level of proficiency to safely perform such a critical step as an anastomosis can take a long time and repetitions, during which the patients' safety is compromised. The limitations of laparoscopic instruments were recognized very early during the introduction of the new techniques. Even while in practice laparoscopic surgery was being increasingly used, research was ongoing to improve the ergonomics and functionality of laparoscopic instruments [12].
Dealing with this limitations and bringing a wider range of (safe) possibilities to endoscopic surgery has been the goal of many scientific groups with distinction of the Section for Minimally Invasive Surgery in Tübingen with its engineering and industry partners. In the early 1990's, a joint project of the Tübingen Group and the Karlsruhe Research Centre was started with the goal of developing instruments with increased degrees of freedom and to couple this technology with a robotic manipulator system [79]. The project, named ARTEMIS (Advanced Robotic TElemanipulator for Minimally Invasive Surgery), comprised a large amount of work in basic and applied engineering, ergonomy and

experimental studies in phantom trainers for laparoscopic techniques. While the project came to have great success in developing a complete electronic system for telemanipulation of endoscopic instruments –more widely known as “robotic surgery”, a critical point was reached on which an industrial partner was necessary for future development of a system suitable for clinical use. This was not possible for the telemanipulator part of the project. However the know-how acquired during years of work in the field permitted further development and refinement of a mechanical manipulator that offers six degrees of freedom: the Radius Surgical System (RSS, ®Tübingen Scientific GmbH).

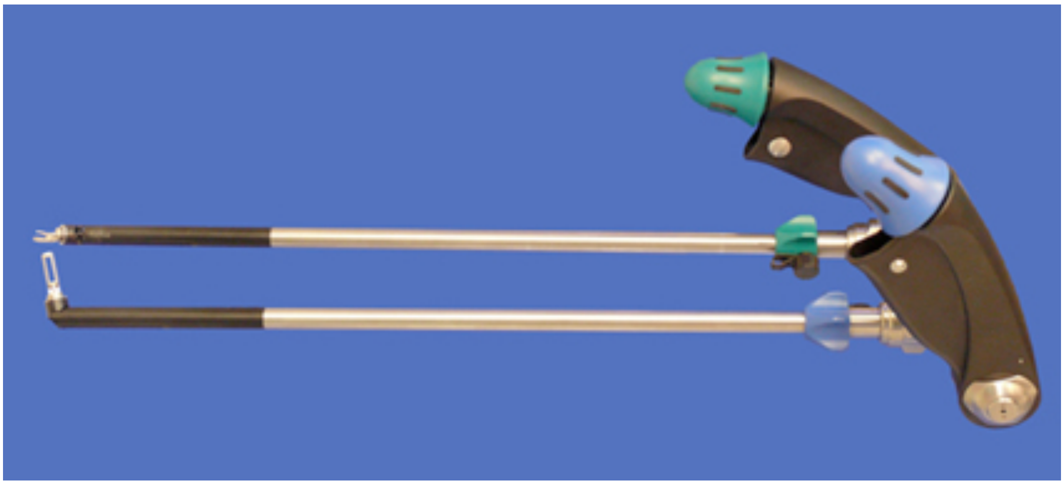

Figure 7 Radius Surgical System I. Left hand (blue knob) and right hand (green knob) instruments. Note the different kind of tips and their position on each instrument.

The RSS was intended to be the simplest solution possible to the problem of decreased DOF. It was completely engineered with ergonomics and functionality in mind, with the goal of making its use intuitive [79]. Figure 7 and 8 depict the most recent version of the instrument. More details can be obtained directly from the manufacturer.

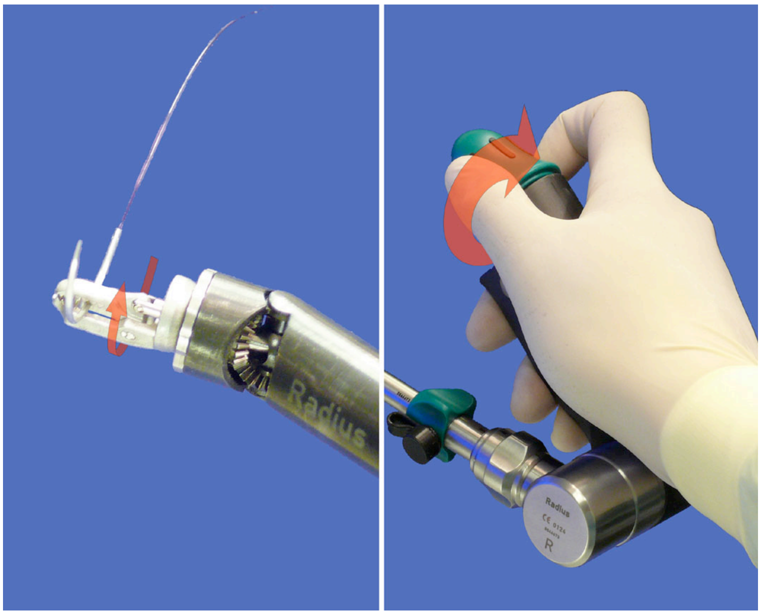

Figure 8 Detail of the increased degrees of freedom of the RSS. The tip is rotated independently from the shaft, which permits deflection of the instruments tip to adjust to different suturing planes.

The performance of the RSS in isolated suturing/stitching tasks has been thoroughly studied by Waseda et al [92]. In their study they compared the performance of trained surgeons with CLI with the RSS in suturing tasks (knot tying, sagittal and frontal suturing exercise, and in needle control in a stitching exercise meant to reproduce different angulations between the plane of view and the surface to be sutured. Regarding time to finish the tasks, there was no difference in performance between RSS and CLI in knot-tying (61.1s ±27.6s vs. 54.9s±22.3s) and frontal suturing (156.6s±36.6s vs. 145.0s±35.1s). Suturing in the sagital direction proved faster with RSS than with CLI (152s±34s vs. 220s±55s, $p<0.001$). In the needle control tasks, the RSS performed better than the CLI, with a significantly better precision when controlling the path of the needle during both frontal and sagital stitches. With the target at a 30º angle from the optical plane, frontal stitch, the exit points of stitches with the RSS were 0.8±0.5mm off target, while stitches with CLI were scattered on average 3.0±1.4mm ($p<0.001$). At a 30º angle with sagittal stitches the exit points of RSS was scattered 0.7±0.5mm around the target and those with CLI 4.2±3.4mm ($p<0.001$). Similar results were obtained at a 60º and 90º angle between suturing plane and optical plane.

An intestinal anastomosis, requires precise and regularly distant sutures that permit adequate approximation of the intestinal wall ends. The RSS permits increased precision in stitches regardless of the direction of motion or position of the tissue relative to the plane of the instrument shaft. This is desirable when constructing a duodenojejunal anastomosis.

1.5 Study aim and objectives

Our aim is to describe a standard experimental and training model for advanced laparoscopic procedures. We chose to focus on the duodenoenteral anastomosis in the laparoscopic Duodenal Switch. Technical deficiencies in this critical step are responsible for a large percentage of grave complications after this procedure. A training module that teaches a reproducible and safe technique is crucial for the safe adoption of this procedure by surgeons. For that purpose we have set ourselves the following primary objectives.

1. Describe an appropriate reproducible model with special consideration of tissue preservation of the small bowel for the training of advanced laparoscopic gastrointestinal procedures.
2. Evaluation of the model for future use as a training tool for the Radius Surgical System and for duodenojejunal anastomosis as needed in the Duodenal Switch procedure in bariatric surgery.

The first objective includes the initial face- and content-validation of the model as part of the process. The second objective will give insight into the learning curve of the chosen technique within the whole learning process and is meant to be the foundation of future objective evaluation of the model and learning module.

2 Materials and Methods

2.1 Simulation model design

The first part of the study consisted in finding the best simulation model for the training of a duodenojejunal anastomosis. Based on previous experience on the teaching of laparoscopic procedures of the upper abdomen [91], upper abdominal organ blocks from swine were used. The required organ blocks were obtained regularly from the local slaughterhouse in coordination with the animal owner and slaughterers. The slaughtering process is tightly regulated in the EU, and no additional suffering to animals is caused by the procurement of the organs in this way.

To arrive at an adequate model, a sequence of steps was followed.

- Model preparation:
  - Visits to the slaughterhouse were made in collaboration with the slaughterers to determine the characteristics of the standard block.
  - The block was cleaned and the stomach and duodenum lumen rinsed completely clean and drained. Each block was then packed in a sealed plastic bag and frozen to -14 to -20ºC. It was kept frozen until used.
  - The block was taken out and thawed inside its packing on warm water for 2-4 hours. It was then fixed inside the Tuebingen trainer and modified according to previously agreed specifications constituting thus a version of the model.
- Model evaluation:
  - Each model version was evaluated for tissue quality (looks, consistency), and overall content (necessary/unnecessary parts, quality and limits of dissection done at the slaughterhouse) by at least two surgeons. Modifications on the organ block contents or the process method were suggested and carried out to create a new model version.

- If the previous evaluation was satisfactory, the surgeons then concentrated on the surgical-anatomical qualities (visual and spatial relations between the organs under direct and endoscopic view, and under manipulation with laparoscopic instruments). Modifications to the model layout in the trainer and to the block organs were suggested and the next version of the model was made under the agreed specifications.

A total of 7 general and laparoscopic surgeons of varying experience did direct evaluations of the progressively more accurate versions of model. The feedback of each surgeon was noted and considered for the next model version design. We did not consider a preset number of iterations for this process; instead the process was done until the model was considered the best possible without excessive and unpractical modifications to the organ block.

Figure 9 describes the general process used to arrive at an adequate model for further experimental work.

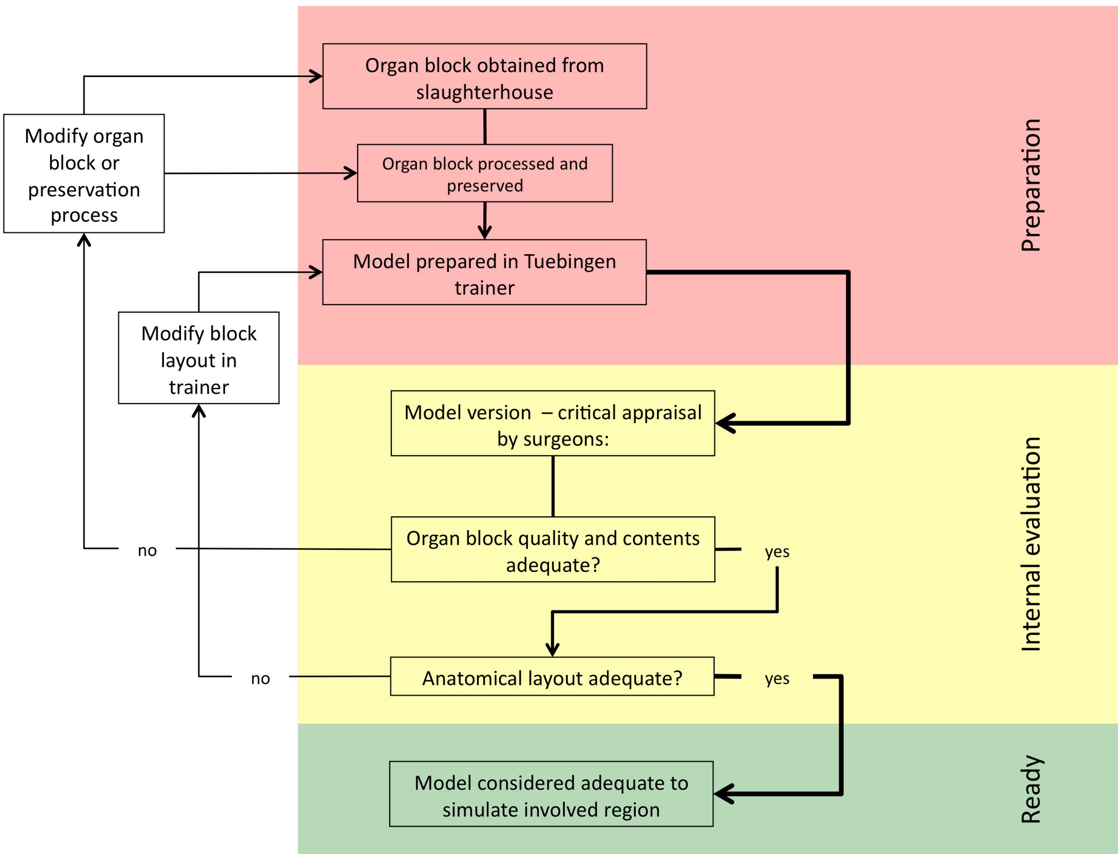

Figure 9 Description of model development process.

2.2 Preservation technique of small bowel

2.2.1 Preservation of realistic look and feel

Porcine small bowel sections were obtained at the local slaughterhouse and processed within thirty minutes after animal sacrifice. Sections of ca 1m were rinsed clean inside and out with normal saline solution and transported to our lab for further processing.

The candidate Glycerol (85% in water)/Ethanol (100%) solutions were prepared beforehand. Solution A: 30% Glycerol/70% Ethanol; Solution B: 50% Glycerol/50% Ethanol; Solution C: 70% Glycerol/30% Ethanol; Solution D: 80% Glycerol/20% Ethanol.

Sections of 15cm were cut and immersed in each of the candidate solutions for a total of 1, 2, 6, 12 or 24 hours. After the assigned time, they were each individually packed and frozen at -20ºC for one week awaiting further evaluation.

After one week, all small bowel sections were thawed at room temperature and rehydrated in normal saline for one hour. They were then photographed and evaluated by three surgeons who classified them independently as “acceptable” or “non-acceptable” regarding realistic look and feel.

Only “acceptable” treatment solutions/times were further used to prepare small bowel for mechanical testing.

2.2.2 Preservation of biomechanical properties

The following groups were tested for tear strength and leak pressure after a through-and-through stitch in the antimesenteric border of the bowel:

- Small bowel sections treated with solution C and solution D for 1, 2 and 6 hours (C1, C2, C6, D1, D2, D6),
- Small bowel sections rinsed intraluminally with 4% formaldehyde for 1, 2 or 6 hours before immersion in solution C or D for 1, 2 or 6 hours (F1C1, F1C2, F1C6, F2C1, F2C2, F2C6, and so forth).

- Fresh small bowel sections from jejunum and ileum, rinsed with normal saline and tested fresh, within two hours after animal sacrifice were used as positive controls.
- Small bowel sections, rinsed with saline but otherwise untreated were frozen-thawed (as usual practice would dictate) and used as negative controls.

2.2.2.1 Tear strength

Fresh small bowel sections and thawed and rehydrated sections of treated small bowel were sectioned transversely with a scalpel and a single stitch of monocryl® 2-0, round needle [Ethicon] was made at 5mm from the edge; the thread was pulled while attached to a digital gauge (maximum strength measured in Newtons). Stitches were made alternatively at the mesenteric border, antimesenteric border and halfway between, with used intestine being sectioned to have a clean edge each time. A total of twenty stitches per specimen were tested.

2.2.2.2 Leak pressure after through-and-through stitch

Fresh small bowel sections and thawed and rehydrated sections of treated small bowel were prepared for leak pressure testing. One end was occluded with a clamp and the other was connected to a digital barometer (maximum intraluminal pressure measured in mbar). A single stitch with monocryl® 2-0, round needle, was made near the mesenteric border at middle length of the section, pulling the thread completely out. Sections were then submerged in water and insuflated with room air. A total of five specimens of each group were tested. Each air leak test was video recorded and the exact pressure inside the system in mbar at the moment of the first air bubble was recovered by reviewing the video frame-by-frame. Figure 11 depicts a similar setting used later in the study for anastomotic leak testing.

2.3 Technique standardization

Once the experimental and training model was described (see above), work concentrated in standardizing the anastomosis technique with the use of the

Radius Surgical System (RSS). A single layer running sutured anastomosis was considered as the ideal technique to do with the RSS. The choice of technique is supported by extensive research on the matter (See above section for background). Nevertheless, several technical issues needed to be addressed and decided upon before formal evaluation of the ultimate technique began. These issues were as follows:

- Optimal trocar placement for the optic, the RSS (left and right hand instruments) and assisting instruments
- Optimal position of the surgeon and assistant
- Description of the tasks done by the assistant
- Stepwise description of the optimal anastomotic technique
    - Site of initial stitch/knots
    - Number of sutures and knot placements

For this purpose, a single surgeon (Subject A) with previous training in endoscopic surgery and the use of the RSS did several short series of experiments. Each series was preceded by a discussion on the technique proposal and followed by a new discussion on the problems and advantages encountered during the series. A test procedure was done together with a second surgeon (Subject B) with vast experience in endoscopic surgery. This process was repeated until satisfactory solutions were found for each of the issues previously mentioned (Figure 10). A total of five different technique proposals were sequentially tested and analyzed.

It is important to emphasize that although the procedure time and anastomosis quality was recorded in this part of the study, no objective evaluation was made. Finishing the procedure was not considered essential at this step. The subjective evaluations of the surgeons were more important for the actual development of a standard technique.

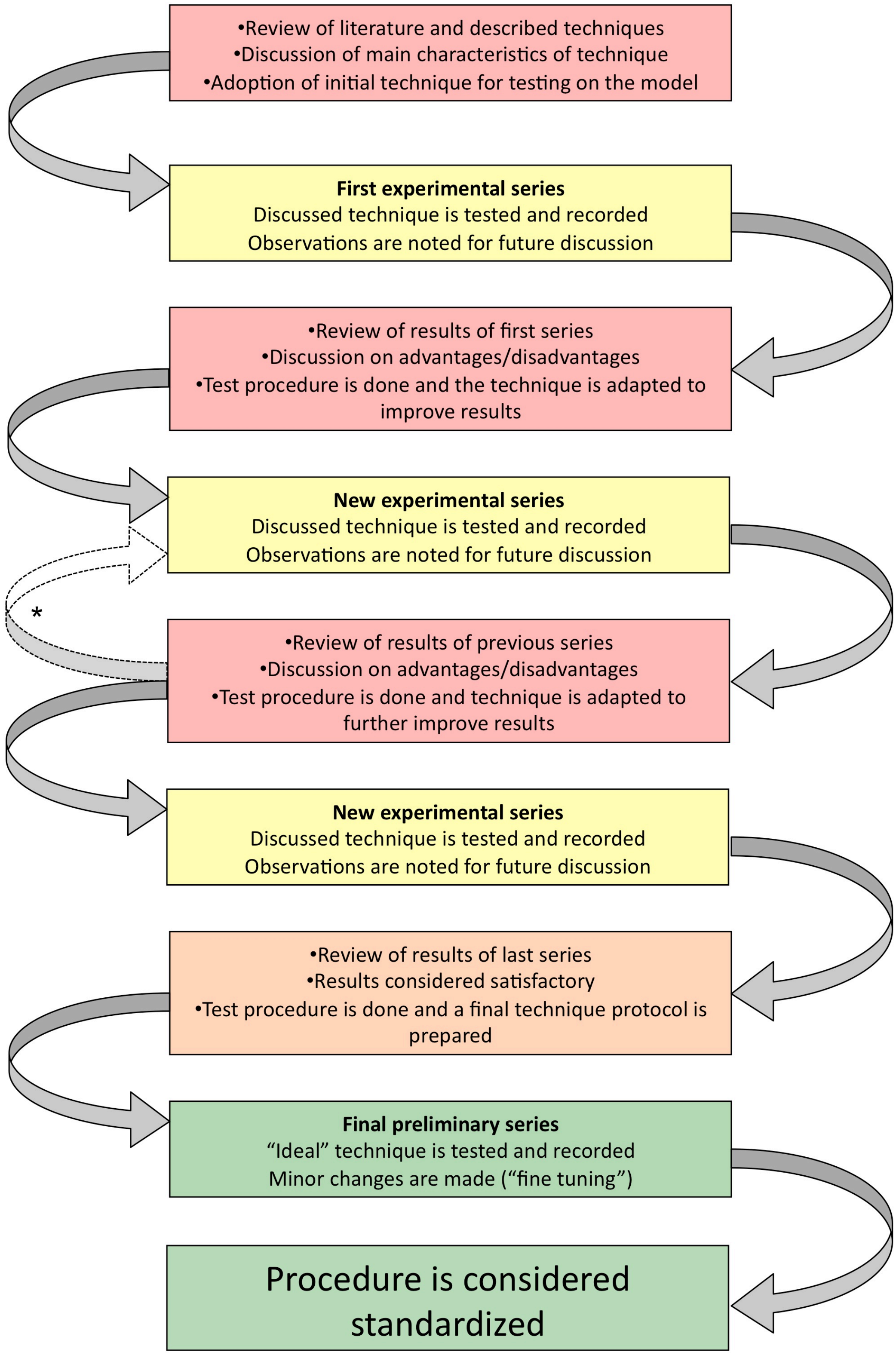

Figure 10 Depiction of the process used to standardize a surgical technique using our model. *= cycle is repeated as needed

Each procedure was recorded on videotape and reviewed to retrieve the total procedure time of the finished anastomoses. A critical appraisal was done after each two or three procedures and required modifications to the technique were made accordingly. The final technique was jointly determined and used for a prospective trial to objectively evaluate the technique.

2.3.1 Surgical instruments and equipment

Both for the standardization process and subsequent experimental trial, the following equipment was used.

- Tuebingen trainer with neoprene cover
- Trocars
  - 12mm reusable trocars (Richard Wolf GmbH) for the RSS
  - 5mm reusable flexible trocar (Richard Wolf GmbH) for assisting instrument
  - Endofreeze ™ (Aesculap GmbH) with sphere trocar as optical port
- Surgical instruments
  - RSS
    - Self-aligning needle holder tip on the right hand instrument
    - Tissue grasper tip on the left hand instrument
  - Maryland type grasper or
  - Golden tip suture assisting grasper (Richard Wolf GmbH)
- Optical system
  - 10mm 25º rigid endoscope (Olympus)
  - 3-chip camera (Lemke)
  - Cold light source (Richard Wolf GmbH)
  - Two HD monitors with adjustable position
- Video recording system
  - Mini DV recorder (PAL)

2.4 Technique evaluation

After agreement on a standard technique, an experimental trial was initiated to further evaluate the learning process and to objectively analyze the anastomosis technique with the RSS.

Three surgeons participated in the study. Subject A had participated in the first part of the study and had earlier experience with the RSS and laparoscopic suturing. Subject B had also participated in the first part of the study as described. Subject C entered the study at this point and had only basic training on the use of the RSS and basic training on laparoscopic suturing.

Subject A did 20 experiments with the standard technique with the purpose of defining the learning curve. Subjects B and C did 10 experiments each in order to analyze with more detail the initial part of the learning process of the technique with the RSS.

The data from all the procedures was analyzed.

2.4.1 Experimental setup

All subsequent experiments where done using the previously defined experimental and training model (see results section). A swine upper abdominal organ block was set inside the Tuebingen Trainer simulating human anatomy up to the angle of Treitz. A 30cm to 50cm long segment of specially treated small bowel was set inside the trainer as well.

Video recordings were made of each experiment from the moment of instrument introduction until the anastomosis was finished.

Each procedure consisted in dissection of the first portion of duodenum, transection of duodenum and the end-to-end anastomosis of duodenum to jejunum. The anastomosis was done as described in the results section of this work. Using three 2-0 reabsorbable monifylament suture (Monocryl®) a one layer continuous sutured anastomosis with three anchoring points and invaginating stitches was made.

For each procedure and its subsequent video recording review, a data collection sheet was used.

2.4.1.1 Time variables and error analysis

Time to complete an anastomosis (from the introduction of the suture in the trainer until the cutting of the last knot thread) was the main outcome variable. Video recordings were reviewed to retrieve the total time and to determine the time needed for the task of stitching and for the task of knot tying separately. For documentation purposes only, the time needed for dissection was also noted.

The total number of stitches and the total number of knots of each anastomosis were annotated.

Performance was further analyzed by counting common mistakes during suturing tasks. These have been previously described and used for evaluation of laparoscopic suturing techniques [87]. The following errors were annotated from reviewing the video recordings of each procedure:

- Needle or thread drops – complete loss of control on the needle or the thread with both left and right instruments.
- Failed tissue-grasping motion – a completed tissue grasping motion with either instrument that fails to actually grasp tissue.
- Failed needle/suture-grasping motion – a completed needle- or suture-grasping motion that fails to actually grasp either.
- Failed stitching motion – a stitching motion (rotation of the instrument head holding the needle), that fails to put the needle through tissue or that does so insufficiently, so that the needle is taken out and the whole process reinitiated. Any initial stitch (without an anchoring point) after which the thread is inadvertently pulled completely through the tissue and therefore must therefore be redone.
- Failed knotting motion – any failed looping motion during the knotting task; any loss of previously formed loops that causes repetition of the task; any failure to “pull-through” the knot that requires repetition of the task.
- Failed needle/suture grasping motion during knotting task – a completed needle- or suture-grasping motion that fails to actually grasp either during a knotting task.

2.4.1.2 Anastomosis quality and acute leak pressure measurement

The outside and inside diameter of the anastomoses was measured in millimetres. Any sites of gross defects were annotated in a diagram on the data-collecting sheet intended for that purpose. These defects were eversion of the mucosa from either end of the anastomosed tissue, and any site with distance of more than 3mm between any two stitches.

Each anastomosis was then carefully handled and prepared for an acute air leak test. The antrum was closed with clamps and transacted proximal to these. The small bowel was divided 10cm distal to the duodenoenteral anastomosis and a cannula was inserted 2cm inside it and secured by tying the bowel around it to achieve an airtight seal. The cannula was then connected to a digital barometer, which gives continuous measurements in mbar. The anastomosis was submerged in water in a tray with a mirror in the bottom that permitted accurate visualization of air bubbles leaking. Each air leak test was video recorded and the exact pressure inside the system in mbar at the moment of the first air bubble was recovered by reviewing the video frame-by-frame. Figure 11 depicts the principles of the acute pressure leak test of an anastomosed specimen.

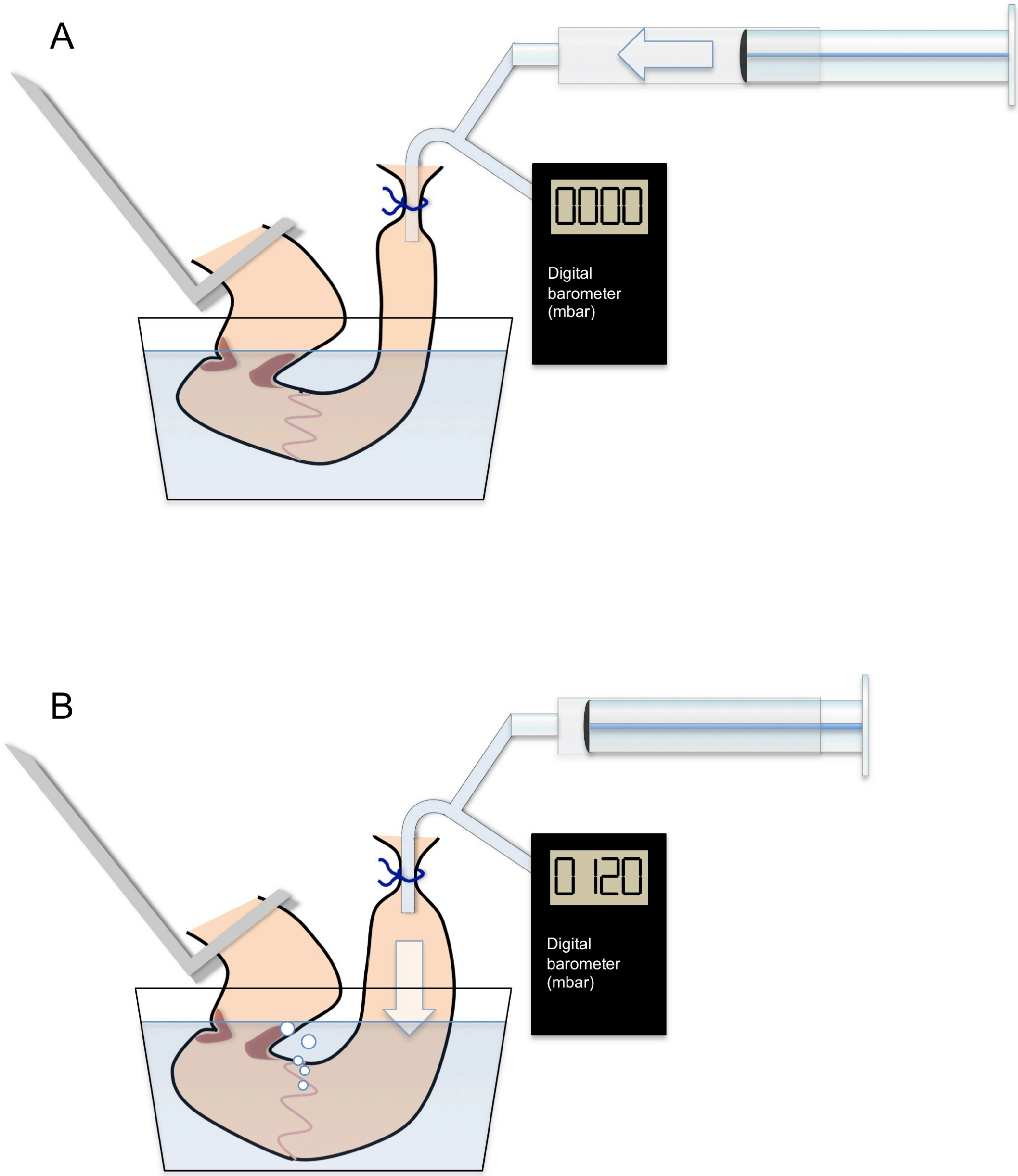

Figure 11 Acute air leak test of the anastomosis. (A) Before insuflation. (B) After insuflation (pressure shown is only for didactic purposes).

A leak pressure above 40mbar (30mmHg, 40 cm$H_2$0) was considered satisfactory, since the maximum recommended pressure for a clinical

transoperative test of a newly made anastomosis is of 25 cmH_2O [35]. The pressure was increased further until a leak occurred to document the mean bursting pressure of the hand-sewn anastomosis with the RSS.
The exact location of leak(s) for each anastomosis was also marked in a diagram. This served to correlate the leak site to the actual moment in the video recording when that portion was being sutured in those cases where the leak pressure was below satisfactory.

2.4.2 Statistical analysis

Descriptive statistics were used to present the results overview. The procedure time of subsequent experiments for subjects A, B and C were plotted to depict the learning curve. The best-fitting trend line was used. ANOVA was used for comparison between groups in the small bowel preserving techniques as well as in the anastomosis learning curve, considering $p<0.05$ as significant. Pearsons correlation coefficient was used to evaluate the relationship between variables and the relevant outcomes of anastomosis pressure and time.

3 Results

3.1 Experimental model development

3.1.1 Organ block procurement and preparation

The optimal organ block obtained in the slaughterhouse should contain the following organs (please note the letter codes, which relate to the figures):

- Oesophagus (E)
- Descending thoracic aorta (TA) and initial portion of abdominal aorta (AA) with celiac plexus (*)
- Diaphragm (D) with intact oesophageal hiatus (H) and complete diaphragmatic pilarsr (DP)
- Liver and gallbladder (L)
- Spleen (S)
- Pancreas head, body and tail (P-h, P-b, P-t)
- Stomach fundus, body, antrum (S –f, S-c, S-a)
- Pylorus (p)
- Duodenum (d)
- Jejunum (around 30cm) (j)
- Greater omentum
- Retroperitoneal fat below the vertebral diaphragmatic insertions.

The block is obtained during the normal slaughtering process. This involves the evisceration of the animal while hanging head down after being sacrificed. The evisceration is done through a midline incision from the pubis to the neck. The rectum is deinserted and the mesenterium is cut close to its insertion. This pulls the abdominal organs out of the cavity exposing the retroperitoneum. The diaphragm is cut close to its insertions on the ribcage and the vertebrae. This in turn permits easy dissection of the posterior mediastinum. The slaughterer then cuts through the upper mediastinum and the neck to free the complete pharynx, including the animals tongue.

A skilled slaughterer does the complete evisceration of a pig in less than one minute. Two points were determined very important to clarify with the slaughterer in order to obtain a block suitable for this model: the initial incision should not be too deep in order not to damage stomach, liver and diaphragm unnecessarily; the diaphragm should be cut at its insertions in the vertebrae to assure that the hiatus and pancreas are intact. The thus obtained block is shown in Figure 12 through Figure 16.

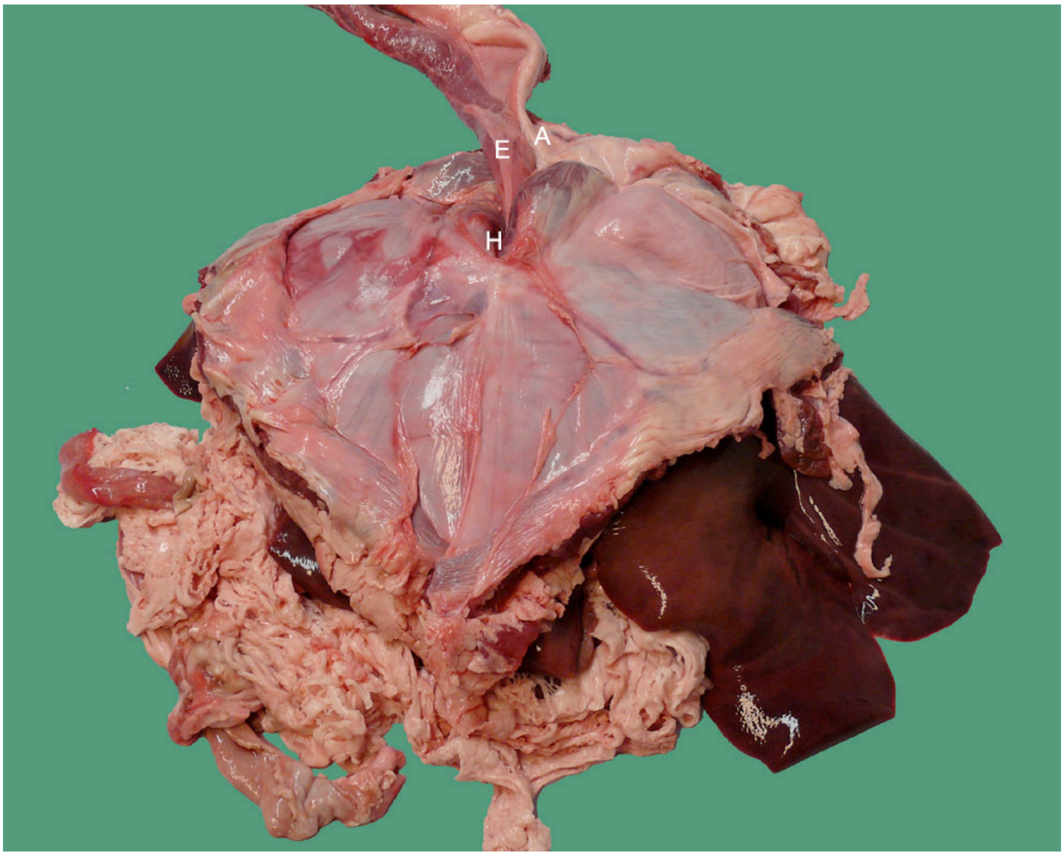

Figure 12 Organ block I. Superior view with the diaphragm covering the abdominal organs. The hiatus (H), oesophagus (E) and aorta (A) are visible.

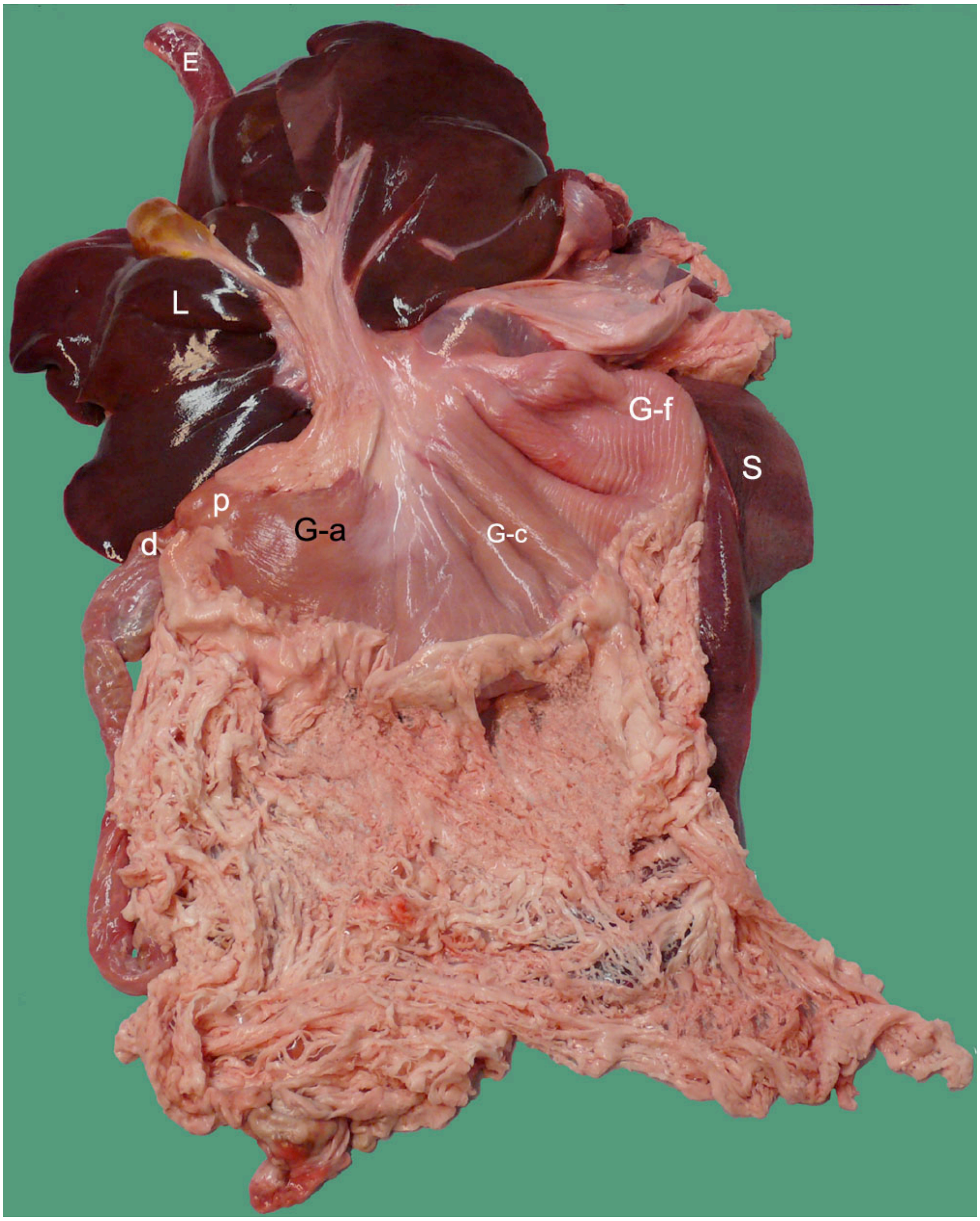

Figure 13 Organ block II. Anterior view of abdominal organs. E-Oesophagus; L-Liver; P-Pylorus; d-duodenum; S-Spleen; G-gastric- a-antrum, c-corpus, f-fundus.

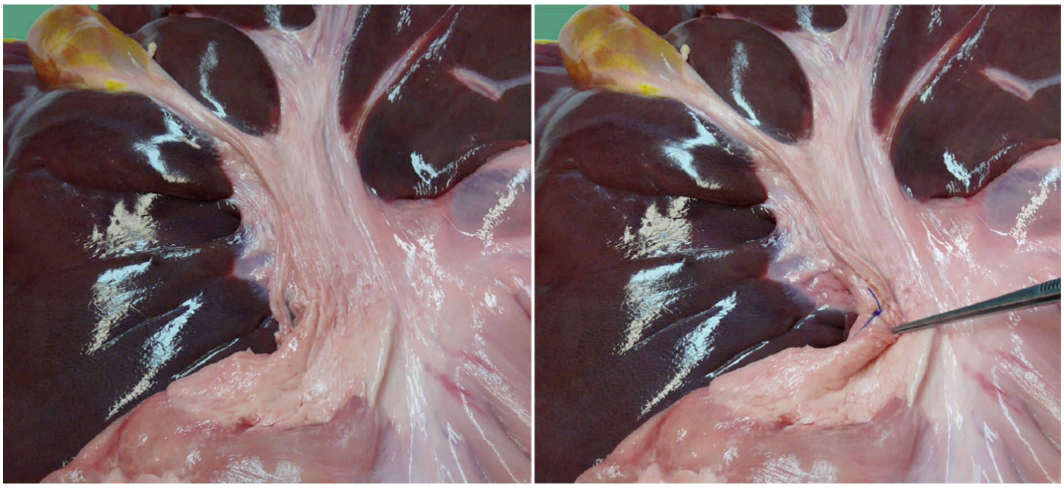

Figure 14 Organ block III. Detail of the hepatic hilium. The common bile duct is tyed closed to prevent emptying of bile into the duodenum.

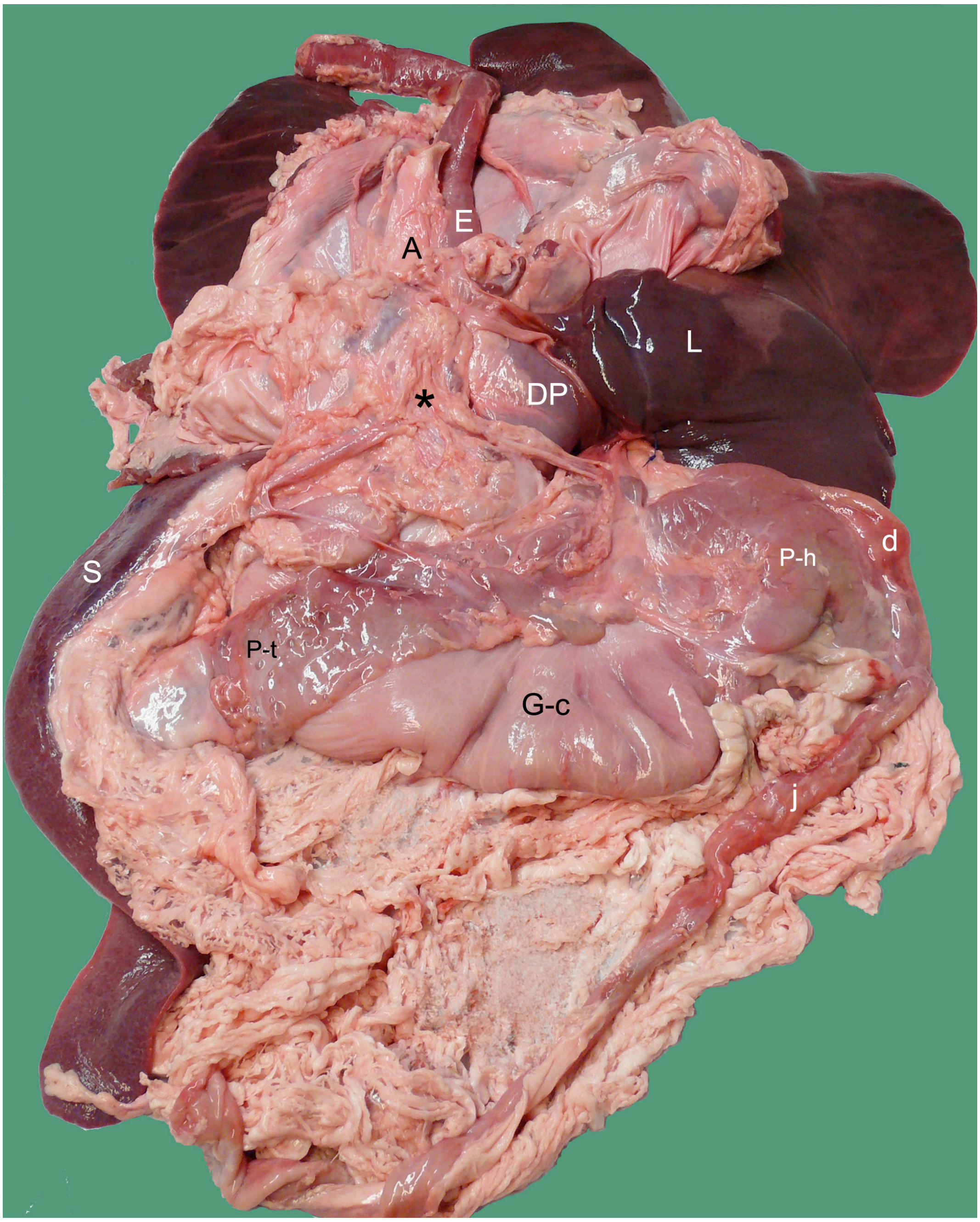

Figure 15 Organ block IV. Posterior view with diaphragm and retroperitoneum displaced to expose the celiac trunk (*) and right diaphragmatic pilar (DP). E-Oesophagus; A-Aorta; L-Liver; S-Spleen; P-Pancreatic- t-tail, h-head; G-Gastric- c-corpus; d-duodenum.

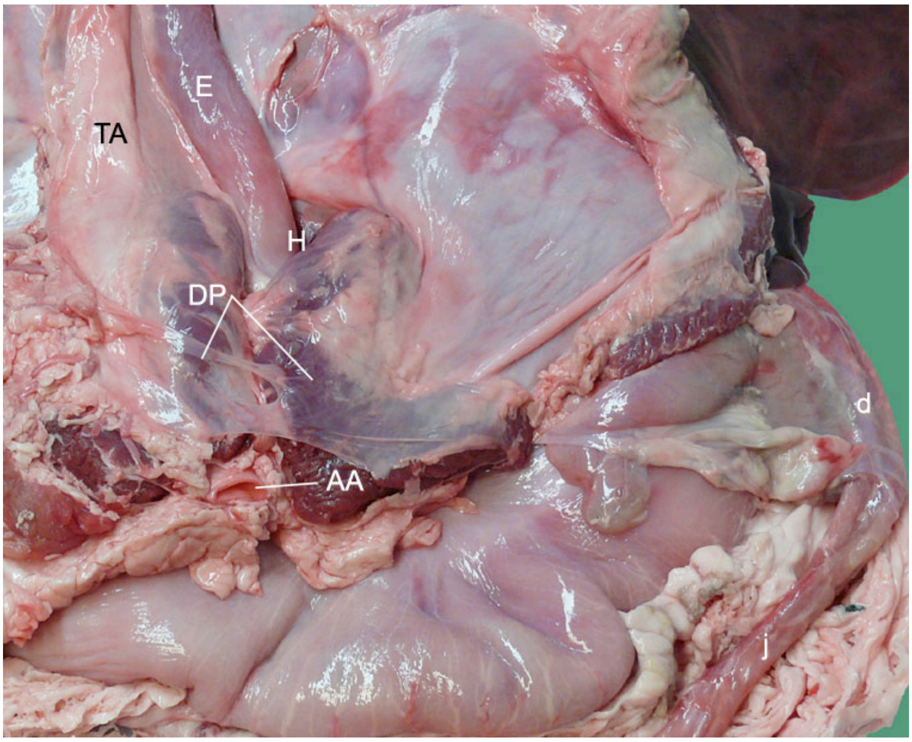

Figure 16 Organ block V. Detail view of posterior aspect with the diaphragm in place. E-Oesophagus; TA-Thoracic aorta; H-Hiatus; DP-Diaphragmatic pillars; AA-Abdominal aorta; d-duodenum.

The described block can be used fresh or packed in a sealed plastic bag and frozen to -14ºC to -20ºC until needed. The thawing process can be done overnight at room temperature or by immersion, in the plastic bag, in warm water for 2-4 hours.

3.1.2 Final model version description

The final and accepted version of the model was the result of seven documented iterations of the process explained in Figure 9. It consists of a swine upper gastrointestinal organ block as described in the preceding section. The method for placing and fixing the block to the Tuebingen Trainer is explained in the following picture sequence.

Figure 17 Close up of the Tuebingen Trainer's upper abdominal cavity. The opening on the midline of the metal mesh and support plate is intended for the thoracic esophagus.

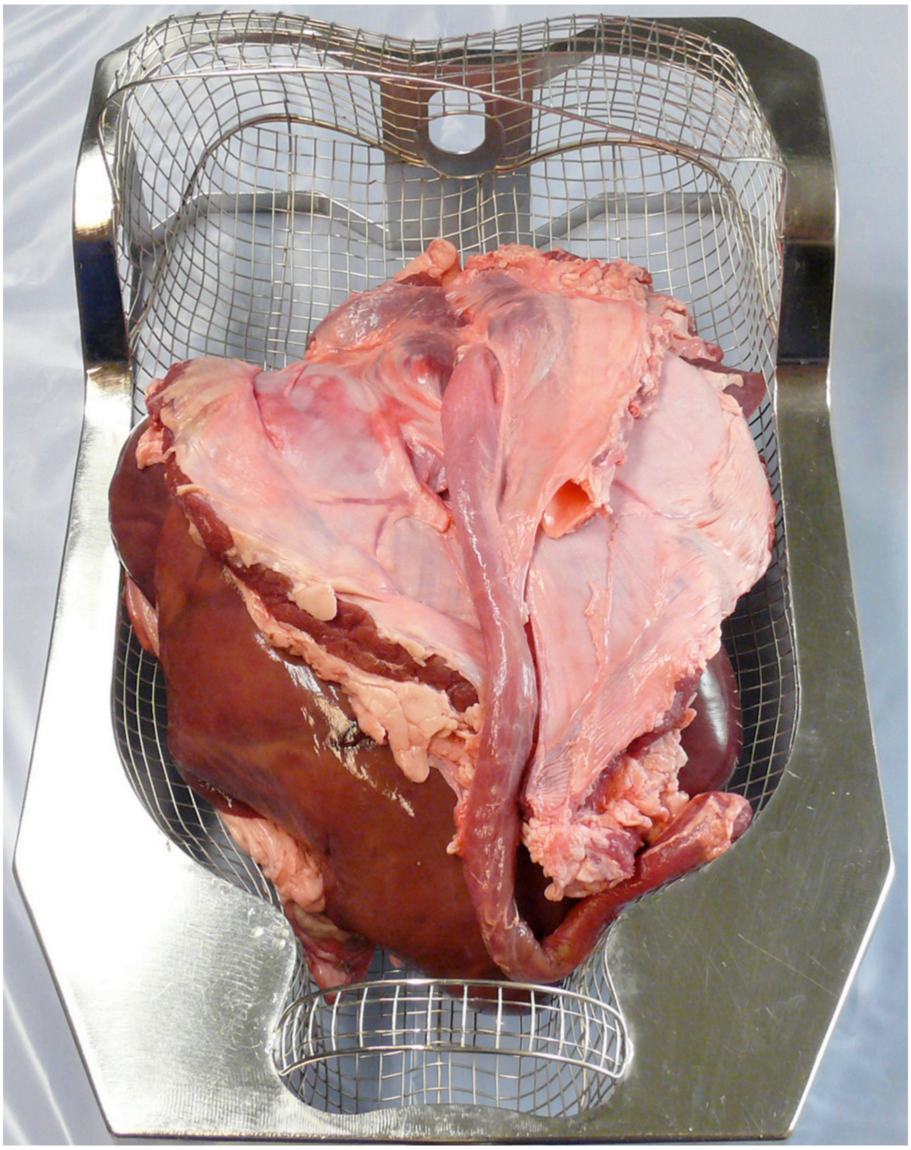

Figure 18 Organ block's initial placement inside the trainer.

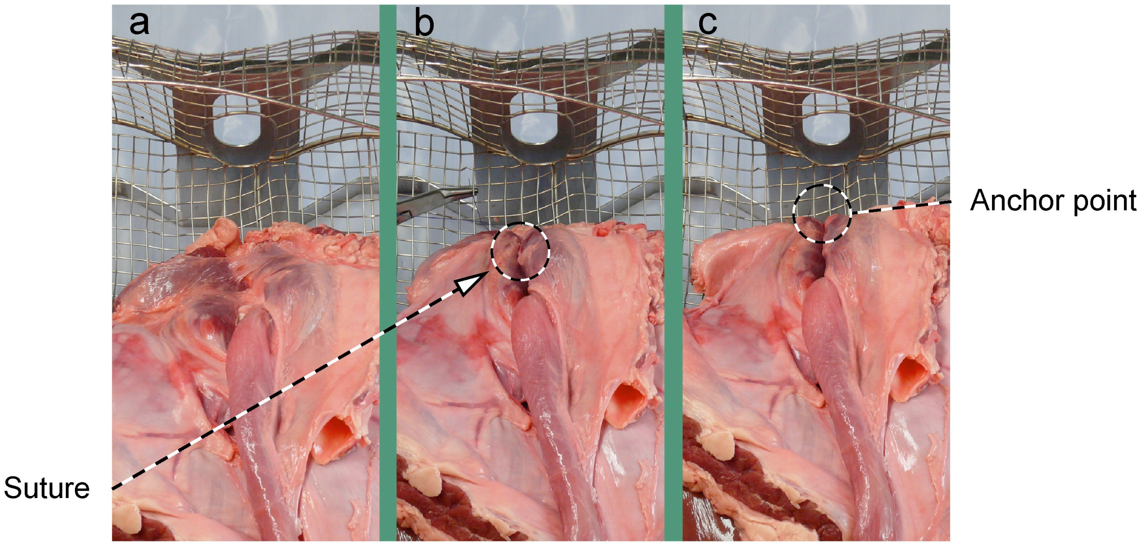

Figure 19 Posterior anchor point is placed, fixing the diaphragmatic pillars with a deep suture (b) to the posterior metal mesh wall (c).

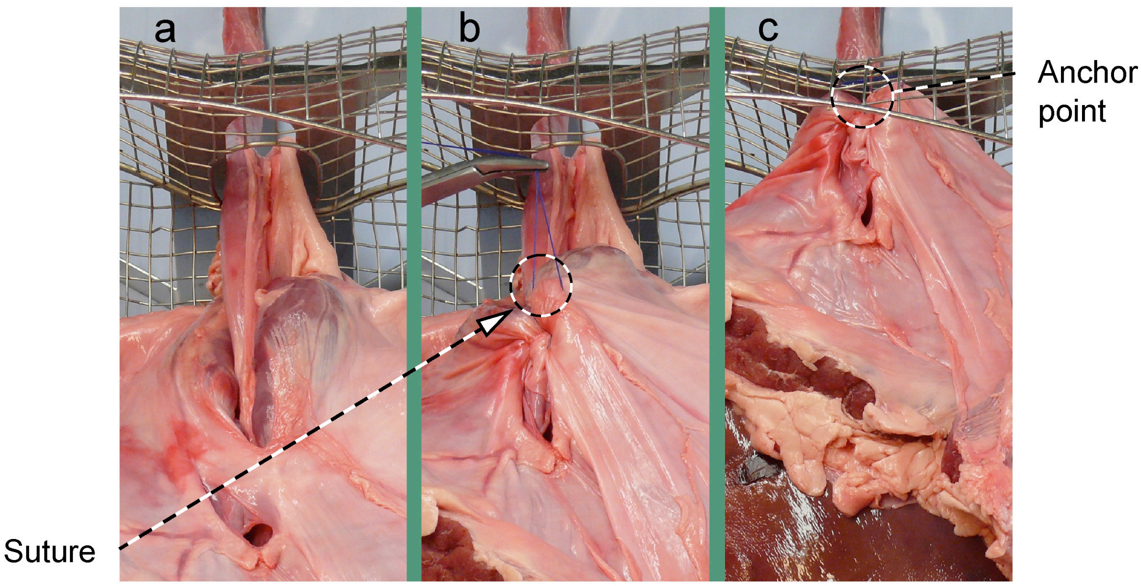

Figure 20 After passing the oesophagus and aorta through the metal openings (a), a suture is placed at the vertix of the diaphragmatic hiatus (b). This is fixed anterior to the exit point of the oesophagus from the trainer (c).

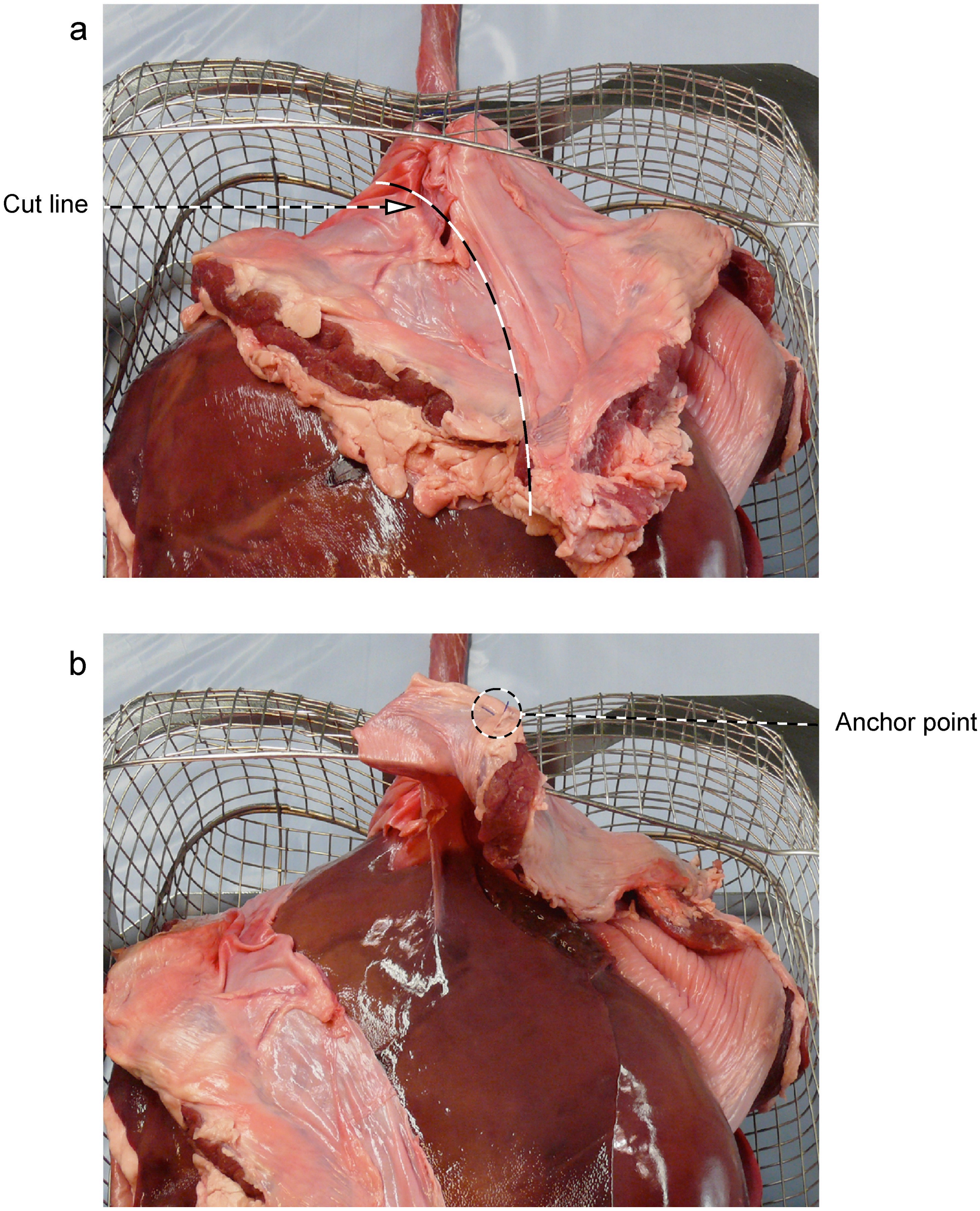

Figure 21 After fixing the hiatus, the diaphragma is divided along the marked cut line (a). The left hemidiaphragma is fixed to the metal border of the simulated rib-cage (b).

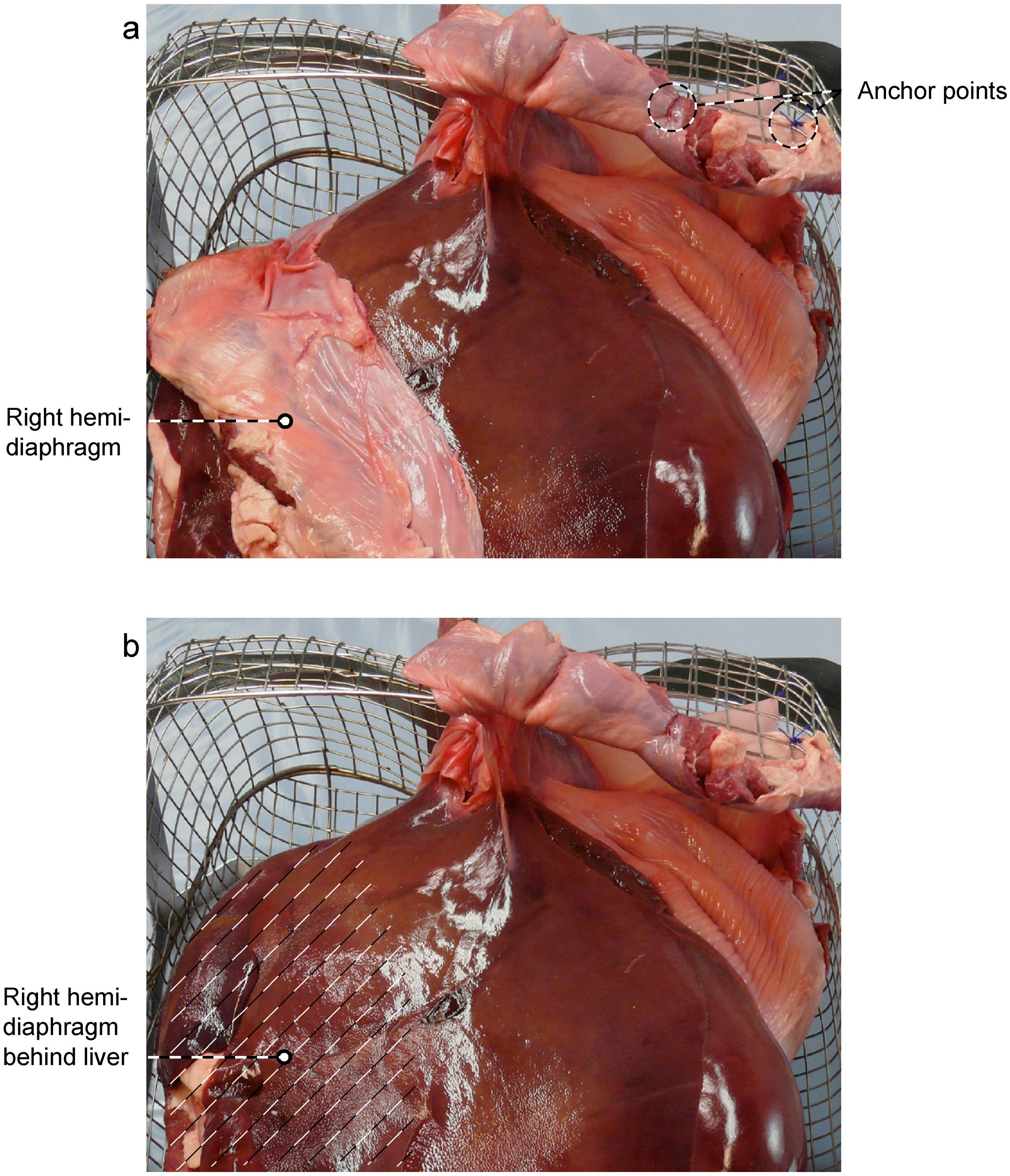

Figure 22 The left hemidiaphragm is further fixed to the rib-cage border (a). The remaining right hemidiaphragm (still joined to the diaphragmatic pilar) is rotated and placed bellow the whole organ block to simulate the posterior abdominal wall (see below).

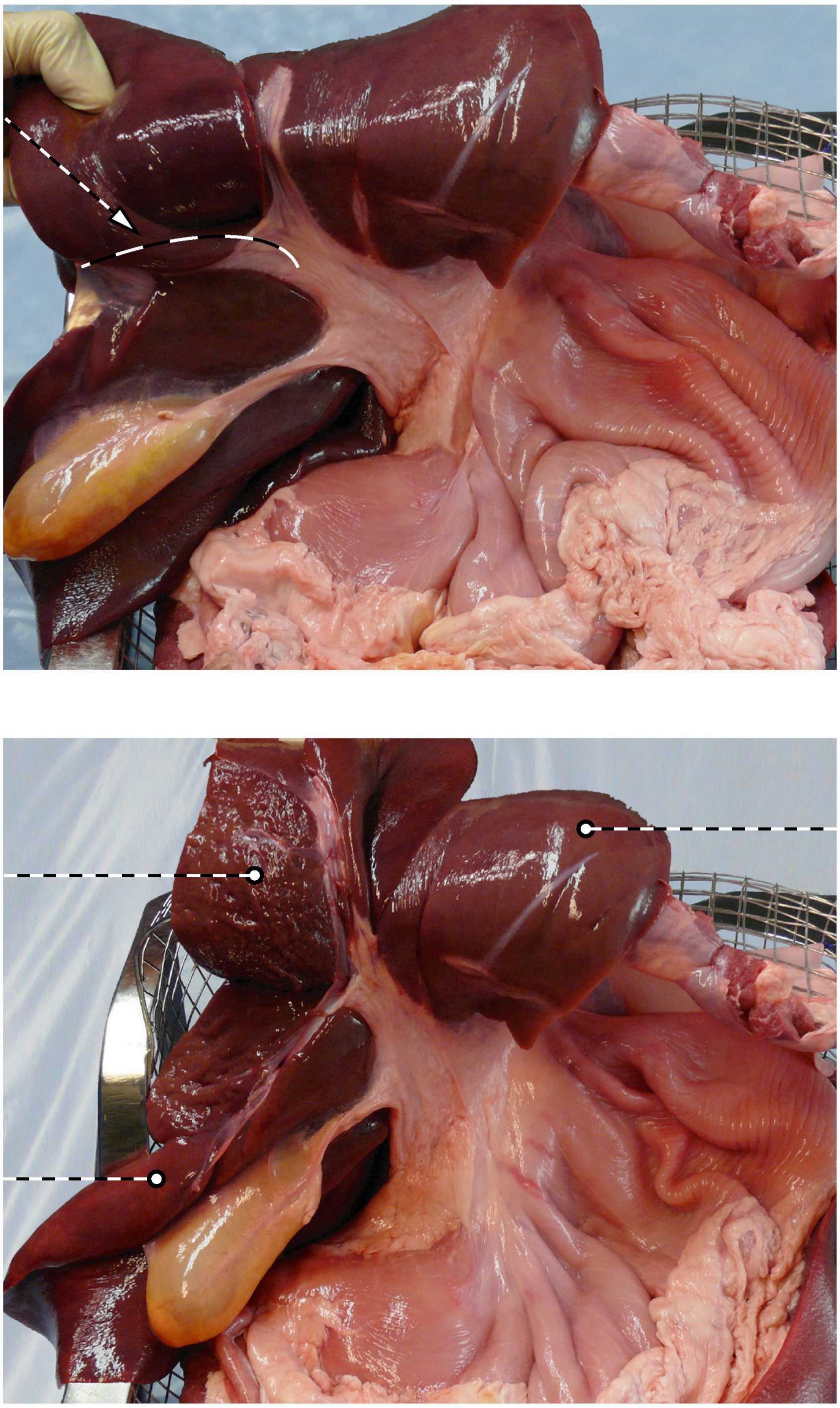

Figure 23 The underside of the swine's liver exposes the gallbladder. An incision should be made at the indicated cut line (a) The resulting right, middle, and left lobes will be further modified (b).

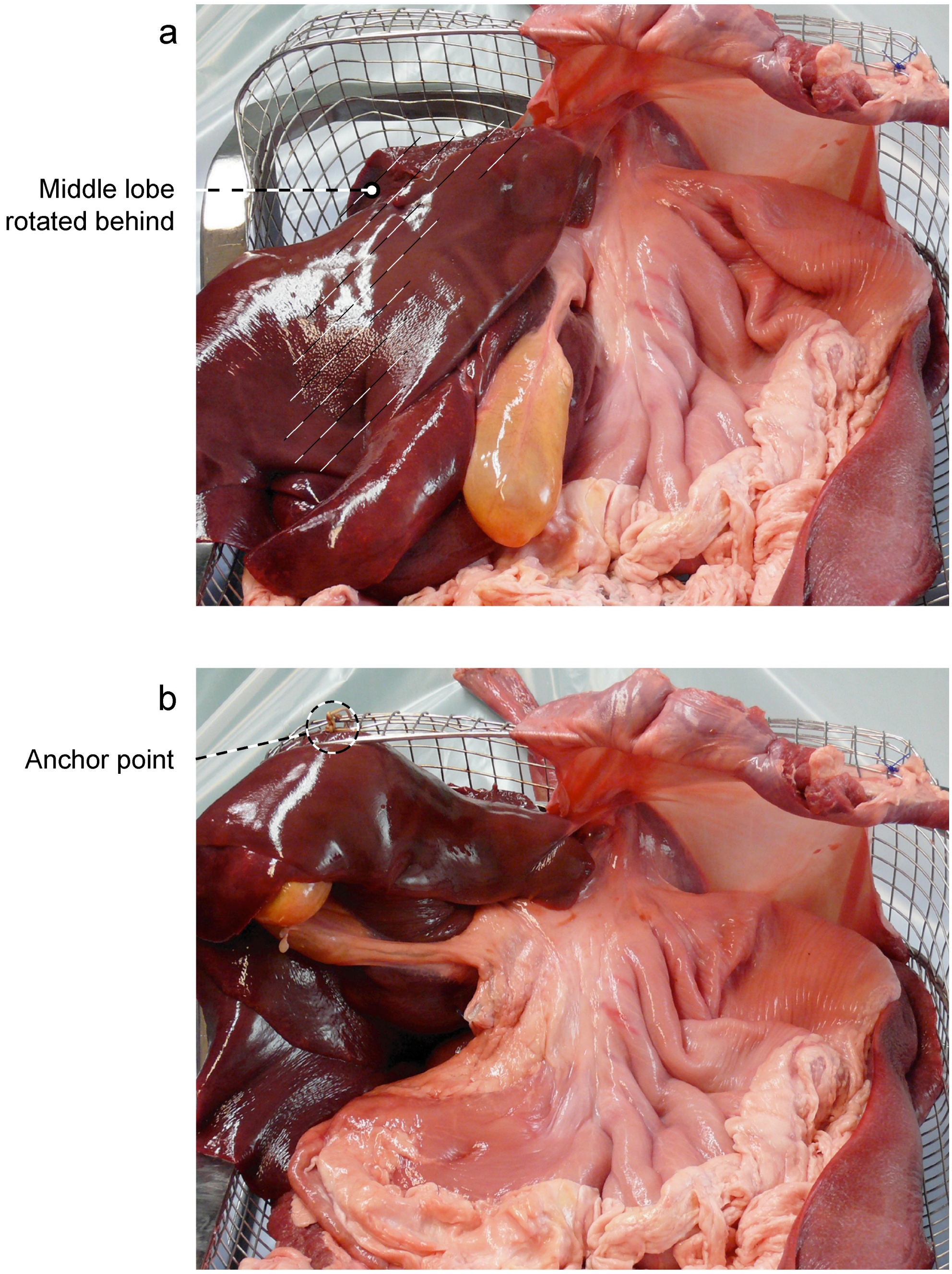

Figure 24 The middle lobe of the liver is rotated behind the right lobe; the left lobe remains on top (a). The left and right lobe with the gallblader is fixed with a thick transficting suture to the indicated anchor point (b).

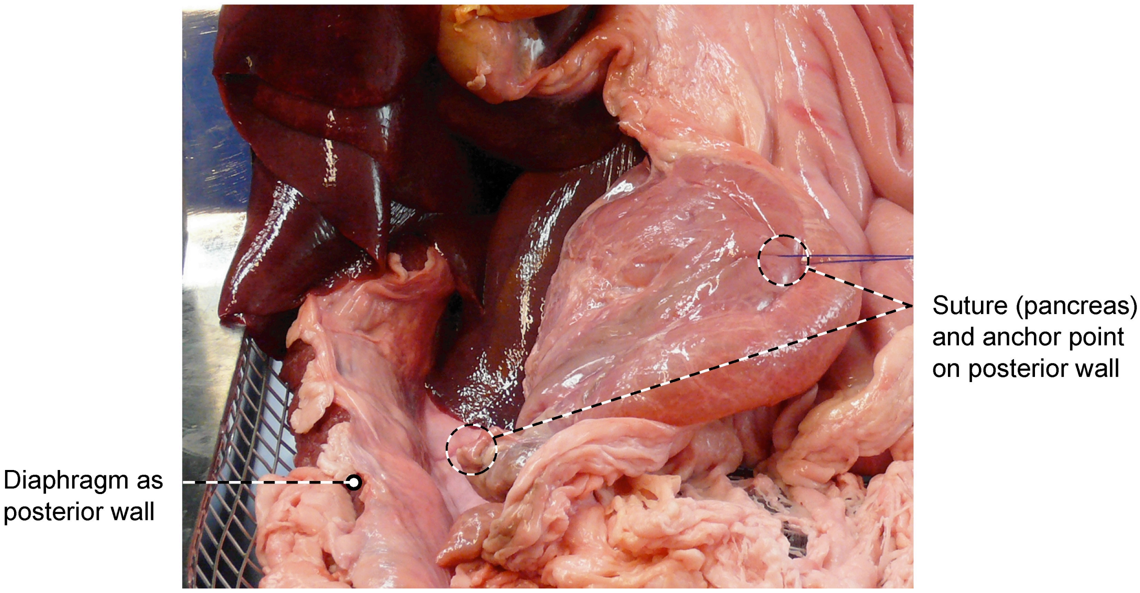

Figure 25 The posterior surface of the pancreatic head is fixed to the posterior wall of the trainer (metal mesh), which is now covered with the right hemidiaphragm serving as the posterior abdominal cavity surface.

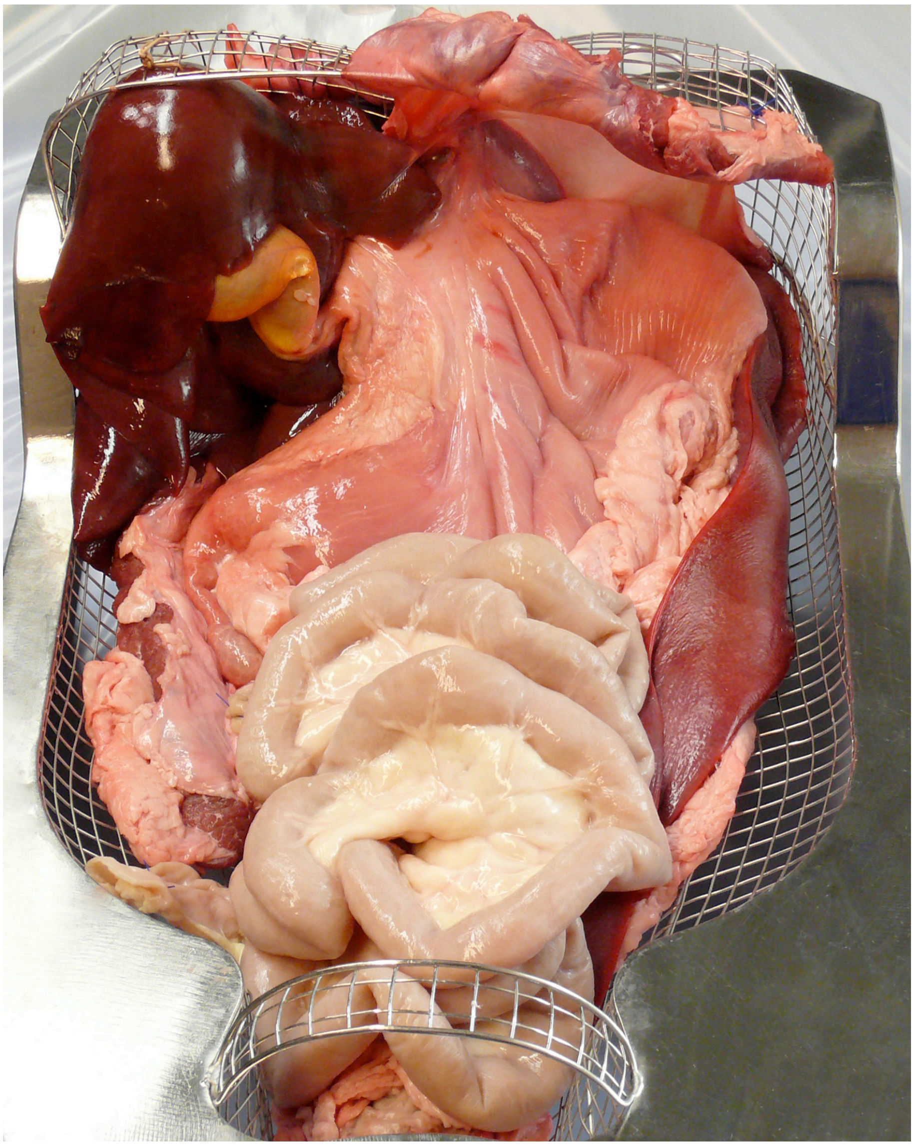

Figure 26 Overview of the finished model. A segment of preserved small bowel of variable length has been also placed.

The placement of the organ block in the Tuebingen trainer following the described steps usually takes a single person 15 to 20 minutes to prepare. This is shorter with assistance.

Six people further evaluated the final version of the model: Two professors of surgery, three laparoscopic surgeons and one non-surgeon with vast experience in laparoscopic surgical training curricula. All considered the model realistic and adequate for the proposed use. This internal face and content validation through consensus was necessary before continuing experimental work using the model.

3.2 Small bowel preservation technique

3.2.1 Preservation of realistic look and feel

The following table depicts the results of the treatment groups evaluated individually by three surgeons. Only bowel prepared with solutions C and D for 1, 2 and 6 hours were considered acceptable for realistic look and feel by at least two surgeons and were further tested for their mechanical properties.

Table 3 Results of evaluation of realistic look and feel of preserved small bowel.

	1h treatment	2h treatment	6h treatment	12h treatment	24h treatment
Solution A	X	X	X	X	X
Solution B	X	X	X	X	X
Solution C	OK	OK	OK	X	X
Solution D	OK	OK	§	X	X

X= non-acceptable; §= graded acceptable by least two surgeons; OK= graded acceptable by all surgeons

Intraluminal treatment with formaldehyde for 1 and 2 hours before treatment with the same solutions did not change the surgeons' evaluation.

3.2.2 Preservation of mechanical properties

3.2.2.1 Tear strength

Fresh jejunum and ileum (positive control group) showed an average tear strength of 4.4085N (SD 0.877) and 4.3495N (SD 0.0.79) respectively. In contrast, untreated small bowel held an average 3.0025N (SD 0.88) before tearing. This difference was significant ($p<0.01$).
The results of tear strength measurement for the most relevant treatment groups are summarized in the following table.

Table 4 Average tear strength for most relevant treatment groups

Group	Average Tear strength in N
C 1	4.983*
C 2	5.419
C 6	3.1895
D 1	4.8545*
D 2	4.6085*
D 6	3.349
F2C1	5.188*
F2C2	4.688*
F2C6	3.897*
F2D1	4.889*
F2D2	4.824*
F2D6	3.973*
ILEON	4.3495
JEJUNUM	4.4085
Untreated	3.0025

* Significantly different (p<0.01) from untreated group; no significance when compared with Ileon or Jejunum group

Almost all treatment groups showed similar tear strength to fresh ileon and jejunum and had significantly higher tear strength than untreated-frozen-thawed small bowel. The groups showing an average tear strength closest to that of fresh bowel were F2C2, F1C2, and D2.

3.2.2.2 Leak pressure

Fresh ileon and jejunum segments had no leak at 300mbar, after which point the measurement was stopped in order to save the system unnecessary strain. Untreated small bowel segments had an average leak pressure of 59.6mbar ($p<0.01$).

The following table summarizes the results for the most relevant treatment groups.

Table 5 Average leak pressure for most relevant treatment groups

Group	Average leak pressure in mbar
C 1	51.4
C 2	34.4
C 6	48.8
D 1	38
D 2	27.8
D 6	22.4
F2C1	68
F2C2	148.2*
F2C6	78.2
F2D1	66.8
F2D2	101.2*
F2D6	67.4
ILEON/JEJUNUM	300*
Untreated	59.6

*Significantly different from untreated group ($p<0.01$)

None of the treatment groups reached as high a leak pressure as fresh small bowel (all had significantly lower leak pressures, $p<0.01$). Only treatment groups F2C2 (average 148.2 mbar) and F2D2 (average 101.2mbar) showed a significantly higher leak pressure when compared with the untreated group ($p<0.01$)

3.2.3 Overall performance

Treatment groups F2C2 and F2D2 showed the highest leak pressure without exceeding that of fresh bowel, performed similarly to fresh bowel on the tear strength test and were considered acceptable for look and feel in preliminary testing. Since F2C2 treatment performed slightly better in the leak test (closest to normal, fresh bowel) and had a lower tear strength than F2D2 (again, closest to normal, fresh bowel), it was chosen as the standard treatment for preservation of small bowel used in all subsequent experiments.

3.3 Duodenojejunal anastomosis technique with the RSS

3.3.1 Development of the standard technique

As described in the Methods section, a formal sequence (explained in Figure 10) was used to arrive at a standard technique for the duodenojejunal anastomosis using the RSS. The actual process is resumed in Figure 27.

Twenty consecutive experiments were done by Subjects A and B, with a critical hands-on evaluation after every group of 3 to 5 procedures. Total procedure time was measured and the resulting anastomoses were inspected for gross defects –eversion of mucosa, loose sutures, and tissue damage. Nevertheless, performance evaluation was not an objective of this study phase. During the critical evaluations, experiments were initiated, interrupted and sometimes continued with modifications of the technique. The completion of an anastomosis was secondary to the discussion-development process in this phase of the study.

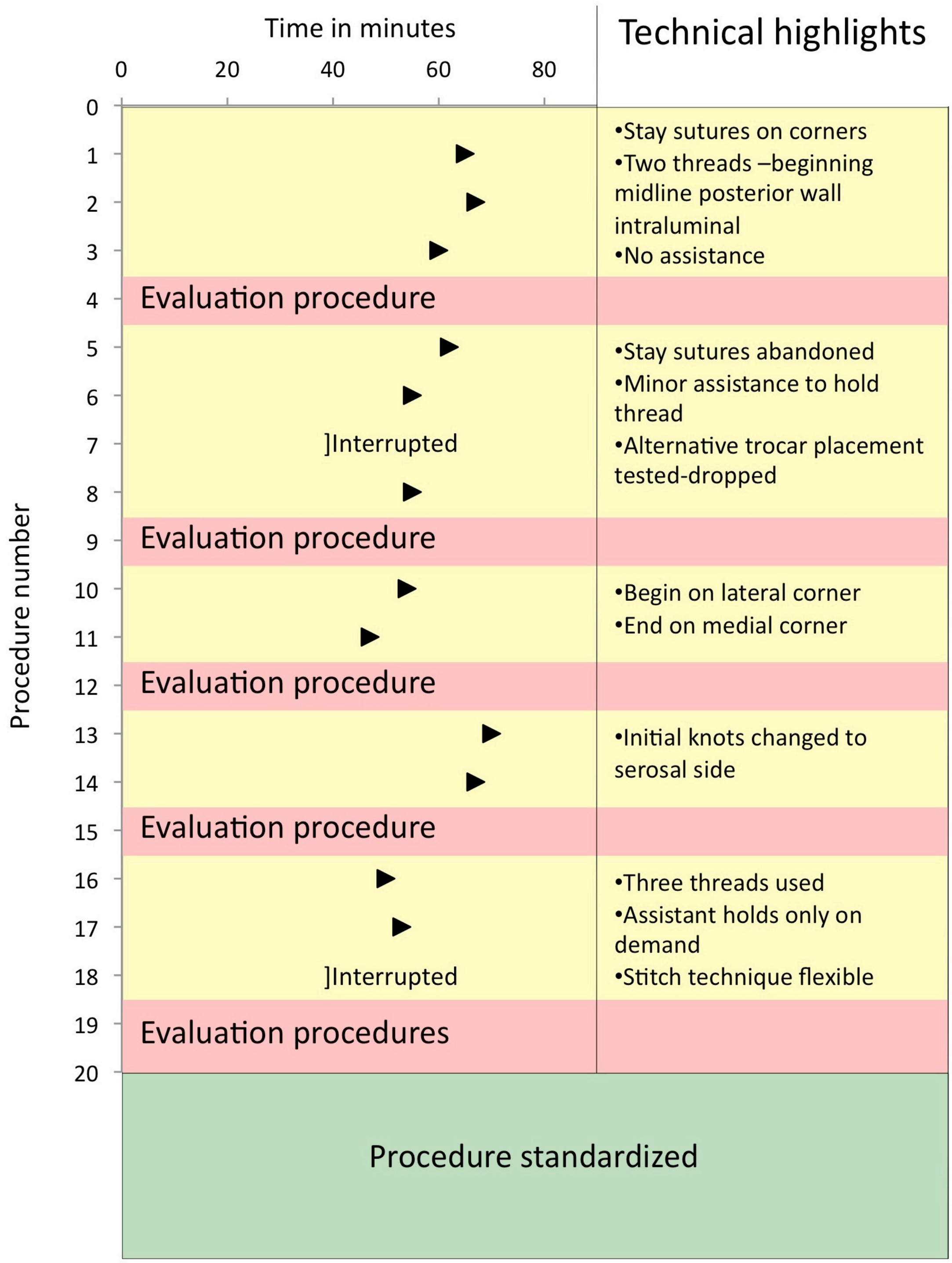

Figure 27 Overview of the procedure standardization phase of the study. The main technical modifications for each group of procedures are displayed on the right column. The triangles represent the time for each procedure when finished. Five distinct technique versions were evaluated (A through E).

The goal was to adopt a technique that permitted precise suturing of the intestinal ends under adequate visualization of the posterior and anterior wall of the bowel. This had to be possible using standard trocar placements and should require as little assistance as possible. As seen on the above figure, five distinct technique versions were tested and evaluated (A through E), progressively incorporating, modifying and eliminating tasks as deemed necessary.

3.3.2 Standard anastomosis technique description

After the development process –described in the previous section-, a standard technique was adopted. The standard technique for anastomosing the duodenum to jejunum with the RSS with the instruments and equipment described in section 2.3.1 is described in the following text and picture sequence.

3.3.2.1 Overview

The anastomosis between the proximal open end of duodenum and an open end of jejunum was done end-to-end using three 2-0 monofilament absorbable sutures (Monocril ®) cut at 20cm length. The technique sequence -knot placement and suture direction- is depicted in the following figure.

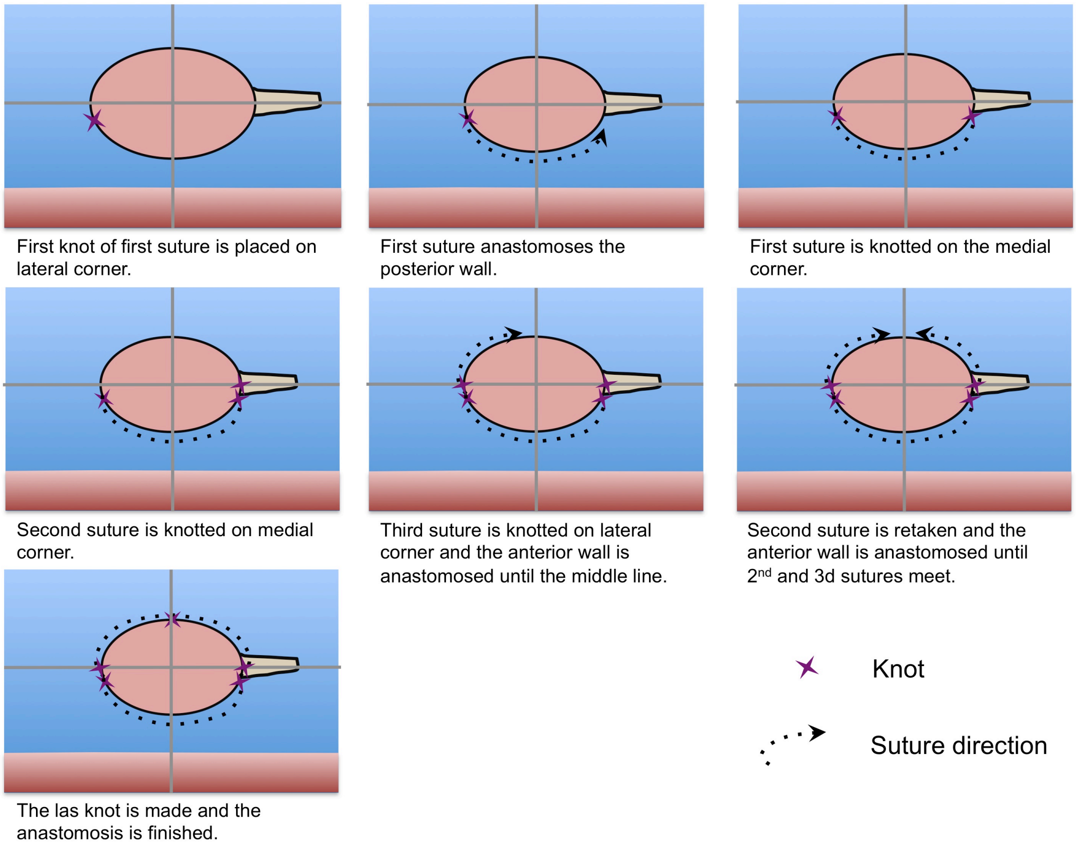

Figure 28 Anastomosis: technique sequence.

In short, the first suture is begun on the lateral corner of the anastomosis, with the knot on the exterior wall. This suture is then continued medially until it reaches the internal edge of the anastomosis. There, a second suture is knotted right after the last stitch of the first suture; the first suture is then knotted to this same knot. The second suture is left in place and a third suture is knotted on the lateral corner; the anterior wall is anastomosed with the second and third sutures meeting on the middle line where they are knotted to finish the anastomosis. The following section describes these steps in detail.

3.3.2.2 General description of the technique

The first stitch is placed in the lateral border of the anastomotic circumference. The bowel (duodenum) is held in place with the left hand instrument while the stitch is taken with the right hand. Precise stitch placement and adequate amount of tissue on each 'bite' is essential. The same principle is applied when placing the stitch on the proximal end of the jejunum, i.e., the tissue is held in place with the left instrument and the right instrument takes the stitch with precision using the rotation of the tip to direct the needle.

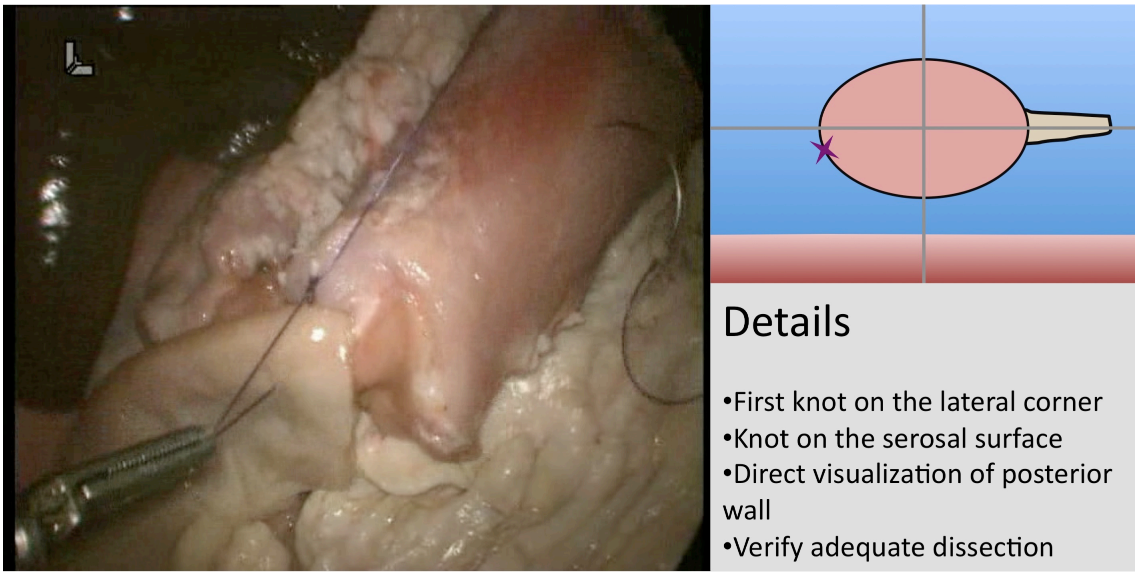

Figure 29 Anastomosis: detail of first stitch in duodenum, taken on the lateral edge of the circumference.

Once the stitch has been placed on the duodenum and jejunum, the first knot is made in a regular fashion. When placed correctly, the serosal surfaces of the anastomotic ends should appose easily as seen on Figure 29.

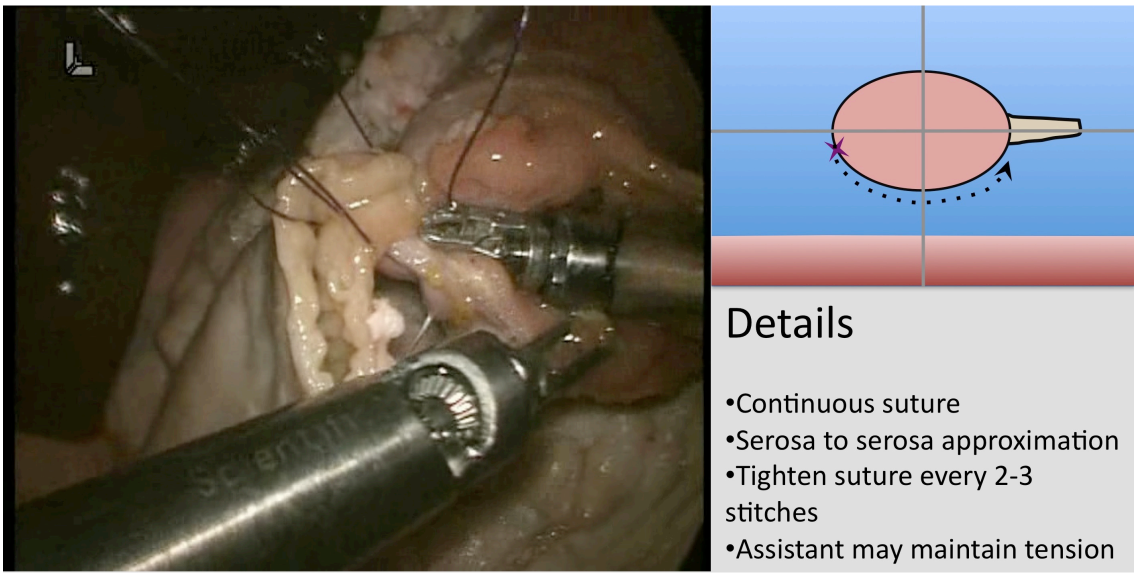

Figure 30 Anastomosis: detail of continuous suture on the posterior wall.

The first stitch after the knot is made out-to-in only on the jejunum, placing the thread in the interior side of the jejunum. This allows the following stitches to invert the bowel ends, joining the serosal surfaces of the posterior bowel walls.

The first inverting stitch on the duodenal wall is taken. For this purpose, the posterior wall of the duodenum should be visualized, to ensure that on each stitch the needle comes at the appropriate distance from the edge on the serosal side. After placing the stitch on the duodenal wall, the thread is pulled through completely and tightened by the surgeon. The assistant holds the thread in place before the surgeon takes the stitch on the jejunal wall. This step is repeated on every other stitch taken on the duodenal side. The stitch on the jejunal side is taken while the assistant (through the thread) and the surgeon's left instrument hold the tissue in place (Figure 30).

After taking the 'bite' on the jejunal side, the surgeon immediately takes the next stitch on the duodenal side. This coordinated sequence is continued until the medial corner of the anastomosis is reached (Figure 31). Once the medial corner of the anastomosis is reached, the direction of the stitches is changed in order to keep the bowel edges inverted (Connel-Mayo stitch) while allowing a more comfortable instrument position. With this last stitches using the first suture, the medial corner is inverted properly.

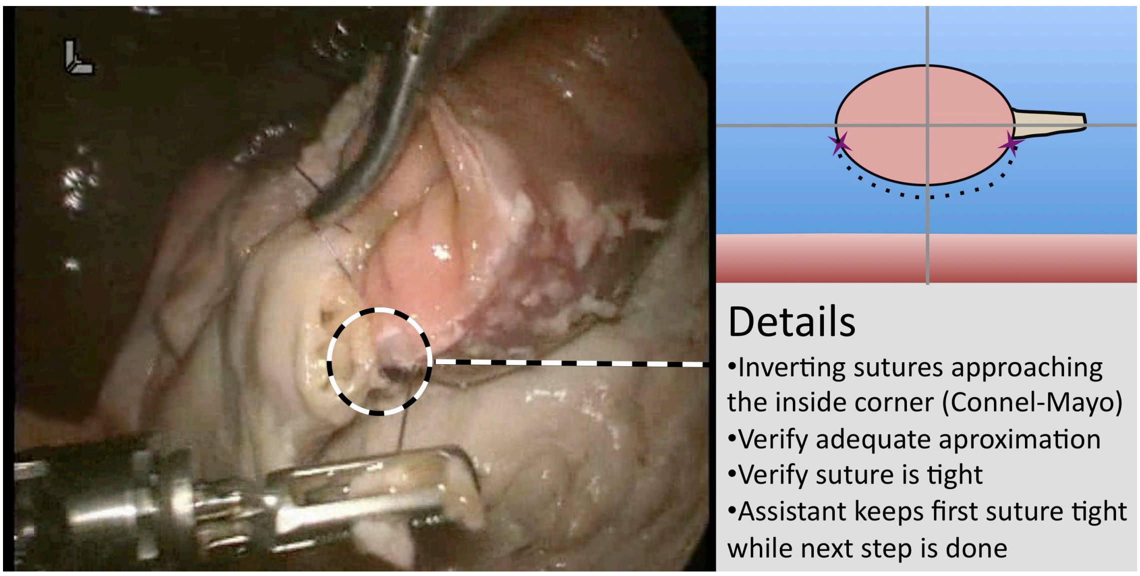

Figure 31 Anastomosis: detail of inverting sutures on the medial edge of the bowel, where the suture is kept tight until it is knotted in the next step.

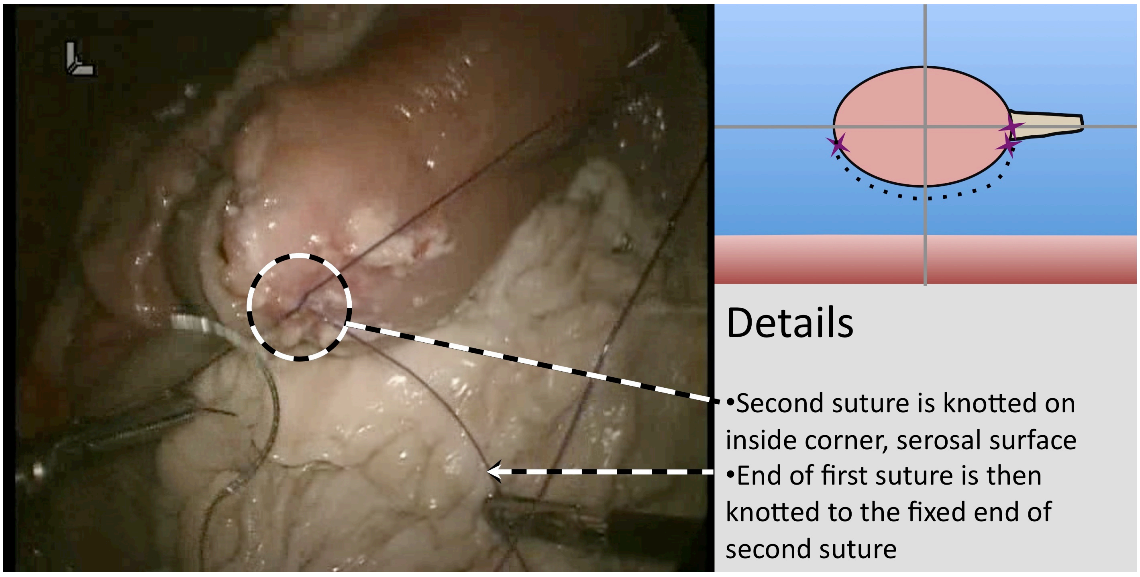

Figure 32 Anastomosis: A second suture is placed in the medial corner and the end of the first suture is knotted to it. This second suture is kept aside for later closing of the anterior wall.

Once the serosal surfaces are correctly apposed, the assistant keeps the first suture tight. The surgeon places the first stitch of the second suture immediately adjacent to the last stitch of previous thread. The second suture is knotted in a regular fashion. The first suture is anchored to the knot of the second suture, finishing the anastomosis of the posterior wall. The second suture remains in place, ready for later use in the anastomosis of the anterior wall (Figure 32).

A third suture is placed beginning at the lateral corner again. The same principles of traction and countertraction are applied by the surgeon in order to take precise ‘bites’ of tissure. The anterior wall stitches are also made to invert the bowel edges. The anterior wall is anastomosed with a simple running suture, making sure the serosal surfaces are apposed. This can be difficult with simple stitches. When needed, inverting stitches are made (Figure 33).

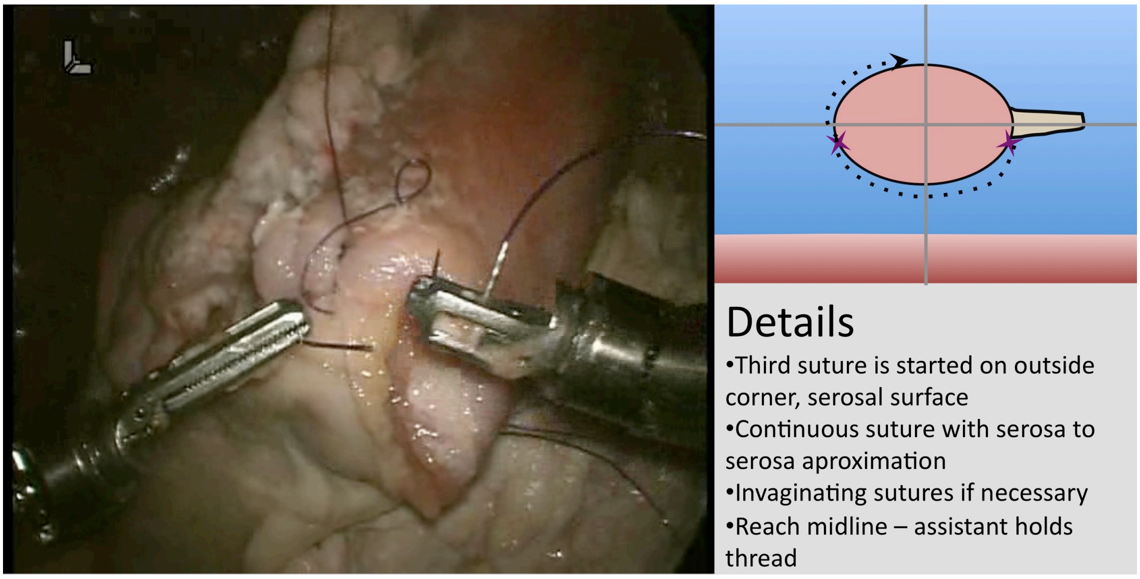

Figure 33 Anastomosis; a third suture is placed on the lateral edge of the anastomosis and a lateral-to-medial running suture on the anterior wall is made up to the midline of the circumference.

The anastomosis is continued with the second suture using a combination of simple and inverting running stitches on the anterior wall. The assistant holds the third suture in place during this last step of the anastomosis (Figure 34).

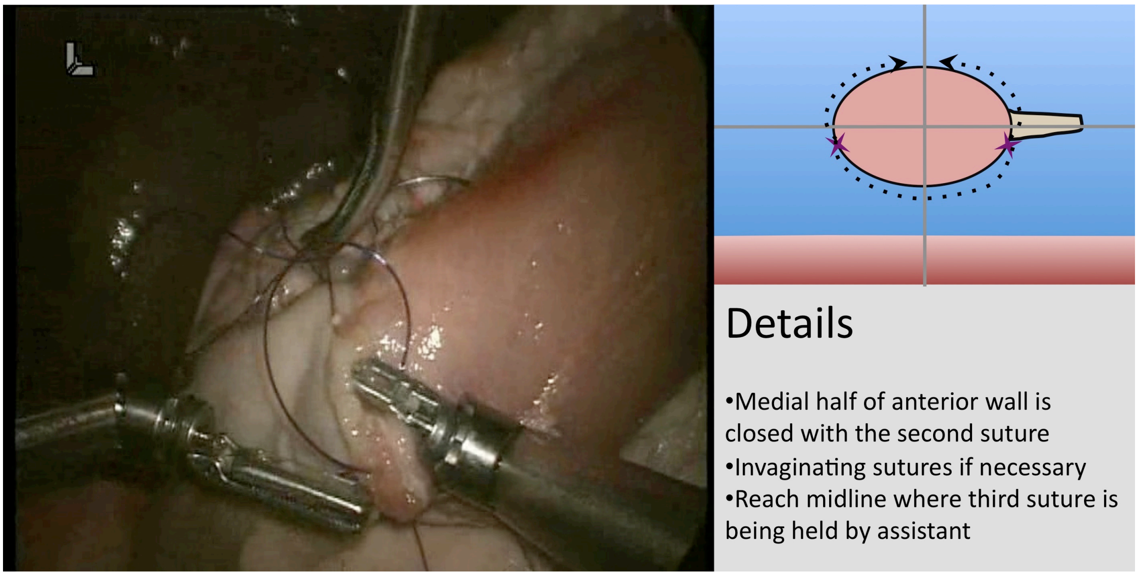

Figure 34 Anastomosis: The second suture, left in place previously, is used to make a running suture of the remaining anterior wall of the anastomosis.

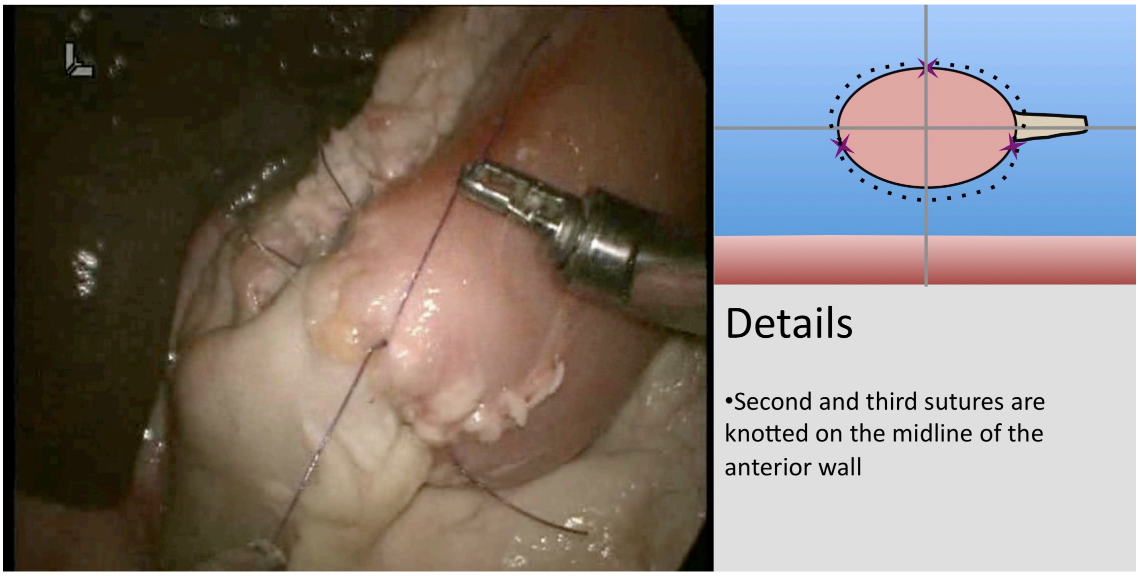

Figure 35 Anastomosis: the second and third sutures are knotted with each other finishing the anastomosis.

Once the midline is reached, the third and second sutures are tied together in a regular fashion, thus finishing the anastomosis.

General aspects to keep in mind during the anastomosis are:

- When the open ends of duodenum and jejunum are approximated no tension should be allowed.
- The use of stay sutures is avoided to allow for the complete range of movements of the RSS to be exploited.
- The stitches should be placed at 3-5mm on the serosal side and at 1-2mm on the mucosal side. This promotes tissue iinvagination.
- When possible, the surgeon should control the tissue indirectly using the suture.
- The surgeon should tighten the sutures regularly.
- The assistant should hold the suture in place, but the surgeon must check correct suture tension when retaking the suture from the assistant.
- Every stitch should be taken in the most comfortable position possible.
- A combination of stitching techniques (simple running, inverting) is permissible, since the goal is to fabricate a safe anastomosis.

- The knot placement and suturing sequence described are the basis of the technique, but adjustments may be necessary from case to case due to anatomical and surgical variations.

A streaming quality video can be seen online: http://mic.uni-tuebingen.de/mic/. All subsequent experiments and evaluations were done with this technique.

3.4 Duodenal Switch technique evaluation

3.4.1 Results overview

Three surgeons participated in the study as described in the methods section 2.4.1. A total of 40 procedures were done following the standardized procedure presented in the previous section. All procedures in this phase of the study were completed. The data from all the procedures was initially analyzed together. The results overview for the main outcomes can be seen on Table 6.

Table 6 Results overview. Anastomosis characteristics.

Variable	Mean	Range
Total time	50.93 minutes	33.25 – 71.35
Knotting task time	12.7 minutes	7.37 – 20.50
Knot time average	2.63 minutes	17.8 – 4.72
Stitching task time	38.20 minutes	23.32 – 55.57
Number of stitches in anastomosis	21.39	16 – 26
Stitch time average	1.81 minutes	0.94 – 2.74
Internal diameter	20.74 mm	18 – 24
Acute leak pressure	96.93 mbar	29 – 311

The mean anastomotic time was 50.93 minutes (range 33.25 – 71.35). The time needed for each of the five knotting tasks of the anastomosis was added together to determine the time component for this task; mean knotting time was

12.77 minutes (range 7.37 – 20.5). By substracting this time to the total anastomosis time we determined the time needed for stitching tasks: 38.20 minutes (range 23.32 – 55.57).

Since every procedure followed the same technique, each anastomosis had five knots. The average time per knot was 2.62 minutes (range 1.78 – 4.72).

The total number of stitches was not predetermined, although a distance no higher than 3mm between each stitch was encouraged. The mean number of stitches required to complete the anastomosis was 21.3 stitches (range 16 – 26). The average time per stitch was 1.81 minutes (range 0.94 – 2.74).

The mean internal diameter was 20.74mm (range 18 – 25), measured after the acute leak test.

Mean anastomotic acute leak pressure was 96.93mbar (range 29 – 311; Std Dev: 57.46). This mean leak pressure converts to 98.84 cm H2O and 73.66 mmHg. A pressure unit conversion table is available for reference (Table 7). The 40mbar (30mmHg, 40.7cm H2O) threshold is relevant, since in clinical practice, no acute leak test exceeds this pressure. This means that we only considered anastomoses leaking at a pressure bellow this threshold as an anastomotic failure.

Table 7 Pressure unit conversion table.

milibar	mmHg	cmH_2O
1 mbar	0.75 mmHg	1.02 cmH_2O
10 mbar	7.50 mmHg	10.2 cmH_2O
25 mbar	18.7 mmHg	25.5 cmH_2O
40 mbar	30.0 mmHg	40.7 cmH_2O
50 mbar	37.5 mmHg	51.0 cmH_2O
75 mbar	46.3 mmHg	76.5 cmH_2O
100 mbar	75.0 mmHg	102 cmH_2O
150 mbar	112.5 mmHg	127 cmH_2O

Four anastomosis had leak pressures below the 40mbar threshold. A graphic of the leak pressures for all the procedures analyzed is shown in Figure 36.

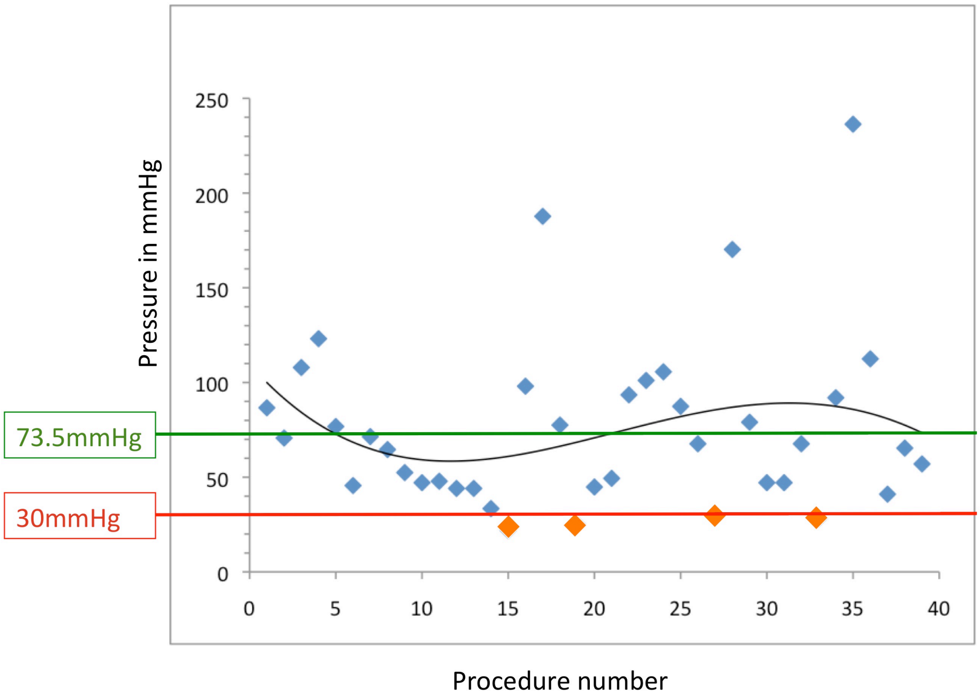

Figure 36 Leak pressure for all procedures. Mean leak pressure is shown in green. Clinical leak test threshold is shown in red. Anastomotic leaks bellow this threshold are marked as orange diamonds.

Five different types of error events were considered as described in the methods section. The mean number of errors for all procedures was 51 (range 28 – 98). The most frequent error event was the failure to grasp either thread or needle (missed grasping motions), with a mean 29.76 events (range 5 – 64). Failed knotting motion (loss of knotting loop, failure to pull-through knot) occurred a mean 6.55 times (range 1 – 26). Error events are summarized in Table 8.

Table 8 Results overview. Error types.

Error type	Mean	Range
TOTAL	51	24 – 98
Failed stitching motion	5.46	1 – 15
Needle drops	3.44	0 – 7

Failed thread grasping motion	29.67	5 – 64
Failed tissue grasping motion	5.88	1 – 28
Failed knotting motion	6.55	1 – 25

3.4.2 Learning curve

The main analysis of the learning process was done on the procedures done by subject A. Further; all the procedures were evaluated for correlation between the variables and the main outcome, which was the leak pressure and anastomotic time. A "group learning curve" was also determined by grouping together the procedures according to level of experience. The first five procedures of each subject were level 0, the next five level 1 and so on.

The following scatter graphic shows the learning curve for subject A. The logarithmic trend line shows high correlation with the plotted results (R=0.6)

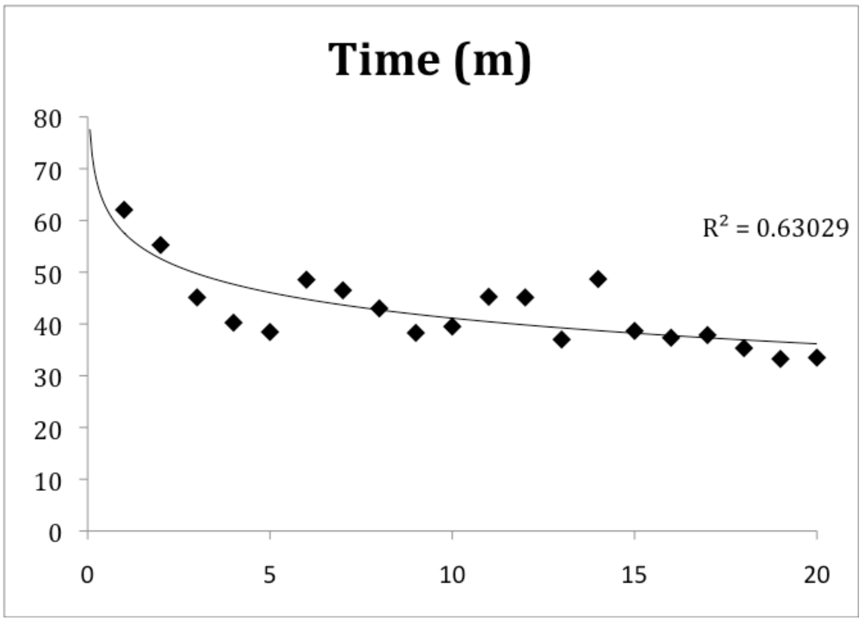

Figure 37 Learning curve for subject A

After grouping the procedures as mentioned, the mean results for each variable were used for ANOVA (Table 9). Total time was reduced from 48.22 minutes to 35.45 min in the last group ($p<0.05$). Similar reductions were observed in other time related variables although not all reached statistical significance.

Table 9 Comparison between groups according to experience for all subjects.

	Group 1	Group 2	Group 3	Group 4	ANOVA (G1 vs. G4)
Time					
Total time	48.22	44.08	42.94	35.45	P<0.05
Stitch time	35.63	32.20	31.66	25.43	NS (P=0.05)
Mean time/stitch	1.661	1.506	1.447	1.125	NS (P=0.07)
Knotting time	12.588	11.885	11.284	10.02	NS (P=0.07)
Mean time/knot	2.518	2.480	2.257	2.004	P<0.05
Errors					
Total	43.2	41.8	37.4*	31	P<0.01
Failed stitching motion	6.2	5.2	4.2*	3.8	P<0.01
Failed suture grasping	21	20.4	19.6	16.2	P<0.05
Failed tissue grasping	4.6	5.6	5	5.2	NS
Needle drops	4.6	3	1.8	1.8	NS (P=0.05)
Failed knotting task	6.8	7.6	6.8	4	P<0.05**
			*P<0.05		** for G2 vs. G4

The mean total errors were reduced from 43.2 to 31 (P<0.01). The majority of error related variables showed a significant reduction with increasing experience. Failed stitching movements were reduced from 6.2 to 3.8 (p<0.01). Failure to grasp the suture or needle was reduced from 21 to 16.2 mean events (p<0.05). Failed knotting tasks were also significantly reduced from a mean of 6.8 in group 1 and 7.6 in group 2 to a mean of 4 in group 4 (p<0.05 G2 Vs. G4). Although needle dropping was less frequent with increasing experience, this reduction in frequency did not reach statistical significance. There was no reduction in the frequency of failed tissue grasping movements with increasing experience.

3.4.2.1 Error analysis of anastomotic leaks

As mentioned, four anastomoses leaked at a pressure under 30mmHg. Two of these anastomoses belonged to group 1 (experience level 0), one belonged to group 2 and one to group 3. There were no low-pressure anastomotic leaks in group 4. Subject B had one anastomotic leak and subject C had three anastomotic leaks bellow 30mmHg each.

The precise location of the anastomotic leak in the circumference was identified in all four cases and is depicted in Figure 38.

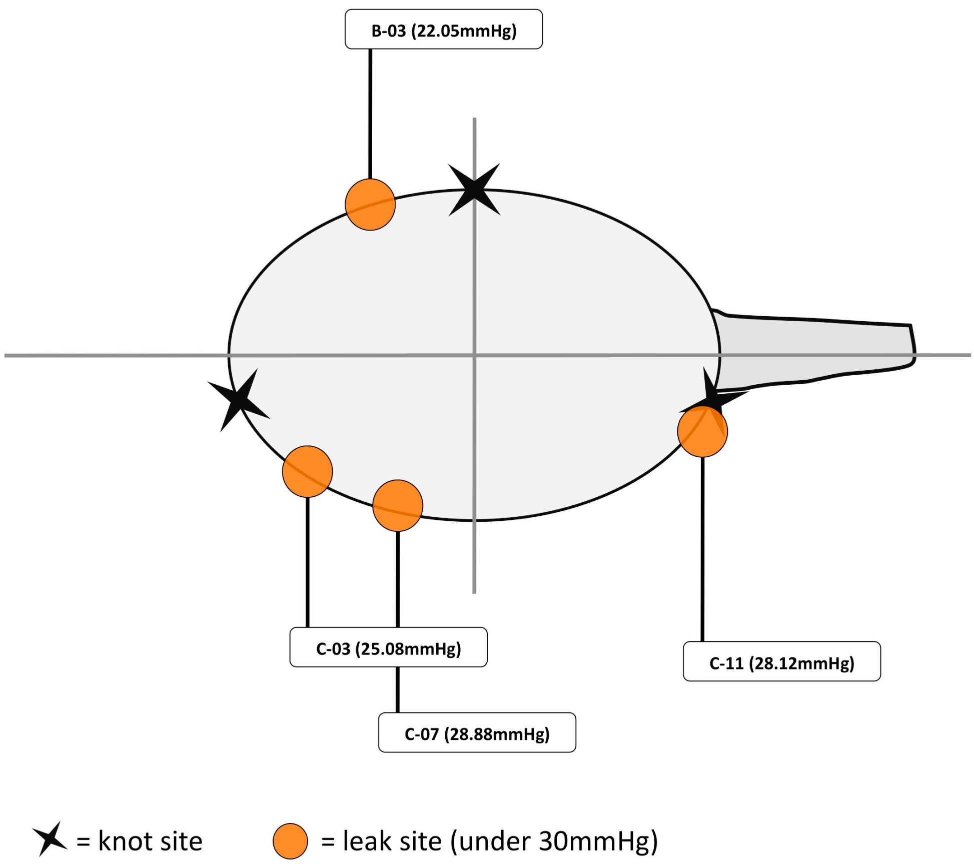

Figure 38 Site of anastomotic leaks under 30mmHg

The corresponding procedure videos were analyzed further to identify the cause or series of factors contributing to the low pressure leak.

- Case B-03 (leak pressure 22.05mmHg): A small perforation on the anterior wall of the duodenal first portion was inadvertently made during the dissection phase of the procedure. This perforation was partially closed with the anastomotic suture, but eventually leaked during the acute pressure test.
- Case C-03 (leak pressure 25.08): The leak occurred on the posterior wall, lateral segment, at a site where the mucosa was exposed. Video

review showed that the surgeon had not tightened the suture as recommended in the procedure protocol.

- Case C-07 (leak pressure 28.88): The leak occurred on the posterior wall, on the lateral segment, at a site where the mucosa was exposed. Video review showed that the surgeon had difficulty while suturing this segment, due to incomplete dissection of the posterior wall. Examination of the anastomosis showed a gap of 5mm between stitches at the site of leak, with evertion of the mucosa.
- Case C-11 (leak pressure 28.1): The leak occurred at the site of the medial corner of the anastomosis, and was related to complete knot dehiscence. Video review showed that the surgeon knotted the threads only TWO times, a fact that was missed both by assistant and surgeon.

No further analysis was made of the remaining anastomoses, since the pressure at which they leaked was higher than the clinical threshold.

4 Discussion.

4.1 The case for an advanced model for training laparoscopic anastomosis.

The importance of a reliable, realistic and validated model for training such a complex procedure is underscored by the fact that anastomotic complications can be fatal and are avoidable in many instances. We have chosen the duodenoenteric anastomosis of the duodenal switch as an example case for testing the model.

4.1.1 Complications related to anastomosis technique in BPD/DS

Although all bariatric procedures have been described as “safe” in several studies, complications after bariatric procedures are not uncommon. A complication is any event in the postoperative period that causes a deviation on the ideal clinical course [70]. There have been several efforts to classify complications in bariatric surgery in order to aid in description, management and ultimately prevention of some of them.

Complications can be either technical/surgical or medical in nature. They also are classified in relation to the time of onset as either early (before the 30th postoperative day) or late.

Late complications are mainly nutritional or gastrointestinal in nature, the latter being mostly represented by intractable symptoms that may significantly affect a patient’s well being. These late consequences have been the focus of many studies to which the reader can refer if necessary [83,56].

Early complications of bariatric surgery in general have been studied in detail. Some risk factors for early complications such as age >65, male patients, higher weight, and surgeon experience have been identified [29,32]. In essence, these proposed risk factors relate directly to perioperative care and surgical technique.

The overall early complication rate of bariatric surgery is considered to be between 9% and 25%. This wide range is in part due to the discrepancy in definitions within studies. Another reason is that some studies report complications for bariatric surgery as a single entity and others for each specific technique.

In a study of 780 bariatric operations done in a single institution by Parikh et al, the complication rates for the LAGB, RYGB and BPD-DS were 9%, 23% and 25% respectively [70].

Some proponents of BPD-DS argue that this higher complication rate is partially due to the fact this procedure is offered mainly to patients with a BMI >50kg/m^2 as opposed to RYGB because of the better and faster weight loss [72]. Heavier patients have a higher incidence of cardiovascular comorbidities that may cause medical complications in the perioperative periods. These heavier patients also pose technical difficulties, which add to the risk of developing a surgical complication.

In accordance to the previously mentioned classification, it can be clearly said that around 20% to 30% of early major complications are medical or infectious in nature. The vast majority of early postoperative complications are surgical complications, which include hemorrage, wound or fascial dehiscence, surgical infection, small bowel obstruction, and anastomotic leaks. The distribution of complications in the perioperative period have been reported in a study by O'Rourke [69]. According to this and other studies, anastomotic leak represents 30 to 35% of all complications of bariatric procedures that involve a gastrointestinal anastomosis and is thus the most common early complication [69].

Anastomotic leaks in open and laparoscopic BPD-DS are reported to occur in 2% to 6.7% of all procedures [42,60]. The BPD-DS involves three potential sites of leak –the gastric sleeve, the duodenoenteral anastomosis and the enteroenteral anastomosis. The duodenoenteral anastomosis has been clearly shown to be the site where the vast majority of leaks occur. It is also the most technically challenging of the anastomoses.

As mentioned earlier, studies analyzing potential risk factors for complications in bariatric surgery have suggested that patient volume and surgeon's experience play a significant role in the reduction of complication rates. Indeed, anastomotic leak rate can be as high as 7% in centres with low volume or during the initial experience of surgical groups [5]. Anatomical characteristics – e.g. shortness of duodenal first portion – are also often cited as potentially playing a role in this phenomenon but this has not been investigated [93]. Despite these well-known facts, there has been no study on the specific technical details that may be involved in the observed higher anastomotic leak rate in the duodenojejunal anastomosis.

An anastomotic leak may be due to different causes, yet it is generally accepted that early leaks (occurring within one to five days postoperatively) are due to technical defects or inadequate tissue being anastomosed. Later leaks may be due to decreased healing of the anastomosis due to local ischaemia, overall deterioration of the patient due to other complications and other factors. In both situations, the intraluminal pressure exceeds the strength that the anastomosis –tissue, staples and or suture together – is able to withstand [86]. The majority of leaks occur in the early postoperative period and are thus considered related to technique or mechanical causes. Clinical detection of an early anastomotic leak may be delayed, which usually complicates the clinical course. Consequences of an anastomotic leak may include sepsis, fistula, need for reintervention, and death.

4.1.1.1 Fatal complications of bariatric surgery

The published overall mortality rate of patients that undergo bariatric surgery ranges from 0.05% to 2.0%. As with complications, these mortality rates vary widely between studies and are different for each specific bariatric operation.

There is an increase in mortality with advanced age and with increasing complexity of the procedure. Specific mortality rates for LAGB, RYGB and BPD-DS were reported to be 0.1%, 0.54% and 0.80% respectively in a study based in the Italian national registry of bariatric operations [66]. This difference reached statistical significance.

Studies looking into mortality rates on bariatric surgery patients report pulmonary embolism as the commonest cause of death (30-38%) followed by cardiac failure. Intestinal leak is reported in these studies to comprise around 17% of all deaths [62,30]. The disadvantages of registry based retrospective studies are well known. Depending on the population studied, cause of death may be recollected from different sources and autopsy is not done on all patients. Definite autopsy reports are not always available. Further, these studies fail to identify the sequence of clinical events that lead to a patient's death.

An autopsy-based study done in the United States on deaths due to complications of 97 bariatric surgery patients yielded completely different results [36]. Technical complications were found in 45% of autopsies. An anastomotic leak was found in 36% of autopsies and was to the most common complication leading to postoperative death. Of these, half were detected within 5 days postoperatively, not withstanding the fact that a later detection does not exclude an early leak, which as was mentioned before is related to technical failure. Haemorrhage in the surgical site was the second most common technical complication.

The non-technical complications comprised 38% of all complications. Pulmonary embolism was present in only 12% of cases. Of interest was the coexistence of pulmonary embolism in some patients with an anastomotic leak. Anastomotic leaks may be thus underrepresented in registry-based studies on mortality in bariatric surgery patients.

The fact that a technique related event is the most common complication of bariatric surgery and is a common cause of death should be regarded as extremely relevant and should merit action to prevent its occurrence.

Anastomotic leak, as the gravest and the single most frequent complication of the BPD-DS, is the focus of this work. Since it is related to surgical technique, it may be potentially preventable in an undetermined number of cases. In order to prevent it, however, a careful analysis of the technical details of this complex step in the procedure is needed.

4.1.1.1.1 Critical step: The duodenojejunal anastomosis

As previously discussed, this step of the procedure is involved in a large proportion of postoperative complications after BPD-DS in the form of an anastomotic leak. The impact of an anastomotic leak on the postoperative course can be dramatic not only for the patient but also for the surgical team.

The duodenoenteral anastomosis in laparoscopic BPD-DS has been done using many different techniques by different authors. The detail with which these different techniques are described varies and it is therefore difficult to draw conclusions about their adequacy. Surgical techniques are usually described and published during the initial phases of a surgical team's experience. Seldom are complications reported in the same paper and if they are they pertain to a small number of cases –usually the first standardized cases and not the actual first cases when the technique is subject to frequent modifications – and the reported complication rates are not reliable for comparison. The difficulty of dealing with these potential biases in surgical research is well known [76].

We found a preoccupying lack of information about what makes a duodeno-jejunal anastomosis safe and especially about anatomical and technical considerations that may determine a leak. While we have discussed putative risk factors for complications –anastomotic leak among them -, the creation of an anastomosis is under the control of the surgeon. Risk factors are either present or not and when present they may play a role or not; technical know-how may actually make a difference

There are several technical descriptions of duodenoenteral anastomosis using stapling devices – circular and linear – as well as laparoscopic sutured techniques [77,52,5]. As mentioned earlier, we have found only one publication relating the experimental testing of the laparoscopic technique prior to clinical application [41]. We therefore consider that our step-by-step description of the development of the technique and the technique itself is valuable. The process through which a surgeon or group of surgeons arrives at a standard technique has not been thoroughly evaluated. Our description of how we arrived at a standard technique could be seen as an example of a metacognitive tool at work.

4.2 Laparoscopic intestinal anastomosis

Laparoscopic surgery offers reduced operative trauma to patients, yet it is also characterized by visual, tactile and spatial constraints on the surgeon. Only through newer technologies, training and cumulated know-how have these restrictions been overcome [18]. Initially, laparoscopic surgery was limited to “less complex” procedures such as cholecystectomy –which nevertheless requires vast experience to master.

More complex laparoscopic gastrointestinal surgery required that the surgeon could resect and reconstruct parts of the gastrointestinal tract. Laparoscopic intestinal and major organ resection was initially done through a mixed approach, with small laparotomy incisions for organ extraction and subsequent reconstruction –i.e. intestinal anastomosis. Extracorporeal intestinal anastomosis is a common and safe practice in laparoscopic procedures. It consists of an anastomosis done by traditional open techniques after the portions to anastomose are brought outside the abdominal cavity through a minilaparotomy [13]. However, this approach is not feasible for the whole gastrointestinal tract: the proximal stomach, duodenum, and rectum cannot be sufficiently mobilized to be anastomosed in this fashion. This involves the particular anastomosis that is evaluated in this work: the duodenoenteral anastomosis.

Anastomosis technique is one of the oldest subjects of debate in modern surgery. Many different hand sutured techniques, mechanical tissue approximation devices –staplers, reabsorbable rings – and modifications of their use have been described for open surgery [82]. The debate has been further carried into the era of laparoscopic surgery. It is generally accƒepted that stapled and hand-sutured gastrointestinal anastomoses have similar efficacy and are equally safe, with comparable leak rates [58]. It is fair to say that the ultimate decision, as to which anastomosis technique is adequate, is left to the surgeon at the operating table. His or her previous experience, training, and access to different options will influence this decision.

In the case of the laparoscopic duodenoenteral anastomosis, however, there are certain anatomical and technical characteristics, which justify its study separate from the bulk of other gastrointestinal anastomoses.

4.2.1 Laparoscopic stapled anastomosis

Stapling devices for intestinal anastomosis have been present for more than a century. It was, however, in the late part of the 19th century that their use became common in open gastrointestinal surgery [3]. They offer the advantage of saving procedure time and have become safer with the years. Soon after the introduction of laparoscopic surgery, modified versions of stapling devices entered the market and were made available for clinical use, including intestinal anastomosis [55]. The majority of stapling devices permit the use of preloaded sterilized staple cartridges. Today, the majority of laparoscopic anastomoses are made with stapling devices of different kinds.

Stapling devices for laparoscopic surgery fall into two main categories: linear and circular. Their working principles have been reviewed elsewhere and are available from the commercial distributors [65]. In short they apply two double rows of staples, which are then separated by a cutter blade. For optimal function, the tissue should be compressed to a defined limit that permits a tight seal without crushing the tissue, producing excessive ischemia or causing the device to malfunction. In the case of linear staplers, there are models with different staple dimensions that can accommodate tissue of corresponding thickness. Circular stapling devices are available with different diameters (21mm, 25mm, 28mm, 31mm). The circular staplers are not designed for a specific compression or tissue thickness limit; instead they compress progressively until reaching a predefined limit and it is left to the surgeon to decide the optimal compression before firing the device.

Since some years, absorbable and nonabsorbable reinforcing materials are available for linear GI stapling devices (SeamGuard®, Surgisis®) [25]. These extra layers of material have the purpose of aiding in tissue healing and increasing tissue compression to decrease leaks and haemorrage.

The mechanical properties of gastrointestinal staple lines have been investigated by Baker et al [3] in an experimental model with human cadaveric organs. In their study they describe that the mean leak pressure of a gastric linear staple line is 62+-8 cmH2O. When reinforcement material was used this increased to 107+-20cmH2O. Downey and co workers investigated the acute leak pressure in small bowel staple lines with and without reinforcement material (Surgisis ®) on a live porcine model [25]. The staple lines leaked at a mean 52.92 mmHg without and at 83.14 mm Hg with reinforcement.

Before the commercial introduction of reinforcing materials, Dziki et al compared the mechanical properties of stapled and hand-sewn colonic anastomoses [26]. In their study on a live canine model, they evaluated the anastomotic diameter, the burst pressure, and the histological appearance under microscopy on both techniques at 1, 4, 7, and 28 days postoperatively. In their analysis of anastomotic diameter they found that at 1, 4, and 7 days the stapled anastomosis had a larger diameter than the hand-sewn anastomosis. This difference was not statistically significant. At 28 days, however, there was a significantly greater diameter in the hand-sewn anastomosis than in the stapled anastomoses. This seemed to correlate with the microscopic evaluations, which showed no difference between the groups at 1, 4, and 7 days but that demonstrated more complete epithelialisation, less inflammation and better tissue alignment than the stapled anastomosis. Regarding burst pressure, hand-sewn anastomoses had a higher mean burst pressure at all times measured than stapled anastomoses, reaching statistic significance at 4 (250mmHg vs. 140mmHg) and 28 days (270mmHg vs. 200mmHg) postoperatively. The mean burst pressure after one day was 150mmHg for the hand-sewn anastomoses and 110mmHg for the circular stapled anastomoses.

The results of this study slightly favour the hand-sewn anastomosis and confirm the clinical observation of higher stenosis rates with circular gastrojejunal and colonic stapled anastomoses as argued by the authors.

Besides the higher stenosis rates and potentially lower burst pressure, there are other drawbacks in using stapling devices.

Stapling devices have the risk of malfunctioning, particularly when crossing existing staple lines. This is of particular concern in the duodenum, where there is only limited length available to anastomose and there is no room for a second attempt should the device fail. Each staple line is in itself a possible leak site and carries the same risk as an anastomosis; stapled techniques, as mentioned, involve at least one extra staple line besides the anastomosis.

As discussed, the performance of stapling devices is increased by the new reinforcement materials, the use of which adds to the already high cost of stapling devices. Cost issues are of particular concern in health systems with low health insurance coverage. The additional costs of the reinforcing materials may preclude their use and in essence signify a less than optimal therapy if stapling devices are used.

Another inconvenience is posed by the lack of control by the surgeon of several aspects of the stapled anastomosis. A surgeon tends to rely on technical ability to solve special situations that appear during a procedure. An anastomosis, in the duodenum, may sometimes be particularly challenging. Stapling devices may malfunction if conditions are not optimal; worse still, they may actually work properly but unknowingly fail to approximate tissues in an appropriate manner since they do so in a mechanical non-adaptable fashion, which is out of the surgeon’s control. A surgeon should therefore not rely solely on stapling devices for GI surgery. The development of laparoscopic suturing techniques was therefore essential for the advancement of laparoscopic surgery.

4.2.2 Laparoscopic sutured anastomosis

Suturing is a complex task that involves, when done with the hands and common surgical instruments, the complete range of movements of the hand and upper extremity –i.e. complete freedom of movement. To date laparoscopic suturing has been applied in practically every area where sutures would be used in open surgery. It is considered a task requiring advanced skills and is a common part of the curricula in laparoscopic training courses worldwide.

Laparoscopic instruments enter the abdominal cavity through a pivotal point, reducing the degrees of freedom of movement considerably [38]. This restriction in movement can be partially overcome with careful placement of the instruments. Regarding suturing and knot tying, the manipulation angle (i.e. the angle formed between the two instruments) should be kept between 45º and 75º in order not to hinder the knot quality or difficult the tasks [40]. Other details that influence the precision of laparoscopic sutures such as insertion angle of the needle relative to the tissue (80º-100º) and optimal needle placement on the tip of the instrument have been investigated [49]. The attention to these details outside a controlled experimental setting may be difficult for surgeons. Further, laparoscopic surgery –and in particular difficult tasks such as suturing with conventional instruments – has been shown to cause significant physical and mental strain on practicing surgeons.

Despite the limitations, there are many studies reporting the use of laparoscopic sewn anastomosis in several settings, including bariatric surgery. Nevertheless, they repeatedly acknowledge the fact that it is associated with increased difficulty and a higher incidence of complications during the initial experience [4].

4.2.3 Anastomosis using the RSS

The quality of colorectal anastomoses done with the RSS has been previously investigated in an experimental setting with acute evaluation of leaking pressures in calf's colon [87]. Time to create a single layer continuous suture anastomosis was similar with RSS and CLI (33min Vs 35min in average). The quality of the anastomoses was evaluated in 20 experiments (10 with RSS and 10 with CLI) in two ways: First, an acute leak-pressure test was done, showing a higher leak pressure for the RSS group than for the CLI group [124 cmH_2O (range 120-130) and 72.7cmH_2O (range 35-130), respectively, $p< 0.01$]. Afterwards, the lumen diameter was measured and although having a similar mean value in both groups (2.9cm), it was significantly more consistent in the RSS group (range 2.5-3.8cm) than in the CLI group (range 0.3-3.1cm, $p<0.01$).

Further studies have evaluated the superior strength of stitches made with RSS in a laparoscopic inguinal hernia mesh repair model compared to stapling devices [45] and its performance compared to CLI in a gastrojejuno anastomosis model [33]. The bulk of experimental work on RSS was the basis for the development of a basic training course for the RSS, which is part of the program of training courses in the training centre at the university hospital in Tübingen.

Clinical applications of RSS are various. It has been used to suture on the oesophagus after thoracoscopic enucleation of a tumour, as suturing device for oversewing the suture line in sleeve gastrectomy, in inguinal hernia repair with a normal laparoscopic approach and with a novel single port approach again for inguinal hernia repair [46,24].

The better results of suturing and anastomoses created with the RSS in the acute setting are promising. Particularly relevant to the duodenojejunal anastomosis is the precission in stitches in any suturing plane that this instrument permits.

4.2.4 Intraoperative testing of gastrointestinal anastomosis

As evidenced by the previous discussion, any anastomotic technique has pros and cons, which the surgeon has to consider. There is no single technique that is applicable in 100% of cases and the surgeon must be familiar with a reasonable number of different possibilities in order to offer the best solution that suits each case. Beyond tissue approximation technique, however, an even more critical step is the immediate intraoperative testing of an anastomosis.

Intraoperative testing of an anastomosis and gastrointestinal staple line is even more relevant in laparoscopic surgery where there is reduced tactile and visual information the surgeon can use to decide if an anastomosis is well built or not. The accuracy of surgeons' clinical judgement to predict an anastomotic leak has been previously investigated. Karliczek et al [50] found that independent of their training level, surgeons' clinical risk assessment had a low predictive value for colorectal anastomotic leak after open colorectal resection with sensitivity of only 44% and no more than 59% specificity. Although many factors play a role in the appearance of an anastomotic leak, testing the mechanical quality of any anastomosis should identify gross technical defects that may be corrected immediately.

Two main intraoperative testing techniques are commonly used: the methylene blue and the pneumatic leak tests. Many surgeons use the methylene blue test in bariatric surgery, particularly in the RYGB. It consists in instilling a methylene blue solution via nasogastric tube in the gastric pouch while occluding the intestine distal to the anastomosis; the solution is instilled until distension of the stomach is seen and a visual inspection is made around the anastomosis and along staple lines. In case methylene blue is seen flowing through any point an immediate repair is made.

The air-leak test has been proposed as a better alternative for intraoperative testing [2]. The test consists in insuflating the stomach/intestine while submerging the suture/staple lines in saline solution. This is done until visible but not excessive distension is seen. The insuflation may be done through a nasogastric catheter or through an endoscope during intraoperative endoscopy [54]. Several theoretical advantages of the air test over the methylene blue test have been described: 1) air is compressible and water isn't, so that there is less risk of excessive distension with the air test than with the methylene blue test; 2) it is easier and faster to perform; 3) it has been proven to be more sensitive, with smaller leaks being identified even in the posterior wall of an anastomosis, which may not be visible laparoscopicaly. Further, it may be readily repeated after repairing a leak; methylene blue tends to dye everything it touches, so that depending on the size of the leak a second test may be less sensitive if the surrounding tissues are already tainted.

The use of precise instruments, a standard anastomosis technique and an intraoperative test should allow trained surgeons to acquire a close to null leak rate irrespective of their cumulated experience.

The results of acute leak pressure measurement in the finished anastomoses of our work (average 96.98mbar; 73mmHg; 95cmH_2O) compare favourably with the known acute leak pressure done on ex-vivo gastric staple lines done by Baker (62 cmH_2O without- and 107 cmH_2O with-reinforcement material) and with colorectal anastomosis in a live pig model as described by Downey (52.92 mmHg without- and at 83.14 mm Hg with-reinforcement).

4.3 Learning curve and error analysis

No previous work has concentrated on the learning process of this specific technique. We demonstrated a learning curve effect for the standard technique of duodenoenteral anastomosis with the RSS and identified specific variables that would help evaluate trainees learning this technique in the future. The learning effect was noticed after as little as 15 procedures. Time to complete the procedure and the different technical error-variables evaluated are potential indicators of performance. Technical error analysis (with help of video analysis) has been proposed as a useful assessment tool for laparoscopic surgeons performing laparoscopic cholecystectomy [85,14]. Further work would be needed to design a training program and to develop and validate an evaluation tool specific for the technique that focuses on the identified indicators of performance.

As discussed previously, the learning curve is only a representation of the actual learning process relating to a specific procedure. We have focused on the actual process itself by analyzing the failed anastomoses in depth. This proved fruitful because in each of the four anastomotic leaks we were able to identify a cause for the leak. In all four cases the cause was human error. In two instances (Case B-03 and case C-07), the cause could be traced back to surgeons' error during the dissection part of the procedure –the data of which was not analyzed- after reviewing the video recordings of the anastomosis and finding no major technical error. The other two cases (C-03 and C-11) could be traced directly to technical errors by the surgeon and assistant during the anastomosis.

One of the main advantages of simulation training is the possibility to use a constructive approach to surgical errors that result in failure. [73,41,81]. The quality of the educational experience is improved through the feedback the trainee receives after error analysis is applied. In this case, it is of further value, since the results suggest that an anastomosis using the standardized technique with the Radius Surgical System is feasible and that anastomotic failures were not related to the instrument itself.

4.4 Simulation model for training advanced laparoscopic procedures

We designed our own model based on a well-established teaching method in endoscopic surgery developed by Professor Gerhard Buess in Tuebingen, Germany [91]. A common misconception in experimental surgery and technology development is that procedures and devices should be tested in live animals to prove feasibility and safety before clinical use. We do not agree on such a generalization and not only because of ethical issues regarding unnecessary training and experimentation with animals, which should hold by themselves. Further reason for non-live testing of this technique is that the RSS does not introduce any new tissue approximation technology; it only provides a more precise and controlled tool for making the widely proven hand-sewn anastomosis (see above).

The use of live pigs for laparoscopic training is expensive, restricts for that same reason the number of procedures a trainee can perform during a training course and although realistic to some extent, it is inadequate for training some laparoscopic procedures. Although the abdominal organs of the pig resemble to some extent those of the human, their anatomical situation and relations are different; first, the duodenum and pancreas are intraperitoneal and relatively free of retroperitoneal fixations on the pig. Second, the liver has three large lobes and lies differently in the abdominal cavity than in the human. Other differences are that the stomach wall is thicker than in the human –particularly at the antrum –and that the spleen is long and free of ligamental insertions. Further, the abdominal cavity of the swine has completely different dimensions that modify instrument port placement and thus the surgeon's movements and spatial orientation requirements. In our model, the organ block is modified to fit in the Tuebingen Trainer in a manner simulating human anatomy as close as possible. This helps overcome the important anatomical differences and permits a more realistic experience throughout the procedure.

Although organ block harvesting, preparation and final setup before a training/experimental session are time consuming, it can be done by a single non-medical trained staff member on any surgical education department. This compares favourably with the human and material resources needed to maintain live animals and to prepare them for surgical procedures. The organ blocks are easily preserved frozen and are available on short notice, a further advantage over live animal use. Since only organs from pigs killed for human consumption are used, no additional animal sacrifice is needed and no unnecessary suffering is inflicted to the animals who are spared the “lab animal” condition throughout their life. The use of practical and less expensive tools for teaching surgical technique is increasingly encouraged [88].

Further adding to the reliability of the model as a training and experimental tool is the introduction of specially preserved small bowel for training intestinal anastomoses that performs similarly to fresh bowel. It was critical to have a model that performed consistently as well as being realistic. Although frozen-thawed small bowel has been used as a tool to measure performance in laparoscopic suturing skills among residents in other studies [61,62], we have shown that it looses its mechanical properties in a significant manner, becoming unreliable as an evaluation tool and even as a teaching/training tool. From the previous discussion on performance indicators follows that the anastomotic acute test would be the single most relevant end point for a surgeon who is learning to do an anastomosis. We consider that the proposed preservation technique would allow for reliable, reproducible acute leak tests during future training courses.

The model developed and subsequently used in this study can be now considered to have face and content validity. Although this was done in an internal evaluation, it is methodologically sufficient for this level of validity as shown in Table 2. Further validation of the model as an educational tool is warranted; for this purpose a larger number of surgeons should be exposed to assess its fidelity objectively.

5 Conclusion

The adequate evaluation of new techniques and technologies before their introduction to clinical practice is being increasingly advocated by surgical research groups [28]. It is now recognized that there is an ethical mandate for surgeons to become proficient without putting patients at risk [95,1]. In this context, we must acknowledge that the RSS is already and established technology, which has been used in several clinical settings. On the other hand, the DS is a well recognized and approved procedure for the treatment of obesity and potentially DM2. Nevertheless, the RSS is a relatively unknown tool and the DS has gained a reputation of being technically challenging and complication prone. We consider that rigorous evaluation of modifications to already established techniques as we have presented is of relevance. We also give insight as to what performance outcomes may be evaluated on future trainees of this particular procedure.

We have used the Duodenal Switch procedure during part of this work as a practical example. Of much more importance, however, is that the model we have developed – including the abdominal organ block and the preserved small bowel –, considerably improves on existing training models and Its applications are by no means restricted to bariatric surgery. It has face and content validity and is ready for use as a training tool. The availability of a reliable and reproducible model for training intestinal anastomosis will surely be welcome by surgeons interested in improving the quality of surgical training.

6 Abstract

Background: Surgical training in general has seen a profound change since the introduction of laparoscopic surgery. Simulation training, learning curves and performance indicators are important concepts for skill training as well as new surgical technique development. There is growing concern over avoidable complications related to surgeon inexperience. Bariatric surgery is an increasingly important field where advanced laparoscopic surgical skills are essential for good patient outcomes. The duodenoenteral anastomosis needed for the Duodenal Switch procedure is a difficult task with increased risk of technical complications. No simulation model has been described that may help train this difficult procedure. Current models have certain disadvantages such as tissue damage and anatomical inaccuracies that limit their use. We set out to develop an adequate model for training laparoscopic intestinal anastomosis and proceded to test the model with a technique for duodenoenteral anastomosis using the Radius Surgical System (RSS).

Methods: Using the Tuebingen Trainer (Richard Wolf, GmbH) we used a stepwise approach to develop an anatomically accurate model of the human foregut from porcine organs. We also measured the mechanical properties of porcine small bowel submitted to different treatments with preserving solutions to arrive at a realistic looking model that retained the characteristics of living/fresh tissue. We used the resulting model to standardize a technique for duodenoenteral anastomosis for which we evaluated the learning process as well as the immediate technical results for three surgeons with an acute anastomotic leak test.

Results: We arrived at a realistic model of the human foregut. We determined the significantly decreased quality of frozen-thawed small bowel regarding tear strength and leak pressure tests when compared with fresh small bowel. We identified a preservation process through which these characteristics are preserved, allowing for a reproducible model that performs reliably in the experimental and training settings. After standardizing an anastomosis technique using the newly developed model, we found a measurable learning

effect and identified several potential performance indicators such as time to complete procedure and other task error indicators. We determined that a duodenoenteral anastomosis with the RSS in the experimental model has an average acute leak pressure of 96mbar, which compares favourably with other experimentally measured intestinal anastomosis.

Conclusion: The technique of duodenoenteral anastomosis with the RSS seems feasible and potentially safe. The model we have developed considerably improves on existing training models and its applications may extend beyond bariatric surgery. It has face and content validity and is ready for use as a training tool. The availability of a reliable and reproducible model for training intestinal anastomosis will surely be welcome by surgeons interested in improving the quality of surgical training.

7 References

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8 Addendum

8.1 Acknowledgements

This work represents but a small part of what my time in the Section for Minimally Invasive Surgery in the University of Tübingen actually means to me: a Journey.

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8.2 Curriculum vitae

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Career

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