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TESIS DOCTORAL

ANÁLISIS COMPARATIVO DE INSTRUMENTAL, DISPOSITIVOS DE ACCESO Y CURVAS DE APRENDIZAJE EN CIRUGÍA LAPAROSCÓPICA DE PUERTO ÚNICO EN SIMULADOR FÍSICO

Comparative analysis of instruments, access devices and learning curves in LaparoEndoscopic Single Site Surgery on physical simulator

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Surgery, gaining much from the general advance of knowledge,
will be rendered both knifeless and bloodless.
(John Hunter, 1972)

A mis padres, a quién todo debo.

A mis hermanos, que siempre se queden a mi lado, y yo al suyo.

A los que han llegado conmigo a este lugar en el tiempo.

Y a los que empezaron a vivir otro tiempo demasiado temprano,
y que siempre serán parte de mi.
Esta va por vosotros dos.
Saudades.

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ÍNDICE

LIST OF ABBREVIATIONS

MIS	Minimally Invasive Surgery / Minimally Invasive Surgical (approaches)
LESS	LaparoEndoscopic Single-Site Surgery
R-LESS	Robotic LaparoEndoscopic Single-Site Surgery
MARC	Mobile Adjustable-focus Robotic Cameras
MAGS	Magnetic Anchoring and Guidance System
STEP	Single port Transvesical Enucleation of the Prostate
OR	Operating Room / Operating Theatre
NOTES	Natural Orifice Translumenal Endoscopic Surgery
FIS	Fondo de Investigación Sanitaria
a-GRS	Adapted Global Rating Scale
OSATS	Objective Structured Assessment of Technical Skills
SILS	SILS™ Port, Covidien, USA
GPN	GelPOINT Advanced Access Platform, Applied Medical, USA
XCN	XCONE, Karl Storz GmbH, Germany
ART	Dynamic articulating single use LESS instrument
PRB	Pre-bent reusable LESS instrument
STR	Straight laparoscopic instrument

I. Introduction

Over the past decades, minimally invasive surgery (MIS) approaches have gradually become a plausible alternative for the great majority of surgical interventions, with laparoscopy already representing the standard of care in most scenarios. From the continuous development of the numerous available strategies and the growing demand for scarless results, Laparoendoscopic Single Site (LESS) surgery has emerged to constitute the nowadays most rapidly evolving option. Among its potential advantages we find the decrease in postoperative pain, lower incidence of wound complications and better cosmetic outcome when compared with laparoscopy. However, and due to entailed technical difficulties derived from nowadays limitations of available equipment and surgeons' ability to guarantee patients' safety, it has yet to be applied to daily clinical practices worldwide.

Although many surgical teams have been attempting to benefit their patients with this theoretically less invasive alternative, surgeons are still confronted with various technical drawbacks related to the proximity of instruments through single entry ports that allow access to the abdominal cavity: lack of triangulation, reduced quality of field exposure and tissue traction, external and internal clashing of instruments, limitations to procedural safety, among others.

Simultaneously, and since its early beginnings, many laparoscopic training models and resources have been adapted, or directly used, for the learning and acquisition of LESS skills. Several specialized teams in training centres and hospitals are now guided by a consensual White Paper on LESS published in 2010, and apply a stepwise program in their courses on this demanding new approach. Herein, and preferably including surgeons with extensive experience in other alternatives like laparoscopy, attendants are initiated by expert tutors on simple tasks on box trainers and follow on to carry out entire procedures on the most adequate animal model, according to their specialty. Afterwards, surgeons assist on procedures performed by their course tutors on real human patients to observe the constraints entailed by LESS on a true clinical scenario. Once all these steps are completed, the now trained professionals are accompanied on their first cases, until attainable proficiency is achieved.

After decades of experience in surgical training, our centre applies the same training method. Its first phases constituted the basis of this preliminary study, and are here subject to compartmental analyzed. It is our group's belief that only a specific training program in LESS will progressively allow for optimal operative times and maintenance of standard minimal invasive procedural safety for the patient.

While developing this work at our research centre equipped with dry and wet laboratory facilities, we further hypothesized that, with regulated training and validated learning methods, laparoscopic surgical skills could in fact be translated to LESS, without the need to acquire expensive aiding devices or the use of any additional ports. The abilities could later be applied to real surgical scenarios, in an effort to maintain operating surgeons' comfort and patients' safety.

We hope that the results obtained with this work will shed light on the means to safely apply LESS surgery with the current available technical resources, along with the identification of the limitations and the advantages of such means, and we will further be able to contribute with experimental scientific evidence regarding the amount of training necessary to gain proficiency in these physical simulator manoeuvres.

1.1 OBJECTIVES

With this hands-on simulator experimental study, we aimed to:

1. Assess the relative technical difficulty and performance benefits of the use of dynamic articulating and pre-bent instruments, combined or not with conventional laparoscopic tools, during the completion of basic and intermediate skills simulation tasks by surgeons initiating their training in LESS surgery;

2. Establish the differences regarding instrument-dependent learning progress, hopefully providing insight into the most easily adoptable LESS access device, which may influence not only training and simulation performance, but also the applicability of this approach in the clinical setting. Herein, we expect to be able to compare the ease of use of three different LESS access devices in the same controlled experimental tasks and provide information on which of the available access device alternatives will better fit the needs of surgeons in all specialties;

3. Analyze the learning curve for pure LESS intracorporeal suturing on box trainer;

4. Complete our analysis with a comparison between the different levels of previous experience in minimally invasive surgical approaches and its influence on the performance of LESS manoeuvres.

II. State of the Art

2.1 LaparoEndoscopic Single-Site Surgery (LESS)

In the field of minimally invasive surgical (MIS) approaches, laparoscopy has established itself in the last decades as a less traumatic alternative and even as the gold standard for many therapeutic interventions[1]. This MIS strategy presented excellent results over the years in terms of patient recovery and reduction in surgical trauma. However, the will to further improve post operative outcomes has led surgeons to develop new tactics to enter the abdominal cavity, simultaneously stimulating technological developments for its safe application.

LaparoEndoscopic Single-Site Surgery (LESS), which consists in the reduction in the number of trocar incisions to a single incision in the abdominal wall, requires the introduction of both instruments and vision systems through a single access device or through conventional trocars placed in different close fascial incisions under one single skin incision of about 2-3 cm.[2] Usually, and in the search for "scarless" results, the most common point of entry is at the umbilicus as it allows for nearly undetectable reconstruction, being in itself a natural "scar". Although this field has lately experienced great evolution, initial reports on single incision surgery appeared as early as 1972 in Gynaecology[3, 4], or in General Surgery with the first reported cholecystectomy in 1997[5], carried out without the need for extra entry ports. The prompt recognition of such procedures has nevertheless been impaired by the amount of acronyms and terms (SPA, SILS, NOTUS, OPUS, etc.) attributed over the years to the single incision technique[6]. In 2009, a group of dedicated expert surgeons formed LESSCAR[2], a specialized consortium that, among other aspects, determined the acronym LESS as the most accurate to characterize the broad aspects of the field.

On its White Paper[2], and alongside with the distinction between the two single-access strategies (use of single access specialized device or the introduction of multiple laparoscopic trocars through one single skin incision), another practical distinction that should always be reported on published studies relates to the resources used for the establishment of abdominal access and for the completion of surgical manoeuvres. In this manner, LESS can be considered pure, if no aiding port or percutaneous instrument is introduced to restore triangulation or favour tissue retraction; or hybrid or assisted, when small diameter instruments (2-3mm, 5mm) or other devices are placed to reduce the ergonomic and functional impairments of LESS surgery[6].

Despite evident difficulties, early reported experiences have varied in the different medical specialties, which forced a classification of the several surgical procedures in terms of feasibility and suitability when completed through LESS[1].

Extirpative procedures are usually considered feasible and perfectly suitable, especially if linear staples can be used (appendectomy, gastric sleeve resection, left pancreatectomy, splenectomy, left colorectal resections, ovariectomy and nephrectomy).[7-10] Cholecystectomy, as with Laparoscopy, constituted the most common performed procedure in the first years of LESS, and is therefore considered to be highly feasible through single-site surgery, although with limitations in severe inflammatory or perforated cases. Adhesiolysis is also found to be suitable through this approach as long as adhesions are not too complex, and hernia repair techniques have been regarded as feasible by transabdominal techniques[1].

Concerning reconstructive procedures, surgeons' experience is limited and has been determined by the development of different suturing[11, 12] or robotic tools[13], or the use of additional transabdominal trocars for the completion of advanced intracorporeal manoeuvres. Fundoplication as well as gastric bypass procedures are considered of limited feasibility and suitability through pure LESS surgery.[1]

Since its early beginnings, LESS surgery has been regarded as an approach that entails several potential post operative advantages, namely the reduction in pain scores and in the incidence of wound infections, faster recovery with consequent decrease in hospitalization times, and improved cosmetic effect. Among the different published studies, the true benefits of LESS remain to be confirmed as superior to the established advantages of laparoscopy, the latter being better in every aspect with the exception of improved cosmetic results[10, 14-18], which result directly from the decrease in number of incisions and placement of one single incision at the umbilicus, a naturally hidden site that avoids muscle lesions. Furthermore, and although some authors have published reports on improved pain scores[19, 20] and faster recovery[21], there is still a gap in what concerns controlled randomized studies with longer follow-up periods. These are absolutely needed to prove that LESS provides further reduction of surgical trauma compared to laparoscopy, hopefully overcoming its ergonomic difficulties in the process, and providing expectable improvements in patients' healthcare.

Working in line with the vision system through either multiple ports placed in one incision or through specialized single access devices, LESS forces the surgeon to face several intraoperative ergonomic constraints: crossing of the tip of the instruments with consequent inversion on the monitor's image and need for surgeon's total ambidexterity, external and internal clashing between instruments and optical axis, loss of surgical field, image instability, lack of triangulation leading to incapability of tissue retraction or elaborate manoeuvring, and access device torque with consequent loss of pneumoperitoneum[1, 6, 22-26].

Additionally, other aspects1 render the widespread use of LESS surgery a difficult event, as this approach demands for greater economic investment due to the use of expensive disposable single access devices and instruments (expense that can be reduced with reusable alternatives[27, 28], or homemade single access devices[29]), increased operative times with overall increment of surgical costs, and indirect as well as direct costs for the surgeons who need to accomplish a new learning curve in order to safely carry out these procedures. Curiously enough, Lee et al[27] published one study with an improvised single port for appendectomy, where the added operative and post operative costs were reduced compared to laparoscopy. In any case, further evidence is also needed on the economic balance of the application of this approach on health services.

As mentioned before on the first paragraph of this review, technological evolution has accompanied the application of LESS surgery from its early beginnings, stimulated by the ergonomic defaults of the single-site approach. New developments try to provide the surgeon with safer and more comfortable means to complete LESS surgical procedures, and include instruments and cameras that aim to prevent crowding and inadvertent torque, as well as specialized access devices adapted to 2-3cm incisions and equipped with multiple entrance cannulae.

Moreover, new purpose-built LESS articulating platforms and robotic strategies have emerged over the years, to ease the passage from laparoscopy's commodities to existing LESS constraints. The development of suitable technology, apart from the verification of feasibility and safety of the technique, constitute key steps necessary for the broad application of LESS surgery.[7, 30]

2.2 Instruments

In order to surpass conflict of instruments, loss of triangulation and difficult tissue retraction during the performance of single-site procedures, dedicated industry companies and experts worldwide worked together to develop new tools providing solutions to these problems (Table 1, and Figures 1 and 2).[7, 23, 30]

In LESS, there are three basic instrument possibilities available for operating surgeons[30, 31]: dynamic articulating or wristed instruments, curved or pre-bent instruments, and straight or standard laparoscopic instruments, the latter usually used in combination with the first two sets of tools[9, 32, 33]. Surgeons are also presented with the possibility to combine instruments and optics of various lengths, preferably with discrete profiles, in order to achieve separation and decreased crowding near the single-site access.[31] In fact, all purpose-built LESS alternatives have longer shafts than the instruments available for laparoscopy, although usually their length does not vary within the same tool design line.

Dynamic articulating instruments are single use tools, which in the most recent versions present 85° shaft working angles that can be turned in all directions. These are commonly equipped with locking mechanisms and maintain the 360º rotation at effectors' tip. Until the angle is activated, either by wrist positioning or by specific manual controls, these instruments appear as standard laparoscopic tools, and thus can be introduced through all 5mm cannulae. They do, however, demand a learning curve[7] due to right-left crossed triangulation, and low stability when strong tissue retraction is required.

Figure 1. Examples of different single use LESS purpose-built instruments. A, SILS™ Hand, (Covidien, USA); B, Realhand HD®, (Novare Surgical, USA); C, Autonomy™ Laparo-Angle™, (Cambridge Endo, USA).

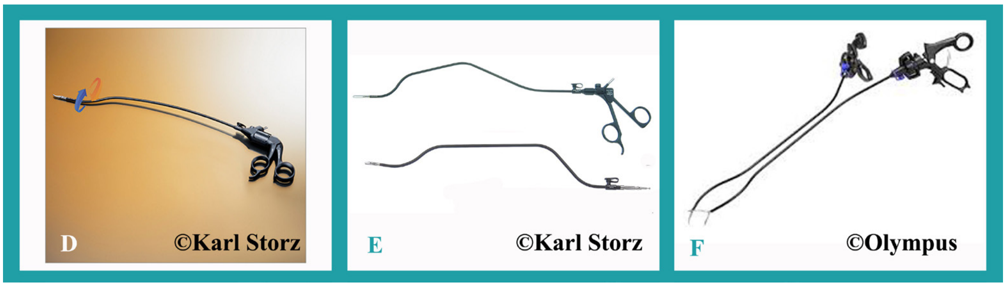


Figure 2. Available reusable alternatives in the LESS surgery armamentarium. D, ROTATIP™ (Karl Storz GmbH & Co. KG, Germany); E, S- Portal pre-bent instruments according to Leroy (Karl Storz GmbH & Co. KG, Germany); F, HiQ™ LS (Olympus Co., Japan).

Designation	LESS adapting strategy	Use	Size (mm)	Manufacturer	Description / Comments
Realhand HD®	Wristed/Dynamic articulating.	Disposable	5	Novare Surgical, Cupertino, CA, USA	Graspers, needle holders, dissectors, cautery, and scissors available. Provides tactile feedback.
Autonomy™ Laparo-Angle™	Wristed/Dynamic articulating.	Disposable	5	Cambridge Endo., Framingham, MA, USA	Graspers, needle holders, dissectors, cautery, and scissors available. Equipped with axial rotation knob and locking mechanism.
SILS™ Hand	Wristed/Dynamic articulating. 85° articulation and 360° tip rotation.	Disposable	5	Covidien, Mansfield, MA, USA	Clinch, dissectors, hook and scissors available. Tip rotates independently and angle of shaft is in tandem with hand deviation from instrument's axis. SILS™ Stitch available for intracorporeal suturing.
S-Portal Pre-bent standard, and acc. Leroy, Cushieri, and Carus	Pre-bent displaceable shaft, with different shapes according to the developer's line.	Reusable	5	Karl Storz GmbH & Co. KG, Tuttlingen, Germany	Scissors, dissector, cautery, hook, atraumatic graspers. Three types of handles are available for assembly.
ROTATIP™	Pre-bent shaft, single shape, rotating tip and displaceable shaft.	Reusable	5	Karl Storz GmbH & Co. KG, Tuttlingen, Germany	Independent jaw rotation, versatile shafts for the left or right hand, one type of handle with laparoscopic-type design. Scissors, dissector, cautery, atraumatic graspers.
KeyPort DuoRotate and InLine	Pre-bent on one or two areas, independent shaft and tip rotation.	Reusable	5	Richard Wolf GmbH, Knittlingen, Germany	Atraumatic grasper, scissors, Maryland dissector and 90° angled dissector
HiQ™ LS	Curved, angulated distal and proximal ends, and rotator action.	Reusable	5	Olympus Co., Tokio, Japan	Independent jaw rotation, versatile shafts for the left or right hand, a low-profile handle design. Scissors, hook, cautery connection, both Maryland and 90°angle dissectors, and multiple graspers.

Table 1. Descriptive list of the different available instrument alternatives for LESS surgery.

Some authors recommend that at the beginning of the learning curve, a novice uses either one dynamic articulating instrument with a straight laparoscopic on the dominant hand, or two of these purpose-built instruments.[30]

Reusable pre-bent instruments entail a decreased need for crossing and better force distribution on their shaft. Surgeons experience a steeper learning curve[31] with these tools due to nonadjustable angles, as the shaft is built following a specific design for each procedure. The different designed lines aim to place the hands in the same axis as the instrument's tip inside the patient, making surgical manoeuvres more intuitive once the surgeon gets used to its design. First generation curved instruments were more cumbersome than the most recent versions, as they also lacked effectors' tip rotation and as such forced the surgeon to twist their hand in order to perform the adequate surgical manoeuvres, leading to the loss of any ergonomic benefit brought by inline images. These alternatives are said to be more cost effective despite of the necessary initial investment[34], and have been reported to reduce operative times once the initial learning curve is surpassed[35].

Both flexible or articulating, and pre-bent or curved LESS instruments require time to master and entail an evident learning curve.[36]

In all surgical approaches, and more so during the performance of MIS, the achievement of proper haemostasis control constitutes a constant concern for the operating surgeon. Although "single-site rescue" should always be present, reflected on the everlasting possibility of conversion to multiple port or even open surgery as a valid option for stopping uncontrollable haemorrhages, several thermal energy delivery systems, staples, clips and mechanical sutures are available, and most can be used through a single access device. Nevertheless, friction and multiple exchanges of instruments through the access cannulae limit LESS procedures, and therefore efforts should be pursued in the development of new strategies to reduce repetitive instrument introduction, leading to decreased instrument deleterious interaction, and maintaining adequate surgical exposure as well as minimizing surgeon distraction and enhancing operative efficiency[2]. Virtually all 5mm thermal or ultrasonic ligation devices (LigaSure Advance™, Covidien, CT, USA; Harmonic™, Ethicon Endo-Surgery Inc., OH, USA; among others) can be used in LESS surgery, as long as they fit through the access cannulae. Stapled suture systems can also be used (Endo-GIA Roticulator™, Covidien, CT, USA), as long as the single access device allows for at least a 12mm entrance, and the assistant is prepared for the loss of field exposure which can be caused by the manoeuvring of a large instrument in a confined space.

Due to the lack of surgery-enabling tissue retraction, and in an attempt to avoid any extra scars on the patient's abdominal wall, numerous aiding exposure strategies have been reported, among which we find: fixation percutaneous sutures that, in turn, may increase the risk of vessel or nerve injury in the abdominal wall[22, 37], devices like the EndoGrab™, a port-free organ anchoring and traction system developed by Virtual Ports Ltd. (Caesarea, Israel)[10, 30, 38], and the resource to minilaparoscopic assistance[2]. The latter consists in the introduction of ancillary 1.9-3mm instruments through a simple skin puncture which does not require closing of the wound, leaving no scar and causing minimal to no morbidity. This form of hybrid LESS enhances patient safety, increases operative dexterity in tissue traction and intracorporeal advanced manoeuvres, and favours the expansion of LESS array of possibilities. On the down side, most of the needle instruments available nowadays require improvements in terms of tensile strength and reliability.

When we consider the desired technological improvements, we observe that special focus

Designation	LESS adapting stategy	Use	Diameter (mm)	Manufacturer	Description / Comments
EndoEye™ Flex HD	Bending tip and camera head connection.	Reusable	5	Olympus Co., Tokio, Japan	Forward viewing angle (0º), 100º degrees bending of the tip in any direction. CCD at the end of the scope, high image quality. Working length of 37cm. Only compatible with Olympus video platform system. Can be associated with robotic camera drivers.
EndoCAMeleon™	Rigid shaft with special vision tip.	Reusable	10	Karl Storz GmbH & Co. KG, Tuttlingen, Germany	Range of vision from 0° to 120°, adjusted with a special knob.
IDEAL EYES HD™ Articulating Laparoscope	Alternates between rigid and flexible tip	Reusable	10	Stryker Endoscopy, San Jose, CA, USA	Over 100° in all directions.
Eyemax CCD Endoscope™	In line design	Reusable	5-10	Richard Wolf GmbH, Knittlingen, Germany	0°-30°, keeps off the instrument axis.

Table 2. Detail of available optical systems for LESS surgery.

Figure 3. Optical systems for LESS surgery. M, HOPKINS® Telescope 5mm, 30º (Karl Storz GmbH & Co. KG, Germany); N, EndoEyeTM Flex HD (Olympus Co., Japan); O, EndoCAMeleonTM (Karl Storz GmbH & Co. KG, Germany).

has been given on optic systems. Commonly, when performing LESS surgery, practitioners opt by a versatile 5mm 30º rigid laparoscope, operating out of axis with the instruments. Entering side by side with right and left instruments and at times with a fourth instrument placed through the single access device for retraction purposes[1], improvements and purpose-built designs have centred on various strategies.

Among these, we find slimmer profiles and extended lengths (up to 50cm), which reduce the transmission of light and convey poorer surgical view[30], in line configuration or right angle adapters for light cables, and angled camera heads, but also more complex digital platforms equipped with bending tips like the EndoEye™ Flex HD (Olympus Medical, Tokio, Japan), or even optics inherently equipped with dynamic vision axis modifications as the EndoCAMeleon® (HOPKINS® Telescop, Karl Storz GmbH & Co. KG, Tuttlingen, Germany).[39] The use of special laparoscopes increases costs and requires extensive experience in camera assistance.[1]

2.3 Access Devices

No advantageous differences have been reported to this day between the different purpose-designed access devices for LESS, with the surgeons' preference usually conditioning the choice between the different available alternatives.

Available single-access devices can be classified into three broad categories: according to access[30] (gel, multiple channels or structural access), wall retracting technology[30] (sleeve, soft structural retraction or rigid structural retraction), and on the basis of use (multiple use or reusable, or single use devices).

The use of a special single-access trocar usually leads to an approximate minimum of 300€-350€ of extra costs in the case of disposable devices[1]. A few cases have reported the use of homemade devices[29], a cost effective strategy compared to commercialized alternatives. Complete description of all available access devices can be consulted on tables 3 and 4.

Among the most used disposable ports we find the Quadport® (Advanced Surgical Concepts/Olympus, Ireland)[40, 41,] SILS™ Port (Covidien, MA, USA)[10, 42, 43], and the GelPOINT Advanced Access Platform (Applied Medical, CA, USA)[44, 45]. The AirSeal®[25] has not been widely accepted and the readjustment regarding its field of application followed close after its launch, although it provided reports on the reduction of intraoperative times by 15%[46].

On the other hand, one of the newest available options is the OCTO-Port™ (Dalim Surgnet, Seoul, Korea) which, after initial positive reports[47, 48], is becoming very popular among general surgeons for its versatility in the use of instruments of various diameters and the provided advanced manoeuvrability.

The use of rigid sterilizable alternatives has also played an important role in the last years, as low cost options for LESS procedures despite of the necessary initial investment, as reported by Schwentner et al[49] with the use of the XCONE (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) for the performance of several urologic procedures in 52 patients.

Recently, the KeyPort[23] (Richard Wolf GmbH, Knittlingen, Germany) has additionally been used as a possible single access system for the teaching and the acquisition of skills in LESS surgery. Also, in Urology, Greco and colleagues successfully completed a series of partial nephrectomies on 33 oncologic patients with the ENDOCONE (Karl Storz GmbH & Co. KG, Tuttlingen, Germany)[50].

2.4 New LESS Platforms, Systems and Robotic Tools

In 2009, when Kaouk and colleagues[51] started their trials with robotic-assisted LESS procedures, a promising path for single-site surgical approach was set[6]. Several platforms have since then been designed and developed for Robotic LESS (R-LESS), and include Da Vinci S VeSPA (Da Vinci System, Intuitive, Sunnyvale, CA, USA)[52-55], and the SPIDER Surgical System (TransEnterix, Morrisville, NC, USA) [56-58].

Benefits of da Vinci S[59] include superior ergonomics, optical magnification of the operative field, enhanced dexterity, and greater precision. The robotic platform allows for the crossing of the instruments inside the patient without any consequence for the surgeon, who can just invert the controls and operate as if there was no crossing.[30]

The SPIDER platform is constituted by an 18mm cannula with four working channels (two are flexible and allow for 360º movements, and the other two are rigid), and three distinct ports for insufflation or smoke evacuation. The steerable tubes through which the instruments are introduced can be bent in such way as to restore triangulation.[30] At least one study on porcine model has established the feasibility of cholecystectomy with the SPIDER platform,

Figure 4. Three of the nowadays most common single use LESS access devices. G, SILSTM Port (Covidien, USA); H, GelPOINT Advanced Access Platform (Applied Medical, USA); I, OCTO-PortTM (Dalim Surgnet, Korea).

Figure 5. Various options regarding multiple use single access devices. J, XCONE (Karl Storz GmbH & Co. KG, Germany); K, ENDOCONE® (Karl Storz GmbH & Co. KG, Germany); L, KeyPort (Richard Wolf GmbH, Germany).

Brand	Lumens	Access	Retracting Tech.	Use	Incision size (cm)	Manufacturer	Description / Comments
R-Port/Triport	2x5mm, 12mm	Multiple channels	Sleeve	Disposable	2-3	Advanced Surgical Concepts/Olympus, Wicklow, Ireland	These devices vary in number of available ports, but the same plastic wound protectors are used for abdominal wall retraction. The Quadport allows for enhanced movement freedom when the same number of instruments is inserted. Equipped with a blunt tip introducer tool for safe and easy insertion into the abdominal cavity. The retraction sleeve provides wound protection and favours specimen removal. It self-adjusts to different incision lengths and accommodates abdominal wall thicknesses up to 10 cm.
Quadport	5mm, 15mm, 2x10mm	Multiple channels	Sleeve	Disposable	2.5-6.5	Advanced Surgical Concepts/Olympus, Wicklow, Ireland	
Uni-X	3x5mm	Multiple channels	Rigid Structural	Disposable	2	Pnavel Systems, NJ, USA	Maintains a cone-like structure outside of the incision, allows for the insertion of curved and straight instruments. Additional port for gas insufflation.
SILS™ Port	3x5mm, or 2x5mm, 12mm	Structural access	Soft Structural	Disposable	2	Covidien, Mansfield, MA, USA	Foam structure, with small cannulae insertion holes. Maintains pneumoperitoneum by naturally adapting to the incision. It admits up to four instruments and optics, if the insufflation channel is removed (CO_2 can enter through one of the luer-lock equipped cannulae).

Table 3. List of available single use LESS access devices, and its main characteristics.

Designation	Lumens	Access	Retracting Tech.	Use	Incision size (cm)	Manufacturer	Description / Comments
GelPORT Advanced Access Platform	3x5-10mm, 1x5-12mm	Gel	Sleeve	Disposable	2-7	Applied Medical, Rancho Santa Margarita, CA, USA	Any trocar can be introduced through the gel cap. Pseudoabdomen platform, with minimal resistance to external mobility and adequate maintenance of pneumoperitoneum. Newer versions of this access device are available: GelPOINT Mini Advanced Access Platform (5-10mm trocars), for smaller incisions (1.3-3cm) and smaller specimen extraction; and GelPOINT Path Transanal Access Platform (5-10mm trocars), for transanal resection of distal benign and malignant lesions. It is relatively expensive compared to SILS™ Port and Triport.
OCTO-port™	5-12mm (ports can adapt to different instrument diameters)	Multiple channels	Sleeve	Disposable	3 and 5	Dalim Surgnet, Seoul, Korea	Detachable soft silicone cover, varying from one to four channels. Two sizes: 30 and 50mm. Performs smoke filtration during insufflation. Cap can be levered or rotated.
Airseal®	not applicable	Structural access	Rigid Structural	Disposable	3	SurgiQuest, Connecticut, USA	Built with no physical sealing mechanism, but maintaining pneumoperitoneum by creating an air vortex inside (noise pollution in the OR). Technology currently adapted to regular trocars of 5mm, 8mm and 12mm.

Table 3 *(cont.)*. List of available single use LESS access devices, and its main characteristics.

Designation	Lumens	Access	Retracting Tech.	Use	Incision size (cm)	Manufacturer	Description / Comments
KeyPort	5mm, 10mm, 15mm	Multiple channels	Rigid Structural	Reusable	< 3	Richard Wolf GmbH, Knittlingen, Germany	The seal is made of high-tech silicone, extremely flexible, very resilient and reusable. There ia a fourth port built-in the seal cap, available for perforation by an instrument if necessary.
XCONE	4x5mm, 10mm	Multiple channels	Rigid Structural	Reusable	2.5-3	Karl Storz GmbH & Co. KG, Tuttlingen, Germany	Three operating channels on a detachable plastic cover. Separate valve for insufflation inserted on metallic structure. Diametric anchoring to internal abdominal wall.
ENDOCONE®	5x5mm, 2x10mm	Multiple channels	Rigid Structural	Reusable	3.5-4	Karl Storz GmbH & Co. KG, Tuttlingen, Germany	More than three operating channels can be considered for use, through a metallic lid with sealing plastic valves. Separate valve for insufflation inserted on metallic structure. 360° anchorage to internal abdominal wall.

Table 4. List of some of the most common multiple use LESS access devices, and its main characteristics.

Figure 6. New surgical platforms and devices that favour LESS procedural. P, Radius® surgical system (Tuebingen Scientific Medical GmbH, Germany); Q, EndoGrabTM (Virtual Ports Ltd. Israel); R, SPIDER Surgical System (TransEnterix, USA).

with less tissue trauma when compared with the four-port laparoscopic procedure.[57] Other reported procedures include colectomy and adjustable gastric banding.[58]

The use of instruments or devices that take advantage of magnetic forces is gaining popularity nowadays. In the Magnetic Anchoring and Guidance System (MAGS)[60, 61], instruments are delivered intracorporeally through the single entry site, and are anchored and manipulated externally by magnetic devices. This platform, still under development, will in the future allow for continuous adjustable positioning of available camera, hook and graspers, reduction in collisions, improvements in visualization and renewed triangulation. However, magnetic systems are inevitably limited by abdominal wall thickness and distance to the surgical field, as well as limited illumination of surgical field, aspects that are currently under amelioration. Similar internally deployed systems include Mobile Adjustable-focus Robotic Cameras (MARC) and mobile biopsy graspers. Other robotic-type tools can also be introduced through the port but maintain a base that exits through the same port which results uncomfortable, requiring wireless control improvements for better intraoperative ergonomics. These tools also lead to fewer instrument collisions, improve surgical space and provide an image comparable to the 5mm laparoscope[60]. Applications for these tools are still limited and new developments are focused on increasing battery life and manoeuvrability[31, 62], as well as developing cleansing and wireless mechanisms[63].

Among simpler alternatives, we find the Radius® surgical system (Tuebingen Scientific Medical GmbH, Tuebingen, Germany) which represents an intermediate stage of development between conventional laparoscopic instruments and electromechanic robotic systems. Although these instruments need further refinement, they have been successfully applied in the clinical practice, and reported as ergonomically adequate[64].

Future perspectives for LESS instrumentation look promising, despite the excessive costs of some of these devices which may limit its application, regardless of the benefit that they might entail for the patient and healthcare system.[30]

2.5 LESS on experimental in vivo models

Feasibility studies on experimental models are essential to understand the limitations of LESS and its resources before its routine application to clinical patients.[2, 65]

Stolzenburg and associates performed nephrectomies on porcine animal models with the aim to clarify effectiveness and manoeuvrability of the different available instruments for LESS.[35] Similarly, in order to test different sets of reusable instruments and access devices, Autorino et al[34] performed a total of 12 nephrectomies in swine, objectively comparing their results by measuring device insertion and operative times, and carrying out a subjective assessment of the different technological resources by evaluating freedom of movements, CO_2 leakage, and triangulation, among other parameters.

Cáceres et al[66] used 20 porcine models to complete the second level training of hands-on animal model practice. A single-access device (KeyPort, Richard Wolf GmbH, Knittlingen, Germany) was introduced in all animals at umbilical level to complete lymphadenectomies, bilateral total nephrectomy, cystotomy and cystorrhaphy, and uterovesical anastomosis.

The use of intralumenal magnets was also subjected to numerous trials[60, 67-69], some on porcine animal models like in the case of Leroy et al[70], who used these tools to assist in single-port sigmoidectomy. Also, in 2011, Cusati and colleagues[71] performed multiple laparoscopic procedures to compare the available single access devices, electing the swine model to do so.

Regarding robotic LESS (R-LESS), Haber et al[52] explored the feasibility and efficiency of VeSPA, a new modification of the Da Vinci S robot, on 4 female swine through the performance of 16 extirpative and reconstructive renal procedures.

2.6 Ethical introduction of LESS surgery

The concept of LESS surgery awoke uncertainty among the members of the scientific community in a variety of essential aspects.[72] Should we use one big incision instead of multiple small almost undetectable trocar entrances? Does this new approach represent a truly advantageous alternative compared to the already established laparoscopic standard? Other questions orbit around aspects like the safety of LESS procedures performed by trained surgeons, or if this approach is appropriate for every case of cholecystectomy for example, or does patient and procedure selection condition its application[31].

Larger incisions compared to laparoscopy may imply increased risk of incisional hernias (especially if placed at the umbilicus where the muscle layer is thinner), increased pain due to fascial dissection, and higher chances of infection. Regardless of complication risks, advantages of LESS must be clearly defined by prospective randomised trials before its worldwide acceptance as a superior approach[17]. And if, at the end, better cosmetic results are the only proven benefit, this should be clearly stated by surgeons' and it should be adequately explained to patients.[72]

A primary focus on safety must be attained, and the practicing surgeon should be aware of the idea of LESS rescue at all times, simply achieved by conversion to multiport laparoscopy or open surgery. Another essential priority should be the development of trainable and attainable techniques.[26, 30] The patients' wish for "scarless" surgery should not be disregarded as irrelevant, but not at the cost of increased risks and complications.[73]

2.7 Current Clinical experience

Numerous clinical cases and multiprocedure series have been published in all surgical specialities. Patient inclusion criteria have been defined in human medicine and initially focused mainly on BMI, acute inflammation and registry of previous abdominal surgeries[1, 22], although it has lately been used for bariatric surgery with a BMI>40[10]. One consensual idea that should be present at all times for the operating surgeon is the need to consider a low threshold for the introduction of one or two extra trocars or convert to open surgery, always keeping in mind the best interest and the safety of the patient[74].

In Urology, Raman et al[75] and Desai et al[76] provided the first reports on single incision multiport nephrectomy and single-port transumbilical pyeloplasty, respectively. After comparing these procedures with its laparoscopic and conventional surgery registries, they stated that a high selectivity for oncological and partial nephrectomy procedures is essential, and that the LESS technique is feasible, with low conversion and complication rates. Studies published afterwards[17, 21, 77] showed no significant benefits of LESS over other approaches in terms of post operative analgesia requirements, length of stay or operative time. One of these studies did notice an increase in operative time attributed to the learning curve, and less pain after oncologic extraction of partial nephrectomy specimen through the umbilicus instead of using a low pfannenstiel incision.[21] Among the different MIS urologic procedures performed by LESS surgery, we find simple prostatectomy (with or without ancillary ports, and/or robotic assistance), STEP (transvesical enucleation of the prostate), pyeloplasty, donor[78], partial, radical and simple nephrectomies, and renal cryotherapy.[31, 79]

Described procedures for General and Gynaecologic Surgery include the first single incision tubal ligation in 1972[4]. Afterwards, other gynaecologists followed Wheeless footsteps and carried on to perform advanced techniques such as total abdominal hysterectomy[80]. Other procedures include cholecystectomies, appendectomies, upper gastrointestinal (GI) surgeries, few hepatopancreatobiliary procedures, adrenalectomies, colorectal surgeries, as well as bariatric interventions.[5, 10, 25, 30]

In Veterinary Medicine, some professionals have adapted the knowledge acquired with the human experience, and benefited their patients with single access or single port ovariectomy, promoting better recovery and virtually no scar in spayed dogs and cats[81-84]. Other “LESS” techniques applied in Veterinary patients include thoracoscopic and laparoscopic exploration, lung, liver, pancreas and intestinal biopsy, gastrectomy, among others[85].

2.8 Training in LESS

In 2009, it was unanimously recommended by the LESSCAR2 that each surgeon should possess standard laparoscopic experience and should have undergone a certain amount of training in LESS. Like our centre’s training program[65, 86], their White Paper2 states the necessity of a stepwise training, starting with inanimate box trainer hands-on sessions where the surgeons gets acquainted with all available instruments, access devices and purpose-built vision systems. Attendants should then proceed to hands-on training on animal model[86], if possible, and carry on to the observation of live clinical LESS procedures followed by tutoring and guidance during the initial elected cases.

On box-trainer or physical simulator, tasks should be successful in favouring the development of ambidexterity, depth perception, handling materials, manipulating instruments and access devices, and completing the required basic and advanced manoeuvres in a fluid and rhythmic manner[87].

Several programs have been instated for LESS training, as some authors considered that previously validated programs for laparoscopy[88] may eventually be inappropriate for adequate skills acquisition in single-site surgery[89]. Most current programs thus include several coordination, cut and dissection tasks hands-on box trainer[86, 89], and even ex-vivo suturing models[90], whilst some add live animal surgery[86, 89, 91] and video sessions[89], with the aim to understand both technique and technical resources of LESS.

Although there is still no validated standard curriculum for LESS skills acquisition, or a full extent analysis of the learning curve for this approach, extensive preclinical training both ex vivo on box trainer, and in vivo on animal model are highly recommended, with a gradual transition to clinical patients afterwards, preferably with the use of minilaparoscopic hybrid

LESS approaches[74, 86, 87].

Regarding the most adequate exercises for correct skills acquisition in the first steps of training, and whatever the choice might be, the program should include tasks with both face and construct validity. Each exercise should focus on one or two different abilities. As an example, coordination exercises focus on the combined use of vision and hand movement, and cut tasks focus more on bimanual dexterity and tissue handling. More advanced exercises like intracorporeal suturing further build bimanual dexterity, depth perception and hand-eye coordination. All the mentioned tasks have shown transferability of abilities to real clinical situations, which is another important factor to take into account when considering any training program.[92]

Only a specific training program in LESS will allow for optimal operative times and standard safety for the patient. As it is a more demanding approach from a technical point of view, the learning curve will probably vary according to the surgeons' skills and previous MIS experience[66, 86].

2.9 Interest of the Minimally Invasive Surgery Centre Jesús Usón in this Line of Research

The MISCJU is a centre specialized in research and training of minimally invasive surgical techniques. With over 20 years of experience, the centre has made several efforts to perfect and disseminate emerging techniques in this field. Following this ideology, the Laparoscopy Unit of the MISCJU opened a research line focused in LESS and Natural Orifice Translumenal Endoscopic Surgery (NOTES) and its technological developments, as well as technical feasibility of procedures by the pure forms of these new MIS tendencies.

On the other hand, the professional quality of its personnel, the modern facilities, and the efficient management strategy make the MISCJU a reference centre for the learning of these techniques. Our yearly statistic data concerning our training and result dissemination activities can be resumed as follows:

- Over 100 hands-on courses for different experience and skills' levels, of which more than 60% are related to Laparoscopic Surgery, and at least 4 activities are already exclusively focused on LESS and NOTES approaches.

- Around 40 personalized training stays, of which more than 85% are dedicated to Laparoscopic training.

- Participation on and organization of national and international congresses and seminars.

During these activities and collaborative projects, our group maintains constant contact with several experts from various areas of Spain, that share with us their concerns regarding the difficulties and lack of technological solutions for LESS surgery. From this exchange of ideas, we decided to determine the exact limitations of the most probable LESS surgical scenarios and designed a project in which this thesis' objectives are included. As so, we fulfilled the requirements to win the national research grant for the project PI12/01467 attributed by the Institute of Health Carlos III - FIS of Spain.

This study intends to set the base standards for an ideal definition of LESS surgical setup on surgical simulator. The second phase of the granted national FIS project will use the knowledge gathered in this initial phase, and further tests will be performed on porcine animal model, this turn including newly developed ancillary robotic tools.

At the end of the FIS project, MISCJU hopes to have set the standards for the ideal LESS and robotic aiding instruments, most convenient access device for each port, and the exact pre clinical learning curve for single-site dissection and suturing manoeuvres. Hence, with generated knowledge, we aim to design more adequate technological resources for LESS surgery, and define universal guidelines for its training and the attainment of proficiency in this approach.

III. Material and Methods

3.1 MATERIAL

<u>*Operating Theatre Setup*</u> (Figure 7)

For the different tasks that constitute this study we used the following material:

- Physical simulator and task templates:
  - Validated physical simulator[93] SIMULAP® (MISCJU, Cáceres, Spain), set on an operating table adjusted for individual height;
  - Articulated metallic arm for optics stabilization;
  - Coordination wells plate, with chickpeas and thumbtacks (®MISCJU, Cáceres, Spain);
  - Level 1 cut template (®MISCJU, Cáceres, Spain);
  - Ex-vivo organs: porcine half stomach and porcine male bladder and urethra;
- Laparoscopic Tower:
  - 10mm, 0º rigid laparoscope (Karl Storz GmbH, Tuttlingen, Germany);
  - 3 CCD HD1 Camera head (Karl Storz GmbH, Tuttlingen, Germany);
  - Laparoscopic xenon light source (Karl Storz GmbH, Tuttlingen, Germany);

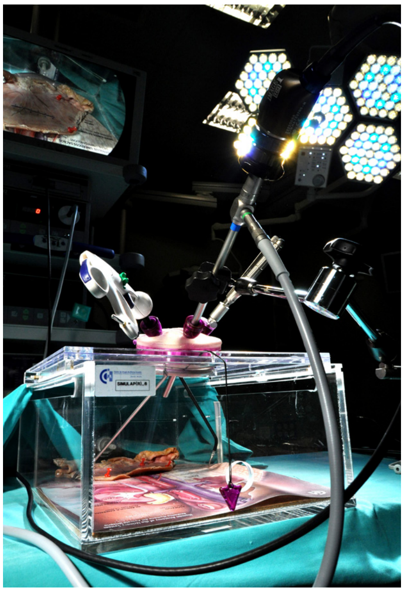


Figure 7. Operating theatre setup, prepared for linear intracorporeal suturing task with the use of GelPOINT Advanced Access Platform (Applied Medical, California, USA).

  - 21″ HD Wide View monitor (Karl Storz GmbH, Tuttlingen, Germany).
- LESS instrument lines:
  - SILS™ Hand, Covidien, Mansfield, USA;
  - S-Portal™ CLICKLINE, according to Leroy, Karl Storz, GmbH & Co, Tuttlingen, Germany.
- LESS access devices
  - SILS™ Port, Covidien, Mansfield, MA, USA;
  - GelPOINT Advanced Access Platform, Applied Medical, CA, USA;

- XCONE, Karl Storz, GmbH & Co, Tuttlingen, Germany.

• Other material:

- DVD recorder (Sony®, Showview™, Dolby™ RDR-GX2200);

- Multifilament sutures (Polysorb™ 2/0 (CL-883), Syneture, Covidien, Mansfield, USA).

• Validated objective performance assessment scales:

- Adapted-Global Rating Scale (a-GRS) for coordination and cut tasks[94];

- Objective Structured Assessment of Technical Skills (OSATS)[95];

- Task specific Checklist 1/0[96] for intracorporeal suturing tasks.

3.2 METHODS

<u>*3.2.1 Method justification*</u>

Study subjects and groups according to previous MIS experience level

In previous published works, the definition regarding a minimum number of subjects per group was set at 9, in order to obtain significant differences with an α of 0.05 and a study power of 0.80 when using objective assessment scales[97]. In this study, we were able to recruit a population of 24 subjects among the MISCJU's personnel. We were however limited in what concerns availability of subjects for each experience level. As such, we complied to Palter et al[97] determination of minimum number of subjects for both novice and laparoscopic experienced participants. This condition was nevertheless impossible to achieve with the LESS experienced group, due to continuous nature of the study and the short evolution time of the technique.

Use of a physical simulator and elected tasks

The acquisition of surgical skills using simulators has gained momentum in recent years due to important time and economic limitations that compromise training in the operating room[98, 99], along with ethical and medical concerns about patient safety.[98, 100] The SIMULAP®, a physical simulator developed at our centre, has been previously validated[93], and is thus adequate for the training and acquisition of skills in MIS.

Regarding the elected tasks, we based our choice on the extensive training experience acquired by the MISCJU in the last 20 years of activity. Among the available possibilities, we selected those that could favour a better demand of specific skills and transferability of learnt manoeuvres[92]. In this manner, we chose a basic coordination task to focus on eye-hand coordination, and a cut task as an intermediate difficulty level exercise, which favours the enhancement of bimanual dexterity and the improvement of tissue handling. More advanced tasks combine several other essential skills and help to distinguish between experience levels. For this study we chose two intracorporeal sutures of increasing difficulty thus analyzing the improvement of dexterity and depth perception of each subject.

Choice of Instruments and Access Devices

For this study we considered the most readily available instrument alternatives for LESS surgery at the time of the beginning of the trials.

Once the comparisons between different instruments were completed, and based on available literature[9, 32, 33, 101] and experts' advice, we opted for combining purpose-built tools with conventional laparoscopic instruments, standardizing the performance of each task for access device comparison and intracorporeal suturing analysis. The use of the same tools on more demanding exercises favours subjects' adaptation to the LESS approach and platform stability during the completion of the aforementioned trials.

Concerning the LESS access devices, we chose three of the most commonly used, and sampled each from one of the attributed classes[30]. Thus, we were able to carry out a comparative analysis between the main characteristics of the available alternative for single access surgery.

Schedule

At the beginning of the study we established a subject-specific random rotation, in order to prevent biased outcomes resultant from acquired task knowledge. The trials were distributed over time but the intense training schedule was intended to build enough self confidence on the newly acquired skills, and favour translational passage of this knowledge.[102]

Assessment Methods

Subjective assessment questionnaires allowed us to establish contrast between the objective performance scores and the subjects perception of the single access devices, as well as the training tools used in the structured learning program. All these constitute influential factors for the general population of LESS practicing surgeons when faced with the question of choosing the most adequate single-access device and the best process for the learning of basic necessary operative skills in order to perform safe patient interventions.

Objective assessment scales for performance scores determination during the different tasks have previously shown validity[94-96], and herein been used to obtain significant differences between the different assessed parameters.

Assessments were performed over DVD video recordings of the different trials, which enable multiple raters to perform a reliable evaluation within a shortened period of time whilst adapting time for assessment observations to their daily routine[103].

Comparative analysis	Technological setups	Assessment trials	Objective Assessment Parameters	Subjective Assessment Methods	
LESS instrument alternatives	ART-ART ART-STR PRB-PRB PRB-STR	Coordination trials (Ti, Tf)	a-GRS Completion time		Questionnaire on training method and resources
		Cut trials (Ti, Tf)	a-GRS Completion time		
LESS access devices	SILS with ART-STR	Cut Trials (W1-W9)	a-GRS Completion time	Questionnaire on Technical and Functional Aspects	
	GPN with ART-STR	Linear intracorporeal suturing (W1-W9)	Summative Score Completion Time		
	XCN with PRB-STR	Circular intracorporeal suturing (W1-W9)	Summative Score Completion Time		
LESS learning curves	SILS with ART-STR	Linear intracorporeal suturing (W2-W7)	Summative Score Completion Time		
		Circular intracorporeal suturing (W2-W7)	Summative Score Completion Time		

Table 5. Different elements of the study design, defined according to each comparative analysis. ART-ART: two dynamic articulating instruments; ART-STR: one dynamic articulating instrument combined with a straight conventional laparoscopy tool; PRB-PRB: two reusable pre-bent instruments; PRB-STR: one pre-bent instrument used in combination with a straight laparoscopic tool; SILS: SILS^{TM} Port (Covidien, USA); GPN: GelPOINT Advanced Access Platform (Applied Medical, USA); XCN: XCONE (Karl Storz GmbH, Germany); Ti: initial trial, Tf. final trial; W1: first week of project; W9: last week of project; W2-W7: from week 2 to week 7 of trials; a-GRS. adapted global rating scale.

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
Group 1 NOVICE	27 Feb	12 Mar	26 Mar	09 Apr	23 Apr	07 May	21 May	04 Jun	18 Jun
EL10	SsP	XCn	GPn	XCn	GPn	SsP	GPn	XCn	SsP
EL11	XCn	GPn	SsP	GPn	SsP	XCn	SsP	GPn	XCn
EL12	GPn	SsP	XCn	SsP	XCn	GPn	XCn	SsP	GPn
EL13	SsP	GPn	XCn*	GPn	XCn*	SsP	XCn*	GPn	SsP
EL14	SsP	XCn	GPn	XCn	GPn	SsP	GPn	XCn	SsP
EL15	XCn	GPn	SsP	GPn	SsP	XCn	SsP	GPn	XCn
EL16	GPn	SsP	XCn*	SsP	XCn*	GPn	XCn*	SsP	GPn
EL17	GPn	SsP	XCn	SsP	XCn	GPn	XCn	SsP	GPn
EL18	SsP	XCn	GPn	XCn	GPn	SsP	GPn	XCn	SsP
EL19	XCn	GPn	SsP	GPn	SsP	XCn	SsP	GPn	XCn
Group 2 LAP Exp	05 Mar	19 Mar	02 Apr	16 Apr	30 Apr	14 May	28 May	11 Jun	25 Jun
EL20	SsP	XCn	GPn	XCn	GPn	SsP	GPn	XCn	SsP
EL21	XCn	GPn	SsP	GPn	SsP	XCn	SsP	GPn	XCn
EL22	GPn	SsP	XCn	SsP	XCn	GPn	XCn	SsP	GPn
EL23	SsP	GPn	XCn*	GPn	XCn*	SsP	XCn*	GPn	SsP
EL24	SsP	XCn	GPn	XCn	GPn	SsP	GPn	XCn	SsP
EL25	XCn	GPn	SsP	GPn	SsP	XCn	SsP	GPn	XCn
EL26	GPn	SsP	XCn*	SsP	XCn*	GPn	XCn*	SsP	GPn
EL27	GPn	SsP	XCn	SsP	XCn	GPn	XCn	SsP	GPn
EL28	SsP	XCn	GPn	XCn	GPn	SsP	GPn	XCn	SsP
EL29	XCn	GPn	SsP	GPn	SsP	XCn	SsP	GPn	XCn
Group 3 LESS Exp	EL30 + EL31 + EL32 + EL33 GPn	SsP	XCn	SsP	GPn	XCn	XCn	SsP	EL30 + EL31 + EL32 + EL33 GPn

Figure 8. Randomized schedule for simulator hands-on sessions. Trials were set a fortnight apart, during a total of 18 weeks and thus constituting 9 assessment sessions. Each subject completed the requested tasks three times with the three elected LESS access devices. SILS: SILS^{TM} Port (Covidien, USA); GPN: GelPOINT Advanced Access Platform (Applied Medical, USA); XCN: XCONE (Karl Storz GmbH, Germany); EL10 to EL33: code designation for each of the 24 study participants.

3.2.2 Method

Study groups

In this study we included a total of 24 subjects, recruited from the personnel of the MIS-CJU's surgical area. These were divided in three groups according to their degree of MIS experience:

- Group 1 – NOVICE: 10 subjects with no experience at all in MIS;

- Group 2 – LAP Experienced: 10 subjects, with over 50 laparoscopic procedures performed as first surgeon. None of the participants in this group had any previous experience in LESS surgery;

- Group 3 – LESS Experienced: 4 subjects, with vast experience in Laparoscopy (over a 100 procedures completed as first surgeon) and some experience in LESS approach, with over 50 completed surgeries.

Study Design

On Table 5, the project's task distribution throughout the different phases of execution is represented.

Schedule

A subject-specific randomized schedule (Figure 8) was established for this study. Following this order, each subject completed a total of 9 hands-on sessions, during the course of 18 weeks, thus performing one trial each fortnight.

Subjects had no permission to access the operating theatre outside the pre established schedule. However, short explanatory videos were made available for voluntary consult in order to allow for concept reviewing of essential manoeuvres between training sessions.

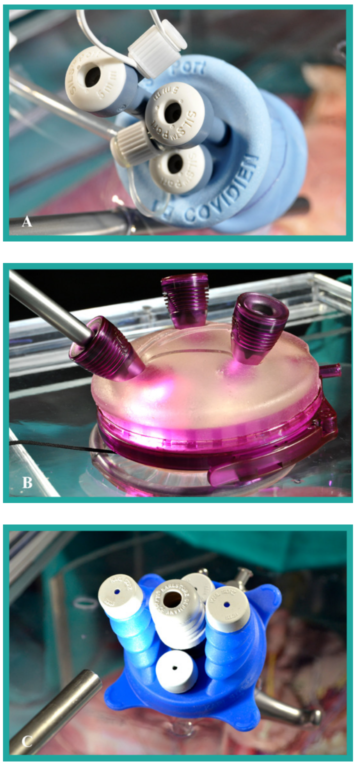


Figure 9. LESS single access devices. A. SILS™ Port (Covidien, Mansfield, MA, USA). B. GelPOINT Advanced Access Platform (Applied Medical, CA, USA). C. XCONE (KARL STORZ GmbH & Co. KG, Tuttlingen, Germany).

In order to oblige to the objectives planned at the beginning of this study, different evaluation times were considered for each analytic process:

1. Regarding the comparison of the different LESS instrument setups, two mandatory assessment trials were carried out on week 1 and on week 9, constituting **Ti** (initial assessment) and **Tf** (final assessment) with a training period of fourteen weeks completed in between. In each of the accessory training sessions, subjects were randomly assigned to either **setup II (ART-STR)** or **setup IV (PRB-STR)** according to the attributed LESS access device. On Ti and Tf, we completed the objective assessment of coordination and cut tasks performance.

2. For the comparison of the three elected LESS access devices all the nine hands-on sessions were included, resulting in a **total of three assessments per surgeon with each access device**. These were compared on the basis of the performance scores obtained during intermediate (cut) and advanced skills' tasks (linear and circular anastomoses).

3. For the analysis of LESS intracorporeal suturing learning curves, we initially established that in each trial from week 2 to week 8 (**7 consecutive assessments**), subjects should perform extra linear and circular anastomoses with the SILS™ Port (Covidien, Mansfield, USA). Results assessed on these hands-on sessions were used to describe the degree of skills' acquisition over time.

<u>*Instruments and Single Access Devices*</u>
(Figures 9 to 12)

The elected LESS Access Devices for this study were:

- The single use SILS™ Port (Covidien, Mansfield, MA, USA) - **SILS**;

- The single use GelPOINT Advanced Access Platform (Applied Medical, CA, USA) - **GPN**;

- And the multiple use XCONE (KARL STORZ GmbH & Co. KG, Tuttlingen, Germany) - **XCN**.

The choice regarding the different available instruments was defined according to each task and assessment objectives.

As such, in the *coordination task* and for the comparison of different LESS instruments, we combined the purpose-built single use dynamic articulating, the reusable pre-bent and the con-

Figure 10. Dynamic articulating LESS scissors - SILS™ Hand Shears (Covidien, Mansfield, USA).

Figure 11. Pre-bent LESS atraumatic graspers S-Portal™ CLICKLINE, according to Leroy (Karl Storz GmbH, Tuttlingen, Germany).

Figure 12. Straight laparoscopic 5mm scissors (EndoShears™, Covidien, Mansfield, USA), 5mm atraumatic grasper (EndoGrasp™, Covidien, Mansfield, USA) and 5mm axial handle needle holder (Karl Storz GmbH, Tuttlingen, Germany).

ventional laparoscopic tools, and established four different tools setups described below:

Setup I – ART-ART: two dynamic articulating Maryland dissectors (SILS™ Hand, Covidien, Mansfield, USA);

Setup II – ART-STR: one dynamic articulating Maryland dissector (SILS™ Hand, Covidien, Mansfield, USA) and one straight laparoscopic dissector; (; Autosuture™, Covidien, Mansfield, USA);

Setup III – PRB-PRB: two pre-bent instruments, a curved dissector and an atraumatic grasper (S-Portal™ CLICKLINE, according to Leroy, Karl Storz GmbH & Co, Tuttlingen, Germany);

Setup IV – PRB-STR: one pre-bent curved dissector (S-Portal™ CLICKLINE, according to Leroy, Karl Storz GmbH & Co, Tuttlingen, Germany) and one straight laparoscopic atraumatic grasper (Autosuture™, Covidien, Mansfield, USA).

Cut task assessments were used both for the comparison of different instruments and the comparison between LESS access devices. In the first case analysis, the LESS SILS™ Hand Shears (Covidien, Mansfield, USA) substituted the dominant hand dissector on **setup I**. Similarly, on **setup III** a pre-bent scissors (S-Portal™ CLICKLINE, according to Leroy, Karl Storz GmbH & Co, Tuttlingen, Germany) was used. For **setups II** and **IV**, attendants recurred to a conventional laparoscopic scissors (EndoShears™, Autosuture™, Covidien, Mansfield, USA) also as a dominant hand tool.

The choice of instruments on the second case analysis was preconditioned by the single access device scheduled in each hands-on session. In his manner, when using the single use devices **SILS** and **GPN**, all participants handled one dynamic articulating Maryland dissector (SILS™ Hand Dissect, Covidien, Mansfield, USA) on the non dominant hand, and one straight laparoscopic scissors (AutosutureTM, Covidien, Mansfield, USA) for the dominant hand (**setup II**). In the trials performed with the **XCN**, subjects used one pre-bent curved dissector (S-Portal™ CLICKLINE, according to Leroy, Karl Storz GmbH & Co, Tuttlingen, Germany) and one straight laparoscopic scissors (Autosuture™, Covidien, Mansfield, USA) (**setup IV**).

During the *intracorporeal suturing tasks*, the above mentioned setups were also used with the corresponding LESS access device, by replacing the conventional laparoscopic scissors of **setup II** and **setup IV** with a laparoscopic needle holder (Karl Storz GmbH & Co, Tuttlingen, Germany).

<u>*Simulator Tasks*</u>

Before the start of the training program, subjects were given a step by step demonstration of each task, with specific guidelines as on how to use the different instruments, how to place the LESS access device through the simulator's 2.5cm opening, and how to carry out each specific task.

When starting the trials and exclusively for the instrument comparative trials, a hollow single access device structure was inserted through the opening on the simulator's cover. This was not a commercial device, nor was it equipped with access cannulae, so that there was no interference with the use of the different instrument setups.

Coordination task: The first task focused on basic coordination abilities, where participants had to transfer six objects in three consecutive trials onto predetermined wells. This task was completed at two levels of difficulty according to the characteristics of the object itself: rough (chickpeas) or irregular (thumbtacks) (Figure 14, A and B).

The coordination task was carried out only on the first (W1 - Ti) and on the last week of trials (W9 - Tf).

Cut task: This second task was completed on a specific template with drawn straight and curved patterns, developed and registered at our centre, and amply used on our basic surgical training courses. This exercise assesses intermediate dexterities and demands higher care in tissue handling and improved combined use of both instruments (Figure 14, A and B).

So as to be able to complete the analysis of the different instruments available for LESS

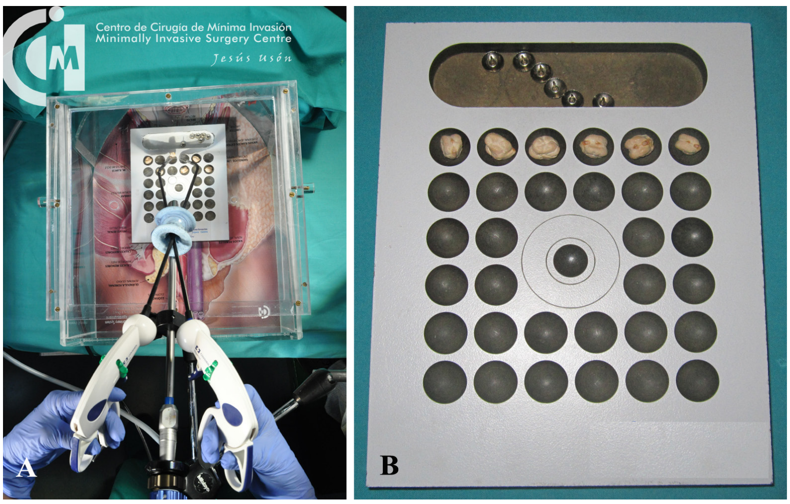


Figure 13. A. Performance of LESS coordination tasks with two dynamic articulating dissectors (SILSTM Hand, Covidien, Mansfield, USA). B. Detail of the coordination well plate.

and also evaluate the different single access devices, the cut task was established in two different time frames. This task was performed once on the first (W1 - Ti) and on the last week of trials (W9 - Tf), with each of the instrument setups. Also, subjects completed a cut task on each hands-on session for the comparison between LESS access devices.

Linear intracorporeal suturing task: on this exercise subjects had to complete six intracorporeal interrupted sutures. These were previously drawn on a straight line on the seromuscular layer of an ex vivo porcine stomach, each separated by 1 cm (Figure 15, A and B). The stomach was placed in the distal half of the internal cavity of the box trainer, and always at the same distance to the entry port.

Circular intracorporeal suturing task: to complete the urethrovesical anastomosis on ex vivo male porcine bladder and urethra, subjects were asked to carry out a maximum of eight intracorporeal sutures, half placed on the posterior side and the other half on the anterior side of the anastomosis (Figure 16, A and B). The ex vivo specimen was placed on a reduced "pelvic" area inside the simulator. In order to be able to reach the anastomotic junction with the different instruments, we were obliged to place the simulator's cover 5cm further from the surgeon. This distance was appropriately marked and standardized in each trial.

A maximum completion time of 15 minutes was set for both intracorporeal suturing trials. All sutures were performed with a multifilament material, mounted on a 26cm taper needle (PolysorbTM 2/0, Syneture, Covidien, Mansfield, USA).

<u>*Subjective Assessment*</u>

At the end of the nine weeks of trials, all subjects were handed a *subjective evaluation questionnaire* (Appendix 1). In these, participants had to score technical aspects of the access devices (dimensions, shape and length of access cannulae, surface and materials, and weight), as well as port-related questions concerning the learning process and the practice of LESS skills on simulator, which included ease of use, triangulation and working space. Moreover, we determined each subject's perception regarding the usefulness of the cut and intracorporeal suturing tasks for the acquisition of LESS specific skills, as well as the benefits of the SIMULAP® (MISCJU, Cáceres, Spain) in the performance of these tasks.

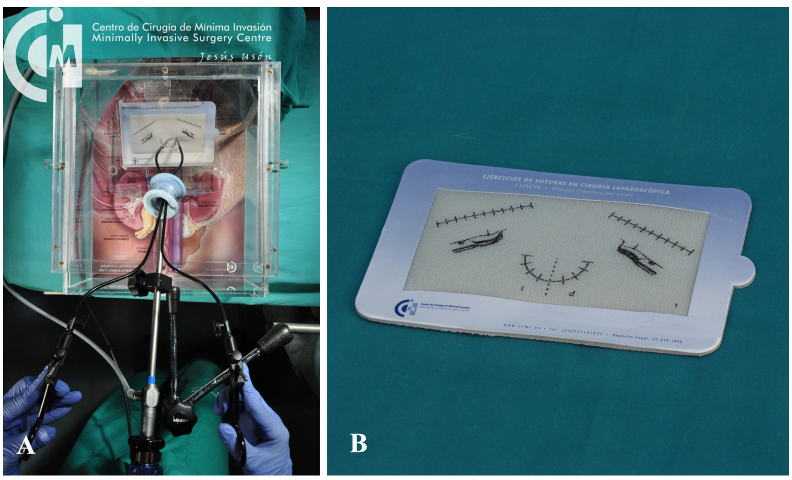


Figure 14. A. Performance of LESS cut task with two pre-bent instruments (S-Portal™ CLICKLINE, according to Leroy, Karl Storz GmbH, Tuttlingen, Germany). B. Detail of the cut template number 1 (MISCJU, Cáceres, Spain).

The first questions of the subjective questionnaires were divided in technical (questions 1 to 5) and functional (questions 6 to 8) aspects of the single access devices for better result interpretation. All items were scored on a 1-5 scale, except questions related to the global assessment on the use of physical simulators for the acquisition of intermediate and advanced LESS skills, which were scored on a scale from 1 to 10.

Additionally, a *demographic survey* was carried out to characterize the study's subject population (Appendix 2).

Objective Assessment

Objective performance analysis was performed on every trial and assessed by two independent expert surgeons over video recordings of each session. The expert raters were blinded to subject and study week.

The considered parameters for objective assessment were total or partial task completion times required for each suture, and performance assessment scores calculated on the basis of specific validated scales.

As mentioned earlier, for the comparison of the different LESS instrument alternatives, we considered coordination and cut tasks. Execution quality was rated on a specific global rating scale (a-GRS), adapted from a previously validated assessment tool.[95, 104] The adaptation of the GRS took into account the essential aspects necessary for the completion of task specific manoeuvres, and scored on a 1-5 Likert scale, with detailed objective assessment anchors. According to the specificities of the task itself, the maximum summative score for coordination was set at 10 points, and in the cut task, subjects could achieve a maximum of 20 points (Appendix 3). These a-GRS emonstrated construct validity during these trials.[94]

Performance assessment scores for the intracorporeal suturing tasks were based on an OSATS (scored on a 1-5 Likert scale) (Appendix 4) associated with a 1/0 suturing checklist (Appendix 5).[95, 96] Due to the nature of the study, we eliminated two of the parameters of the assessment tool reported by Martin and colleagues[95]: *knowledge of instruments*, as this was set for each task before the beginning of the trials; and *use of assistants*, which did not apply to the performance of the considered tasks on simulator. Thus, the maximum achievable score on the suturing task OSATS rating scale was set at 25 points.

Statistical Analysis

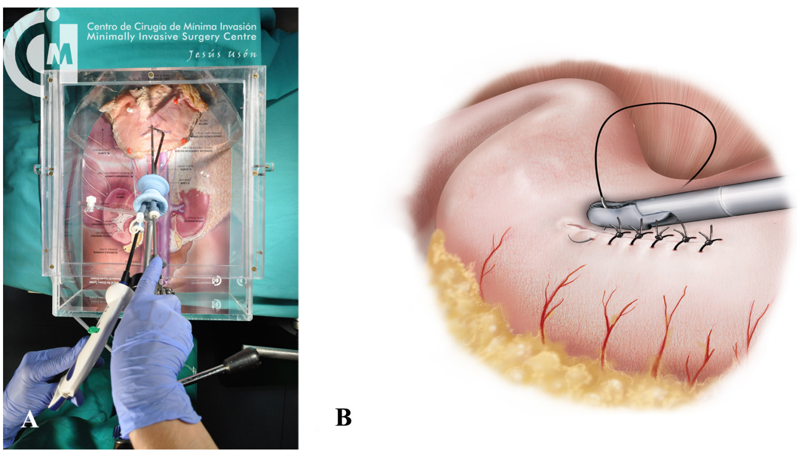


Figure 15. A. Image of the completion of a linear anastomosis on ex vivo porcine stomach. B. Representation of an interrupted suture pattern on porcine stomach.

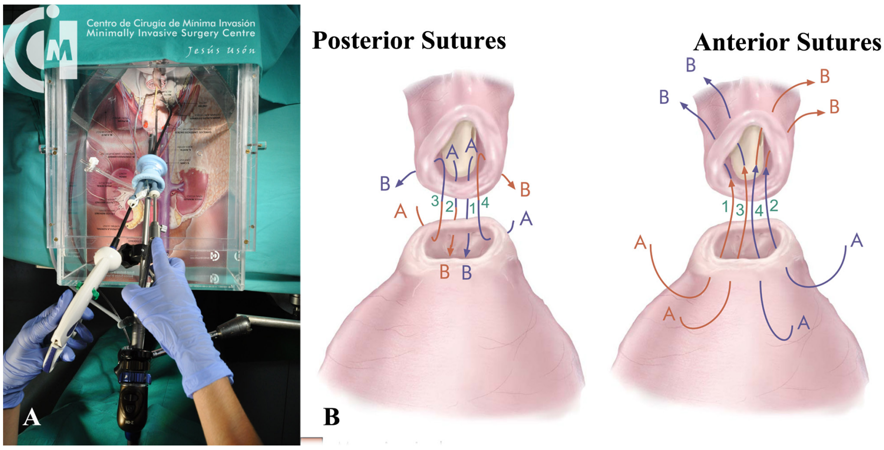


Figure 16. A. Performance of the circular anastomosis task. B. Correct placement of the 8 sutures to complete the urethrovesical anastomosis.

All data are expressed as mean ± standard deviation, and analyzed with Statistical Package for Social Sciences (IBM SPSS Statistics® v20.0, Chicago, USA) software. Statistical significance was set at $p<0.05$ for all tests.

Inter-rater reliability was assessed as a measure of scale consistency by calculating Pearson's correlation factor between registries, as previously described by Vassiliou in 2006 [105].

The results were evaluated for all subjects as a whole regardless of their experience level for the comparative analysis of LESS technological resources (instruments and access devices), as we consider this as the ideal setting to obtain a representative sample of the population able to apply these techniques. However, a comparison between the different levels of experience was pursued afterwards and again when we analyzed the acquisition of skills by means of learning curves.

To determine the statistical behaviour of the obtained data, performance scores and completion times in each task were initially tested with the Kolmogorov-Smirnov for normality determination.

Comparative analysis of LESS instrument setups

For this comparison, we included the 20 participants grouped in Novice and LAP experienced. Parametric statistical comparisons of the four instrument setups were determined for each time point, with a factorial design which considered two independent variables (tool and expertise), with four (instrument setup) and two levels (novice and expert on laparoscopic surgery) for each, respectively. For significances determined without interaction, a one way-ANOVA variance analysis followed by pairwise comparisons was conducted with the Bonferroni criterion.

For all non parametric variables, Wilcoxon signed ranks test was used to compare each pair of instrument settings, and between study weeks. A Student T-test or a Wilcoxon signed ranks test were used to compare between both study times -**Ti** and **Tf,** depending on the normality of the variables.

Comparative analysis of LESS Access Devices

On this section, the number of participants used was the same as on the comparison of LESS instruments. Parametric statistical comparisons were determined for each time point, with a factorial design which considered two independent variables (access device and expertise), with three (access device used) and two levels (novice and expert on laparoscopic surgery) for each, respectively. When statistical significance was determined without interaction, a one way-ANOVA variance analysis followed by pair-wise comparisons conducted with the Tukey criterion was performed for each access device. A Student's T-test was used for the comparison between first (**W1**) and last (**W9**) weeks' results.

For non parametric variables, a Kruskal-Wallis test was used to compare between the different access devices followed by pair-wise comparisons with Wilcoxon signed ranks test. The latter was also applied to compare between first (W1) and last (W9) study weeks for each of the devices.

Regarding the intracorporeal suturing tasks, we determined the frequencies of completed knots in the allowed 15 minutes. In order to normalize and combine the scores obtained with both objective scales, we first determine the Spearman rho correlation between both. The mathematical combination of both CL and GRS scores, using the formula **SUM = (GRS/50) + ((CL*1,724)/100)**, determined the summative score (SUM), as a new performance assessment variable for each trial. Obtained SUM values range between 0 and 1.

For parametric variables, an ANOVA variance analysis was completed, followed by pair-wise comparisons conducted with the Tukey criterion for comparison of the different access devices, and with the Bonferroni method for comparison between trial weeks. To compare the results from first to last week, a paired-samples Student's T-test was applied. For non parametric variables, a Kruskal-Wallis test was applied, followed by pair-wise comparisons whenever significant differences were identified, using Wilcoxon signed ranks test or a Mann-Whitney U test according to the dependence of variables.

<u>Determination of LESS intracorporeal suturing learning curves</u>

For the determination of learning curves and parameters, data from each suture was considered as a single trial and used to produce a learning curve for each experience group, and for the whole of the subjects' population, using a nonlinear regression model (Y=a-b/x). The generated curve was then used to define two values, the "**learning plateau**" (asymptote) and the "**learning rate**" (number of trials required to achieve 90% of the learning plateau and calculated as 10*b/a[106, 107]. As such, learning rate conveys a proportional value to the curves' slope and develops in inverse proportion with the asymptote.

<u>Comparisons between levels of MIS experience</u>

This last analysis was performed on data obtained during the comparison of the different LESS instruments and access devices, where the differences between each level were determined for each objective parameter.

For parametric variables, an ANOVA variance analysis was completed, followed by post hoc Tukey test. In the case of non parametric variables, a Kruskal-Wallis test was applied, followed by pair-wise comparisons with Mann-Whitney U test.

IV. Results

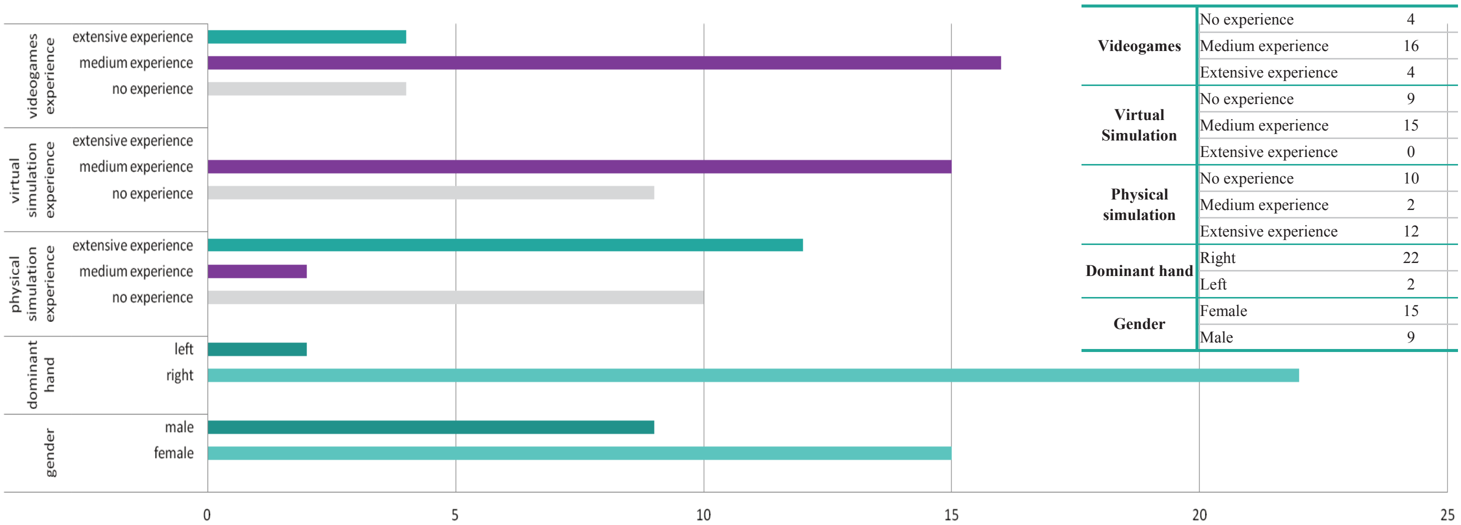
Demographic data

Among the 24 subjects included in these trials, 63% were female and 37% male. Concerning dominant hand in daily activities, 22 were right-handed and 2 were left-handed. Regarding simulation experience, 42% (n=10) declared to have no previous experience on physical simulator and 8% had little experience with this tool, against 50% which stated to have used the physical simulator extensively on their previous period on surgical training. Considering virtual simulation and experience with videogames, 37% and 17% of the subjects had no experience with either tool respectively. 63% stated to have practiced at least once with the virtual simulator, and 66% had little to average experience playing computer videogames (Figure 17).

Subjective Assessment

Regarding the results of the subjective evaluation (Figure 18), and focusing on technical (Tec) and functional (Fun) characteristics of the trocars which included dimensions, weight, ease of use, triangulation and working space among other aspects, the XCN was considered to be significantly inferior to both disposable LESS access devices (SILS Tec 4.18 ± 0.83 and Fun 4.09 ± 0.82, GPN Tec 3,79 ± 1.04 and Fun 4.21 ± 0.82, XCN Tec 2.27 ± 0.99 and Fun 2.39 ± 0.99, XCN < SILS, GPN, $p<0.001$.). Additionally, regarding the assessment of ports' technical parameters, SILS was deemed significantly superior to GPN (SILS 4.18 ± 0.83, GPN 3.79 ± 1.04, XCN 2.27 ± 0.99, SILS > GPN, $p=0.004$).

All aspects regarding the usefulness of coordination, cut and intracorporeal suturing tasks for the acquisition of LESS skills, were consid-



Videogames	No experience	4
	Medium experience	16
	Extensive experience	4
Virtual Simulation	No experience	9
	Medium experience	15
	Extensive experience	0
Physical simulation	No experience	10
	Medium experience	2
	Extensive experience	12
Dominant hand	Right	22
	Left	2
Gender	Female	15
	Male	9

Figure 17. Graphical representation of demographic data regarding gender, dominant hand and simulation, as well as videogames previous experience of all participants.

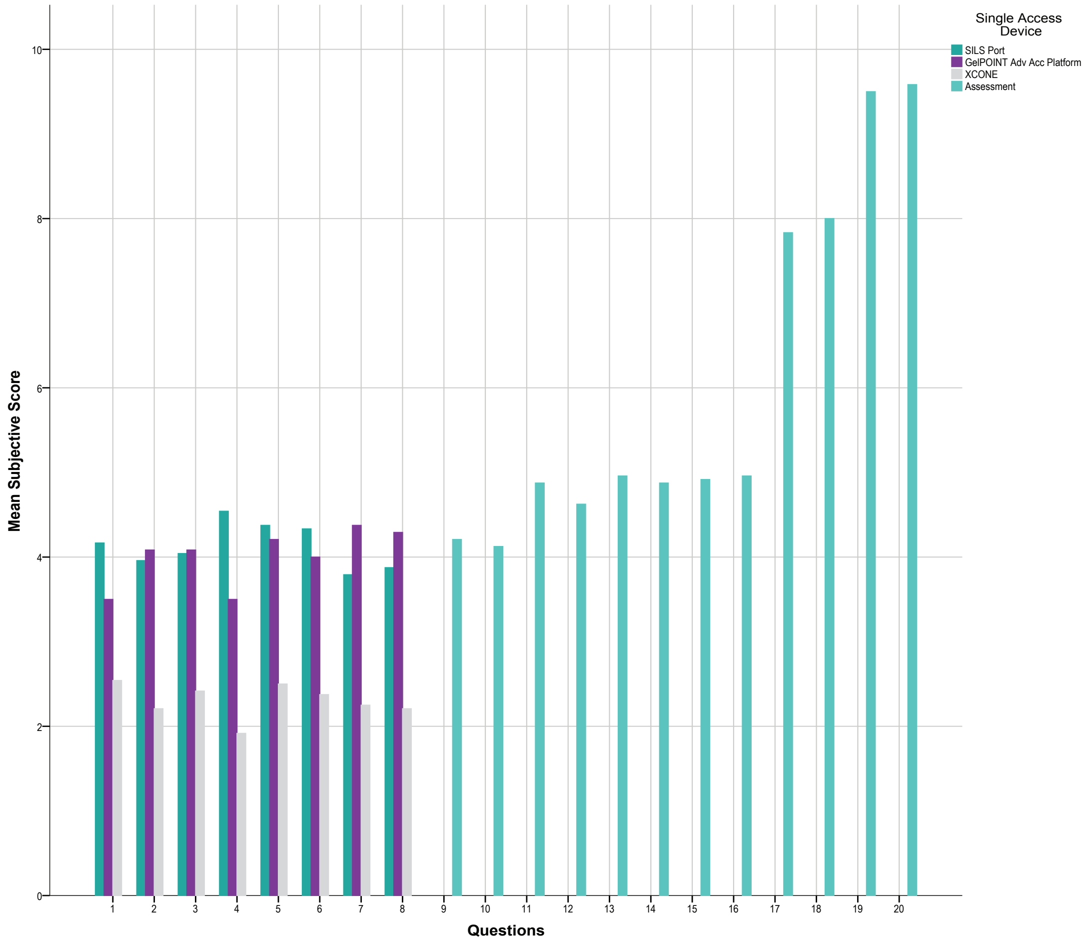


Figure 18. Subjective assessment scores.
1. Dimensions; 2. Shape and length of access cannulae; 3. Surface and materials; 4. Weight; 5. Ability to allow for the practice and learning of LESS skills on simulator; 6. Ease of use; 7. Triangulation; 8. Workspace. 9. Usefulness of the coordination tasks as a basic level LESS exercise; 10. Usefulness of the cut tasks as an intermediate level LESS exercise; 11. Usefulness of intracorporeal suturing of ex vivo porcine stomach as an advanced LESS skills exercise. 12. Usefulness of intracorporeal suturing of ex vivo porcine urethrovesical anastomosis as an advanced LESS skills exercise. 13. I believe that the training in basic LESS skills before its application in the clinical practice is necessary, regardless of previous minimally invasive surgical experience level; 14. I believe that the SIMULAP® and proposed tasks are a useful tool to assess skills in LESS; 15. I believe that simulation offers a safe environment for the training in basic LESS skills. 16. I believe that the continous practice of LESS tasks under controlled environment will help develop the necessary abilities to overcome the technique's constraints; 17. Final assessment for the coordination task, 18. Final assessment for the cut task; 19. Final assessment for the linear suturing task; 20. Final assessment for the circular anastomosis task.

ered of high to very high value, especially the latter (coordination: 4.20 ± 1.06, cut task: 4.12 ± 0.90, linear suturing task: 4.88 ± 0.61, and circular anastomosis 4.63 ± 0.89). These tasks also scored very high on global assessment concerning its ability to favor LESS skills development: coordination task: 7.83 ± 1.52, cut task: 8.00 ± 1.22, linear anastomosis: 9.50 ± 0.83; and circular anastomosis: 9.58 ± 0.65.

Almost all subjects considered that regulated training in LESS is highly essential regardless of previous minimally invasive surgical experience level (4.96 ± 0.20), and that the use of box trainers offers a safe environment for the practice of these new techniques (4.92 ± 0.28). Furthermore, participants considered that the continued practice would render easier the improvement in the handling of LESS technical constraints (4.96 ± 0.20).

Validity of Objective Assessment Tools and Scores

Regarding construct validity of the objective assessment tools designed for cut and coordination tasks' performance, expert surgeons (E) showed significantly superior performance (a-GRS) when compared with novices (N) on the first week (coordination task: N 7.18±1.02 vs. E 9.35±0.87, $p<0.001$; cut task: N 12.35±1.84 vs. E 16.83±1.81, $p<0.001$), establishing a high degree of accuracy in the measurements of intended scores.

A high-very high degree of inter-rater reliability was determined (0.830), indicating scale consistency and that more than 95% of the variance in scores can be attributed to a "true" difference between participants.

Concerning LESS suturing tasks, we obtained a good correlation value between both global rating and checklist scales of 0.724 ($p<0.01$), enabling the application of the summative score variable for standard objective assessment in these trials. More specifically, we determined the SILS CLvsGRS correlation: 0.706, the GPN CLvsGRS correlation: 0.702, and the XCN CLvsGRS correlation: 0.724, all significant at $p<0.01$.

Coordination task	**I (ART-ART) (*n*=20)**	**II (ART-STR) (*n*=20)**	**III (PRB-PRB) (*n*=20)**	**IV (PRB-STR) (*n*=20)**	**Significant differences (*p* value)**
GRS score					
1st week (**Ti**)	6.97±1.27	8.19±1.17	8.08±1.23	8.44±1.08	I < II, III, IV ($p<0.001$); II < IV ($p=0.001$); III < IV ($p=0.011$).
9th week (**Tf**)	8.12±1.27	8.46±0.97	8.77±0.99	8.63±1.05	I < II, III, IV ($p<0.001$); II < III ($p<0.001$); II < IV ($p=0.002$); III > IV ($p=0.001$).
Total Completion Time (min)					
1st week (Ti)	6.67±2.21	3.99±0.94	4.02±1.30	4.03±1.47	I > II, III, IV ($p<0.001$).
9th week (Tf)	4.59±1.04	3.68±0.73	3.93±0.96	3.80±0.72	I > II ($p=0.005$); I > IV ($p=0.02$)

Table 6.Objective assessment parameters for the coordination task registered during the first and last sessions of the training program.

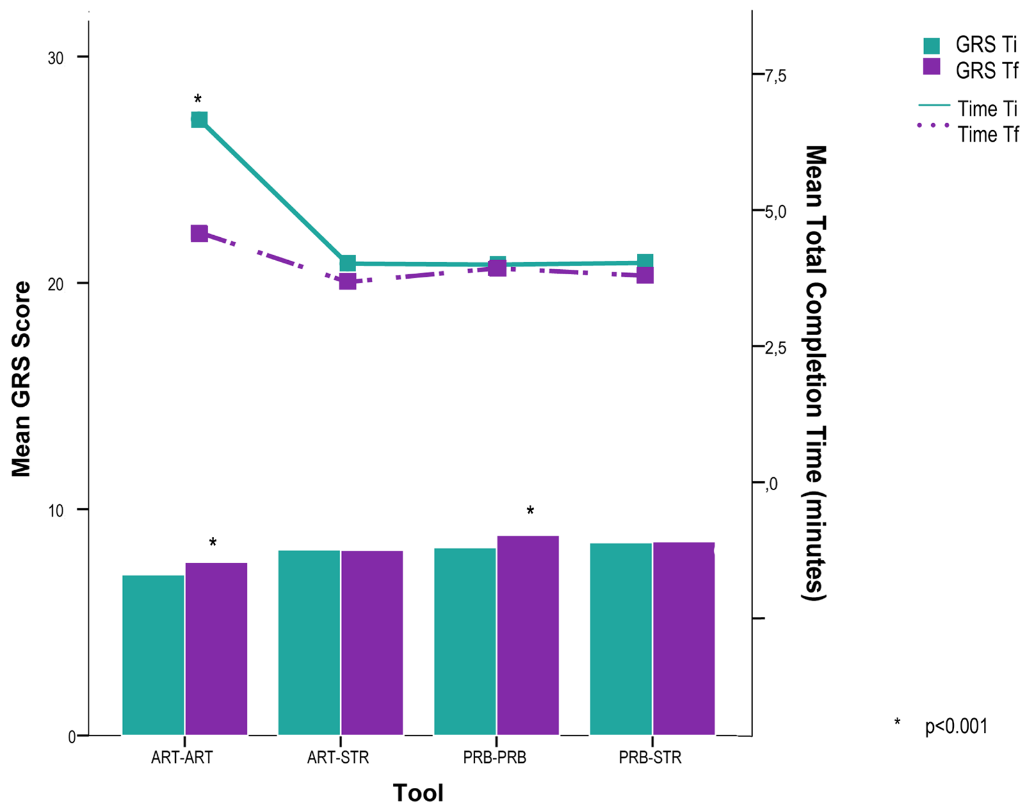


Figure 19. Graphical representation of a-GRS and completion time during coordination task for each of the instruments setups. Asterisk represents statistically significant differences between Ti and Tf.

Comparative analysis of LESS instrument setups

Overall, 120 coordination trials and 20 cut task templates were assessed for each of the established LESS instrument setups. In both coordination and cut tasks, the effects of tool and expertise on total completion time and a-GRS score showed significance, which was not encountered when we analyzed the interaction between both factors.

Coordination trials

As detailed on Table 6, we observed that on the coordination task and before the training period (Ti), the combination of a multiple use pre-bent Maryland dissector and straight laparoscopic grasper (setup IV) obtained the highest GRS score with significant differences compared to all other LESS setups, whereas the use of two dynamic articulating instruments (setup I) obtained the lowest significant score (*p*=0.001). Regarding total completion time, subjects carried out this task with similar speed for all instrument sets with the exception of the combined use of two dynamic articulating grasper and Maryland dissector (I), which required a significantly higher amount of time (*p*<0.001) to complete the coordination trials in both difficulty levels.

At Tf registries, we observed that the ART-ART setup (I) continued to show significant lower scores compared to all other combinations (*p*<0.001), and higher completion times compared to setups II (dynamic articulating tip and conventional laparoscopic instruments) (*p*=0.005) and IV (pre-bent Maryland dissector combined with conventional laparoscopic grasper) (*p*=0.02). The highest significant a-GRS score was obtained with the use of two

Cut task	I (ART-ART) (*n*=20)	II (ART-STR) (*n*=20)	III (PRB-PRB) (*n*=20)	IV (PRB-STR) (*n*=20)	Significant differences (*p* value)
GRS score					
1st week (**Ti**)	12.45±1.81	12.78±2.72	13.35±2.13	13.25±1.94	NS
9th week (**Tf**)	12.55±1.46	13.65±1.46	13.90±1.65	13.52±1.74	NS
Total Completion time (min)					
1st week (**Ti**)	4.99±2.23	3.60±1.77	3.88±1.30	3.53±1.05	I > II (p=0.037); I > IV (p=0.023).
9th week (**Tf**)	2.77±0.93	2.19±0.64	1.89±0.55	2.21±0.59	I > III (p=0.001).

Table 7.Objective assessment parameters for the cut task registered during the first and last sessions of the training program.

pre-bent grasping instruments (setup III). However this did not constitute the fastest combination. Subjects performed faster on the last assessment week (Tf) with the combination of a dynamic articulating tip dissector and a straight laparoscopic grasper (setup II), without statistical significance compared to all other setups with the exception of setup I (p=0.005).

As detailed on figure 19, in the cases of ART-ART (setup I) and PRB-PRB (setup III), a significant a-GRS score improvement was observed (p<0.001). Also, at Tf, subjects significantly improved their execution times when completing the coordination trials with two dynamic articulating tip instruments (setup I) (p<0.001), not reaching however speed levels of other tool setups.

Cut trials

On the cut task (Table 7), obtained results were more homogeneous between the various instrument setups, with no observed significant differences in objective performance scores. Nevertheless, the combination which obtained the best scores on both assessment times was setup III, in which subjects used two pre-bent instruments to cut the appropriate template. The worst scores were observed with the use of two dynamic articulating tip Maryland dissector and curved scissors (setup I).

During this second basic task, subjects cut faster in the first assessment trials (Ti) when using a pre-bent Maryland dissector and straight laparoscopic scissors (setup IV), although this difference was only significant when compared with setup I (two dynamic articulating instruments) (p=0.023). Moreover, the use of two

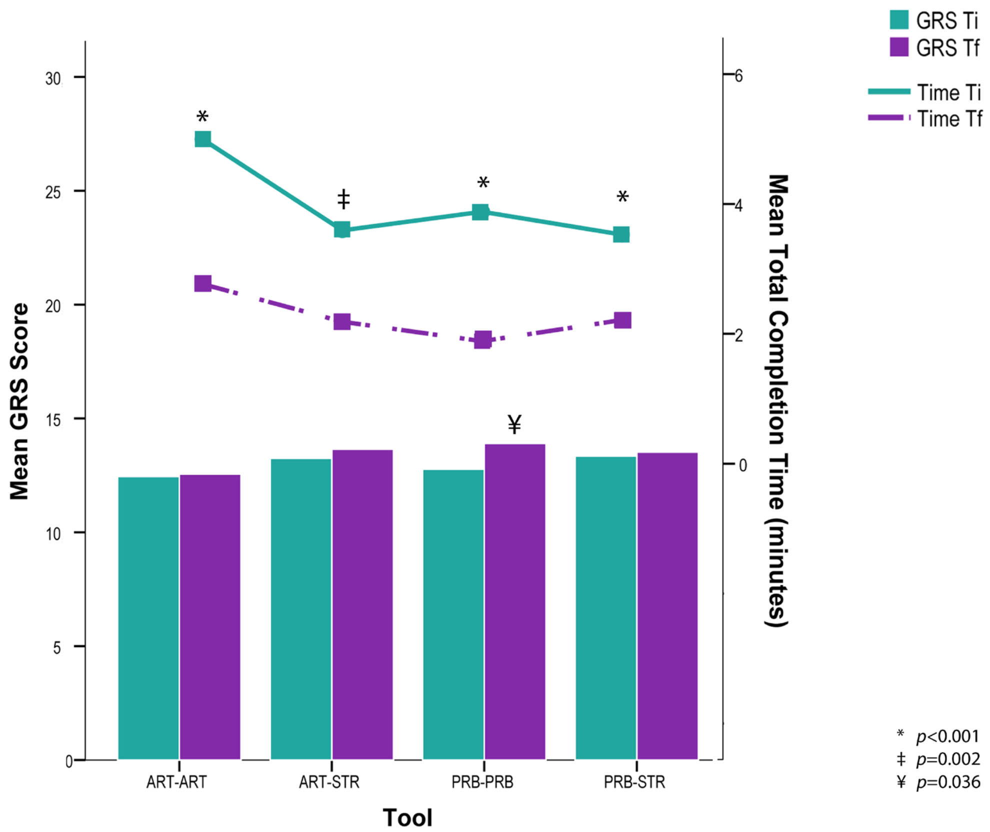


Figure 20. Graphical representation of the a-GRS and completion time on cut task for each of the instruments setups. Different symbols represent distinct statistically significant differences between Ti and Tf.

single use articulating instruments (setup I) favored the slowest performance also with statistical significance with regards to the alternative combination of one LESS designed instrument with a straight conventional laparoscopy scissors (setup II p=0.037, and setup IV p=0.023).

After completing the 7-session training program (Tf), setup III (two multiple use pre-bent instruments) still constituted the fastest combination with statistical significance compared only to the two dynamic articulating tip instruments (setup I) (p=0.001), which was once again the slowest instrument setup.

In the cut task assessment at Tf, we observed significant improvement in a-GRS scores compared with Ti (Figure 20) only for instrument setup III, i. e. the combination of two pre-bent instruments (curved tip Maryland dissector and straight tip scissors) (p=0.036). Nevertheless, all setups favored a non significant increase in assessed scores at Tf. Additionally, all instrument combinations showed a decrease with variable statistical significance concerning total completion times at the end of the training program (Tf).

Comparative analysis of LESS Access Devices

Overall, 60 cut task templates were assessed for each of the established LESS single access device. Concerning the intracorporeal suturing task, each subject had the possibility to complete, at the end of the nine hands-on sessions, a maximum of 18 completed sutures on the linear and of 24 completed sutured on the circular anastomoses, per access device.

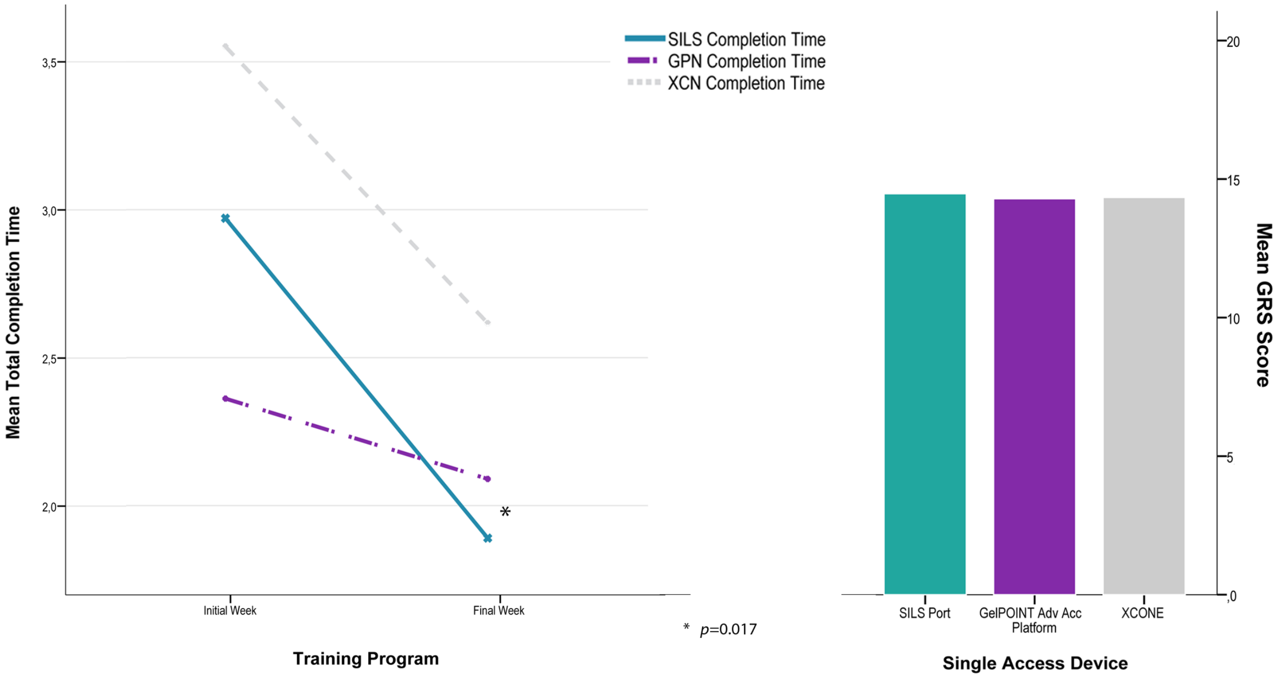


Figure 21. Graphical representation of total completion time and average a-GRS score for the cut task registered during the nine weeks of training. Asterisk represents statistically significant differences between initial and final week.

Cut Task Results	Week 1 (W1)	Week 9 (W9)	Average score	*p* value W1vsW9
Total Completion Time				
SILS	2.97±0.96	1.89±0.47	2.94±0.99	*p*=0.017
GPN	2.36±0.51	2.09±0.29	3.21±1.32	NS
XCN	3.55±0.67	2.62±0.87	3.16±1.02	NS
Comparison between devices (*p* value)	GPNvsXCN p=0.006	NS	NS	
a-GRS score				
SILS	14.50±1.41	13.81±1.75	13.83±1.66	NS
GPN	14.92±1.36	12.75±1.37	13.80±1.40	*p*=0.002
XCN	13.42±1.50	14.08±0.80	13.68±1.67	NS
Comparison between devices (*p* value)	NS	NS	NS	

Table 8.Objective assessment parameters for the cut tasks, registered during the first and last weeks of the study. Average values were obtained from a total of three trials carried out with each access device.

Cut task

Regarding the cut task (Table 8 and Figure 21), and focusing on total average completion time, after the nine weeks of practice, SILS represented the fastest LESS port for the participant surgeons, without significant differences when compared to the other devices (total completion time: SILS<XCN<GPN). The use of the GPN entailed a significantly faster performance for the study participants when compared with the time needed to complete the cut task with the XCN on week 1 (GPN 2.36±0.51 min vs. XCN 3.55±0.67 min, p=0.006), and week 6 (GPN 2.54±0.49 min vs. XCN 3.48±0.51 min, p=0.013). Participants showed improvement with all devices from first to last week of the program, and significantly so with the use of SILS (W1: 2.97±0.96 min vs. W9: 1.89±0.47 min, p=0.017).

On the global average a-GRS, SILS obtained the highest score, followed by GPN and lastly the XCN, without statistical significance for all devices. When we consider the acquisition of cut skills between the first and the last week of the program, we observe that the only port that favored a non significant improvement in performance was the XCN (W1: 13.42±1.50 vs. W9: 14.08±0.80), with the SILS and the GPN decreasing their a-GRS scores (SILS W1: 14.50±1.41 vs. W9: 13.81±1.75), the latter with statistical significance (GPN W: 14.92±1.36 vs. W9: 12.75±1.37, p=0.002).

Linear intracorporeal suturing task: ex vivo porcine stomach

On the linear intracorporeal suturing task completed on an ex vivo porcine stomach (Table 9 and Figure 22), and regarding the time necessary to complete each interrupted suture, SILS resulted to be the fastest LESS access device on the overall assessment during the nine weeks of practice. XCN constituted the access device with significant longer completion times when compared to SILS (XCN 4.00±2.37 min vs. SILS 3.18±1.85 min, p<0.001) and with

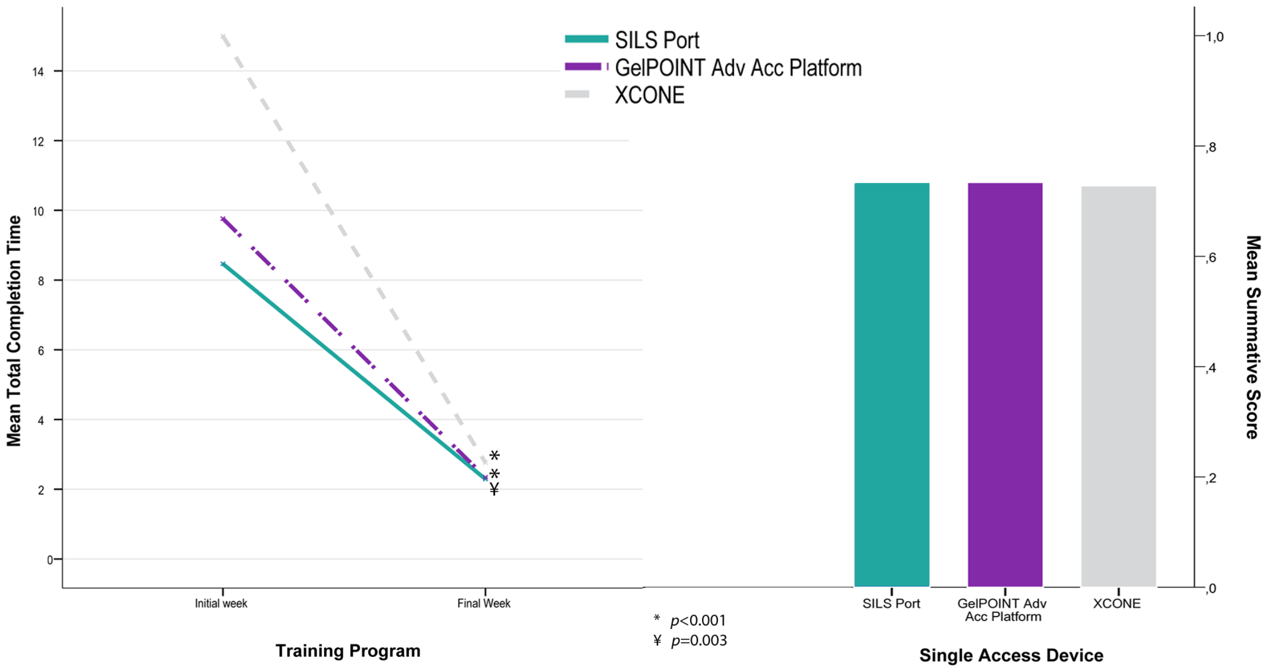


Figure 22. Graphical representation of mean total completion time and mean summative score for the linear intracorporeal suturing task registered during the nine weeks of training. Completion time refers to the minutes needed to complete one simple interrupted suture. Different symbols represent distinct statistically significant differences between initial and final week.

Linear Suturing Task	**Week 1 (W1)**	**Week 9 (W9)**	**Average score**	***p* value W1vsW9**
Total Completion Time				
SILS	8.47±1.82	2.29±0.68	3.18±1.85	*p*=0.003
GPN	9.76±3.68	2.34±0.88	3.40±2.16	*p*<0.001
XCN	**15.00±0.01***	2.77±1.03	4.00±2.37	*p*<0.001
Comparison between devices (*p* value)	NS	NS	SILSvsXCN *p*<0.001 GPNvsXCN *p*<0.001	
Summative score				
N	**4**	**46**		
SILS	0.75±0.02	0.81±0.09	0.78±0.08	*p*=0.003
N	**5**	**33**		
GPN	0.60±0.11	0.82±0.09	0.78±0.09	*p*=0.001
N	**0**	**30**		
XCN	-	0.85±0.05	0.76±0.09	*p*<0.001
Comparison between devices (*p* value)	SILSvsGPN *p*=0.014	NS	NS	

*Maximum time allowed for task completion. N: number of completed sutures

Table 9. Objective assessment parameters for the lineal suturing task, registered during the first and last weeks of the study. Average values were obtained from a total of three trials carried out with each access device. Number of complete sutures performed is also noted.

GPN (XCN 4.00±2.37 min vs. GPN 3.40±2.16 min, *p*<0.001). Similarly to previously analyzed parameters, there was significant improvement on performance times from the first to the last week with SILS (W1: 8.47±1.82 min vs. W9: 2.29±0.68 min, *p*=0.003), GPN (W1: 9.76±3.68 min vs. W9: 2.34±0.88 min, *p*<0.001), and XCN (W1: 15.00±0.01* vs. W9: 2.77±1.03 min, *p*<0.001).

We obtained no statistical significant differences on mean summative score of sutures performed over a linear incision on ex vivo porcine stomach with the different LESS access devices. During the first week, SILS performance was significantly better than the one observed with the GPN (SILS 0.75±0.02 vs. GPN 0.60±0.11, *p*=0.014), whilst none of the participants could complete any suture with the XCN. Differences between LESS access devices diluted towards the end of the program, with the XCN surpassing all other devices (XCN 0.85±0.05 > GPN 0.82±0.09 > SILS 0.81±0.09, NS) in what concerns assessment of performance quality. As

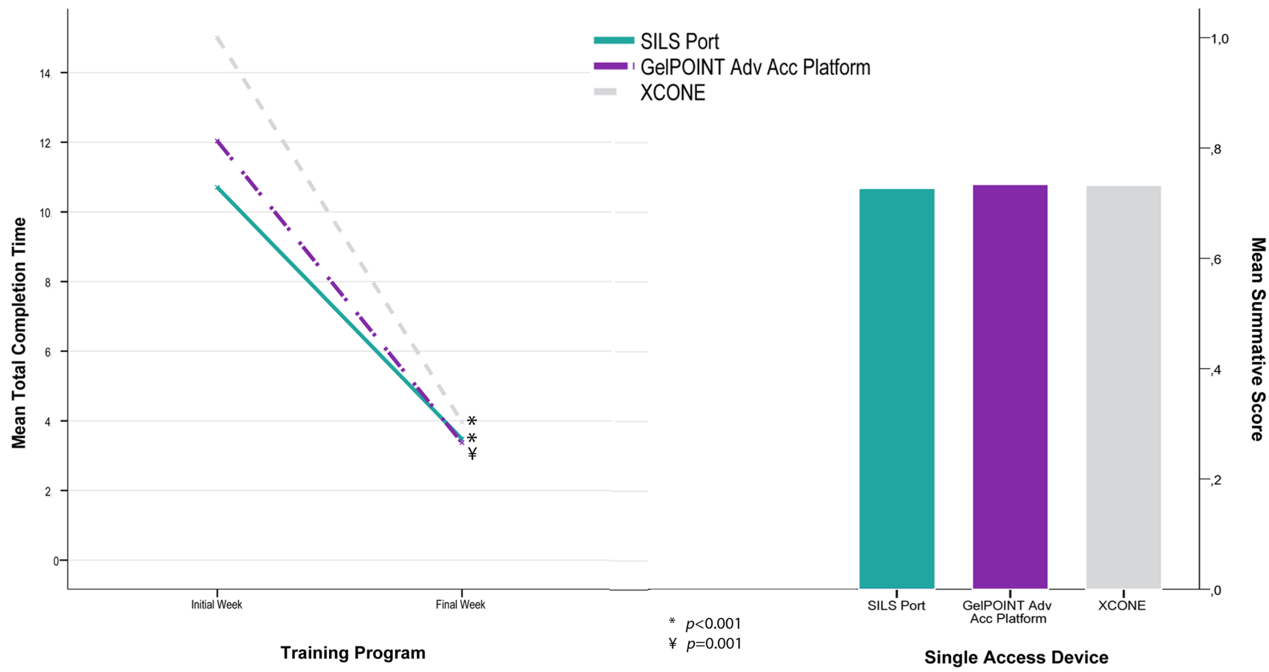


Figure 23. Graphical representation of mean total completion time and mean summative score for the circular anastomosis task registered during the nine weeks of training. Completion time refers to the minutes needed to complete one simple interrupted suture. Different symbols represent distinct statistically significant differences between initial and final week.

expected, we observed a significant improvement in performance with all LESS access devices from the first to the last week of training (SILS W1 (4 sutures):0.75±0.02 vs. W9 (46 sutures):0.81±0.09, p=0.003; GPN W1 (5 sutures):0.60±0.11 vs. W9 (33 sutures):0.82±0.09, p=0.001; XCN W1: no suture was completed vs. W9 (30 sutures):0.85±0.05, p<0.001).

<u>Circular anastomosis: ex vivo urethrovesical anastomosis</u>

On the circular intracorporeal suturing task for the completion of an anastomosis on ex vivo porcine urethra and bladder neck (Table 10 and Figure 23), and regarding the time necessary to complete each interrupted suture, SILS constituted the fastest LESS access device when we consider the total number of trials. Once again, XCN constituted the access device with significant longer completion times when compared to SILS (XCN 5.56±2.83 min vs. SILS 4.89±2.24 min, p=0.019) and with GPN (XCN 5.56±2.83 min vs. GPN 5.26±2.62 min, p=0.032). Also in these trials, we observed significant improvement on performance times from the first to the last week with SILS (W1: 10.71±0.92 min vs. W9: 3.47±1.15 min, p<0.001), GPN (W1: 12.04±0.33 min vs. W9: 3.37±1.12 min, p=0.001), and XCN (W1: 15.00±0.01* vs. W9: 3.97±1.46 min, p<0.001).

We obtained no statistical significant differences on mean summative score of sutures performed to establish urinary excretory patency on ex vivo porcine urethrovesical anastomosis. During the first week, only 3 sutures were carried out with both disposable access devices (SILS and GPN), whilst none of the participants could complete any suture with the XCN. There were no observed differences between LESS access devices during the entire duration of the hands-on trials in what concerns assessment of performance quality. As expected, we observed a significant improvement in performance with all LESS access devices from the first to the last week of training (SILS W1 (3 sutures): 0.67±0.11 vs. W9 (32 sutures): 0.80±0.13, p=0.001; GPN W1 (3 sutures): 0.62±0.04 vs. W9 (23 sutures): 0.85±0.07, p=0.001; XCN W1: no suture was completed vs. W9 (20 sutures): 0.82±0.06, p<0.001).

Circular Suturing Task	Week 1 (W1)	Week 9 (W9)	Average score	*p* value W1vsW9
Total Completion Time				
SILS	10.71±0.92	3.47±1.15	4.89±2.24	$p<0.001$
GPN	12.04±0.33	3.37±1.12	5.26±2.62	$p=0.001$
XCN	**15.00±0.01***	3.97±1.46	5.56±2.83	$p<0.001$
Comparison between devices (*p* value)	NS	NS	SILSvsXCN p=0.019 GPNvsXCN *p*=0.032	
Summative score				
N	**3**	**32**		
SILS	0.67±0.11	0.80±0.13	0.73±0.10	$p=0.002$
N	**3**	**23**		
GPN	0.62±0.04	0.85±0.07	0.74±0.09	$p=0.001$
N	**0**	**20**		
XCN	-	0.82±0.06	0.74±0.08	$p<0.001$
Comparison between devices (*p* value)	NS	NS	NS	

*Maximum time allowed for task completion. N: number of completed sutures

Table 10. Objective assessment parameters for the circular suturing task, registered during the first and last weeks of the study. Average values were obtained from a total of three trials carried out with each access device. Number of complete sutures performed is also noted.

Determination of LESS intracorporeal suturing learning curves

Linear intracorporeal suturing task: ex vivo porcine stomach (Table11, and Figures 24 and 25)

For the group as a whole, the mean ± standard deviation observed starting score for linear intracorporeal suturing was 0.72±0.13, which evolved to 0.81±0.08 on the last week ($p=0.042$) (NOV Ti: 0.59±0.11 and Tf: 0.77±0.07; LAP Ti: 0.74±0.09 and Tf: 0.82±0.08; LESS Ti: 0.82±0.09 and Tf: 0.87±0.07; Ti vs. Tf, $p<0.05$). At first, participants took an average of 4.30±3.17 minutes to complete each suture, finishing with 2.21±0.91 minutes at the end of the seven training sessions ($p<0.001$) (NOV Ti: 7.50±4.43 min and Tf: 2.57±1.09 min; LAP Ti: 3.66±1.85 min and Tf: 2.09±0.67 min; LESS Ti: 2.56±1.11 min and Tf: 1.69±0.55 min; Ti vs. Tf, $p<0.001$).

Linear Suturing Task Summative Score	**Slope**	**Learning Plateau**	**Learning Rate**	r^2
All Groups	-0.335	0.826	4,056	0.000 (p=0.659)
Novice (n=10)	-0.134	0.724	1,851	0.009 (p=0.106)
LAP Experienced (n=10)	-0.256	0.891	2,873	0.000 (p=0.817)
LESS Experienced (n=4)	-0.207	0.871	2,377	**0.068 (p=0.001)**
Linear Suturing Task Suture Completion Time	**Slope**	**Learning Plateau**	**Learning Rate**	r^2
All Groups	5.650	2.716	20,803	**0.018 (p<0.001)**
Novice (n=10)	4.137	3.309	12,502	**0.000 (p=0.035)**
LAP Experienced (n=10)	3.038	2.541	11,956	**0.024 (p=0.003)**
LESS Experienced (n=4)	2.972	1.891	15,717	**0.101 (p<0.001)**

Table 11. Descriptive values of the learning curves for the 24 study participants as a whole, and divided by experience level, for the lineal intracorporeal suturing tasks and regarding objective assessment scores and total completion time. Goodness of fit and curve significance are shown.

Considering the performance of the 24 participants, average assessment values obtained during the seven training sessions for the linear suturing task were 0.82±0.90 for summative scores and 2.75±1.76 minutes for suture completion time.

Estimated learning plateau in terms of summative score for the 24 participants was 0.83, with an estimated learning rate of 4.05 trials to achieve 10% higher score than the best potential (NS, p=0.659). However, for suture completion time, the learning plateau was calculated as 2.71 minutes, with a learning rate of 20.80 sutures (r^2 0.018, p<0.001).

Circular anastomosis: ex vivo urethrovesical anastomosis (Table 12, and Figures 26 and 27)

The mean ± standard deviation summative score observed for the entire group of participants on the first training session during the circular anastomosis task was 0.66±0.63, which evolved to 0.78±0.12 on the last week (p=0.003) (NOV Ti: 0.48±0.13 and Tf: 0.69±0.10; LAP Ti: 0.69±0.11 and Tf: 0.73±0.11; LESS Ti: 0.79±0.08 and Tf: 0.89±0.09; Ti vs. Tf, p<0.01). Participants started with average times of 6.07±3.91 minutes per suture, and took 3.60±1.89 minutes on the last of the seven training sessions (p<0.001) (NOV Ti: 9.38±5.01 min and Tf: 4.55±1.68 min; LAP Ti: 5.48±2.77 min and Tf: 3.84±1.95 min; LESS Ti: 3.75±1.62 min and Tf: 2.11±0.94 min; Ti vs. Tf, p<0.001).

Assessment values obtained for the group as a whole during the seven training sessions for the end-to-end circular urethrovesical anastomosis were 0.73±0.13 for objective performance scores, and 4.33±2.67 minutes for completion of each suture.

Estimated performance score for learning plateau of the 24 participants was 0.73, with an

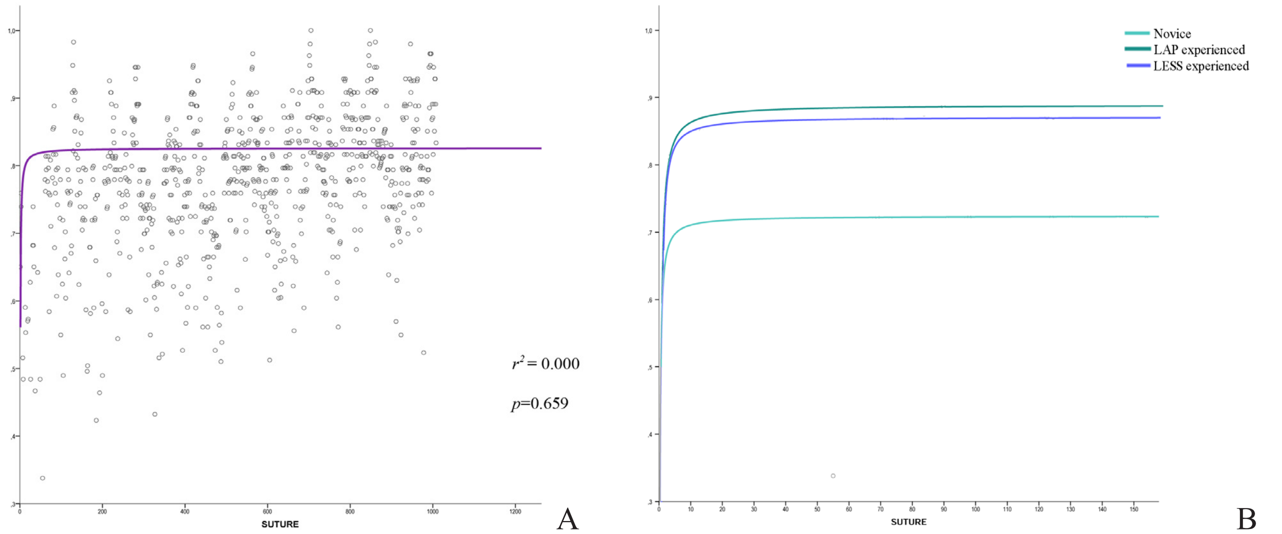


Figure 24. Inverse curve fit for performance of 1008 suture repetitions in a linear anastomosis on simulator. For each experience level group, the suture axis was reduced to a maximum of 150, so that the initial line of the curve could be more clearly depicted. A. Curve for all 24 participants. B. Curves adapted to the performances of the different experience groups.

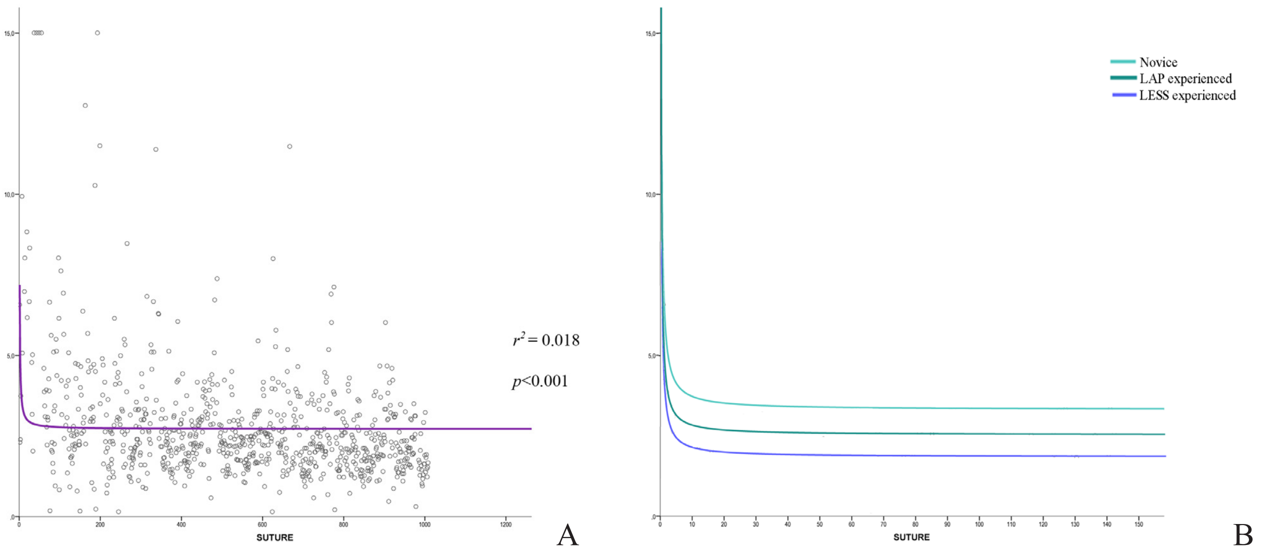


Figure 25. Inverse curve fit for total completion time of 1008 suture repetitions in a linear anastomosis on simulator. For each experience level group, the suture axis was reduced to a maximum of 150, so that the initial line of the curve could be more clearly depicted. A. Curve for all 24 participants. B. Curves adapted to the completion times per suture of the different experience groups.

estimated learning rate of 4.00 trials (r^2 0.011, p=0.014). In turn, for each suture on the circular anastomosis completion time, the learning plateau was calculated as 4.29 minutes, with a learning rate of 17.60 trials (r^2 0.018, p=0.001).

General aspects of the obtained fitted curves

There was significant intragroup variability, which led to poor fit (r2<0.07) of the inverse curve in all evaluated parameters. Furthermore, and regarding statistical significance, the fitted curve for the summative scores on linear suturing was not significant (p=0.659), along with the curves fitted to the performance assessment scores for both suturing tasks and completion times on the circular anastomosis for the different experience level groups. The LESS experienced group was the exception to this evidence, with all significant fitted curves and the highest quantification of fit goodness (r^2), although this never reached fair quality values.

Circular Suturing Task Summative Score	**Slope**	**Learning Plateau**	**Learning Rate**	r^2
All Groups	-0.292	0.73	4,00	**0.011 (*p*=0.014)**
Novice (n=10)	-0.122	0.63	1,93	0.008 (*p*=0.250)
LAP Experienced (n=10)	-0.012	0.72	0,17	0.000 (*p*=0,891)
LESS Experienced (n=4)	-0.233	0.86	2,72	**0,054 (*p*=0.004)**
Circular Suturing Task Suture Completion Time	**Slope**	**Learning Plateau**	**Learning Rate**	r^2
All Groups	7.553	4.29	17,60	**0.018 (*p*=0.001)**
Novice (n=10)	4.974	5.72	8,70	0.016 (*p*=0.091)
LAP Experienced (n=10)	2.060	4.27	4,83	0.005 (*p*=0,253)
LESS Experienced (n=4)	5.147	2.59	19,89	**0.114 (*p*<0.001)**

Table 12. Descriptive values of the learning curves for the 24 study participants as a whole, and divided by experience level, for the lineal intracorporeal suturing tasks and regarding objective assessment scores and total completion time. Goodness of fit and curve significance are shown.

Curiously, we observed that LESS experienced group presented a slower learning rate on every task when compared with the other groups. On the contrary, when we consider learning plateau for each parameter, their stabilization level was always higher than the other two groups, with the exception of the summative score obtained during the linear suturing task, which was lower than the laparoscopic experienced group.

Additional comparison between levels of MIS experience (Tables 13 to 19)

Comparison of LESS instrument setups

On the first week of the coordination trials, and for the different studied instrument setups of purpose-built tools combined or not with straight laparoscopic instruments, we observed significant differences in all performance scores during the coordination trials between the different experience levels (Figure 28). Regarding total completion time for the same trial week, there were significant differences between novices and laparoscopic experienced subjects for setups II, III and IV, and between novices and LESS experienced participants on setup III (Figure 29).

On the last week of trials, the LESS coordination abilities of the participants showed improvement at almost all experience levels, reflected on the significant decrease in total

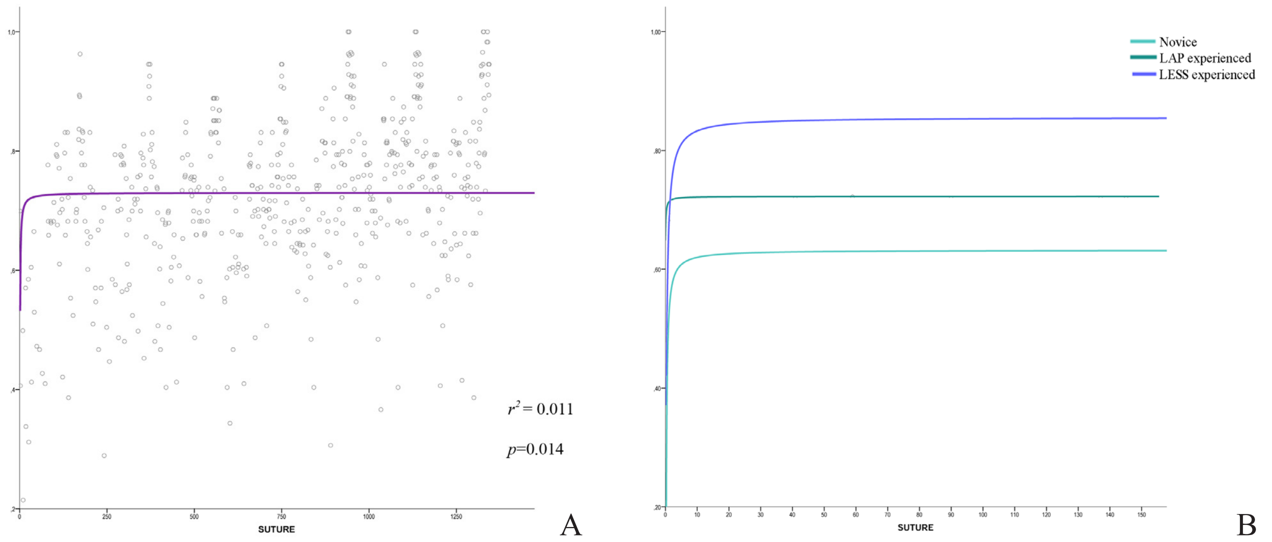


Figure 26. Inverse curve fit for performance of 1344 suture repetitions in a circular end-to-end anastomosis on simulator. For each experience level group, the suture axis was reduced to a maximum of 150, so that the initial line of the curve could be more clearly depicted. A. Curve for all 24 participants. B. Curves adapted to the performances of the different experience groups.

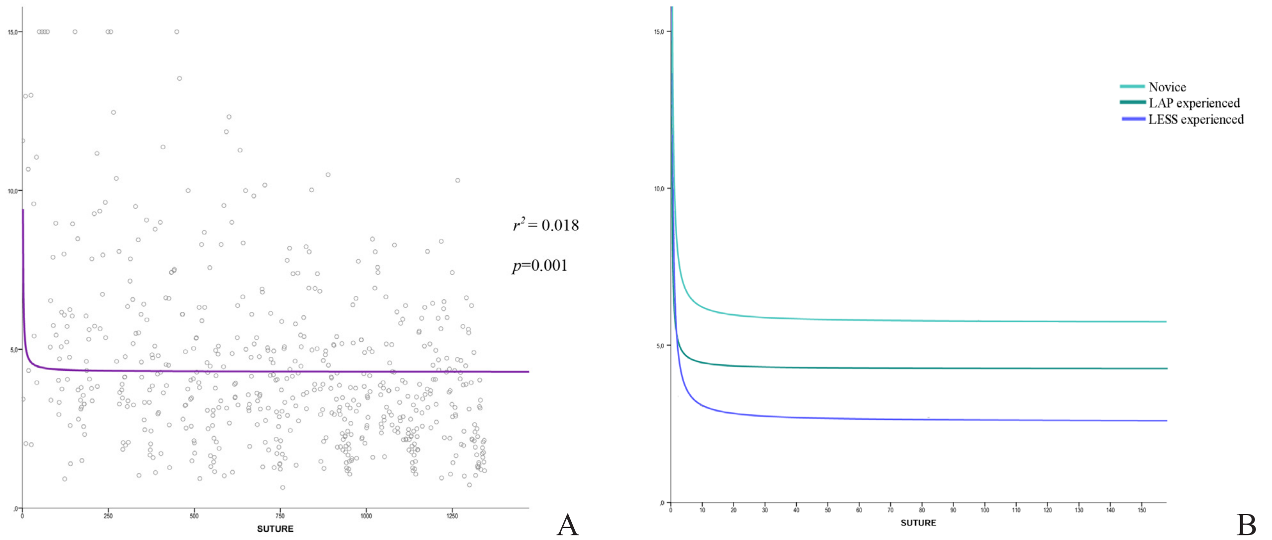


Figure 27. Inverse curve fit for total completion time of 1344 suture repetitions in a circular end-to-end anastomosis on simulator. For each experience level group, the suture axis was reduced to a maximum of 150, so that the initial line of the curve could be more clearly depicted. A. Curve for all 24 participants. B. Curves adapted to the completion times per suture of the different experience groups.

completion time (Table 14). However, when we consider the parameter of performance quality, there was only evident improvement with setup I (two dynamic articulating grasping instruments), and the differences between experience levels were maintained.

During the cut trials no statistical significance was observed with any of the instrument setups between the different experience levels in what concerns task execution time. Nevertheless, and regarding objective adapted global rating performance scores, there was variable significance in all setups between levels, especially between novices and the other two groups. (Figure 30). These differences were not reduced after the nine weeks of training in LESS.

During both basic tasks, LESS experienced subjects obtained a higher average performance score than the other two groups, although with

Coordination task			Novice	LAP experienced	LESS experienced
<u>**a-GRS score**</u>					
	I	Ti	6.65±0.99	7.28±1.44	8.83±1.17
		Tf	7.67±1.39	8.57±0.95	9.37±0.88
		Ti vs Tf (*p* value)	<0.05	<0.05	<0.05
	II	Ti	7.28±0.94	8.88±0.94	9.58±0.77
		Tf	8.37±1.10	9.17±0.64	9.79±0.42
		Ti vs Tf (*p* value)	<0.05	NS	NS
	III	Ti	7.35±0.86	9.03±0.76	9.33±0.70
		Tf	8.12±1.01	8.80±0.80	9.75±0.44
		Ti vs Tf (*p* value)	NS	0.048	NS
	IV	Ti	7.75±0.91	9.13±0.72	9.46±0.72
		Tf	8.30±1.21	8.97±0.74	9.83±0.38
		Ti vs Tf (*p* value)	<0.05	NS	NS

Table 13. Mean objective performance scores for each level of previous experience in MIS, during the completion of basic coordination tasks when comparing between different LESS instrument setups at first and last study trials.

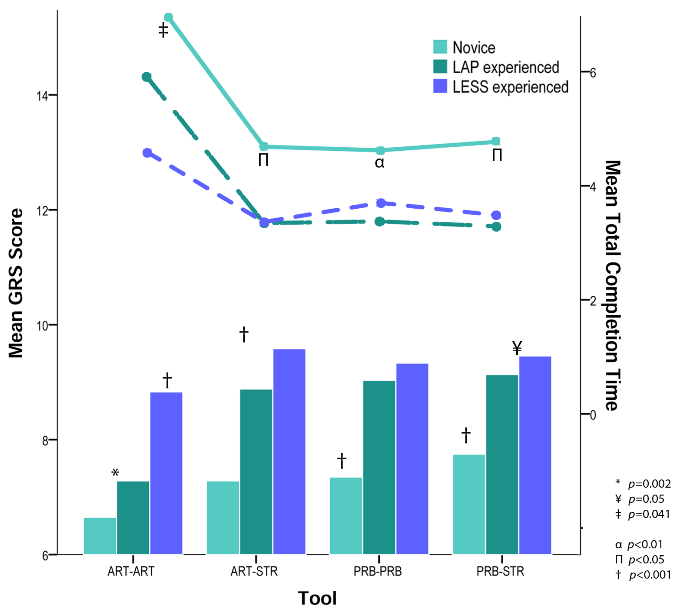


Figure 28. Graphical representation of mean total completion time and mean a-GRS score for the coordination task registered during the first (Ti) training session, according to previous experience levels of the participants. Different symbols represent the various statistically significant differences found between the different experience levels for each instrument setup.

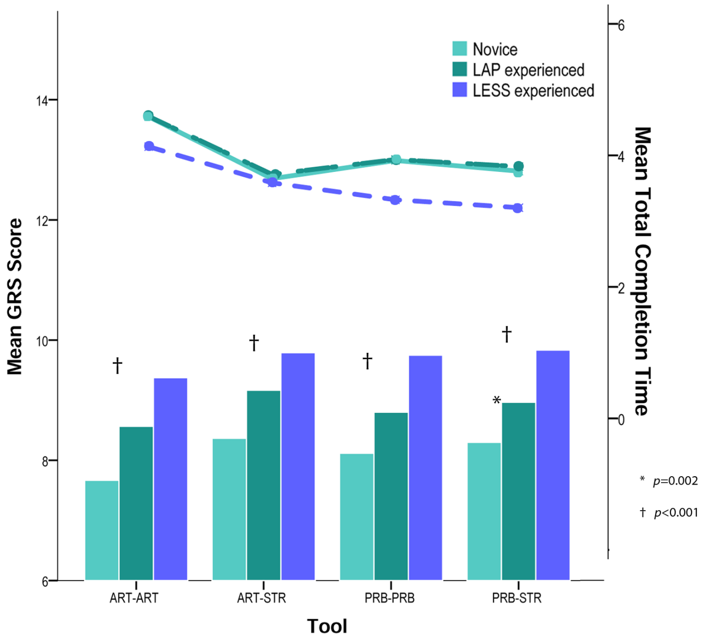


Figure 29. Graphical representation of mean total completion time and mean a-GRS score for the coordination task registered during the last (Tf) training session, according to previous experience levels of the participants. Different symbols represent the various statistically significant differences found between the different experience levels for each instrument setup.

Coordination task			**Novice**	**LAP experienced**	**LESS experienced**
Total Completion Time*	**I**	Ti	7.45±2.75	5.90±1.18	4.59±1.68
		Tf	4.59±1.09	4.59±1.05	4.13±1.04
		Ti vs Tf (*p* value)	<0.001	<0.05	<0.05
	II	Ti	4.69±1.53	3.35±0.49	3.37±0.74
		Tf	3.65±0.93	3.71±0.51	3.58±0.42
		Ti vs Tf (*p* value)	0.043	<0.05	NS
	III	Ti	4.62±0.83	3.37±0.57	3.70±0.32
		Tf	3.92±0.96	3.93±1.01	3.33±0.69
		Ti vs Tf (*p* value)	<0.05	NS	<0.05
	IV	Ti	4.77±1.79	3.29±0.38	3.48±0.63
		Tf	3.76±0.89	3.83±0.54	3.21±0.64
		Ti vs Tf (*p* value)	<0.05	<0.05	NS

*Total completion time expressed in minutes.

Table 14. Mean total completion time for each level of previous experience in MIS, during the completion of basic coordination tasks when comparing between different LESS instrument setups at first and last study trials.

setups II, III and IV they took longer to complete the consecutive coordination trials, evidence also observed with setups I, II and IV on the cut task.

Comparison of LESS access devices

On the cut trials during the nine weeks of hands-on sessions, we observed significantly different performances between different expertise levels for all access devices, although these variations were not manifested with similar statistical weight in what concerns task completion times (Figure 32).

Concerning both intracorporeal tasks, statistical significant differences were observed between all experience groups for all assessment parameters and regardless of elected single access device (Figure 33 and Figure 34).

Cut task		**Novice**	**LAP experienced**	**LESS experienced**
a-GRS score				
I	Ti	11.65±1.53	13.25±1.77	17.63±1.55
	Tf	12.45±1.12	12.65±1.80	16.88±1.44
	Ti vs Tf (*p* value)	NS	NS	NS
II	Ti	12.25±1.60	14.25±1.78	16.88±2.29
	Tf	13.30±1.36	14.00±1.56	17.75±0.65
	Ti vs Tf (*p* value)	NS	NS	NS
III	Ti	10.70±1.92	14.85±1.55	16.38±1.89
	Tf	13.10±1.43	14.70±1.51	17.38±2.10
	Ti vs Tf (*p* value)	$p=0.01$	NS	NS
IV	Ti	11.90±1.33	14.80±1.78	16.00±2.08
	Tf	12.55±1.28	14.50±1.63	17.88±0.63
	Ti vs Tf (*p* value)	NS	NS	$p<0.05$

Table 15. Mean objective performance scores for each level of previous experience in MIS, during the completion of intermediate level cut tasks when comparing between different LESS instrument setupsat first and last study trials.

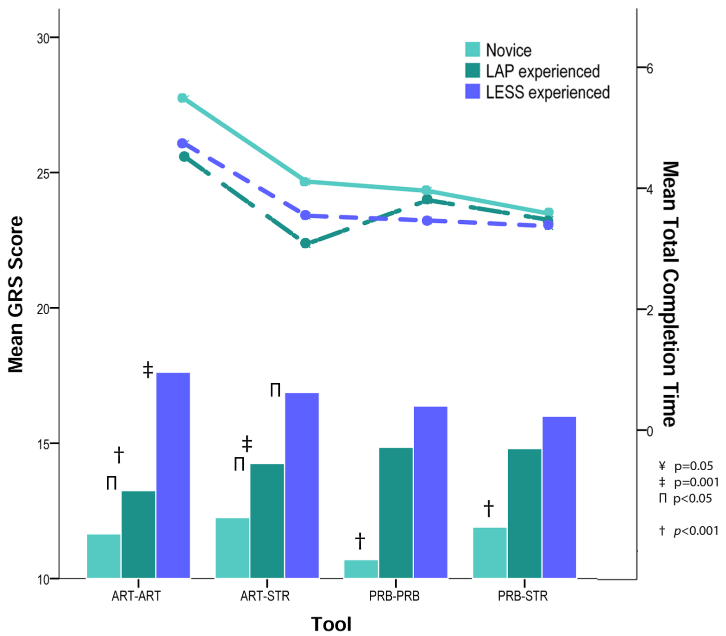


Figure 30. Graphical representation of total completion time and mean a-GRS score for the cut task registered during the first (Ti) training session, according to previous experience levels of the participants. Different symbols represent the various statistically significant differences found between the different experience levels for each instrument setup.

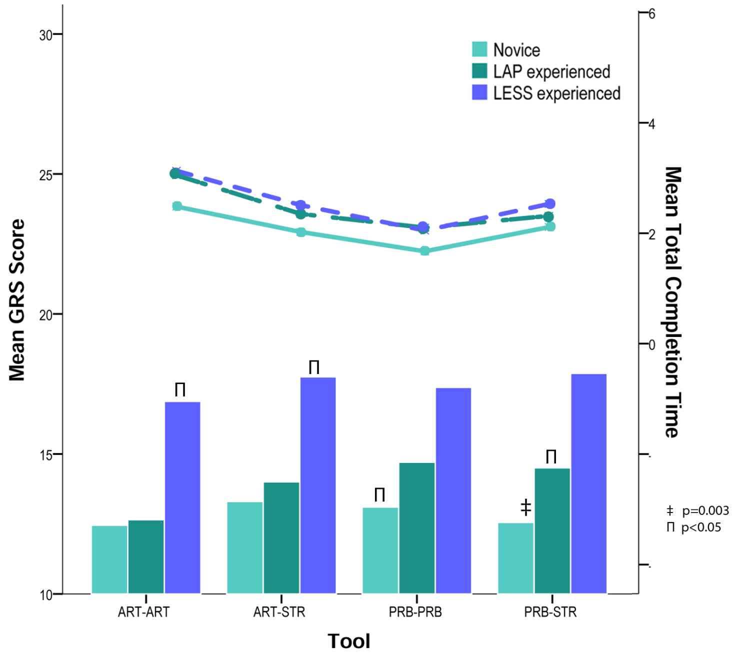


Figure 31. Graphical representation of total completion time and mean a-GRS score for the cut task registered during the last (Tf) training session, according to previous experience levels of the participants. Different symbols represent the various statistically significant differences found between the different experience levels for each instrument setup.

Cut task			**Novice**	**LAP experienced**	**LESS experienced**
Total Completion Time*	**I**	Ti	5.47±2.39	4.52±2.06	4.73±0.39
		Tf	2.48±1.00	3.05±0.80	3.31±0.43
		Ti vs Tf (*p* value)	p<0.001	p<0.001	p<0.05
	II	Ti	4.11±2.24	3.08±1.01	3.55±0.42
		Tf	2.02±0.55	2.35±0.72	2.51±0.37
		Ti vs Tf (*p* value)	p<0.001	p<0.05	p<0.05
	III	Ti	3.96±1.44	3.80±1.23	3.47±0.71
		Tf	1.67±0.43	2.10±0.59	2.05±0.22
		Ti vs Tf (*p* value)	p<0.001	p<0.05	p=0.043
	IV	Ti	3.58±0.97	3.48±1.17	3.37±0.81
		Tf	2.11±0.41	2.32±0.73	2.53±0.84
		Ti vs Tf (*p* value)	p<0.05	p<0.05	p<0.05

*Total completion time expressed in minutes.

Table 16. Mean total completion time for each level of previous experience in MIS, during the completion of intermediate level cut tasks when comparing between different LESS instrument setups at first and last study trials.

Cut tasks		Novice	LAP experienced	LESS experienced	*p* value
a-GRS score	SILS	13.32±1.34	14.33±1.82	16.50±1.42	NOV vs. LAP *p*=0.034; other *p*<0.001
Total Completion Time*	SILS	2.97±1.11	2.92±0.89	3.30±0.99	NS
a-GRS score	GPN	13.32±1.34	14.29±1.31	16.71±1.74	NOV vs. LAP *p*=0.014; other *p*<0.001
Total Completion Time*	GPN	3.10±1.24	3.33±1.41	2.93±0.87	NS
a-GRS score	XCN	13.07±1.60	14.30±1.54	16.30±1.63	NOV vs. LAP *p*=0.004; other *p*<0.001
Total Completion Time*	XCN	3.22±1.10	3.10±0.95	3.07±0.74	NS

*Total completion time expressed in minutes.

Table 17. Mean objective performance scores and mean total completion time for each level of previous experience in MIS, during the completion of intermediate level cut tasks when comparing between elected LESS access devices.

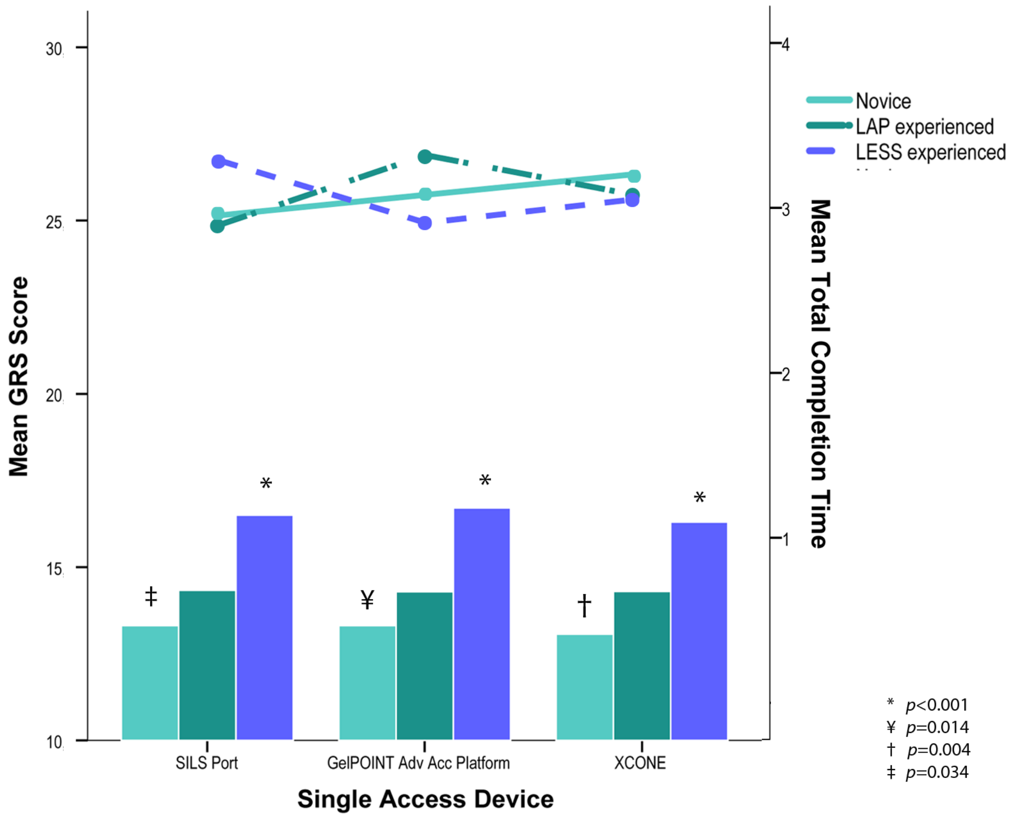


Figure 32. Graphical representation of total completion time and mean a-GRS score for the cut task registered during the nine training sessions, according to previous experience levels of the participants. Different symbols represent the various statistically significant differences found between the different experience levels for each studied single access device.

Linear intracorporeal suturing					
Summative score	SILS	0.72±0.11	0.78±0.11	0.86±0.08	*p*<0.001
Total Completion Time*	SILS	3.75±3.07 min	3.05±1.97 min	2.06±0.87	NOV vs. LAP *p*=0.037; other *p*<0.001
Summative score	GPN	0.70±0.12	0.79±0.09	0.90±0.07	*p*<0.001
Total Completion Time*	GPN	4.06±3.11	2.97±1.66	2.27±1.62	*p*<0.001
Summative score	XCN	0.68±0.12	0.76±0.10	0.87±0.06	*p*<0.001
Total Completion Time*	XCN	5.50±3.81	3.55±2.52	2.12±0.88	*p*<0.001

*Total completion time expressed in minutes.

Table 18. Mean objective performance scores and mean total completion time for each level of previous experience in MIS, during the completion of advanced level lineal suturing tasks when comparing between elected LESS access devices.

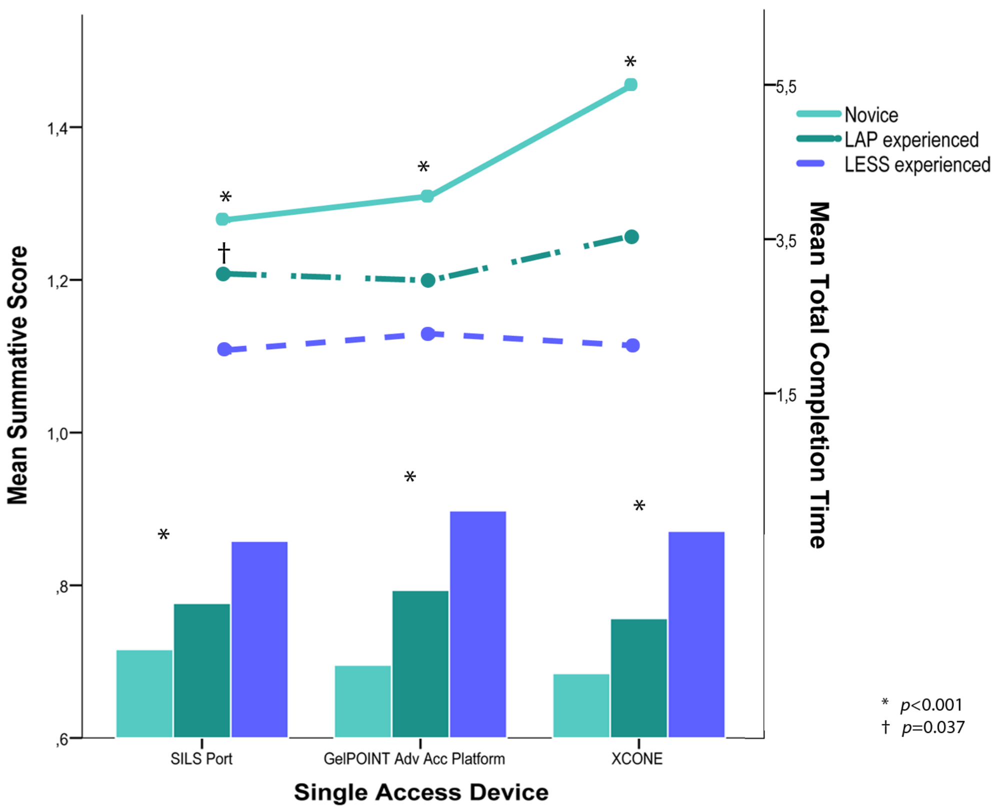


Figure 33. Graphical representation of total completion time and mean summative score for the linear suturing task registered during the nine consecutive training sessions, according to previous experience levels of the participants. Different symbols represent the various statistically significant differences found between the different experience levels for each studied single access device.

Circular intracorporeal anastomosis					
Summative score	**SILS**	0.67±0.08	0.77±0.09	0.83±0.08	*p*<0.001
Total Completion Time*		5.35±2.30	4.56±2.15	2.92±1.54	NOV vs. LAP *p*=0.009; other *p*<0.001
Summative score	**GPN**	0.70±0.08	0.76±0.09	0.87±0.10	*p*<0.001
Total Completion Time*		6.01±2.79	4.80±2.42	2.83±1.83	*p*<0.001
Summative score	**XCN**	0.71±0.09	0.76±0.07	0.86±0.08	*p*<0.001
Total Completion Time*		7.32±3.50	4.62±1.81	2.51±1.02	*p*<0.001

*Total completion time expressed in minutes.

Table 19. Mean objective performance scores and mean total completion time for each level of previous experience in MIS, during the completion of advanced level circular anastomosis tasks when comparing between elected LESS access devices.

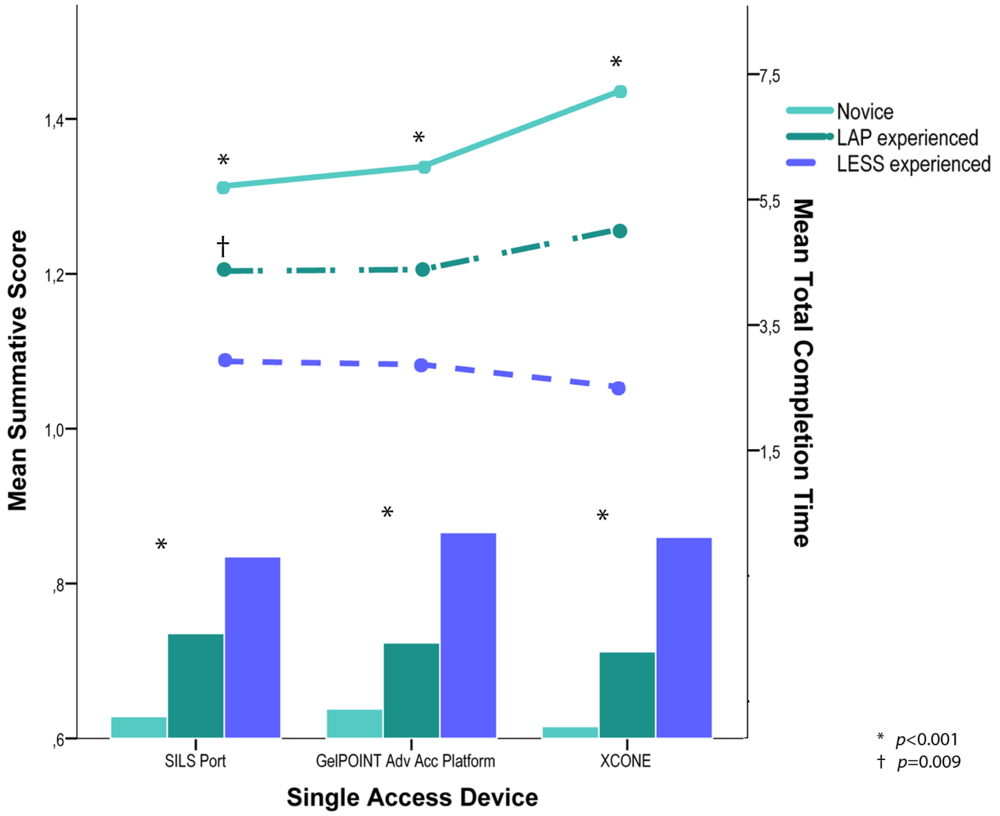


Figure 34. Graphical representation of total completion time and mean summative score for the circular end-to-end anastomosis task registered during the nine consecutive training sessions, according to previous experience levels of the participants. Different symbols represent the various statistically significant differences found between the different experience levels for each studied single access device.

V. Discussion

The concept of LaparoEndoscopic Single-Site surgery gained shape in the search for further reduced invasiveness[5] and is presently being applied to general, urologic and gynaecologic surgery. LESS surgery has nowadays attracted the attention of the surgical community and its advocates still promote it as the next evolution in minimally invasive surgery.[2, 24] Apart from the obvious ameliorated cosmetic effect resulting from decreased extent of total incisional trauma (97% improvement on surgeons' subjective assessment[108]), early reported impressions among general surgeons showed a subjective belief that LESS leads to 25% decreased post operative pain and 18% faster recovery. This approach emerges along with added difficulties, recognized by professionals and reflected on the 97% which considered LESS to be a more demanding approach, with a subjective assessment of a probable 73% increase in complication rates108. Although some authors have published objective evidence of reduced post operative pain and faster convalescence1[9, 21, 42], not all practitioners are ready to implement these techniques.

Despite the initial drawbacks that this approach implies, most surgeons are willing to foster its safe adoption after appropriate training[108]. Robust simulation methods are thus advised by many authors[11, 86, 87, 89, 91, 109-113], for training and promotion of skills acquisition and retention, through repetitive controlled practice and verification of proficiency to such a level that safe adoption of the technique can be fostered.

Careful patient selection, increased number of more experienced surgeons and improved instrumentation have also led into further clinical investigation in LESS.[114] Nevertheless, it is common sense that it is in the patients' best interest to be able to convert early in order to prevent serious morbidities, thus improving procedural safety. As experience with this surgery rises, we will hopefully observe improvements in exposure techniques and available purpose-built instruments.[22]

With this project, we tried to establish the bases of differentiation between the different purpose-built LESS technological resources, simultaneously establishing proficiency training guidelines for the different essential surgical manoeuvres. The dry laboratory setting allowed us to control and safeguard several aspects, including the use of standardized tasks analyzed with objective assessment metrics.

Since the very dawn of the new minimally invasive approaches of LESS and NOTES, tangible effort has been made by the main manufacturers and collaborating expert surgeons in developing the most adequate instruments, vision systems and single access ports.[62, 115, 116] These led to expectedly longer instrument-derived learning curves compared to the more conventional MIS alternatives. Although many comparisons have been made focusing on specially developed LESS instruments[33, 34, 117-120] and robotic systems and platforms with multiple degrees of freedom[121, 122], on this study we chose to compare the most clinically probable instrument combinations, according to availability, surgeons' preference between single use and multiple use tools, ergonomics and adaptation to the most common LESS access device.

To determine the **ideal instrument set** for the development of abilities on single site surgery, and observe if the initial performance levels for basic laparoscopic simulator tasks could be ameliorated after training, we used two basic tasks: coordination and cut tasks. In other minimally invasive surgical approaches the completion of adequate training has always been considered of extreme importance[65, 123, 124], and the use of box trainers or virtual simulators advocated as a safe and reliable method to do so[65, 124-127]. The coordination and cut tasks are introduced to novices in minimally invasive surgery as the early steps in hand-hand and hand-eye training, and constitute initial skills' acquisition demands in the laparoscopic learning curve[65]. Gaining from our centre's extensive experience in MIS training courses and its validated methods[93], we chose these two tasks in order to determine the early instrument derived obstacles to the development of LESS basic skills. Notwithstanding, the coordination task manoeuvres, similar to peg transfer task included in the FLS program[11, 107, 128], entail low clinical applicability and its translation to real LESS skills should be carefully considered.

The cut task performed on MISCJU's basic cut templates has similar skill demands as the ones included in other training programs[91, 129], and is considered an intermediate level exercise[130], teaching the importance of a coordinated action of both dominant and non dominant hand for the creation of adequate workspace. In order to assess the performance, we registered both completion times and a developed scoring reference (a-GRS) based on the particular features of each task[94].

Completion times constitutes an easy, valid and practical parameter for objective task assessment[131], and is nowadays one of the most used tools for performance analysis and evaluation either on simulator, experimental or clinical settings, whilst the search for the perfect universal objective assessment tool continues. Among other available methods[104, 132-134] it is possible to find the use of objective score assessment scales that, when adequately adapted to the task at hand, provide a more complete tool, by allowing for extended data registries by evaluation task performance quality and not only execution times. In this study, we combined the score of both general global rating scale and checklist scores to determine a new summative score. The formula developed to obtain a thus normalized value is easily applicable to other studies and may help to standardize similar assessments.

In order to be able to use the adapted **GRS**, we initially demonstrated its construct validity, with expert surgeons showing significantly superior performance when compared with novices, and establishing a high degree of accuracy in the measurements of intended scores. Furthermore, with the registered assessments completed by the two blinded expert raters, we were able to obtain a high degree of correlation (0.830) between their individual scores, which further supports the consistency of the elected a-GRS anchors for objective assessment of both coordination and cut tasks[105].

The two dynamic articulating tip instruments statistically proved to be the worst instrument set for the *coordination trials*. These tools provide a more unstable and less intuitive tool, and although they are commonly the first choice for surgeons performing LESS procedures and laboratory trials[75, 108, 117, 135], their configuration causes a "mirror effect" on the monitor, with the operators' right hand appearing on the left, and the left hand moving on the right side of the monitor image. The crossed image on the monitor constitutes another technical difficulty which novice surgeons and those at the beginning of their LESS learning curve must encounter, making it harder for users' to adapt to these purpose-built tools.

Moreover, and during the hands-on trials, the dynamic articulating single use instruments showed a deficient grasping ability, with many slipping errors occurring in all experience levels. This aspect, combined with the abovementioned image crossing, justifies the increase in performance times for all subjects during the first week's trials. This slower performance was partially compensated by training, as evidenced by the reduced differences when compared with the other instrument setups in the final assessment. Moreover, the observed improvement with training was greater with the two dynamic articulating tip instruments (setup I: 16.50% vs. from 2.25% up to 8.54% for the other setups), although its performance did not reach quality levels comparable to the other LESS instrument setups.

From our results it can be particularly inferred that, on the coordination task, the use of pre-bent tools combined with conventional laparoscopic instruments showed a superior performance tendency on the first week when compared to all other combinations. At the end of the training period, setups that included the use of pre-bent instruments, whether exclusively or combined with straight laparoscopic graspers remained the highest scored setups. Pre bent instruments evidently benefit the surgeon with a very adequate grasping strength (comparable to multiple use laparoscopic instruments), as well as a marked stability of the shaft, which constitutes them as advisable surgical tools. Considering the nature of the coordination task (grasping and transference of objects), the inherent features of multiple use LESS tools probably led to the observed ameliorated results.

As other authors previously reported [33, 34], multiple use pre-bent instruments represent a less time consuming and manoeuvrable alternative for the initiation in LESS surgery, which may also be extremely cost-effective due to its durability. Although it is true that the specific design line of pre-bent instruments used in this study, and in those carried out by Miernik and colleagues[33], lacks effectors' tip rotation, we observed that this did not represent a handicap for the purpose of performing basic coordination tasks on simulator. At this time, manufacturers have already made more advanced multiple use instruments available, which present a design with rotating tips[66] that will probably lead to higher comfort and better surgical results.

Regarding task completion time, we observed that this was reduced with training for all instrument setups, and significantly so with the use of the two dynamic articulating grasper and dissector in the coordination trials. Significant reduction in completion times was also verified for all instrument combinations during the cut tasks. The observed increase in speed was expected due to knowledge and habit acquired during the learning program completed by all attendants. Although significantly improved with training, we observed that the use of two dynamic articulating instruments still presented the highest challenge, which is probably, as stated before, mainly derived from the loose grasping ability of these commercially available instruments, the low stability of effectors' tip and the building of mirrored images on the monitor.

For the completion of the *cut task*, the grasping strength of the instrument tips becomes a variable of minor influence, as it is not a highly dependable factor needed to complete the exercise. Nevertheless, the use of pre-bent Maryland dissector and scissors still maintained the highest GRS scores before and after training. Although this difference was not significant when compared with the remaining tool setups, this indicates that choosing multiple use instruments with a bent shaft that avoid external clashing and draw effectors' tip closer, may constitute a valid alternative for surgeons worldwide who are able to make the necessary monetary investment. Furthermore, after the completion of the training program, setup II (dynamic articulating dissector combined with straight laparoscopic scissors) obtained the second highest non significant a-GRS score, presenting itself as the most adequate setup whenever disposable instruments are preferred by the surgical team or hospital management. Regarding time necessary to complete this task, setup II was surpassed by the use of two pre-bent Maryland dissector and scissors (setup III), probably due to the inherent characteristics of these pre-bent instruments, as they do not cross once introduced through a single incision, maintaining a similar eye-hand coordination as with conventional laparoscopy, and facilitating the learning process.

On the cut tasks, similarly to Santos et al.[109] in their comparison between different LESS and laparoscopic instrument configurations, we observed no statistical differences on performance scores between the various instrument combinations. Thus, it is possible that this task provides a more stable learning curve, with fewer oscillations than the one corresponding to the object transfer ability. Also, as all cutting manoeuvres are usually carried out with the use of the surgeons' dominant hand, the importance of an auxiliary instrument is reduced exclusively to tissue traction, decreasing between-instrument interactions and facilitating the completion of the task.

At the beginning we were unsure if the comparison between instruments could provide truly unbiased results, as during the seven weeks of the training program, on which different LESS instrument combinations were not assessed, we attributed one specific instrument setup per session for each participant, and opted only by the ones that combined LESS specific tools with conventional straight laparoscopic instruments[32, 33]. However, this does not seem to have affected the learning process or biased final assessment trials, as the chosen setups (II and IV) did not show significant improvement from Ti to Tf, observed only in the "pure" LESS instrument setups. To this effect, it also indicates that the initial adaptation to LESS and laparoscopic combined instrument setups is easier for the average user, as its initial performance levels were maintained throughout the program.

Another of our proposed objectives was to demystify the fixed ideas regarding s**ingle-access device superiority** over another. In order to be able to choose the most adequate LESS access device, we decided to compare one reusable and two disposable LESS access devices readily available for surgeons around the world. These did not present strong differences in terms of performance quality or total completion time in any of the included cut and intracorporeal suturing trials. The lack of distinctive advantages between LESS access devices was also reflected on a review published by Carus et al.[1]

Each access device has its own limitations and advantages, which can be related to the results obtained in these trials. Few comparisons have been made between GelPOINT Advanced Access Platform, SILS™ Port and other disposable LESS access devices[128, 136]. With the first, surgeons' are usually very comfortable due to the flexible structure of the wound retractor and the device's gel cap, which allows for reduced impairment in freedom of movement.

The SILS™ Port is nevertheless easier to insert, and although it does not adapt to thick abdominal walls, it constitutes one of the most demanded access devices. Based on our results, its use entails more clashing between instruments and camera compared with the GelPOINT Advanced Access Platform. However, it seems to facilitate performance in the beginning of the LESS learning curve for intermediate and advanced simulator manoeuvres. Both alternatives are readily available, and do not present significant differences in what concerns performance quality or total completion time during cut and intracorporeal suturing manoeuvres.

Regarding *total completion time* during the **cut task**, we observed that there were no significant differences between the access devices, probably due to the reduced need to actively coordinate both operating instruments when compared with more advanced surgical skills, which leads to a decreased influence from the access cannulae on task performance. It is, nevertheless, odd that there are almost no statistical significant differences between the different LESS access devices in the cut task, contrary to the results obtained with the suturing tasks. We consider this may be due to the evident difficulty differences between the two tasks, which demand higher coordination and more attentive practice from the surgeon during the performance of the latter, and which probably allows for greater contrast among technical and ability constraints.

On our trials we noted an improvement tendency in almost all objective assessment parameters after the completion of a regulated training program. This improvement was observed with the three LESS access devices and on all assessed parameters, with the exception of the a-GRS score on the cut task carried out with the two disposable devices which decreased, although not significantly for the SILS™ Port (Covidien, Mansfield, MA, USA). This apparent inconsistency can be attributed to the faster and more careless completion of the cut template by the study subjects, which progressively and expectedly become more at ease with less demanding tasks. Also, and as detailed before, the disposable dynamic articulating instruments gradually lose their shaft and tip stability, with the consequent decrease in performance end quality.

On the other hand, and although we did not observe any benefit of the disposable devices over the XCONE (KARL STORZ GmbH & Co. KG, Tuttlingen, Germany) on the cut trials, in the *intracorporeal suturing tasks* the latter conveyed a significantly slower performance for each completed suture. The reusable LESS access device XCONE is a heavy port with a plastic cap covered with entry valves of various diameters that cause friction, and which demand for the use of specific pre bent instruments. Although cumbersome and hard to get used to, this access device is not difficult to insert through a single incision. It is nevertheless limited by abdominal wall thickness, as is the SILS™ Port. Associated pre bent instruments are very stable and allow for similar handling as conventional laparoscopic graspers, with the more recent versions of these tools already equipped with tip and angle rotation[66]. The acknowledged stability of the reusable instruments and the need to proceed slower due to friction and clashing during the completion of the hands-on simulator trials most likely justifies the increased end quality of the cut manoeuvres and, albeit to a lower degree, of the intracorporeal suturing.

On previously published laboratory trials on LESS suturing manoeuvres, most authors focused on techniques to overcome the problems generated from entering the abdominal cavity or the simulator from one single 2 cm opening, and mostly used extracorporeal[137] or special knot tying techniques[138]. On the trials included in this study, we tried to apply the principles of laparoscopic intracorporeal suturing as far as possible. In laparoscopy, a triangulating configuration is highly advisable in manoeuvres such as intracorporeal suturing. This allows the surgeon to work with the instruments set in a manipulation angle ranging from 45 to 75 degrees, which correlates with improved task efficiency and enhanced performance quality.[139] As manipulation angles below 45 degrees increase tasks' difficulty, we tried to apply these same principles to LESS simulator trials by choosing the adequate instruments[94] without causing excessive wrist stress[140], and establish the correct distance of the access device to the target tissue with maximum angle of the effectors' tip.

The knot-tying technique applied in this study differed from conventional laparoscopy only in the inevitable crossing of instruments when these are introduced through a single access device. Thus, the subjects had to suture as if they were using their non dominant hand, despite handling the needle holder and driving the needle and the different loops with the dominant hand. To carry out the surgeons' square knot, we taught each subject how to perform the adequate manoeuvres following an objective checklist. Additionally, subjects were advised to avoid lateral movements of the needle holder when forming the different loops, and rather execute in and out depth variations of its tip over a static dissector placed on the non dominant hand.

Both **intracorporeal suturing tasks** were elected as advanced complex tasks which award skills absolutely necessary for the operating surgeon.[13] Without aiding strategies, surgeons have constantly avoided the use of these manoeuvres due to the high technical difficulty entailed. Compared to the linear intracorporeal suturing, the urethrovesical anastomosis demands even more ability from the participant surgeons. This was reflected by the number of completed sutures on this last task, which was inferior to the linear suturing task in every case. Once again in these trials no statistical significant differences between single-access ports were determined, rendering it impossible to objectively determine the most adequate device for the completion of LESS surgical manoeuvres.

However, in most of the considered variables in this study, we observed that the access device to which the surgeons more readily adapt during the completion of intermediate and advanced level LESS tasks is the SILS™ Port, which was the fastest option on week 1 of the suturing trials (although in the cut trials this "champion" status was rather only observed on the last week and on average time), and which afterwards showed a significantly reduction in completion times after nine weeks of practice. This was also the single access device with consistently the higher number of completed sutures. Although surgeons should acquire LESS simulator skills with the access device they are most likely to use on their patients, we must reflect on the possibility of the reduction of the necessary learning curve with the SILS™ Port[86, 137], probably due to its ease of use and adaptable structure.

On the distributed questionnaires, subjects confirmed the general opinion regarding the main technical and functional strong and weak aspects of each platform[45, 101, 128, 137]. The participants considered the SILS™ Port to be the best device in terms of weight but observed that it was hard to triangulate through its cannulae during the hands-on sessions. On the contrary, the GelPOINT Advanced Access Platform provided satisfactory triangulation but was criticized for its large dimensions and weight. Overall, the reusable device XCONE received low to very low subjective evaluation on all technical and functional aspects and on average score, in the ability to allow for the learning of LESS intermediate and advanced skills. Our observations sustain the impression previously stated by Khanna et al.[136], that surgeons' preferences are nowadays surpassing the technical and functional demands of the LESS access devices when it comes to making the choice between the available alternatives. Lately it has become clear that, in order to ensure safety, surgical teams should adapt their choice to the specific characteristics of the procedure and the patient itself[71].

Regardless of chosen access device or instrument setup, we observed that advanced LESS manoeuvres like intracorporeal suturing can be learned and the necessary skills progressively acquired, as evidenced by the significant improvement in performance score as well as suture completion time after nine consecutive training sessions.

For the evaluation of the **learning curve** in more advanced manoeuvres, we excluded the first and last sessions, as these were overloaded with assessment objectives. Thus, and after a series of seven consecutive training sessions we were able to observe significant development on pure Laparoendoscopic Single-Site surgery hands-on simulator intracorporeal suturing skills. Moreover, we saw that for the four experts the initiation of their learning process was set at an already high level of expertise, although they had not developed any LESS intracorporeal suturing abilities beforehand. This has led us to believe, as Lewis et al. stated in 2012[141], that extensive previous experience in Laparoscopic procedures and LESS basic and non reconstructive manoeuvres awards the necessary preparation for the acquisition of these advanced MIS abilities.

The difficulty of the tasks is evident in the increase of summative score as quality parameter, which evolved in a less steady way than the suture completion time. This was more marked on the circular anastomosis task, which inherently requires better technical knowledge and additionally forces the surgeon to work in a more confined space than when the subjects completed the ex-vivo linear suturing task on porcine stomach. We advanced the box trainer's cover, drawing it near to the ex vivo bladder, in order to reduce the clashing of the instruments with the fixed laparoscopic camera, but there were still moments when the manoeuvres could not be completed without confliction with the laparoscope and between both hands outside the box trainer. Surgeons learned to adapt to these restrictions throughout the seven training sessions, but we however believe that these would be harder to overcome if the subjects were working on a live patient with further impairment due to the interaction with a camera driving helper.

In the analysis of the obtained s*cores and completion times* in each training session, we observed that registered values varied with no apparent technical reason during the various weeks of the training program. However, the participants in these trials were obviously subjected to their every day routine prior and, most of the times, after these trials. As no change in setup conditions was reported, we can only attribute the punctual score reductions to exerted external pressures, probably leading to fatigue and loss of concentration during the completion of the demanding intracorporeal suturing tasks[142, 143].

As advised by Santos et al. in 2011[11], we wanted to study the learning curve for LESS surgery using objective standardized tasks and validated metrics to assess the performance of subjects with different previous MIS experience levels. As it was not practicable to complete this analysis with all available instrument sets and access devices available in the market, we elected one of the most accessible single ports SILS™ Port (Covidien, MA, USA) and one purpose-built dynamic articulating dissector combined with a straight laparoscopic needle holder. Although we could not, at the beginning of the project, corroborate our choice with herein presented data, the SILS™ Port has been extensively used over the years in the clinical practice and on experimental trials[11, 42, 137, 144-148], described as easier to place, allowing for reduced leakage of pneumoperitoneum, and easier to reinsert when necessary, by comparison with similar single use LESS access devices[144].

There is no standard method for the analysis of surgical learning curves. Furthermore, most published statistical methods are considered insufficient for the characterization of the learning process and ultimate performance levels.[149-152] Ramsay et al.[153] described a method of curve fitting useful for the estimation of the learning curve that was later applied by Feldman et al.[106], and Sodergren et al.[107], to hands-on simulator trials which provides a determination of the learning plateau and learning rate of different subjects.

Herein we used the same method for the continued data assessment obtained during the performance of both intracorporeal suturing tasks. Nevertheless, obtained curves, albeit with variable statistical significance, did not provide r^2 values in adequacy with an average or good fitting to registered data for the different assessed parameters, whether we considered all participants as a whole or divided in groups determined by previous MIS experience levels. In our opinion, this can be justifiable by an excessive dispersion of valid cases due to the unstable performance of the trials by each participant. The fact that the curves fitted best to scores and completion times of the LESS experienced surgeons, reflecting the highest goodness of fit in each task, supports our assumption. Moreover, we verify that the performance of these more experienced subjects was in itself insufficient to assume their proficiency in the techniques, and it is unlikely that the theoretical plateau of their individual learning process was reached with this training program.

Other possible proficiency assessment methods can be based on expert-derived performance goals used as end points in simulator training to help trials' participants to achieve their learning needs[154]. In this manner, a 90% proficiency limit could for example be empirically described as a reference for efficient performance of the designated tasks after a training schedule of seven weeks.

LESS remains a more challenging approach than standard laparoscopy, but the surgeons' personal previous experience in MIS approaches influences performance[11]. Regarding the study sample herein defined, we aimed to provide balanced groups in what concerns previous MIS experience levels. The three groups were defined according to number of completed procedures in both laparoscopy and LESS techniques. Novice and laparoscopy experienced groups obliged to Palter's condition[97], but we could not attain to it when grouping LESS experienced subjects, because it is a very recent approach and the availability of experts is, therefore, reduced. Moreover, the four elected expert surgeons reported to have performed more than 100 laparoscopic procedures before the beginning of these trials, evidently superior to the level of experience of the subjects in the laparoscopic group. This is a desirable condition, although strange from an analytical point of view, as we believe that the inherent technical and procedural difficulties of LESS surgery demand a higher degree of previous experience in order to be able to truly distinguish between levels on dry laboratory trials.

In this study, we observed that obtained objective performance scores allowed for the distinction between the different MIS experience levels on every assessed trial and for each used purpose-built access device and instrument setup. We also observed that mean total completion time at the end of the training program presented a lower number of significant differences between levels on the basic and intermediate difficulty tasks.

Some authors believe that the fact that the novices start their training without any preconceived notion of the appropriate surgical technique should lead to a faster skills' acquisition process[109]. Herein, we have become in agreement with this assumption as we found that novices did not present the highest learning rates, which would reflect a slower learning process. This also supports the adequacy of an early stage surgical education in these techniques[117] for the prompt development and implementation of new surgical alternatives among operating teams.

To summarize, the results of this study show that there are differences in the performance of basic LESS tasks on physical simulator, when combining different sets of market available instruments, independently of the preference regarding available single port devices. The results of these trials also suggest that there is no clear objective performance benefit of one LESS access device over the other. Nevertheless, we observed that it is easier for a surgeon to adapt to the available disposable alternatives of LESS access trocars, when performing cut and suturing manoeuvres with dynamic articulating instruments, than to the more stable structure of a reusable multichannel device and its specific tools.

Furthermore, our results show that the ability to perform LESS intracorporeal suturing can be acquired and developed with the practice of these manoeuvres on consecutive training sessions. Although we recognize that these are demanding skills in what concerns intraoperative time, as well as surgical team coordination and extensive training, we believe that these data shed new light on this approach's range of application.

Nonetheless, there are some limitations to this study. The first resides in the simulator setup, in which we worked with a non operator driven external camera. This optical system further hinders the ability of the simulation trials to emulate LESS inherent instrument-camera clashing occurring in clinical scenarios.

Also, regarding the study's protocol, this was designed in a way to provide only minimal to absent guidance during the different hands-on sessions, with the exception of the first and last tutored trials. It can be considered that with more attentive assistance by experts in the field, participants would have performed better and developed more accurate and shorter learning curves. Also, participation was voluntary and time consuming, and many times scheduled on busy days, with the consequent influence in obtained results.

A possible third limitation for the correct evaluation of LESS learning process can be due to the high degree of difficulty of the intracorporeal suturing task. In these tasks, performance results forcefully derive from multiple factors155 apart from technical abilities, which include previous performed tasks, amount of effort either physical or mental before the beginning of the trials, rest hours among others. These weekly changes were less evident when we focus on the time needed to complete each suture, which showed a relatively constant decrease from the beginning to the end of the training program. Although completion times are the most used objective parameter to analyze and evaluate performance, we believe that it must be complemented with other parameters, as the one used in this study. We combined the score of both GRS and checklist scores to find a summative score with an end result between 0 and 1. The mathematical formula developed to combine objective scores into a normalized value is easily applicable to other studies and may help standardize similar assessments.

This newly determined assessment parameter leads us to a fourth limitation. Although this objective score system resulted extremely useful for double scale objective assessment of skills, the correlation obtained in order to develop the summative scoring system (0.706, significant at $p<0.01$) was only moderately high. This might be overcome with increasing the experience of the two expert evaluators during the use of both scales. This can, however, be due more likely to the difference in type of parameters classified by each tool, as the checklist focuses on technical suturing aspects, and the general OSATS concentrates on tissue handling and general surgical gestures.

In view of possible conclusions and clinical application of our results, our study presents an additional limitation. In this study, there were important device characteristics not considered, including an actual report on the clinical use of each access device and instrument setup, as we limited our research to simulator trials on a controlled environment. Moreover, aspects like access device durability, cost of the platform and associated instruments, and specific procedural applicability were disregarded as objectives of the hands-on simulator trials, but will be included in future studies carried out on animal model and clinical contexts.

Future work developed in this line of research is intended to overcome this study's limitations, and simultaneously give solution to unanswered questions. As mentioned beforehand, the results included in this study constitute the first phase of a larger project which will carry on the learning process on porcine model surgery, where we expect that the specialized training course leads to the improvement of specific attainable single-port laparoscopic skills such as time and motion, instrument handling, and operative workflow.[91] We hope that if we reproduce the same learning assessment methods, these will lead to more significant results.

We will follow on the results obtained in these trials by continuing our work on experimental animal models, in which complete surgical procedures demanding cut, dissection and suturing abilities will be carried out. This will also allow us to evaluate and favour the retention of ability over-time[156, 157], after the completion of an intensive training program. Finally, and although we observed significant skills improvement especially on the advanced LESS manoeuvres, we consider that the learning curve of the 20 included subjects with different experience levels was not completed, and would demand more hands-on tutored sessions, as it was demonstrated by Supe et al.[158]. At this point we are limited by time and subject availability, and we will request of the interested subjects to carry on this learning process on animal model during the project's next phase.

Reduced iatrogenic trauma to the abdominal wall is essential in all surgical approaches, benefiting patients' recovery by preventing wound complications, reducing hospitalization periods and minimizing costs.[159] Nevertheless, the risk of inferior performance compared to other MIS approaches should be balanced against potential benefit for the patient, as poorer performance also results in longer operative times, and greater risk of inadvertent injuries or other misadventures, which increase costs and conversion rates.[11]

Although we are sensible to the training needs required to perform these advanced manoeuvres[86], we hope to be able to awaken interest in the idea of LESS as a safer and liable approach for reconstructive procedures without the need to recur to expensive robots54 or other technical resources[64, 69].

Thus, important questions still remain concerning the true benefit of promoting this technical modification of laparoscopy, taking risks of suboptimal workspaces and vision as well as instrument angles. Our study supports evidence that LESS skills can be acquired, and performances improved, albeit on surgical simulator. We believe that, until more experimental and clinical studies can obtain scientific objective proof that this new surgical approach favours better recovery and pain scores for the patient, single-site surgery should be adopted with extreme care, focusing towards patients' safety and well-being. Moreover, the technological innovative input that has been launched to overcome LESS surgery constraints will most definitely benefit global endoscopic surgical approaches, improving the more traditional and implemented MIS techniques, as well as rendering possible progressive adoption of LaparoEndoscopic Single-Site Surgery.

VI. Conclusiones

1. The most adequate instrument sets for the initiation in LESS surgery are the ones that combine specially designed instruments (single use articulated tip or pre-bent multiple use tools) with the more familiar straight conventional laparoscopic instruments, as these have obtained the most stable results. Multiple use instrument alternatives with a pre-bent shaft presented very positive results, and constitute a reliable option for those able to invest monetarily in these techniques.

Sanchez-Margallo FM, Matos-Azevedo AM, Perez-Duarte FJ, et al. Performance analysis on physical simulator of four different instrument setups in laparo-endoscopic single-site (LESS) surgery. Surg Endosc. 2014 May;28(5):1479-88. doi: 10.1007/s00464-013-3337-1.

2. We conclude that the studied LESS access device alternatives present no objective significant benefit over a similar port. Nevertheless, from a subjective point a view and reflecting an easier adaptation to more advanced manoeuvres, the SILSTM Port appears to be the best access device for LESS procedures, regardless of objective assessment metrics on dry laboratory.

Matos-Azevedo A, Díaz-Guëmes Martín-Portugués I, Pérez-Duarte F, et al. Comparison of single access devices during cut and suturing tasks on simulator. Subjective and objective assessment of available ports. Sent to Journal of Surgical Research (February 2014).

3. The learning curves obtained do not reflect the entire learning process for the included subjects. A longer training program is necessary to determine the true learning plateau for surgeons of different experience levels. Other methods for evaluation of the learning process of the expert surgeons included in this study showed that the ability to perform LESS intracorporeal suturing can be acquired and developed with the practice of these manoeuvres on consecutive training sessions.

Matos-Azevedo A, Díaz-Güemes Martín-Portugués I, Pérez-Duarte F, et al. Analysis of LESS intracorporeal suturing learning curve for linear incisions and urethrovesical anastomosis. Evaluation of experts' skills progress on a controlled environment. Sent to Surgical Endoscopy and Other Interventional Techniques on 13th March 2014.

4. Previous MIS experience level has influence over the acquisition of basic, intermediate and advanced skills in LESS surgery, and appears to be increase with the difficulty's degree of the task at hand.

VII. Abstract

Over the past decades minimally invasive surgery has experienced continuous development due to the demanded need for scarless results, with LaparoEndoscopic Single Site (LESS) surgery constituting one of the nowadays most cherished alternatives. In this study, we aim to assess the relative technical difficulty and performance benefits of the different technological resources of LESS (instruments and access devices), and also present a preliminary analysis of the learning curve and its parameters on single-site intracorporeal suture manoeuvres.

Twenty four surgeons were included and performed four simulator tasks: basic coordination, intermediate level cut task, and two advanced intracorporeal suturing tasks. The study was divided in nine different training sessions carried out a fortnight apart. Assessment took place at several distinct time points according to the specific objective at hand. Performance data was objectively analyzed over video recordings by two blinded expert raters, by means of validated global rating scales, OSATS and chekclists. Total completion time for each task was also registered. Participants were also subjective evaluated by means of a questionnaire rated on Likert scales anchored on 1-5 or 1-10 detailed scores.

The two dynamic articulating tip instruments also constituted the most time demanding setup on both assessment trials. They showed however significant improvement with training in all measured parameters except for performance in the cut task, in which the increase in a-GRS score was not significant. Participants showed improvement with all devices after the nine weeks practice. Nevertheless, we were unable to detect any objective significant differences in registered scores. The learning curve for each level of expertise and for the whole of the participants was drawn, although our results are not able to accurately determine the exact learning plateau and rate necessary for a surgeon to achieve in order to reach proficiency in LESS surgical maneuvers hands-on simulator.

We conclude that the least adequate instrument set for the initiation in LESS surgery is the one that combines two dynamic articulating tip instruments, as this has consistently obtained the worst results on all trials. Further data on more complex tasks and on a complete learning and skills acquisition program must be obtained to confirm these findings. Although we advise surgeons to focus on the specific procedures and patient characteristics to select the most adequate access device to maintain procedural safety standards, single use devices appear to confer an easier adaptation to LESS surgery. We were able to observe significant development on pure Laparoendoscopic Single-Site surgery intracorporeal suturing skills hands-on simulator. However, these are demanding manoeuvres which probably require a higher investment in intraoperative time as well as surgical team coordination and training than the length of training proposed in this sudy.

VII. Resumen

En los últimos anos, la Cirugía Mínimamente Invasiva ha experimentado un desarrollo continuo y gradual debido a la cada vez más presente necesidad de resultados quirúrgicos acicatriciales. La Cirugía Laparoscópica de Incisión Única (LESS) surge de esta manera como uno de los abordajes más desarrollados. En este estudio, quisimos analizar las dificultades técnicas inherentes a los recursos tecnológicos (instrumental y dispositivos de acceso) actualmente disponibles en LESS, bien como determinar que beneficios en la ejecución quirúrgica aportan unos y otros. Presentamos además un análisis preliminar de la necesaria curva de aprendizaje en sutura intracorpórea, bien como la medición objetiva de los parámetros de la misma.

Se incluyeron 24 participantes, con diferentes grados de experiencia en Cirugía Mínimamente Invasiva. El programa de entrenamiento contaba con 4 tareas en simulador físico: coordinación, corte, y dos tares de sutura intracorpórea (lineal y de anastomosis circular). El estudio se distribuyo por nueve sesiones de entrenamiento, una cada dos semanas. Las evaluaciones se realizaron de forma oportuna acorde con el objetivo del estudio, por 2 evaluadores independientes, ciegos, y a través de grabaciones de video en formato DVD. Los evaluadores tenían, como herramientas de determinación de la performance, escalas objetivas y validadas (GRS, OSATS y Checklists 1/0), y el registro del tiempo total de realización de la tarea. Se realizó además una evaluación subjetiva del programa y de los dispositivos de LESS a través de un cuestionario clasificado en 20 cuestiones valoradas bien de 1-5 o de 1-10 en escalas Likert.

Las dos pinzas de articulación dinámica y de un solo uso constituyeron el conjunto más exigente en ambas las pruebas de coordinación y corte. Observamos sin embargo que con estas pinzas los participantes mejoraron significativamente al final del programa de entrenamiento. Fuimos, sin embargo, incapaces de detectar diferencias objetivas entre los diferentes dispositivos de acceso LESS. La curva de aprendizaje en sutura intracorpórea por incisión única en un simulador fue determinada para los 24 participantes, y en cada nivel de experiencia, sin lograr determinar de forma fiable el nivel estable de competencia y la tasa de entrenamiento para ahí llegar.

Concluimos que el peor conjunto de pinzas para la iniciación en LESS es la combinación de dos pinzas desechables de punta articulable, ya que este obtuvo los peores resultados en las pruebas. Son necesarias más pruebas de mayor complejidad y a lo largo de un mayor periodo de tiempo para confirmar estos hallazgos. Aunque aconsejamos cada cirujano a iniciarse en LESS con un dispositivo que mejor le convenga de forma a mantener la seguridad del procedimiento, los dispositivos de acceso desechables o de un solo uso parecen aportar una más fácil adaptación a LESS. Para allá de la naturaleza exigente de las maniobras de sutura intracorpórea en simulador físico, pudimos observar un desarrollo gradual y estable de esas habilidades en los participantes en este estudio, lo que nos lleva a considerar que un plan de entrenamiento estructurado como el que aquí se presenta aplicado durante más tiempo, aportará gradualmente más capacidades y beneficios al cirujano capaz de invertir su tiempo en ese formación.

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IX. Appendix

APPENDIX 1

Subjective Assessment Questionnaire: Sheet nº 1

Centro de Cirugía de Mínima Invasión
Minimally Invasive Surgery Centre
Jesús Usón

ASSESSMENT ERGOLEARN

Minimally Invasive Surgery Centre Jesús Usón

SUBJECTIVE ASSESSMENT

DATE:

Please score from 1 (Very negative) to 5 (Very positive, the following aspects concerning the different single access devices:

	Very Negative				Very Positive
General aspects of LESS access devices					
1. Dimensions SILS™, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5
2. Shape and length of access cannulae SILS™, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5
3. Surface and materials SILS™, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5
4. Weight SILS™, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5

APPENDIX 1

Subjective Assessment Questionnaire: Sheet nº 2

Centro de Cirugía de Mínima Invasión
Minimally Invasive Surgery Centre
Jesús Usón

ASSESSMENT ERGOLEARN

Minimally Invasive Surgery Centre Jesús Usón

5. Ability to allow for the practice and learning of LESS skills on simulator SILS^{TM}, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5

ADDITIONAL COMMENTS

APPENDIX 1

Subjective Assessment Questionnaire: Sheet nº 3

Centro de Cirugía de Mínima Invasión
Minimally Invasive Surgery Centre
Jesús Usón

ASSESSMENT ERGOLEARN

Minimally Invasive Surgery Centre Jesús Usón

Aspects concerning the use of LESS access devices	Very Negative				Very Positive
6. Ease of use SILS™, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5
7. Triangulation SILS™, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5
8. Available workspace SILS™, Covidien	1	2	3	4	5
XCONE, Karl Storz	1	2	3	4	5
GelPOINT Adv Acc Platform, Applied Medical	1	2	3	4	5

Specific aspects concerning didactic tasks	Very Negative				Very Positive
9. Usefulness of the task COORDINATION WELL PLATE 	1	2	3	4	5
10. Usefulness of the task CUT ON INORGANIC TISSUE (Cut template nº 1 (®MISCJU) 	1	2	3	4	5

APPENDIX 1

Subjective Assessment Questionnaire: Sheet nº 4

Centro de Cirugía de Mínima Invasión
Minimally Invasive Surgery Centre
Jesús Usón

ASSESSMENT ERGOLEARN

Minimally Invasive Surgery Centre Jesús Usón

11. Usefulness of the task INTRACORPOREAL SUTURING ON EX VIVO PORCINE STOMACH 	1	2	3	4	5
12. Usefulness of the task URETHROVESICAL ANASTOMOSIS ON EX VIVO PORCINE ORGANS 	1	2	3	4	5

Score from 1 (In total disagreement) to 5 (totally agree) the following statements:

	Totally disagree				Totally agree
13. I believe that the training in basic LESS skills is necessary before the clinical practice, regardless of the level of MIS previous experience.	1	2	3	4	5
14. I believe that the box trainer and its proposed taks are a useful tool to assess the dexterity degree in LESS surgery.	1	2	3	4	5
15. I believe the simulator offers a safe environment for the practice of basic LESS skills.	1	2	3	4	5
16. I believe that the **continued practice** would allow for the improvement in the handling of LESS instruments, bidimensional view, spatial orientation, ambidexterity, …	1	2	3	4	5

ADDITIONAL COMMENTS

APPENDIX 1

Subjective Assessment Questionnaire: Sheet nº 5

Centro de Cirugía de Mínima Invasión
Minimally Invasive Surgery Centre
Jesús Usón

ASSESSMENT ERGOLEARN

Minimally Invasive Surgery Centre Jesús Usón

FINAL ASSESSMENT

- Please score from 1 to 10, previously performed tasks according to the degree of LESS skills improvement you believe each provides:

- 17. COORDINATION WELL PLATE ☐
- 18. CUT ON INORGANIC TISSUE (Cut template nº 1 (®MISCJU) ☐
- 19. INTRACORPOREAL SUTURING ON EX VIVO PORCINE STOMACH ☐
- 20. URETHROVESICAL ANASTOMOSIS ON EX VIVO PORCINE ORGANS ☐

→ ADDITIONAL COMMENTS

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APPENDIX 2

Demographic Questionnaire

Centro de Cirugía de Mínima Invasión
Minimally Invasive Surgery Centre
Jesús Usón

ERGOLEARN ASSESSMENT

Minimally Invasive Surgery Centre Jesús Usón

DEMOGRAPHIC QUESTIONNAIRE

DATE:

Gender:

Age:

Degree of Health Professional Training

1. OR Nurse or Assistant
2. Veterinary Doctor
3. Other (please indicate):

Dominant Hand

1. Right
2. Left
3. Both

MIS PREVIOUS EXPERIENCE

Experience as first surgeon	None	>10	>50	>100
Conventional Laparoscopy				
LESS surgery				

Simulator	None	Some	A lot
Physical			
Virtual			

PREVIOUS EXPERIENCE WITH:

Videogames	None	Some	A lot
Previous experience with videogames			

APPENDIX 3

Adapted Global Rating Scale for Objective Assessment of LESS Coordination Tasks

GRS Coordination	1	2	3	4	5
Grasping	Many unnecessary moves, object slips often from the grasper, object falls instead of being placed in a controled fashion in target well, unable to change it from hand to hand		Efficient relation time/motion but unnecessary moves still present, ocasional slipping of objects, ability to exchange object from one hand to the other in almost every attempt		Maximum time/motion efficiency, continuously controls grasping forces without slipping of any object, efficient exchange of objects between graspers, controlled placement of object in every case
Target acquisition	Unable to deposit the object in the intended well		Able to direct the object towards desired well but sometimes not reaching objective		Perfect planning and movement coordination towards target well, and controlled placement
Instrument choice and coordination	Chooses only traumatic graspers to attain better grasping surface for each rough, smooth or irregular object; uses only one active hand		Chooses grasper according to expected object surface traction; shows a dominant hand to handle but sometimes changes it according to distance to object		Uses atraumatic graspers controling grasping force without aid of tip surface; uses both hands equally to grasp closer objects increasing movement efficiency

Adapted Global Rating Scale for Objective Assessment of LESS Cut Tasks

GRS Cut plates	1	2	3	4	5
Manoeuvres	Incorrect placement and choice of instruments (rotic vs straight); unable to coordinate both grasper and scissors to reach target guideline, does not rotate scissors in order to respect direction of final cut; always uses entire cutting surface of instruments		Regular coordination between grasper and scissors, adequately roticulating almost every time, sometimes loosing correct placement for effective manoeuvres; occasional crossing of hands; rotates and uses tip of scissors often		Perfect coordination between hands, with continuous maintenance of surgical plane and without crossing hands; always adequately rotates tip of scissors and does not introduce entire mandibule to cut; roticulates adequately necessary instrument and combined used with straight instrument
Tears	Constant tearing of tissue when grasping and frequent inadvertent perforations		Occasional tearing observed; separation of layers when traction is applied		Absent tearing
Regular cut	Cut is performed with indentations		Some indentations on line transitions or specific plate areas		Cut is performed without indentations, always perfectly directing
Guidelines	Does not follow drawn guidelines		Respects most of drawn guidelines		Always follows each guideline

APPENDIX 4

Objective Structured Assessment of Technical Skills (OSATS) used in LESS Suture Tasks

OSATS (+checklist)	1	2	3	4	5
Respect for tissue	Frequently used unnecessary force on tissue or caused damage by innapropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissues appropriately with minimal damage
Time and motion	Many unnecessary moves		Efficient time/motion but some unnecessary moves		Economy of movement and maximum efficiency
Instrument handling	Repeatedly makes tentative or awkward moves with instruments		Competent use of instruments although occacionally appeared stiff or awkward		Fluid moves with instruments and no awkwardness
Flow of operation and forward planning	Frequently stopped operating or needed to discuss next move		Demonstrated ability for forward planning with steady progression of operative procedure		Obviously planned course of operation with effortless flow from one move to the next
Knowledge of specific procedure	Deficient knowledge. Needed specific instruction at most operative steps		Knew all important aspects of the operation		Demonstrated familiarity with all aspects of the operation

APPENDIX 5

Checklist 1/0 for Intracorporeal Suturing Tasks used in this study on LESS skills

Number (code: subject- suture number):________
(example: EL10-2)

SUTURING CHECKLIST (Moorthy et al. 2004)

Name:

Access Device: Date:

			Yes=1, No=0
Needle position-1	1	Held at ½ to 2/3 from the tip	
	2	Angle = 90° ± 20°	
	3	Uses tissue or other instruments for stability	
	4	Attempt at positioning (3 or <3)	
Needle driving through tissue-1 (entry to incision)	5	Entry at 60°-90° to the tissue plane	
	6	Driving with one movement	
	7	Single point of entry through tissue	
	8	Removing the needle along its curve	
Needle position-2 (incision to exit)	9	Held at 1/2 to 2/3 from the tip	
	10	Angle- 90° ± 20°	
	11	Uses tissue or other instrument for stability	
	12	Attempts (3 or <3)	
Needle driving-2 (incision to exit)	13	Driving with one movement	
	14	Removing the needle along its curve	
Pulling the suture through	15	Needle on needle holder in view at all times	
	16	Using pulley concept or walking along the suture	
Technique of knots	17	Two-handed overwrap/underwrap followed by same or if one-handed, one followed by the other	
	18	Correct C loop (no S or O loops)	
	19	Smoothly executed throw, no fumbles	
	20	Correct inverse C loop (no S or O loop)	
	21	Smoothly executed throw, no fumbles	
	22	Knot squared (capsized reef/surgical)	
	23	Correct third C loop (no S or O loops)	
	24	Smoothly executed throw, no fumbles	
Knot slippage	25	Knot left loose to slip	
	26	Knot slippage attempts 3 or <3	
Knot quality	27	All throws squared	
	28	Not too tight or too loose	
	29	All knots laid on the side (not over the incision)	
		Total Score (maximum 29)	

APPENDIX 6

Participants' Self Registry Form – Compulsory on every trial

Trials Registry Form ERGOLEARN

NAME ______________________________ DATE __________

Place your name tag inside the box trainer

TROCAR 1 ______________________________

CUT TASK

TIME __________

Please write your name on the back side of the cut template nº 1

SUTURING 1 Stomach

(15')

Total time __________

	TIME
Suture nº 1	
Suture nº 2	
Suture nº 3	
Suture nº 4	
Suture nº 5	
Suture nº 6	

Please take a picture of the completed task

SUTURING 2 UV Anatomosis

(15')

Total Time __________

	TIME
Suture nº 1	
Suture nº 2	
Suture nº 3	
Suture nº 4	
Suture nº 5	
Suture nº 6	
Suture nº 7	
Suture nº 8	

Please take a picture of the completed task

TROCAR 2 SILS™ Port, Covidien

SUTURING 1 Total Time __________

	TIME
Suture nº 1	
Suture nº 2	
Suture nº 3	
Suture nº 4	
Suture nº 5	
Suture nº 6	

SUTURING 2 Total Time

	TIME
Suture nº 1	
Suture nº 2	
Suture nº 3	
Suture nº 4	
Suture nº 5	
Suture nº 6	
Suture nº 7	
Suture nº 8	

Please take a picture of the completed task

APPENDIX 6

Independent Raters Registry Form for Assessment Scores I

Trial Registry ERGOLEARN - Performance Scores

EL CODE ______________________ DATE ______________

LESS instruments

Coordination

OSATS	a	b	T	**Time**	a	b	T	**Time**	a	b	T	**Time**
I												
II												
III												
IV												

Cut

OSATS	a	b	c	d	T	**Time**	a	b	c	d	T	**Time**
I												
II												
III												
IV												

LESS Access Device

Access Device ______________________

Cut

OSATS	a	b	c	d	T	**Time**	a	b	c	d	T	**Time**

APPENDIX 6

Independent Raters Registry Form for Assessment Scores II

Subject:
Date:

Tasks	Suture							
Repetitions	1	2	3	4	5	6	7	8
Respect for tissue								
Time and motion								
Instrument handling								
Flow of operation and forward planning (+-)								
Knowledge of specific procedure (+-)								
Total Score								

Subject:
Date:

Tasks	Suture							
Repetitions	1	2	3	4	5	6	7	8
Respect for tissue								
Time and motion								
Instrument handling								
Flow of operation and forward planning (+-)								
Knowledge of specific procedure (+-)								
Total Score								

Subject:
Date:

Tasks	Suture							
Repetitions	1	2	3	4	5	6	7	8
Respect for tissue								
Time and motion								
Instrument handling								
Flow of operation and forward planning (+-)								
Knowledge of specific procedure (+-)								
Total Score								

X. Relevant published works and performed research

Participation in Research Projects

Single-Port Surgery and NOTES in Gynaecology 2009-2010 *Project Collaborator in the OR*

Study of the performance of Nissen Funduplication by Single Port approach January 2011 Project *Collaborator in the OR*

Movement captation system for 3D recreations 2010-2013 *Collaboration through reference research and consultation*

Study to evaluate an inguinal mesh implantation procedure and its tissue tolerance - Comparison of inflammatory reaction to different mesh materials pre peritoneal implanted surrounding the spermatic chord 2011-2012 *Execution of all experimental trials on animal model and human cadaver. Collaborator on post trials' dissemination plan*.

Experimental Study on NOTES techniques Applied to Biliary Surgery Feb 2012 *Project Collaborator in the OR*

Applied Ergonomics to Single Port Laparoscopic Surgery. Feb-Sept 2012 *Chief of Project* All knowledge gathered here is being applied and constituted the first phase of project PI12/01467 carried out with a grant awarded by the Institute of Health Carlos III - FIS of Spain (2013-2015): "Definition of ergonomic guidelines in Laparoendoscopic Single Site surgery (LESS), and establishment of technical and functional criteria for LESS tools." (Head of Research: Francisco Julián Pérez Duarte; Research Team: 9 participants).

Comparative study in LESS: advantages and disadvantages of TERUMO robotic tools compared with commonly used LESS instruments.2013 *Collaborator on OR hands-on simulator trials*

Feasibility and surgical outcomes of low rectal resections through the use of transanal single access devices and abdominal mini laparoscopic assistance. Experimental study on animal model." (FAECP Grant 2013). Sept 2013-Sept 2014 *MISCJU Chief of Project*

CONGRESS COMMUNICATIONS

Oral

Hernández Hurtado, L; Díaz-Güemes Martín-Portugués, I; Sánchez Hurtado, MA; Pérez Duarte, F; Enciso Sanz, S;Moreno Naranjo, B; Soares Azevedo, AM; Carrero Gutiérrez, A; Sánchez Margallo. Evaluation of different minimally invasive surgical approaches for the creation of ureteral obstruction models for training purposes. LXXVI National Congress of Urology, 8th-11th June 2011, Málaga, Spain Robotic, Laparoscopic and Endoscopic Surgery

Video and Poster Communications

Sánchez Margallo, F. M.; Pérez Duarte, F. J.; Sánchez Hurtado, MA; Soares Azevedo, A. M.; Díaz-Güemes Martín-Portugués I.Retroperitoneal nephrectomy: feasibility of NOTES and LESS approaches. LXXVI National Congress of Urology, 8th-11th June 2011, Málaga, Spain Robotic, Laparoscopic and Endoscopic Surgery

F. Pérez, MA Sánchez, I Cano, A Azevedo, I Díaz-Güemes, FM Sánchez-Margallo. Unilateral orchiectomy in porcine animal model through single incision laparoscopic surgery. National Paediatric Surgery Congress16th-19th May 2012, Córdoba, Spain.

M Lucas Hernández; AM Matos Azevedo; FJ Pérez Duarte; JB Pagador Carrasco; FM Sánchez Margallo. Training in Laparoscopic surgery: effect of instrument in the surgeon's muscle activity. XXX CASEIB, 19th-21st November 2012, San Sebastián, Basque Country, Spain.

Ana Maria Matos-Azevedo, José Antonio Fatás Cabeza, Cristóbal Zaragoza Fernández, Juan Marín, Francis Navarro, Francisco Miguel Sánchez-Margallo Experimental preliminary study on the anatomic and histological effect of a 3D shaped mesh implant for inguinal hernioplasty. 36th Annual Congress of the European Hernia Society, 28th-31st May 2014, Edinburgh, UK

Sanchez-Hurtado MA, Matos-Azevedo AM, Fatás JA, Díaz-Güemes I, Sánchez-Margallo FM An Analysis of Advanced Laparoscopic Skills Acquisition in an Intensive Laparoscopic Colorectal Training Program. 14th World Congress and 22nd EAES International Congress, 25th-28th June, Paris, France

Oral (International Congresses)

Ana María Matos-Azevedo, Silvia Enciso Sanz, Laura Hernández-Hurtado, Francisco Miguel Sánchez-Margallo. Evaluation of the learning curve in laparoscopic intracorporeal suture hands-on physical simulator. ESSR 47th Annual Congress, 6th -9th June 2012, Lille, France

F. Pérez, MA Sánchez, I Cano, A Azevedo, I Díaz-Güemes, FM Sánchez-Margallo. Unilateral orchiectomy in porcine animal model through single incision laparoscopic surgery. European Society for Surgical Research 47th Annual Congress, 6th-9th June 2012, Lille, France

Sánchez Margallo, Francisco Miguel, Pérez Duarte, FJ, Azevedo, AMA, Sánchez Margallo, JASM, Sánchez Hurtado, MA, Díaz-Güemes, IDG. Effectiveness of a training program in laparoendoscopic single-site surgery (LESS surgery). 20th International Congress of the EAES, 20th - 23rd June 2012, Brussels, Belgium

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