Comparative Evaluation of Laparoscopic Access Systems:

A study of entry force, intraperitoneal pressure and incisional characteristics with a novel bladeless design ("ADAPt") and a composite dilating system ("VersaStep")

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Introduction

Laparoscopic surgical techniques have been integrated into virtually all surgical fields thereby reducing the need for laparotomy and its inherent morbidity. Such procedures require the positioning of an access port or cannula that is designed to allow the insertion of narrow caliber instrumentation while maintaining the required pneumatic seal. These access systems typically comprise a hollow cannula and an internal, removable, tapered obturator with a sharp or blunt tip that is designed to penetrate and dilate the body wall under force applied by the surgeon.

Although complications associated with the placement of laparoscopic access systems are relatively rare, when they involve the great vessels or viscera, morbidity is often high and mortality may occur,[1, 2, 3] Furthermore, late sequelae such as incisional hernia may also be related to the use of these devices.[4] Consequently, safe and effective laparoscopic surgery mandates that these ports be positioned in the abdominal wall in a way that minimizes complications.

It has been perceived that sharp-tipped obturators, usually called "trocars", are safer than other designs, including those with conical tips, largely because of ease of insertion. However, there seem to be few existing data supporting such a contention. Evidence from a rabbit model suggests that conical devices, that require more force to insert[5], may be associated with a reduced chance of entry-related vascular trauma.[6] Furthermore, the so-called "safety shields" designed to cover the tip of the trocar just after insertion do not seem to provide additional patient protection as the majority of published vascular and visceral injuries have occurred despite their use. [7, 8] The incidence of intraoperative port-site bleeding, and postoperative hernia have been investigated in one, relatively small randomized trial comparing a large-caliber blunt dilating system to similar diameter traditional cutting trocar-based access devices.[9] With the blunt-tipped conical device studied there was no incisional bleeding and there were no hernias despite the fact that the fascial incisions were not closed. Despite the existence of these data, there remains an overall deficiency of evidence comparing data regarding laparoscopic access systems that has limited the ability of surgeons to identify those devices with the highest safety profile and thereby optimally reduce the chance of potentially morbid or even lethal complications. [10]

A few years ago our group began to explore access system design parameters in a search for factors that affect insertion force, intraperitoneal insertion pressure, and a number of wound parameters using a computerized entry force/pressure measurement device, and a standardized incision assessment system. [11, 12, 13, 14, 15] In these studies we found that there were substantial differences in both insertion force and defined wound parameters based upon the design of the access system. For those systems that employ an obturator it seems clear that a blunt dilating tip is associated with fascial wounds that are significantly smaller and muscle injury that is significantly less than those wounds created by a bladed tip.[12,15] One other group has demonstrated similar findings.[5] These observations appear to be to due to the mechanism by which a blunt, dilating obturator traverses the abdominal wall by splitting and dilating fibromuscular planes, as opposed to

the transection of tissue that occurs with pyramidal and at least some bladed tips. In our porcine model, these differences were so profound that the wound metrics associated with 12mm blunt conical devices were similar to those of an 8mm pyramidal device.[15]

In addition to the diameter of the device and the design of the obturator, there exist a number of other factors that may impact wound metrics. One such variable is the stress placed on the cannula after placement that occurs both as a result of instrument insertion and removal and of the fulcrum-like movements required for the instrument manipulation inherent to operative laparoscopy. Our earlier work has suggested that wound metrics do not change following standardized manipulations of a blunt conical device. However, with pyramidal systems or when access cannulas are inserted following the creation of an incision, wound area may increase in following the application of a standardized set of cannula movements. [14, 15]

One of the issues encountered with the blunt conical designs is that entry force was much greater than that required for insertion of pyramidal devices.[11] Recently, a new access system has been developed by Taut Inc (Geneva Il). This bladeless, blunt-tipped device (ADAPt®) was designed to preserve or enhance the advantages of blunt conical devices with respect to wound metrics while reducing the force required for peritoneal entry. In this study we sought to evaluate the performance of the Adapt system with that of a two step access system that was evaluated in two of our previous studies, and called the VersaStep® system (United States Surgical division of Tyco Healthcare Group LP, Norwalk CN).[12,11] We hypothesized that the two systems would be associated with similar wound metrics, both before and after manipulation, but that the Step system would require a greater amount of force for insertion of the operating cannula.

Materials and Methods:

The protocol was reviewed and approved by the UCLA Office for the Protection of Research Subjects and all procedures were performed in the UCLA Surgery Laboratory. For our study model we used eight white swine weighing 60-65 kilogram. These are large animals with a double layer of abdominal fascia in the lower abdomen that is morphologically similar to that in the human. Each animal was anesthetized with ketamine and butorphanol and maintained with inhaled halothane, titrated to effect. The abdomens were shaved, an insufflation needle was positioned supraumbilically in the midline, and CO_2 gas was insufflated to maintain pressure between 13 and 15 mm Hg. A 12mm (internal diameter – ID) access system was positioned in a separate midline site in the supraumbilical area following the creation of a suitable skin incision. A laparoscope was inserted to confirm freedom of the insufflation needle and to allow visualization of experimental instrument entry. When the tip of the insufflation needle was confirmed to be free in the peritoneal cavity, the insufflation tubing was detached and the needle attached to a pressure transducer for intraperitoneal pressure measurements.

There were four study groups each comprising eight insertions of new, packaged, sterile 12 mm internal diameter ID access systems. Group 1 comprised the ADAPt system, with incisional measurements made immediately following insertion. Group 2 was also a set of ADAPt insertions, but wound measurements were made after the application of a

standard group of cannula manipulations. Group 3 comprised VersaStep insertions without manipulation while the incision metrics in Group 4 were obtained after the standardized cannula manipulation.

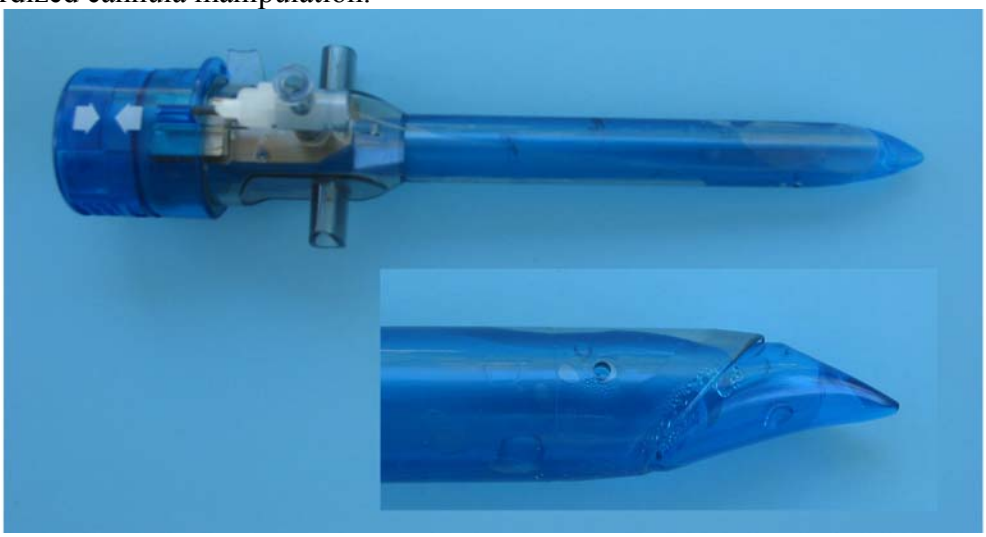


Figure 1. ADAPt Laparoscopic Access System (12 mm internal diameter).

The obturator has a blunt tip and is assymetrical. The lateral view is demonstrated in the inset photo.

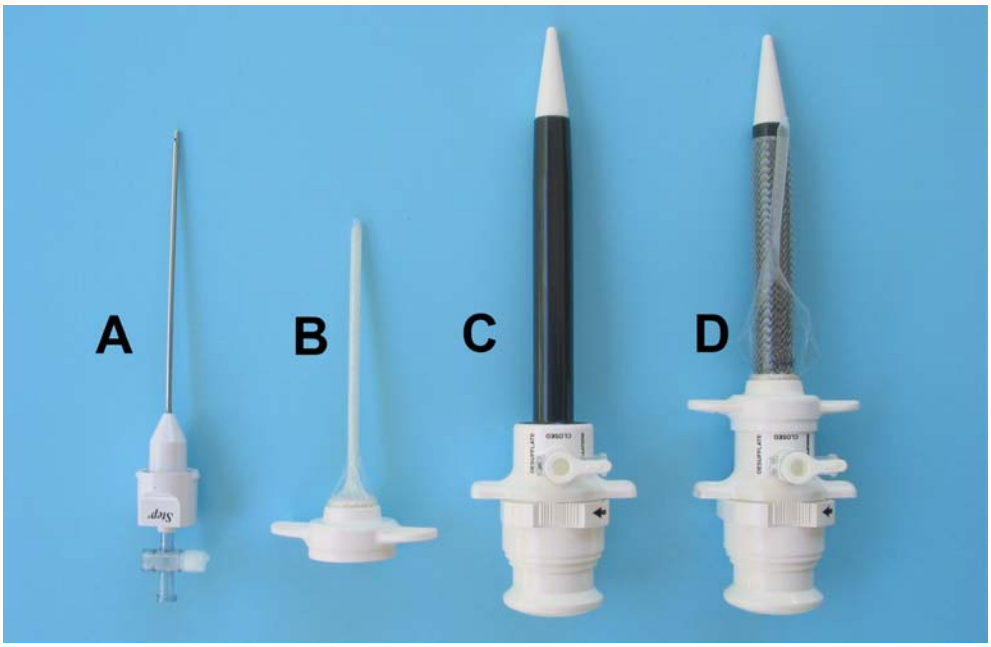


Figure 2. VersaStep Laparoscopic Access System (12 mm internal diameter).

The system comprises, (A) a sharp insufflation needle with a sprung obturator; (B) a dilating sheath which is inserted using the insufflation needle; (C) a laparoscopic cannula (black) with a blunt symmetrical obturator (white). The fully configured device is shown (D), as it exists after being inserted through the abdominal wall with the dilating sheath surrounding the cannula.

The locations of insertion of the instruments were randomized using a Latin Square method. Study access systems were inserted under direct vision through transverse 1.8 cm paramedian incisions that were made in a uniform manner below the level of the umbilicus and separated by 8-10 cm.

Entry Force Measurements: Each of the systems were attached to our universal adaptor via a custom molded stainless steel cradle and introduced by the same experienced operator (MGM), at a 90-degree angle to the horizontal. Insertion of the VersaStep device requires two unique steps. An insufflation needle placed within the dilatable sheath is positioned first. Then following removal of the needle, the cannula with its dilating obturator is introduced with one hand while the other hand provides continuous countertraction by holding the sheath. The Adapt device is inserted by applying moderate force on the device while simultaneously twisting the wrist back and forth through approximately 180 degrees of rotation. For all devices, data were acquired during the time interval surrounding port insertion. The force and pressure data were sampled at 100 times per second using a strain gauge signal conditioning board, analyzed with a data acquisition card, processed with Labview software and stored on a Microsoft Excel spreadsheet[11]. Calculations of mean and median maximal insertion force and corresponding peak intraperitoneal pressure were tabulated for each device allowing 16 such measurements for each of the two study instruments.

The Effect of Movement: After access system insertions were completed in a given animal, the devices that were randomized to the movement group (Groups 2 and 4) were identified. A 10 mm laparoscopic hand instrument was inserted into these cannulas and then withdrawn a total of ten times. Then the hand instrument was moved in an arc of approximately 150 degrees in a transverse plane and then cephalad to caudad in a sagital plane, thus covering four directions, a total of 50 times. These standardized movements were designed to mimic instrument manipulation at surgery.

Incisional Parameters: After applying the standardized manipulations to the appropriate cannulas, the intraperitoneal gas was allowed to escape and the cannulas were removed. The skin and subcutaneous fat of the anterior abdominal wall were then dissected and removed exposing the anterior rectus fascia for objective evaluation of the fascial component of each wound for each of two different parameters[12]. Wound length was obtained with metric calipers to measure the maximal length of exposed underlying muscle. Wound area was determined by tracing the borders of the double-layered defect on a transparency of 2 mm grid squares that was placed over each wound. The sum of the grid box quartiles was tabulated and the area calculated in square millimeters by an observer (CMT) for each insertion. This calculation was done at a remote time without reference to the device assignment for each wound. After the fascial parameters were obtained, the fascia was carefully dissected from each wound and muscle damage for each wound was graded on a zero to three scale where zero is no damage, 1 is minimal damage, 2 is damage less than the fascial incision, and 3 is damage equal to or greater than the fascial incision.[13]

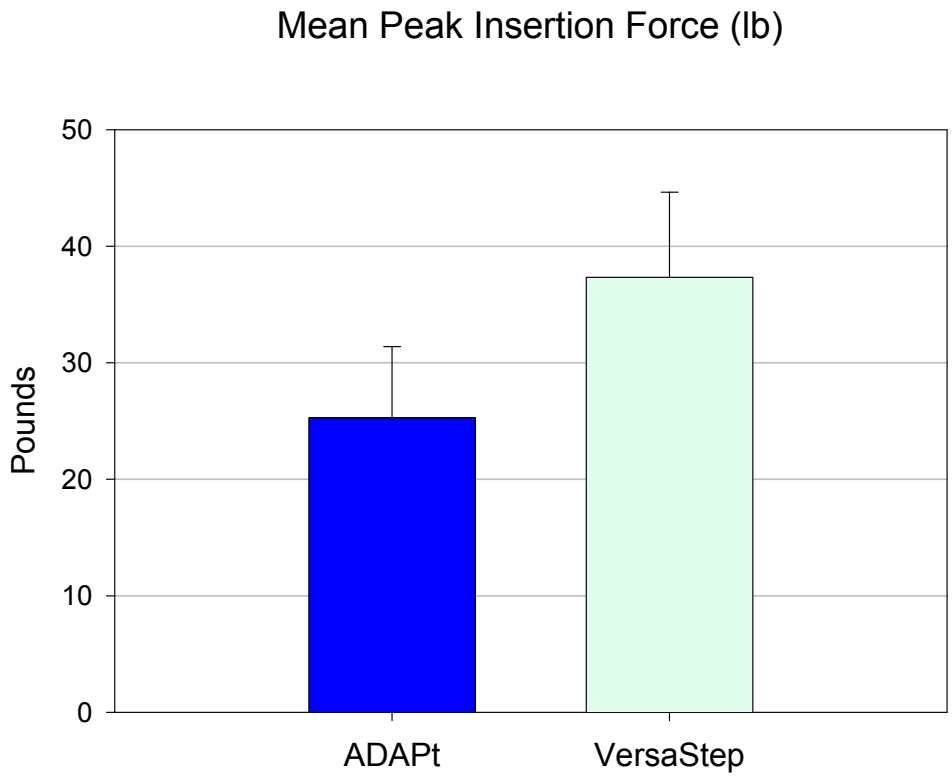
At the end of all testing, the animals were euthanized according to institution protocol using Eutha-VI. Means of each outcome variable were compared using a two way repeated measure analysis of variance model under the Latin square design.

Results

Force and Pressure

Peak entry force for each insertion is displayed as means for each device: In order of increasing value in pounds were Adapt 25.27 and Step 37.32 (Figure 3)

Figure 3



Intraperitoneal pressure results were calculated as maximal pressure change from baseline. Baseline pressures were regulated at standard operative pressure ranging between 13 and 15 mmHg. The mean maximal intraperitoneal pressure changes observed during insertion were 6.26 mm Hg for the Step device and 13.33 mm Hg for the ADAPt.

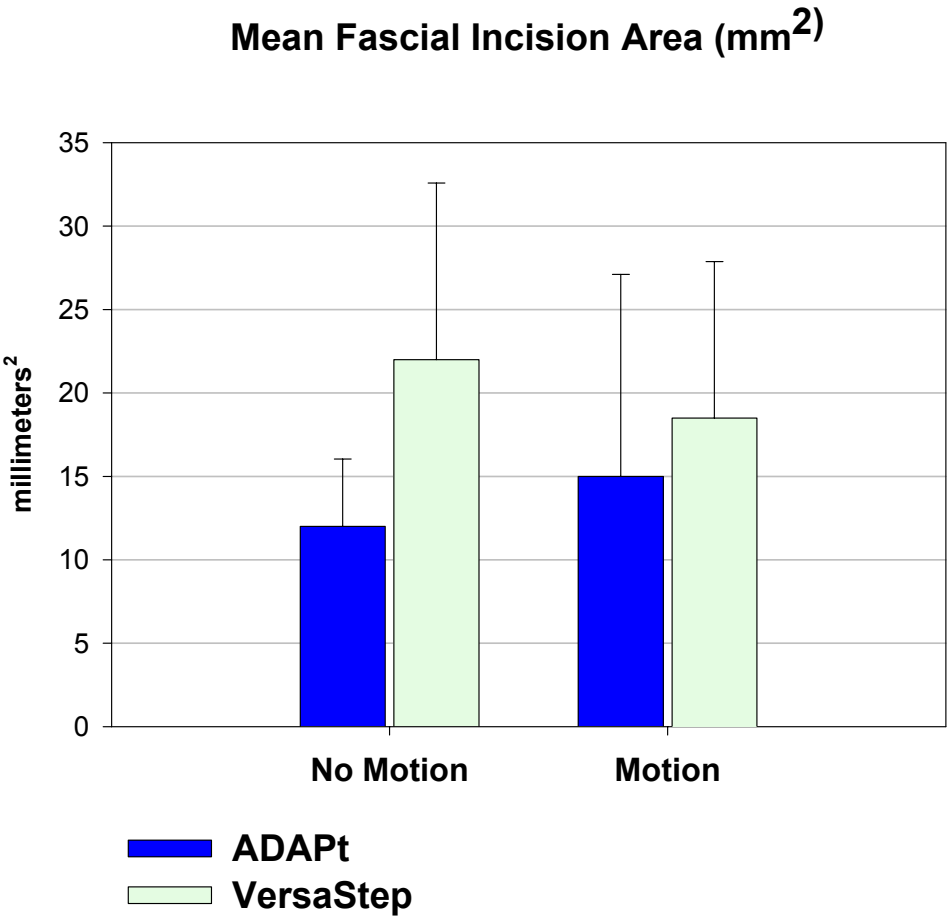
Incision Parameters

Mean and median wound areas in mm^2 are shown in Table 1 and Figures 4 and 5 while incision lengths in mm are displayed in Figure 6.

Table 1. Mean and Median Wound Areas

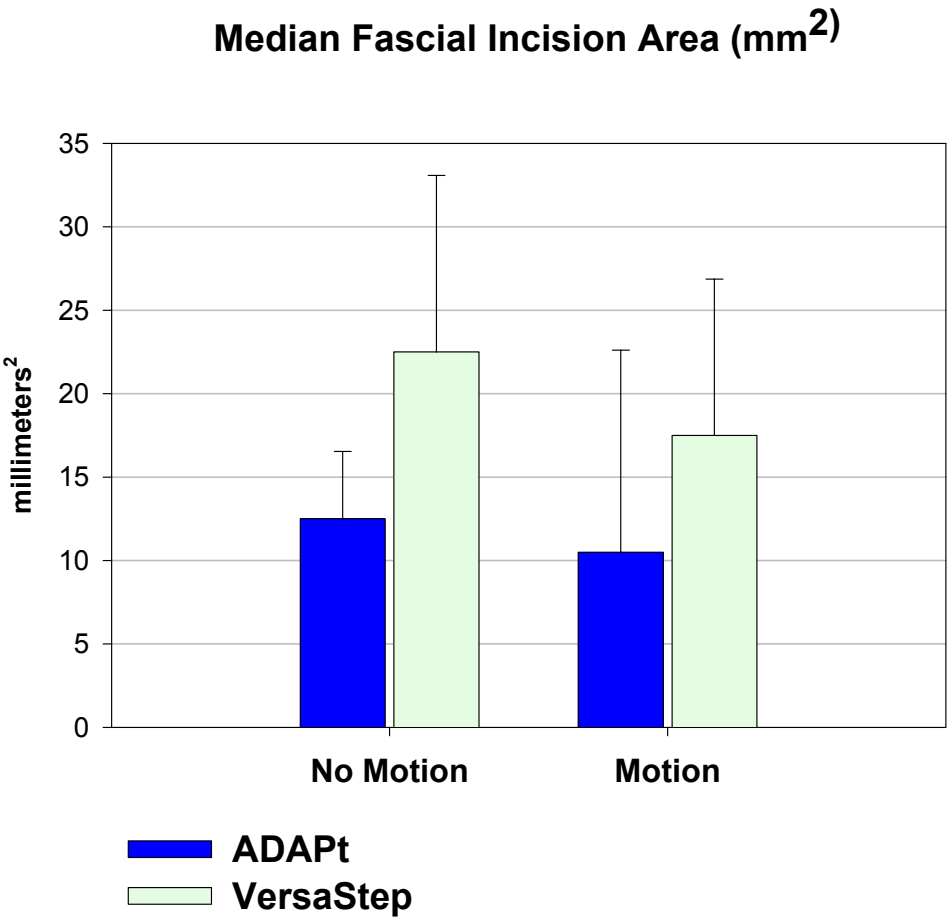
Device		Motion	Mean	Median	SD
			Area (mm^2)		
Taut	ADAPt	No	12.00	12.50	4.04
Taut	ADAPt	Yes	15.00	10.50	12.10
USSC	VersaStep	No	22.00	22.50	10.58
USSC	VersaStep	Yes	18.50	17.50	9.37

Figure 4



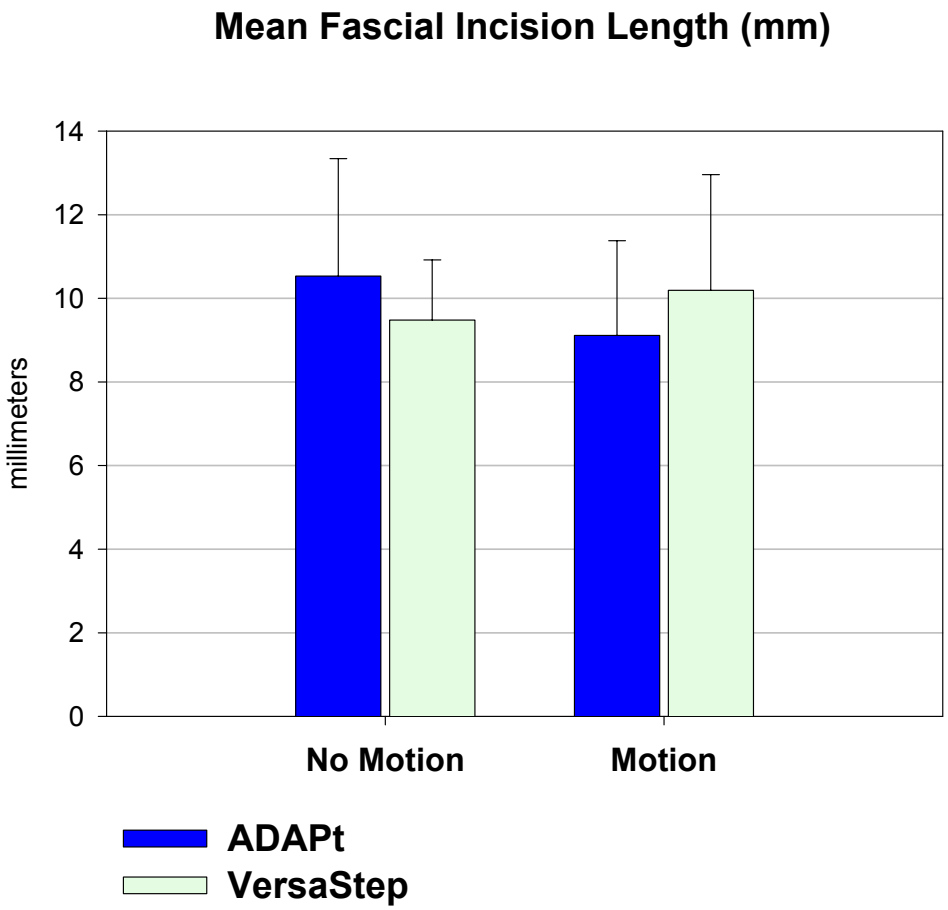
Mean fascial wound areas of the ADAPt and VersaStep devices are plotted without and with standardized cannula motion or manipulation. The mean fascial wound areas associated with ADAPt were 45% less than the VersaStep without manipulation (motion) and 19% less following cannula or port manipulation.

Figure 5



The median fascial wound areas of the ADAPt and VersaStep devices are plotted without and with standardized cannula or port manipulation (motion). The median fascial wound areas associated with ADAPt were 44% less than the VersaStep without manipulation (motion) and 40% less following manipulation.

Figure 6



Mean fascial wound lengths are plotted against the ADAPt and VersaStep devices without and with standardized cannula manipulation. There is no significant difference between devices and there are no differences with and without cannula manipulation.

Table 2. Muscle Damage Scoring System

Score	Muscle Damage
0	No detectable injury
1	Minimal bruising/fiber injury
2	Damage less than the fascial incision
3	Damage equal to or extends beyond than the fascial incision

Muscle Damage Scores: Table 2 displays the muscle damage scoring system. The mean muscle scores for ADAPt without and with motion are 1.25 (± 0.83) and 0.29 (± 0.45); and for the VersaStep system 0.25 (± 0.43) and 1.75 (± 0.66).

Discussion

In this study, the peak force required to insert the ADAPt device through the lower abdomen of our porcine model was significantly less than that for the VersaStep system. The time to insertion was slightly longer for the ADAPt entry than for the VersaStep device. Aside from making the ADAPt device somewhat easier to insert, we cannot comment upon what, if any safety advantages this finding might suggest, particularly given the blunt design of the obturators in the two devices. Incision lengths and muscle damage scores were similar for the two devices, regardless of cannula manipulation. However, to our surprise, the VersaStep device created a double fascial wound defect that was approximately 1.5 times larger than both the ADAPt system, and the original "Step" model tested in our previously published work.[12] The reasons for the differences between the two versions of the "Step" systems remain unclear but could be related to the fact that in the earlier study, systems were positioned at a 45 degree angle to horizontal, while in the present comparison, the insertion was at 90 degrees. It is possible that with the angled insertion there is greater overlap of the uninjured portions of the two fascial layers thereby reducing the area of the exposed underlying muscle.

The previously published comparative trial showed that blunt conical systems, including the VersaStep device, created a fascial wound area that was significantly smaller than those associated with pyramidal devices of similar caliber. This may lead to conjecture that the hernia risk with 12mm blunt conical might be much lower than that for pyramidal trocar-based systems and at least some other bladed designs.[12] A randomized trial has suggested that hernia risk for the VersaStep system without port closure is similar to that for bladed systems with closure. However, the relatively small sample size (250 patients total), and the lack of standardization of cannula diameter, in our opinion, makes conclusions regarding such risks premature.[9] The same authors demonstrated that the blunt device virtually eliminated the risk of intraoperative bleeding from the port site, a complication found relatively commonly with the bladed systems, which likely traumatize and incise encountered abdominal wall blood vessels. The results of the current work, demonstrating similar or smaller incisional wound metrics for the blunt-tipped ADAPt device, suggest that the ADAPt system would be associated with elimination of wound bleeding and similar or even reduced hernia risks compared with

comparable caliber, pyramidal trocar-based devices. Our standardized set of cannula manipulations did not significantly alter wound size for either of the devices examined in this study, a finding consistent with our other study of blunt dilating devices.[15]

A composite view of wound metrics from this and previous studies of 12 mm devices is shown in Figure 7 and a graphical display of the composite incision area data is presented in Figure 8.

Figure 7. Wound Metrics Composite
Comparison of data from present study with those from previous work in our laboratory. The Endopath Dilating data were reported in 1999[12] while the Endopath Tristar data are from our 2002 study.[13] Photos are approximately to scale. It should be noted that the Endopath dilating devices were inserted at a 45-degree angle to the horizontal, while all other devices were positioned at 90 degrees. The impact, if any, of these differences in insertion angle on wound metrics is unknown.

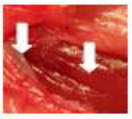
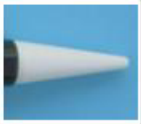
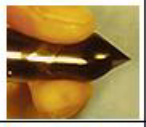
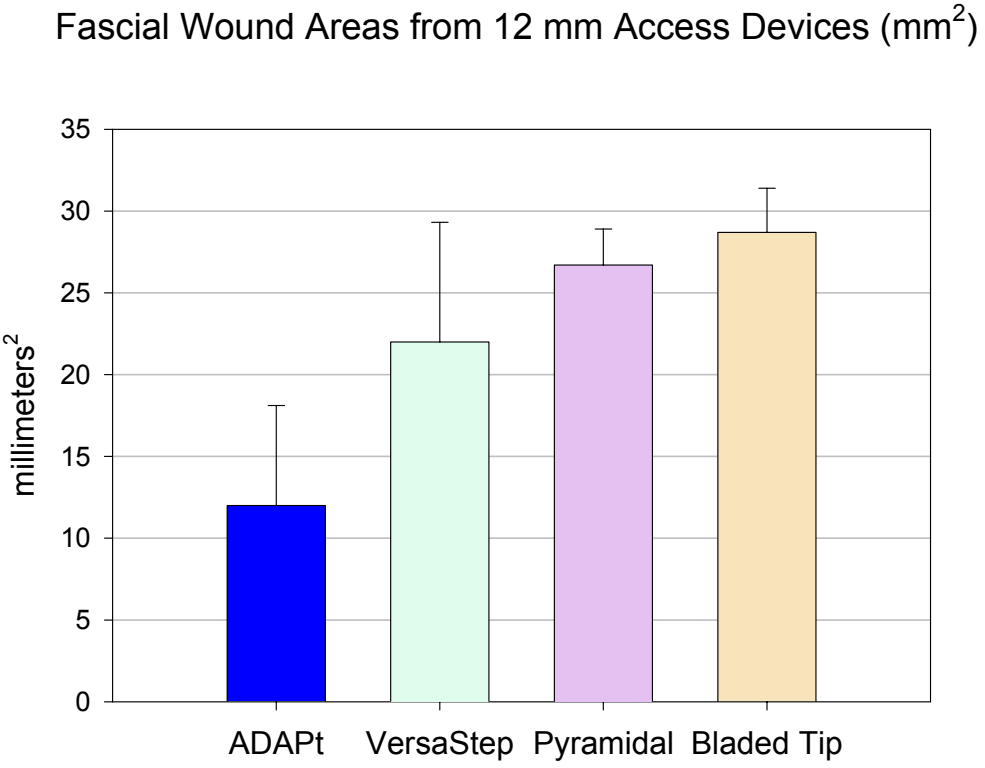
Device	Manufacturer	Tip Design	Tip Image	Mean Wound Area (mm^2)	Fascial Wound Image	Mean Muscle Damage Score No Motion/Motion	Muscle Wound Image
ADAPt	Taut	Blunt Dilating		12.0		1.3 / 0.3	
VersaStep	USSC	Blunt Dilating		22.0		0.3 / 1.8	
Endopath Tristar	Ethicon Endosurgery	Pyramidal		26.7		1.9 / 2.0	
Endopath Dilating	Ethicon Endosurgery	Cutting - Dilating		28.7		N.A.	N.A.

Figure 8. Wound Area by Tip Design for 12-mm Access Devices (Composite Data) Comparison of mean wound area data (without cannula manipulation) from present study with those from previous work in our laboratory. The Bladed –Tip is the Endopath Dilating tip and data were reported in 1999[12] The pyramidal device Endopath Tristar data are from our 2002 study.[13] Both the pyramidal and dilating tip devices were inserted at a 45-degree angle to the horizontal, while the devices in the current study were positioned at 90 degrees. In addition, the wound areas associated with the predecessor of the VersaStep were much smaller than those observed in the current work, and similar to those observed for the ADAPt device. The impact, if any, of these differences in insertion angle on wound metrics is unknown.



Conclusions

From this comparison, we are able to conclude that 12mm diameter ADAPt laparoscopic access systems can be inserted through the abdominal wall with reduced force compared to similar caliber VersaStep access devices, and that the areas of the abdominal wounds associated with the ADAPt device are smaller. Incisional length and muscle damage scores were similar and none of the wound metrics changed significantly with standardized cannula manipulation. Intraperitoneal pressure was lower with the VersaStep device, a feature that reflects the pressure/counterpressure method of cannula insertion. The clinical importance of any of these differences is yet to be determined.

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