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Radially expanding dilatation

A superior method of laparoscopic trocar access

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Abstract
Trocars used in laparoscopic surgery occasionally produce serious complications, such as bleeding, visceral injury, or incisional hernia. We report the evaluation of a new, potentially safer laparoscopic access device in which the cutting obturator of a standard trocar is replaced by a blunt, radially expanding device. Conventional and radially expanding trocars were used in laparoscopic cholecystectomies in 12 pigs. Their abdominal walls were excised and the defects caused by the trocars were examined. The defects caused by the radially expanding devices were about 50% narrower ($P < 0.001$), and the incidence of abdominal wall bleeding was considerably less (0% vs 21%) with the radially expanding trocars. Since incisional hernias at trocar sites are related to the size of the abdominal wall defect, the use of radially expanding trocars should decrease the incidence of this complication. There should also be less risk of visceral injury.

Key words: Laparoscopy — Trocar complications — Incisional hernia — Radially expanding devices

Most of the laparoscopic trocars in use today rely upon a metal stem with a cruciate cutting tip to penetrate the layers of the abdominal wall. As a safety feature, the disposable trocars are designed so the cutting tip is automatically covered by a plastic sleeve immediately after the tip enters the peritoneal cavity.

Trocar-related complications are an occasional problem. Bleeding from the abdominal wall or intraabdominal blood vessels and visceral injury may be caused by the sharp metal tip before it becomes covered by the safety sleeve. Postoperative incisional hernias and small bowel obstruction may develop from the residual defect in the muscular fascia, which is often difficult to close [1–11].

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In this study we evaluated a new laparoscopic access device whose novel features involve the cutting trocar being replaced by a needle and a blunt plastic obturator and the defect in the abdominal wall being created by radial expansion. We compared the size and shape of the defects caused by the new device with those caused by conventional 10-mm disposable trocars.

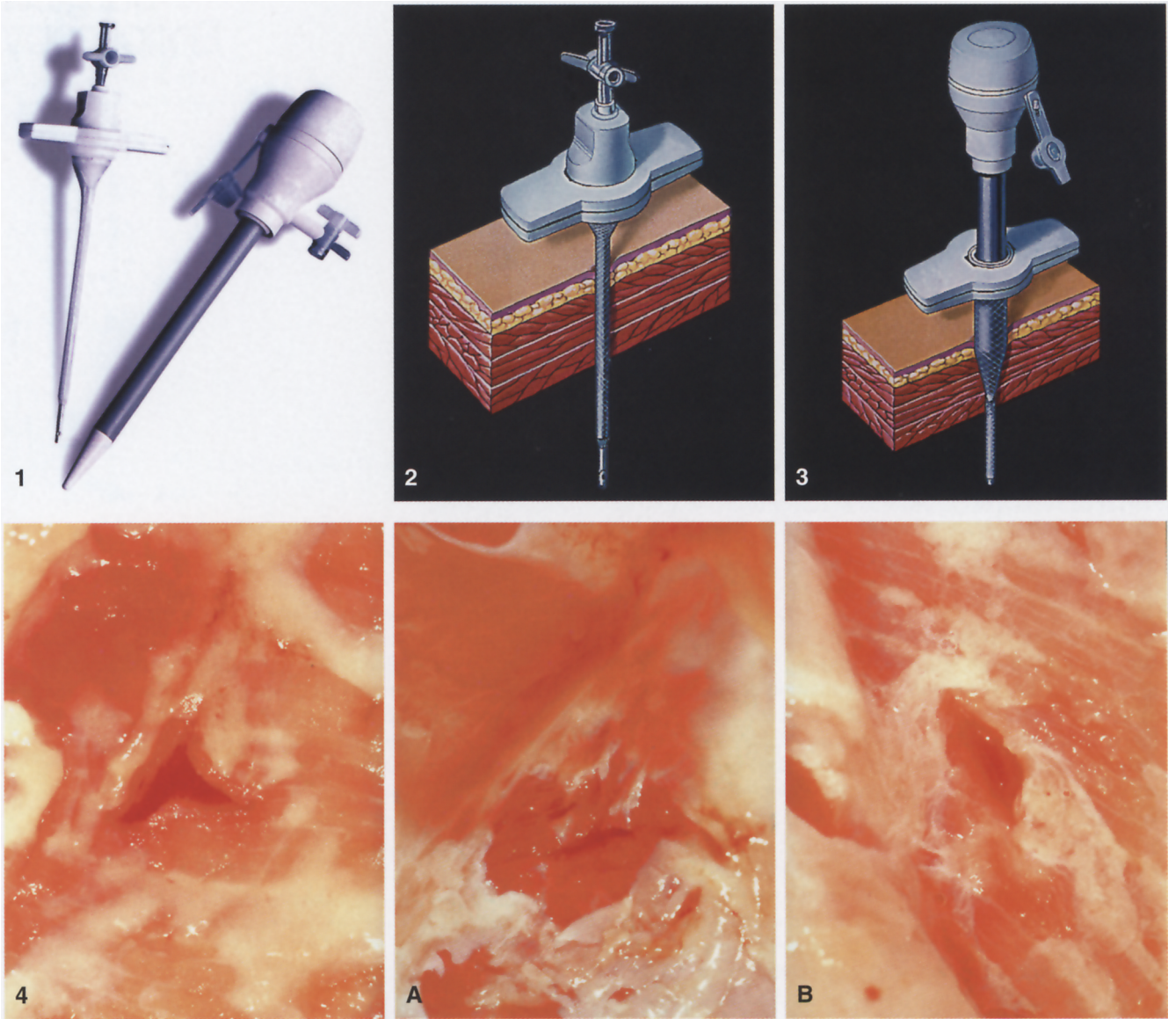
Materials and methods

Pigs were used because their abdominal wall resembles that of humans. Twelve female Hampshire farm pigs (weight range 60–80 lb) were used. General anesthesia was administered using ketamine (20 mg/kg, IM), xylazine (2 mg/kg, IM), sodium pentobarbital (15–25 mg/kg PRN IV), and atropine (0.05 mg/kg IM). During the study the animals were cared for by the staff of the UCSF Animal Care Facility, following NIH protocols. At the end of the procedure, the animals were euthanized using pentobarbital (150 mg/kg, IV) followed by bilateral thoracotomy. The study was approved by the UCSF Committee on Animal Research.

Following the introduction of general anesthesia, a Veress needle was inserted above the umbilicus, and a pneumoperitoneum (15 mmHg) was created using CO_2 and an automatic insufflator. Trocars were then inserted in the midline for the laparoscope and through each quadrant of the abdomen (one each for right upper quadrant, left upper quadrant, right iliac fossa, left iliac fossa) for the instruments. The 12 pigs were divided into 2 groups. In group A ($n = 6$), conventional 10-mm disposable trocars (Surgiport, US Surgical Corporation, Norwalk, CT) with cutting trocars and no fascial grips were used. In group B ($n = 6$), radially expanding trocars (Innerdyne Inc., Mountainview, CA) were used.

In group B, the trocar assembly consisted of a Veress needle, a radially expandable sheath, and a tapered, blunt, plastic obturator (Figs. 1–3). The Veress needle was mounted within the radially expandable sheath, and the needle-sheath assembly was inserted into the peritoneal cavity, where it was first used to create the pneumoperitoneum. The needle was then removed, leaving the sheath in place. The blunt obturator was inserted into the cannula (we used the cannulas from Surgiport trocars, US Surgical Corporation), and the obturator-cannula assembly was inserted through the sheath using a gentle twisting motion in order to stretch the tract in the abdominal wall and leave a working cannula in place. After completing the laparoscopic procedure, the trocars were removed by first withdrawing the cannula from the sheath and then withdrawing the sheath.

After the cannulas were in place, a laparoscopic cholecystectomy was performed via the cannulas in the midline, right iliac fossa, right upper quadrant, and left upper quadrant. The same two surgeons performed all



Figs 1–3. The new method of laparoscopic access using radially expanding trocars.

Fig. 1. The radially expanding trocar assembly including Veress needle, radially expandable sheath, and blunt plastic obturator.

Fig. 2. The initial puncture is made with the Veress needle and sheath.

Fig. 3. The needle is removed from within the sheath, and the plastic obturator and cannula are inserted, causing radial dilatation of the tract. A working cannula is left in place.

Fig. 4. A typical example of a stellate muscular defect caused by a 10-mm disposable trocar, without a fascial grip.

Fig. 5. Typical slit-like muscular defects caused by the radially expanding trocars. **5A** The fascial edges were deliberately excised to reveal the muscular defect. **5B** Another example of a defect caused by a radially expanding trocar.

operations. One hour after the last cannula had been inserted, the pneumoperitoneum was deflated, the cannulas were removed, the animal was sacrificed, and the anterior abdominal wall was excised.

Each layer of the abdominal wall was dissected individually in the fresh state, and the defects created by the trocars were analyzed. The shape of the defects, the relationship to the muscular fibers, and the presence or absence of bleeding were noted. The *length* of the defect was defined as a straight line connecting the extremes of the defect. The widest point of the defect along this straight line was termed the *width* (see Figs. 4 and 5). The lengths and widths of the defects were measured and recorded.

Statistical comparison was performed between groups using the double tailed Student's *t*-test. *P* values of <0.05 were accepted as significant.

Results

Shape and orientation of defects

The trocar defects in group A were stellate and bore no consistent relationship to the orientation of the muscle fibers. The muscle fibers were cut, and in 5 (21%) out of 24 trocar insertions there was ecchymosis or bleeding into the muscular layers. A typical example is shown in Fig. 4.

Table 1. Mean length, width, and percent difference of trocar wounds

The mean length (millimeters ± SEM) of the muscular defects caused by the conventional trocars (group A) and by the radially expanding trocars (group B); $n = 24$ observations in each group of 6 animals

Muscle layer	Group A	Group B	*P* value
External oblique	16.8 (0.37)	15.4 (0.36)	0.01
Internal oblique	16.9 (0.57)	15.8 (0.55)	0.33
Transversus abdominis	16.5 (0.55)	14.3 (0.49)	0.01
Peritoneum	15.1 (0.57)	11.6 (0.73)	0.001

The mean width (millimeters ± SEM) of the muscular defects caused by the conventional trocars (group A) and by the radially expanding trocars (group B). $n = 24$ observations in each group of 6 animals

Muscle layer	Group A	Group B	*P* value
External oblique	10.2 (0.47)	5.5 (0.24)	<0.001
Internal oblique	9.3 (0.41)	3.6 (0.22)	<0.001
Transversus abdominis	8.8 (0.43)	3.8 (0.22)	<0.001
Peritoneum	11 (0.63)	5.8 (0.49)	<0.001

% Difference in width between group A & B: (A − B)/A × 100

Muscle layer	% Difference
External oblique	46
Internal oblique	61
Transversus abdominis	55
Peritoneum	47
Mean % diff (all layers)	52

The defects in group B were slit-like and parallel to the muscle fibers. The muscle fibers were not cut, and ecchymosis or bleeding in the muscular layers was uniformly absent. Typical examples were shown in Fig. 5A and B.

Size of the defects

Table 1 shows the mean length ± SEM and the mean width ± SEM of the defects in each muscular layer. The percentage difference in the width of the defects between the groups is also shown. As the difference in the lengths was not always significant, the percentage difference in the length of the defects between the two groups was not calculated.

The defects caused by the radially expanding trocars were always narrower (average 52%) than the defects caused by conventional trocars. The defects created using the radially expanding trocars were slightly shorter than those caused by the conventional trocars in the external oblique, transversus abdominis, and peritoneum, but there was no difference in the length of the defects in the internal oblique muscle layer.

Discussion

This anatomic study in pigs showed that a radial expanding trocar stretched the muscular fibers rather than cutting them as occurs with conventional trocars. This resulted in much smaller muscular defects and less bleeding. Although this was an acute animal study, it should be possible to extrapolate the findings to humans for two reasons. First, the anatomy of the abdominal wall in pigs is similar to that in humans. Second, the trocars were inserted and used in a comparable manner to a laparoscopic cholecystectomy in humans. The evaluation of defects could not be blinded because the muscular defects (see Figs. 4 and 5) caused by the two types of trocar were visibly dissimilar.

The aim of this study was to compare the tissue effects of the trocars rather than the cannulas. Thus, identical cannulas were used in both groups and fascial grip devices were not used in either group. In group B, however, the radially expanding trocars did not really need fascial grips, because the friction between the cannula and the tissue was enough to fix the cannula in place when in use for performing surgery. Thus, in this study the conventional trocars probably created smaller defects than they would have if they had been used with fascial grips, the standard practice. The radially expanding trocars can and should be used without fascial grips.

Several design features of the radially expanding trocar should decrease trocar complications. First, it has a blunt obturator. Tews and colleagues [10], using a blunt obturator of similar dimensions for laparoscopic access, showed that in over 1,800 cases there was no instance of visceral or vascular injury. The incidence of injury using cutting obturators has not been determined by prospective studies, but such complications do occur, and they are potentially fatal and not always prevented by the safety shields [1–3]. The Hasson (open laparoscopy) cannula was devised to avoid insertion injuries, but it too is associated with complications [9], and it obviously cannot influence the risk of bleeding and hernia formation at the other trocar sites. The Hasson technique can also be difficult in obese patients. The radi-

ally expanding trocar may decrease the risk of vascular or visceral injury without having to resort to the Hasson technique. In the presence of a previous midline incision, the primary puncture can still be made with a radially expanding trocar by inserting it at one of the lateral cannula sites, or the radially expanding trocar can be inserted using the open technique through the midline.

The new device does not eliminate the risk of Veress needle injury during the first puncture. This highlights the importance of using correct technique for insertion and for checking placement of the Veress needle, as described in standard texts. In addition, however, Veress needle injuries are usually not as serious as trocar injuries [8].

The most common serious complication from the trocar defect in the abdominal wall is incisional hernia and subsequent small-bowel obstruction. Retrospective studies [4, 5, 7] indicate that the risk of incisional hernia formations is proportionate to the size of the trocar and resulting defect. For example, Kadar et al. [5] reported that incisional hernias are rare when using 5-mm ports, uncommon when using 10-mm ports (0.23%), and more common when using 12-mm ports (3.1%). Our finding that the defects created by radial dilatation are about 50% smaller and are oriented in the direction of the muscular fibers (similar to a gridiron incision) suggests that incisional hernia formation should be less with this device—an idea that obviously will have to be confirmed in humans. It may still be sensible to remove the cannulas under direct vision on the notion that sudden gas flow through the opened defect could theoretically suck a piece of omentum or intestine into it. Most laparoscopic surgeons routinely close the fascia at 12-mm port sites, and many close it at 10-mm port sites. Because the risk of incisional hernia is probably greater in the lower abdomen, we perform a full-thickness closure of all 10- and 12-mm port sites in the lower abdomen, all 10-mm port sites in the midline, and only 12-mm port sites in the upper abdomen. We also routinely close the external fascia at 10-mm port sites in the upper abdomen. Whether it is necessary to perform a full thickness closure of the smaller defects created by the new radially expanding devices can only be determined with prolonged follow-up of human cases.

Conclusion

This study has demonstrated in pigs that the defects created by radially expanding trocars are considerably smaller than those caused by conventional cutting trocars. The radially expanding trocars also split the muscles in the direction of their fibers rather than cutting them. These findings suggest that a shift to radial dilatation of the trocar access site may decrease the risk of trocar site hernias. Further work in humans is required to confirm these findings.

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