Jaime Daniel Pacheco Martinho Vilaça **Minimal Invasive Surgery: Contribution of three dimensional image on single-site endoscopic surgery**

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STATEMENT OF INTEGRITY

I hereby declare having conducted my thesis with integrity. I confirm that I have not used plagiarism or any form of falsification of results in the process of the thesis elaboration.

I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

RESUMO

Cirurgia Minimamente Invasiva:
Contribuição da imagem tridimensional na cirurgia de acesso único

Os sistemas endoscópicos são usados em medicina ha mais de duzentos anos. Durante as três últimas décadas houve um esforço tecnológico considerável para desenvolver sistemas de imagem tridimensional para uso em cirurgia endoscópica. Os atuais sistemas disponíveis têm alta definição de imagem e são fáceis de usar, pois apenas necessitam que o cirurgião coloque uns óculos leves com lentes polarizadas. A cirurgia por acesso único apareceu no início deste milénio como uma proposta para diminuir ainda mais o trauma da cirurgia endoscópica e melhorar o resultado estético. Combinando este dois elementos, colocou-se a hipótese que a imagem 3D pudesse melhorar o desempenho na execução de procedimentos por acesso único. O principal objetivo desta tese é comparar em ambiente laboratorial o desempenho de principiantes e de cirurgiões experimentados na execução de cirurgia por acesso único usando sistemas de imagem 3D e 2D. Para cumprir este objetivo, dois estudos foram realizados, o primeiro usando exercícios validados com modelos inanimados e o segundo, um modelo orgânico. Vantagens na execução, aprendizagem e preferencia pelo sistema 3D foram significativas, e os resultados foram publicados. Para além disso, uma revisão baseada na evidencia foi feita para avaliar os possíveis benefícios clínicos da imagem 3D em cirurgia endoscópica de múltiplas portas. Ganhos na execução, curva de aprendizagem e redução do cansaço em favor do uso 3D foram encontrados.

Nesta tese, o conhecimento destas áreas é revisto, a evolução tecnológica, as indicações para cirurgia de acesso único e as perspectivas futuras são criticamente analisadas. Conclui-se que a cirurgia por acesso único tem sido um motor de desenvolvimento na cirurgia minimamente invasiva e que a imagem 3D possivelmente beneficia a maioria dos executantes independentemente da sua experiência.

Palavras-chave: cirurgia de porta única; cirurgia minimamente invasiva; imagem 3D;

ABSTRACT

Minimal Invasive Surgery:
Contribution of three dimensional image on single site endoscopic surgery

Endoscopic systems are more than 200 years old and have always relied on a two-dimensional image. In the late 1980´s, the advent of video-assisted surgery ushered in the era of minimally invasive surgery. The past three decades have seen a technological effort to provide endoscopic surgery with three-dimensional imaging. Currently 3D systems are high definition and easy to use with polarized and lightweight glasses. Single-site surgery is a proposal to further reduce trauma and improve the aesthetic result of endoscopic surgery, an option that started to develop at the beginning of this millennium. Combining these two elements, we hypothesize that a 3D imaging system can bring about better performance in executing single-site endoscopic procedures. The main objective of this thesis is to compare the performance of beginners and experts in a laboratory environment while conducting single-site surgery using a 3D system or a 2D system.

To this end, two studies were carried out, using validated phantom exercises and an organic model. Benefits in performance, learning and user preference proved significant, and the results were published. Apart from this, an evidence-based review was carried out to assess the possible clinical benefits of 3D technology in multi-port endoscopic surgery. Gains in execution, learning curve and decreased workload were found.

In this thesis, the knowledge of this area is reviewed, along with the technological evolution, the indications for single-site surgery and critical analysis of its foreseeable future implementation.

We conclude that single-site surgery has been a driver for the development of minimally invasive surgery and that a 3D image likely benefits most performers regardless of their experience.

Keywords: 3D system; Laparoendoscopic single-site surgery (LESS); Minimally Invasive Surgery (MIS);

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ABBREVIATIONS

2D - Two dimensional

3D - three dimensional

ANOVA - Analysis of variance

BMI - Body mass index

CCD - Charged-coupled device

EAES - European association for endoscopic surgery

ERCP - Endoscopic retrograde cholangio-pancreatography

E-BLUSS - European training in basic laparoscopic urologic surgical skills

eNOTES - Embryonic NOTES

FDA - Food and drug administration

FLS - Fundamentals of laparoscopic surgery

IGS - Intragastric surgery

LCD - Liquid cristal display

LESS - Laparo-endoscopic single-site surgery

MIS - Minimally invasive surgery

MISTELS - McGill inanimate system for training and evaluation of laparoscopic skills

NASA TLX - The national and aeronautics and space administration task load index

NOTES - Natural orifice transluminal endoscopic surgery

NOTUS - Natural orifice trans umbilical surgery

OPUS - One-port umbilical surgery

RANDOT - Random dot stereo test

SIES - Single-incision endoscopic surgery

SILS - Single-incision laparoscopic surgery

SIMPL - Single-instrument port laparoscopic surgery

SLAPP -Single laparoscopic port procedure

SLIT - Single laparoscopic incision trans abdominal surgery

SPA - Single port access

SPL - Single-port laparoscopy

SPLS - Single-port laparoscopic surgery

SSL - Single-site laparoscopy

SPPT - Single-port pneumovagina technique

SUS - The system usability scale

TaTME - Transanal total mesorectal excision

TEM - Transanal endoscopic microsurgery

TOETVA - Transoral endoscopic thyroidectomy vestibular approach

TS - Transanal surgery

USA - United States of America

VATS - Video-assisted thoracic surgery

LIST OF FIGURES AND TABLES

KEEP WALKING
JOHNNIE WALKER

PART 1

INTRODUCTION

1. Endoscopy and the beginning of Minimal Invasive Surgery

The first optical instrument to peek inside the human body was developed in the distant year of 1803 by Phillip Bozzini, a doctor in medicine from the German city of Mainz. Under the protection of the Archduke Karl of Austria, his *Lichtleiter*

(Figure 1) was improved and tested in corpses for multiple uses including rectal, bladder, vagina and peritoneal cavity observation. This invention using artificial light, various mirrors and specula was the beginning of a large family of endoscopes. Unwittingly, his monocular instrument subjected the medical world of endoscopy to a bi-dimensional image (1).

Throughout the 19th century the use of endoscopes was restricted to studying cavities through natural holes. Appropriate specula made it possible to insert the instrument into the bladder, rectum or vagina. Sometimes, trans-illumination was used to increase the low light inside cavities such as the bladder. The observer was forced to look directly through the end of the device.

Figure 1 Phillip Bozzini first endoscope

From European Museum of Urology. Bozzini's original light conductor with specula. Created by Gottfried Wiesner, Leipzig. (Int.Nitze-Leiter Reserach Society for Endoscopy/Nitze-Leiter Collection). Courtesy of the European Association of Urology's History Office and the European Museum of Urology.

It was only at the beginning of the next century that intra-abdominal observation with endoscopes began after the famous presentation of George Kelling at the 1901 German Congress of Naturalists and Physicians in Hamburg, with a live demonstration of the use of *Kolioskopie* in a dog. Several names were proposed for this new diagnostic technique: celioscopy, ventroscopy, laparoscopy, organoscopy, abdominoscopy and splanchnoscopy. Eventually the most popular name became laparoscopy, thanks to German surgeons.

During the first half of the 20th century, several publications demonstrated the feasibility and safety of laparoscopy in humans. An accuracy rate superior to 90% for diagnosing cirrhosis, tertiary syphilis, metastatic tumors and tuberculous peritonitis was reported (2). In the second half of the twentieth century, the tireless work of the German gynecologist, Kurt Semm, allowed for developing therapeutic techniques via laparoscopy. Responsible for creating the CO2 pneumatic insufflator, the development of electrosurgery and other hemostatic techniques, Semm is credited for being the first to perform a laparoscopic appendectomy in 1982. Furthermore, his work is the development of the pelvi-trainer that will come to revolutionize all surgical teaching that started to have its first step in laboratory training.

Throughout the 20th century, the use of endoscopes was made with direct observation through the eyepiece at the end of the instrument (3). It was only in the late 1980's that technological evolution, namely with the development of the charge-couple device (CCD), made it possible to relay the image to a monitor. This marked the beginning of assisted video endoscopic surgery with the world-famous first cholecystectomies performed by Phillipe Mouret in Lyon, France. Hundreds of non-video, direct-view laparoscopic procedures had been done prior to this (4).

A new era for contemporary surgery was inaugurated at that time. Soon, it became clear that minimal access operations have many more advantages than merely upgrading the aesthetic result. Evident improvement in early recovery, as well as a decrease in aggression provoked by surgery, caused this approach to become the gold standard for most surgical conditions.

Advantages of this new surgical approach include less pain, fewer infectious complications, less hernia formation, shorter hospital stay, faster resumption of work activity, and better aesthetic results. All of these undeniable improvements in surgical results have given way to a new concept of minimally invasive surgery (MIS).

MIS aims to reduce trauma resulting from surgical intervention. The exacerbated inflammatory response, as well as the increased risk of complications from open surgery, can be greatly reduced with interventions that follow the same principles of resection or reconstruction with less impact on the patient's homeostasis. Today, minimally invasive interventions are considered those performed with rigid endoscopes such as laparoscopy, thoracoscopy or cervicoscopy, those being performed by flexible intervention endoscopy, such as removing digestive tumors or urinary calculi, and percutaneous image-guided procedures, such as abscess drainage or vascular embolizations.

In video-assisted endoscopic surgery, the image is captured with an endoscope that the assistant holds, while the surgeon has both hands free to handle the instruments that allow him to perform the intervention using both hands. In these interventions, the surgeon does not directly look at the operative field. The entire operation is based on what the surgeon sees on the monitor. Thus, the surgeon's complete dependence on technology has been created, with the video system being fundamental for adequate performance. This circumstance has been and still is a source of anxiety and insecurity for many operators.

Although laparoscopic surgery has demonstrated undeniable advantages for patients, it has not gained the acceptance of all surgeons. There are several reasons to justify the resistance of many surgeons to accepting video-assisted surgery. From the outset, comfort and training in executing open techniques has made the peri-operative benefits of the mini invasion undervalued. The learning curve of laparoscopic surgery is longer and technical excellence more difficult to achieve, so that surgeons already trained in traditional methods are reluctant to learn these techniques. A reason for citing greater technical difficulty is the two-dimensionality of the endoscopic image, which presupposes a whole depth of field learning (5).

The strategy of laparoscopic surgery uses the principle of triangulation, where the instruments converge in the operative field allowing optimal dissection, manipulation and vision. Like the head in the middle of the arms, the central position of the endoscope is the optimal location for laparoscopy.

The development of laparoscopy and minimally invasive surgery has brought an obsession among surgeons in the search for lower aggression for patients, due to the excellent results that quickly became evident. Since the beginning of this millennium, new proposal have begun to gain in popularity.

Such interest started first with endoscopic single-incision surgery and then with transvisceral surgery, imposing major technical and technological challenges (3, 6).

At a certain point, the enthusiasm of its precursors was such that they compared these new tendencies to a revolution at the level of the appearance of laparoscopy. The so-called Natural Orifice Transluminal Endoscopic Surgery (NOTES) appeared as an even less damaging surgery, without cutaneous scarring. Considerable limitations were imposed by the technical difficulty of execution, by the lack of stable work platforms for flexible endoscopes and by the secure closure of the violated viscera. On the other hand, single incision surgery advocates the umbilical scar as the primary entry point, which is presented as a natural abdominal orifice. The lack of triangulation of the instruments, space conflict and risk of hernia were the main criticisms of this approach.

As techniques even more difficult to perform, NOTES and single-incision surgery still had more resistance from surgeons. Nevertheless, its contribution to the technological development associated with endoscopic surgery is undeniable. One of the fundamental limitations of endoscopic surgery is undoubtedly the two-dimensional view that brings important challenges in learning and proficient execution. It follows from this that the improvement of instrument platforms and vision can contribute to reducing technical difficulties and easing learning.

Moreover, since the early 2000s, the robotization of minimally invasive surgery has become more and more popular. These non-autonomous robots that work in a master-slave approach aim to facilitate video-assisted surgery by optimizing vision, ergonomics and instrument platforms for performing surgery. Proposals for single incision surgery are already on the market (7).

In short, many improvements have transformed endoscopic surgery into high quality procedures reaching vision and accuracy levels that exceed those of conventional surgery. However, laparoscopy is still struggling with important limitations such as the difficulty of achieving proficiency.

In this thesis the importance of three-dimensional imaging for single-site endoscopic surgery is explored and discussed.

2. Three-dimensional video system for endoscopic surgery

Video imaging technology has evolved significantly in the last decades to provide high definition images for endoscopic surgery. Conventional systems use traditional Hopkins rod lenses (tubes with multiple pieces of transparent glass with thin air gaps to allow for powered surfaces) or "chip-on-tip" technology with sensors that digitalize the image at the distal end of the scope. Miniaturization has allowed today's smaller than 1mm sensors to be assembled on flexible instruments with very high definition (8).

Nonetheless, the image of most endoscopes continues to have a major limitation given that it is still two-dimensional. The lack of depth field evaluation results in delicate movements being impaired, such as dissection or suturing. This is specially noted when the surgeon is operating in a different than usual environment as is the case during a new operation, an anatomical variation, working with organs having a lot of inflammation, or during the learning curve of novices. At times, the surgeon has to actually touch the structures with the tip of an instrument in order to gauge depth, thus reducing the dexterity, speed and accuracy with which minimally invasive surgery can be performed. Without different images to be presented to both eyes, so called disparities, the surgeon has to rely on indirect clues that result from a long learning curve. The comparison of textures, size, color and shadows, as well as the vision given by parallax movements or recalled images are fundamental to realize the sense of depth (9, 10).

Even when assuming that endoscopic surgery has a long learning curve and the surgeon has to distrust optical illusions of two-dimensional imaging, as well as to live with indirect depth-of-field clues, it is important to underline that the loss of stereopsis penalizes both the novice and the expert (11). Beginners experience difficult and painful learning, while experts have slightly slower and less precise movements, with a fatigue that is the result of this constant adaptation to the two-dimensional environment. Since the early years of laparoscopic surgery, the issue of shallow depth has arisen in the surgical community and considerable efforts have been made to develop three-dimension (3D) camera systems.

In a monograph from the year 1994, Asim Durrani and Glenn Preminger described the principles of three-dimensional video imaging for endoscopic surgery that remains valid until today (12). Four steps to process the image were pointed out: (i) the capture (stereo endoscope), (ii) the convertor (camera system), (iii) the display (monitor) and (iv) the presentation (glasses) - Figure 2

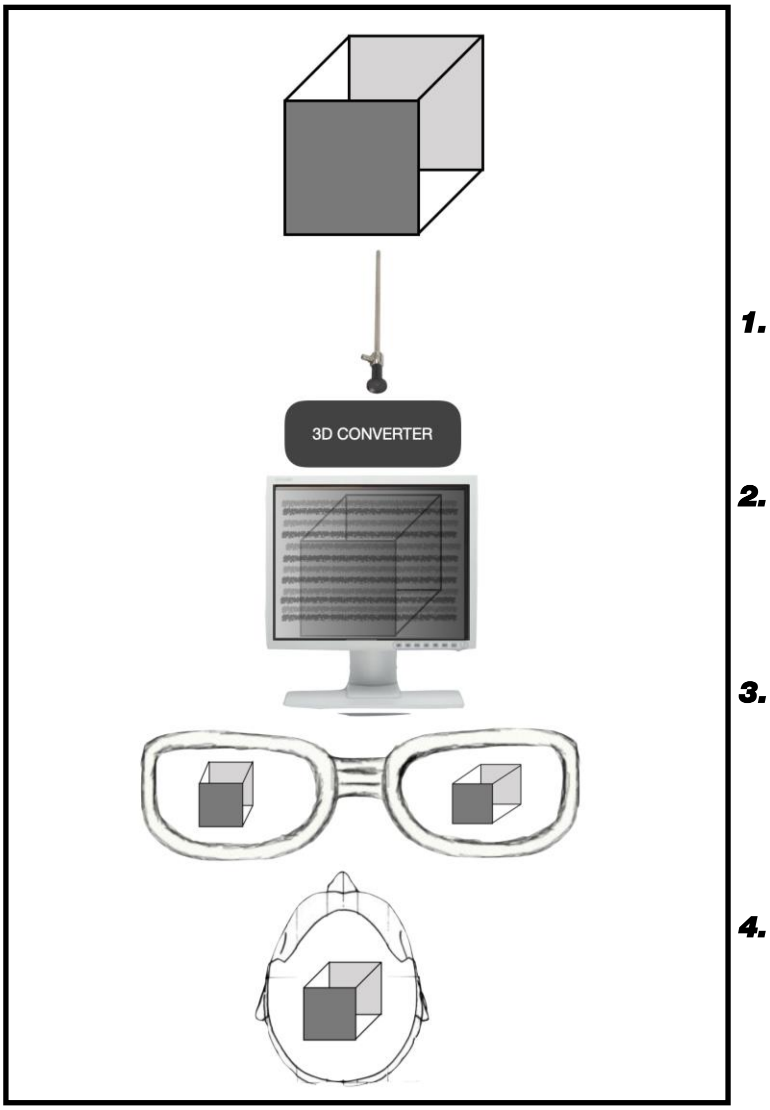


Figure 2 Stereoscopic image processing

1. Image capture; 2. Camera and 3D converter; 3. Monitor display; 4. 3D image presentation;

(i) The stereo laparoscope capture

The capture of stereoscopic images for endoscopic surgery mimics the eyes of the surgeon with the aim to present a right and left view of a specific scenario. Two different types of scopes were considered: single channeled scopes and two channeled scopes.

Scopes with one channel are common Hopkins rod-lens for 2D systems. Compared to others, these are larger in optic diameter and could present brighter images. The same principle of a 3D microscope, in which the images are divided for the stereoscopic picture, is used. To split the image into left and right eye a special device called the “stand alone image splitter” can be attached to any available conventional endoscope. Another option would be to capture the image already divided at the tip of the endoscope. Although one-channel endoscopes could provide better resolution and brighter images (especially for close-up situations), the sense of depth was quite artificial and they were supplanted by two-lenses scopes (13).

Figure 3 Bichaneled scope

From Imaging and Visualization in the Modern Operating Room, Yuman Fong, Pier Cristoforo Giulianotti, Jason Lewis, Bas Groot Koerkamp, Thomas Reiner. © Springer Science+Business Media New York 2015

Bi-channeled endoscopes (Figure 3) have a dual-lens system that captures slightly different images as if the surgeon's eyes could be placed on the tip of the scope. Each one of the two channels is much narrower than is the case in a single channel endoscope and important improvements have been made with light production and diffusion, as well as CCD miniaturization technology to assure high quality image. The complete separation of image capture for each eye gives a much better 3D sense. These endoscopes incorporate two monocular endoscopes, one for each eye, with a diameter less than half the total diameter.

(ii) The camera system and 3D convertor

The process of digitalization of the image is made by the camera system and can be done at the tip of the scope, so called “chip-on-tip” technology, or at the head of the camera after optical capture of the image. Two different and separate images are converted into a high frequency screen presentation according to the specific 3D system.

Since the beginning it has been clear that images must be presented at a frequency of a minimum of 120 Hz, in order to avoid flickering images and surgeon's vertigo (14).

(iii) The monitor display

Images for each eye are sent to the monitor to be displayed simultaneously or alternately. The first systems used 120 Hz display with an alternate frequency of 60 Hz for each eye. An infrared emitter would synchronize the image to the right eye with the use of shutter glasses. More recently, high definition monitors with 1080 horizontal and vertical lines (pixels) are able to simultaneously present images for both the left and right eyes. Polarized horizontal rows of pixels are displayed on the 3D monitor, with each pixel row alternating between the left and right eye camera images captured by the dual-channel 3D laparoscope.

(iv) Presentation with glasses

For the final effect, the surgeons retinae should be sensitized with different images to construct a three dimensional object at the visual cortex. Active liquid crystal display (LCD) shutter glasses expose the right image to the right eye, covering the other side at the same time. Absolute synchronous monitor display and shutter glasses system is of paramount importance for a 3D effect, as well as high frequency image display to decrease the flickering effect. A second proposal derived from robot consola, bypasses the monitor presentation of images, and provides different images to both eyes with helmet-like equipment that delivers images separately to the right and left side. This head-mounted system presents each eye with its own screen to achieve stereopsis. More recently, systems with simultaneous image projection in different polarized waveforms for both sides on the screen use passive polarized glasses that allow one of the retina to be excited only by its image (15).

The first 3D systems for laparoscopy used a dual Hopkins rod lens in a 10 mm laparoscope. These lenses lacked adequate light distribution and had low definition. They used one chip camera for each channel, even when 3 CCD technology was already available for 2D systems. Moreover, 3D display needed active and heavy shutter glasses that frequently produced visual strain and caused dizziness in users. These early systems did not gain popularity because they had poor image quality, unwanted effects and a high cost.

A second generation of three-dimensional systems was developed for assisted robotic surgery and than were adapted to conventional endoscopic procedures. The concept was to immerse the surgeon in a 3D environment with the use of a helmet-style head-mounted system that gives the two eyes a different image through a small monitor on each side. These gadgets were bulky, heavy and therefore uncomfortable. In addition, the rate of headache increased due to visual stress caused by observing the operating room through the open sided head units (16).

The gradual development of high resolution and brightness for narrowed scopes, as well as monitors with a high number of total pixels and high frequency, enabled simultaneous display of images to both eyes with excellent quality. The comfortable and affordable lightweight polarized glasses can be worn for all in the surgical team and the system, giving good color rendition on a wide-angle monitor with low rate of side effects. These new developments are making the third-generation 3D systems into an extremely competitive choice compared to their high quality full HD 2D counterparts (17). Furthermore, such systems can be switched easily between 2D and 3D modes.

3. Benefits of three-dimensional systems for endoscopic surgery - from the lab

Until recent years, several drawbacks impaired the current use of 3D systems in clinical practice. Concerns about price, image quality and undesirable side effects were the main reasons for reluctance of the surgical community to accept these systems. The more recent generation of 3D systems, due to its ease of use, low cost and comfort, rekindle the flame of hope for the everyday use of these devices.

Since the beginning of the 1990's, numerous publications came out with conflicting results as to the comparison of 2D vs 3D endoscopic performance (18). These were mainly experimental laboratory studies with phantom exercises not validated for 3D systems and with significantly heterogeneous conditions of equipment and participants. It should be noted that the different laboratory exercises to develop technical skills in endoscopic surgery do not call into question the lack of depth of field in any way.

As noted elsewhere, the correct selection of participants in their stereo acuity as well as the conditions of 3D viewing can have an important impact on disclosure of the possible added value of this technology (15). On the other hand, the side effects of the first devices made their use unwelcome and the gradual improvement of high definition 2D imaging systems has delayed the implementation of 3D systems.

Especially in the last ten years, several studies have tested the new generation of 3D devices, using polarized glasses, with high definition 2D technology. Very important issues are pointed out in these studies that can be summed up in three main topics: flat learning curves, better performance and diminished workload.

Here, we review five important questions: (i) Are there shorter learning curves for novices? (ii) Is surgery faster? (iii) Is there greater precision and safety for delicate and complex procedures? (iv) What is surgeon preference and level of fatigue in long surgeries? (v) What is the importance of robotic surgery in this context?

(i) Are there shorter learning curves for novices?

Several studies have focused on understanding whether 3D shortens the learning curve for novices. Most of them demonstrated the superiority of 3D systems. Two end-points were: time for completion of different tasks and number of errors made while doing the exercises.

In the study of Cicione (19) conducted with a validated assessment tool (the E-BLUSS), there was a clear advantage in three of five tasks for the novice group with a 3D system, and this was more evident in the less complex exercises, which are more closely related to the easiest procedures of the initial laparoscopic practice. Wagner (20) and Storz (21) revealed more precision and speed with the use of 3D laparoscope. The first of these studies went further and compared the performance of exercises under stereoscopic or monocular vision. The benefit of depth perception was evident regardless of being used in conjunction with open, laparoscopic or robotic approach.

Prior to this, Patel et al. (16) and Sam Bhayani (22) also demonstrated a benefit of 3D technology with the Viking system (second generation, head-mounted system), making it clear that stereoscopic laparoscopy significantly accelerate the learning process in the novice group. Votanopoulos (23) specifically stressed the impact of 3D vision on laparoscopic training and concluded that there was clear improvement for inexperienced individuals with the use of these systems. They stated that 3D imaging greatly facilitates the initial performance for novices in laparoscopy in terms of both speed and accuracy.

Nevertheless, studies with conflict results were also published. For example, Mistry et al. (24) showed inferior performance when using 3D systems in a novice population doing four exercises from the validated McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS). Yet, some criticisms can be pointed out in this study like authors using a technology not approved by the Food and Drug Administration (FDA). Moreover, these results were likely penalized by the difficulty of these exercises and by the fact that those participants exceeding the time limit for the completion of a specific task received an automatic score of zero. Indeed, several studies with novices showed that 3D has a greater impact on accuracy than time does (19, 25).

Another important conclusion of some of these laboratory experiments is the transition results from 3D skills to work in 2D. The comparative study of Votanopoulos demonstrated that previous experience with laparoscopy significantly improves task performance regardless of the system used (23). Expertise seems to be interchangeable between both image systems.

(ii) Is surgery faster?

Wagner (20) stated that regardless of the surgical approach chosen (open, laparoscopic or robotic), the loss of 3D vision delayed the completion of a task proportionally to the difficulty of the task. Along the same line, Tanagho (26) showed a significant reduction in time in a group of those with varying laparoscopic experience performing the Fundamentals of Laparoscopic Surgery (FLS) program tasks. This was also proved by Storz (21) who demonstrated the ability to perform faster exercises with 3D technology regardless of the expertise of the performer.

(iii) Is there greater precision and safety for delicate and complex procedures?

With the capacity of capture and recall images, the human brain can transform a bi-dimensional image with somewhat limited depth. This ability to understand flat images in three dimensions is significantly reduced when the surgeon is confronted with a scene which has not been viewed before. Especially in complex and critical situations, the required mental substitution of spatial information can lead to suboptimal performance.

Cicione et al. found that experts and novices feel more comfortable carrying out difficult tasks with the aid of 3D images (19). Kong showed a tendency towards fewer errors related to overconfidence with 3D viewing and the authors' interpretation was that 3D systems could likely help operators to perform surgeries more safely and accurately in stressful situations, such as when there is a substantial bleeding (25).

This trend of identifying an advantage of using 3D images in more demanding technical situations for expertise laparoscopic surgeons has also been observed by others (23).

(iv) What is surgeon preference and level of fatigue in long surgeries?

Stereoscopic vision is an ability taken for granted by most humans. Yet, when operating with 2D image, this is an obvious cause of strain that results in fatigue.

Even in those studies where it was not statistically evident that 3D was superior, it was clear that there is a user preference (24). Overall free comments overwhelming favorable stereoscopic laparoscopic visualization (22, 25-28).

A test with electromyography revealed a better distribution of usage of both arms with 3D than with the 2D system. The authors also hypothesize that the dispersion of muscular tension could reduce fatigue (25).

(v) What is the importance of robotic surgery in this context?

In the early 2000's, the FDA approval of the Da Vinci robotic system for surgery resulted in the rapid and widespread distribution of this technology. One of the most cited virtues of it was the three-dimensional view that resulted in the ability to undergo complex reconstructions and meticulous dissections with a shorter learning curve (11). This was particularly evident among surgeons without previous experience in laparoscopy (5).

Since its implementation, it has been more evident that laparoscopy requires a very steep learning curve. Through clinical experience with robot-assisted surgery, it became clear that this long-lasting process of learning could be shortened (29).

In 2005, Bhayani (22) underlined the costs of the da Vinci robot compared with the head-mountain Viking system. The cost associated was 10 times greater for the robot. In terms of performance, the advantages of robot are the wrist-like instruments and stereoscopic vision. At that time, many hypotheses pointed towards the robotic system likely not offering any advantages over a small and less expensive 3D head-mounted system. Nevertheless, Wagner (20) concluded that robot-assisted task performance tends to be faster than 3D laparoscopy except when haptic feedback is required, such as a suture. They also showed that the lack of 3D vision impairs accuracy regardless of the surgical approach (open, laparoscopic or robotic-assisted).

Various recent clinical studies have emphasized the interest of 3D laparoscopy over the robot because it is equally accurate and much cheaper. This is especially highlighted in studies of developing countries.

4. Single-site surgery - evolution and current application

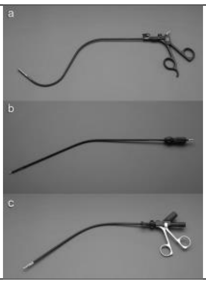
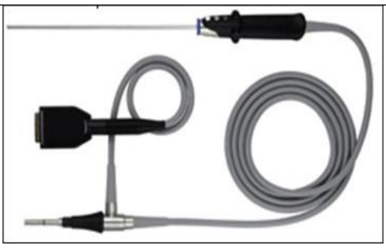
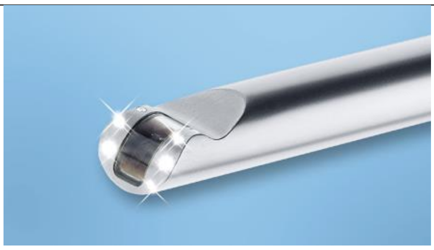
Laparoendoscopic single-site surgery (LESS surgery) is a concept that arose within the world of minimally invasive surgery at the beginning of this millennium. The fundamental idea is to have all instruments coming in through the same skin incision with the aim of reducing trauma and improving the aesthetic result. Right from the beginning, two major concerns were pointed out: the lack of triangulation and the so-called inline view. Another important restraint is the limited workspace inside and outside the body with conflicting and clashing instruments being very frequent (3).

To overcome these difficulties a lot of new devices were developed: (i) sophisticated platforms to serve as ports for the instruments with increased degrees of freedom, using an hourglass shape to pass through a small skin incision; (ii) articulated and curved instruments; (iii) cross-handed instrumentation; (iv) instruments of variable lengths and (v) flexible-tip laparoscopes with an in-line cord and a low-profile camera head; (Figure 4)

A wide range of nomenclature proposals have been made: Single port access (SPA); Single-incision laparoscopic surgery (SILS); Single-site laparoscopy (SSL); One-port umbilical surgery (OPUS); Trans umbilical endoscopic surgery (TUES); Embryonic NOTES (eNOTES); Natural orifice trans umbilical surgery (NOTUS); Single laparoscopic port procedure (SLAPP); Single-port laparoscopic surgery (SPLS); Single-port laparoscopy (SPL); Single laparoscopic incision trans abdominal surgery (SLIT); Single-instrument port laparoscopic surgery (SIMPL); Single incision endoscopic surgery (SIES). We have adopted LESS surgery, a name suggested by a consensus of experts with no implications for the medical industry (30).

Figure 4 (next page) - Instruments and strategies for LESS - Examples:

Line 1 - Platforms for instrument introduction; **Line 2** - Articulated and curved instruments; **Line 3** - Cross-handed instruments; **Line 4** - Instruments of variable length and shape together; **Line 5** - Laparoscopes with variable angles of vision;

		
multi-instruments laparoscopic port - Gel Point by Applied Medical	**single Incision Laparoscopic Surgery (SILS) port by Medtronic**	**daVinci single-site instrumentation**
		
curved instruments by Karl Storz	**SILS clinch grasper by Medtronic**	**S-Portal X-Cone by Karl Storz**
		
articulated instruments	**crossing articulated instruments**	**SPIDER by TransEnterix**
		
combining different instruments	**different length instruments**	
		
Flex tip EndoEye by Olympus	**In-line cord EndoEye by Olympus**	**Endocameleon by Karl Storz**

The use of and medical reports on LESS surgery had a great boom about ten years ago. Many series reporting safety, reproducibility, better cosmetic and less post operative pain were published and the diversity of procedures enlarged from appendectomy and cholecystectomy to colorectal resections, bariatric surgeries, urological interventions and so on (31-35). After an initial period of great enthusiasm, excitement diminished as several experts pointed out fear of adding unjustified technical difficulty and risk. On the other hand, the use of incisions greater than 1 cm across for port introduction was penalized with an increased rate of incisional hernia (mainly in high BMI population) (32, 36, 37), postoperative pain was not consistently lower than with conventional laparoscopy and esthetically issues were largely subjective.

Today, LESS abdominal surgery is somehow residual in the world of laparoscopic surgery, and there is a great expectation with the development of single incision robotic systems of overcoming the technical challenges of these approaches. Eventually different fields of use of single-site operation have opened, spreading its use, and benefiting from its innovative technologies. Current applications are: (i) Laparoscopic procedures; (ii) Uniportal VATS (videoassisted thoracic surgery); (iii) Transanal surgery; (iv) Other.

(i) Laparoscopic procedures

The implementation of LESS abdominal surgery was looking for reduced trauma with lower pain, a better cosmetic result and faster recovery after surgery. For procedures with an incision to withdraw a specimen from the abdomen, the supposed aesthetic benefit or the prospect of less pain is in some way obscured by wound trauma. As far as the simplest procedures are concerned, attention must be paid to the number and width of ports used for common laparoscopy. With mini-laparoscopic instruments there are almost no scars one year after the operation, and an evident technical benefit is achieved by maintaining triangulation and the absence of instrument conflict.

Although with great enthusiasm in the results of the first studies comparing LESS with multi-port laparoscopy, especially for cosmetic improvement and pain reduction, strong serious concerns involve the surgical community not advocating slightly better cosmetic value over safety (38). In fact there is a considerable technical challenge involving single-site surgery.

An important technical issue for LESS surgery is instrument conflict occurring inside and outside the body. It seems that the combination of one straight and one curved or articulating instrument could make some surgeries easier. That could be particularly important when dissecting in a relative small space with converging instruments, like the gallbladder hilum during a cholecystectomy. On the other hand, for surgery in a wider space it could prove beneficial if instruments diverge, getting one for traction and another for dissection, as in colorectal surgery.

A systematic review and meta-analysis was published in 2016 by Brockhaus on LESS surgery versus multi-port laparoscopic surgery in colorectal benign and malignant context (35). These authors aimed to include exclusively randomized studies and found only two of those studies with a total of 82 patients, and one of these two with high risk of bias. There were no relevant differences detected between LESS and conventional laparoscopy, and since the results are so few, they state that LESS surgery for colorectal resection should still be considered as an experimental procedure.

In 2017, The European Association for Endoscopic Surgery (EAES) organized a Consensus Conference on Single Incision Endoscopic Surgery (SIES). The results of that conference are summarized on Table 1. Only for simple procedures like elective cholecystectomies and non complicated appendectomies, are high level of evidence favoring SIES in terms of post operative pain (cholecystectomy) and length of hospital stay (appendectomy). Although the cosmetic result seems to be improved in these two techniques, there is no impact on quality of life (cholecystectomy). No other studies exist to access the real impact on quality of life comparing multi-port

Procedure	Selection criteria	Op Time	PO Pain	Cosmesis	LoS	Hernia	QoL	Feasible & Safe
Cholecystectomy	Elective, BMI <35	- (LoE1)	+ (LoE1)	+ (LoE1)	Same (LoE1)	?	Same (LoE1)	Concerns about iatrogenic BDI
Appendectomy	Non perforated appendicitis	Same (LoE1)	Same (LoE1)	+ (LoE1)	+ (LoE1)	?		OK
Colectomy	<T4, <5cm, BMI <35, no PAO		+ (LoE3)	?	+ (LoE3)	?		Same morbidity Lack of long term results
Rectal ressection	<4cm, BMI <30		+ (LoE2)	?	+ (LoE3)	?		Similar histological outcome
Bariatric (Sleeve and GBP)	BMI <50, no PAO, XUD <25 cm	- (LoE2/3)	+ (LoE2/3)	+ (LoE2/3)				OK
Splenectomy	< 500g	- (LoE4)		+ (LoE4)		?		OK
Adrenalectomy	Left	Same (LoE4)	Same (LoE4)		Same (LoE4)	?		OK
Hepatectomy	Minor	?	?	?	+ (LoE3)	?		OK
Pancreatectomy	Distal	- (LoE3)	?	?	- (LoE3)	?		OK
Fundoplication	ASA1 or 2	- (LoE3)	?	+ (LoE3)	Same (LoE3)	?		OK
Gastrectomy	Early gastric cancer, BMI <25	- (LoE4)			+ (LoE4)			Similar histological outcome
Inguinal Hernioplasty		- (LoE2)	Same (LoE3)	Same (LoE3)				OK
Ventral Hernioplasty		Same (LoE3)		?				OK Concerns about recurrence

Table 1 EAES Consensus Conference on SIES - Frankfurt Congress 2017

Morales-Conde S, Peeters A, Meyer YM, Antoniou SA, Del Agua IA, Arezzo A, Arolfo S, Yehuda AB, Boni L, Cassinotti E, Dapri G, Yang T, Fransen S, Forgione A, Hajibandeh S, Hajibandeh S, Mazzola M, Migliore M, Mittermair C, Mittermair D, Morandeira-Rivas A, Moreno-Sanz C, Morlacchi A, Nizri E, Nuijts M, Raakow J, Sánchez-Margallo FM, Sánchez-Margallo JA, Szold A, Weiss H, Weiss M, Zorron R, Bouvy ND. European association for endoscopic surgery (EAES) consensus statement on single-incision endoscopic surgery. Surg Endosc. 2019 Apr;33(4):996-1019. doi: 10.1007/s00464-019-06693-2. Epub 2019 Feb 15.

+ Better SIES than multi-port laparoscopy (ML)
- Worst SIES than ML
? No data
NM Not Mentioned
Same Comparable results of SIES and ML
LoE Level of Evidence
QoL Quality of Life

LoS Length of hospital Stay
GBP Gastric By Pass
BMI Body Mass Index
PAO Previous Abdominal Operation
XUD Xipho-Umbilical Distance
BDI Bile Duct Injury
ASA American Society of Anesthesiologist surgical risk score

laparoscopy with SIES. Concerning the risk of hernia, there are still doubts as to increased incidence, even with very well selected patients. Lastly, some fears remain in regards to the lack of long term oncological results and in regards to specific and relatively rare events, like iatrogenic common bile duct lesions during cholecystectomy (39).

(ii) Uniportal VATS

Video assisted thoracic surgery evolved together with laparoscopy and faced equal skepticism and fear. The aggression caused by a thoracotomy was the basis for developing equally effective surgeries with optimal patient recovery. VATS was the answer and slowly it was making its name in the world of lung surgery. At the beginning of this millennium some concerns still remained with VATS, like "post-thoracotomy" pain in the site of small port incisions and the speed for emergent conversion to open procedures (40, 41).

A surgeon from Catania, Marcello Migliore introduced the concept of Uniportal VATS for minor thoracic procedures in the year of 2000. In a larger intercostal space for its more anterior location, the placement of surgical instruments and the camera were introduced through the same incision. In a short period of time, Uniportal VATS evolved to include more and more complex procedures from lobectomies for cancer to bronchoplastic techniques, advanced lung tumors resections together with chest wall surgeries (42). The use of these techniques spread rapidly around the world and was quickly adopted in some high volume centers.

Intra-operative major Uniportal VATS complications should be considered and prevented by means of adequate pre-operative planning. Coordination of all the surgical team is crucial to face emergencies such as major bleeding. One of the biggest advantages of Uniportal VATS seems to be the conversion speed. In fact, since it is using the anterior fifth intercostal space, traditional thoracotomy follows bleeding-site compression, and is fast to enlarge the incision posteriorly and introduce a rib retractor.

A recently published systematic review and meta-analysis comparing Uniportal and Multiportal VATS for lung cancer showed improved outcomes with Uniportal VATS in terms of overall rate of complications, length of hospital stay and duration of postoperative drainage (43). However, pain sensation after Uniportal VATS has not yet proven to be better. Therefore, more comparative and randomized trials are needed to find out the superior results of Uniportal VATS (41).

Gonzalez-Rivas, a well-known enthusiast and lieder of the Uniportal VATS implementation, emphasizes the development of technology that has allowed for more complex procedures to be done this way. Specifically, he highlights the evolution of endoscopic staplers which have a curved tip and are narrower. Other important novelties are the retraction instruments using magnets, flexible tip and angulated scopes, and 3D imaging systems “adding depth perception and facilitating faster and more accurate grasping and suturing during surgery” (42).

New frontiers for the Uniportal VATS are the subxiphoid approach to overcome intercostal nerve damage and trans thoracic esophageal resection for cancer. Likely new technology such as wireless cameras, single port robotic system and better instruments will spur its widespread use.

(iii) Transanal surgery

Another important field of development and increased interest to the surgical community in recent years is transanal surgery (TS). First with the works of Professor Buess from Germany in the late 1980’s with the so called TEM - Transanal Endoscopic Microsurgery, to the great enthusiasm surrounding the new concept of TaTME - Transanal Total Mesorectum Excision - introduced by Sylla et al. in 2010, TS benefited from LESS surgery technological improvements (44).

Apart from flexible endoscopic techniques that include mucosal, submucosal and some limited full-thickness resections, TS with rigid scopes is an evolved technique with the same theoretical benefits and challenges as single incision laparoscopic procedures. Lack of triangulation, in-line view and instruments conflicts are also present. The new platforms for trocar introduction (like Gellpoint from Applied Medical) or the pressure barrier for sustaining pneumorectum (like Airseal from SurgiQuest), were “imported” from abdominal LESS surgery and are key factors for the democratization of these approaches.

The concept of TaTME appeared to overcome the difficulties in the laparoscopic approach to locally advanced medium and low rectal cancer. Laparoscopic total mesorectal excision is a high demand surgical procedure, above all, for patients with a narrow pelvic anatomy, high body mass index, male, and fatty mesorectum (45). TaTME is a bottom-to-top strategy that is performed transanally, starting with the endo-anal closure of the rectum distally to the tumor, circumferential full thickness incision of the rectal wall and total mesorectal excision in a retrograde way. Potential benefits of this technique are a better control of distal and circumferential margins of the tumor. However, considerable difficulty reproducing the procedure is observed as well as a significant learning curve (45).

A recently published systematic review and meta-analysis by Dongping Hu et al. (46) including thirteen studies with a total of 859 patients (205 in randomized controlled trials) conclude that TaTME is associated with an increased complete tumor resection and reduced positive circumferential resection margin. The risk of intra-operative complications was similar and total time for the operation favors the TaTME approach. Curiously, distal rectal margin and positive distal margin were similar between two groups.

Larger and more robust multi-center randomized controlled trials are needed as well as studies to evaluate long-term survival, quality of life, and local recurrences for a complete validation of TaTME for the treatment of mid-low rectal cancers. New devices and better optical systems could improve performance and the steep learning curve.

(iv) Other

a. Single Incision Robotic Surgery

Intuitive is an American company founded in 1995 and is the producer of the da Vinci robot assisted system that has dominated the market since the beginning of this millennium. A few years ago, a new model for single-site surgery was tried and is now available in the USA. A relevant number of publications are coming out this year with the first series of operated patients. This new system overcomes the technical challenges of LESS surgery using sand-clock-shape trocar, 3D image and crossing instruments that appear inverted at the platform.

Feasibility and safety are patents in series from different specialities like lymphadenectomy for endometrial cancer (47), radical prostatectomy (48) and cholecystectomy in obese patients (49). Possible advantages, apart from ergonomic issues and workload, could be: same day discharge and no Trendlemburg position in the case of prostatectomy, and less need for an additional port for completing cholecystectomy in obese patients.

However, in a very recent systematic review and meta-analysis of robotic single-port platform in general (29 articles), urologic (10 articles), and gynecologic (18 articles) surgeries, a significant increment of complications was found when compared with the standard multi-port laparoscopic approach (50). The authors conclude that although this technology may be very effective, the prolongation of operating time an the risks of its implementation should be the subject of controlled clinical trials.

b. Single Port Pneumovagina Technique

Using a single-port device for transanal surgery, an approach called Single-Port Pneumovagina Technique (SPPT) was described to optimize viewing and ergonomics in vaginal surgery. Two success cases were presented, one of a bicornuate unicollis uterus for resection of the septum, and another of a proximal vaginal leiomyoma for myomectomy (51).

c. Intragastric Surgery

Another recent proposal for single-port surgery is IntraGastric Surgery (IGS). This can be used for the resection of submucosal stromal tumors, like those placed in difficult locations (cardia and near the pylori sphincter), as well as to approach the gastric remnant (after obesity surgery) for gastric procedures or to access the biliary tree. A small series of patients described eight cases of IGS after Roux-en-Y gastric bypass for Endoscopic Retrograde Cholangio Pancreatography (ERCP). All were successfully performed (52).

d. In Line Multiports Surgery

Finally, even when using different ports, other approaches in surgery put the instruments very close to each other in a similar strategy as LESS surgery. An example of this is TransOral Endoscopic Thyroidectomy Vestibular Approach (TOETVA), a technique with significant diffusion worldwide in recent years. Like in LESS surgery, the learning curve is steep due to the same type of limitations to overcome, such as the non-triangulation of instruments and in-line view (53).

To conclude, even though LESS surgery has not progressed rapidly in abdominal surgery, it has indelibly altered endoscopic surgery by opening other fields, other techniques, and promoting many new devices and instruments.

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THESIS OBJECTIVES

- To compare single-site surgery performance in a laboratory experience using two dimensional and three dimensional systems
- To analyze varying impact on novices and experienced surgeons during the use of three dimensional vs two dimensional system in single-site surgery
- To use a model of fixed distance scope with minilaparoscopic instruments to make such comparisons

THESIS STRUCTURE

This thesis is divided into three main chapters and an addenda.

I. Part one is dedicated to reviewing the knowledge areas that support the hypothesis of the experimental work - *maybe three dimensional image systems could improve comfort and performance in LESS surgery*-in a comprehensive way. This is a specific topic that has never been studied before.
II. In Part two, the author presents his publications
III. The last Part is the discussion based on results of the studies as well as on the current knowledge and future evolutions on these topics.
IV. The addenda will join a review related to this thesis "clinical use of three dimensional image in endoscopic surgery" (submitted and accepted for publication).

PART 2

PUBLICATIONS

COMPARATIVE STUDY OF 2D AND 3D OPTICAL IMAGING SYSTEMS: LAPAROENDOSCOPIC SINGLE-SITE SURGERY IN AN EX VIVO MODEL.

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Comparative Study of 2D and 3D Optical Imaging Systems: Laparoendoscopic Single-Site Surgery in an Ex Vivo Model

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Abstract

Background. Usually laparoscopy is performed by means of a 2-dimensional (2D) image system and multiport approach. To overcome the lack of depth perception, new 3-dimensional (3D) systems are arising with the added advantage of providing stereoscopic vision. To further reduce surgery-related trauma, there are new minimally invasive surgical techniques being developed, such as LESS (laparoendoscopic single-site) surgery. The aim of this study was to compare 2D and 3D laparoscopic systems in LESS surgical procedures. *Materials and Methods*. All participants were selected from different levels of experience in laparoscopic surgery—10 novices, 7 intermediates, and 10 experts were included. None of the participants had had previous experience in LESS surgery. Participants were chosen randomly to begin their experience with either the 2D or 3D laparoscopic system. The exercise consisted of performing an ex vivo pork cholecystectomy through a SILS port with the assistance of a fixed distance laparoscope. Errors, time, and participants' preference were recorded. Statistical analysis of time and errors between groups was conducted with a Student's *t* test (using independent samples) and the Mann-Whitney test. *Results*. In all 3 groups, the average time with the 2D system was significantly reduced after having used the 3D system ($P < .05$). In the postexercise questionnaire, two thirds of participants showed a preference for using the 3D system. *Conclusion*. This study suggests that the 3D system may improve the learning curve and that learning from the 3D system is transferable to the 2D environment. Additionally, the majority of participants prefer 3D equipment.

Keywords
minimally invasive surgery, laparoscopy, LESS, 3D, single port

Introduction

Since the beginning of the 1990s, laparoscopic surgery has become the preferred approach for many abdominal procedures.[1] The development of these techniques has been increasing rapidly ever since. When compared to classical laparotomic surgery, the minimally invasive laparoscopic approach is associated with numerous advantages, due to the reduction in tissue damage.[2,3] Furthermore, it has been proven that it decreases the pain in the postoperative period, the length of hospital stay, and the time of global recovery for patients.[4-6] Nevertheless, there are some disadvantages for the surgeon, namely, limited surgical field vision, the difficult work axis forced by the most commonly used optical systems, as well as the lack of depth vision.[7]

Laparoscopy is usually performed with a 2-dimensional (2D) optical system.[7] This type of imaging system, despite being an accessible and simple technology, presents a major disadvantage. Monitors and cameras fail to transmit stereoscopic information.[8] Depth perception is very important for good performance in manual tasks.[8] The lack of depth perception in 2D systems is attenuated by the human brain's ability to compare dimensions using light and shadow, motion parallax, and visual memory.[9] Therefore, the 2D imaging system has the following limitations: a long learning curve, errors through misinterpretation, and slow movements.[10]

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In the early 1990s the first prototypes of 3-dimensional (3D) systems were used in laparoscopic surgery. The main advantage was stereoscopic vision.[11] However, these rudimentary optical systems, besides providing low image quality, also originated multiple unpleasant symptoms including eyestrain, high adaptation time, and physical discomfort (headache, nausea).[11] With the technological evolution came new 3D systems allowing for the use of 2 separate optical channels and creating 2 separate images for the right and the left eye resulting in stereoscopic vision.[12] Another improvement in technology has resulted in the reduction of unpleasant symptoms and improved resolution of image quality.[8]

In addition to the technological development of imaging systems, an evolution has occurred in terms of enabling laparoscopic tools for use in even less invasive procedures.[13] LESS (laparoendoscopic single-site) surgery is performed through a single port obtained through a small incision in the skin.[13] With the decrease in the number of ports this minimally invasive technique reduces tissue trauma and improves aesthetic results.[14] However, it has limitations that relate to added difficulty of optimal instrument triangulation, contrary to what happens in classical laparoscopy with multiple ports, thus creating a space conflict.[15]

The use of 3D optical systems could improve the depth of field and keep away the optical in LESS surgery, reducing the conflict of instruments. Until the present, there has not been a 2D versus 3D comparative study conducted in LESS surgery in the literature.

The goal of our study was to compare the performance and preference of participants with different levels of expertise in classical laparoscopic surgery using the 2D versus 3D in LESS surgery.

Materials and Methods

To achieve the proposed objectives, we carried out experimental sessions in the Surgical Sciences Domain of the Institute for Research in Life Sciences and Health (ICVS), School of Medicine, University of Minho, Braga, Portugal, with surgeons, residents, and medical students who agreed to participate in the study.

Materials

Study Population. Three different groups participated in the study (n = 27): a novice group (without any experience in laparoscopic surgery), an intermediate group (from 1 to 50 laparoscopic surgeries), and an experienced group (over 50 laparoscopic surgeries performed). From the information gathered in the questionnaires of the 27 participants, 10 belonged to the novice group, another 10 belonged to the experienced group, and 7 to the intermediate group. Previous experience is related to multiport laparoscopy. None had past experience in LESS surgery.

Figure 1. Two-dimensional laparoscopic simulator system.

Instruments. To perform the laparoscopic tasks, the laparoscopic instruments used by participants were 3-mm Karl Storz curved forceps, dissecting scissors, a grasper, and a 5-mm Ultracision harmonic scalpel (Ethicon, Johnson and Johnson, Somerville, NJ). A SILS port (Medtronic, Minneapolis, MN) was used as a single-port device to introduce instruments.

Imaging Systems. This study used 2 types of imaging systems: 2D and 3D, developed by Karl Storz (Tuttlingen, Germany).

The 2D imaging system (Figure 1) consists of a tower, which is connected to a high-definition video monitor, through a camera with a 10-mm lens 0°.

Regarding the 3D imaging system (Figure 2), it is composed of a 3D camera that is connected to a high-definition monitor, and the image is displayed through the use of special polarized light eyeglasses that are part of the Karl Storz equipment.

Since there is variability in the adaptation time for stereoscopic vision person to person, procedures started only after this process occurred.[16]

Figure 2. Three-dimensional laparoscopic simulator system.

Two-dimensional and 3D monitors were placed at eye level of the participants and the distance between the monitors and the eye was fixed at 175 cm, respecting the recommended distance (3 times the monitor's diagonal size). The input distance between the optics and the endo-trainer was also set at 12.4 cm.

Models. The organic model used to conduct this study was pork liver with the gallbladder and intact biliary tract, and 2 livers were available to each participant, making for a total of 54 livers used at the end of all experiments.

For abdomen simulation a Karl Storz endo-trainer was used, and a wooden support was placed inside to allow for placement of the liver in anatomical position.

The procedure conducted was a cholecystectomy in the organic model.

Methods

Randomization. Before performing any laparoscopic task, each participant performed a depth perception test. Only participants with stereoscopic vision and without strabismus were included in the study.[9] Then, each participant completed a prequestionnaire in order to be included in 1 of the 3 categories of experience/level of expertise.

All participants underwent laparoscopic warmup tasks. These exercises were preceded by reading a memorandum of the technique as well as watching a step-by-step video of the procedure. The order of working with the different imaging equipment was determined by random distribution as 3D → 2D or 2D → 3D.

The tasks were performed using the Karl Storz endo-trainer in which laparoscopic instruments were introduced through a single-port SILS (Medtronic). The 2 holders used were always placed in the same manner within the endo-trainer for all participants.

As warmup exercises, each participant performed 2 tasks: cutting between 2 circles removing the center circle using tweezers/grasper and scissors; passing objects on one side of a support to the other transferring from grasper to tweezer or vice versa, without dropping.

A minimum time of 5 minutes to perform the 2 tasks and a maximum time of 15 minutes was set. No data as to the performance of the participants in these 2 tasks were recorded, as the goal was becoming accustomed to the instruments and imaging systems. Both initial tasks were performed on each of the imaging systems (2D and 3D) before the cholecystectomy.

Performance Evaluation: Error and Time. At the end of warmup exercises, each participant was provided with a memorandum summarizing the steps of the surgical procedure to be performed in each of the imaging systems: a single-port laparoscopic cholecystectomy in liver pig model.

Each participant was allowed up to 2 times to read the memo prior to each surgery. Participants then watched a video showing the procedure. Laparoscopic cholecystectomy by single port was divided into 3 main steps: isolation of the gallbladder hilum (Step 1), ligation and transection of the cystic duct (Step 2), and resection of the gallbladder from its bed (Step 3). Detected errors that were recorded were as follows: Step 1, laceration of the cystic duct, nonisolation of the cystic duct in 360°, and perforation of the gallbladder; Step 2, cystic duct partial clamping, sealing/section more than once and dehiscence after sealing; Step 3, perforation of the bladder and perforation of the liver parenchyma. During surgery, times for each of the steps and as well as total imaging system time, in addition to errors associated with each step, were recorded. Tasks using the 3D system were performed in a room with the lights off to allow for better image display.

Evaluation of Preference. After completing the experiment, each participant answered a questionnaire regarding the imaging system. The purpose of this step was to obtain the participant's views as to the possible advantages of 3D versus 2D imaging systems and also determine their preference for the 2 imaging systems.

Table 1. Descriptive Statistics (Mean, Standard Deviation, Sample Size) for the Groups in 4-Way ANOVA (Dependent Variable: LOGTIME).

				Time Step 1		Time Step 2		Time Step 3	
Video	Group	Order	N	Mean	SD	Mean	SD	Mean	SD
2D	Expert	2D → 3D	6	14.255	7.833	0.962	0.388	18.50	12.232
		3D → 2D	4	11.078	4.446	1.100	0.708	28.49	21.566
	Intermedium	2D → 3D	3	21.773	17.687	1.620	0.726	26.97	9.991
		3D → 2D	4	9.320	3.759	1.300	0.810	22.36	20.627
	Naive	2D → 3D	4	56.038	25.061	4.798	2.610	36.40	22.124
		3D → 2D	6	24.402	14.332	4.993	3.657	29.46	10.103
3D	Expert	2D → 3D	6	8.963	5.885	1.265	1.110	12.61	3.888
		3D → 2D	4	15.000	6.785	2.605	3.103	34.31	25.398
	Intermedium	2D → 3D	3	17.500	15.668	1.077	1.085	18.06	15.773
		3D → 2D	4	17.977	4.489	0.900	0.536	21.59	5.925
	Naive	2D → 3D	4	24.448	16.396	3.183	2.600	25.75	6.329
		3D → 2D	6	36.212	10.499	3.923	2.228	49.56	31.952

Statistical Analysis

For the statistical analysis we used IBM SPSS Statistics 22.0 for Windows.

After checking for normality, data were processed comparing end-points (time and errors). Three mixed design factorial ANOVAs (one for each of the 3 tasks) were performed with 2 between-subjects factors: experience and video order, and the time to perform the task according to 2D or 3D vision as the within-subject factor.

A P value of <.05 was regarded as statistically significant.

Results

Normality Assumption

The Kolmogorov-Smirnov ($P > .05$) and the visual analysis of the histograms, QQ standard plots, and box plots show the normal principle achieved for most of the variables. Despite the normality assumptions being violated for experienced participants categories 2D (1.170 asymmetry and kurtosis 0.084) and 3D (asymmetric 3.494 and kurtosis 1.896), participant through 3D (asymmetry 4.335 and kurtosis −1.882), 3D display and execution order 3D monitor first (asymmetry 0.780 and kurtosis 0.386) and total number of errors in 2D monitor (1 error—asymmetry 1.526 and kurtosis 2.203), we continued the study performing the parametric tests using one-way ANOVA and mixed design factorial ANOVA.

Descriptive Statistics (Table 1)

Time. The beginning of the experiment using the 3D imaging system (order 3D → 2D) helped, overall, develop better performance in the participants when undergoing the experience with the 2D imaging system, namely, in Step 1 (from 24.40 to 56.04 minutes) and Step 3 (29.46 to 36.40 minutes) for the novice group; in Step 1 (from 9.32 to 21.77 minutes), Step 2 (1.30 to 1.62 minutes), and Step 3 (of 22.36 to 26.97 minutes) for the intermediate group; and in Step 1 (11.08 to 14.26 minutes) for the experienced group.

In comparison, regarding the experiment performed in the 3D imaging system, all participants performed better when they began the experiments in order 2D → 3D, regardless of the step to be executed and to which group they belonged, except in Step 2 performed for 3 of the 7 participants of the intermediate group (from 1.08 to 0.9 minutes).

Errors. When the tests were made starting by using the 3D imaging system (order 3D → 2D), the performance of the participants improved in terms of total number of errors, regardless of the imaging system or group, except in the case of tests in the 2D imaging system with the intermediate group (from 1.75 to 1.67 errors).

ANOVA Tests (Figure 3)

Results for the 3 different tasks performed were the following.

Regarding task 1, a significant vision * order interaction effect was obtained, $F(1, 21) = 11.9$, $P = .002$, η^2 $P = .363$. Those who started with 2D vision tended to perform better when using 3D vision (mainly in the Novice group). Additionally, a significant group main effect, $F(2, 21) = 16.7$, $P < .001$, η^2 $P = .614$, was detected, with the time spent performing the task decreasing significantly with medical experience.

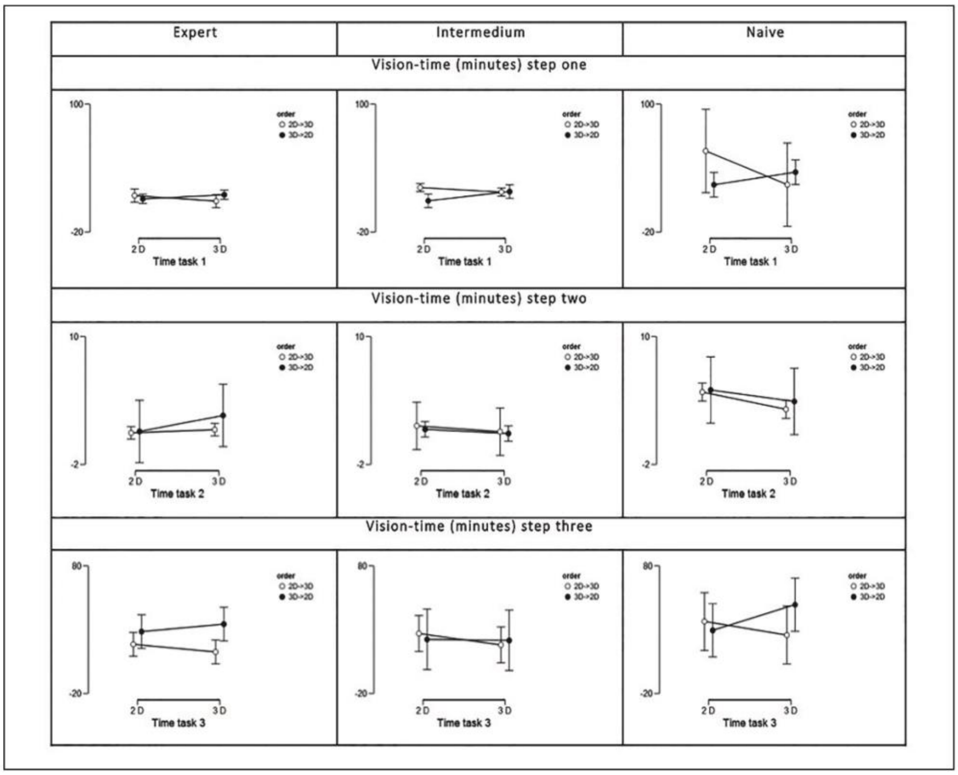


Figure 3. Analyzing the data in terms of time spent by task (or step), taking into account the order by which they are performed: 2D → 3D or 3D → 2D; the results were generally superior when the 3D system was used. We found a statistically significant relationship between the time spent in performing the first step and the order in which the test was performed. The operator's experience proved significantly relevant in carrying out the first and second tasks. Finally, the third task also showed a statistically significant difference in the order in which the test was performed.

Results in task 2 were significant only for group, $F(2, 21) = 8.9$, $P = .002$, $\eta^2 P = .458$; again, the time spent performing the task decreased significantly with medical experience.

For task 3, similar to task 1, a significant vision * order interaction effect was detected, $F(1, 21) = 4.28$, $P = .039$, $\eta^2 P = .188$, showing that those who start with 2D vision tend to perform better when using the 3D vision (mainly in the Novice group).

Preference Questionnaire

Compared to 2D view, 11.1% of respondents considered 3D vision much easier, 55.6% easier, 25.9% similar, and 7.4% more difficult. In terms of the advantage that the 3D view provides in some steps of the surgery, 14.8% of the participants considered that it gave advantage only in Step 1 (gallbladder hilum isolation), 3.7% in Step 2 (ligation and transection of the cystic duct), 14.8% in Step 3 (gallbladder removal of its bed), 11.1% in Steps 1 and 3, 7.4% in Steps 2 and 3, and 29.6% considered that there was advantage in all 3 steps. A minority of 18.5% considered that the 3D vision did not confer significant advantage in any of the 3 steps.

When evaluating the unpleasant symptoms in the use of a 2D imaging system, 96.3% of the participants did not report having any unpleasant symptoms and 3.7% reported pain in their hands and wrists. In relation to the 3D imaging system, the vast majority of the participants, 70.4%, did not mention any unpleasant symptom. Four of the 27 participants complained of headache, one of nausea, and one of both.

All participants admitted there is at least one advantage associated with the use of 3D imaging system, of which 59.3% considered it to be the perception of depth, 7.4% pointed out mostly spatial orientation, 3.7% both perception of depth and bimanual ability, 11.1% spatial orientation and perception of depth, and 18.5% reported finding all 3 advantages (bimanual ability, depth perception, and spatial orientation). In terms of current 3D technology development status, 18.5% did not consider it to be developed and 81.5% fairly developed. When asked about their preference, 66.7% of the participants preferred the 3D system compared with the 2D version.

Discussion

Minimally invasive surgery has undeniable advantages despite having several limitations. Technological developments can help improve its use, particularly through the development of new instruments and better image systems.

Limitations of 2D image are well documented. This study evaluated whether the use of a 3D imaging system in a LESS organic model cholecystectomy confers performance advantages.

Participants having different levels of practice in multiport laparoscopy were divided into 3 different groups (novice, intermediate, and experienced), later carrying out the surgical simulation in 2D and 3D.

When comparing the average total experiment time, taking into account the order, there was improved performance in the 3D imaging system when the order of 2D → 3D was followed and the time was better in the 2D display when the order was 3D → 2D, which revealed the existence of a learning curve, as we can see in other studies.[9]

The learning curve is the improved performance resulting from the repetition of the exercise.

The learning curve was more notable when the order was 2D → 3D compared to the inverse sequence, as demonstrated by our work in 2016.[17] This can be explained by increased depth perception afforded by 3D systems after going through the 2D experience.

For the analysis of average time per step and the order of imaging systems, it was found that in the sequence 2D → 3D, the experiment performed in 2D took longer on average in Steps 1 and 3; in the inverse sequence of 3D → 2D, the experiment performed in 2D took less time on average in any of the 3 steps individually. This demonstrates a positive learning effect, taking into account the average time of each step, in contrast to the total of the experiment, when starting the experiment using the 3D imaging system. The analysis of average time per order of groups and imaging systems showed that 2D → 3D order was better in all groups using 3D, and performance decreased in view of the experience of the participants; in the order of 3D → 2D, performance was improved when using the 2D system, and the average highest time occurred in the novice group and the performance of the intermediate group was better than the experienced group. This can demonstrate the benefit of the 3D system in accelerating the learning curve, particularly in subjects with average experience or who were inexperienced.

Comparing times and errors with 2D as the first or second exercise (before or after 3D), it was clear that 3D experience is transferable to 2D in terms of the learning curve.

By analyzing the preference of the participants, it was possible to conclude that most choose the 3D system over the 2D system. This imaging system can possibly benefit during longer surgeries and with those of a higher degree of difficulty.

There were some drawbacks that are important to point out, however. To obtain more consistent results, the study sample could have been greater and it would be interesting to compare another 2 groups—2D after 2D and 3D after 3D—to better determine the effect of 3D systems in the learning curve. To avoid operation errors, all participants should have the same degree of experience with laparoscopic instruments. Although it is not possible to control the size of the liver or bladder, it is important to note that there was variability. Finally, in future studies besides recording the quality of the mistakes, also the number of times each mistake occurred could better distinguish participants' performance.

Conclusions

Taking into account the obtained results it can be concluded that the 3D imaging system may improve the learning curve for the implementation of LESS surgery. The 3D imaging system can accelerate the learning process in individuals without any experience and those with limited previous laparoscopic practice.

Furthermore, background experience in multiport laparoscopy is an advantage for LESS surgery.

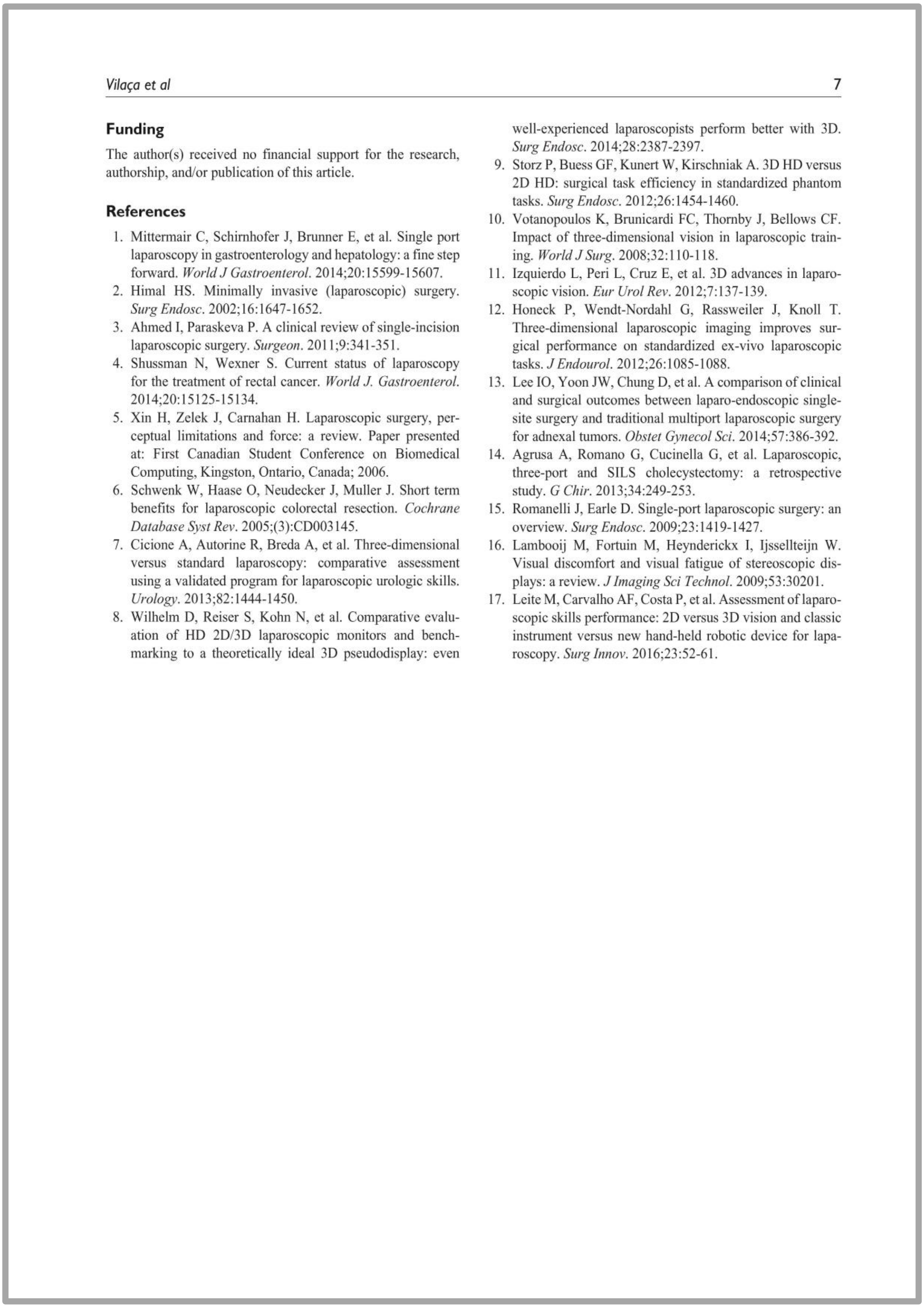
The preference of the majority for the 3D system demonstrates added comfort afforded by this equipment, and this can mean improved and sustained performance in complex and prolonged surgical procedures.

Author Contributions

Study concept and design: Pedro Leão and Jaime Vilaça
Acquisition of data: Jaime Vilaça, José Pedro Pinto, and Sandra Fernandes
Analysis and interpretation: Jaime Vilaça, Patrício Costa, Jorge Correia Pinto, Pedro Leão, and José Pedro Pinto
Study supervision: Pedro Leão, Jaime Vilaça, and José Pedro Pinto

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.



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THE INFLUENCE OF 3D IN SINGLE-PORT LAPAROSCOPY SURGERY: AN EXPERIMENTAL STUDY.

Vilaça J, Leite M, Correia-Pinto J, Högemann G, Costa P, Leão P.

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ORIGINAL ARTICLE

The Influence of 3D in Single-port Laparoscopy Surgery: An Experimental Study

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Abstract: The aim of this experimental study was to analyze the effect of 3-dimensional (3D) imaging in laparoendoscopic single-site surgery. End points were time, errors, and preference. Twenty-six participants were enrolled in the study, and these were divided into Beginners and Experts, in exercises either with a 2-dimensional or a 3D system. The 4 phantom exercises were chosen from the E-BLUS—European Training in Basic Laparoscopic Urological Skills from the American Fundamentals of Laparoscopic Surgery (FLS) system. A postexercise questionnaire was delivered. Statistical analyses using SPSS 22.0 for Windows yielded a 1-way analysis of variance. There was a significant positive impact of 3D imaging on experts' performance: faster exercise completion with fewer errors. The majority reported improved performance with the 3D system (86%, Beginners; 100%, Experts). 3D systems for laparoscopy would likely increase experts' performance for laparoendoscopic single-site surgery and improve comfort during difficult procedures.

Key Words: LESS, SILS, 3D, 2D, laparoscopy, performance

(*Surg Laparosc Endosc Percutan Tech* 2018;00:000–000)

Since the appearance of laparoscopy, the viewpoint needed to perform surgery is not dependent on the surgeon's eyes only. In fact, video equipment has determinant of the result even if the surgeon has got a highly developed skills set.

The standard imaging for laparoscopy has been 2-dimensional (2D), resulting in lack of depth perception. This limitation has been offset by several means such as parallax movements and image recall. However, misperception is a common cause for injury. Learning curves are long, and even experts in laparoscopy experience fatigue and difficulty in prolonged and delicate procedures.[1]

Efforts to create 3-dimensional (3D) laparoscopes began in the early 1990s. This first-generation equipment did not overcome the 2D counterpart, because images were of lower definition, light was poorer, costs were higher, and side effects were limiting. More recently, new proposals of 3D systems have arrived, providing better images, lower costs, and added comfort.[2,3]

Several publications in the past years comparing these 2 different technologies have given new strength to this old question of laparoscopic surgery. In fact, there have been studies showing some advantages associated with 3D systems: a shorter learning curve, faster and more accurate movements, surgeons' preference, and reported greater convenience. It seems, nowadays, that 3D technology will likely have more impact on novices, shortening their learning curves, and on experts, raising their accuracy and performance for complex procedures.[4–9]

Another issue that dragged new proposals forward was the aim of lesser invasiveness in laparoscopy. Approaches like minilaparoscopy, laparoendoscopic single-site surgery (LESS), and natural orifice transendoscopic surgery, increased technical demand. When performing LESS interventions, instruments move in a tight space. Conflict of these tools arise as a consequence.

Therefore, we hypothesize that 3D technology could enhance depth perception, and the performance of LESS surgery could be improved when fixing the scope at a set distance.

To our knowledge, there are no studies comparing 3D and 2D systems in the context of LESS surgery, making this the first study aiming toward this proposal.

MATERIALS AND METHODS

These experiments were conducted at the Life and Health Sciences Research Institute (ICVS), School of Health Sciences, University of Minho, Braga, Portugal. Professionals with varying levels of experience in laparoscopic surgery agreed to participate.

Population of the Study

Twenty-six subjects participated in the study. A pre-experiment inquiry included data from the participants, such as age, sex, use of eyeglasses, dominant hand, number of previous laparoscopic surgeries performed as a surgeon, and previous experience in LESS and in laparoscopy with 3D systems. This allowed a division of the subjects into 2 groups according to their experience in laparoscopic surgery: A, <50 procedures performed; B, > 50 procedures performed. Group A was called the novice group (14 subjects) and group B was called the expert group (12 subjects).

Of 14 novice participants, only 4 had performed > 10 laparoscopic surgeries. None had previous experience, whether in LESS or with 3D systems. Half of the experts had previous experience in LESS, and 3 had performed laparoscopic surgery with a 3D imaging system. Forty-six percent of all participants wear eyeglasses.

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Laparoscopic Tasks

Four phantom exercises were chosen from the E-BLUS—European Training in Basic Laparoscopic Urological Skills, which is derived from the Fundamentals of Laparoscopic Surgery American system:

(1) Peg transfer: grasping 6 rubber rings, one at a time, transferring them from 1 side of the board to the other. While transferring the rings, subjects change the rings from 1 grasper to the other. After moving all 6 rings from the left side to the right, subjects repeat the procedure from the right side to the left. An error is recorded in the data each time the ring is either dropped or when it is not exchanged from 1 grasper to the other.

(2) Cutting a circle: using scissors to cut a circle in a piece of gauze between 2 concentrically drawn circles. An error is recorded in the data whenever participants cut through either of the drawn lines.

(3) Clip and cut: isolating each rubber strip that represents a blood vessel and then putting a rubber tie around them as a reference. Clipping must be performed at 2 points in each of the strips, followed by cutting in the middle of the clips. Errors were recorded because of the following: (i) if a rubber band was detached while isolating it, (ii) if a clip was not placed completely across the vessel, and (iii) if the cut was not made between the clips.

(4) Needle guidance (also called "rings"): guiding a needle through a circuit of 10 metal rings attached to a sponge board. Whenever the needle was dropped or 1 ring was by-passed, an error was recorded.

Materials Used to Perform Laparoscopic Tasks

Exercises were carried out within a trainer box with an SILS Port (Covidiem, Medtronic). One 10 mm 0 degree laparoscope was fixed 11 cm from the end to the surface of the SILS Port. Exercises were carried out using 3 mm instruments from Karl-Storz and a Ligamax Clip Applier (J&J Ethicon).

Two separate Karl-Storz working stations were used. 2D laparoscopy used the latest generation equipment with a HD flat screen video monitor. 3D laparoscopy was conducted in a darkened room with the system attached to a 32″ monitor. Participants wore light-polarized glasses while working with the 3D system.

Participants' Distribution

Subjects were randomly distributed to start the 4-exercise sequence, either with a 3D or 2D system.

For sample size determination, we have considered the interaction between the exercise (peg transfer, cutting a circle, clip and cut, and needle guidance) and video (2D and 3D). A total sample size of 24 required surgeries was calculated on the basis of a medium effect size ($f = 0.25$), a type I error of 0.05, and a power ($1-\beta$) of 0.80.

Questionnaires

Participants completed 2 separate inquiries: pre-experiment and postexperiment. The pre-experiment is described in the topic "Population of the study"; the postexperiment form was a preference questionnaire comparing 2D versus 3D in accordance with the following topics: preferred system, preferred exercise with 3D, and reported specific advantage of the 3D system.

TABLE 1. Time in 2D Versus 3D Monitors

Descriptive—Time

Group	Exercise	Monitor	Mean	SD	N
E	Circle	2D	341.8	154.172	12
		3D	257.3	69.636	12
	Clip and cut	2D	470.5	207.357	12
		3D	362.4	84.604	12
	Peg transfer	2D	276.3	128.366	12
		3D	221.5	52.152	12
	Rings	2D	582.6	29.557	12
		3D	554.8	111.075	12
N	Circle	2D	266.6	57.872	14
		3D	240.8	85.309	14
	Clip and cut	2D	400.1	142.592	14
		3D	404.1	145.700	14
	Peg transfer	2D	196.6	64.831	14
		3D	191.2	93.729	14
	Rings	2D	600.0	0.000	14
		3D	598.4	6.250	14

Expert group average times for execution of the 4 different exercises were inferior with 3D monitor, regardless of the monitor sequence. Novice group average times were inferior with 3D monitor in all except 1 exercise, "clip and cut."

2D indicates 2-dimensional; 3D, 3-dimensional.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) 22.0 for Windows. A *P*-value of <0.05 was considered as the threshold for statistical significance.

Comparison between 2D and 3D LESS surgery included performance ratio, measured in time and errors, as well as participants' preference. The former factors were studied using a one-way analysis of variance (ANOVA) while the latter related to preference used the answers of the postexperiment inquiry described as a percentage.

TABLE 2. Errors in 2D Versus 3D Monitors

Descriptive—Error

Group	Exercise	Monitor	Mean	SD	N
E	Circle	2D	0.700	0.949	12
		3D	0.000	0.000	12
	Clip and cut	2D	0.500	0.707	12
		3D	0.000	0.000	12
	Peg transfer	2D	0.500	1.080	12
		3D	0.400	0.699	12
	Rings	2D	3.000	2.000	12
		3D	2.500	2.415	12
N	Circle	2D	1.438	1.263	14
		3D	0.750	1.342	14
	Clip and cut	2D	0.375	0.719	14
		3D	0.063	0.250	14
	Peg transfer	2D	0.625	1.088	14
		3D	0.938	1.063	14
	Rings	2D	4.813	4.385	14
		3D	6.813	3.953	14

For the expert group, fewer errors were committed whenever using the 3D monitor in each exercise. The novice group performed better with the 3D monitor in "clip and cut" and "cutting circle" exercises. In this group, average errors were more frequent with 3D in "peg transfer" and "needle guidance" exercises.

2D indicates 2-dimensional; 3D, 3-dimensional.

TABLE 3. Differences Between Group and Monitor Variables

ANOVA—Time

Cases	Sum of Squares	*df*	Mean Square	*F*	*P*	η^2 *P*
Group	22,071	1	22,071	2.141	0.145	0.011
Exercise	3.844e +6	3	1.281e +6	124.330	< 0.001	0.660
Monitor	71,095	1	71,095	6.898	0.009	0.035
Group×exercise	55,015	3	18,338	1.779	0.152	0.027
Group×monitor	46,698	1	46,698	4.531	0.035	0.023
Exercise×monitor	13,509	3	4503	0.437	0.727	0.007
Group×exercise×monitor	12,182	3	4061	0.394	0.757	0.006
Residual	1.979e +6	192	10,307			

A significant difference between group and monitor variables was observed as well as between exercise and monitor.
Type III sum of squares.

RESULTS

Descriptive Statistics

Table 1 summarizes descriptive statistic results on the basis of time. The expert group achieved shorter execution times for all tasks when using the 3D system. The novice group had similar results in 3 of the 4 exercises; only in "clip and cut" did they achieve a shorter time, performing the exercise with the 2D system (400.1 vs. 404.1).

Table 2 summarizes descriptive statistic results for errors. In all exercises, a better result was achieved when using the 3D system for the expert group. The novice group had lower error with 3D system in "circle" (0.750 vs. 1.438) and "clip and cut" (0.063 vs. 0.375), whereas in "peg transfer" (0.625 vs. 0.938) and "needle guidance" (4.813 vs. 6.813) the best results occurred using the 2D system.

1-Way ANOVA

Table 3 summarizes the results of the 1-way ANOVA for the variable *time*. A significant effect of exercise and monitor was found on average time ($P < 0.05$). Average time was significantly different between group/monitor ($P < 0.05$) as well.

Figure 1 shows timelines and the relationship between monitor and group. There was a large difference between novice and expert groups in regard to time required for executing the laparoscopic tasks according to the type of the monitor: less time was required when the 3D monitor was used by the expert group; the novice group did not demonstrate a significant reduction in time when using 3D; in fact, the time taken was very similar with both types of monitors.

Figure 2 shows timelines and the relationship between monitor, group, and exercise. The expert group showed a decrease in execution time for all laparoscopic tasks when the 3D monitor was used; the most dramatic reduction was recorded for "clip and cut." In contrast, the novice group only showed a slight decrease in time with 3D for the "cutting a circle" task.

In Table 4 the error variable results are included using the 1-way ANOVA. A significant effect of group and exercise on the mean error ($P < 0.05$) was reported. The mean error was significantly different between group/exercise ($P < 0.05$) also. The statistically significant effect found in the mean error by group is shown in Figure 3 (the error is lower in the expert group).

Figure 4 shows error lines and the relationship between monitor, group, and exercise. In the expert group, the mean error markedly decreases in the tasks "cutting a circle" and "clip and cut" when a 3D monitor was used; a smaller decrease is observed for the other tasks ("peg transfer" and "needle guidance"). In the novice group 2 completely opposing situations occurred: error reduction in the tasks "cutting a circle" and "clip and cut" with a 3D monitor, as was the case in the expert group; in contrast, there was an increase in the error for 3D monitor in "peg transfer" and "needle guidance."

Preference—Questionnaire

Results of the participant preference postexercise inquiry are presented in Table 5. When compared with 2D vision, one third of experts rated working with 3D equipment as much easier; two thirds found it easier. None of the experts reported 3D to be similar or worse than the 2D counterpart. Novices' opinions were not as favorable in regard to 3D, despite being positive: none found it to be much easier, 12 reported it easier, 1 similar, and 1 reported it more difficult to work with the new technology.

With regard to the technical advantage per exercise, results were quite similar; however, more exercises were found to benefit from the use of 3D vision, in the case of experts. The exercises that benefited most from 3D vision were those with wider depth movements like "cutting a circle" and "needle guidance" (also called "rings").

Finally, the greatest advantage of 3D features reported by participants was "depth perception" for both groups.

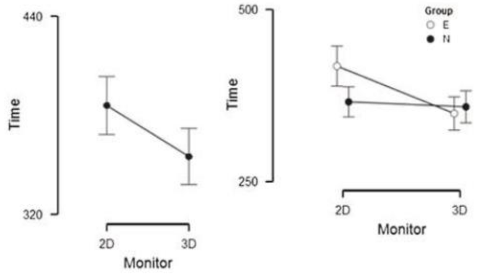

FIGURE 1. Monitor effect on average time. These graphics confirm descriptive and ANOVA statistical analysis. ANOVA indicates analysis of variance; E, expert group; N, novice group.

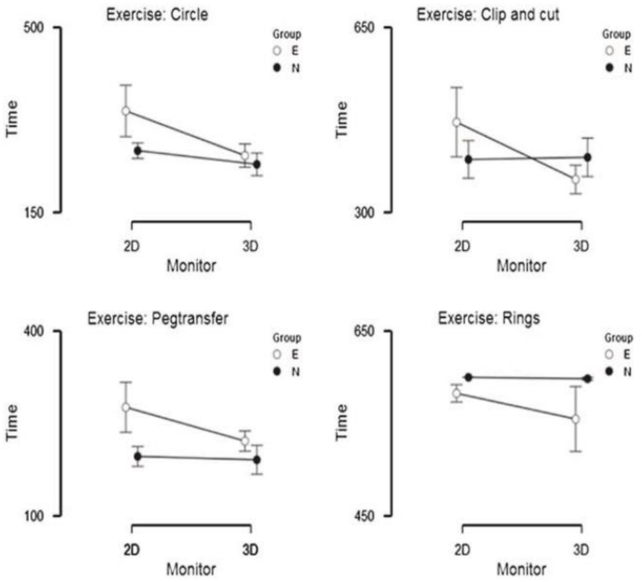

FIGURE 2. Monitor effect on average time per group and exercise. A much more relevant reduction on the average time was recorded in the expert group in each of the 4 exercises. The novice group only demonstrated significantly faster performance in the "circle" exercise. In this group, the "rings" exercise yielded slower performance with 3D technology. 3D indicates 3-dimensional; E, expert group; N, novice group.

DISCUSSION

The authors present an experimental study with validated phantom exercises to identify advantages and preferences in regard to the use of new generation 3D system versus standard 2D HD equipment in the context of LESS surgery. A group of 26 participants was included in the study.

This series reveals that 3D technology for LESS surgery has a better positive impact in terms of time and errors for expert surgeons rather than for novices. A direct relationship with subjective postexperience inquiry results was also observed. Experts felt more comfortable with 3D technology, particularly when performing exercises involving wider depth movements.

Less straightforward results for the novice group were observed in this series, better and worse results mixed together, presenting no apparent pattern. It can be postulated that high-expertise demand techniques like LESS surgery would downplay and obscure possible 3D image performance improvement.

Nevertheless, novices reported feeling better with 3D imaging: 86% reported easier performance with this technology. Both groups revealed the same sensibility for the possible advantages of 3D imaging: enhanced depth perception (58% for novices vs. 53% for experts), better spatial orientation (35% for novices vs. 31% for experts), and 2-handed maneuvre (7% for novices vs. 16% for experts).

TABLE 4. Error Between Group and Exercise

ANOVA—Error

Cases	**Sum of Squares**	***df***	**Mean Square**	***F***	***P***	**η^2 *P***
Group	51.881	1	51.881	13.586	< 0.001	0.066
Exercise	527.722	3	175.907	46.065	< 0.001	0.419
Monitor	0.183	1	0.183	0.048	0.827	0.000
Group×exercise	71.722	3	23.907	6.261	< 0.001	0.089
Group×monitor	7.452	1	7.452	1.951	0.164	0.010
Exercise×monitor	14.834	3	4.945	1.295	0.277	0.020
Group×exercise×monitor	12.411	3	4.137	1.083	0.357	0.017
Residual	733.188	192	3.819			

Error analysis revealed a statistically significant difference between group and exercise. There was also a significant difference according to group and exercise.

Type III sum of squares.

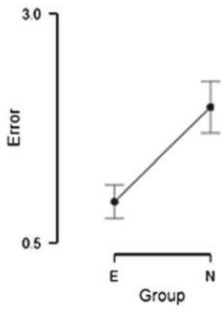

FIGURE 3. ANOVA result for the entire group of participants. ANOVA indicates analysis of variance; E, expert group; N, novice group.

The use of a fixed-distance laparoscope may well also provide further advantages in performance and participant comfort with 3D technology. The sense of depth with 2D imaging worsens as the distance of the scope to the surgical field increases. Only a very active engagement with constant forward and backward motion of the scope can offset the lack of depth perception.

The fixed distance of the laparoscope can enlarge the space of work while allowing for less conflict between instruments. It can also improve image stability and reduce collision between the surgeon and his assistant. In specific situations such as transanal procedures, it is very difficult to assist in a surgeon's performance, because the space between the legs is limited to 2 people.

The Storz study with new generation 3D systems suggested better performance for experts in the context of complex and difficult surgeries.[8] Besides that, the proof that 3D imaging is more comfortable for prolonged procedures than 2D standard imaging will probably be related to better outcomes.

LESS surgery has been gaining renewed interest in the last years, in part because of the adaptation of these approaches to transanal surgery.[10,11] With recent advances in rectal oncology, more conservative and natural orifice transendoscopic surgery techniques tend to increase the use of the transanal route.[11] An enhanced imaging technology that improves depth perception would be of utmost importance in a narrow space.[12] In fact, such a conclusion has already been widely reported in terms of the advantages of 3D robotics view for lower rectal surgery.[13]

Another field of expanding indications for LESS is thoracic surgery. Here, improved image quality can be of paramount importance for tasks such as "clip and cut."[14] In this series, this particular exercise showed better performance not only for experts but also for novices (less errors).

This study reveals several limitations: sample size, homogeneity of groups, and the monitoring of side effects. An increased number of participants would clarify 3D imaging impact on novice performance. The introduction of participants with intermediate experience in the novice group jeopardizes the results of this category even more. Conversely, experts with previous LESS surgery experience probably would be better included in a super-expert group. Finally, the record of side effects would be of interest, despite the subjective preference questionnaire. Undesirable effects such as numbness and headaches were frequently reported with first-generation 3D laparoscopic equipment.

We conclude that 3D systems for laparoscopy would likely increase experts' performance for LESS procedures. Larger experimental and clinical studies are needed to validate this advantage definitively.

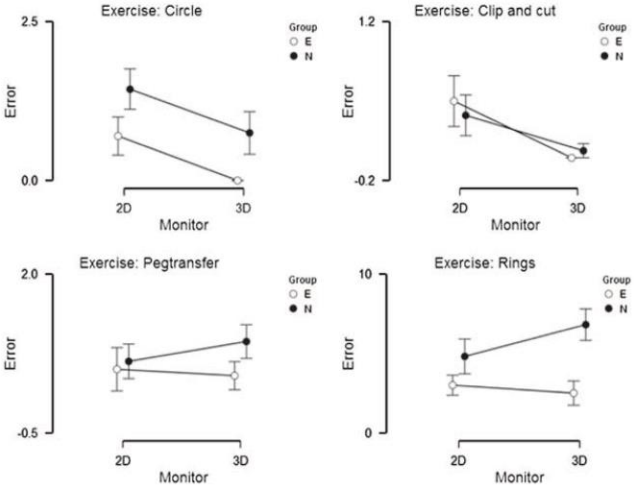

FIGURE 4. ANOVA results for 3 variables: exercise, monitor, and group. Both experts and novices demonstrate a significant reduction in errors while using 3D imaging for "clip and cut" and "cutting circle" exercises. For the expert group, better performance was observed for the "peg transfer" and "needle guidance" also. For these 2 exercises, novices performed better in this series. ANOVA indicates analysis of variance; 3D, 3-dimensional; E, expert group; N, novice group.

TABLE 5. Postexercise Inquiry

A. Overall, Compared With 2D Vision, You Feel the 3D Vision is			B. If You Feel That 3D Vision Provides a Significant Advantage in Any Task, Please Mark Them (%)			C. What is (are) the Most Important Advantage(s) of 3D Vision? (%)		
	Novice	**Expert**		**Novice**	**Expert**		**Novice**	**Expert**
Much easier	—	4	Peg transfer	43	56	Depth perception	58	53
Easier	12	8	Cutting circle	71	67	2-handed maneuvre	7	16
Similar	1	—	Clip and cut	28	44	Spatial orientation	35	31
More difficult	1	—	Needle guidance	50	78			
Much more difficult	—	—						

Question A—results per number of participants. Better impression among experts. Questions B and C—percentage results. Each question can comprise > 1 answer. Very similar results in terms of advantage distribution per exercise and enhanced feature.

2D indicates 2-dimensional; 3D, 3-dimensional.

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PART 3

DISCUSSION

5. Stereoscopy

Stereoscopy is a method that artificially presents two different images separately to each eye, triggering the effect of stereopsis (1).

The phenomenon of stereopsis was described for the first time by Sir Charles Wheatstone in 1838. He realized that our mind perceives an object in three-dimensions through the fusion of two dissimilar pictures projected on both retinas. He then created the "Wheatstone Stereoscope" to give the illusion of exaggerated volume by projecting different images to each eye, and proved his theory in this way (2).

Stereopsis is a word derived from the greek (stereo, meaning solid and opsis, meaning appearance or sight) and refers to the effect that is obtained from fusing slightly different views from binocular distance of the two human eyes. These positional differences are referred to as horizontal disparities or, more generally, binocular disparities. These slightly different views are processed in the visual cortex of the brain to yield field depth perception.

Depth perception itself is the impression of "real" separation of objects in their distance from the observer. The correct evaluation of the movement length has been suggested as a guide for planning motor action. When depth perception is lacking, like in a monocular bi-dimensional image, the gesture to reach a structure distant from the observation point follows an arc path, a ballistic movement (Figure 5). Due to evaluation difficulties of the exact point to reach, the depth movement of the instrument is constantly adjusted in

precision.

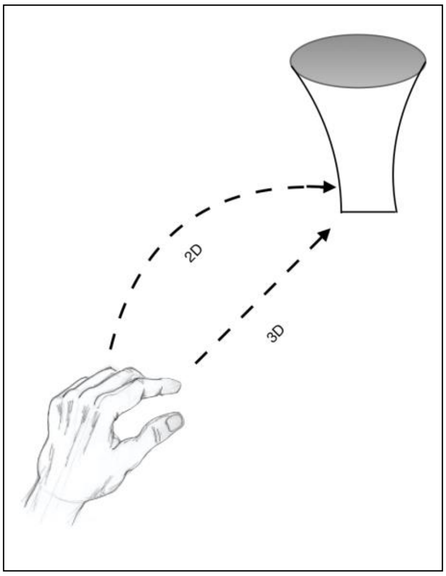


Figure 5 Deep motion with two and three dimensional image

Depth-of-field-learning in two-dimensional (2D) vision uses specific clues to compensate for the lack of the third dimension. This is a slow process in which the comparison between elements of the image assumes a primordial role. Static observation uses dimension, overlap, textures, color, brightness, and shadow, while moving observation primarily uses the parallax effect. This can be the comparison between the right and left eyesight as well as views from different angles. The differences in position between left and right retinal images, termed binocular disparities, can be used by the visual system to recover the third dimension information from 2D images. Lastly, other important subterfuge of two-dimensional vision is the comparison with recalled images. Due to the capability of the image center within the brain to capture and recall images, the view of 2D images appears with somewhat limited depth (3), the so-called two-and-a-half dimension. Recognizing a familiar visual environment helps to identify the volume of space. As a consequence, the perception of depth is more impaired whenever 2D image is used for novel spaces of action, or when facing a new scenario in a common situation.

In an extensive study conducted by Lawrence W. Way on etiology of common bile duct iatrogenic lesions during laparoscopic cholecystectomy, misperception or visual perception illusion was identified as the cause for 97% of injuries (4). This may result from misinterpreting two-dimensional images. As commented by the author, “in most cases the surgeon did not recognize a problem”.

Another important feature of three-dimensional vision is spatial orientation. In fact, two types of stereopsis can be considered: Coarse stereopsis, also called qualitative or gross stereopsis, which is used to judge stereoscopic motion in the periphery. This is very important for space orientation during movement. We can even say that it is the responsible for the sense of immersion in the three-dimensionality of the surrounding space; the other type is quantitative. This other variety can also be called fine stereopsis and is based on static differences, giving us an exact sense of depth of displayed objects. It corresponds to the central visual area, the so-called Panum’s fusional area; an example of fine stereopsis is threading a needle, and an example of gross type is orientation in space while descending a flight of stairs (5).

Fine stereopsis is of the utmost importance for delicate and precise movements, like surgery. It can be measured with specific random-dot tests (Figure 6). These are considered the gold-standard for stereoacuity evaluation. Easy to use, these tests consist of sets of circles in which, thanks to the cross disparity of one of them, it will appear closer than the others when viewed through the testing glasses containing cross-polarized filters. With these tests, different levels of stereoacuity can be detected (6).

Figure 6 The RANDOT Stereo Test (Stereo Optical, Chicago, IL, USA)

In the general population, it is estimated that about 30% have some level of decreased visual acuity and approximately 3% of individuals are actually stereo-blind. Impairment of stereo acuity has also been noted in individuals after the age of 60 years with no previous history of eye disease. One population study showed that 97.3% were able to distinguish depth at horizontal disparities of 2.3 minutes of arc or smaller, and at least 80% could distinguish depth at horizontal differences of 30 seconds of arc. Many people lacking stereopsis have (or have had) visible strabismus (7).

It is critical for the surgical community to understand that stereo-blind individuals or those with some degree of visual acuity impairment, will not benefit from three-dimensional images to such a degree as individuals with normal visual stereoacuity can.

Furthermore, there are studies showing that when contrast is the same in both eyes, binocular acuity is better than the best monocular acuity by an average of 11%, which means that normal vision improves functional vision by summation and stereopsis (5).

Binocular disparities are the result of inter pupillary distance, that for human vision is approximately 60 mm. The brain's interpretation of this disparity at the retinal fovea (*panum region*) gives the sense of depth. The eyes' convergence on a specific point (point of fixation) is where the object is brought into sharp focus on the retina. The region of depth, also called comfort zone, is between the near and far points that an object can be seen by the eye and still be in focus (Figure 7). The human eyes have the ability to clearly visualize objects which are in this region, a phenomenon called accommodation (3).

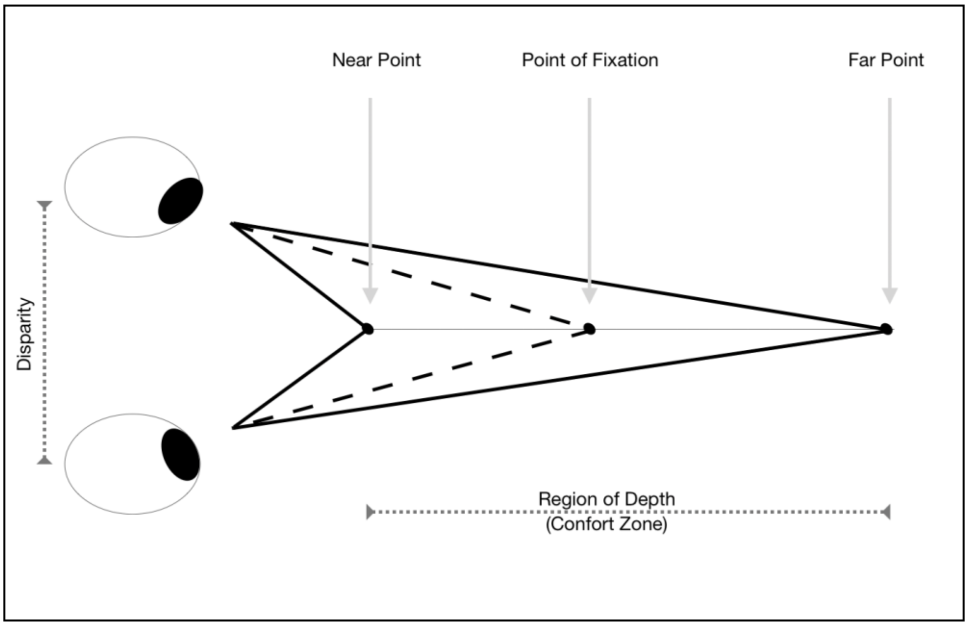


Figure 7 Basic aspects of stereoscopic vision in humans

When stereoscopic is displayed on a monitor, two different images are presented at the same time. The way images are presented to each eye is determinant of the quality of stereopsis. Furthermore, the exact horizontal position of the viewer with eye level held at half the screen height, the darkness of the room, the maintenance of the camera in an upright position and the distance to the near point, are all important issues to get a quality image.

A situation in which each eye sees a combination of the image intended for that eye, and some of the image intended for the other eye is called crosstalk (6). This condition can degrade the perceived image quality and lead to unwanted symptoms, like fatigue, dizziness and motion sickness.

6. Possible advantages of three-dimensional image for single-site surgery

Since stereopsis is an innate characteristic of most humans, it is taken for granted. In everyday situations in which we move in space, this ability is essential for our equilibrium and for the most basic tasks such as holding objects or avoiding collision with obstacles.

The limitations of depth perception coming from two dimensional images are overcome with acquired strategies that are somewhat empirical for the experienced surgeon. These include permanent lateral and approach movements of the endoscope. Hence, active camera man assistance is of utmost importance for complex procedures. Constant get-close and move-away movements are crucial for delicate steps like fine dissection, clip & cut, and suturing. This makes the learning curve for complex surgeries a team work, where surgeon and assistant have to be permanently in tune for excellent performance.

Therefore, team coordination is essential to minimize the lack of depth of field of endoscopic surgery with two-dimensional systems. In the real world, diverse constraints make it very difficult to maintain the stability of surgical teams, especially in University Hospitals where constant training of surgeons brings constant changes.

Three-dimensional technology provides the stereoptic fit surgeon with improved performance and decreased tiredness (8). Since approaching movements are not so necessary for delicate gestures, we can postulate that difficult procedures can be made easier to assist as a camera man with 3D imaging. In this context, the experienced surgeon would feel more comfortable with less experienced assistance, like is so common in hospitals with surgery training programs. Thus, at the limit we might think that the camera could be held by a robot arm with minimal movements during the intervention. More important than reducing personnel for surgery, it would decrease surgeon's strain while ensuring better performance.

Single-site procedures are technically demanding and deal with limited space for instruments and scope (9). Constant clashing happens inside and outside the single site used for the surgical intervention. Performing procedures with the camera at a fixed distance without an assistant could be doubly advantageous in this context, reducing endoscope motion and increasing the workspace. Another possible advantage of using 3D image at a fixed distance for LESS surgery is the reduced frequency of dirtying the lens of the laparoscope. In fact, the close proximity of the edge of the scope to the surgical field increases lens contact with smoke caused by tissue dehydration, protein desaturation and fried fat.

Due to in-line view, limited space and lack of triangulation, single-site surgeries are extremely difficult procedures to control technical risk of failure gestures and still be proficient. The surgeon's best comfort combined with less strain and fatigue, gives the 3D image an immediate and end-of-the-day advantage. This is likely why almost all studies that compare performance using 2D or 3D systems, give preference to 3D whether by novices or by experienced surgeons (10-15).

7. Translating laboratory experience into clinical practice

Video-endoscopic surgery inaugurated a new era of surgery, not only with the concept of minimal invasiveness but also with new methods for surgical training. In laparoscopic surgery, the senior surgeon uses only verbal orders to guide the apprentice in training, making technical learning much more difficult and ethically controversial. Also, the slower learning of laparoscopy when compared to conventional surgery has led to the development of simulation strategies to exhaustively train gesture.

As a matter of fact, it took almost a century for the Halsted principle *see one, do one, teach one* to be called into question. With laparoscopy, learning in the operating room is preceded by simulation of the surgical gesture in the laboratory. Basic and advanced practical courses have appeared everywhere and the existence in surgical departments of pelvic trainers or digital simulators to practice laparoscopic technique has become commonplace (16-18).

Laparoscopic training comprises a surgical strategy distinct from conventional surgery, as well as the acquisition of new technical skills. The first of these challenges is the synchronization between vision and gesture, so-called hand-eye coordination. Video surgery changes the surgeon's line of sight from direct observation of his hands to the monitor causing frequent dislocation image and instrument misorientation. The effects are very confusing at the beginning and require an intensive and long training period to overcome (19). The other main difficulties of starting laparoscopic techniques are bi-manual performance and learning to work in a three-dimensional space with a two-dimensional image. Although in conventional surgery there is a clearly dominant hand, in endoscopic surgery, advanced performance implies the use of both hands for the technical execution with excellence. This is another skill that requires a great deal of effort and perseverance from the surgeon.

Thus, to perform laparoscopic surgery there are three important challenges that imply specific learning: hand-eye coordination, bi-manuality and adaptation to the lack of depth of field. Apart from these, other difficulties also require specific accommodation: lack of haptic sensitivity (sense of touch), fulcrum effect (mirror movement), image magnification (increasing the size of the structures), and ergonomics (clinician position, port placement, tool angle, monitor placement and mental workload).

For the above, when novices begin their practice in laparoscopy, they face learning a demand technique while dealing with the limitation of depth perception caused by a two-dimensional system. Basic exercises that integrate the Fundamentals of Laparoscopic Surgery (FLS) or European training in Basic Laparoscopic Urological Surgical Skills (E-BLUSS) programs aim to surpass all these adversities at once, bringing more confidence and accuracy to depth instrument movement, movement coordination and bi-manuality. As the exercises are not specifically designed to develop a single skill, some are more likely than others to overcome the lack of depth of field. An example can be found in the clip & cut exercise.

Regardless of being created for another purpose, the use of these validated exercises for the apprenticeship of multi-ports laparoscopy became popular at the time of testing the impact of 3D image in endoscopic surgery. In addition to the above and despite some encouraging results, other limitations soon became clear at the time of developing depth perception with 2D image in the laboratory environment. Indirect clues, like texture, brightness, shadow, and dimension comparison, as well as the importance of recalled images, were missing, imposing a major difference to the clinical environment.

With the appearance of a new generation of 3D systems for laparoscopy, characterized by high definition and light polarization glasses, a wave of experimental studies in the laboratory appeared to evaluate the benefits of these devices. In the year 2013, one of these studies was carried out at Life and Health Sciences Research Institute, School of Health Sciences, University of Minho, by some of our group (20). With all the listed limitations, an enhanced performance in laparoscopic surgery was clear for surgeons without a laparoscopic background. This impact on the learning curve was the stimulus for other studies, such as those related to this thesis.

The measures encountered to evaluate performance in almost all the experimental laboratory studies to compare the performance of 2D vs 3D images in laparoscopy were time and errors. Well-designed studies revealed superiority with 3D equipment, as mentioned before in detail (Part 1 - Section 2).

Since the early years of laparoscopy, several reports showed that the learning process of laparoscopic surgery is very long and risky. Proficiency is therefore a challenge likely not available to everyone. Equipment that provides three dimensional vision seemed to flatten the curve as well as improve performance when compared with a 2D system.

Also in the laboratory setting, it was evident that 3D image system reduces physical and physiological strain for the surgeon (8), and that an unanimous subjective preference was reported by participants, regardless of their previous experience. This advantage can be very relevant in prolonged and highly demanding procedures, as well as in long workdays consisting of many surgeries performed by the same surgeon.

The translational process of extrapolate results from the controlled laboratory setting to the complex clinical operating room scenario is a challenge with a great deal of bias. When it comes to the operating room, apart from selection of real stereo-vision fit surgeons and adequate monitor visualization conditions, there are a variety of other variables that can impact the outcome, like surgeons' experience, previous workload, unexpected situations, or team commitment. Notwithstanding the above, very rare clinical studies classify minor events during surgery. The difference in clinical outcome, measured by morbidity and mortality, may be too high in this context. The use of 3D technology, bringing less stress to the surgeon may only impact the last patient on the surgical day, even if the patient is operated on with 2D technology. However, we must recall that very rare complications mean 100% for the patient affected.

In other words, the added comfort that can be seen by the undeniable preference of users for 3D devices (21-24) can benefit the patient operated, the surgeon or the patients awaiting surgery on the same day. In the overall analysis of the studies, the non-inferiority of the 3D system stands out in terms of performance measured by errors time, and learning. Encouraging results reveal superiority in many of the studies.

8. Single-site laboratory studies comparing two and three-dimensional systems

The starting point of these experiments was the hypothesis that three-dimensional laparoscopic system could improve performance and comfort for single-site procedures. With the increased availability of 3D systems, this technology could also be offered to beginners starting their practice and flattening the learning curve, particularly for demanding techniques like LESS surgery.

Single-site procedures are technically difficult due to the constant clash between instruments, in-line view and lack of instrument triangulation. Conversion of instruments becomes very hard. Thus, LESS surgery adds even more technical demands on top of what is already needed for conventional laparoscopy.

In an effort to normalize laboratory procedures and reduce conflict between instruments, the model would entail having the scope at a fixed distance and with the use of mini laparoscopic instruments of 3mm in diameter. Three-dimensional images theoretically decrease the need for close proximity between the scope and the surgical field. The procedures selected in the dry laboratory setting, as well as with an organic model, required mainly delicate and precise movements, with a need for bimanual dexterity and hand-eye coordination.

The first of our studies revealed better performance for experts with a 3D system. This was not so evident for novices and we postulated that LESS surgery is so highly demanding that using it overshadows possible advantages for novices. Analyzing specifically the type of exercise, there is a clear advantage with the advent of three dimensional image in moving back and forward, like "clip and cut" exercise.

Although time differences were not significant for the novice group, time analysis with one-way ANOVA was clearly better crossing Group/Exercise/Monitor (p=0,006). All exercises were performed faster by the expert group using the 3D image. Interesting is the fact that of the four E-BLUS exercises chosen, the one that was the most dependent on depth perception was clip & cut, which suffered the most reduction with 3D.

Also the impact of three dimensional image was greater for the expert group when the errors were analyzed. Again, the performance boost for the clip & cut exercise with the 3D system was significant, and here, not only for experts but also for beginners was there a clear decrease in errors.

While there was a preference in the subjective questionnaire for the three dimensional system in both groups, the experts were unanimous in their preference considering the 3D system superior for performing LESS surgery. The advantage felt by the participants was in-depth view. The exercise training this deep-moving ability, clip & cut, was best for experts (time and errors) and showed an improvement tendency for novices (fewer errors). In any case, the second in-depth work exercise, cutting circle, was felt to hold great benefit from 3D imaging for both groups of participants (both time and errors for both groups).

In Figures 8.1 and 8.2 the predominant movements of each E-BLUS exercise as well as the steps of the cholecystectomy in an organic model, and their relationship to the depth of field are presented in a schematic way.

Our second experiment used an organic model, a pig liver with a gallbladder to perform a cholecystectomy in an endo-trainer. Some interesting results emerge: first it was clear that the 3D system can be adopted without previous practice and that it positively affects the performance of the less experienced; second, it was verified that previous experience with 3D has a positive effect on 2D performance, meaning that the learning process of LESS procedures can be interchangeable between the two systems; third, it was found that previous experience in conventional laparoscopy is an advantage in performing LESS procedures; and finally, the most important result of the study was the “flat learning curve effect” of 3D image.

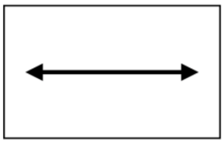
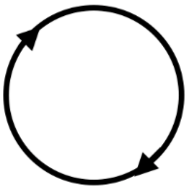
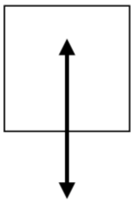
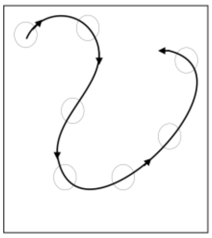
	Peg Transfer	Circle	Clip & Cut	Rings
				
Hand/Eye Coordination	++	+++	++	+++
Bimanuality	+++	+	+	++
Depth Perception	+	++	+++	+

Figure 8 Phantom exercises: main movements of the instruments according to surgeon's perspective and relative importance of acquired capacities

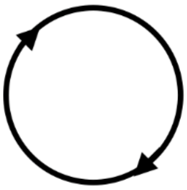
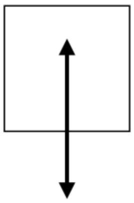
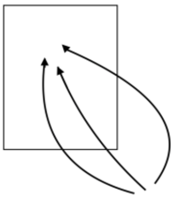
	Hilum isolation	Clip & Cut	Gallblader dissection
			
Hand/Eye Coordination	+++	++	+++
Bimanuality	+	+	+
Depth Perception	++	+++	++

Figure 9 Cholecystectomy in organic model: main movements of the instruments according to surgeon's perspective and relative importance of acquired capacities

Just as in the first of our studies, there was a majority preference for three dimensional equipments when evaluated with subjective inquiries. Participants felt that 3D increases depth perception by 92,6%, this technology being fairly developed and two thirds preferring to operate with this equipment. Better comfort can justify preference and can be of great importance if it decreases workload and strain, as was demonstrated in multi-port laparoscopic surgery.

These two laboratory studies of image impact on LESS performance are aligned with conventional laparoscopy experimental non-clinical studies. In fact, as previously mentioned, laboratory studies carried out in recent years concluded that the use of 3D imaging in multi-port laparoscopy improves performance, accelerates the learning curve and decreases tiredness.

Due to the difficulties of extrapolating laboratory results in the clinical setting, a review of the clinical use of last generation three dimensional in conventional multi portal endoscopic procedures was conducted. Even with significant heterogeneous publications, it seems we are experiencing a democratizing process of this technology and relevant advantages in terms of performance, learning curve and workload can be expected.

For better evaluation of the impact of three-dimensional image on LESS procedures, clinical experimental randomized multi-center studies using different approaches, like transanal, single port VATS or abdominal surgeries, would be of great interest.

9. Limitations, critical appraisal and future recommendations

The laboratory studies presented in this thesis are pioneer experiences comparing 2D and 3D laparoscopic systems in LESS surgery. In fact, to our knowledge there are no other publications concerning this topic.

The first important limitation of the experiments is sample size. Certain tendencies noted would be clarified with more participants. Although significant differences were observed between groups and a learning curve was detected, LESS procedures are highly demanding even for surgeons with extensive experience in multi-port laparoscopy. This means that even the most trained make frequent mistakes and take time to adapt to the difficulties of the technique.

These studies can be seen as pilot experiments to test the hypothesis that 3D image can improve performance in LESS procedures. To do so, two different variables were analyzed, errors (continuous type) and time. The larger the population variability or the smaller the difference the investigator wishes to detect, the larger the sample size must be to detect a significant difference. Sample size determination starts with some estimated factors: effect size (the difference between two groups), population standard deviation (for continuous data) , desired power of the experiment (probability of detecting a difference between treatment groups, the postulated effect) and the significance level. The first two are unique to the particular experiment. The last two are generally fixed by convention. Determination of power and significance are fundamental to avoid a type II error (no difference between groups exists when, in fact, there is a difference) and a type I error (concluding that a difference between groups exists, when in fact there is no difference) respectively. After designing the study with clarification of these factors, the researcher can meet with the statistician to compute this data in specific formulas that allow for calculating the necessary sample size (25).

In these two experiments, groups of participants were considered by their experience, novices and experts for the experimental E-BLUS study, and novices, intermediates and experts for the ex-vivo model study. Selection was based on the multi-port experience and number of procedures done. Only few of them had little previous experience in single-site procedures as well as laparoscopy with 3D image system, and these participants were not selected apart from the others.

In terms of experience in laparoscopy, it would be more convenient for it to be divided into three levels: beginner (no experience at all), intermediate (experience with basic laparoscopic procedures, no suturing skills) and expert (experience with advance laparoscopic procedures, like those with resection and reconstruction techniques). Due to little global experience in single-site procedures, participants are classified according to their experience in multiple port surgery.

A group of super-experts in LESS surgery could be considered and compared with these, and those who have already used 3D technology should also be marked for separate results analysis.

As previously reported in studies with multiple ports in laparoscopy, learning with 3D systems is transferable to 2D systems and the reverse is also true. So the same procedure done in 3D after 2D is usually better than initial 3D (before 2D), and also 2D after 3D is better than initial 2D (before 3D). For a better understanding and evaluation of the learning impact at the expense of previous experience, including two other sequences (2D after 2D and 3D after 3D) in these studies would prove informative.

This aspect was discussed and pointed out as a limitation in the ex-vivo model study. The comparison between the same system in two different sequences (after the same or after the other system) requires subdividing the groups, going from two to four different sequences. The differences found in this context are estimated to be of minor magnitude. Consequently, the number of participants must be much higher according to sample size calculation.

The exercises validated for learning laparoscopy simultaneously train different skills that may or may not benefit from stereoscopic vision. An important ability, such as coordination between vision and movement of the instruments or the use of both hands, may be more relevant to the performance of a specific exercise than depth of field. On the other hand, indirect data that help the surgeon to work with 2D image are not present in most exercises carried out in the laboratory. As only the elements of the exercise are present, there are no objects closer and others farther away that allow for inferring by textures, shapes, dimensions, brightness or color. The exact distance when observed with a 2D optics can therefore be difficult to calculate

In this sense, the exercises validated for learning laparoscopy do not fully serve for assessing the impact of 3D image in the performance of laparoscopic surgery, whether through multiple ports or per single site. As suggested before, the predominant movement in the third dimension must be taken into account and other elements also added to the visual field in a simulation closer to the reality of clinical exercises. Like Clip&Cut exercises or suturing (for more advanced performance), delicate and precise movements in the depth of the surgical field are the ones that best evaluate the potential advantages of 3D image.

Selective screening of participants is another highly relevant point to assess the impact of 3D image in laparoscopy. In fact, as previously stressed, an important fraction of the population has some type of limitation in stereoscopic vision and there is even a not negligible percentage (about 3%) that is even stereo-blind (7). To reduce this possible confounding factor as much as possible, participants should undergo ophthalmological evaluation tests such as the RANDOT stereo-test (6).

Using appropriate stereopsis test glasses, the individual under evaluation selects the circle that is sticking out by group of circles. The groups of circles, figures and shapes are graded from easiest to most difficult and this allows one to properly classify level of stereoscopy.

Conditions for 3D display are required for optimal results. With current 3D imaging systems for endoscopic surgery, the monitor simultaneously displays information for both eyes in alternating lines. Optimal distance to the monitor should be around 100-150 cm, the surgeon's line of sight should be horizontal and directed towards the center of the screen, and the monitor must be perfectly aligned for the surgeon and in an absolutely vertical position. All these measures are necessary to decrease cross talk (8, 26).

Regarding the conditions of the operating room, the importance of lowering the surrounding light should be stressed. This is more important under fluorescent light that is used in most operating theaters. In fact, unwanted effects like flickering, judder, edge banding and motion blur, was reported (27).

Although preference evaluation uses subjective inputs, its analysis is objective and thus suitable metrics should be used. When testing in a lab, one should consider using any of the standard questionnaires for assessing subjective reactions to a system.

Subjective inquiry used in both experiments was direct to underline possible advantages of 3D systems rather than leaving the possibility of no preference or 2D choice more open. A validated questionnaire would likely be better to evaluate the preference of the participants. The System Usability Scale (SUS) that includes rating scales such as the Likert scale, has been shown to be robust even with relatively small numbers of participants. It consists of 10 statements to which users rate their level of agreement. Half the statements are worded positively and half are worded negatively.

An example of the System Usability Scale to evaluate the impact of 3D system in LESS surgery is presented in Figure 9 as well as an explanation of how to calculate SUS score.

Unwanted effects for the surgeon using 3D systems for endoscopic surgery have been reported since the first generation. With the new low-weight polarized glasses systems, there is less reference to these aspects, also relating to the optimization of the conditions of visualization and proper selection of the subjects. Reported side-effects include nausea, dizziness, headache and eyestrain. Adequate physical

	Strongly disagree				Strongly agree	Score
1. I think that I would like to use this system of image frequently	1	2	3	4	5	__- 1
2. I found the system unnecessarily complex on the top of single-site difficulties	1	2	3	4	5	5 -__
3. I feel that 3D vision provides significant advantages to adequate perform the exercises	1	2	3	4	5	__- 1
4. Some tasks can be done more easily with 2D system	1	2	3	4	5	5 -__
5. The most advantage of 3D system is depth perception	1	2	3	4	5	__- 1
6. The vision with the 2D system is better in terms of light and contrast	1	2	3	4	5	5 -__
7. The 3D image allows for a more delicate surgical gesture with fewer errors	1	2	3	4	5	__- 1
8. Adaptation to the 3D system is difficult and the use of glasses is uncomfortable for surgery	1	2	3	4	5	5 -__
9. 3D surgery is more natural and produces less fatigue	1	2	3	4	5	__- 1
10. I see no advantage in using a 3D system for single-site surgery	1	2	3	4	5	5 -__

Figure 10 The System Usability Scale, developed by John Brooke at Digital Equipment Corporation

Calculating a SUS Score: To calculate a SUS score, first sum the score contributions from each item. Each item's score contribution will range from 0 to 4. For odd items (positive questions) the score contribution is the scale position minus 1. For even items (negative questions) the score contribution is 5 minus the scale position. The maximum score is 40 and the factor to multiply is 2,5. Final result is presented as a percentage.

From the analysis of SUS scores for many products and systems, Bangor and colleagues suggested the following interpretation:

<50% not acceptable

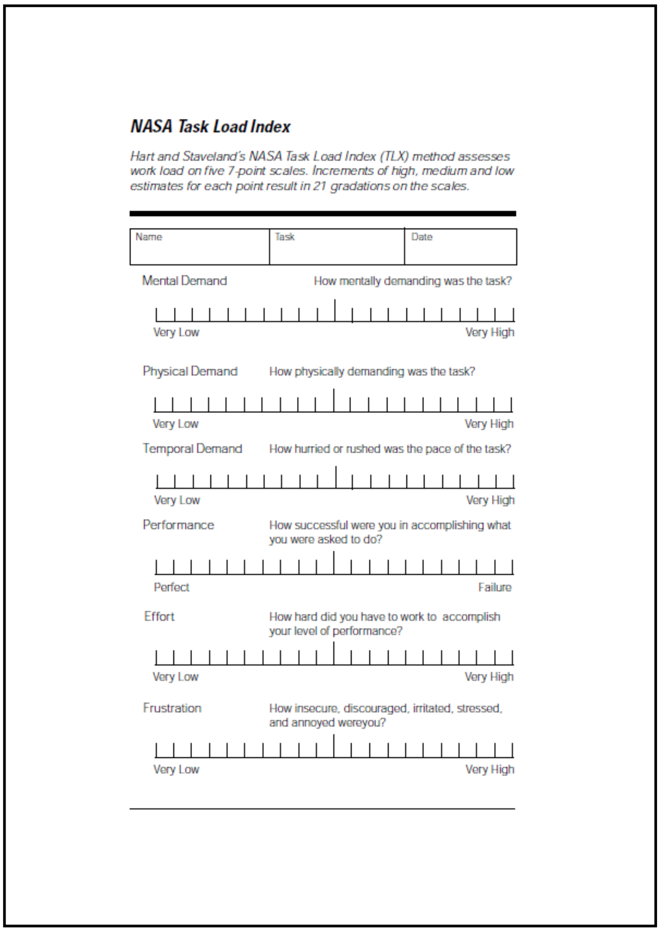
50-70% marginal

>70% acceptable

warm-up when using the 3D system seems to be relevant for better and less stressed performance. For a gradual assessment of side effects, a 5-point Likert scale should be used for each.

Another issue to consider is workload, which is a term used to describe physical and mental wear resulting from work activity. One of the possible advantages of using 3D imaging in laparoscopy seems to be the reduction of tiredness. The National Aeronautics and Space Administration Task Load Index (NASA TLX) is a questionnaire that emerged to assess perceived workload in pilots and that quickly became a validated standard in different contexts, including surgeons subject to new environments or using new devices. The aim of this evaluation is redesigning processes to reduce technical errors. In Figure 10 this simple questionnaire is presented (27).

Physical strain is also part of the NASA TLX rating scale. As has been discussed extensively before, single-site surgery adds to the requirements of conventional laparoscopic surgery with respect to ergonomics. The permanent conflict of the instruments coupled with lack of space for the surgeon's hands and the laparoscope provoke a greater and likely more exhausting physical effort. If the endoscope fixed at a distance from the surgical field allows the assistant to be dismissed, more space will be left for the hands and the laparoscope. The ergonomic evaluation of the execution can be made using video recording of the subject to perform the exercise for critical analysis of the positioning. Other specific stress locations, like shoulder, elbow, wrist or lumbar region can be assessed using numerical Likert scales (10,28).



NASA Task Load Index

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

Name	Task	Date

Mental Demand — How mentally demanding was the task?

Very Low — Very High

Physical Demand — How physically demanding was the task?

Very Low — Very High

Temporal Demand — How hurried or rushed was the pace of the task?

Very Low — Very High

Performance — How successful were you in accomplishing what you were asked to do?

Perfect — Failure

Effort — How hard did you have to work to accomplish your level of performance?

Very Low — Very High

Frustration — How insecure, discouraged, irritated, stressed, and annoyed wereyou?

Very Low — Very High

Figure 11 from NASA (1986). Nasa Task Load Index (TLX) v. 1.0 Manual - human performance research group - NASA Ames Research Center, Moffett Field, California, USA

According to what was described before, Table 2 summarizes a list of suggestions for future laboratory experiments comparing 2D vs 3D image for LESS surgery.

To adequately reduce the likelihood of Type I errors, the homogeneity of populations must be taken into account, paying particular attention to the appropriate selection of materials and methods. Future experiments in this field should take into account with limitations for enhanced results.

Item to be considered	Recommendation
1. Sample size	Define the types of variables to be measured (dichotomous, continuous or time of an event) and resume the hypothesis to a simple question. Select adequate formula to calculate the sample size (*).
2. Groups by experience	Divide between zero, basic and advanced experience. consider experience in conventional laparoscopy and LESS
3. Sequence of exercises	Randomized sequence including 2D after 2D and 3D after 3D to evaluate the learning effect
4. Chosen exercises	Consider validated exercises to evaluate depth perception rather than laparoscopic performance as a whole
5. Selection of participants	Use RANDOT Stereo-Test to select participants and choose only those with high stereo acuity
6. Conditions for 3D display	Adequate normalized darkness of the operating room, distance between the operator and the monitor, and in-line view to the middle of well aligned monitor
7. Preference evaluation	Use validated preference questionnaire to access subjective preference, comfort and work load evaluation
8. Side-effects	Use a 5 point Likert scale to evaluate the grade of side effects like dizziness or headache
9. Perceived workload	Use NASA TLX questionnaire for perceived workload evaluation

(*) National Research Council (US) Committee on Guidelines for the Use of Animals in Neuroscience and Behavioral Research. Washington (DC): National Academies Press (US); 2003.

Table 2 Recommendations for laboratorial experiments comparing 2D vs 3D image in LESS surgery

10. The future for LESS surgery and imaging in endoscopic surgery

The term laparo-endoscopic single-site surgery comprises a minimally invasive strategy with a single opening to access a cavity or space virtually created in the depth of the body (29). The definition is wide enough to include transcutaneous or transvisceral approaches (NOTES) using rigid or flexible endoscopes. Foreseeably, the boundary between laparoscopic procedures and natural orifices will not be considered relevant, and new platforms, robotic systems, and high-quality three-dimensional images, will allow for interventions through minimal orifices with a high level of safety.

Three main drawbacks can be pointed out in respect to LESS surgery according to current technology: instruments conflict, in-line view and lack of triangulation. Thus, the future of these approaches involves improving the ability to execute and well as increasing versatility and security.

<u>(i) Robotic and Ergonomic optimization</u>

In the execution of LESS surgery in a narrow space like transanal procedures, or while dissecting delicate structures such as the gallbladder hilum, clashing instruments together can be critical. The convergence of instruments in a triangular fashion, like in multi-port laparoscopy, is simply not possible in LESS surgery with straight instruments. To overcome this limitation, curved and articulated instruments were produced. Dissection with two of these instruments seems to be very difficult, as well as working with crossing instruments. It appears that the least difficult way to do so is by using a straight and a curved instrument at the same time. For procedures where the tip of the instruments diverge everything becomes easier. This is the case of colorectal surgery and the reason for this practice having had a relatively wide acceptance in this field.

On the edge of new proposals for LESS surgery comes the robotic platform. In fact, single-port robotic surgery can be the answer for all the technical challenges that were described before (30).

Robot assisted procedures offer four possible advantages over conventional laparoscopic surgery: execution, vision, distance and ergonomics (31). The new single-site surgical robot system has these benefits using crossed instruments (that seem not crossed to the surgeon), improving triangulation and bringing with it, precision and dexterity. Possible advantages of robotic LESS would be a reduction in pain, a decrease in surgical risk, and ease of execution. Despite this, some conflicting results have been published (32-34).

The well-being of the surgeon sitting in a comfortable chair, with a high definition 3D view and without a conflict of instruments, may extend the indications for LESS surgery. When flexible endoscopes can be robotized in the future, with mini-instruments on the tip, on stable platforms, the point of entry into the body can be determined through the skin or through natural orifices according to the greatest convenience of the patient. This will be a major advance for robotic surgery, definitely moving away from conventional laparoscopic surgery, offering up next to superhuman capabilities (35).

(ii) Miniaturization of instruments

The past 10 years have seen a remarkable development in biomaterials that has allowed behaviors that were previously impossible for fine instruments. These so-called mini-instruments became available with a choice of diameters and lengths, better shaft insulation and electrosurgery capability, improved shaft strength and rotation, better ergonomic handles, and improved instrument durability.

The use of mini-instruments with the same performance, allows a surgeon to perform single-site surgery with more free space and with proficiency. This trend towards the development of harder and more resistant alloys will allow for improved vision and tips with wrist movements, positively facilitating LESS surgery.

(iii) Advanced flexible scopes and instruments

During the era of the NOTES concept, advanced flexible endoscope prototypes appeared with the aim of allowing transvisceral surgery to be performed. Examples are the Anubis platform (from Karl Storz), EndoSamurai (from Olympus) and COBRA (from USGI) (35). These multitask platforms had a flexible endoscope and several working channels in common that, in a miniaturized way, allowed for traction and counter-traction, electrosurgery and application of clips. The arrangement of the endoscope at the tip simulated the classic triangulation of instruments from laparoscopic surgery. The instability of these platforms made it very difficult to perform any procedure in the peritoneal cavity and this caused interest in this instrument to decline. Another major limitation to the implementation of NOTES remains the development of a safe and reliable visceral closure system.

Regardless of needed improvements, the evolution of endoscopes for advanced endoluminal or transvisceral procedures will continue and will be associated with the development of increasingly accurate and resistant flexible instruments.

(iv) Retractors

Currently approved by the FDA, new retractors use magnetic energy allowing surgeons to decrease the number of ports and to mitigate the amplitude of movement of the instruments. The new Levita Magnetics (Ca, USA) is designed to magnetically grasp and retract the target tissue in laparoscopy (36). It consists of 3 parts: (i) the magnetic grasper, which is introduced through one of the ports, and the shaft, which is removed after delivery application of the tip; (ii) the grasper tip, which holds target tissue and provides shiftless magnetic retraction; (iii) the magnetic controller, which is positioned externally on the abdominal wall to magnetically attract the grasper tip intra-abdominally.

Several, quite recent publications have demonstrated its clinical use associated with conventional single-site or robotic surgery (37,38). These magnetic retractors are licensed for use in cholecystectomy, prostatectomy and bariatric surgery and are recommended for retracting hollow viscera like the gallbladder or massive organs like the liver or the prostate. Most likely in the future this technology will expand and facilitate the exposure of the surgical field to LESS surgery.

(v) Glasses-free three-dimensional display technology

Despite the great improvements that 3D systems have demonstrated in their third generation, still some drawbacks can be pointed out: (I) the passage of light through the polarizing lens significantly reduces its intensity, resulting in a relatively dark image; (II) the use of glasses can be quite irritating for certain unaccustomed surgeons, with complaints of fogging and discomfort in the nose and ears; and (III) Current 3D videos record in 2D, which favors neither learning nor sharing experience;

The common Liquid Cristal Displays (LCD) panels use parallax barrier technology, which is relatively simple to manufacture, but users experience severe loss of intensity and Moiré fringes. This has hampered its development and prevented the clinical application of 3D technology without glasses. For glasses-free 3D technology, two images with parallax are combined into one and displayed on the 3D screen, and then, a layer of lenticular lenses (array of magnifying lenses, designed so that when viewed from slightly different angles, different images are magnified) is added in front of the display screen. The image plane is located on the focal plane of the lens and divided into several sub-pixels so that the lens can project each sub-pixel in different directions, enabling the left and right eyes to obtain separated images. By using the infrared light emitted from an auxiliary device, the system can rapidly rapidly encounter the position of human eyes.

This technology is taking its first steps, yet encouraging clinical experiences have already been published. Some possible advantages over existing systems are: display brightness; great viewing area thanks to tracking and positioning technology; and anti-interference performance of the system that quickly recognize and find the position of human eyes with enhanced real-time performance.

Regarding the clinical experience in the field of video-assisted thoracoscopy, glasses-free 3D display systems were found to manage to obtain a real three-dimensional image of thoracic structures, capable of magnification up to 20 times, making surgery clearly safer, more precise and easier to learn (39).

In spite of everything, several limitations can still be pointed out: (i) with cross talk rate of 4% phantom images still occurring occasionally during surgery and (ii) for a sufficiently clear image, the lens has to be kept at an appropriate distance from the target area without changing the axis of vision, therefore imposing a high demand on the camera holder.

It seems that glasses-free 3D display technology will be the next step in the evolution of the 3D image for endoscopic surgery.

(vi) Increased image definition

The definition of a digital image stems from the number of pixels per display area. With ultra-high definition images, also called 4K, the surgeon can benefit from large screens where his vision can "immerse" into the surgical field. A major advantage of 4K ultra high definition systems is magnification, maintaining the high quality image (40). It is supposed that with the advent of CCD miniaturization, 3D technology will provide 4K definition in the near future. Thus, the endoscope can be kept at a distance from the target organ and thus, free up more space for the instruments.

The fixed endoscope is a possible feature of 3D image because no parallax clues are needed for depth perception. When using a 2D system, it is necessary to approach the laparoscope to have this perception of the third dimension while performing delicate and precise gestures. With the improvement of image definition in the 3D binocular system, the perception of depth is preserved at a distance and detail necessary for precise gestures safeguarded through magnification.

Maintaining this reasoning, one can guess the development of short-length endoscopes, angulated and with low-profile a small camera head that will leave enough space for instruments outside and inside. And going a little further, it is easy to imagine a camera guided by magnetic forces that moves inside the peritoneal cavity, providing images from different viewing angles, magnified or not, controlled by a robotic system under vocal command.

11. Conclusion

All theses prove to be a path towards enrichment. The definition of the research process, the systematic review of knowledge, the development of scientific criticism, and the contribution to progress are greatest prizes of this journey. In the end, there are countless new ideas that can only move us further.

Normal vision for most humans has three dimensions and is a fundamental feature in relation to the surrounding space. The loss of stereoscopic vision requires a difficult adaptation, only surpassed by some, with ongoing effort, an unnatural process. Chance, technology and lack of knowledge have led endoscopy along the path of two-dimensional vision, imposing a long learning process when it comes to intervention.

Minimally invasive surgery uses video-assisted endoscopic imaging and is now the most common way of operating in reference centers. Undeniable advantages have been widely documented although difficulties in execution, learning and acceptance are still felt. It is easy to see that one of the obstacles is the monocular vision which these techniques have been confined to.

Definitely calling into question the importance of wall trauma in the recovery of the surgical patient, MIS is evolving with new proposals that are even less invasive. Laparo-endoscope single-site surgery is a concept of mono-axial intervention regardless of the point of entry or the instruments used. Focused on the study of the importance of 3D image while executing LESS surgery, laboratory models were used to compare execution, learning and preference, using a common 2D system. It is an unprecedented topic, never studied before.

The hypotheses placed at the beginning of this process was that perhaps three dimensional image can contribute positively to single-site endoscopic surgery. The four main objectives of this thesis have been fulfilled and we can say that quite possibly the three-dimensional image improves performance in LESS surgery and has a positive impact on novice learning. The experimental findings are in line with that observed in multiple port laparoscopy and with current clinical evidence in regards to benefit of three dimensional image compared to two dimensional image. Better and broader laboratory studies, as well as clinical studies, can validate and reinforce this evidence.

With the constant evolution of technology and knowledge, we will not be able to see the future of MIS without integrating it into emerging trends. Augmented reality and artificial intelligence will soon change the face of surgery. The clear identification of major structures as well as hidden lesions will guide more accurate and safe operations. Artificial intelligence will advise the surgeon for suitable movements and decisions.

In addition to all these improvements, it is not enough to know what to do technically, it is crucial to be able to do it. Surgery entails being accurate and safe, but also democratic and accessible.

There is an undeniable place for LESS 3D surgery in the future and this is undoubtedly a drive of development in Minimally Invasive Surgery.

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PART 4

ADDENDA

CLINICAL USE OF THIRD GENERATION 3D IMAGING SYSTEMS IN ENDOSCOPIC SURGERY - A SYSTEMATIC REVIEW.

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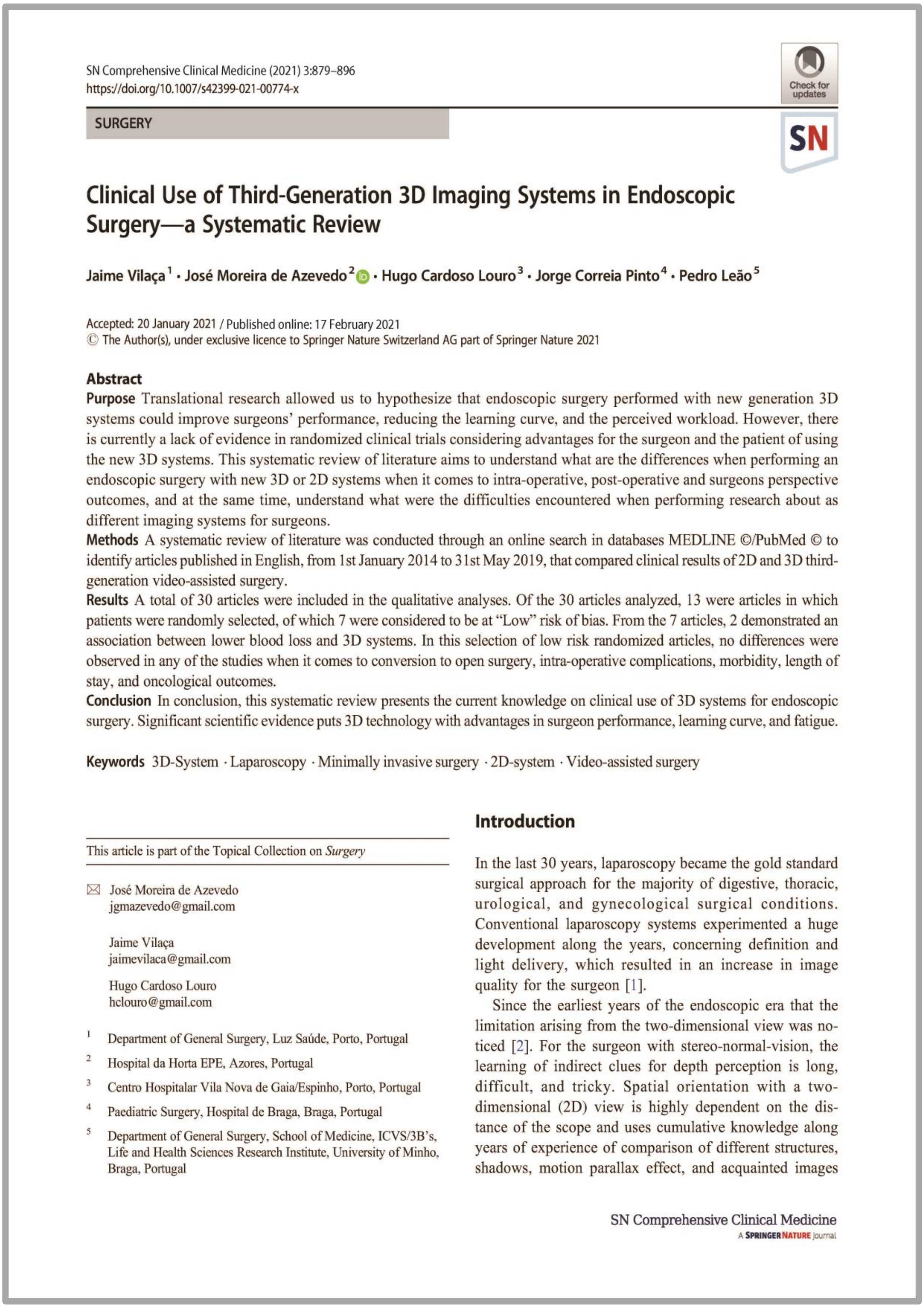

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SURGERY

Clinical Use of Third-Generation 3D Imaging Systems in Endoscopic Surgery—a Systematic Review

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Abstract

Purpose Translational research allowed us to hypothesize that endoscopic surgery performed with new generation 3D systems could improve surgeons' performance, reducing the learning curve, and the perceived workload. However, there is currently a lack of evidence in randomized clinical trials considering advantages for the surgeon and the patient of using the new 3D systems. This systematic review of literature aims to understand what are the differences when performing an endoscopic surgery with new 3D or 2D systems when it comes to intra-operative, post-operative and surgeons perspective outcomes, and at the same time, understand what were the difficulties encountered when performing research about as different imaging systems for surgeons.

Methods A systematic review of literature was conducted through an online search in databases MEDLINE ©/PubMed © to identify articles published in English, from 1st January 2014 to 31st May 2019, that compared clinical results of 2D and 3D third-generation video-assisted surgery.

Results A total of 30 articles were included in the qualitative analyses. Of the 30 articles analyzed, 13 were articles in which patients were randomly selected, of which 7 were considered to be at "Low" risk of bias. From the 7 articles, 2 demonstrated an association between lower blood loss and 3D systems. In this selection of low risk randomized articles, no differences were observed in any of the studies when it comes to conversion to open surgery, intra-operative complications, morbidity, length of stay, and oncological outcomes.

Conclusion In conclusion, this systematic review presents the current knowledge on clinical use of 3D systems for endoscopic surgery. Significant scientific evidence puts 3D technology with advantages in surgeon performance, learning curve, and fatigue.

Keywords 3D-System · Laparoscopy · Minimally invasive surgery · 2D-system · Video-assisted surgery

Introduction

In the last 30 years, laparoscopy became the gold standard surgical approach for the majority of digestive, thoracic, urological, and gynecological surgical conditions. Conventional laparoscopy systems experimented a huge development along the years, concerning definition and light delivery, which resulted in an increase in image quality for the surgeon [1].

Since the earliest years of the endoscopic era that the limitation arising from the two-dimensional view was noticed [2]. For the surgeon with stereo-normal-vision, the learning of indirect clues for depth perception is long, difficult, and tricky. Spatial orientation with a two-dimensional (2D) view is highly dependent on the distance of the scope and uses cumulative knowledge along years of experience of comparison of different structures, shadows, motion parallax effect, and acquainted images

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recognition. Actually, anatomical misperception can be a major cause of error, as illustrated in a study on biliary iatrogenic injury in laparoscopic cholecystectomy [3].

The lack of depth perception and spatial orientation led to technological efforts to overcome these limitations of 2D vision. The first generation of 3D systems were launched during 1990s. This equipment provide an artificial 3D image captured with a mono-channel optical system transmitted to shutter glasses. Image quality was poorly defined, lighting was scarce and caused many side effects on users, such as headache and dizziness. These limitations were the impediment to its widespread use [1].

Later on, a second generation of equipment offered bi-channel scopes to present different images to each eye. This was a big leap to provide a true 3D image that results from the disparity of retinal images. The necessity to wear a heavy head mounted display restraint its use by surgeons, with frequent complains of discomfort and secondary effects [1].

More recently, with polarized technology, a new set of tools arises in the surgeons' arsenal. Images are captured with high definition double channel scopes and transmitted to a screen that displays simultaneously images to the right and left eyes. With the use of light polarized glasses, the surgeon can now easily obtain a three-dimensional high definition image. Special considerations in the position of the surgeon and monitor, as well as room lightning, should be optimized to improve depth perception and alleviate undesirable effects, such as blurred vision [1].

A correct selection of stereo impairments within 3D systems users is obligatory. Population studies have shown that about 30% of people have some kind of stereopsis limitation and at least 3% are actually stereo-blind. It is clear that these professionals cannot benefit from the advantages of a 3D display [1].

In the last 10 years, several laboratory studies comparing third-generation 3D vs. 2D results were published. Most of them used validated phantom exercises like E-BLUS and FLS models. The advantages found for new 3D systems were shorter learning curve for novices [4–7], faster performance [5, 7, 8], error reduction [4, 9, 10], surgeons preference [8, 10–12], and reduced strain [9].

Translational research allowed us to hypothesize that endoscopic surgery (laparoscopy, thoracoscopy, cervicoscopy, retroperitoneoscopy) performed with new generation 3D systems could improve surgeons' performance, reducing the learning curve and the perceived workload. However, there is currently a lack of evidence in randomized clinical trials considering advantages for the surgeon and the patient of using the new 3D systems.

This systematic review of literature aims to understand what are the differences when performing an endoscopic surgery with new 3D or 2D systems, when it comes to intra-operative, post-operative, and surgeons' perspective outcomes, and at the same time, understand what were the difficulties encountered when performing research about different imaging systems for surgeons.

Methods

A systematic review of literature was conducted through an online search in databases MEDLINE ©/PubMed © to identify articles published in English, from 1st January 2014 to 31st May 2019, that compared clinical results of 2D and 3D third-generation video-assisted surgery. A search using the terms 2-dimensional [All Fields] AND 3-dimensional [All Fields] AND ("laparoscopy" [MeSH Terms] OR "laparoscopy" [All Fields]) and (2D[All Fields] AND 3D[All Fields]) was performed. Filters were applied: "last 5 years," "Review," "Clinical trial," and only prospective or randomized studies were included. All laboratorial, animal, or robotic studies were excluded from the analyzes. Additional articles were added to the analysis based on the references of the works included. Repeated articles were excluded from the review and all articles with a summary eligible according to the criteria described above were included and evaluated through the full text of the article. No direct contact with authors of the included articles was done. Articles excluded after evaluation of the full text had the exclusion reasons presented in the text. The articles to be included were considered for qualitative synthesis analysis. Quantitative synthesis analysis and meta-analysis was not performed. The articles were analyzed by two authors independently and when doubts arose regarding the inclusion of articles the decision was reached through a consensus between the two authors (Fig. 1).

Basic information and study design were collected from the included studies such as year, author, country, methodology, risk of bias, number of patients, surgeon's experience, and stereoscopic capacity. Technical aspects were collected such as type of 3D and 2D video system used, description on the text of viewer condition, surgical technique, and type of minimally invasive approach. A four-grade procedure complexity grading system (Appendix Table 1) was used to classify the surgeries performed in each study (I—organ resection; II—plasty; III—resection and anastomoses; IV—complex multi-resection and anastomoses). Intra-operative factors such as operative time, blood loss, complications, conversion, and post-operative factors such as morbidity, length of stay, and oncological outcome were collected. References to side effects of 3D systems and surgeon's perspectives when using 3D third generation systems were also collected.

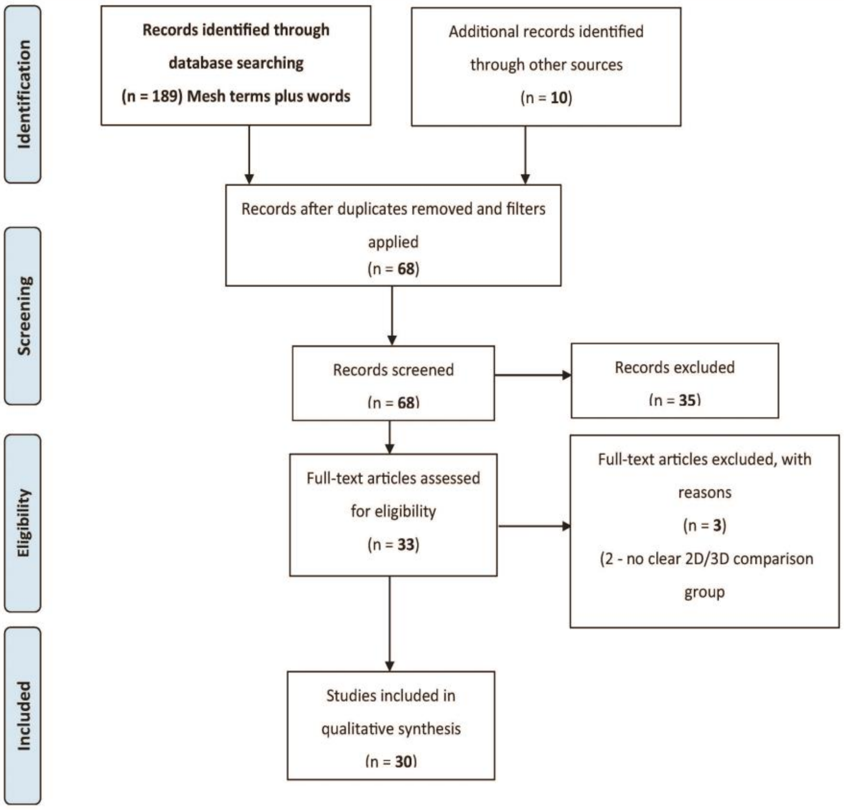

Fig. 1 PRISMA flow diagram

Statistical measures were described, if possible, including risk measures, differences between means, and measures of association. A categorical analysis of risk of bias was performed for randomized studies using the Risk-of-Bias 2.0 Tool from Chocrane Collaboration. In this two-step tool, seven specific domains are addressed: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and “other bias.” The bias of each domain is evaluated on basis of their reporting in the RCTs and the overall risk of the domain is then categorized as low risk of bias, high risk of bias, or unclear risk of bias thus giving support for an overall judgment to be applied. As operative time was studied in all RCTs included, it allowed the authors to evaluate the risk of bias in a transversal way through all the studies comprised in this review.

Randomized studies with low risk of bias had their results grouped and analyzed separately. Studies describing financial support or conflicts of interest were described.

This study received no funding. The authors declare that they have no conflict of interest.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Results

According to the search terms described above, authors identified 189 articles. From this, 10 articles were added through references. A total of 68 articles were ready for screening after duplicates removed and filters applied. After screening, 35 articles were excluded, and 33 full-text articles were assessed for eligibility. A total of 3 full-text articles were excluded, two for no clear 2D/3D comparison groups and one because it was an interim report of a paper already included in the analyses. In the end, a total of 30 articles were included in the qualitative synthesis [13–42]. (PRISMA flow diagram).

Characteristics of Included Studies

Of the 30 articles analyzed (Appendix Table 2), 13 were articles in which patients were randomly selected, of which 1 was considered to be at high risk of bias according to the RoB Score used, 5 as "Some Concerns" in their methodology, and 7 as "Low" risk of bias. Low risk of bias articles (Appendix Table 6) are presented separately in Appendix Table 3 and described below.

A total of 3513 patients were included in the 30 articles, 1933 (55%) of patients were operated with 2D systems, and 1580 (45%) had surgery with 3D systems. In 18 studies, every surgery was performed by the same surgeon or the same team; in 11 studies, two or more surgeons or teams operated the patients. A single article did not mention who performed the operations. Seven (23%) articles quantified surgeon expertise. The variability of what was considered expertise surgeon ranged from 1 to 500 surgical procedures performed by surgeon. Four (13%) articles mentioned a prior evaluation of the surgeon's stereoscopic capacity.

Four (13%) articles [22, 30, 37, 41] did not detailed the surgical technique steps used, and in 3 (75%) of these, surgeries were performed by 2 or more surgeons. As shown in Appendix Table 2, in 60% of the articles, patients underwent a minimally invasive surgery requiring resection and surgical anastomosis (grade III). Just one study include high complexity surgeries [17]. In 23 (77%) studies the approach was laparoscopic, in 6 (20%) was thoracoscopic, and in 1(3%) was retroperitoneal.

Intra-operative Results

Operative time was substantially decreased in all the results (Appendix Table 4). In 22 (73%), an association with $p < 0.05$ between a decrease in operative time and the use of 3D systems was found; from these 22, two authors described this difference only when analyzing the group of novice surgeons and not when expert surgeons were performing the procedure.

Data on blood loss was not presented in 8 studies. In the other 22, there was an association between the use of 3D systems and a decrease of blood loss in 5 articles [14, 16, 27, 31, 41]. There were no data regarding a possible difference between expert surgeons and novices regarding blood loss. Considering only studies in which the degree of complexity of the intervention was equal to or greater than III, 5 (24%) did not mention blood loss, 12 (57%) obtained similar results with the 2D or 3D system, and 4 (19%) obtained a decrease in blood loss with $p < 0.05$ when using 3D systems.

There was no association between different visualization systems and the rate of conversion. Besides, there was no paper showing a significant association between different system used and operative complications or errors; a total of 30 complications were observed in the 2D group and 13 were observed in the 3D group (detailed in Appendix Table 4).

Post-operative Results

Concerning post-operative results (Appendix Table 5), from the 30 articles analyzed, only one article presented post-operative complications according to a validated classification, such as Clavien-Dindo. Three papers did not mention if there was any post-operative complication. From the other 27, in 6 (22.2%), authors stated that there were no complications with the patients involved in the study. Authors from two articles stated that complications within 2D vs. 3D were similar; however, they did not present them in the paper. Only one article demonstrated an association between the use of 3D systems and lower complication rate. In the paper by Padin [37], novice surgeons that were within their learning curve (< 100 procedures) for performing gastric bypass and sleeve gastrectomy had lower fistula rate using 3D systems when they were performing the procedures with 2D systems (0 vs. 6.9% $p = 0.02$).

Hospital length of stay (Los) was mentioned in 20 (67%) studies, both in days and in hours. 3D systems resulted in lower Los in 3 (15%) studies including the study mentioned above by Padin [37], in which 3D systems were both associated with lower LoS in experienced and novice surgeons. No randomized studies demonstrated an association with lower Los and lower post-operative complications and from the studies that observed this association two were retrospective analyses and one was a prospective single center study where data was compared to an historical cohort.

Fourteen studies presented data on oncological outcomes of the performed resection, which included resections for gastrointestinal, urologic (prostate, kidney, and bladder), and gynecologic tumors.

In this 14 studies, one presented data on R0 resection, one on a oncological and functional outcome composite called Pentafecta [42], and 12 on the number of lymph nodes harvested. A single retrospective analysis of a prospective database of consecutive patients performed by Yoon [31] demonstrated higher number of lymph nodes harvested with 3D systems (41.0 (32.0–51.5) 2D vs. 47.0 (37.5–60.0) 3D $p = 0.001$).

Surgeons Perspective Outcomes

No mention on side effects of 3D systems were done in 14 (46.7%) of the articles, and 8 articles mentioned that there were no symptoms felt by the surgeons using the new generation 3D systems. From the other eight studies, 4 used a validated score to assess side effects and/or symptoms. Kinoshita [15] used the Fatigue by Simulation sickness questionnaire

(SSQ) and critical flicker fusion (CFF) test for surgeons and "*scopists*" separately. The scores consist of the Flicker test—a critical perceiving frequency according to reducing the frequency of red flicker light: % prolongation = [(postsurgical CFF−presurgical CFF)/presurgical CFF]*100, and a the SSQ a questionnaire of 16 questions for various symptoms. The choices for each question are based on the 4 point Likert scales, none (0), slightly (1), moderate (2), and severe (3). No difference in pre- and post-operative symptoms were found between 2D and 3D. Curro used the Surgical Strain Score in both studies for bariatric surgery and colectomy; similar results were presented. In both bariatric surgery and colectomy, lower neck strain and eye strain were associated with 3D systems ($p = 0.024$; $p = 0.0006$). Patankar [41] utilized the STAI score, a State-trait anxiety inventory for adults (short version), and demonstrated better symptoms with 3D systems (13 vs. 17, $p < 0.0001$). All articles that used validated scores were randomized studies.

The remaining 4 studies that mentioned side effects of 3D systems used non-validated scores to analyze symptoms such as nausea, dizziness, ocular fatigue, etc. Lui [30] demonstrated an association between nausea, dizziness, ocular fatigue, and blurring of vision when using 3D systems (5.3% 2D/45.9% 3D ($p < 0.001$) with a non-validated score in a randomized study. No differences were found in the other studies where a non-validated score was used.

Most of the works that presented results on the side effects of 3D systems also presented a surgeon's perspective of using these systems compared to conventional 2D. The surgeon's preference was analyzed through subjective questionnaires at the end of the operation in 11 studies. An association to 3D systems and a general satisfaction of the surgeon was observed by Kinoshita. Similarly, all the studies where a questionnaire was performed at the end of the operation reported better precision, enhanced surgical planes' definition, improved depth perception, and reduced workload. Of the studies that evaluated the surgeon's preference, seven (70%) had a single surgeon performing the operations and answering the questionnaire, three had two or more teams operating, and nine (90%) of them were randomized studies.

Randomized, Low Risk Studies

Seven randomized articles [13, 18–20, 26, 29, 34] had a low risk of bias after the Cochrane RoB score was applied. The results for intra-operative and post-operative factors of these articles are presented in Appendix Table 3. Only one article did not demonstrate a lower operative time with 3D systems. From those that did, two demonstrated lower operative time when a novice was performing the procedure [20, 26] and one study demonstrated lower operative time in one of the procedures performed (gastric bypass) [18]. From the seven articles, 2 demonstrated an association between lower blood loss and 3D systems [26, 29]. In this selection of low risk randomized articles, no differences were observed in any of the studies when it comes to conversion to open surgery, intra-operative complications, morbidity, length of stay, and oncological outcomes.

Discussion

3D systems for endoscopic surgery have three very important potential benefits: better performance, faster learning curve, and reduced workload. Since the appearance of the last generation of 3D equipment, characterized by bi-channeled scopes, simultaneous high definition display of the image for the right and left eye, and light polarized glasses for the surgeon and all the surgical team, many experimental studies addressed these advantages with quite evidence of superiority for 3D systems. However, clinical studies are scarce and with methodological limitations.

Performance: Time and Errors

The majority of studies included in this revision showed a reduction in total operative time, regardless of the surgeons' expertise. Of particular interest is the fact that critical steps in specific complex operations benefit significantly with 3D systems. This was observed during different surgical steps between the articles included such as the time of warm ischemia and suturing during partial nephrectomy in the studies of Yuan[43] and Komatsuda [39], the performance on anastomotic and suturing in six of the presented articles [14, 18, 19, 27, 41, 42], or the lymphadenectomy procedure in three articles [25–27].

No clear benefit of decreased complications during surgery was observed. However, it is important to address that surgical procedures may have important variability of its own and that this variability was not addressed in most of the included articles, even though the procedure to be compared was the same. For instance, when comparing performance, surgeons could try and quantify the difficulty of the surgery performed on individual level; in this case, it would be possible, for instance to separate surgery performed for an acute cholecystitis with difficult dissection, necessity of biliar exploration, and significant adhesions and fibrosis than a linear, early onset cholecystitis with a less technical demanding procedure. This could be important in a near future when performing comparative studies to analyze different techniques or technologies. Even though, standard protocoled surgeries performed by well-experienced surgeons probably will reveal errors or significant intra-operative complication differences in larger series or in the presence of unexpected intra-operative scenarios. Anyway, when analyzing the studies that detail total blood loss account, in 23% of the studies [14, 21, 23, 34, 36], the total blood loss account was significantly less when 3D systems were used. In the group of controlled randomized trials with low risk of bias, 29% of the studies [18, 21] referred a significant reduction in the total blood loss account, when 3D technology was applied (Appendix Table 3).

Learning Curve

Although most participants had experience in 2D, the same was not true with 3D technology. Immediate use with clear improvements in performance, as well as no harm to patients with the use of 3D, shows that the application of these systems has no learning curve.

In what concerns to novices learning curve, several studies addressed this particular topic. In a prospective randomized clinical trial ran by Fanfani and colleagues [26], the operative time of pelvic lymphadenectomy performed by surgeons with less than 10 procedures done was significantly lower in the group using 3D technology. The authors state that 3D may help in the learning curve for novice surgeon for difficult steps. In the retrospective cohort study of Esther Padin and colleagues [37], 312 consecutive patients who underwent bariatric surgery were included. Of these, 141 were operated by three surgeons with less than 50 surgeries before the beginning of the study. A significant difference in terms of total time ($p < 0.005$) and complications ($p = 0.034$) favoring the use of 3D was observed. The authors suggest that the total number of procedures to be proficient in gastric bypass or sleeve gastrectomy could be significantly reduced with the availability of 3D systems in bariatric surgery training centers.

Another example of clear benefit of 3D systems for novices is well evident in the prospective randomized trial of Curro with a series of laparoscopic cholecystectomies [20]. Forty consecutive operations for uncomplicated gallstone disease were performed by a single novice surgeon (around 20 previous laparoscopic cholecystectomies) using either 2D or 3D systems. There was a significant difference favoring 3D, in the time for Calot's triangle dissection ($p = 0.03$), gallbladder removal ($p = 0.02$), and complete procedure ($p = 0.02$). Moreover, the total time of all operations after the 9th case with 3D system was in the time range of an experienced surgeon that participated in the same study. On the contrary, all twenty procedures done with 2D system were above that range (Appendix Table 6).

Workload: Strain, Feasibility, and Preference

It is known that surgeon's comfort while performing laparoscopic procedures is of utmost importance to reduce the rate of error, complications, and burnout. In the clinical studies compiled in this revision, single procedures are included and compared, but no data about cumulative strain after several laparoscopic surgeries is available. In fact, to avoid bias depending on surgeon's warming-up and strain, the procedure selection for comparison is the first of the day in some studies [18]. Anyway, there is sufficient evidence that 3D technology can reduce fatigue and be preferred by most surgeons.

Different methodologies are used in the evaluation of surgical strain. Kinoshita [15] studied the use of 2D compared with 3D systems in a high-demand grade III procedure (radical prostatectomy). In this multicenter controlled randomized study with 122 patients, feasibility of basic tasks and fatigue of surgeons and scopists were evaluated. For feasibility measurement, questionnaires using 7-point Likert scale were used (from none or worst (0) to excellent (6)). This subjective evaluation showed 3D imaging was better, namely recognizing needle direction, precise position of the target tissue, and in the recognition of various fine structures. Regarding fatigue appraisal, two methods were used before and just after the procedure; one was the Simulation Sickness Questionnaire (SSQ) and the other the Critical Flicker Fusion test (CFF) for eye fatigue evaluation. These two tests were similar between groups, which means that at least, actual HD 3D image does not increase fatigue when compared to HD 2D systems.

Considering the controlled randomized trials with low risk bias included in the systematic review, six out of seven addressed the topic of preference, strain, and feasibility evaluation [13, 18–20, 29, 34]. All these 6 used non-validated questionnaires rating the answers on a scale of 3–5, and observed undeniable advantage for 3D systems. Better depth perception was found in all of them, but also better definition of planes[18, 19, 34], better precision[13, 18, 19], and better hand-eye coordination and image quality[13] was observed. Two studies of Curro and Navarra [18, 19] subjected surgeons to a 5-point questionnaire considering fatigue at the end of the operations. Significant better scores with 3D systems were observed for the evaluation of neck strain, and eye strain in sleeve gastrectomy, gastric bypass, and right colectomy. In this same paper, it was found that feasibility and fatigue advantages with 3D systems were noted particularly during longer periods of surgery.

In the publication of Pakantar and colleagues [41], a senior surgeon intervened on 108 patients subjected to urological procedures that were randomly assigned to either 2D or 3D laparoscopic surgeries. They used the well validated test, State-Trait Anxiety Inventory for Adults (STAI-6) Short version, to quantify emotional, physical, and cognitive aspects of stress experienced during each operative procedure. There was a significant STAI score difference favoring the use of 3D system ($p < 0.0001$) for the entire group, as well as for each of the patient subgroups (simple nephrectomy, pyeloplasty, and radical nephrectomy).

First- and second-generation 3D systems were criticized to have frequent adverse effects on their users. The seminal randomized study by George Hanna with grade I surgeries (cholecystectomies) used first-generation (shutter-glasses) systems and significant adverse symptoms like visual strain, headache, and facial discomfort were reported by surgeons [36]. Also complains of head-mounted systems were pointed out. These heavy systems were uncomfortable for surgeons that frequently referred headaches and dizziness, about everything when they need to peer through the side vents of the helmet to see the operating room. New generation equipment offers a much more wearable light polarized glasses with high-definition image. Although none of the 7 controlled randomized trials with low risk of bias included in the review referred increased undesirable effects with 3D systems, still some conflicting results appeared in some studies. The study of Lui and colleagues [30] include grade I complexity surgery (ovarian cystectomy) and no data were given concerning stereo-acuity selection of participants and conditions of visualization of the screen. As stated in the review of Scinichiro Sakata [9], "suboptimal viewing conditions caused by head tilt from display elevation and acute eccentric viewing angles increase crosstalk by incorrect orientation of glasses relative to the display". Likewise, Sakata underlines that high levels of crosstalk reduces stereoacuity and raised the rate of fatigue, motion sickness, and other symptoms.

A considerable variety of studies were selected for this review. Ten of 30 (30%) papers are Chinese studies, 10 countries are represented, and 3 continents with just one study from an American country (Canada). Some general criticisms can be made of the selection of existing works. First, only 7 out of 30 (23%) are CRT with low risk of bias. Second, surgeon's expertise in 2D laparoscopic surgery was quantified in a small number of studies (23%), and yet expertise criteria was widely variable. Third, more than half of the studies (60%) include operations performed by a single surgeon. Fourth, only a minority of studies select participants for their stereo acuity (13%) and standardized visualization conditions (20%). Five, no single study analyzes the rate of minor events during surgery.

Minor events like miss the target in needle puncture, or fail to grasp a specific structure, are associated with a higher incidence of major intra-operative complications. The study of these inconsequential incidents could be an important and definitive way to establish 3D technology as safer. At the same time, it is uncertain if minor events that may induce complications can have a significant impact capable of being observed in a prospective or randomized trial. As noted in our results, although no study could find significant less complications favoring 3D, a total number of morbidities was verified (2D:30 vs. 3D:13). Perhaps an increase in the sample size and power could show a small difference in complications when using different systems. On the other hand, only one of the included articles classified complications according to a validated score. Predictably, no difference was found on hospital length of stay, except scientific works with low level of evidence. As referred in same articles, an impediment to the implementation of 3D systems in public hospitals may be the differential in cost. A limitation of our article was that we did not performed a cost calculation; however, it is the opinion of the authors that this difference in cost may be diluted along the years, especially when the benefits of 3D systems are confirmed, with articles such as the one presented here.

This revision used only comparative studies published on the last 5 years. Regarding the difficulties encountered when performing research about the different imaging systems for surgeons, the feeling of the authors is that besides there being a significant amount of recent clinical studies evaluating the benefits of 3D endoscopic procedures, there is still an important outcome variability and lack of consensus when it comes to assessment scores used. Methodological refinements from correct stratification of participants according to their stereoscopic acuity and experience, conditions of display visualization, multiple surgeons and multiple centers involvement, performance fine evaluation (like interpretation of an unexpected scenario), feasibility and performance precision (like recorded instrument-movement evaluation and minor events), and validated strain and fatigue measurement after a single operation and at the end of the day are examples of measures that may help to improve randomized studies in the future. Therefore, one could more fully demonstrate the superiority and benefit of 3D systems.

In conclusion, this systematic review presents the current knowledge on clinical use of 3D systems for endoscopic surgery. Significant scientific evidence puts 3D technology with advantages in surgeon performance, learning curve, and fatigue. More well-designed and powerful studies are needed to assess the clinical impact of these benefits on surgical performance.

Code Availability Not applicable.

Authors' Contribution All the authors contributed to the design of this study, acquisition, and analysis of data. All the authors participated in revising it critically for intellectual content and for final version to be published.

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Data Availability Not applicable.

Declarations

Ethics Approvals and Consent to Participate All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to Publication The authors consent this study publication.

Conflicts of Interest The authors declare no conflict of interest.

Appendix

Table 1 Complexity grading system

Grade	Definition	Type of surgery
I	Simple resection without suturing < 60 min	Appendectomy
		Cholecystectomy
		Ovarian cystectomy
II	Organ resection or plastic surgery with suturing < 120 min	Fundoplication
		Sleeve gastrectomy
		Adrenalectomy
		Hysterectomy
		Nephrectomy
		Pyeloplasty
		Pulmonary atypical resection
III	Organ resection and reconstruction < 240 min	Gastrectomy
		Gastroenteric Bypass
		Colectomy
		Rectal resection
		Minor hepatectomy
		Prostatectomy
		Radical cystectomy
		Partial nephrectomy
		Pulmonary lobectomy
IV	Multiple resection and complex reconstruction > 240 min	Esophagectomy

Table 2 Study general characteristics and type of imaging used

Study ID			Study design					Technical factors				
Author	Year	Country	Method	Risk of Bias	N (2D vs 3D)	Surgeon's experience	Evaluation stereoscopic capacity	System	Viewer condition	Surgical technique	Procedure complexity	Approach
Sahu	2014	India	Randomized, single center	Some Concerns	53–40 2D/13 3D	Single surgeon, "vast experience"	Yes	3D-HD Viking Camera/2D not mentioned	No	Yes	I	Laparoscopy
Aykan	2014	Turkey	Retrospective, single center		95–66 2D/29 3D	Single surgeon, experienced (> 600 procedures)	No	3D-HD Vision System/2D Full HD Karl Storz	No	Yes	III	Laparoscopy
Kinoshita	2014	Japan	Multicenter, open-label, randomized trial	High	116–57 2D/59 3D	9 surgeons into 2 subgroups: 3 surgeons > 200 surgeries, 6 surgeons < 200.	No	Olympus 3D LTF-Y0009, 2D HD	Yes	Yes	III	Laparoscopy
Li	2015	China	Retrospective review of a prospective database, single center		93–48 2D/45 3D	Not mentioned	No	Not mentioned	Yes	Yes	IV	Thoracoscopy
Velayutham	2015	France	Prospective cohort study matched to a retrospective database, single center		60–40 2D/20 3D	Single surgeon, experience not mentioned	No	Olympus 3D HD Vision System	No	Yes	IV	Laparoscopy
Curro	2015	Italy	Randomized, single center, computer allocation	Low	40–20 2D/20 3D	One experienced > 500 procedures and one novice in laparoscopy with < 40 procedures	Yes	3D Karl Storz and Olympus2D/HD system	Yes	Yes	I	Laparoscopy
Curro	2015	Italy	Randomized, single center, computer allocation	Low	40–20 2D/20 3D	One experienced surgeon	No	3D Karl Storz and Olympus2D/HD system	Yes	Yes	II/III	Laparoscopy
Bove	2015	Italy	Retrospective, single center		86–43 2D/43 3D	One experienced surgeon	No	2D-HD Storz/3D-HD Viking Camera	Yes	Yes	III	Laparoscopy
Tao	2016	China	Retrospective, single center		58–31 2D/27 3D	One experienced surgeon	No	2D-HD Storz/3D-HD Viking Camera	No	Yes	III	Laparoscopy
Curro	2016	Italy	Randomized, single center, computer allocation	Low	50–25 2D/25 3D	One experienced > 500 procedures and one novice in laparoscopy with less than 40 procedures	No	3D Karl Storz and Olympus2D/HD system	Yes	Yes	III	Laparoscopy
Lara-Dominguez	2016	Spain	Prospective non-randomized		60–29 2D/31 3D	Multiple surgeons, more than 10 procedures of experience	No	2D X-6000 Striker/3D passive polarized Karl Storz	Yes	No	I/II	Laparoscopy
Raspagliesi	2016	Italy				Same team, expert surgeons	No		No	Yes	II	Laparoscopy

Table 2 (continued)

Study ID			Study design					Technical factors				
Author	Year	Country	Method	Risk of Bias	N (2D vs 3D)	Surgeon's experience	Evaluation stereoscopic capacity	System	Viewer condition	Surgical technique	Procedure complexity	Approach
			Prospective, single center, data compared with historical cohort (2D)		75–60 2D/15 3D			Not mentioned, 3D Karl Storz				
Agrusa	2016	Italy	Case-control study		39–26 2D/13 3D	One experienced surgeon	Yes	Same brand Karl Storz HD systems	Yes	Yes	II	Laparoscopy
Tang	2016	China	Retrospective, single center		42–24 2D/18 3D	One experienced surgeon	No	3D-HD Viking Camera/2D Olympus HD	No	Yes	III	Laparoscopy
Fanfani	2016	Italy	Randomized trial–block randomization method	Low	90–48 2D/42 3D	Experienced surgeons (> 50 procedures) and novice surgeons (< 10 procedures)	No	3D Endoeye Flex Olympus/2D modality	No	Yes	III	Laparoscopy
Pakantar	2017	India	Randomized trial–block randomization method	Some concerns	108–53 2D/55 3D	One experienced surgeon	No	2D Mayer 3 Chip HD/Viking 3D HD	No	No	II	Laparoscopy
Kanaji	2017	Japan	Retrospective, single center		30–15 2D/15 3D	Two experienced surgeons and three experienced assistants	Yes	3D Endoeye flex by Olympus/2D-HD system by Karl Storz;	Yes	Yes	III	Laparoscopy
Leon	2017	Italy	Randomized, single center, computer allocation	Some concerns	36–17 2D/19 3D	One experienced surgeon	No	3D Endoeye flex by Olympus/ "conventional 2D with 30° scope"	No	Yes	II	Laparoscopy
Zheng	2017	China	Randomized, single center, computer allocation	Low	419–208 2D/2-11 3D	Experienced surgeons	No	Not mentioned	No	Yes	III	Laparoscopy
Lui	2018	China	Randomized, single center, computer allocation	Some concerns	75–38 2D/37 3D	15 Experienced (52%) and non-experienced surgeons (48%)	No	3D Endoeye flex by Olympus/2D Karl Storz	No	No	I	Laparoscopy
Yoon	2018	Korea	Retrospective review of a prospective database		278–167 2D/1-11 3D	One experienced surgeon	No	3D Endoeye flex by Olympus/2D HD system by Stryker	No	Yes	III	Laparoscopy
Wang	2019	China	Randomized, single center, computer allocation	Some concerns	80–40 2D/40 3D	One experienced surgeon	No	Same brand Karl Storz HD systems (3rd gen 3D)	No	Yes	III	Laparoscopy
Yang	2016	China				2 experienced teams	No		No	Yes	II	Thoracoscopy

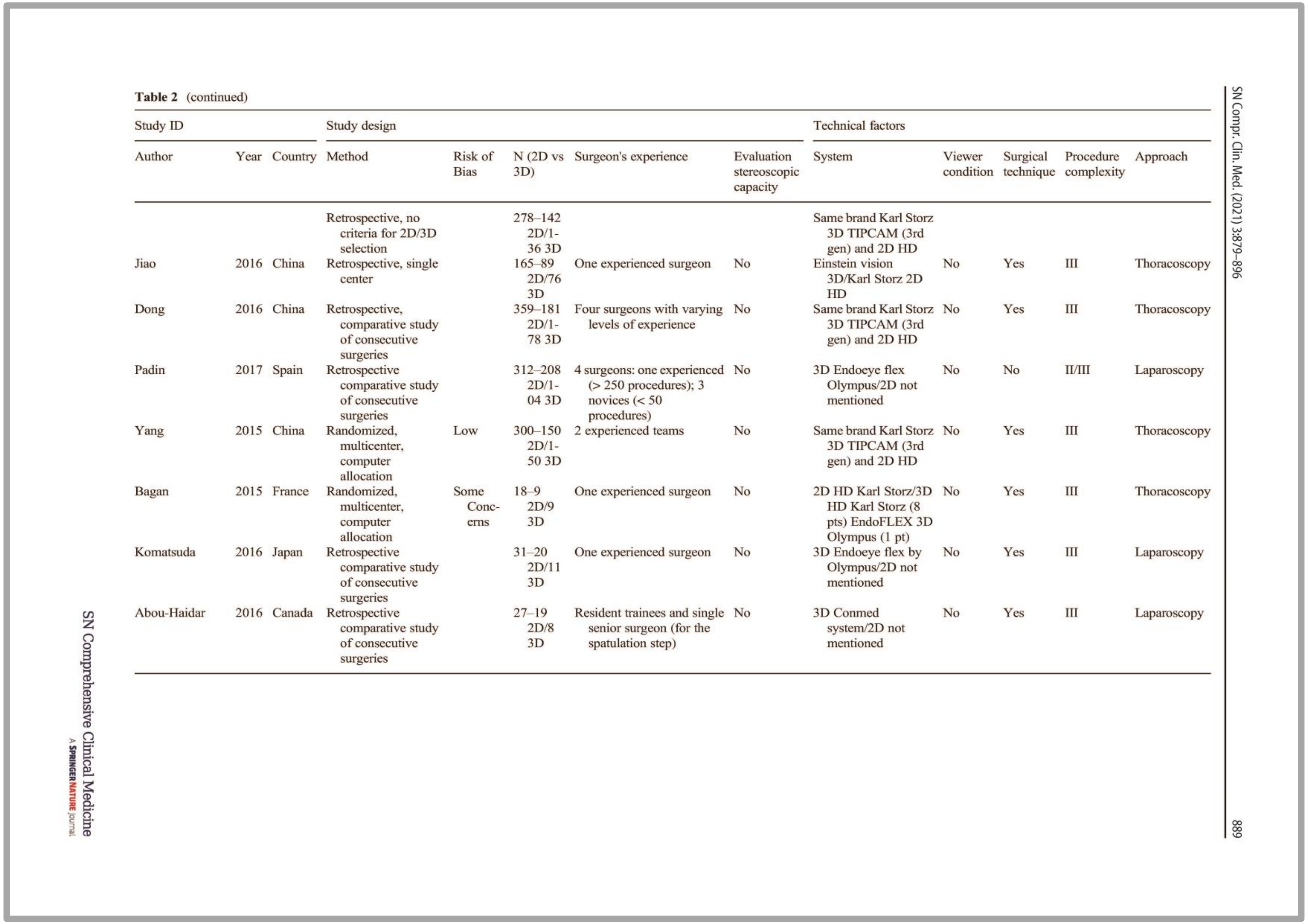

Table 2 (continued)

Study ID			Study design					Technical factors				
Author	Year	Country	Method	Risk of Bias	N (2D vs 3D)	Surgeon's experience	Evaluation stereoscopic capacity	System	Viewer condition	Surgical technique	Procedure complexity	Approach
			Retrospective, no criteria for 2D/3D selection		278–142 2D/1-36 3D			Same brand Karl Storz 3D TIPCAM (3rd gen) and 2D HD				
Jiao	2016	China	Retrospective, single center		165–89 2D/76 3D	One experienced surgeon	No	Einstein vision 3D/Karl Storz 2D HD	No	Yes	III	Thoracoscopy
Dong	2016	China	Retrospective, comparative study of consecutive surgeries		359–181 2D/1-78 3D	Four surgeons with varying levels of experience	No	Same brand Karl Storz 3D TIPCAM (3rd gen) and 2D HD	No	Yes	III	Thoracoscopy
Padin	2017	Spain	Retrospective comparative study of consecutive surgeries		312–208 2D/1-04 3D	4 surgeons: one experienced (> 250 procedures); 3 novices (< 50 procedures)	No	3D Endoeye flex Olympus/2D not mentioned	No	No	II/III	Laparoscopy
Yang	2015	China	Randomized, multicenter, computer allocation	Low	300–150 2D/1-50 3D	2 experienced teams	No	Same brand Karl Storz 3D TIPCAM (3rd gen) and 2D HD	No	Yes	III	Thoracoscopy
Bagan	2015	France	Randomized, multicenter, computer allocation	Some Conc-erns	18–9 2D/9 3D	One experienced surgeon	No	2D HD Karl Storz/3D HD Karl Storz (8 pts) EndoFLEX 3D Olympus (1 pt)	No	Yes	III	Thoracoscopy
Komatsuda	2016	Japan	Retrospective comparative study of consecutive surgeries		31–20 2D/11 3D	One experienced surgeon	No	3D Endoeye flex by Olympus/2D not mentioned	No	Yes	III	Laparoscopy
Abou-Haidar	2016	Canada	Retrospective comparative study of consecutive surgeries		27–19 2D/8 3D	Resident trainees and single senior surgeon (for the spatulation step)	No	3D Conmed system/2D not mentioned	No	Yes	III	Laparoscopy

Table 3 Intra-operative and post-operative results for articles with low risk of bias

Study ID	Intra-operative				Post-operative				
Author	Operative time	Blood loss	Conversion	Errors or complications	Morbility	Lengh of stay (days)	Oncological outcome	Side effects	Surgeon's perceptions
Sahu	Lower in 3d ($p = 0.04$)	Not mentioned	0	0	0	Not mentioned	Not mentioned	Not mentioned	3D better perception from surgeons
Curro (cholecystectomy)	Lower in 3D ($p = 0.02$) for novice surgeon	Not mentioned	0	NSS	0	Not mentioned	Not mentioned	No symptons	Not mentioned
Curro (bariatric)	Lower in 3D ($p = 0.03$) for MGBp	Not mentioned	0	0	0	Not mentioned	Not mentioned	3D better Surgical Strain Score	3D better perception from surgeons
Curro (right colectomy)	Lower in 3D ($p = 0.06$)	Not mentioned	0	0	NSS	Not mentioned	NSS	3D better Surgical Strain Score	3D better perception from surgeons
Fanfani	3D better time for pelvic lymphadenectomy for novice ($p = 0.047$)	Lower with 3D (lymphadenectomy) $p = 0.033$	0	NSS	NSS	NSS	NSS	Not mentioned	Not mentioned
Zheng	NSS	Lower with $p = 0.045$	Not mentioned	NSS	NSS	Not mentioned	Not mentioned	No symptons	3D better perception from surgeons
Cheng-Liang Yang	Lower with 3D ($p = 0.006$)	NSS	NSS	NSS	NSS	NSS	NSS	No symptons	3D better perception from surgeons

Table 4 Intra-operative results. MGBp–mini gastric bypass, SG–gastric sleeve

Author	Intra-operative factors											
	Surgical time (min)			Blood loss (ml)			Conversion			Errors or complications		
	3D	2D	*p* value	3D	2D	*p* value	3D	2D	*p* value	3D	2D	*p* value
Sahu	40	54	0.04				0	0		0	0	
Aykan	131	190	< 0.001	102	138	< 0.001	0	0			3 minor rectal tears	
Kinoshita	150	148	0.98				0	0		4 leakage	6 leakage	0.44
Li	138	167	< 0.01	68.2	89.8	< 0.01	0	0		0	0	
Velayutham	225	284	0.031	204	252	0.291	1	1		0	0	
Curro (cholecystectomy)	36*	42*	0.1*				0	0		1 (novice–2)	2 (novice–5)	
Curro (bariatric)	SG 68/MGBp 88	SG 72/MGBp 100	0.1/0.03				0	0		0	0	
Bove	162	241	0.01	383	532	0.11	0	0		0	0	
Tao	130	152	0.005	80.8	84.7	0.563	0	0		0	0	
Curro (right colectomy)	105	100	0.06				0	0		0	0	
Lara	97	67	0.024	20.5	17.9	0.442	0	1		4	6	0.413
Raspagliesi	177	216	0.09	50	50	0.88	0	0			1	1.00
Agrusa	110	120	> 0.05	NSD			0	0			2	1.00
Tang	133	151	0.014	211.7	217.5	0.829	0	0				
Fanfani	108	110	0.593	94**	82**	0.242**	0	0				
Pakantar	150	111	< 0.0003	150	203	0.028						
Kanaji	157	183	0.026	10	20	> 0.05	0	0				
Leon	70	90	0.006				0	0		1	3	0.52
Zheng	174	176	0.562	61	83	0.045						
Lui	51.6	47.6	0.198	58.2	55.1	0.825	0	0				
Yoon	155	150	0.186	50	100	< 0.001	0	0				
Wang	106	122	< 0.001	7	8	0.706	0	0			1 urether injury	1.00
Yang	86	108	0.002	50	54	0.066	NSD	NSD				
Jiao	113	126	0.096	125.3	121.4	0.859	1	1				
Dong	163	184	< 0.001	109	144	0.064	5	6	0.781			
Padin	172	144	0.001				0	0				
Yang (2)	145	176	0.006	120	116	0.798	4	6	0.751	2	4	0.684
Bagan	146	177	< 0.001	216	238	0.74	0	0				
Komatsuda	158	175	0.348	37.3	22.8	0.335	0	0				
Abou-Haidar	217	265	0.02									

Table 5 Post-operative factors. *Pentafecta, depth perception (DP), hand-eye (HE), image quality (IQ), operative strain (OS), subjective (Sub), questionnaire (Qst), simulation sickness questionnaire (SSQ), critical flicker fusion (CFF), state-trait anxiety inventory for adults short version score (STAI), Likert scale (LS), lymph nodes (LN)

Post-operative factors											
Author	Morbidity (Clavien-dindo)			Lenght of stay (days)			Oncological outcome (LN's)			Side effects	Surgeons' perceptions
	3D	2D	*p* value	3D	2D	p-value	3D	2D	*p* value		
Sahu	0	0								HE coordination > in 3D. Sub, Qst, NV.	IQ, DP, Knotting better > 3D; advantage of 30° scope < 3D
Aykan	0	0									
Kinoshita										Fatigue by SSQ and CFF, NSS	General satisfaction, moving instruments, recognition of structures in favor of 3D. LS, NV
Li	13	8	0,328	9,07	10,85	0,003	Better thoracic LN's		0,008		
Velayutham	I–II 5/III–IV 1	I–II 10/III–IV 3	> 0.99	9	8	0.122				No symptons	
Curro (cholecystectomy)	0	0								No symptons	
Curro (bariatric)	0	0								Neck strain and HE strain > 3D in both interventions. NV Qst	Precision, IQ, DP better with 3D
Bove	8	15		5.5	7.6	0.18	67%	62.7%	NSS*		
Tao	3	4	NS	8	9	0.132	20.4	19.3	0.455		
Curro (right colectomy)	1	0	NS						NSS	Neck strain and HE strain > 3D. NV Qst	Precision, DP, IQ better with 3D
Lara	1	4	NS	58	62	0.722					
Raspagliesi	0	2	0,1	2	4	0.004	25.8	25.4	0.90		
Agrusa	0	0								9 cases Headache/Dizziness with 3D, NV	Precision, IQ, DP better 3D. More interest in procedures by young doctors.
Tang	5.6%	16.7%+B17:C32	0.271	8.9	9.1	0.840	13.2	12.5	0.627		
Fanfani	1	0	0.320	2	2	0.359	30	28	0.252		
Pakantar						NSS					STAI better with 3D–13 vs. 17 $p < 0.0001$
Kanaji	0	0		13.5	12.0	0.355	41	40	0.895		

Table 5 (continued)

Post-operative factors											
Author	Morbidity (Clavien-dindo)			Lenght of stay (days)			Oncological outcome (LN's)			Side effects	Surgeons' perceptions
	3D	2D	*p* value	3D	2D	p-value	3D	2D	*p* value		
Leon									Not applicable	No symptons	Impression of a feeling of enhanced vision and reduced workload with 3D
Zheng	5	5	0.99							No symptons	DP better 3D. Sub Qst
Lui				2.4	2.6	0.489			Not applicable	More symptons with 3D: 5.3% 2D/45.9% 3D ($p < 0.001$)	
Yoon	0	2	0.519	6	6	0.087	47	41	0.001		
Wang				15	15	0.930				NSS	Precision, DP better with 3D. LS. NV
Cheng-Liang Yang	8	8	0.566	6.89	6.86	0.059					
Peng Jiao	11	14	0.822	8.4	8.1	0.314	23.2	21.9	0.216		Impression of IQ better with 3d
Song Dong	29	24	0.459	6.9	7.1	0.399	21.3	19.5	0.064		
Esther Mariño Padin	Fistula: 0%; GB 0; Novices fistula 0%; Novices complications 1.8%	Fistula: 3.8%; FGB 4.4%; Novices fistula 6.9%; Novices complications 10.2%	Fistula: $p = 0.01$; GB $p = 0.11$; Novices fistula $p = 0.02$; Novices complications $p = 0.034$	5	8	< 0.005				No symptons	Impression reduction of surgical time
Cheng-Liang Yang	27	29	0.882	7	8	0.213	17	16	0.128	No symptons	DP better 3D. Sub Qst
Patrick Bagan	1	1				"similar between groups"	5.3	4.5	0.1	No symptons	DP, moving instruments better with 3D
Akari Komatsuda	9.1%	10%	0.719						All negative margins		
Hiba Abou-Haidar	1	0	0.85	2	3	0.02				No symptons	

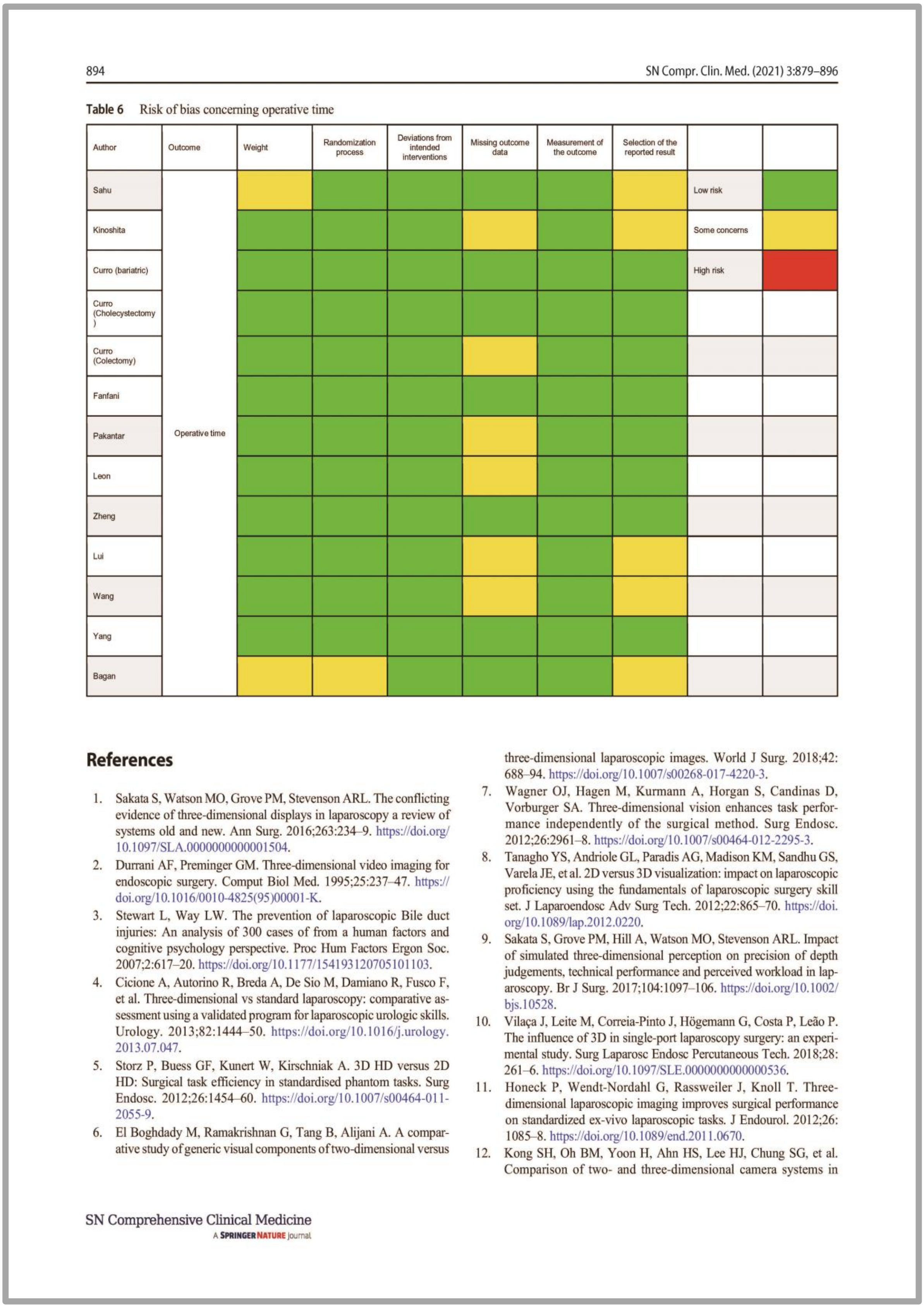

Table 6 Risk of bias concerning operative time

Author	Outcome	Weight	Randomization process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result		
Sahu	Operative time	🟨	🟩	🟩	🟩	🟩	🟨	Low risk	🟩
Kinoshita		🟩	🟩	🟩	🟨	🟩	🟨	Some concerns	🟨
Curro (bariatric)		🟩	🟩	🟩	🟩	🟩	🟩	High risk	🟥
Curro (Cholecystectomy)		🟩	🟩	🟩	🟩	🟩	🟩		
Curro (Colectomy)		🟩	🟩	🟩	🟨	🟩	🟩		
Fanfani		🟩	🟩	🟩	🟩	🟩	🟩		
Pakantar		🟩	🟩	🟩	🟨	🟩	🟩		
Leon		🟩	🟩	🟩	🟨	🟩	🟩		
Zheng		🟩	🟩	🟩	🟩	🟩	🟩		
Lui		🟩	🟩	🟩	🟨	🟩	🟨		
Wang		🟩	🟩	🟩	🟨	🟩	🟨		
Yang		🟩	🟩	🟩	🟩	🟩	🟩		
Bagan		🟨	🟨	🟩	🟩	🟩	🟨		

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