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TESIS DOCTORAL

VALIDITY OF THE LAPAROSCOPIC SIMULATOR SIMULVET® AND ITS APPLICATION IN TRAINING ON VETERINARY LAPAROSCOPIC SURGERY

VALIDACIÓN DEL SIMULADOR LAPAROSCÓPICO SIMULVET® Y SU APLICACIÓN EN LA FORMACIÓN EN CIRUGIA LAPAROSCÓPICA VETERINARIA

Memoria presentada por

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CERTIFICAN:

Que la tesis doctoral que tiene por título **"VALIDITY OF THE LAPAROSCOPIC SIMULATOR SIMULVET® AND ITS APPLICATION IN TRAINING ON VETERINARY LAPAROSCOPIC SURGERY"**, de la cual es autor el Licenciado en Veterinaria **Angelo Elías Tapia Araya,** se ha realizado bajo nuestra dirección.

Y para que así conste, a efectos de ser presentada como trabajo de Tesis para optar al grado de Doctor en Veterinaria, se firma el presente certificado en Bellaterra, 12 de Junio de 2015.

Fdo.

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“La investigación es como la maternidad:
No es posible reconocer que el propio hijo es feo”

“Demasiado a menudo olvidamos que la formulación de hipótesis se basa no en un ejercicio de ingenuidad sino en el trabajo de verificación”

Clifford Allbutt

Dedicado a mis Padres Manuel y Helia;

A mi hermano Richard;

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ACS: American College of Surgeons

ACGME: Accreditation Council for Graduate Medical Education

BEME: Best Evidence Medical Education

CLS: Canine Laparoscopic Simulator

CPD: Continuous Professional Development

CT: Computed Tomography

EMG: Electromyography

EAES: European Association of Endoscopic Surgeons

FLS: Fundamentals of Laparoscopic Surgery

GOALS: Global Operative Assessment of Laparoscopic Skills

GRS: Global Rating Scales

JUMISC: "Jesús Usón" Minimally Invasive Surgery Centre

MVC: Maximal Voluntary Contraction

MIS: Minimally Invasive Surgery

MISTELS: McGill Inanimate System for Training and Evaluation of Laparoscopic Skills

LSS: Laparoscopic Surgical Skills

OSATS: Objective Structured Assessment of Technical Skills

OSCE: Objective Structured Clinical Examination

RULA: Rapid Upper Limb Assessment

RACS: Royal Australasian College of Surgeons

SAGES: Society of Gastrointestinal and Endoscopic Surgeons

SLS: Society of Laparoendoscopic Surgeons

VAS: Visual Analogue Scale

VMAS: Validation, Metrics and Simulation

I. Introduction

Essentials of Laparoscopic Surgery Simulators

To certify surgeon's proficiency in laparoscopic surgery, it is mandatory to develop and assess their psychomotor skills in surgical simulators. These skills are preferred to be evaluated in an objective and quantifiable way through different metrics. Many studies have evaluated the role of surgical training simulators and exercises practiced in them[1-6]. Regarding the role of simulators as an evaluation method in laparoscopic surgery, a major study established the existence of current deficiencies in the standardization of tasks, measure parameters and levels of validation of the devices used[7]. More specifically, the most important deficiencies were: the lack of universally accepted metrics; the variety of simulators, tasks and parameters used, with varying degrees and stages of validation and reproducibility; the discrepancy in the training levels of the subjects performing the experiments; and the small population size of those studies[8-10]. Other studies indicate that the practice in physical simulators is, at the moment, the basic tool for laparoscopic training initiation, in which surgeons can practice basic tasks to improve the coordination and intracorporeal suturing[11-13]. Therefore, training in simulators is helpful in developing laparoscopic surgery skills and should be part of the training of the surgeon[14].

Although there is no universal classification regarding surgical simulators, they are usually classified according to their level of realism, type of exercises performed, or depending on whether or not they include any technological element. Based on their nature, simulators have been divided into three types[7, 15-16] (Table 1 and Figure 1):

- Physical simulators are also known as box-trainers, pelvitrainers or boxes. They have the lowest cost and offer realistic haptic or tactile sensation. They are the most accessible and simple, but are less objective than the virtual simulator as they need a skilled surgeon to effectively evaluate the exercises performed. Basic exercises like coordination, and other more advanced tasks, such as cutting and suturing on different types of synthetic or organic material are usually performed on these physical simulators[17].

- Virtual simulators are less accessible and more sophisticated. They provide an objective assessment but represent a higher cost and show deficiencies in the haptic sensation and in the tissues' deformity. This deformity of the tissue is considered one of the most useful insights for surgeons to determine the force applied to the tissue. Hence, the fidelity of this deformation on the monitor is very relevant for the exercises that comprise coordination tasks of various objects and other more advanced procedures such as cutting, dissecting and suturing[18-19].

One of the most important areas of research in this type of simulation focuses on the deficiencies in the haptic sensation. The incorporation of force feedback is one of the most controversial issues in the design of these simulators; however, it has not been demonstrated yet whether this is a determining factor in the performance of laparoscopic surgery[20]. The haptic sensation allows the perception of the tip of the instruments when contacting the tissue, the pressure when closing the handle of the instrument, and the elasticity of structures compressed using force feedback systems[21]. Although virtual reality simulators represent a technological breakthrough, there is scarce literature that demonstrates the added value of this type of simulation as an alternative to traditional training[6, 22-23].

- Hybrid simulators, also known as augmented reality simulators, are based on computer or tracking systems. They belong to a branch of traditional physical simulators that use technologies to objectively evaluate surgical actions and record user feedback. They present a realistic tactile sensation and provide objective assessment through specifically developed computer software. The main limitation is its high cost, sometimes equivalent to that of the virtual simulators[24].

Figure 1. Physical simulator (left), hybrid simulator (centre) and virtual simulator (right).

TYPE OF SIMULATORS	ADVANTAGES	DISADVANTAGES
Physical simulators	Realistic haptic sensation The lowest cost	Need a skilled surgeon to evaluate the exercises
Virtual simulators	Objective evaluation Record user feedback	High cost and deficiencies in the haptic sensation
Hybrid simulators	Realistic haptic sensation Objective evaluation	High cost, similar to virtual simulators

Table 1. Summary of the main advantages and disadvantages of different types of simulators.

More specifically, for simulations in medical education, the use of such technology leads to desired and demonstrable learning outcomes. To address this issue, under the auspices of the Best Evidence Medical Education (BEME) Collaboration, it was conducted and published a detailed and systematic review of the literature (spanning 34 years and 670 peer-reviewed journal articles). Based upon the principles that have been elaborated by the BEME group, this study identified ten features and uses of high-fidelity medical simulations that lead to effective learning[25]:

- Feedback is provided during the learning experience

- Learners engage in repetitive practice

- The simulator is integrated into the medical curriculum

- Learners practice with increasing levels of difficulty

- The simulator is adaptable to multiple learning strategies

- The simulator provides clinical variation

- The simulator is embedded in a controlled environment

- The simulator allows individualized learning

- Outcome measures are expressed clearly

- The simulator is a valid (high-fidelity) approximation to clinical practice

Many of these features are consonant with Ericsson's model of deliberate practice for achieving mastery in professional performance[26].

Simulators Validity

During the validation process it is verified that the design of the simulator, the exercises performed, the recorded parameters and the expected improvement in skills, fulfill the objectives raised during the development phase. Medical and veterinary professionals are increasingly demanding training programs that certify surgical skills. However, these should be validated studies showing how evaluation methods are useful for this purpose. Currently, there is no completely acceptable assessment methodology[7-8, 27].

In addition, these simulators are known as part task trainers since they do not need to recreate very elaborated surgical environments, both oriented to the practice of partial and specific tasks[10]. The simulator must provide feedback information to the user, who can then detect which aspects must be improved. Such information should be quickly processed, clear and easy to interpret by the user, in order to determine the level of improvement achieved in each performance. It is recommended that this feedback is not purely informative, but it also sets goals to move on to more advanced levels. Traditionally, measurements of the skills of a surgeon on physical simulators, or during actual operations in human or animal patients, are usually performed with evaluation tables or checklists, since there are not computer-based systems available to record the performances.

In all cases, prior to its use in a particular training program, a simulator must have been subjected to a complete validation process. Having demonstrated its validity, it could be used as a tool for evaluating surgical skills. Although it is generally accepted that the validation of simulators starts with the subjective and objective studies, the fidelity-calibration and verification studies should be the first to be performed[28].

The fidelity is defined as the degree of realism that a simulator presents. It establishes how the setting should resemble reality, provided that the tool is efficient[7]. A low-fidelity simulator can be used as a training tool for novice trainees and for initial training phases.

Check-calibration, also known as technological reliability, internal validation, validation of program or internal consistency of a model, is the process by which it is verified that the simulator operates according to its design[27, 29]. Throughout this procedure, it is necessary to correct any structural deficiencies in design and operation before moving to the validation phase.

The validation strategies can be grouped into subjective strategies, where users must assess the appearance (face validity and content validity), and objective strategies, where the results achieved by the simulator are studied[8, 10-11, 28, 30-34] (Table 2).

Subjective strategies:

- ***Face validity*** consists in a panel of novice subjects that revise the system and issue opinions on its appropriateness. It is an assessment with a high subjective component usually carried out during the early stages of the system's development. Although it is not a formal concept of validity, it is a very important factor for its future implementation because it provides interesting information about the user's feelings about the system. The questions are varied: realistic feel of various aspects of simulation, attractive design, practicality and usefulness of the exercises performed, among others[35].

- ***Content validity*** assesses if the test is suitable for measuring the skills of the surgeon. It questions whether the content that raises the evaluator method is appropriate, they are related or measured all the skills that are presupposed. This type of validation is also based on expert judgment about the relevance and appropriateness of the tasks to exercise, which confirms the subjective nature of this validation[36].

Objective strategies:

- ***Construct validity*** assesses the extent to which the results can identify the quality, skills or aspects for which they were designed. Validity is constructive when the simulator is able to discern between the different skill levels of the users, from the records obtained. For example, by comparing the scores obtained by surgeons with varying levels of experience (Beginners vs Experts)[37].

- ***Criterion validity*** aims to demonstrate that there is a relationship between scores on the simulator and the technical skills displayed during surgery. Such a comparison would be desirable, but, due to the logistical constraints that often make *in vivo* tests in animals or humans impossible, the results are often compared with those obtained in other previously validated simulators. The correlation coefficient between scores on a simulator versus performance in the operating room, or on another simulator, is acceptable if kept between 0.4 and 0.8, although it is always better as it approaches to 1. It must be noted that there exist two types of validation criteria: concurrent and predictive validation[28].

Concurrent validation: in this validation the results of the assessment or training tool studied are compared to a gold standard or reference method. For this purpose, we measure the correlation of the scores obtained by the surgeon in the simulator and compare them to the scores achieved in the real surgical field or in another validated simulator. This shows the usefulness of this tool for educational purposes, as it provides a clear understanding of the improvement in the skills and performance of the trainee after practicing on the device[34].

Predictive validation: this strategy seeks to demonstrate how the records kept on the device allow predicting future performance. This prediction would be the last stage of evaluation and, clinically, is the most important one, because it will offer reliability to the surgeon about its surgical practice routine on patients.

Validation of simulation technologies for surgical training simulation assessment has focused research during the last years[8]. An example of this effort is the constitution in the 2002 of the Validation, Metrics and Simulation (VMAS) Committee which aims to develop a robust scientific methodology to demonstrate the value of the surgical training program based on simulation during the learning curve.

A learning curve is a plot of the acquisition of skills along time, measured by different metrics like dexterity, time or errors. If these metrics have been shown valid, a learning curve is a proof of how trainees acquire technical skills. For example, a simple box trainer (physical simulator) has demonstrated that the learning curve for operator seep is shorter than for operator accuracy[38].

VALIDATION METHODS			
SUBJECTIVE		**OBJECTIVE**	
Face validity - Novice	**Content validity** - Expert	**Construct validity** - Beginner ≠ - Expert	**Criterion validity** - *Concurrent:* Gold standard - *Predictive:* Future performance

Table 2. Summary of the validation methods in laparoscopic simulators.

Training Program in Laparoscopic Surgery

Teaching procedures for laparoscopic surgery cannot be adapted to the traditional learning systems; that is, tutored learning with real patients. There are certain drawbacks that the surgeon must overcome as the process of adaptation to laparoscopic surgery cannot be developed in the same way as conventional surgery, according to the principles of Halsted "see one, do one, teach one"[1, 14, 39]. In this area, the acquisition of basic skills should be conducted outside surgical settings before putting them into practice on patients[2, 40-41].

Laparoscopy learning should be achieved through practicing new maneuvers on simulators prior to executing them in real surgery. Moreover, it is noted that there is no universal training program in laparoscopic surgery, so that current methods of learning in this discipline may have a number of shortcomings and inconsistencies. This component of variability and lack of uniformity in the educational standards is one of the most controversial and difficult issues to solve, and it is, therefore, widely discussed in current learning programs[42-43].

After the implementation of laparoscopic surgery in the late 80s, surgeons were already raising awareness of the need for a change in the apprenticeship system. In particular, laparoscopic surgery requires a quality assurance, the establishment of minimum training standards and a proper accreditation process[17, 32]. In addition, certain associations and medical societies, such as the Society of Gastrointestinal and Endoscopic Surgeons (SAGES) - which created the Fundaments of Laparoscopic Surgery (FLS) - the Society of Laparoendoscopic Surgeons (SLS), the European Association of Endoscopic Surgeons (EAES) or the Accreditation Council for Graduate Medical Education (ACGME), have established minimum requirements for the different skills needed in laparoscopic surgery, involving knowledge, surgical skills, and level of professionalism, among others[44-45].

These programs combine clinical and non-clinical training. The first type of training consists in training programs (fellowships) and residences at hospitals, and the second corresponds to eminently practical modules with atypical duration of 2-3 days, which include the use of simulators and animal models[46-47]. One of the most extended approaches through which learning is imparted is via an intensive course (2-3 days) that residents and surgeons take both for initial learning and Continuous Professional Development (CPD), respectively[48]. Due to their nature, these courses are highly structured, aiming to convey the largest amount of knowledge possible in the short time available. Depending on the country, these courses may be compulsory or not[49].

The courses at "Jesús Usón" Minimally Invasive Surgery Centre (JUMISC) are an excellent example of this trend. They are structured in a four level pyramid, in which the trainee gradually moves from basic to advanced training: (1) basic and advanced skills training with box trainers and virtual simulators, (2) anatomical protocols and advanced skills training with animal models, (3) advanced procedural skills training combined with the use of information and communications technology applications and (4) practice in the operating room (Figure 2).

Figure 2. JUMISC. Minimally invasive surgery training pyramid.

A non-clinical teaching method that has proved to be reliable and valid is the FLS program, in which the SAGES and the American College of Surgeons (ACS) are involved. The FLS program includes a training module and a test to assess the competence of the surgeon in the "McGill Inanimate System for Training and Evaluation of Laparoscopic Skills" (MISTELS)[50-52] (Figure 3 and 4). This program represents the first validated simulation model for national implementation. Furthermore, it is one of the many examples of the positive impact of simulation in medical education and the growing acceptance of using simulators prior to actual clinical practices by the medical community[23, 53]. The implementation of this program in the clinic has made it compulsory to obtain the pass mark for this exam in order to practice as a laparoscopic surgeon in the United States[22]. This program has spread to Canada, where there exists a number of accredited centers for certification, and Australia, where the Royal Australasian College of Surgeons (RACS) has recently incorporated the FLS program in their training.

The main disadvantage of this program is that supervisors (trained to apply specific criteria) conduct the evaluation of the program, and it can only be performed in accredited centers. This makes it impossible to use it in other programs of individual training[15]. In Europe, the EAES has initiated the development of a program called "Laparoscopic Surgical Skills" (LSS), in order to validate and implement a strong base for accredited training in laparoscopic surgery. Unlike the FLS program in the LSS, basic skills on specific procedures are also included, as well as how to deal with real life situations arising in the operating room, such as unexpected intraoperative problems. This program combines different training modalities offering immediate evaluation, not only through the supervision of an expert but also through simulation tools. This program is divided into two parts, the first consisting of 3 levels[54-55]. Another feature is the possibility of monitoring the improvement of specific technical skills that users develop within the clinical practice (learning curve)[38, 56]. This is defined by the observation of improved motor skills as the exercises are repeated over time.

Figure 3. FLS online didactic platform (Source: www.flsprogram.org).

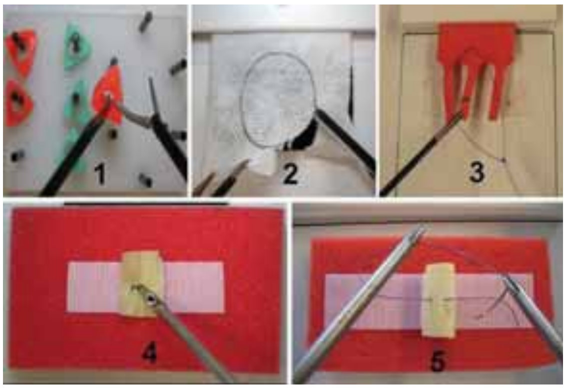

Figure 4. The five FLS simulator tasks: (1) peg transfer, (2) pattern cutting, (3) ligating loop, (4) extracorporeal suture, (5) intracorporeal suture (Source: www.sages.org).

Challenges in Laparoscopic Surgery

Laparoscopy requires that surgeons perform tasks supported on a two-dimensional video image of the operative field, in which only the distal part of the laparoscopic instruments are visible. This leads to some psychomotor challenges such as loss of depth perception and 2D interpretation of 3D structures. In addition, laparoscopic instruments are longer than traditional instruments, and consequently the surgeon's hands are far from the working ends of the instruments, which can cause hand tremors after long periods of use. Definitely, surgeons have to relearn the skills of physical manipulation in order to deal with the loss of the sense of touch and the reduced degrees of freedom of laparoscopic instruments. In fact, laparoscopic surgery is a technically demanding discipline, which imposes significant psychomotor challenges on surgeons (Table 3).

Medical training programs are based on the evaluation of six competences. These competences are considered necessary for surgical residents and for surgeons who are already trained but want to be certified. The six competences include: clinical skills and patient care (including surgical formation), medical knowledge, communication skills, ethical and legal aspects, health system and social context, updating, and professional and personal development[11, 57-59]. It is surprising that none of the six existing competences is exclusively dedicated to the acquisition of technical or manual skills, as indicated by a broad and recent review on the current challenges in the education of residents[60]. In 2011, an article about competency in laparoendoscopic surgery proposes that the acquisition of technical or manual skills has sufficient importance as to be the seventh competition[61]. It is now considered a key target in surgical and training assessments, and for the correct certification on the learning trajectory[30, 62]. Therefore, it is necessary to have technological means to monitor learning in novice surgeons and to revalidate the skills of expert laparoscopic surgeons[15]. The growing interest in establishing that residents possess surgical skills and the ability to adequately train future surgeons[63], operating room personnel[64] and veterinarians[65], has led an active research stream on the need to implement training and assessment methods. Simulators must provide an objective information in terms of registrations and usefulness as an educational tool[48]. Eventually, simulators for training and evaluating medical and surgical skills should provide an individualized learning in which the tasks are graded to suit the user level and the records are individually stored for each user.

CHALLENGES	IMPLICATIONS FOR SURGEONS
Loss of stereoscopic vision	Interpretation of three-dimensional structures by means of two-dimensional screen
Loss of deep perception clues	Reduction of shadows, tissue deformation, angle and motion parallax
Diminished tactile feedback	Impaired judgment of applied forces or tissue consistency
Movements restricted	Reduced to four degrees of freedom versus the seven of open surgery
Ergonomic considerations	Operator discomfort and fatigue, cumbersome elongated instruments
Fulcrum effect	Pivotal effect of body wall, creating inversed movements
Enhanced tremor	Fine dexterity tasks more challenging
Orientation and safety	Reduced visual field on screen and new anatomical viewpoint

Table 3. Summary of the psychomotor challenges in laparoscopic surgery.

Laparoscopic Surgery Assessment

Regarding the certification of basic surgical skills, current surgical evaluation processes are based on subjective and generally unreliable methods. Therefore, an objective assessment would be vital in order to provide feedback and to structure learning surgical skills[66-67]. Simulators, both physical and virtual, offer means of training and assessment of the skills of the surgeon. However, there is insufficient evidence of the ability of these simulators to predict the performance of the surgeon in the real surgical field. In fact, the impact of simulation in medical-surgical education provides substantial benefits, representing an established and endowed method that is necessary during the surgical training program. In the literature, the role of simulation in medical education has been criticized. The importance of research in medical education is suggested by *McGaghie W. et al.* (2010) who showed that results are often difficult to coordinate due to the large variety of procedures, specialties and skills that must be learned[32]. Other authors demonstrated the appropriateness of using simulators as useful tools in training future surgeons in both laparoscopy and other disciplines[68]. References about evaluation methods of medical knowledge and surgical skills are largely available[7, 30, 48, 60, 69-70].

Surgical skills assessment is divided into two main groups: traditional methods, for cognitive skills; and more recently developed methods, for technical/psychomotor skills (Table 4). The simplest are the traditional examinations. Among them, the most widespread system of evaluation is the direct observation by experts. These include a list of various aspects of the surgical practice (knowledge, communication skills, professionalism and technical skills) to be scored. However, they are not valid for the assessment of technical skills and are also hardly reproducible and unreliable. Probably, the most influential evaluation system in the development of medical skills assessment was the Objective Structured Clinical Examination (OSCE), for open surgical procedures[71]. It was created to evaluate the surgical technical skills, focusing solely on theoretical knowledge. Moreover, most indicators are equipped with intra and postoperative objectivity, measuring the time it takes the surgeon to perform an intervention, the recorded data and the mortality rates. Afterward, there is the measurement of technical/psychomotor skills, which comes in the simulation itself. This method, which has greater dissemination and application, is the direct observation, with specific and predefined criteria.

The Objective Structured Assessment of Technical Skills (OSATS) examination represents a modification of the OSCE. It is a combination of performance lists or checklists and global rating reports or Global Rating Scales (GRS). The checklists consist of binary tables 1/0 or Yes/No in which surgical steps and very specific maneuvers of the procedure are taken into account. Global OSATS standard reports are a sum of 7 general surgical procedures (tissue protection, time and motion, instrument handling, suture handling, flow of operation, knowledge of procedure and overall performance) from 0-5 grade points (Likert scale).

Note that since 2005 there is an adapted OSATS for evaluation in laparoscopic surgery, called Global Operative Assessment of Laparoscopic Skills (GOALS). Its constructive, concurrent and predictive validity and its reliability have been widely demonstrated in literature[44, 70, 72-73]. In GOALS the checklist is preserved, while the overall report is reduced to 5 maneuvers specific to laparoscopic surgery rather than to conventional surgery, as described in OSATS. In addition, a third review and a Visual Analogue Scale (VAS) are added. In this scale the examiner qualifies the difficulty of the procedure as it is usually done in vivo (with experimental animal or human models) and assesses whether the candidate is competent or highly dependent on the tutor while performing the procedure. Qualification of the VAS is not numeric, but marked by a given point on a straight line of 10 cm. The only disadvantage of this method is its cost in human resources and the time taken to register and interpret data. Furthermore, at least two evaluators are required in each study with an acceptable coefficient of correlation between them, called inter-observer reliability ($R \geq 0.8$).

Lastly, the training program of the FLS was conducted in the MISTELS simulator. Its assessment system is based on the time it takes to complete each exercise and on the accuracy of the performance. This training program is done by calculating a score through default penalties. Constructive, concurrent and predictive validity values have been established, as well as their reliability[44, 51, 74]. Cut off values for the correct certification of skills have also been established [44, 75].

<table>
<tr><th>TRADITIONAL METHODS</th><th>RECENT METHODS</th></tr>
<tr><td>Traditional knowledge examinations</td><td rowspan="5">Direct observation with objective criterion: OSATS, GRS, Checklists, GOALS, VAS

Hybrid and virtual simulators metrics

Tracking motion analysis systems

Time + penalties in physical simulator (FLS)</td></tr>
<tr><td>Direct observation without objective criterion: OSCE</td></tr>
<tr><td>Register of training activity:
Book resident</td></tr>
<tr><td>Measuring the time it takes the surgeon to perform an intervention</td></tr>
<tr><td>Mortality and morbidity rates</td></tr>
</table>

Table 4. Summary of the different assessment methods for surgeons.

Ergonomics in Laparoscopy

Ergonomics can be defined as the science of adapting the workplace to the worker[76]. The importance of ergonomics in the design of the workplace has been recognized in multiple disciplines as well as in veterinary[77-78]. For over 20 years, a number of guidelines have been developed, seeking to adjust the height of the tables in office workers or industries that perform precision work or physical toughness[79]. Nonetheless, in the scientific literature there are not many publications related to the design of operating rooms and instruments for laparoscopic surgery[80-81].

Although laparoscopic surgery has many advantages for patients, it also has a number of disadvantages for surgeons. These are related to the need to handle laparoscopic instruments through a fixed orifice, the need for fine manipulation of a large number of instruments, the limited view through a two-dimensional screen where the surgeon loses all tactile sensation having difficulty in eye-hand coordination, the loss of appropriate sense of depth and, finally, the adoption and maintenance of forced postures for relatively long periods of time (Table 5). The combination of all these factors reduces the performance and accuracy of the surgeon, while increasing the physical fatigue and musculoskeletal diseases[82-84].

There are two main drawbacks associated with laparoscopic surgery that seem to contribute to physical fatigue and musculoskeletal disorders: an increase in static postures of the head and trunk, and the increase in abnormal movements that the shoulder and arm should perform during surgery[80, 85]. In addition, there are two specific aspects of the instrumental used that contribute to the occurrence of musculoskeletal problems: their low mechanical efficiency and the inadequately designed gripping systems[86-87].

Nevertheless, laparoscopic surgery is being implemented in all areas of general surgery. The improved image resolution and laparoscopic instruments have enabled the performance of more technically complex laparoscopic procedures. However, despite these advances, there have been no changes in the design of the surgical environment and the gripping systems or instruments[88-89]. Although the number of courses in laparoscopic surgery has increased in the last years, very few deal with ergonomic issues[90].

FIVE KEY ASPECTS THAT INFLUENCE THE POSITION OF THE SURGEON
1. Static postures
2. Height of the operating table
3. Design of the grips of instruments
4. Position of the monitor
5. Use of pedals to control diathermy systems

Table 5. Summary of the five key aspects that lead to forced postures of the surgeon in laparoscopy.

The five key aspects that influence the position of the surgeon are described below in order to comment the specific features and current recommendations:

- ***Static postures***: One of the first issues studied was the difference between conventional and laparoscopic surgery, in terms of postural attitude and appearance of physical and mental fatigue[87, 91]. Early studies considered the physical work involved for the surgeon in open and laparoscopic surgery, using for this electromyography (EMG) station (Figure 5). EMG of the arm, forearm and hand muscles is usually the method of choice for determining muscle fatigue related to the exercises practiced[92-93].

It was concluded that in laparoscopy there is greater physical effort and it requires more runtime. *Berguer P. et al.* (1997) focused on the study of the movements carried out by the upper extremity, which are needed during both laparoscopic and conventional methods[94]. Results show that during laparoscopy the surgeon retains a static posture of the neck and trunk, while also having to conduct incorrect movements at the upper end. Maintaining these static positions for long periods of time, increases muscle fatigue. Furthermore, the laparoscopic surgeon tends to maintain a more upright posture, lower back mobility and less change in weight distribution than those who practice conventional methods[95-96]. Additionally, the duration of the minimally invasive surgery in certain procedures is longer than in conventional surgery and the process is more stressful[97]. Most of these authors conclude that new designs in the operating room environment and the instrumental can significantly improve posture and reduce the fatigue and musculoskeletal stress produced[76].

Figure 5. Detail of the ergonomic study. The surface electromyography is combined with three-dimensional video-analysis.

- ***Height of the operating table***: height of manual work tables is the major determinant in the effort required by the upper extremity and, therefore, in the risk of developing musculoskeletal disorders[98]. In traditional surgery, the ideal height of the table matches up the position of the elbow of the surgeon. However, laparoscopic surgery requires the use of longer instruments than those of conventional surgery. This factor, coupled with the abdomen of the patient is higher due to the instruments and the pneumoperitoneum, proves that the optimum height of the tables should be different for both types of surgery[99]. Wrong adjustment of the height of the tables in laparoscopic surgery causes a forced posture on the surgeon, resulting in greater muscle fatigue and discomfort. Consequently, several studies have attempted to determine the optimal height of the table[80, 98, 100]. In fact, one of the first studies that focused on this aspect, concluded that operating tables should be between 64 and 77 cm high, depending on the individual's physical characteristics, which is lower than most available surgery tables[101].

- ***Design of the grips of instruments***: At the moment, there exists a great variety of laparoscopic instruments, which differ not only in role but also in grip, length and design[94] (Figure 6). Although laparoscopic procedures, techniques and instruments used have evolved in recent years, their appearance and functionality remain very similar to the initial designs[102]. The adaptation of surgical instruments to the type of operation and to the surgeon's characteristics has the following benefits[103]: reduced overhead in joints, ligaments and muscles of the upper limbs, avoiding awkward postures and repetitive movements; improved performance and effectiveness in surgery; improved ergonomics in the design of work systems, making them more cost-effective, increasing the efficiency of performance, and reducing operating costs.

Previous studies show that, in general, gripping systems in laparoscopy have an inadequate design, which causes the onset of muscle fatigue, discomfort and even paresthesia[104-105]. Despite recent efforts to make variations in the instrumental, the design of most of the laparoscopic surgery material currently in use has hardly changed, which means that many advantages that the new developments in ergonomics have to offer are being overlooked[86, 102, 106]. The main laparoscopy instrument generally includes a pistol grip mechanism with finger rings. This locking mechanism, apart from being uncomfortable, can cause compressive neuropathies in the thumb, triggering numbness of the fingers and loss of sensitivity[82, 107].

Many authors argue that manipulating such instruments causes a significant increase (compared to that caused by the use of instruments in conventional surgery) in arm fatigue and in the level of muscle force exerted by the forearm, even when performing simple gripping tasks[90, 108-109]. With regards to this, several studies have attempted to analyze and compare the effectiveness of various ergonomic designs, trying to find the most appropriate for the development of laparoscopic surgery. They studied the levels of muscle fatigue caused by the different types of gripping systems of laparoscopic instruments[110-111]. Although there have been few changes in the current instrumental gripping systems that apply ergonomic criteria, these modifications have meant a revolution, due to the many benefits that they have brought up[112].

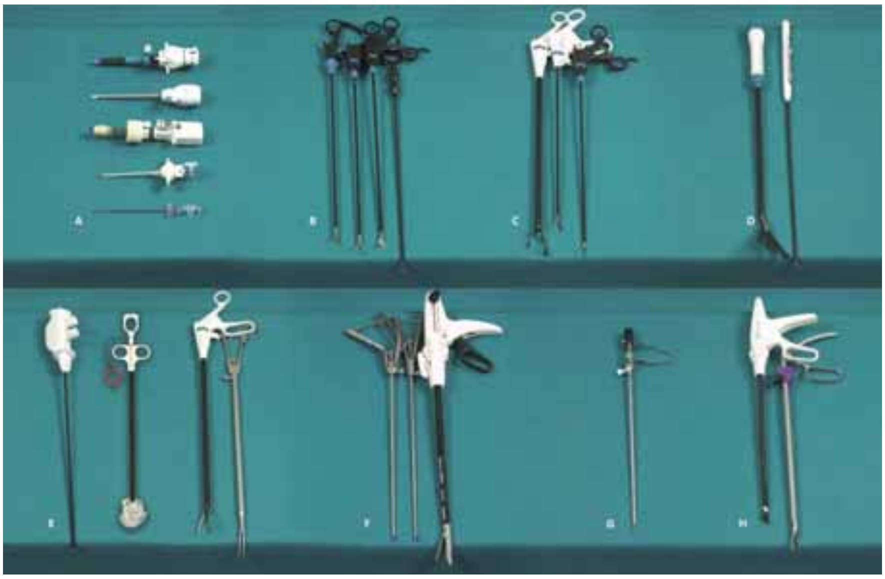

Figure 6. Proposed model for placement of the frequent instruments in laparoscopic surgery.

- ***Monitor position***: Another disadvantage of laparoscopic surgery is the loss of orientation caused mainly by the two-dimensional image, but sometimes also because the monitor is placed in a different direction/position from the surgical field[95, 113-114] (Figure 7). The position of the monitor is important, not only for coordinating movement, but also because it influences the body posture adopted by the surgeon. The monitor has been commonly placed on the laparoscopy tower, making it impossible for the surgeon to adjust its height. This causes discomfort and fatigue in the muscles of the back and neck, especially for short stature surgeons who are forced to continuously look up and consequently straining the cervical spine[115]. Several authors have attempted to determine the ideal position of the monitor in order to minimize stress and fatigue in the muscles of the back and neck. These studies conclude that there should be a monitor opposite the surgeon at eye level, and another monitor at the operative field's level for tasks of high difficulty, because the surgeon becomes less disoriented and can coordinate better the movements required[113].

Figure 7. Surgical team and monitor must be positioned at eye level.

- ***Use of pedal in diathermy systems***: In laparoscopic surgery, diathermy systems are driven by pedals placed on the floor, which increases the risk of errors when stepping them[116]. Therefore, in many cases the surgeon must hold a forced position in order to keep contact with the pedals. *Van Veelen M. et al.* (2004) concluded that the current design of the pedals must be improved and provided some design guidelines[116].

Problem Statement and Aim of this Thesis

Nowadays, the advantages of the minimally invasive surgical approaches are unquestionable in human and veterinary medicine[42, 117]. Laparoscopic interventions versus conventional laparotomy options comprise the following advantages: reduced postoperative pain and hospital stay, less risk of infection, and aesthetic benefits, among others. Thanks to these advantages, this minimally invasive approach has become the technique of choice for many surgical procedures[118-119]. Furthermore, it has improved the surgeons' visualization of the surgical field and anatomical detail, and allowed the entire surgical team to share the same view on the monitor. On the contrary, this procedure requires a more or less extensive learning period to get used to work on a two-dimensional image and its implications: lack of depth perception, diminished tactile sensation (fulcrum effect), and reduced mobility due to the introduction of instruments through the trocars[17]. To overcome these drawbacks, there is now a general consensus on the need of learning using physical, hybrid or virtual simulators. Thus, it has been demonstrated that its use is effective in acquiring and improving surgical skills in laparoscopic surgery. Although the usefulness of the simulation is generally accepted, there is no uniformity of criteria for the simulators used, which implies that the training methods and surgical evaluation of surgeons are not always uniform and objective[51-52].

The main objective of this thesis is to show the development of a Canine Laparoscopic Simulator (CLS) for veterinarians and to determine its usefulness for training laparoscopic surgery. Finally, it aims to assess ergonomic problems in veterinary when performing laparoscopic training tasks with the above-mentioned laparoscopic simulator.

Justification for the Research

Research in this thesis aims at finding optimal training tools in veterinary laparoscopic surgery, which has clear benefits for both animals and veterinarians. As well as in human medicine, there is a need in veterinary medicine of training in minimally invasive surgery outside the operating room, and the physical simulators have played an important role on it in human medicine[120].

Physical simulators already exist and are being introduced in training programs. Moreover, some curricula are being developed with them in human medicine[7, 120]. However, there is scarce information about simulators requirements in medicine veterinary[3-4, 65]. Despite their clear potential advantages, there is no veterinary laparoscopic simulator widely accepted. In addition, there is no universally accepted learning model for veterinary laparoscopy as it exists in human medicine (FLS simulator)[121]. This research wants to develop a Canine Laparoscopic Simulator (CLS) and to arrive to an effective design affordable by every institution to take advantage of the benefits of the simulation technologies.

This study was conducted to develop the specifications of a basic laparoscopic training program in medicine veterinary. The challenge of surgical simulation for training is to deliver a program that improves the learning curve and offers the opportunity to repeatedly practice various laparoscopic skills without risk for the patient. This research also aims to contribute to the definition of a specific training program for veterinarians by determining the relevant aspects. Additionally, the optimization of the laparoscopic training program by improving ergonomics will reduce musculoskeletal disorders and physical fatigue in veterinarians.

II. Hypothesis

This study is part of a thesis-research whose aim is to develop a laparoscopic simulator for veterinarians (CLS, Canine Laparoscopic Simulator) and a specific laparoscopic training program. Based on this approach we have raised a number of hypotheses on the CLS.

H1. The appearance of the CLS should be accepted by the veterinarians of the study, and the training program should be accepted by experienced veterinarians.

H2. The degree of improvement of surgical skills in novice subjects after training on the CLS should shorten the learning curve and decrease their intraoperative errors.

H3. The improved ergonomics in the veterinary laparoscopic surgery training program should reduce the musculoskeletal disorders and physical fatigue.

III. Objectives

The general objective of this thesis is the development, implementation and validation of a Canine Laparoscopic Simulator (CLS) and its training program in laparoscopic surgery for veterinarians. For this purpose the specific objectives will be detailed:

- To describe the CLS for veterinary training and to evaluate its perceived effectiveness during the training performed with this device.

- To assess the content and construct validity of the CLS for veterinarians while performing a set of laparoscopic training tasks.

- To detect and evaluate ergonomic problems in veterinarians during the completion of laparoscopic training tasks using the CLS, by analyzing muscular activity and hand motion.