

**Comparative analysis of five different abdominal access trocar systems:**

**Analysis of insertion force, removal force and defect size**

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## INTRODUCTION

Over the past 15 years, the application of laparoscopic techniques to all areas of surgery has grown exponentially. This explosion has been paralleled by a dramatic increase in research and development of equipment necessary for laparoscopy. One of the critical areas of importance has been the development of an optimal access port system.

Laparoscopic access ports can be divided into cutting and dilating types. All port systems involve a hollow cannula with a removable, internal obturator. Cutting systems have a sharp tip at the end of the internal obturator that divides tissues as force is applied. Dilating systems typically have a blunt tip that separates tissue as force is applied.

In the infancy of laparoscopy, most trocar systems employed metal, cutting tips. Ease of entry through tissue was one of the main advantages. However, reports started to surface describing complications associated with trocar systems. These included major vascular injury, visceral injury, abdominal wall hematomas, trocar site pain and trocar site hernias (1). Because of these complications, new trocar systems were developed to ameliorate some of these complications.

Recent trocar systems have employed non-cutting obturator tips to decrease complications. These systems are reported to dilate or separate tissue, thus decreasing trauma to the tissues as it enters the abdominal cavity. Studies examining the benefits of radially expanding, non-cutting trocar systems have documented decreased pain, less port-site bleeding, shorter wound scars and higher patient satisfaction (2-4). Unfortunately, non-cutting trocar systems typically require greater force to insert into the abdominal cavity, potentially increasing the rate of vascular injury (5).

One of the first and most common non-cutting trocars used is the Step port (Innerdyne Inc., Mountainview, CA). This system creates a wound by separating tissue by inserting an obturator through an expandable sheath. One of the criticisms of this system has been its cost and high insertion force. Recently, a new dilating trocar system, called the Separator, has been developed by Applied Medical Resources (Rancho Santa Margarita, CA). This system was designed to preserve the advantages of a non-cutting trocar system with improved cost. In this study, our objective was to evaluate insertion force, removal force and wound characteristics of the Separator compared to 4 other trocar systems.

## METHODS

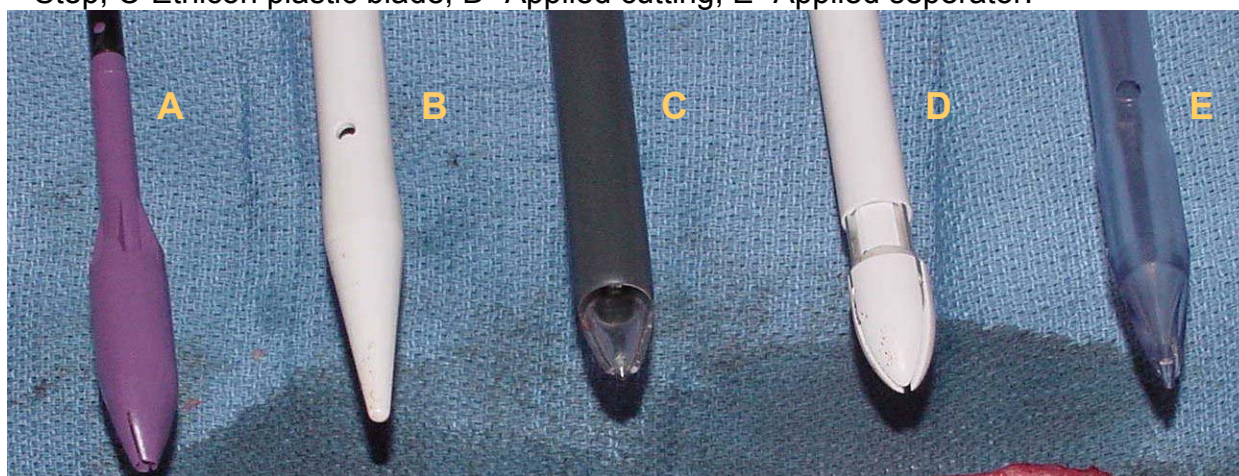
### Subjects

Eight female pigs [average weight 106 ( $\pm$ 6.2)lbs.] were used in the study. Pigs were used because of their similarity of their abdominal wall to humans. The study was approved by the Legacy IACUC committee. All the procedures were performed under general anesthesia with endotracheal intubation. At the end of the procedure, all animals were euthanized using intravenous euthasol.

### Technique

After induction of general anesthesia, a Veress needle was inserted in a supraumbilical position and pneumoperitoneum (CO<sub>2</sub>) was maintained at 15 mm Hg. A laparoscopic was inserted to allow for visualization of trocar entry. Five different 12 mm trocar systems were analyzed (Figure 1). These included Applied Separator, Ethicon plastic dilator, Step radially dilator, Applied cutting trocar and Ethicon cutting trocar. All trocars were entered off-midline in a random fashion by 1 investigator (YK). A total of 10 trocars were entered per pig. After insertion, each trocar was instrumented and manipulated in a 4-quadrant fashion for a total of 15 movements.

Figure 1. Five different 12 mm trocars systems used in the study. A- Ethicon Cuttign, B – Step, C-Ethicon plastic blade, D- Applied cutting, E- Applied seperator.



### Insertion and Removal Force Measurement

Insertion force was measured by a tensiometer engineered to fit on top of each trocar system. Peak force recorded by the tensiometer was defined as the insertion force. After a total of 15 movements of the trocar in a 4-quadrant fashion, removal force was measured by the same tensiometer. Peak measurements were taken by 1 investigator (YK).

### Functional Defect Size

Functional defect size was measured by a custom-designed bead system. This consisted of beads of increasing size (3 mm to 18mm) connected in a linear fashion [Figure 2]. After all trocars were entered, a small midline laparotomy was performed to insert the beads into the abdominal cavity. Once inside the abdomen, the bead system was removed from each trocar site using constant force(4 lb). Functional defect size was defined as the bead size that did not cross the peritoneal defect under gentle traction.

Figure 2 Custom designed bead system.



### Measured Defect Size

After completion of insertion and removal force measurements, the abdomen was desufflated and the anterior abdominal wall was excised. Each layer of the abdominal wall was dissected individually, maintaining the original orientation. Measured defect size was defined as the longest measurement taken at the extremes of the trocar defect.

### Statistical Methods

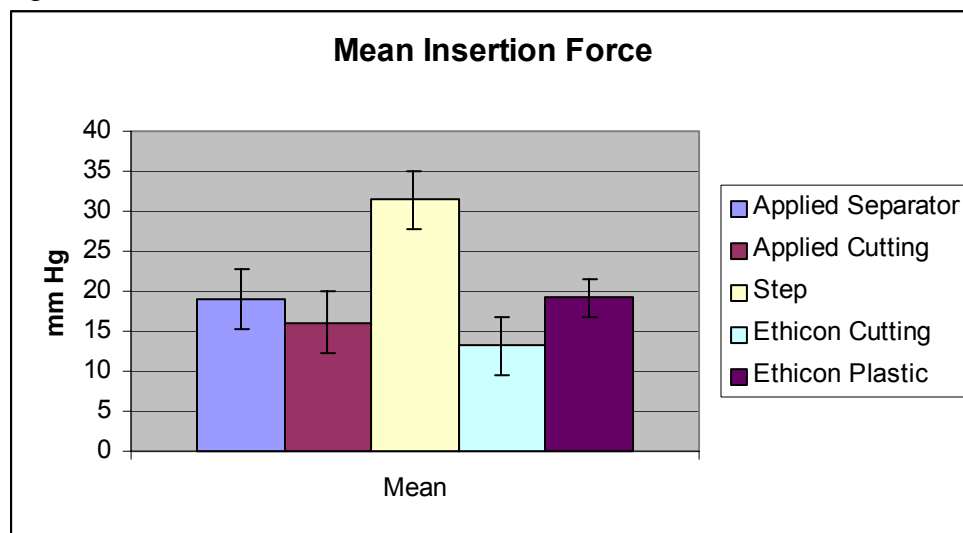
All values are given as mean  $\pm$  standard deviation. Two-tailed Student's t-test was used to compare between groups. Bonferroni correction was utilized for multiple comparisons. P values  $< 0.0125$  was considered statistically significant.

## **RESULTS**

### Mean insertion force

Mean insertion force for each trocar system is shown in Figure 3. Insertion force for the Applied trocar system was higher than both cutting trocars but significantly less than the Step trocar system.

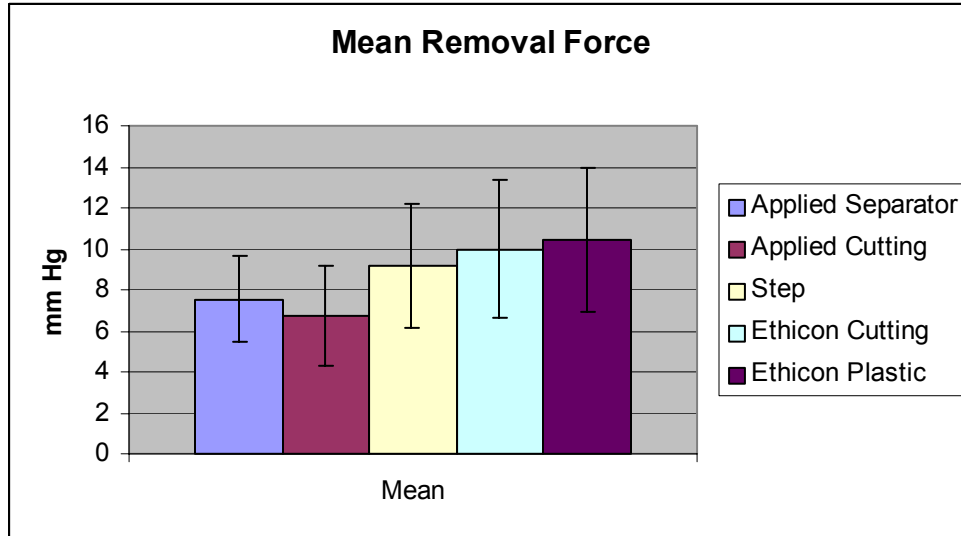
Figure 3



### Mean removal force

Mean removal force is shown in Figure 4. There was no statistical difference between the Applied trocar system and the other 4 trocar systems.

Figure 4



### Measured defect size

The measured defect size of the Applied Separator was significantly smaller than both cutting trocar systems and the Ethicon non-cutting system. Defect size was similar to the Step trocar system (Figure 5). Both Step trocar system and the Applied separator produced uniform separation (without any cutting) of tissue fibres in each layer of the abdominal wall (Figure 6).

Figure 5

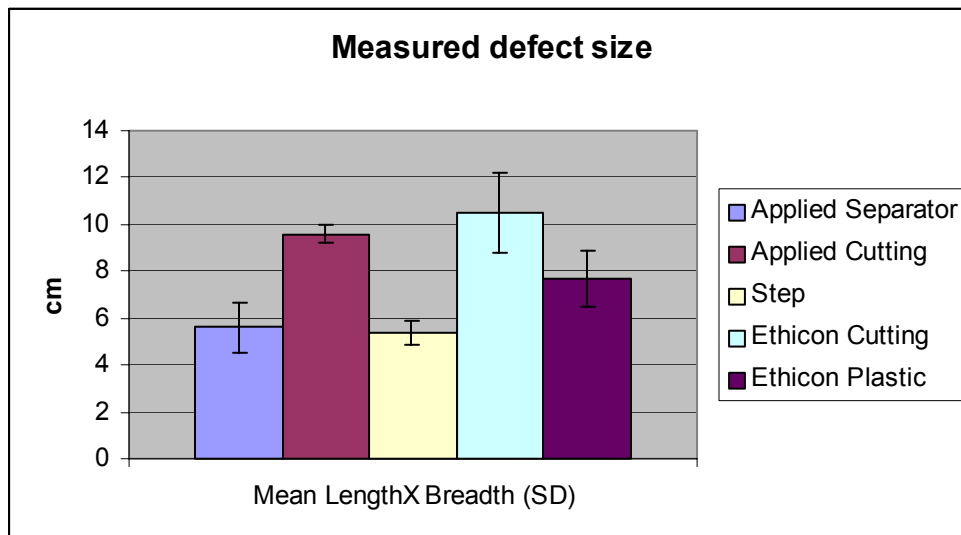
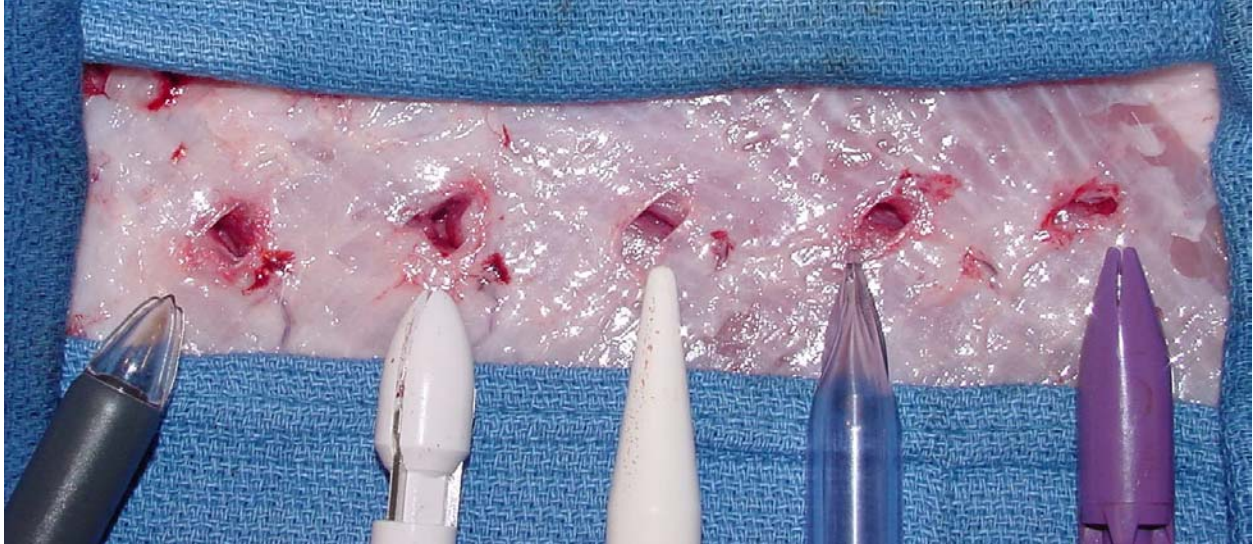


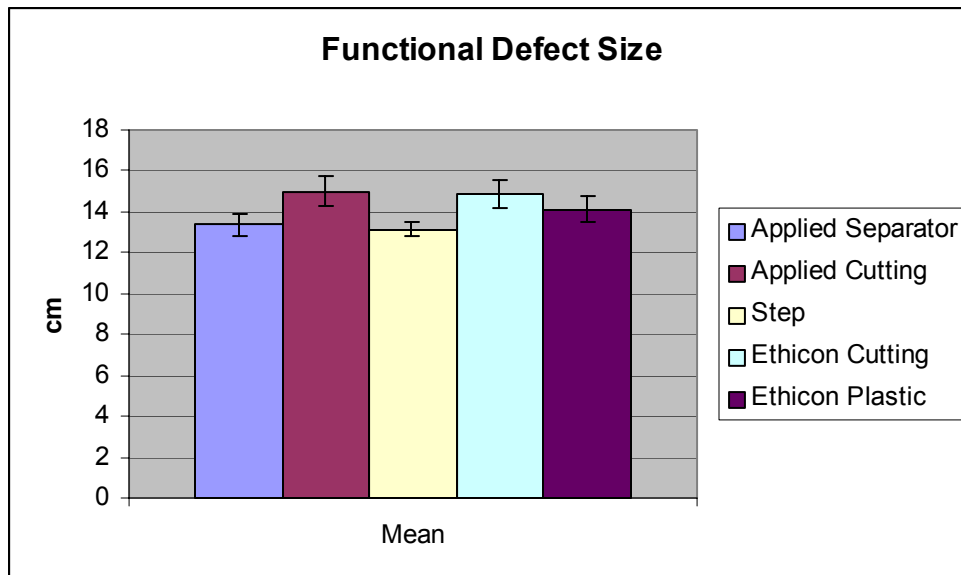
Figure 6: Defects created by various trocar systems



### Functional defect size

Functional defect size as measured by bead technique was similar to the Step trocar system and significantly smaller than the other 3 trocar systems. (Figure 7).

Figure 7



## DISCUSSION

The search for the ideal trocar system has continued in parallel with other advances in laparoscopy. Initial trocars consisted of metal, cutting trocars that divided tissues and subsequently required closure of the fascia to prevent potentially dangerous hernias.. As experience grew, surgeons continued to refine what they wanted in an ideal trocar system. Characteristics of an ideal trocar included decreased tissue trauma and bleeding, decreased pain at the trocar site, ease of entry, a tighter fascial seal to prevent frequent dislodgements during cases, diminished risk of herniation and elimination of time-consuming wound closures. These requirements resulted in the developed of the non-cutting trocar systems. These trocar systems separate tissue fibers rather than cutting them, which results in many of the characteristics of the "perfect" trocar.

In addition to the issue of cutting versus non-cutting, the shape of the trocar tip was also reported to be clinically important (6). Studies suggest that a conical tip is recommended as opposed to pyramidal tips, with the idea that the latter posed more of a risk to intraabdominal structures during insertion (7). Thus the optimal trocar system seems to be a non-cutting trocar with a conically shaped tip.

In recent years, a radially dilating trocar system (Step™ trocar) has been described as the ideal trocar system. Theoretic advantages of this trocar include less tissue trauma and a tighter fascial seal (6). In addition, in a recent review of over 4000 documented Step™ procedures, the rate of abdominal wall bleeding was only 0.04%, the rate of cannula slippage was 0.15% and no incisions hernias were reported (7). Unfortunately, the cost of this complex trocar system is an issue and has limited its widespread application (8).

A new type of non-cutting trocar system called the Separator has been developed by Applied Medical Resources. This trocar system has the potential practical and theoretic benefits associated with the Step™ at a reduced cost. In our current study, the Separator required less force to insert the trocar as compared to the Step™. This may have the theoretic benefit of decreasing retroperitoneal injuries. Both functional and measured defect size was similar to the Step™. Therefore one would expect herniation rates to be similar between the two trocar systems. To our surprise, the removal force was similar between all 5 trocars. Specifically, there was no difference between all 3 non-cutting trocar systems. This will perhaps translate into comparable rates of dislodgment during prolonged laparoscopic cases.

## CONCLUSION

From this comparative analysis of 5 trocar systems, we can conclude that the Applied Separator system requires a higher insertion force than cutting trocar systems, but significantly less than the Step trocar system. The removal force for the Separator system is similar to all other trocar systems. Functional defect size of the Separator

system was similar to the Step trocar system and significantly smaller than the other trocar system. Actual wound defect size was also similar to the Step trocar system and significantly smaller than other trocar systems which leads us to believe that fascial defects created by 10 and 12mm Separator trocars would not need to be closed to prevent postoperative hernias. Overall, the Applied Separator trocar system has similar wound characteristics as the Step trocar system with the added benefits of reduced force required to insert the trocar, and lower cost.

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