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Three-Dimensional Minimally Invasive Surgery Enhances Surgeon's Performances, Reducing Operative Time and Errors.

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**POLITECNICO  
DI TORINO**



**UNIVERSITÀ  
DEGLI STUDI  
DI TORINO**

PhD Program in Bioengineering and Medical-Surgical Sciences

**Three-Dimensional Minimally Invasive Surgery Enhances Surgeon's  
Performances, Reducing Operative Time and Errors.  
Comparative Study in a Pediatric Surgery Setting.**

XXX Cycle

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**Title:** Three-Dimensional Minimally Invasive Surgery Enhances Surgeon's Performances, Reducing Operative Time and Errors. Comparative Study in a Pediatric Surgery Setting.

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## SUMMARY

### 1.Introduction

#### 1.1 State of the art

##### 1.1.1 Definition and Basic Principles

Stereoscopy is a technique for creating or enhancing the illusion of depth in an image by means of stereopsis for binocular vision. The word *stereoscopy* derives from the Greek στερεός (*stereos*), meaning “firm, and σκοπέω (*skopeō*), meaning “to look”.

Any stereoscopic image is called a stereogram.

Originally, stereogram referred to a pair of stereo images which could be viewed using a stereoscope.

Most stereoscopic methods present two offset images separately to the left and right eye of the viewer.

These two-dimensional images are then merged in the brain to give the perception of 3D depth.

Stereoscopy creates the illusion of three-dimensional depth from given two-dimensional images. Human vision, including the perception of depth, is a complex process, which only begins with the acquisition of visual information taken in through the eyes; much processing ensues within the brain, as it strives to make sense of the raw information [Fig 1].

One of the functions that occur within the brain as it interprets what the eyes see is assessing the relative distances of objects from the viewer, and the depth dimension of those objects.

The *cues* that the brain uses to gauge relative distances and depth in a perceived scene include stereopsis, eye accommodation, overlapping of one object by another, subtended visual angle of an object of known size, linear perspective

(convergence of parallel edges), vertical position (objects closer to the horizon in the scene tend to be perceived as farther away), haze or contrast, saturation, and colour, greater distance generally being associated with greater haze, desaturation, and a shift toward blue and finally change in size of textured pattern detail.

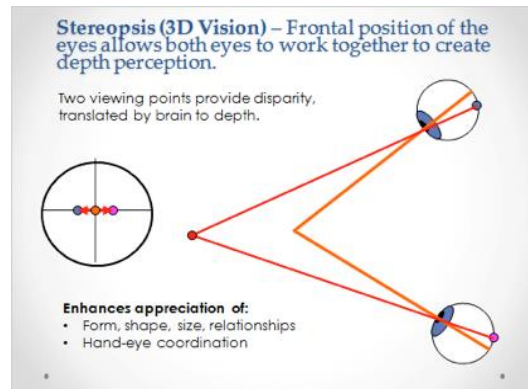


Fig.1: basis of stereopsis.

### 1.1.2 Visual requirements

Anatomically, there are 3 levels of binocular vision required to view stereo images: simultaneous perception, fusion (binocular “single” vision) and stereopsis.

These functions develop in early childhood. Some people who have strabismus disrupt the development of stereopsis, however orthoptics treatment can be used to improve binocular vision.

A person's stereoacuity determines the minimum image disparity they can perceive as depth.

It is believed that approximately 12% of people are unable to properly see 3D images, due to a variety of medical conditions.

According to another experiment up to 30% of people have very weak stereoscopic vision preventing them from depth perception based on stereo disparity.

This greatly decreases immersion effects of stereo to them.

Stereoscopic viewing may be artificially created by the viewer's brain, as demonstrated with the Van Hare Effect, where the brain perceives stereo images even when the paired photographs are identical.

This "false dimensionality" results from the developed stereoacuity in the brain, allowing the viewer to fill in depth information even when few if any 3D cues are actually available in the paired images.

### 1.1.3 3D viewers

There are two categories of 3D viewer technology, active and passive.

Active viewers have electronics, which interact with a display.

Passive viewers filter constant streams of binocular input to the appropriate eye.

#### 1.1.3.1 Active: Shutter systems

A shutter system works by openly presenting the image intended for the left eye while blocking the right eye's view, then presenting the right-eye image while blocking the left eye, and repeating this so rapidly that the interruptions do not interfere with the perceived fusion of the two images into a single 3D image.

It generally uses liquid crystal shutter glasses [Fig 2].

Each eye's glass contains a liquid crystal layer which has the property of becoming dark when voltage is applied, being otherwise transparent.

The glasses are controlled by a timing signal that allows the glasses to alternately darken over one eye, and then the other, in synchronization with the refresh rate of the screen.

The main drawback of active shutters is that most 3D videos and movies were shot with simultaneous left and right views, so that it introduces a "time parallax" for anything side-moving.



Fig. 2: liquid crystal shutter glasses.

### 1.1.3.2 Passive: Polarization systems

To present stereoscopic pictures, two images are projected superimposed onto the same screen through polarizing filters or presented on a display with polarized filters.

For projection, a silver screen is used so that polarization is preserved.

On most passive displays every other row of pixels are polarized for one eye or the other.

This method is also known as being interlaced.

The viewer wears low-cost eyeglasses, which also contain a pair of opposite polarizing filters [Fig 3].

As each filter only passes light that is similarly polarized and blocks the opposite polarized light, each eye only sees one of the images, and the effect is achieved.



Fig. 3: passive polarized glasses.

## 1.2 Clinical application of 3D technology in minimally invasive surgery



Since the introduction of laparoscopic surgery, laparoscopic procedures have increased in all surgical fields with the development of new and advanced instruments, making laparoscopic procedures safe, with many advantages for the patients.

Technology has driven important advances in the field of minimally invasive pediatric surgery over the past two decades and laparoscopy has become a standard technique for a wide range of surgical indications in pediatric surgery.

However, acquisition of laparoscopic skills can be challenging: the monocular, 2-dimensional (2D) visualization obtained with current mini-invasive systems, lacks of depth perception and this significantly reduces the surgeon's ability to determine the size and the precise localization of anatomical structures, thus impairing the ability to operate efficiently.

When viewing a 2D conventional laparoscopic image, both eyes see exactly the same image, missing the physiological binocular horizontal disparity (stereoscopy), which is at the basis of depth perception.

Industry has recently developed novel 3-dimensional (3D) systems for laparoscopic surgery, where the depth perception is achieved by different unique images received by each eye and merged together in the cortical areas.

Some examples are represented by Conmed 3DHD Vision System (Conmed Corp., Utica, NY), Olympus Endoeye Flex 3D Videoscope (Olympus America Corp.), Aesculap EinstenVision 3D System (Aesculap, Tuttlingen, Germany), Storz Image1 S 3D (Karl Storz, Tuttlingen, Germany).

These camera systems are all mounted on 10 mm scopes, adapted for adult surgery but too big for neonatal or infantile procedures.

Advantages in 3D laparoscopy are, moreover, mostly studied and described in adults for better depth perception, precise visualization of anatomical structures, as well as for complex surgical manoeuvres in small spaces, while research is lacking in pediatric general surgery.

Over the last decades multiple studies comparing 3D to 2D laparoscopic vision

have shown inconsistent results for different surgical performances.

That was mainly attributed to limitations of the first generation 3D imaging systems.

In recent years the 3D-view has been shown to be very useful during robotic surgery and has been applied to increasing numbers of procedures.

The robotic system has been introduced to facilitate difficult laparoscopic procedures where narrow spaces and complex anatomical locations play an important role.

With this technique, laparoscopic skills such as intra-corporal suturing and knot tying had a particularly fast learning curve.

Advancements in 3D technologies have improved 3D-equipment such as video endoscopes and monitors for laparoscopic procedures in the last years.

Perfectioning of resolution image characteristics has reduced adverse events of the early 3D imaging systems such as nausea, eye burning and fatigue or vertigo.

Experienced laparoscopic surgeons develop strategies to adjust for the loss of stereoscopic vision, but novices often struggle initially.

Few studies directly compare the performance of a 3D image with that of a 2D image.

Recently, studies comparing 3D versus 2D vision in laparoscopy, concluded that 3D laparoscopy appeared to improve speed and reduce the number of performance errors when compared with 2D laparoscopy [1].

The potential benefits of simulated 3D laparoscopy as a training tool for prospective surgeons, have been highlighted by Votanopoulos et al. [2], who demonstrated that 3D offered significant advantages in the teaching of laparoscopic skills to inexperienced residents.

Only limited investigation exists concerning the utility of modern 3D endoscopic systems in vivo.

### 1.2.1 Previous report in adult surgery

In general adult surgery, some studies have been indicating that less time was needed for gastrointestinal operations performed with 3D laparoscopic surgery than 2D.

Surgeons who performed radical resection of rectal cancer with the 3D system experienced as good depth and spatial perception as in the open surgery compared with 2D system.

Due to the better spatial vision and high-definition images in the 3D system, adjacent organs could be easy to recognize, and also, the possibilities of wound and haemorrhage in operation were reduced, which offer the basis of shorter post-surgery recovery duration.

A comparative study of 3D and 2D laparoscopic surgery in gastrointestinal tumors demonstrated that 3D laparoscopic surgery can improve the spatial location and depth of operation, decrease the difficulty of fine operation, and shorten the operation time [3].

In the study of Zeng et al. [4], they found significant shorter operation duration in the 3D group, which was consistent with previous studies.

Komaei I et al. [5], in a systematic review comparing 3D versus 2D laparoscopic cholecystectomy, wanted to provide enough convincing evidences on superiority and benefits of 3D over 2D imaging systems, from both surgeon's and patient's point of view, justifying the cost-effectiveness of newly developed 3D systems.

A total of 912 articles were initially reviewed by their titles and abstracts for eligibility.

After being filtered through predetermined inclusion and exclusion criteria, and excluding the duplicates, only 10 studies underwent the final evaluation by the full text assessment.

Eventually, only five randomized controlled studies were included in that study.

Operative time and depth perception/image quality were set as the primary and secondary outcomes, respectively.

The operative time was significantly shorter in 60% of the studies.

Of five studies that evaluated the depth perception and image quality, all five

(100%) reported a better depth perception and image quality.

3D imaging systems tended to shorten the operative time compared to 2D systems and result in a better depth perception.

Ji F. et al. [3], in their comparative study, evaluated the technical advantages of 3D laparoscopic and 2D laparoscopic surgery for gastrointestinal tumors.

Clinical data of gastrointestinal cancer patients undergoing 3D laparoscopic or 2D laparoscopic surgery from January 2015 to January 2017 were retrospectively analysed.

These patients included 93 gastric cancer cases undergoing laparoscopic radical resection, 45 rectal cancer cases undergoing radical resection combined with lateral lymph node dissection and 76 right colon cancer cases undergoing radical resection.

The enrolled criteria of cases were the age comprised between 18 and 80 years old and the diagnosis of advanced gastric or colorectal cancer by pathological examination.

The choice of surgical procedure was determined by the discussion between patients and surgeon.

Operations were performed by the same surgical team.

Total operation time, complex operation time (deep lymph node dissection time, endoscopic intestinal anastomosis time), number of harvested lymph node, number of times in wrong grasp (accurate grasp for the same site needs to position for two times or more) and intra-operative bleeding were compared between 3D group and 2D group.

There were no significant differences in baseline data between 3D group and 2D group.

All the patients completed laparoscopic radical operation successfully without conversion to open surgery.

In patients with gastric cancer, compared with 2D group, the total operation time was shorter.

In patients with rectal cancer, compared with 2D group, 3D group had shorter time of lateral lymph node dissection and laparoscopic anastomosis.

In patients with right colon cancer, 3D group had shorter laparoscopic anastomosis time, as compared to 2D group.

The conclusion was that 3D laparoscopic surgery for gastrointestinal tumors, compared with 2D laparoscopic technology, had significant advantages, which can improve the spatial location and depth of operation, decrease the difficulty of fine operation, and shorten the operation time.

### 1.2.2 Previous report in pediatric patients

Few reports explored 3D laparoscopic benefits in pediatric and neonatal surgery.

Feng X. et al. [6] in 2015, tried to demonstrate that 3D laparoscopy would improve operating time in small spaces without impact on hemodynamics and psychomental stress parameters of the surgeon.

They tested 3D versus 2D vision during laparoscopic surgery in rabbits, mimicking the size of a neonatal patient.

Cadaver New Zealand white rabbits (mean weight 2,755 g) were operated by two surgeons experienced in 2D laparoscopic surgery and two surgical residents (with basic skills in 2D laparoscopy).

All surgeons had never performed 3D laparoscopic surgery.

Animals underwent six operations: Nissen fundoplication, small bowel anastomosis, and closure of a diaphragmatic defect using either 2D or 3D.

Primary endpoint was cumulative operating time and operating time of each operation.

Secondary endpoints included the hemodynamic response and psychomental stress level of the surgeons.

Finally, subjective data on depth perception were assessed by questionnaires.

Cumulative operating time of all three types of operations was significantly shorter with 3D laparoscopy in experts and residents.

This effect could be shown for each operation in the expert group, and for the Nissen fundoplication in the resident group.

There were no differences in the hemodynamic response, as well as in the psychomental stress level between 2D and 3D imaging.

3D provided better depth perception.

They concluded that 3D laparoscopy in small spaces was associated with a significant shorter operating time, thus facilitating minimal invasive surgery in neonates and infants.

Kozlov Y. et al. [7], focused on the successful application of 3D laparoscopic surgeries in the treatment of congenital anomalies and acquired diseases in the young pediatric population.

Their experience was based on 110 endosurgical procedures (abdominal and urological surgery) performed in neonates and infants in the 3D format between January 2014 and May 2015.

Depending on the type of operations, all patients were divided into the following groups: (1) inguinal herniorrhaphy, 63 patients; (2) Nissen fundoplication, 22 patients; (3) pyeloureteral anastomosis, 15 patients; (4) nephrectomy, 5 patients; and (5) ovarian cystectomy, 5 patients.

The patients of the first three groups were compared with babies who underwent standard laparoscopic surgery, performed in the two-dimensional (2D) format during the same time period.

The patients were similar in terms of demographics and other preoperative parameters.

There were significant differences in mean operative time between 3D and 2D procedures in the groups of patients with hydronephrosis and gastroesophageal reflux, which used manipulation with internal sutures, but not in the group 1 after inguinal herniorrhaphy.

Postoperative parameters such as length of hospital stay and the number of complications were equivalent between groups.

They concluded that the key to success of 3D laparoscopy in small babies with inguinal hernia, gastroesophageal reflux, hydronephrosis, ovarian cyst, and multicystic kidney, was that laparoscopy in 3D format decreased the duration of complex procedures, which utilize the use of the suture technique into the abdominal cavity.

The perception of depth and the presence of tactile feedback make 3D laparoscopic surgery more acceptable when compared to traditional laparoscopy.

### 1.3 Cost Effectiveness

A recent HTA report by the Italian Society for Endoscopic Surgery, compared 2D and 3D laparoscopy based on economic results and, despite of an increase in the costs, the report stated that the total annual cost, for a similar procedures mix, with the only modification of the technology used (3D, instead of standard 2D), would be reduced, due to a less duration of the procedures.

Moreover, the report established that, in an optimal context of using of the innovative technology, and once the learning curve has been acquired, 3D laparoscopy would allow for a patient-operated savings in a range from a minimum of -1.173% to a maximum of -1.341%, depending on the surgical specialty.

Where the context would not allow an immediate reduction in the surgical time, or in a first phase of the technology learning, it would be necessary a very small investment, equal to +0,232 of the annual budget of a medium volume hospital, to allow the purchase of the device.

For this reason, it is necessary not to consider its use in only one single surgical specialty, and to model a potential technology impact in a medium size hospital where all surgical specialties operate (general surgery, urology, gynaecology, etc.), in order to understand whether the use of the new technology would be sustainable or not, for the whole hospital.

Considering this potential cost increase, the introduction of the new device could allow to a mid-sized hospital, with the three above-mentioned specialties, savings of - € 255000.

The study group assured that the introduction of an innovative technology will surely generate more investments in other technologies and more attractiveness for the hospital.

This would be equally valid in the case where a unit has problems related to the learning curve or has overlapping performances in 2D and 3D.

In conclusion, it is sufficient to consider the reduced operating times in a high volume operating unit, to justify the introducing of 3D technology.

## **2. Aims of the study**

The aim of this study was to determine the benefits of the 3D technology in pediatric laparoscopic and thoracoscopic surgery.

Three steps were planned.

### *- Phase 1*

In the initial phase we aimed to determine the benefit of 3D technology in pediatric laparoscopic surgery in naïve subjects in a pediatric laparoscopic surgery simulator (PLS) and to record their subjective perception regarding 3D laparoscopy.

### *- Phase 2*

In the second phase we conceived an experimental project comparing 2D versus 3D laparoscopic camera in a set-up standardized and validated for pediatric surgeons.

We performed a comparative study between surgical skills achievements in experienced pediatric surgeons.

### *- Phase 3*



Finally, once the new technology was validated, we applied it in laparoscopic and thoracoscopic procedures in children and neonates hospitalized in the General and Thoracic Surgery Unit of the Regina Margherita Children's Hospital, in Torino, Italy.

Operative time and intra- or post-operative complications were recorded.

### **3. Patients, Material and Methods**

#### **3.1 Surgical Equipment and Technology**

We tested two all-new systems specific for pediatric endosurgery, due to the small diameter of their optics (4mm) [Fig 4]:

- Visionsense III miniature stereo camera physically resembles standard monocular cameras but allows through sensors the generation of true stereovision. The system is composed by a 3D HD camera, with remote control buttons and a rod to change focus; a 3D scope with size diameter less than 0.4 cm; a coupler to attach all 2D scopes available on the market; autofocus from 0.5 cm to 5 cm; a console (PC based unit) and a 24" 3D flat screen display.

It can drive multiple 3D displays or 3D and 2D displays in parallel or 2D mode for 2D viewing.

Polarizing eyeglasses enable stereoscopic vision while conducting a surgical procedure; the glasses can be worn on top of regular eyeglasses.

Visionsense miniature stereo camera physically resembles standard monocular cameras.

Both have an objective lens, which focuses light on a sensor (CMOS).

The sensor converts the incoming light into an electrical signal, which is then digitized and processed by a computer.

The sensor maps visually the entire volume in 3-D using an array of micron-sized optical elements that superposes and recovers two viewpoints.

As single stereo sensor, its design is based on optical and computational principles that enable the reconstruction of the natural psychophysical stereovision experience.

The combination of proprietary sensor and complex algorithms permit the generation of true stereovision.

- Karl Storz 3D System is equipped with a 3D Camera Control Unit (CCU), 3D monitor and 3D-TIPCAM.

The CCU transmits the 3D signals to the 3D monitor and allows switching between 2D and 3D.

The 3D-TIPCAM is a video endoscope with a diameter of 4 mm.

Since common cameras usually only catch one image at a time, two distal image sensors were required to generate a 3D image for the KARL STORZ 3D system.

The principle here is similar to human vision, where each sensor plays the role of one eye.

The signals were electronically processed and merged together in the camera control unit using the line-by-line method.

The created double image is pictured on a 3D monitor, which transmits circular polarized light.

Using passive filter glasses, the double image in our vision was put together and thus we were able to see in 3D.

For the different procedures either the 0° or 30° 3D-TIPCAM was used, depending on their availability during simultaneous operations.



Fig 4: Visionsense III and Storz TipCam 3D systems.

### 3.2 Phase 1 – Study Overview

Using Visionsense III Stereoscopic Endoscopy System (Neuromed Spa, Turin, Italy), a 3D HD camera with a 4 mm scope, FDA and CE approved for pediatric surgery, we performed a comparative study between surgical skills achievements using 2D and 3D laparoscopic equipment in a laparo-trainer conceived exclusively for pediatric surgery.

Twenty pediatric residents without any laparoscopic experience were randomly divided in two groups and evaluated doing object transfer and simple surgical manoeuvres [Fig 5].

Each student was then asked to fill out a small questionnaire, answering two questions regarding their 3D-experience.

One question was related to the subjective perception of their surgical performance (*Compared to standard 2D laparoscopy, you feel that 3D laparoscopy is: overall easier, approximately the same, overall more difficult?*), the other was related to the side-effects experienced during the exercises (*Did you*

*experience any issue by using 3D laparoscopy: headache, nausea, visual disturbances, others?).*

The Pediatric Laparoscopy Simulator (PLS or endotrainer box) had internal dimensions of 18 cm (length) × 10 cm (width) × 9 cm (height) as described by Nasr [8][Fig 6].

We used two 3 mm working ports and a 5 mm camera port in a typical triangle-shaped position.

Both the 2D and 3D optical systems were mounted to a holding arm and held in a fixed position showing the complete area of interest within the box trainer.

Pediatric residents ( $n = 20$ ) were randomly divided in two groups: Group 1 ( $n=10$ ), in which the participants started with 2D first, and Group 2 ( $n=10$ ), in which the participants started with 3D first.

The study design was explained to each of them, and they gave their consent to participate.

The students then were given a short time (3 minutes) to become familiar with the instruments and in case of the 3D group to get comfortable with 3D vision.

Each participant was assessed during the performance of three tasks, using both 2D and 3D vision, under the guidance of a tutor, who was not blinded to the type of laparoscopy being used.

Each tutor was assigned to a working station and was instructed to observe the participant performing the assigned task by looking at a screen, either a standard HD-2D screen or an HD-3D screen (in this case, using glasses).

Switching the type of vision from 2D to 3D or vice versa, we evaluated bimanual dexterity, efficiency and efficacy; performance was measured using a scoring system rewarding precision and speed.

Tasks accomplished were as follows [Fig 7]:

*Task 1: Transfer of objects*

Participants were asked to pick up six objects (little black caps) from the left side of a pegboard with their non-dominant hand (i.e., left hand), transfer them to their right hand, and place the objects over pegs on the right side and vice versa.

In this task we evaluated:

- Time needed to complete the exercise (*seconds*), considering a maximum time of 5 minutes;
- Errors occurred during the procedure (*numbers* of pegs that could not be transferred in the allotted time).

*Task 2: Pattern cutting*

Precision cutting involves cutting a marked circle with a diameter of 30 mm on a mounted piece of white paper (60 x 45 mm).

Task score was based on:

- Time needed to complete the exercise (*seconds*) considering a maximum available time of 5 minutes;
- Error score (length of deviations > 5 mm in *mm*).

*Task 3: Threading eyelet*

Participants were asked to point and pass a specific 3D object (a little arrow) through an eyelet-shaped support.

Task score was based on:

- Time needed to complete the exercise (*seconds*) in the maximum time allowed of 5 minutes.



Fig 5: students' workstation.



Fig 6: Pediatric Laparoscopic Simulator.



Fig 7: the three tasks accomplished by the residents.

### 3.2.1 Study Endpoints

The use of 3D imaging seems to quantitatively improve and to subjectively facilitate the surgical performance in novices surgeons.

### 3.3 Phase 2 – Study overview

Experimental project comparing 2D versus 3D laparoscopic camera in a set-up standardized and validated for Pediatric Surgeons.

With Storz TipCam 4mm (KARL STORZ GmbH & Co. KG, Tuttlingen, Germany), we performed a comparative study between surgical skills

achievements in experienced pediatric surgeons.

Four skills were evaluated in 2D and 3D modalities.

10 pediatric surgeons [Fig 8] with more than 50 MIS procedures were randomly divided in two groups and evaluated doing in a laparoscopic simulator (iSIM2 – iSurgicals, Chorley, UK) [Fig 9-10] four training modules (“threading”, “suturing”, “tension suturing” and “intestinal anastomosis”) [Fig 11].

Switching the type of vision from 2D to 3D we evaluated bimanual dexterity, efficiency, tissue handling in both modalities.

The camera position was fixed in a standard position for all the participants.

The start point was with the tips of the left and right hand laparoscopic graspers held just outside the ports.

The end point was the removal of the laparoscopic instruments from the simulator on completion of the task.

Time and error rates (missed attempts and failure to complete the task) were recorded.

Inconveniences related to the 3D vision were also recorded.

Tasks accomplished were as follows:

*Task 1: Threading*

Participants were asked to pass a little rope into 6 rings on a pegboard.

Task score was based on:

- Time needed to complete the exercise (*seconds*) in the maximum time allowed of 2 minutes.

*Task 2: Suturing*

Participants were asked to do a continuous suture on a 2 cm long preformed model (close edges).

Task score was based on:

- Time needed to complete the exercise (*seconds*) in the maximum time allowed of 2 minutes.

*Task 3: Tension suturing*

Participants were asked to do a continuous suture on a 2 cm preformed model

with 1 cm distant edges.

Task score was based on:

- Time needed to complete the exercise (*seconds*) in the maximum time allowed of 2 minutes.

*Task 4: Intestinal anastomosis*

Participants were asked to do an intestinal anastomosis on a preformed model.

Task score was based on:

- Time needed to complete the exercise (*seconds*) in the maximum time allowed of 10 minutes.



Fig. 8: surgeon's workstation.



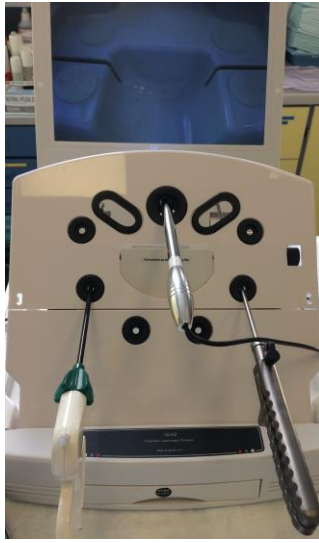


Fig 9: laparoscopic simulator iSIM2 (front view).



Fig 10: laparoscopic simulator iSIM2 (lateral view).



Fig 11: the four training modules for experienced surgeons.

### 3.3.1 Study Endpoints

The use of 3D technology eases complex manoeuvres in small spaces in expert surgeons.

### 3.4 Phase 3 –Study overview

Using Visionsense III Stereoscopic Endoscopy System and Storz TipCam 4mm we performed 40 laparoscopic/thoroscopic procedures in children and neonates hospitalized in our Unit between January 2016 and March 2017 [Fig 12,13,14,15]. Operative time and intra- or post-operative complications were recorded and compared with those of children who underwent standard laparoscopic surgery, performed in the 2D format, during the same time period.

A questionnaire for quality assurance was used.

All surgeons completed the questionnaire after finishing each operative procedure.

Judgment of the 3D system was categorized into four quality aspects.

- *3D monitor* (eye blurring, double vision, image definition, resolution)
- *3D vision of the surgeon* (burning eyes, eye focusing, visual fatigue, visual adaptation)

- *physical complaints of the surgeon during 3D vision* (discomforts, nausea, fatigue, vertigo)

- *3D imaging*

Image definition and resolution were assessed in the categories “very good”, “good”, “fair” and “poor”.

All other categories were judged as being present “not”, “little”, “much” and “very much”.



Fig. 12: operating room overview with Visionsense III.



Fig. 13: intraoperative view.

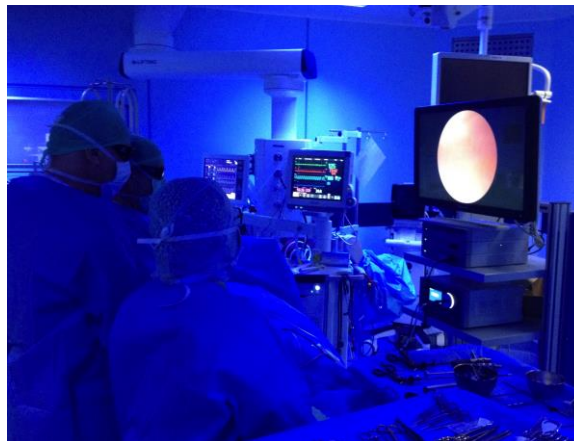


Fig. 14: operating room overview with Storz TipCam.

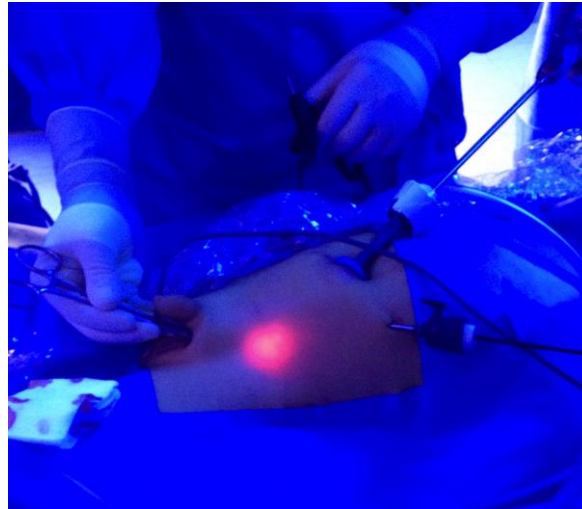


Fig. 15: surgical field.

### 3.4.1 Study Endpoints

The use of 3D technology translates into faster and safer operations in a clinical setting.

## 4 Results

### 4.1 Phase 1

#### *Task 1: Transfer of objects*

Overall task performance (time and number of errors) was significantly better using stereoscopic compared to monoscopic visualization: Time-2D =  $279.8 \pm 52.74$  s, Time-3D =  $180.25 \pm 31.89$ ,  $p = 0,002$  and Errors-2D =  $4 \pm 0.55$ , Errors-3D =  $2.85 \pm 0.35$ ,  $p = 0.001$  (Tab. 1.1).

Taking in consideration both groups, the pediatric residents experienced a 35,6% decrease in the time to complete peg transfer using 3D.

If we consider the two groups separately (Tab 1.2 e Tab 1.3), we can see that in Group 2 there was an improvement in the time needed to complete the task using the 3D camera (2D  $256.6 \pm 70.39$  sec *versus* 3D  $182.6 \pm 52.79$  sec), but this parameter did not reach statistical significance ( $p = 0.073$ ).

In Group 1, the same parameter was significantly better in 3D ( $p = 0.013$ ).

Concerning the numbers of errors, we found a 29% decrease passing from 2D to 3D vision.

#### *Task 2: Pattern cutting*

Overall task performance (time and number of errors) was superior in 3D but did not reach statistical significance: Time-2D =  $311,15 \pm 39,49$  s, Time-3D =  $305,85 \pm 40,07$ ,  $p = 0,84$  and Errors-2D =  $0,25 \pm 0,21$ , Errors-3D =  $0,1 \pm 0,14$ ,  $p = 0.22$  (Tab. 2.1).

Taking in consideration both groups, the medical students experienced only a 1,7% decrease in the time to complete the cutting in 3D.

If we consider the two groups separately (Tab 2.2 e Tab 2.3), we can see the same results.

These results could suggest that for this task it is more important to have a good bimanual dexterity rather than a good 3D visualization; in fact this exercise implies the ability to apply traction, the use of the nondominant hand to create a convenient working angle, and accurate cutting.

#### *Task 3: Threading eyelet*

Overall task performance was significantly better using stereoscopic compared to monoscopic visualization: Time-2D =  $136,5 \pm 21,97$  s, Time-3D =  $93,25 \pm 17,59$  s,  $p = 0,003$  (Tab. 3.1).

Taking in consideration both groups, the medical students experienced a 31,7% decrease in the time to complete the passage of the object through the eyelet in 3D.

If we consider the two groups separately (Tab 3.2 e Tab 3.3), we can see that in Group 2 there is an improvement in the time needed to complete the task using the

3D camera (2D 146,5± 34,52 sec *versus* 3D 105,5± 33,03 sec), but this parameter did not reach statistical significance ( $p = 0.068$ ). In Group 1, the same parameter was significantly better in 3D ( $p = 0.012$ ).

The answers to the *questionnaire* were the following:

*Question 1: subjective perception of surgical performance* (“Compared to standard 2D laparoscopy, you feel that 3D laparoscopy is: overall easier, approximately the same, overall more difficult?”): most participants (65%) “subjectively” defined 3D laparoscopy easier overall. Six participants (30%) did not experience any issue related to the use of 3D technology. One person (5%) from Group 1 found 3D more straining.

*Question 2: Side-effects of 3D-vision* (“Did you experience any issue by using 3D laparoscopy: headache, nausea, visual disturbances, others?”): concerning the side-effects of 3D-vision, we found that 25% of participants reported headache, 20% nausea and 1% visual disturbances.

No side-effects were reported during 2D procedures.

	GROUP 1 + 2		
	2D	3D	<i>p-value</i>
<b>Time (mean ± DS)</b>	279.8 ± 52.74	180.25 ± 31.89	<b>0.002</b>
<b>Errors (mean ± DS)</b>	4 ± 0.55	2.85 ± 0.35	<b>0.001</b>

Tab. 1.1: Results of peg transfer in Group 1 (performance using 2D then 3D) + Group 2 (performance using 3D then 2D).

	GROUP 1		
	2D	3D	<i>p-value</i>
<b>Time (mean ± DS)</b>	303 ± 90.34	177.9 ± 47.21	<b>0.013</b>
<b>Errors (mean ± DS)</b>	3.9 ± 0.98	2.8 ± 0.56	<b>0.041</b>

Tab. 1.2: Results of peg transfer in Group 1 (performance using 2D then 3D).

	<b>GROUP 2</b>		
	<b>2D</b>	<b>3D</b>	<b><i>p-value</i></b>
<b>Time (mean ± DS)</b>	256.6 ± 70.39	182.6 ± 52.79	0.073
<b>Errors (mean ± DS)</b>	4.1 ± 0.71	2.9 ± 0.53	<b>0.007</b>

Tab 1.3: Results of peg transfer in Group 2 (performance using 3D then 2D).

	<b>GROUP 1 + 2</b>		
	<b>2D</b>	<b>3D</b>	<b><i>p-value</i></b>
<b>Time (mean ± DS)</b>	311,15 ± 39,49	305,85 ± 40,07	0,84
<b>Errors (mean ± DS)</b>	0,25 ± 0,21	0,1 ± 0,14	0,22

Tab. 2.1: Results of the cutting exercise in Group 1 (performance using 2D then 3D) + Group 2 (performance using 3D then 2D).

	<b>GROUP 1</b>		
	<b>2D</b>	<b>3D</b>	<b><i>p-value</i></b>
<b>Time (mean ± DS)</b>	317,1 ± 64,43	295,8 ± 60,37	0,59
<b>Errors (mean ± DS)</b>	0,3 ± 0,34	0,1 ± 0,23	0,29

Tab. 2.2: Results of the cutting exercise in Group 1 (performance using 2D then 3D).

	<b>GROUP 2</b>		
	<b>2D</b>	<b>3D</b>	<b><i>p-value</i></b>
<b>Time (mean ± DS)</b>	305,2 ± 59,24	315,9 ± 64,56	0,78
<b>Errors (mean ± DS)</b>	0,2 ± 0,30	0,1 ± 0,23	0,556

Tab. 2.3: Results of the cutting exercise in Group 2 (performance using 3D then 2D).



<b>GROUP 1 + 2</b>			
	<b>2D</b>	<b>3D</b>	<i><b>p-value</b></i>
<b>Time (mean ± DS)</b>	136,5± 21,97	93,25± 17,59	<b>0,003</b>

Tab. 3.1: Results of specific 3D object transfer in Group 1 (performance using 2D then 3D) + Group 2 (performance using 3D then 2D).

<b>GROUP 1</b>			
	<b>2D</b>	<b>3D</b>	<i><b>p-value</b></i>
<b>Time (mean ± DS)</b>	126,5± 32,84	81± 16,31	<b>0,012</b>

Tab. 3.1: Results of specific 3D object transfer in Group 1 (performance using 2D then 3D).

<b>GROUP 2</b>			
	<b>2D</b>	<b>3D</b>	<i><b>p-value</b></i>
<b>Time (mean ± DS)</b>	146,5± 34,52	105,5± 33,03	0,068

Tab. 3.1: Results of specific 3D object transfer in Group 2 (performance using 3D then 2D).

## 4.2 Phase 2

Among the expert surgeons the mean time taken to perform the 4 tasks on the 3D image was generally quicker than on the 2d, but only in exercise 3 and 4 the difference in time was statistically significant [Table 4].

Specialists improved significantly in the more challenging tasks (“tension suturing” and “intestinal anastomosis”) while no significant improvement was noticed in task 1 and 2 in terms of time needed and errors [Table 5].

Surgeons	Time exercise 1 (2D)	Time exercise 1 (3D)	Time exercise 2 (2D)	Time exercise 2 (3D)	Time exercise 3 (2D)	Time exercise 3 (3D)	Time exercise 4 (2D)	Time exercise 4 (3D)
1	3	2	4	3	5	3	15	12
2	3	1	5	3	6	2	17	14
3	4	2	4	3	5	3	16	14
4	3	2	5	4	6	3	17	13
5	3	3	5	4	5	3	18	12
6	3	2	3	3	5	2	19	16
7	2	2	3	2	6	3	17	15
8	3	3	4	2	7	4	16	15
9	2	2	3	2	5	3	17	14
10	3	3	3	2	5	2	15	12

Table 4: operating times of the four exercises.

	Mean time	<i>p-value</i>
Exercise 1 (2D)	3,1	0,33
Exercise 1 (3D)	2,6	
Exercise 2 (2D)	4,2	0,2
Exercise 2 (3D)	3,7	
Exercise 3 (2D)	5,7	0,04
Exercise 3 (3D)	3,9	
Exercise 4 (2D)	17,4	0,03
Exercise 4 (3D)	14,1	

Table 5: *p-values* for the four exercises (2D versus 3D).

### 4.3 Phase 3

16 laparoscopic and 24 thoracoscopic operations (anti-reflux surgery, intestinal biopsies, ovarian cystectomy, thoracoscopic debridement, lung biopsies and thoracoscopic lobectomy) were carried out between January 2016 and March

2017 [Table 6].

The patients of the 3D group were compared with children who underwent standard laparoscopic surgery, performed in the two-dimensional (2D) format during the same time period [Table 7].

The patients were similar in terms of demographics and other preoperative parameters.

There were significant differences in mean operative time between 3D and 2D procedures in the groups of patients with gastroesophageal reflux, which used manipulation with internal sutures (Nissen fundoplication: 62 minutes versus 81 minutes,  $P=0.014$ ) and in the thoracoscopic lobectomy (70 minutes versus 97 minutes,  $P=0.0023$ ) but not in the group of intestinal biopsies (31 minutes versus 38,  $P=0,2$ ) and lung biopsies (29 minutes versus 36,  $P=0,1$ ).

Postoperative parameters such as length of hospital stay and the number of complications were equivalent between two groups.

	Mean time 2D	Mean time 3D	<i>p-value</i>
Nissen fundoplication	62	81	<0,0001
Intestinal biopsy	31	38	0,04
Ovarian cystectomy	50	47	0,29
Thoracoscopic lobectomy	97	70	<0,0001
Lung biopsy	29	36	0,01
Thoracoscopic debridment	62	59	0,53

Table 7: comparison between 2D and 3D operations.

Questionnaire

*3D monitor* (eye blurring, double vision, image definition, resolution).

None of the surgeons complained about double vision and eye blurring problems. Image definition and resolution of the 3D monitor were overall rated as good to very good.

*3D vision of the surgeon* (burning eyes, eye focusing, visual fatigue, visual adaptation of 3D to 2D).

Overall none of the surgeons complained about burning of the eyes.

Eye focusing problems and visual fatigue were seen in none of the cases.

In four cases eye focusing and in two cases tiredness were judged to be much, respectively.

Eye focusing problems and visual fatigue occurred more often during procedures performed in neonates.

*Physical complaints of the surgeon* during 3D vision (discomforts, nausea, fatigue, vertigo).

In 100 % of the cases surgeons complained about none or only little nausea, fatigue or vertigo.

In two cases, overall discomforts such as unease, sickness or tiredness were judged to be barely present, while tiredness was reported in cases of surgical procedures performed in neonates.

*3D imaging* (all over judgment, advantage 3D over 2D).

Overall judgment of the 3D imaging was evaluated to be good to very good.

## **5. Discussion**

### *Phase 1*

One of the recognized limitations of conventional laparoscopy is the lack of depth perception, which represents a challenging issue, especially early in the surgical skills acquisition.

The introduction of robotic technology has addressed this issue by providing 3D

imaging through stereoscopic vision, one of the many attractive features of this technology, which however carries its own cost.

3D imaging is not new to laparoscopy: available studies comparing 2D and 3D laparoscopic imaging show conflicting data concerning a potential benefit of stereoscopic visualization on surgical performance.

This may be attributed to the technology at hand in earlier studies that were not able to show significant difference in surgical performance in both experimental and clinical settings.

In fact, early experience in the 90s was limited by the poor image quality, which did not foster a clinical implementation of the technology.

More recently, industry was able to develop more advanced 3D imaging systems, which can provide a true stereoscopic vision, so that the depth perception is more effectively obtained.

The availability of such systems has generated renewed enthusiasm toward the use of 3D vision for laparoscopy.

As a result, studies have been reported suggesting overall a better surgical performance when using 3D systems during laparoscopic (non robotic) tasks in a preclinical setting.

Stereoscopic vision seems also to improve learning curve in novices.

However, most studies included relatively small numbers of participants (5-10 per subgroup) and/or a small number of phantom tasks with some including non-validated tasks.

Findings from our study suggest that the use of 3D technology facilitates laparoscopic surgical performance of naïve MDs.

Overall task performance (time and number of errors) was significantly better using stereoscopic compared to monoscopic visualization both in task 1 (peg transfer) and in task 3 (threading eyelet).

If we look at the recent literature, Smith et al. [9] also concluded that stereoscopic vision improves novice surgeon performance during acquisition of minimally invasive surgical skills in terms of precision and efficiency.

Honeck et al. [10] highlighted that the advantage of 3D imaging relies on improved spatial orientation and depth perception.

Alaraimi et al. [11] compared the performance of novices with 3D vs 2D laparoscopy using fundamentals of laparoscopic surgery tasks in a randomized trial.

They found that stereoscopic vision translated into an improved accuracy in laparoscopic skills for novices, as manifested by reduced numbers of repetitions and errors.

Also Lusch et al. [12] tested medical students, residents, and expert surgeons; adjusting the results for the surgical level, the results obtained with a 3D camera image were superior in most of the tasks, suggesting a significant improvement in depth perception, spatial location, and precision of surgical performance.

The Authors concluded that expert laparoscopic surgeons as well, may benefit from 3D imaging.

Tanagho et al. [13] also tested their study participants, with a different level of laparoscopic experience, using drills from the validated fundamentals of laparoscopic surgery skill set (peg transfer, pattern cutting, and suturing or knot tying).

A greater speed was recorded for 3D, and also, fewer errors were committed in the peg transfer task.

Subjective impressions of efficiency and accuracy also favoured 3D visualization. The advantage of 3D vision persisted regardless of the participants' level of technical expertise (novice versus intermediate or expert) and participants overwhelmingly preferred 3D visualization.

This was similar to our findings, as most participants (65%) subjectively defined 3D laparoscopy easier overall.

## *Phase 2*

Our study demonstrates that there is a clear advantage of a 3D image over a 2D image in the performance of a laparoscopic task, with regard to the time taken to complete the task.

The explanation for this is multifold: the 3D image confers a superior depth of perception, thereby enabling the surgeon to position the thread in the hoops with greater precision, ultimately leading to quicker task completion time.

### *Phase 3*

3D stereoscopic imaging has not just been applied to television and the film industry, but also to the medical field.

Stereoscopic X-ray devices can provide more realistic images of tissue morphology and anatomy. Therefore, 3D computed tomography (CT) and nuclear magnetic resonance (NMR) have been established.

Filicori et al. [14] presented 3D CT volumetry to predict the outcome of laparoscopic splenectomy for splenomegaly as a predictor of conversion rate from laparoscopy to open surgery.

The use of CT angiography was shown by Mari et al. [15] where 3D reconstructions of mesenteric vessels facilitated later laparoscopic surgery in a randomized controlled trial.

Also 3D sonography for diagnosis and classification of congenital uterine anomalies could improve diagnostic accuracy.

In another study of Sekimoto et al. [16] 3D sonography was shown to visualize the hepatic surface with a high reliability and reproducibility.

The ability to distinguish cirrhotic liver from non-cirrhotic liver improved with the use of the combination of 2D- and 3D- imaging versus 2D-imaging alone.

The application of 3D stereoscopic imaging also included teaching anatomy, digital mammography, diabetic retinopathy, and minimally invasive surgery.

Since the introduction of minimally invasive surgery surgeons have been confronted with numerous handicaps for their learning curve such as loss of binocular vision with loss of depth perception and reduction of dexterity.

Robotic surgery was a challenge with restoration of 3D-vision and dexterity with the "endowrist technology".

Early problems with discomfort, eyestrain or fatigue have been improved and the benefits of 3D to the surgeon have been shown for robotic-assisted performances in an ex vivo model.

With the successful introduction of the robotic system into the fields of urology, cardiology and gynaecology, its use has gradually gained more interest in visceral procedures.

Complex general surgical procedures such as pancreatic, lung and liver resections or sleeve gastrectomies for super obese patients were performed using the robotic minimally invasive technique.

In a meta-analysis robotic gastrectomy for gastric cancer has been shown to reduce intraoperative blood loss and the postoperative hospital length of stay compared to laparoscopic and open gastrectomy at the cost of a longer operating time [17].

Other procedures such as fundoplication, rectal resection and gastric bypass that were performed using the robotic technology could not show any superiority of the robotic system over conventional laparoscopy.

Despite advantages of better accuracy in tissue dissection, depth perception and less tremor of the robotic system limitations such as less dexterity, limited traction, issues with hand-eye coordination and judgment have been reported.

Restoring the 3D vision seems to be an essential tool to improve augmented reality.

Already in 1993, 3D video technique in endoscopic surgery was shown to facilitate complex surgical manoeuvres and preparation in deep spaces.

More enhanced 3D screens and visual technology have been recently developed for conventional laparoscopy where eyestrain and comfort of glasses did not impair vision in limited clinical experiences.

Depth perception was perceived without eyestrain.

Vision was increased and spatial navigation facilitated.



Lusch et al. [18] found in a prospective, randomized comparison of 2D and 3D conventional laparoscopic settings of standardized basic skill tasks a significant improvement in depth perception, spatial location and precision of surgical performance.

Also Cicione et al. [19] described an advantage of 3D over 2D in a comparative assessment using a validated program for laparoscopic urologic skills.

3D visualization produced no more eyestrain, headaches or other side effects than 2D visualization in another work presented by Tanagho et al.

Unlike Storz et al. [20], who could demonstrate superior task efficiency of a 3D HD in comparison with a 2D HD visualization system, Mistry et al. [21] could not find benefits with additional 3D cues in naïve surgical trainees.

Only limited data exist for clinical experiences with stereoscopic visualization.

In a comparison of 3D imaging and 2D imaging for performance time of laparoscopic cholecystectomies, operative time was significantly lower in the 3D group [22].

So far no data concerning the use of 3D laparoscopy or 3D thoracoscopy with children have been published.

3D system equipped with 30° optics has proved to be clearly of advantage due to the better depth perception of the anatomical structures.

Our own data for 3D surgeries indicate no relevant problems with eye blurring or double vision.

Image definition and resolution were judged to be very good or good in all cases, although more problems occurred in very small children as well as eye focusing inconveniences.

These difficulties were mainly addressed to the small distance between the video endoscope and the organ tissue in small children.

Burning eyes, visual fatigue and trouble of visual adaptation of 3D to 2D, or medical discomforts of the surgeon were not relevantly affected.

In none of the cases nausea, fatigue or vertigo occurred.

For children who were two years and younger the distance to the video endoscope

is of crucial relevance.

The image was accurate with a great depth perception and a perfect lighting, regardless of the presence of blood in the operative field; the use of passive polarizing eyeglasses, especially in long lasting operations, required an initial phase of adaption from the surgeon.

Anyway, this system confirmed that 3D viewing eases complex manoeuvres as sutures and dissection in small cavities.

The learning curve seemed less long, especially for less experienced surgeons.

#### *Technical considerations*

Fast movements with the 3D-TIPCAM led to an image blur and in some cases to nausea of the surgeon.

The 0°-3D-TIPCAM had limitations for the inspection of relevant structures because the view was too flat.

The distance between the video endoscope and the instruments or tissue could not be too close, otherwise image definition and eye focusing were not appropriately possible.

A distance of 2,5 metres to 3 metres of the surgeon's eyes to the monitor was necessary to obtain optimal image definition and resolution results.

## **6. Conclusion**

The need for stereoscopic imaging in the medical field increases significantly in accordance with the increasing number of laparoscopic procedures.

The use of 3D imaging seems to quantitatively improve and to subjectively facilitate the surgical performance in our experimental settings.

Participants of all sessions and expert surgeons felt more confident and comfortable when using a 3D laparoscopic system.

Although there are still several optical problems to overcome to realize routine 3D vision for conventional laparoscopic procedures, the advantages of this system may improve surgical accuracy, reduce operative time, and enhance patient safety. Although the benefit of 3D vision in clinical conventional laparoscopic routine remains open to discussion, to us 3D vision has the potential for exponential use and has the potential for overall utilization in the future.

Moreover, the learning curve for laparoscopic training and performance could be shortened for trainees by the use of a 3D laparoscopic camera as opposed to a 2D camera.

We can conclude that 3D laparoscopy confers a shorter operating time, a shorter learning curve, and better depth of perception.

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