Original Article

A Preliminary Study on the Use of an Automatic Trocar for LAparoscopic Surgery (ATLAS)

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A B S T R A C T

Purpose- This article is dedicated to introduce an Automatic Trocar for LAparoscopic Surgery (ATLAS). The first step in laparoscopic surgery is the port insertion which is known as the most important and potentially dangerous step. An inaccurate Veress needle placement or uncontrolled overshoot of a sharp, blind trocar toward the viscera are the common causes of an unsuccessful procedure. Therefore, a mechatronic device was designed and developed to overcome the shortcomings of the current port insertion techniques.

Methods- The system incorporates an automatic insertion apparatus and an automatic stop mechanism to halt the procedure upon reaching the abdominal cavity. A motor was provided to pass the needle through the abdominal layers and a pressure sensor was provided to detect reaching peritoneum and stop the entry mechanism.

Results- The system was tested on an anesthetized canine. ATLAS system stopped upon reaching its peritoneum and avoided injury to intra-abdominal organs. Subsequently, the position of the needle tip was evaluated using another endoscope.

Conclusions- The animal test of the system was promising and showed the potential of this system and its improved version in laparoscopic surgeries.

Keywords:

Medical instrumentation,

Laparoscopic surgery,

Gynecologic surgery,

Automatic insertion,

Mechatronics.

1. Introduction

The first and the main step toward an efficient and safe laparoscopic surgery is successful laparoscopic access to intraperitoneal space with a minimum risk of complications, such as bowel, bladder, or vessel injury during insertion of the insufflation needle and/or trocar [1]. Currently two methods are being used for intra-abdominal access named as closed and open techniques. In the closed technique, after insufflation of the peritoneal cavity with CO_2 gas via a hollow needle called Veress needle, the non-optical trocar penetrates the abdominal wall layers blindly to introduce the laparoscope into the peritoneal space [1, 2]. On the other hand, entering to the abdominal cavity using the open technique (Hasson) is associated with mini-laparotomy [3]. Both techniques suffer from probable sudden uncontrolled overshoot of the sharp instrument which can cause an injury to the intraperitoneal organs as well as wrong placement of the Veress needle or trocar in the abdominal wall which results in a procedural failure [4].

In order to provide an entry under the direct visual control of the surgeon, optical Veress

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needles and optical trocars were developed [5]. Ternamian Threaded Visual Cannula (TVC) EndoTIP system (Karl STORZ GmbH Tuttlingen, Germany) is one such instrument that introduces an incremental measured entry instead of sudden and uncontrolled entry under the endoscopic guidance [6, 7]. However, human control may introduce the danger of probable unintentional downward force and also the deceptive images with difficult interpretation for the surgeon may result in an incorrect positioning of the cannula [4].

Another system to help in correct placement of the Veress needle was a sensor-equipped Veress needle (Marlow Surgical Technologies, Inc., Willoughby, US-OH) developed by Janicki, which was the only automatic system to sense the peritoneal cavity and alarm the surgeon [8]. Neither further studies evaluating the risk profile of this method have been published to date [9] nor the risk of overshoot under the hand guidance was eliminated. On the other hand, the company seems not to supply the device anymore [10].

In spite of the diverse techniques for laparoscopic entry, there is still no unique, safe and optimal method to introduce the central trocar [11]. Therefore, it is believed that the best technique to access the uterine cavity has not yet been found [12]. Even the European Society for Endoscopic Surgeons (EAES) could not give any strong recommendation in their guidelines of 2002 favoring a safe access technique for laparoscopy [13].

In this study a mechatronic system was developed to overcome the aforementioned problems while combining three benefits. The Automatic Trocar for LAparoscopic Surgery (ATLAS) was designed to 1) enter through the abdominal wall automatically to provide a constant and easy entry without a danger of overshoot, 2) stop automatically when the peritoneal cavity is reached to avoid probable injury to the intra-abdominal structures, and 3) expand to the proper diameter to reduce the need for suturing and facilitate faster wound healing. These capabilities were provided by combining the advantages of current entry devices and novel ideas. To the best of authors' knowledge, no previous study has been published about a system with an ability to adjust the entry mechanism automatically.

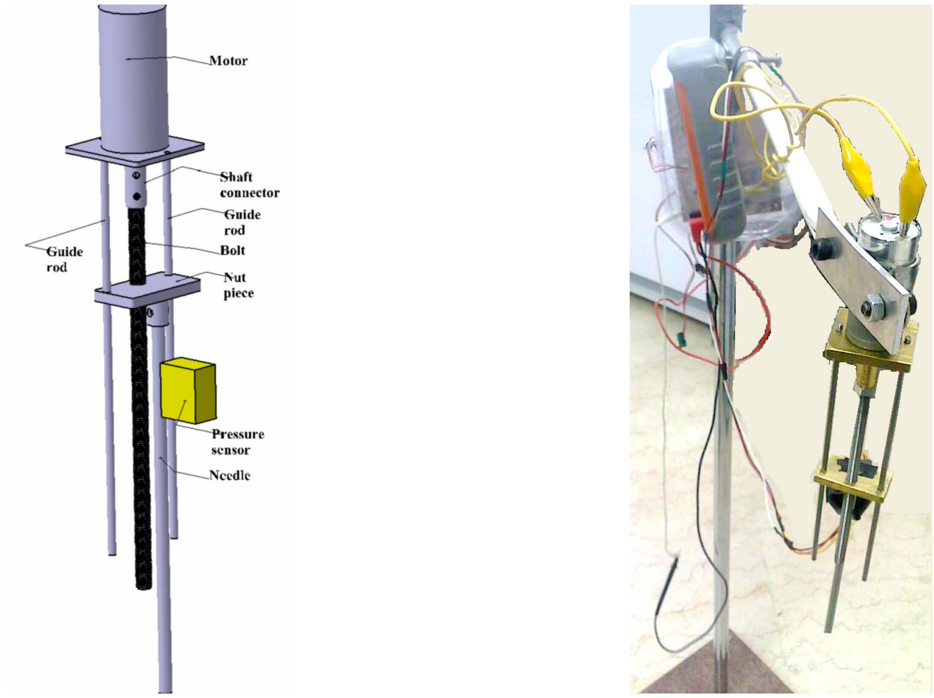
2. Materials and Methods

2.1. Entry Mechanism

The entry system of ATLAS was developed in such a way to benefit from advantages of TVC EndoTIP system while obviating the need for human control. The entry mechanism incorporated a DC motor (DC GEAR 12 V 103 RPM, Shenzhen Guiyuan Industry Development Co., China) with a safe and constant speed and enough torque (13 kg.cm) to penetrate through the abdominal wall layers. The ubiquitous motor driver was designed using four medium-power transistors and two switches to determine the rotation direction. A pair of bolt and nut was used to convert the rotation motion of the motor to linear motion. A hollow needle was attached to the nut piece to move downward during the rotation of the motor which performed the same as the sharp trocars in routine procedures. The penetration speed of the entry part was measured as 1.2 mm/s which resulted in an abdominal insertion within less than one minute.

2.2. Stop Mechanism

The ATLAS system was designed to be used as a first route to the peritoneal space without a need for pre-insufflation. Therefore, it could detect the intraperitoneal negative pressure to provide an automatic stop upon reaching it. A differential pressure sensor (MPXV5004DP, Freescale Semiconductor Inc., US-TX) was utilized to sense the negative pressure of the peritoneal cavity. The sensor was mounted on a small printed circuit board (PCB) to be connected to the main electronic board. The PCB was glued to the needle in order to hold it in place. The sensor could detect up to about 30 mmHg differential pressure. The vacuum side of the sensor was positioned interconnected with the hollow needle of the ATLAS system while the other side was in ambient air exchange. The output of the sensor was amplified and compared with a threshold voltage (1.4 V) corresponding to a pressure of about 2 mmHg. The amplifier and comparator circuits were designed using low power operational amplifiers to turn the motor driver off upon reaching the threshold pressure. An electronic board was provided to include the DC motor driver, amplification and comparator circuits. Figure 1 shows the 3D scheme of the ATLAS system in CATIA program and a photo of the real system.



(a) (b)

Figure 1. (a) The 3D design of the ATLAS system with the corresponding part labels. (b) A photo of the ATLAS system showing the entry apparatus and the sesnsor attached to the needle. Also, the electronic control board and a voltmeter to read the output of the pressure sensor can be seen on the left side of the picture.

2.3. Self-Expansion Mechanism

In order to cause less abdominal wall bleeding and postoperative pain and to eliminate the need for suturing the fascial defects after surgery, the feasibility of implementing a self-expansion capability in the penetrating needle was investigated. The mechanism can incorporate a radially expanding polymeric sleeve which is left in place while the needle is removed like the VersaStep (Covidien, Norwalk, US-CT) access system [14]. A braided polyester sleeve was placed inside the thick enough hollow needle of the ATLAS system. The sleeve was supposed to act as a tract through the abdominal wall that can be dilated up to 10 mm by inserting a blunt obturator with a twisting motion.

2.4. Animal Test

In order to test the feasibility of using this technical design in real–world, a preliminary animal test was performed. The developed ATLAS system was tested on an anesthetized canine. It was treated based on the ethical protocol of Tehran University of Medical Sciences. The ability of the device to stop automatically in addition to the strengths and weaknesses of this design was under investigation. After stopping the needle, its position was checked by an endoscope which was introduced through another distant position.

3. Results

The ATLAS system was positioned above the canine's abdominal skin by a ceramic foundation and L-shaped metal connectors (Figure 1(b)). The basement was put on the ground beside its bed. In order to facilitate the insertion of the device, two clamps were holding and elevating the canine's skin as it is done in routine procedures.

The single entry to peritoneal cavity of a canine was performed after a vertical incision of about 1 cm wide on its abdominal skin. The needle of the ATLAS system was positioned in contact with the fascia. Then, the system was turned on and the needle was being inserted into the abdominal wall until it stopped automatically. The insertion procedure took less than one minute. At that point, the output of the pressure sensor was read from a voltmeter attached to the electronic board. It was corresponding to an intraperitoneal pressure of -2.8 mmHg. In order to verify the ATLAS system functionality, another trocar was inserted through a distant position from the first one to introduce an endoscope to the peritoneal cavity. It showed that the needle tip was tangent to the peritoneal membrane. Figure 2 shows the ATLAS system during the animal test.

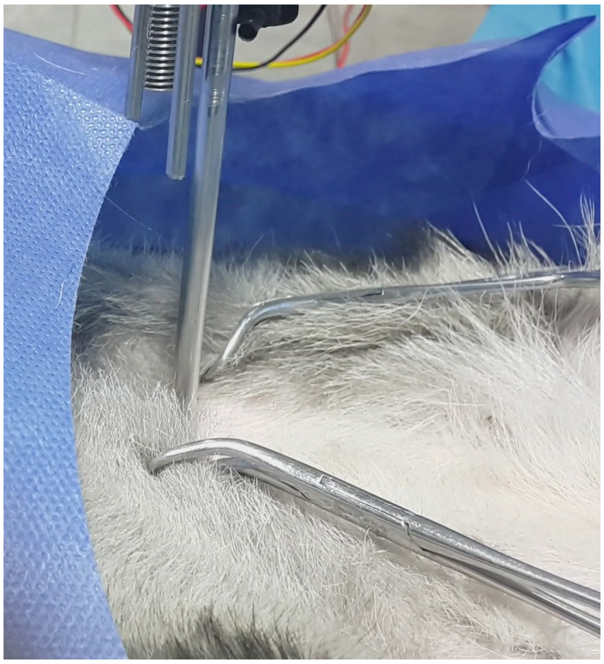


Figure 2. ATLAS system during the animal test. Two clamps to elevate the abdomen skin can be seen. Two guide rods and the bolt to produce the linear motion of the inserted needle are shown too. Besides, the pressure side of the sensor in exchange with air is visible on top of the picture.

4. Discussion

A prototype of an automatic trocar for laparoscopic surgery, named as ATLAS, was developed. The purpose of ATLAS system was to prevent side effects of laparoscopic surgery, like bowel injury, by providing a steady entrance of the access device and automatic stop upon arrival to the peritoneal cavity.

Although visual-based methods have been introduced to reduce the laparoscopic surgery complications, it was shown that the open technique did not reduce the risk of major complications compared with the blind pneumoperitoneum [15]. The technique is too subjective as it depends strongly on the capability of the surgeon to differentiate between the anatomical structures of the abdominal wall and adhesive intra-abdominal contents [16]. Although using the optical trocar can display the vital structures behind the peritoneum, they may be seen too late to avoid an injury [12]. Finally, high cost of the single-use instrument prohibit the routine use of this method [16]. Therefore, the ATLAS system was developed based on a physical characteristic of the abdominal cavity (pressure difference) rather than visual judgment of the surgeon. Currently reading the initial intraperitoneal pressure (4–10 mmHg) or hanging drop of saline test are used to ensure a correct placement of the Veress needle but none of them completely prevent intra-abdominal organ injury [17].

In fact, the ATLAS system can be categorized as a direct entry method without a need for pre-insufflation. The direct access technique is superior to the Veress needle in terms of less operative and anesthesia time and less necessity of equipment and carbon dioxide [12]. A successful direct access requires a sharp trocar, otherwise it pushes the abdominal wall back onto the bowel and vessels without insertion to the peritoneal cavity [12]. According to the animal test, it was found to be a probable mishap for the ATLAS system. However, tangency of the needle tip to the peritoneal membrane was due to the fact that insertion of the ancillary trocar made such a considerable movement that shifted the ATLAS needle from its primary position. The vacuum pressure sensed by the sensor and read from the voltmeter was an evidence for this claim. The ATLAS system stopped upon the detection of -2.8 mmHg pressure during insertion to the canine's abdominal cavity. This pressure was in accordance with the Janicki's study in which such a pressure was detected in 9 out of 11 patients [8].

In order to produce a fascial incision with smaller diameter and make the system simpler and lighter, a straightforward insertion of a sharp needle was selected in lieu of a screw-like movement of a blunt cannula. However, in addition to the aforementioned dullness problem, a sharp needle as well as a sharp trocar can demonstrate larger fascial and muscle defects at the port site. It results in the inhibition of tissue recoil mechanism which necessitates suturing of the abdominal wall [18, 19]. In return, it can result in more postoperative pain, slower postoperative recuperation and longer hospitalization course of the patient. Therefore, it was concluded that an entry port similar to the TVC EndoTIP can perform better than the current design. It can lead to lower incidence of incisional hernia and requires less penetration force [18, 19]. However, two motors should be utilized to provide both linear and rotational movements that can make the system more complicated and heavier.

The automatic entry is necessary to provide more safety during the application of needle or trocar. The aapplication of an uncontrolled linear entry force to a sharp blind device toward the viscera, without any mechanism to temper penetration force, gage insertion depth, and avoid sudden uncontrolled overshoot can injure the bowel or other intraperitoneal organs [4]. To the best of authors' knowledge, no automatic entry mechanism has been developed for laparoscopic surgeries so far. The steady entrance of the ATLAS system was both slow enough to be safe and fast enough for a clinically acceptable procedure. The speed of the entry system is comparable with Visiport Optical Trocar with 38 ± 12 s access time to the pre-peritoneal space [20]. Furthermore, it is less than the TVC EndoTIP, direct access, Veress needle and open access techniques with 1 – 4 min [4], 1.5 ± 0.5 min [21], 3.0 ± 0.4 min [21] and 3 – 10 min [22] access times, respectively.

The self-expanding braided polyester sleeve was applied after insertion of the needle to the peritoneal cavity of the canine. It was deduced that it should cope with two problems including 1) difficult passage through the needle and 2) displacement during the needle withdrawal. The first one can be avoided by applying a greasy material within the needle and covering the sleeve with it. Also, increasing the internal diameter of the needle can facilitate the passage of the sleeve through it. However, it results in a thicker needle and subsequent wider tissue defect. On the other hand, the latter problem is a challenging one without an available and easy solution. Specifically, because the force required to push the blunt trocar through the sleeve is about 3 times the disposable trocars [19], it can displace the sleeve or pierce it. Changing the design of the needle to a threaded blunt-tipped trocar with a routine diameter of 10 mm will obviate the need for self-expansion capability. It is another option to be incorporated in the current ATLAS system toward its evolution.

In conclusion, the idea of automatic entry is feasible and it not only reduces the risk of injury to the internal organs, but also helps the surgeon to enter the abdominal cavity without the exertion of a significant force. The ATLAS system integrates the advantages of the commercial systems and new ideas to overcome the shortcomings of the current techniques. The animal test was promising enough to encourage the authors to improve the system by maximizing the strengths and minimizing the weaknesses. Therefore, changing the design of the entry system while keeping the main idea of the automatic stop intact, can improve the system. The refinement of the system is in progress to provide a system with fewer complications for the main port entry in addition to present a platform for future remote tele-presence laparoscopic surgeries.

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