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ORIGINAL ARTICLE

Electronic device for endosurgical skills training (EDEST): study of reliability

J. B. Pagador · J. Uson · M. A. Sánchez · J. L. Moyano · J. Moreno · P. Bustos · J. Mateos · F. M. Sánchez-Margallo

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Abstract
Purpose Minimally Invasive Surgery procedures are commonly used in many surgical practices, but surgeons need specific training models and devices due to its difficulty and complexity. In this paper, an innovative electronic device for endosurgical skills training (EDEST) is presented. A study on reliability for this device was performed.
Method Different electronic components were used to compose this new training device. The EDEST was focused on two basic laparoscopic tasks: triangulation and coordination manoeuvres. A configuration and statistical software was developed to complement the functionality of the device. A calibration method was used to assure the proper work of the device. A total of 35 subjects (8 experts and 27 novices) were used to check the reliability of the system using the MTBF analysis.
Results Configuration values for triangulation and coordination exercises were calculated as 0.5 s limit threshold and 800–11,000 lux range of light intensity, respectively. Zero errors in 1,050 executions (0%) for triangulation and 21 errors in 5,670 executions (0.37%) for coordination were obtained. A MTBF of 2.97 h was obtained.
Conclusions The results show that the reliability of the EDEST device is acceptable when used under previously defined light conditions. These results along with previous work could demonstrate that the EDEST device can help surgeons during first training stages.

Keywords Electronic device · Minimally invasive surgery · Surgical assessment · Skills training

J. B. Pagador (✉) · J. Uson · M. A. Sánchez · J. L. Moyano · F. M. Sánchez-Margallo
Laparoscopic Unit, Minimally Invasive Surgery Centre Jesús Usón, Cáceres, Spain
e-mail: jbpagador@ccmijesususon.com

J. Uson
e-mail: juson@ccmijesususon.com

M. A. Sánchez
e-mail: mhurtado@ccmijesususon.com

J. L. Moyano
e-mail: jmoyano@ccmijesususon.com

F. M. Sánchez-Margallo
e-mail: msanchez@ccmijesususon.com

J. Moreno · P. Bustos
Lab. of Robotics and Artificial Vision, University of Extremadura, Cáceres, Spain
e-mail: josemore@unex.es

P. Bustos
e-mail: pbustos@unex.es

J. Mateos
Ingeniería Automatización y Diseño de Extremadura (IADEX), Cáceres, Spain
e-mail: jm.iadex@gmail.com

Background

Minimally Invasive Surgery (MIS) procedures are commonly used in many surgical practices. Laparoscopy is one of the disciplines that has become a gold standard technique in several of such procedures, although they need specific training models and devices [1,2]. Laparoscopic surgery has some associated problems such as the lack of tactile perception, movement coordination or adaptation to the two-dimensional image. These problems should be resolved during the first training stage [1]. Usually, specialized postgraduate courses are carried out by surgeons to solve these problems, but objective assessment tools are not available in all of them. Currently, these objective assessment criteria are the subject of numerous studies.

The Fundamentals of Laparoscopic Surgery (FLS) has been created by SAGES to regulate the laparoscopic training [2–4]. This education module includes the cognitive, decision-making and surgical skills tests. The McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) program [5,6] was used and customized for the FLS program. The Objective Structured Clinical Examination (OSCE) technique is another commonly used method for measuring surgical skills [7]. The clinician is examined in a series of short station (5–10 min) by impartial examiners. The Objective Structured Assessment of Technical Skills (OSATS) is a usual one too [8–10].

An operator usually is needed for the application of the techniques described above, although some efforts have been made to automate them. An electromagnetic tracker has been used to develop the Imperial College Surgical Assessment Device (ICSAD) [11–14] and significant results have been obtained in different disciplines [15–20].

Other medical disciplines such as nursing or anaesthesia have devices equipped with highly accurate sensors. These human patient simulators (HPS) are widely used in training and some well-known examples are SimMan by Laerdal [21] or iStan by METI [22]. They are fully computerized simulation mannequins with high fidelity in the physiological behaviour of the human body. Anaesthesia practice [23], radiology resident evaluation [24], nursing education [25] and CPR training [26] among others are common applications of the HPS.

Laparoscopy is often used for other training devices such as pelvic trainers or virtual reality simulators. Although in recent years the use of the computer-enhanced technologies are higher regarded than the ones based on virtual reality among surgeons and medical students [27,28]. There are some accepted and validated hybrid systems of which ProMIS [29], LTS3e [30], CELTS [31] and Red Dragon [32,33] are the most important ones. Augmented and virtual reality are used by the ProMIS simulator to deliver optimum learning and feedback. It comprises different modules: basic skills, laparoscopic colectomy [34] and FLS [35]. Even a junior version (ProMIS-J) has been developed to promote the practice only. The LTS3e self-container simulator uses a structured testing and training of skills. It combines a carousel of physical reality tasks with computerized assessment using validated MISTELS metric [36]. An embedded metric algorithm is used by the CELTS prototype to automatically score the basic surgical skills [37]. Force and torque measure is an important feature added in the Red Dragon simulator [38]. Several modalities such as using animal models or physical and virtual simulation are also possible. The Red Dragon will be marketed by Simulab Corporation with the name of 'the Edge'. Recently, Botden and Jakimowicz [39] have performed a review of all the augmented reality simulators described earlier.

Some recent developments are presented by Noh et al. [40] and Solis et al. [41] where different sensors are used to assess airway management and suture skills respectively. As far as we know, current training systems do not allow training and objective assessment of the triangulation manoeuvre. This work attempts to solve this need.

A major challenge of training systems is to demonstrate its impact on the learning curve. To achieve this, some interesting studies on this regard have been conducted with no conclusive results [42–44]. Additional studies have been developed to analyse the transfer of skills to the Operating Room [45,46]. These studies show that skills transfer occurs in some surgical procedures but not for all analysed concepts.

Reliability and validity tests are performed to demonstrate the utility of any training system [47–49]. These tests are performed to demonstrate that the system is 'consistent in its measurements' (reliability) and 'acceptable in its operation' (validity) [50]. In our experience, a further step may be necessary to achieve greater acceptance of virtual and hybrid systems by surgeons. An estimate of the simulator failures (reliability engineering) is needed to ensure the smooth running of them. The IEEE defines reliability as the ability of a system or component to perform its required functions under stated conditions for a specific period of time [51]. This study has been focused on this kind of reliability.

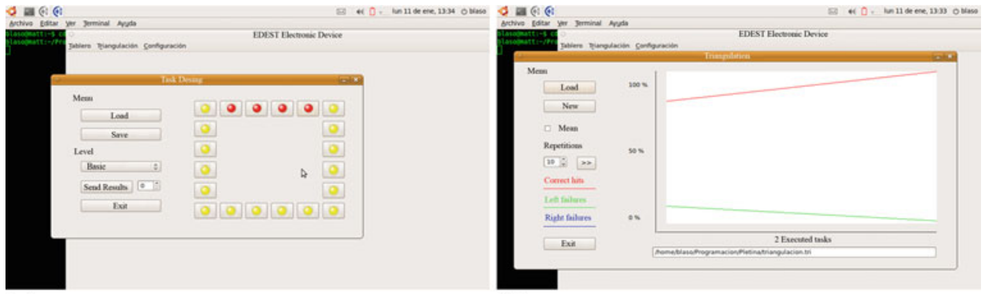
In this paper, a reliability engineering study for the electronic device for endosurgical skill training (EDEST) is presented. A review of its features, advantages and drawbacks are exposed, and finally, some future works and improvements are introduced.

Material and methods

In this section, an electronic device for endosurgical skills training (EDEST) is presented. The EDEST system can measure the total time and fully executed tasks of two basic laparoscopic training procedures: triangulation (one-point coordination) and coordination (grasping and moving) manoeuvres.

EDEST device functions

The EDEST® electronic device includes two tasks for laparoscopic basic training: triangulation and coordination manoeuvres. The first one uses two infrared leds in order to detect the correct coming together of both tooltips at the same time and to the same point. The second exercise is based on covering sockets with chickpeas, beans or drawing pins. These sockets are equipped with light-dependent resistors (LDR) that check the total time and the fully finished task. The system has an standard calibration ("Device and equipments") in order to assure the correct luminosity setting of sensors.



(a) (b)

Fig. 1 The EDEST application can set and analyse the collected data from EDEST device. **a** Snapshots of the triangulation menu and **b** the coordination menu

Triangulation manoeuvre

Novice surgeons must practice the coordination of movements with both hands and achieve an adaptation to the two-dimensional image [1,2]. The EDEST device allowed this initial phase of training with the instrument triangulation task. To perform triangulation, manoeuvre surgeons must move the tip of the two surgical tools closer to the target. A sensorized target was mounted in the EDEST device, and correct movement was counted if both tooltips reach the target with less delay than the designed threshold limit. During the experiment, 10 repetitions needed to be done to complete each triangulation exercise. All occurrences properly complete are required to complete the exercise.

The EDEST software can analyse the collected data from device (as shown in Fig. 1) and shows a graphics with correct and wrong manoeuvres.

Coordination manoeuvre

The exchange and handling of objects are other basic skills that need to be acquired by novice surgeons [1,2]. The EDEST device has a movement coordination board with a series of wells where different smooth and rough surface objects can be placed. These did help the surgeon to get used to the two-dimensional image, learn to calculate distances and perfect their skills handling gripping instruments. Different levels of difficulty were adapted in order to suit the training to the surgeon's experience. During the experiment, 6 sockets needed to be covered to complete each coordination exercise. The exercises changed its difficulty depending on the object used.

The EDEST software (Fig. 1) can set the coordination board with different exercises and show the results of the executed tasks.

Device and equipments

The patent pending training system consists of an electronic device that allows an objective, automatic and adaptable

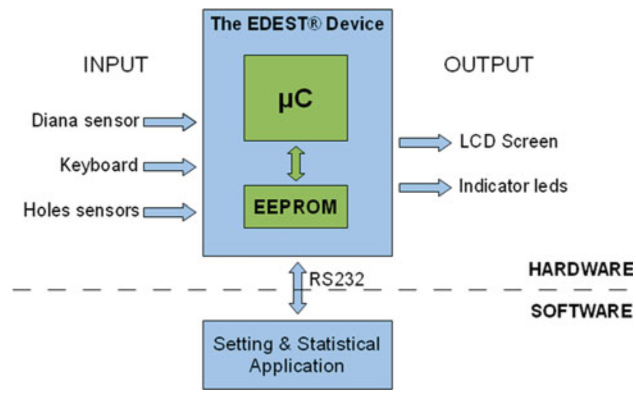


Fig. 2 General view of the EDEST® device: main components, I/O system and communication port

learning model possible. This autonomous device was composed by a microcontroller (μC) processor, an internal memory (EEPROM I2C) and several input and output interfaces (sensors, mini-keyboard, LCD screen and leds). A general scheme is shown in Fig. 2. For the design and construction of this new device was used the AVR Studio 4 with C language to program the microprocessor and the WinAVR 20090313 was the selected compiler. The electronic schemes were developed with EAGLE, and the components were assembled manually using a JBC® soldering station.

Calibration protocols

A previous calibration of the device EDEST was necessary before carrying out the experiment. The settings of the device were obtained in this calibration stage. Two experiments were conducted: first, an experiment with expert surgeons to define the threshold of the target time for the triangulation task, and secondly, a calibration protocol for optimal light conditions for device operation coordination task.

First, the time scored by expert surgeons was taken as references to set the sensibility of the infrared LED of the target. A total of 5 experienced surgeons were used to perform triangulation exercise and they made 10 repetition. The time

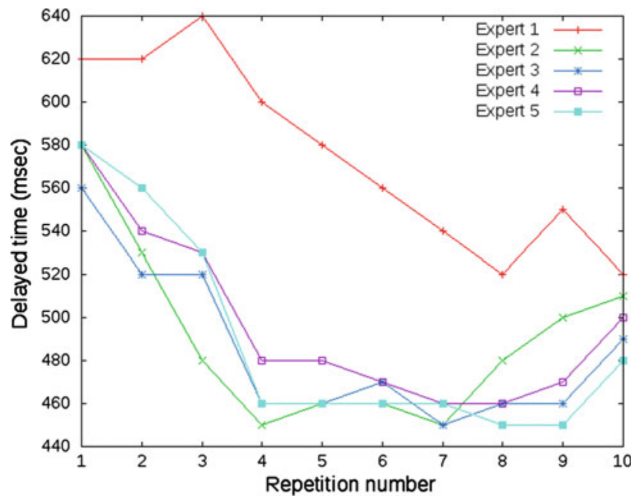


Fig. 3 Obtained time delay for triangulation exercise calibration. Values were obtained to measure time in msec between the right and the second hit to the target or viceversa

delay between a hit with the right tooltip and the one left was registered. A limit threshold to be considered a success was determined in this experiment. Figure 3 shows the obtained time delay between the right and the left tooltip to achieve the target by expert surgeons. A threshold limit of consensus was established in 0.5 s.

Secondly, a detailed study of the operating theatre conditions was developed in order to assure the proper works of the EDEST device. This device (Fig. 4) can be used with three mainly conditions of light: ambient (operating theatre lighting), Simulap IC-05 (internal led system) and laparoscopic light source. A luxometer was used to define patterns of light with the help of a calibration grid placed inside the boxtrainer. The grid was composed of 30 cells (5 columns and 6 rows). In each cell, a measure was taken with the luxometer. A two-dimensional array of light intensity was obtained for each type of light. Three data collections were performed for each type of light. A statistical analysis was done for each type of light, obtaining the mean and standard deviation. The best performance of the device was obtained with a range of light intensity of 800–11,000 lux. These values correspond to the pattern of light boxtrainer Simulap IC-05 (see Fig. 4).

A dynamic calibration of the sensors of the coordination exercise was developed for ideal lighting conditions calculated previously. This calibration was developed using four LDR sensors as reference. A balanced control of the distribution of light intensity was carried out to avoid failures of sensors on board during the conduct of exercises.

A threshold limit is calculated continuously with its current value and the values of the two closest reference sensors. The first Eq. 1 was used for the middle bowls, and the second one Eq. 2 was used for the outside bowls. This second Eq. 2 is needed for bowls without available reference sensor, in which case the value of neighbour sensor is used.

$$T_s = 0.25\left(x_s \frac{(k_{s1} + k_{s2})}{2}\right) \quad (1)$$

$$T_s = 0.25\left(x_s \frac{(k_{s1} + y_s)}{2}\right) \quad (2)$$

where

T_s is the limit threshold for the sensor
x_s is the sensor current value
y_s is the sensor neighbour value
k_{s1} and k_{s2} are the current values of the reference sensors

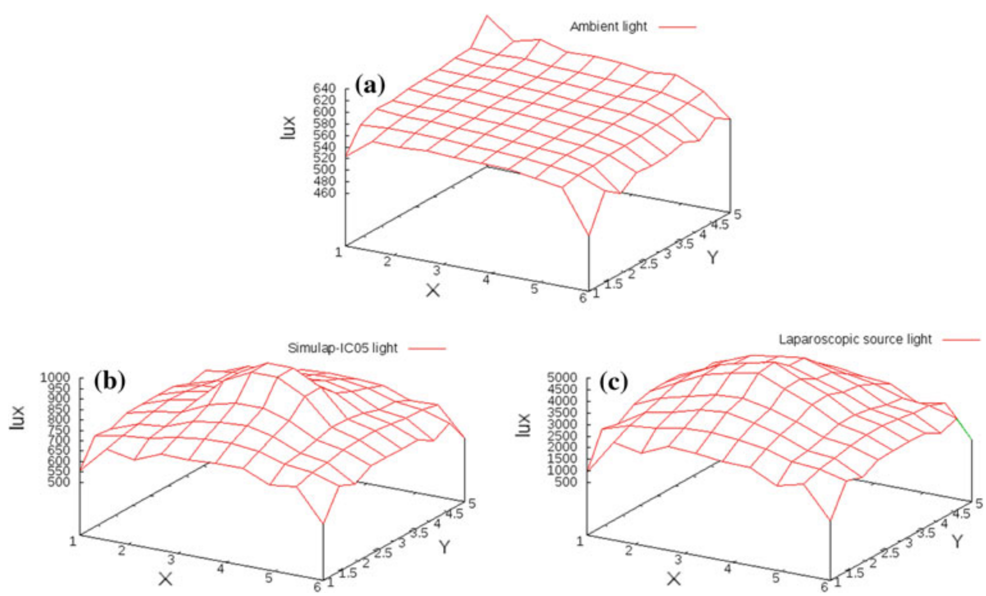


Fig. 4 Three different conditions of light were available into the operating theatre: **a** Ambient light, **b** Simulap IC-05 boxtrainer light and **c** Laparoscopic light source. These graphs show the patterns of light sources described previously

Reliability test

The experimental design used in this study is a reliability testing. System failures in the two basic laparoscopic tasks were analysed. The successes in the target and placement of objects in the sockets were recorded by technicians to check the errors made by the device. A Mean Time Between Failures (MTBF) [52] was calculated for the EDEST device. This basic measure of reliability for repairable items can be described as the time that pass before a system fails.

$$\theta = \frac{1}{\lambda} = \frac{\sum T_{Di} - T_{Ui}}{N_f} \tag{3}$$

where

Θ is the Mean Time Between Failures
λ is the failure rate
$T_D i$ is the failure downtime
$T_U i$ is the uptime of the device
N_f is the number of failures

An exponential distribution is used for statistical analysis of the results. This distribution is commonly used to model items with constant failure rate, and it describes the times between failures in a Poisson process.

The probability density function is defined as:

$$f(t) = \frac{1}{\theta} e^{-t/\theta} = \lambda e^{-t\lambda} \tag{4}$$

And the reliability function is defined as:

$$R(t) = \lambda e^{-t\lambda} \tag{5}$$

A total of 35 surgeons were chosen to constitute the final sample of this study. The subjects were grouped depending on their skill level: 8 experienced surgeons (more than 100 performed procedures) and 27 novice surgeons (inexperienced laparoscopic surgeons).

The experiment was carried out using the physical laparoscopic trainer Simulap-IC05. The performed tasks were displayed on a monitor. These images were collected by the internal camera of the Simulap-IC05. The EDEST device was placed inside the physical simulator, and 35 surgeons performed the basic laparoscopic exercises explained earlier ("EDEST device functions"). Two curved jaws dissectors were used for the triangulation manoeuvre (task 1) and two grasping forceps, chickpeas, beans or drawing pins were used for the coordination manoeuvre (task 2). Each subject performed repetitions of each exercise 3 times.

The MTBF analysis was selected because the EDEST device can be considered a repairable product. To develop the tests, clinical training conditions were reproduced by the subjects as shown by the tasks listed earlier. Triangulation or coordination failures may occur during the training process to be solved by rebooting the system. These failures can be due to electronic or microcontroller components and need to be predicted to ensure reliability of the device. Finally, downtime and recovery time of the system are recorded.

Fig. 5 Prototype version of EDEST® System

In summary, as far as we know, the EDEST® is an unique hybrid training system that implements an objective and automatic exercise for triangulation surgical tasks (one-point coordination manoeuvre). Moreover, it has some sockets with light-dependent resistors in order to assess the bidimensional coordination tasks (grasping and moving). The prototype of the EDEST device and a photograph of final assembly of the experiment can be seen in Figs. 5 and 6, respectively.

Results

Zero errors in 1,050 executions (0%) of the system while the first task was being performed and 21 errors in 5,670 executions (0.37%) with the second task. A test time of 72 h was used and 9.55 h of failure time were registered. Therefore, a MTBF of 2.97 h was calculated. Failure per hour for every 3 devices can be deduced from this value. A failure rate of 0.34 was obtained using the above-mentioned expressions 3 and 5. The resulting exponential distribution is shown in Fig. 7.

Although previous literature indicates the reference values of MTBF for surgical training devices have not been found, a

Fig. 6 This photograph shows the testing conditions of the experiment: **a** Surgeon performs a training task with the EDEST device and **b** Screen shot of the monitor view

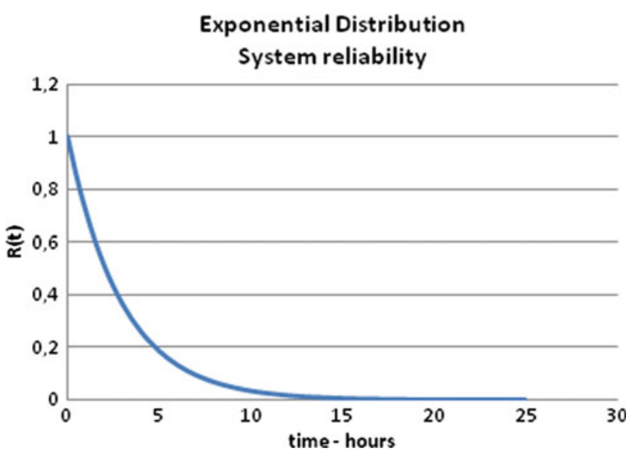


Fig. 7 The system reliability using an exponential distribution

Table 1 Expected values of the future reliability using the ITT Research Institute references.

Time	R (t)	Survival (%)	Failure (%)
0	1	100.00	0.00
25	0.98	97.53	2.47
50	0.95	95.12	4.88
75	0.93	92.77	7.23
100	0.90	90.48	9.52
125	0.88	88.25	11.75
150	0.86	86.07	13.93
175	0.84	83.95	16.05
200	0.82	81.87	18.13
225	0.80	79.85	20.15
250	0.78	77.88	22.12
275	0.76	75.96	24.04

First column defines time in hours

table of typical values [53] defined by IIT Research Institute has been used. According to this table, a personal computer (MTBF of 1,000–5,000 h) was considered the most similar equipment to the EDEST device. To achieve this reference value, the Table 1 with hypothetical values of the exponential distribution model is showed below. With these values, for a time of 72 h (total test time), the device would have a 7 per cent failure probability. This value is obtained during an operating time of 12 min per the device tested.

Discussion

A new approach to the concept of reliability in surgical training devices has been introduced in this paper. Reliability can be understood in two different ways: smooth running probability (engineering) and consistency of a set of measurements (statistics). This study has been focused on the first one: reliability engineering.

To our knowledge, there are not any published data on reliability engineering for other surgical training systems. Therefore, a qualitative comparison is presented in this discussion with other hybrid simulators.

A personal computer (PC) is needed by current laparoscopic hybrid simulators. The EDEST device can operate independently without a PC. This feature makes it portable and easy to use for surgeons. A connection to a computer out of the training session can be done. Uploading new exercises (beforehand) and downloading the results (afterwards) are allowed by the device's software.Other hybrids simulators have coordination tasks (different exercises with similar manoeuvres). As far as we know, the triangulation task is only performed by the EDEST device. Evaluation metrics similar to other hybrid simulators have been used: errors and spent time. These basic surgical tasks have been extracted from a training model based on more than 20 years of experience.

Face and content validity studies of the EDEST device were developed by Sánchez-Margallo et al. [54]. A group of 27 non-experienced surgeons (attendants to training courses) and 4 expert surgeons (regular teachers) were used to perform face and content validity, respectively. Surveys are composed by 16 questions using a 5-point Likert scale. The apparent evaluation (face validity) shows a good acceptance of the device: easiness of use (92.6%), usefulness of triangulation task (85.1%) and usefulness of coordination task (88.8%). On the other hand, the content evaluation (content validity) shows a full acceptance (100%) of teachers of the above three concepts.

MTFB value has been used in this study, but values such as MTTF (Mean Time To Failure) can be added in future works.

The obtained results determine the engineering reliability of the device needs to be improved for the coordination task.

Conclusions

Novice surgeons must complete the first stages of training correctly before accomplishing more advanced tasks [1,2]. Objective assessment methods can be useful for mentors in order to certify the proficiency of future surgeons.

Calibration protocols obtained a stable and useful configuration for the EDEST device in order to use it in training models. Obtained results can conclude that the EDEST device presents a good reliability in its triangulation task.

A face and content validity studies [54] of EDEST® device are accepted that proves its usability and acceptance. The patent pending device will be integrated on the training model of an institution devoted to researching and training in MIS techniques for more than 20 years.

Some increasing validity studies will be carried out in order to show the robustness and reliability of this system. A more complex calibration will be developed in order to adapt the system to different light conditions.

Future developments will be focused on improving the system with an image-processing module and an augmented reality haptic (ARH system) that complement current assessment of the EDEST® device already available. A future hybrid simulator will be integrated with these three components.

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