

## MEDICAL TECHNOLOGY

# Self-Expanding Entry System for Laparoscopic Surgery

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### ABSTRACT

**Introduction:** Statistics indicate that 90% of injuries incurred during laparoscopic surgery occur during the trocar insertion. There are a number of commercially available alternatives to traditional trocars; however many of these systems are complicated to assemble, difficult to use, and expensive. The purpose of this article is to describe the self-expanding entry system, a new design of an access system for laparoscopic surgery that addresses weaknesses of current commercially available models.

**Design Solution:** The new system consists of a Veress needle, an expandable nylon sheath, and an expandable Nitinol stent. The stent is compressed around the Veress needle and covered with a nylon sheath. Access to the peritoneum is gained with the Veress needle using standard procedure. When the Nitinol stent enters the skin, body temperature causes the stent to expand and separate the tissues. The Veress needle is removed and the stent and nylon sheath act as a port for insertion of other surgical tools.

**Methods:** The new system was designed and tested using IDEAS-9 software for finite element analysis, the INSTRON 8872 for prototype testing, mathematical modeling, and basic economic analysis.

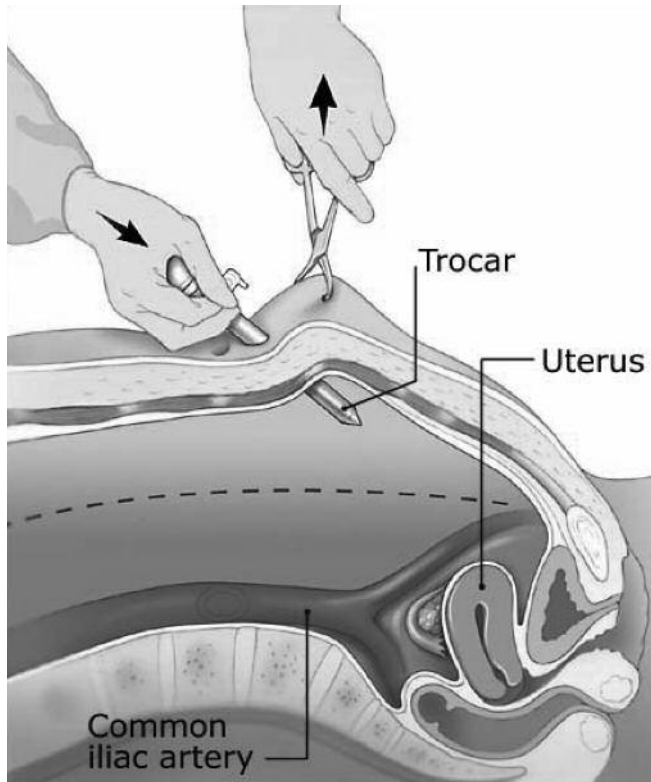
**Results and Conclusion:** The self-expanding entry system for laparoscopic surgery reduces the likelihood of injury during insertion by decreasing the axial forces required to penetrate the peritoneum by five times compared to current systems. It is simple to assemble and use, requiring only one step for insertion. It may be sterilized with a standard autoclave, is reusable, and preliminary economic analysis indicates that it is cost effective.

### INTRODUCTION

During laparoscopic surgery, the first step is gaining access to the peritoneum. This is accomplished by inserting a Veress needle into the peritoneum and insufflating the peritoneal space with carbon dioxide. Once the pneumoperitoneum is established, the trocar - a surgical tool used to create an entry port for passing endoscopic instruments into the body - is inserted into the peritoneum (Figure 1). The initial trocar insertion into the abdomen or pelvis is one of the most dangerous steps in Minimally Invasive Surgery (MIS) and is accountable for the majority of injuries and deaths associated with laparoscopic surgery. Approximately 83% of vascular injuries, 75% of bowel injuries and 50% of local hemorrhages in MIS are attributed to primary trocar insertion.<sup>1</sup> A recent European study found that laparoscopic surgeries have a 1 in 1000 rate of injury, and a 1 in 100,000 rate of death directly attributable to the

use of trocars.<sup>2</sup> Factors contributing to these occurrences during abdominal laparoscopic surgery include poor selection of insertion site, unintentional cutting by a sharp tip, high penetration force, overshooting into the abdominal cavity, surgeon inexperience and undetected injuries.

The axial force, a longitudinal force acting along the length of the trocar, and radial force, a force perpendicular to the trocar, required to penetrate the abdominal wall, make the insertion of some trocars difficult and unpredictable. With excessive force, it is easy for the surgeon to veer off path or to overshoot penetration. The plunge effect, the sudden drop in resistance that occurs instantaneously following penetration of the abdominal wall, typically causes the trocar to plunge deeper than intended by the surgeon.<sup>3</sup> In many patients, the anterior abdominal wall is a mere 2 cm from vascular structures, and penetration of even a fraction of a centimetre too deep can cause damage.<sup>1</sup>



**Figure 1.** A demonstration of standard procedure of trocar insertion. (Gibbs, Leape)

Online source: [http://www.webmm.ahrq.gov/media/cases/images/case3\\_fig1.jpg](http://www.webmm.ahrq.gov/media/cases/images/case3_fig1.jpg) [Accessed September 14, 2007]

While vascular injuries are detected almost immediately, bowel/gastrointestinal injuries can remain unrecognized for hours, days or weeks. Undetected complications such as an intraabdominal abscess or fistula are troublesome. If healing does not occur properly, contents of an injured bowel can leak and contaminate the abdominal cavity, leading to infection, bleeding, and laparoscopic mortalities.

Approximately 1% of laparoscopic patients experience wound complications at the site of the trocar insertion.<sup>4</sup> Cannulas, the surgical tubes used for insertion into the peritoneum, with diameters of 10mm or greater increase the risk of herniation and wound infection.<sup>4</sup> Because vascular, gastrointestinal and wound injuries continue to occur, the conventional trocar blind insertion method is no longer universally acceptable. This article outlines a new entry system for laparoscopic surgery that addresses many of these issues.

## PROBLEM STATEMENT

The purpose of this research is to design an insertion system for laparoscopic surgery that will decrease injuries during insertion, be simple to assemble and use, be sterilizable and reusable, and be economically feasible. The design objectives are to improve the safety of the device by

reducing the insertion force required to penetrate the abdominal wall with the trocar, reducing the size of the initial insertion wound, and reducing slippage during laparoscopic procedures.

## METHODS

A literature review on all commercially available access systems for laparoscopic surgery was performed using PubMed, Cochrane database, and the Food and Drug Administration, using the keywords: trocar, veress needle, cannula, laparoscopic surgery, laparoscopy, and endoscopy to search for publication between 1975 and 2006. Relevant literature from the *Annals of Biomedical Engineering*, *Biomedical Engineering*, and *Surgical Laparoscopy and Endoscopy* was also reviewed. Finally, a broad based Google search was also completed to identify extra resources. This review identified eighty-three articles and three widely used trocars: the bladed tip shielded trocar system, the blunt tip screw trocar system, and the blunt tip dilating trocar system. These access systems were researched and evaluated using a decision matrix. Since there is no gold standard decision matrix for evaluating trocars, key determinants of likelihood of injury were identified across the literature, which included required penetration force, complexity of procedure and equipment, cost, and aesthetic appeal.

The best design alternative indicated by the decision matrix was further researched and evaluated. Strengths and weaknesses of this design were identified and prototypes for a new entry system were drafted. Prototypes were evaluated using IDEAS-9 Finite Element Analysis (FEA), a software package that describes linear modeling of systems under stress, mathematical modeling, a system of equations to describe the prototype, and dynamic systems modeling, a system of equations to describe the parts of the prototype that move.<sup>5</sup> Parameters such as diameter, length, and material of the prototype were optimized using FEA. IDEAS-9 software was chosen due to the ease of accessibility of the program in the Engineering department.

When the optimal prototype had been developed with computer modeling, a physical prototype was constructed and tested against commercially used trocars. The evaluation parameters included penetration force, wound size, complexity of equipment and procedure, cost, and aesthetic appeal. Tissue mimicking material (TMM) was used to approximate the abdominal wall for laboratory testing.

Penetration force was evaluated quantitatively using the INSTRON 8872, a laboratory machine that quantitatively and reproducibly measures the force required to penetrate a given material. Forces required to penetrate the TMM were compared for the commercially available trocars and the prototype. Wound size was evaluated by measuring the diameter of the penetration wound on the tissue mimicking material with calipers. Complexity of the equipment and procedure was evaluated by comparing the number of steps required during insertion, the time required to penetrate the TMM, the number of parts in the system and their reliabili-

ty. Cost was evaluated by completing a longitudinal economic analysis of the prototype compared to currently used systems based on material costs and life-span of the system. Aesthetic appeal was evaluated by presenting the prototype and currently used systems to surgeons, nurses, and patients and having them complete a quantitative evaluation of the appearance of the entry system.

With each round of laboratory testing, the prototype was further optimized with FEA. The final design is a product of a number of iterations of laboratory testing and FEA modeling.

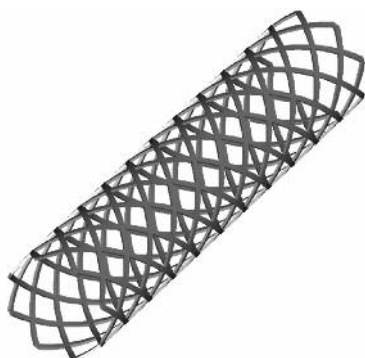
## DESIGN SOLUTION

The final design is a radially self-expanding entry system (SEES) that consists of a Veress needle (Figure 2), an expandable nylon sheath, and an expandable Nitinol stent (Figure 3). The stent is compressed around the Veress needle and covered with a nylon sheath. Access to the peritoneum is gained with the Veress needle using the standard procedure. When the Nitinol stent enters the skin, the body temperature causes the stent to expand and separates the tissues. The Veress needle is then removed and the stent and nylon sheath act as a port for insertion of other surgical tools. When the surgical procedure is finished, cool sterile water is poured on the stent allowing it to cool and compress for removal from the body. Benefits of this system include lower insertion forces than in currently used trocars, a non-cutting self-expanding Nitinol tube that acts as a port, and minimal slippage of surgical tools that are inserted in the port.

The material used for the self-expanding stent is Nitinol, which is a shape memory alloy of approximately 1:1 Nickel:Titanium. It has austenite and martensite structures and the ability to store shape in the austenite structure. When the metal is cooled, it is moldable into any shape. When it is



**Figure 2.** Veress Needle



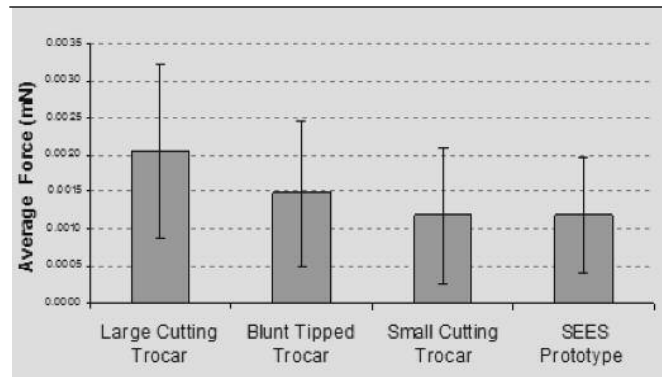
**Figure 3.** Nitinol Stent

heated it recovers its original shape. It is pushable, fatigue resistant, biocompatible, and sterilizable.

## Results

### I. Penetration Force

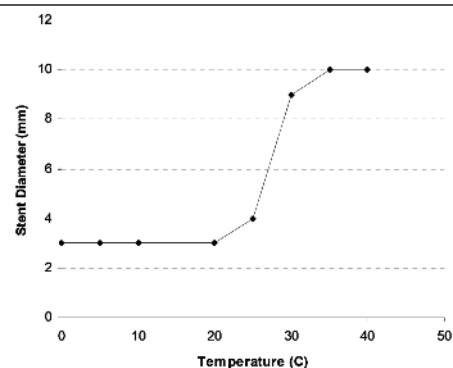
The SEES prototype was evaluated against 3 currently used trocars. SEES had the lowest insertion force at 7.5lbs. SEES reduces insertion force by five times compared to the current radially expanding entry systems ( $p < 0.01$ ) (Figure 4).



**Figure 4.** Penetration Force Comparison. The SEES had the lowest insertion force when compared to currently used trocars.

### II. Expansion Testing

Nitinol material was chilled and compressed, then inserted into a water bath at various temperatures. The Nitinol was inserted into TMM at body temperature and the expansion was 7 mm in diameter and occurred at 30°C ( $p < 0.01$ ) (Figure 5).



**Figure 5.** Expansion Testing. The stent expands from a diameter of 3mm to a diameter of 10mm at body temperature.

### III. Economic Analysis

Preliminary calculations suggest the direct cost to manufacture one SEES system is \$668.43 CAD. Economic bene-

fits of SEES outweigh conventional trocars after 16 surgeries and there are additional benefits from decreases in injury rates. Based on a caseload of thirty laparoscopic surgeries a month, the economic benefit of using SEES for one month is \$584.97.

## DISCUSSION

The SEES built on the strengths and improved the weaknesses of currently used models of dilating trocars. The insertion force was reduced by five times using SEES and the manual expansion force is eliminated due to the material properties of the Nitinol stent. Wound size and tissue trauma is decreased with SEES because tissues are split and stretched along fibre lines as opposed to cutting the tissues. Slippage of the port within the tissue is reduced with the Nitinol diamond-shaped mesh which grips the tissue without cutting or causing trauma because it is covered with the nylon sheath.

Limitations of this research are that the Nitinol mesh cannot be modeled using linear-elastic analysis, which was the only form of FEA available during this project. Therefore it was not possible to model the behaviour of the Nitinol using IDEAS-9 software, and mathematical equations for non-linear behaviour were used to model this system. Finite element analysis for non-linear behaviour must be obtained for further modeling of this system. There are highly specialized software packages for this type of modeling and developing a computer model of the Nitinol mesh is important to optimize parameters for the physical prototype. Computer model optimization allows the most efficient physical prototype to be constructed. In addition, a detailed economic analysis of the use of SEES in hospital was beyond the scope of this paper, but would be essential to developing the final product.

During this project comparisons between the SEES and commercial systems were made in the areas of penetration force and expansion force. The next phase involves more extensive prototype testing in the laboratory, including tests to quantify the amount of slippage during laparoscopic procedures, the wound size compared to currently used trocars, and how easily the SEES is used in a surgical environment. At this time in the study, there is insufficient prototype testing data to perform a complete statistical analysis. Once a

final prototype is modeled mathematically, constructed and validated with TMM in the laboratory, the next step is animal testing of the prototype to determine if the system will function in a surgical environment.

The technology of memory metal has many applications in medicine, for example cardiac stents, and this surgical tool has the potential to be modified and used for other procedures. Once this prototype is constructed and functional in the surgical environment, the next phase of the project is to use this technology and modify the surgical tool so that it can be used for other endoscopic procedures. The system could be further developed to include a temperature control device to better control its heating and cooling during expansion, and compression of the device for passing through narrow areas during endoscopic procedures.

## CONCLUSION

The SEES is a prototype of a surgical trocar that shows promising results in reducing the penetration force required to gain access to the peritoneum, reducing wound size, and reducing tissue trauma. Although further analysis is required to quantify the advantages from these improvements over other currently used systems, this model will likely reduce complications from laparoscopic surgery related to trocar insertion. In addition, the SEES is easy to assemble and use, reusable, sterilizable, and cost effective.

## ACKNOWLEDGEMENTS

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