Safety Profile of Trocar and Insufflation Needle Access Systems in Laparoscopic Surgery

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BACKGROUND: The most common laparoscopic complications are associated with trocar insertion. The purpose of this study was to develop an objective method of evaluating the safety profile of various access devices used in laparoscopic surgery.

STUDY DESIGN: In 20 swine, 6 bladed and 2 needle access devices were evaluated. A force profile was determined by measuring the force required to drive the trocar or needle through the fascia and into the peritoneum, at 0 and 10 mmHg. The amount of tissue deformation, the length of blade exposed, and the duration of exposure were measured using a high-speed digital imaging system.

RESULTS: The needle system without the sheath required the least driving force and had the most favorable force profile. In contrast, the bladed, nonretractable trocar system required a higher driving force and a rapid loss of resistance. Insertion under a pneumoperitoneum did not significantly alter the force profile of the various access devices except for the amount of tissue deformation. With the bladed system, the blade itself was exposed for an average of 0.5 to 1.0 seconds for a distance of 4.5 to 5.0 cm. In comparison, the needle system was exposed for 0.2 seconds for a distance of 1.8 cm.

CONCLUSIONS: We developed a reproducible method of measuring the forces required to place the access systems, their pattern of resistance loss, and the characteristics of the blade exposure. These parameters may provide an adjunctive and objective measurement of safety, allowing for more direct comparison between various trocar designs. (J Am Coll Surg 2009;209:222–232. © 2009 by the American College of Surgeons)

Laparoscopy has become a versatile surgical modality, applicable to various fields and procedures. It offers distinct benefits over open surgery because of its relatively small incisions, minimal tissue injury, less postoperative pain, reduced rate of complications, faster recovery, and improved cosmesis.[1] Albeit clinically beneficial to both patients and clinicians, laparoscopy is not without complications. Although it has been found to be 41% safer than open surgery, the rate of complications can be as high as 5% to 8% for all procedures.[2–6] In laparoscopic surgery, obtaining access into the abdomen and creating a pneumoperitoneum is an essential step. Most access-related complications are associated with placement of the initial trocar.[7]

Currently there are more than 30 types of commercially available trocar access devices. It is estimated that of the numbers of trocars used in the US increased steadily from just over 3 million in 1994 to more than 6 million in 2004.[8] In 2003, the FDA evaluated the incidence of trocar-related injuries.[8] Between 1997 and mid-2002, the FDA received more than 1,300 laparoscopic trocar-associated injury reports, including reports of approximately 30 deaths. Trocar-related injuries accounted for 3% to 6% of complications associated with laparoscopic procedures, with a mortality rate of 0.1% or less. Based on published reports, FDA's product recall data, trocar labeling, and patient educational brochures, the FDA concluded that "[reduction of] morbidity and mortality associated with trocar injuries requires diligence on the part of manufacturers, health care practitioners, regulators, and patients to recognize, manage, and mitigate the risks." But manufacturers' data are limited and the safety of trocar designs has not been for-

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Abbreviations and Acronyms

BNR = bladed nonretractile trocar
BR = bladed retractile trocar
F_d = total drive force
F_f = force needed to go through fascia
F_l = loss of drive force after entering the peritoneum
F_p = force needed to go through peritoneal lining
L_d = the amount of tissue deformation
L_t = the length of trocar exposed in the abdomen after the peritoneum retracts
T_d = time to drive the trocar into the abdomen
T_r = duration of blade exposed unprotected
N = needle

mally or objectively evaluated, making it difficult to assess the risks associated with using these access devices as recommended by the FDA. The purpose of this study was to develop an objective method of evaluating and comparing the profiles of various trocar and access devices used in laparoscopic surgery that may be associated with their safety.

METHODS

The trocars and needle devices were tested on 20 Yorkshire swine (30 kg). They were anesthetized using intramuscular injection of telazol (4.4 to 6.6 mg/kg), xylazine (1.1 to 2.2 mg/kg), and atropine (0.04 mg/kg) for induction, followed by isoflurane (1% to 4%) and oxygen (1 to 2 L) through an endotracheal tube. The animals were placed in a supine position. Designed specifically for this study, an apparatus was constructed to insert the trocars at a constant speed and to measure the axial force applied to the trocar during insertion into the animal's abdominal wall as a function of time (Fig. 1). To ensure a constant rate of insertion, an electric linear actuator was used to power and control the motion of the trocar during insertion. To measure the force as a function of time, an HBM U9B 200-newton force transducer was used along with an HBM AD101B sensor interface board. This transducer had a measurement range of 0 to 200 newtons (0 to 44.96 pounds force) in tension or compression. To ensure an accurate force reading, the trocar, force transducer, and linear actuator were arranged uniaxially in a vertical configuration. To allow for variation in animal size, the height of the device could be varied. It should be noted that the apparatus drove the trocar straight into the abdomen without any twisting motion.

To measure the force required to place a trocar at 0 mmHg of intraabdominal pressure, an axillary-line incision was made from the costal border to the legs of the swine bilaterally. A flap containing the skin, subcutaneous tissue, muscle, and peritoneum was lifted with two metal bars placed at a constant distance apart (Fig. 2). Each trocar was inserted five times in each animal. The skin was incised before each insertion to avoid any additional resistance. The amount of force needed to insert the trocar was quantified and a force profile was generated (Fig. 3). We used this model to ensure that the physical properties of the pig abdomen were consistent. In a preliminary study, we observed that the same trocar had different force profiles when it was inserted in the midline near the rib cage compared with near the umbilicus (data not shown). To be able to compare the trocars, each would need to be inserted at a similar location on the pig's abdomen, requiring a large number of animals for the study. To avoid this requirement, we standardized the physical characteristics of the abdominal wall using the method described earlier. With this method, we found that the force profile of the trocar was the same regardless of where it was inserted on the abdominal wall, allowing multiple punctures to be performed on the same animal.

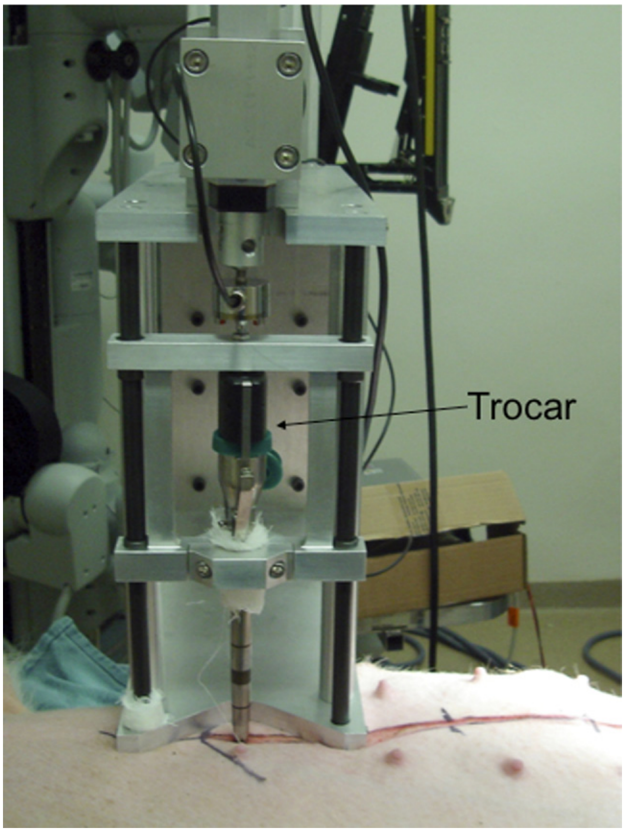

Figure 1. A device constructed for this study to measure force applied during insertion of a trocar. In this case, a trocar was inserted into the pig's abdomen after it was insufflated to 10 mmHg of pressure. Note the skin has been incised to replicate what is done during human surgery.

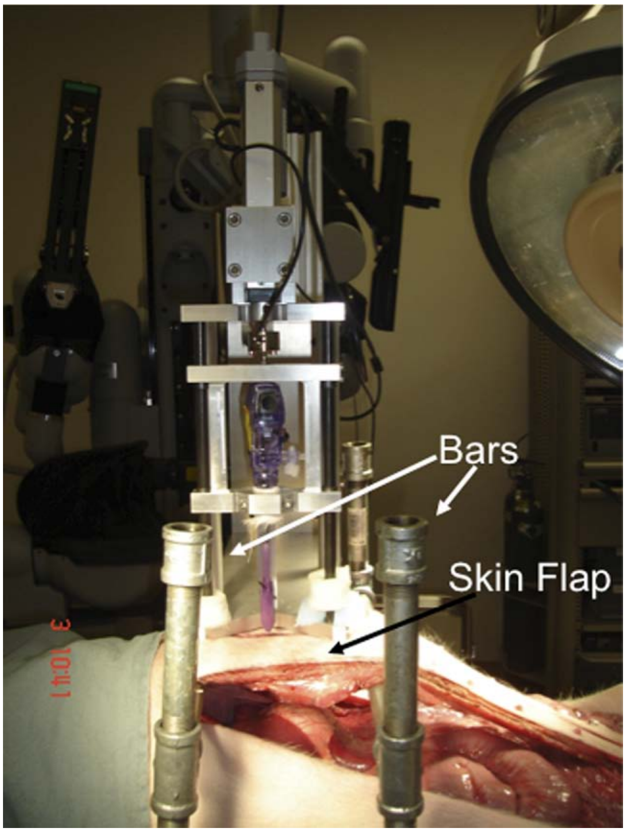

Figure 2. Swine model to replicate abdominal wall tension during trocar insertion at 0 mmHg of intraabdominal pressure.

To measure the force required to place a trocar at 10 mmHg of intraabdominal pressure, the abdomen was filled with carbon dioxide to a pressure of 10 mmHg (Fig. 1). Each trocar was inserted five times in each animal. The skin was incised before each insertion to avoid any additional resistance. In contrast to placing the trocar at 0 mmHg, we observed that the force profile for placing a trocar at 10 mmHg was not significantly different when inserted in the midline within 10 cm of the umbilicus. Consequently, we were able to perform multiple punctures on the same animals without having to modify the abdominal wall.

High-speed digital images were also obtained during trocar insertion to evaluate the length and duration of blade exposure to underlying tissue. A camera (TroubleShooter TS1000ME, Fastec Imaging) that records up to 1,000 frames/second was used. A setting of 500 frames/second was chosen as the optimal speed. The length of trocar inside the abdomen (L_r), the amount of tissue deformation (L_d), and the duration of blade exposure (time from tissue deformation to coverage of the blade with protective sheath [T_r]) were measured (Fig. 4). Although this was performed easily in our model for 0 mmHg of intraabdominal pressure, we were not able to obtain high-speed images of the trocar in a closed abdomen at 10 mmHg because of insufficient lighting. This was not an issue with the 0 mmHg model because high intensity, external lights could be projected around the animal to provide the required lighting needed to obtain the images. Consequently, a plastic model was developed to replicate the abdominal wall insufflated to a pressure of 10 mmHg. To simulate the abdominal wall fascia and peritoneum, respectively, two layers of 1-mm heavy duty plastic (PHS) and one layer of thin plastic wrap (Saran Wrap, SC Johnson) were placed on tension over an O-ring (Fig. 5A). The model was then supported on a 30-cm stand (Fig. 5B). Trocar insertion was performed at the center of the plastic model three times to evaluate for reproducibility. With the plastic model, high-speed imaging of the trocar system could then be obtained with the addition of high intensity, external lights. In a preliminary study, we observed that the force profile of a trocar using this plastic model had similar characteristics to that using the pig's abdominal wall insufflated to a pressure of 10 mmHg (Fig. 5C). Differences in the force profile between various devices were comparable when insertions were performed on the plastic model and on the animal model at 10 mmHg intraabdominal pressure. Despite the reproducibility of the plastic model, an animal model was also used to provide a viable model for comparison in future studies involving animal models.

Correlation between the force profile and the images captured by the camera allowed determination of the amount of force required to go through the different layers of the abdominal wall (Fig. 4). The total drive force (F_d) was defined as the maximal peak force minus the force at baseline. The force needed to go through the rectus fascia (F_f) was defined as the force measured at the first peak minus the force at baseline. The force required to go through the peritoneum lining (F_p) was defined as the force measured at the second peak minus the force at baseline. Loss of drive force after entering the peritoneum (F_l) was defined as the maximal peak force minus the force at the end. We also determine the time required for the trocar to penetrate into the peritoneum.

For each of the measured parameters, a median and a 95% confidence interval were calculated. A Mann-Whitney analysis was performed to determine statistical significance of the force parameters and blade characteristics between the two types of trocars or needle system or between the 0- and 10-mmHg conditions. To compare between three or more trocars or needle system, a Kruskal-Wallis analysis was performed. A p value of < 0.05 was used to determine statistical significance.

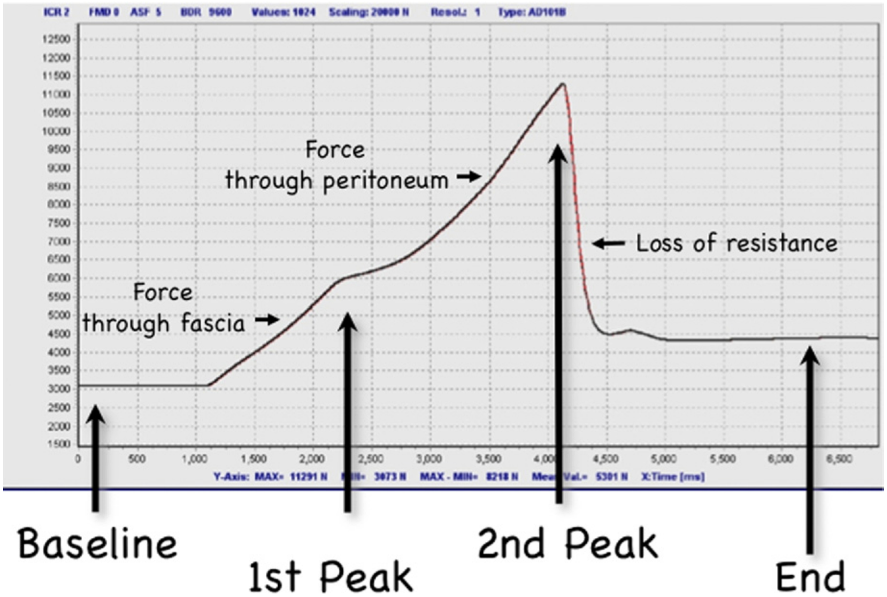

Figure 3. Characteristic force profile generated by each trocar during insertion. The force required to go through the fascia was calculated by subtracting the force measurement at first peak from the baseline force measurement. The force required to go through the peritoneum was calculated by subtracting the force measurement at the second peak from the force measurement at the first peak. The force generated by the loss of resistance after going through the peritoneum was calculated by subtracting the force measurement at the second peak from the end force measurement.

RESULTS

Six bladed trocars (two nonretractile and four retractile) and two needle designs were evaluated (Fig. 6). In addition, two blunt trocars were tested, but they required an excessive amount of force beyond what could be accurately measured by our device. Consequently, these trocars were excluded from the study. The force parameters and blade characteristics for each trocar and needle type are summarized in Table 1 (intraabdominal pressure = 0 mmHg) and Table 2 (10 mmHg). Except for F_d, all measured parameters for the bladed, nonretractile trocar (BNR) #1 were similar to BNR #2 at both 0 and 10 mmHg ($p > 0.05$). BNR #2 had a slightly lower F_d compared with BNR #1, which achieved statistical significance (102.7 newtons versus 118.8 newtons at 0 mmHg and 80.9 newtons versus 114.8 newtons at 10 mmHg). For the bladed retractile trocars (BR), BR #3 had the most favorable force profile, with low F_d (29.7 newtons) and F_l (8.0 newtons) at 0 mmHg. With a pneumoperitoneum of 10 mmHg, BRs #1, #3, and #4 had very similar force profiles. Interestingly, BR #2 continued to required high total driving force at 10 mmHg (96.9 newtons), primarily because of the high driving force required to penetrate the peritoneum (65.0 newtons). This finding was supported by the observation during laparoscopy that the blade of this trocar tended to tent up the peritoneum without piercing it well compared with the blade of the other trocars. The needle system (N w/o sheath) had most favorable force profile with the lowest F_d (8.4 newtons and 17.7 newtons) and F_l (3.3 newtons and 4.0 newtons) at 0 and 10 mmHg, respectively. In addition, the amount of deformation, length of the needle, and the time exposed in the abdomen were the least. Of note, when the nylon-coated sheath was added to the needle system (N

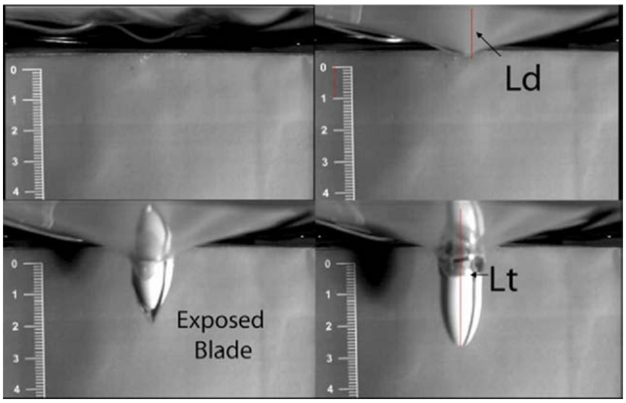

Figure 4. High-speed imaging at 500 frames/sec of a trocar being inserted through an inanimate model constructed to replicate the structural and force characteristics of a pig's abdominal wall. Ld, length of tissue deformation as the trocar is being inserted; Lt, length of trocar inside of the abdomen after the trocar pierces the last layer of the abdominal wall.

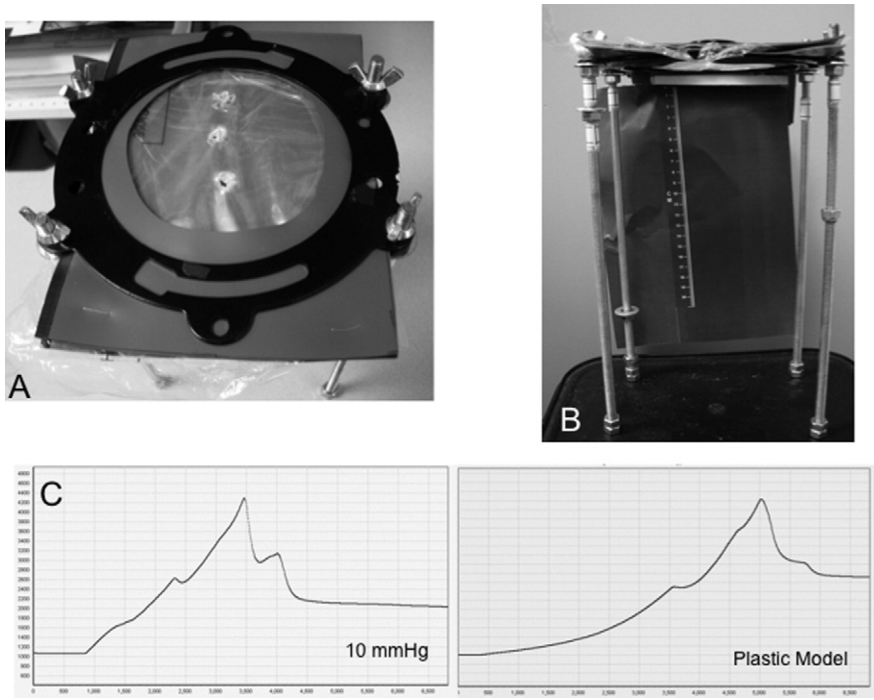

Figure 5. (A) Constructed to replicate the abdominal wall at 10 mmHg of pressure, the plastic model consisted of two layers of 1-mm heavy plastic and one layer of thin plastic placed on tension over an O-ring. (B) This model was then placed on a 30-cm stand and external lights could be applied to obtain high-speed imaging at 500 frames/sec. (C) Pressure profile of a bladed/nonretractable trocar performed in the swine model at 10 mmHg pressure had comparable characteristics with that done with the plastic model.

w/sheath), the force parameters increased to levels higher than those with BR #3 and comparable with those with BR #4. With a pneumoperitoneum of 10 mmHg, the F_d of the N w/sheath improved (28.0 newtons compared with 44.1 newtons, $p < 0.05$). These findings correlated with the observation during laparoscopy that the leading edge of the nylon sheath often got caught on the fascia and peritoneum. With the abdomen under tension, the sheath passed more smoothly into the abdomen.

Although they were from different manufacturers, certain trocars were similar in design (Fig. 6) and had similar force profiles and blade characteristics. Consequently, we grouped the trocars into five categories for easier analysis and comparison (Table 3): BNR system = BNR #1 + #2; BR1 system = BR #1 + #2; BR2 system = BR #3 + #4; N1 system = N w/o sheath; and N2 system = N w/ sheath. At 0 mmHg, the BNR system had the highest driving pressures among the groups of trocar designs; the N1 system had the lowest ($p < 0.05$). For the BNR system, the majority of the total force required to drive the trocar in the abdomen ($F_d = 109.0$ newtons) was used to penetrate the fascial layers ($F_f = 82.1$ newtons). The BR1 ($F_f = 44.9$ newtons) and BR2 systems ($F_f = 41.1$ newtons) required less force to pass through the fascial layers compared with BNR ($p < 0.01$). But the BNR ($F_p = 26.3$ newtons) and BR2 ($F_p = 34.8$ newtons) systems required similar force to pass the trocar through the peritoneal layers. The major difference between the amount of total force required to pass the trocar into the abdomen between the BR1 ($F_d = 77.5$ newtons) and BR2 systems ($F_d = 44.1$ newtons) was the amount of force required to pass through the peritoneal lining ($F_p = 34.8$ newtons versus 15.6 newtons, $p < 0.05$). The loss of driving pressure (F_l) was highest in the BNR system (because its F_d was the greatest), as expected. The N1system had the most favorable force profile for the four parameters measured. With the abdomen desufflated, the amount of tissue deformation (L_d) caused by the introduction of the access system was greatest in the BNR system (5.1 cm) and the least in the N1 system (1.8 cm). The L_d was similar in the BR1, BR2 and N2 systems and was an intermediate value between the BNR and N1systems. The length of trocar with the blade exposed in abdomen (right after loss of driving force) ($L_t = 5.7$ cm) was slighter greater in the BNR system, with a p value of 0.06 compared with all other systems, but the N1 system had the least length ex-

Figure 6. Trocar and blade design of the access systems tested.

tended into the abdomen (L_t = 2.2 cm). The amount of time the blade or needle was exposed in the abdomen ranged from 0.5 to 1.0 seconds in the BR groups to 0.05 to 0.2 seconds in the N system.

Increasing the abdominal pressure to 10 mmHg did not significantly change the F_d of each system except in N2 (44 newtons versus 28.0 newtons, $p = 0.05$). In the BNR system, the amount of force required to drive the trocar through the peritoneal layer (F_p) was increased at 10 mmHg ($p = 0.05$), although the force required to go through the fascia (F_f) was decreased ($p < 0.05$). This finding was not observed in any of the other systems. The opposing effects on F_p and F_l by the increased abdominal pressure resulted in the total driving force for BNR trocars being compared with that at 0 mmHg (F_d = 109.0 newtons versus 100.9 newtons, $p > 0.5$). With the abdomen insufflated to 10 mmHg, the L_d decreased in all systems ($p < 0.01$). The lengths of trocar with the blade exposed in the abdomen were not significantly different from those at 0 mmHg for all systems except for N2. The amounts of time the blade or needle was exposed did not changed greatly from those at 0 mmHg for all systems.

DISCUSSION

Access for laparoscopy can be achieved by several methods: placing a trocar under direct vision into the peritoneal cavity (Hasson technique)[7] or "blindly" with a bladed trocar with the abdomen desufflated. Alternatively, a needle system could be used to access the peritoneum to simultaneously insufflate the abdomen and introduce a sheath through which a blunt trocar could be placed.[9] A variation of this technique is to use the needle system to insufflate the abdomen and then place a bladed trocar or the needle system with a sheath. It has been suggested that insertion of the initial trocar using an open technique is a safer method of placement than blindly inserting an access system. But a metaanalysis of the literature by Corcione and colleagues[10] demonstrated that there was no clear advantage of the open compared with the closed technique in preventing access complications. In another metaanalysis, Ahmad and associates[11] evaluated 17 randomized controlled trials with a total of 3,040 individuals undergoing laparoscopy. The authors concluded that the safest technique for trocar placement could not be determined based on their analysis. In evaluating the incidence and risk factors for complications in 806 children undergoing laparoscopic urologic surgery

Table 1. Force and Blade Parameters at 0 mmHg

	Bladed nonretractile (BNR)		Bladed retractile (BR)				Needle (N)	
Parameter	**#1**	**#2**	**#1**	**#2**	**#3**	**#4**	**Without sheath**	**With sheath**
F_d	118.8* (112.5–133.7)	102.7 (84.1–105.4)	83.1 (74.2–99.4)	71.7 (66.4–75.2)	29.7† (27.4–34.6)	55.4 (53.9–59.2)	8.4 (7.4–27.1)	44.1‡ (30.6–60.8)
F_f	106.0 (92.5–108.5)	67.50 (57.5–70.0)	46.5 (39.5–55.0)	42.0 (38.5–46.0)	29.7† (26.7–34.5)	51.0 (50.0–52.5)	6.7 (5.8–26.1)	23.5 (21.0–37.5)
F_p	17.5 (12.5–32.5)	32.5 (25.0–35.0)	38.0 (33.5–45.0)	28.5 (27.0–32.0)	10.0† (9.0–12.0)	21.5 (18.0–23.5)	3.3 (2.3–4.5)	13.5‡ (9.5–26.0)
F_l	55.0 (50.0–85.0)	60.0 (55.0–60.0)	38.5 (28.5–40.0)	35.0 (31.5–40.0)	8.0† (7.0–9.0)	16.0 (11.0–20.0)	3.8 (3.3–19.5)	14.5 (9.5–22.0)
T_d	3.9 (3.8–4.0)	3.5 (3.5–3.5)	3.8 (3.5–4.3)	3.6 (3.6–3.7)	2.9 (2.7–3.5)	3.8 (3.5–4.0)	2.8 (2.5–3.3)	2.9 (2.4–3.5)
L_d	5.1 (4.2–6.0)	5.0 (4.9–5.1)	4.5 (3.4–4.8)	2.4 (1.8–2.6)	2.9 (2.5–3.2)	4.1 (4.0–4.1)	1.8 (1.4–2.3)	3.6‡ (2.9–4.1)
L_t	5.9 (5.4–6.4)	5.3 (5.1–6.2)	5.4 (4.9–6.0)	4.9 (3.4–5.7)	3.2 (3.0–3.5)	5.8 (5.6–5.9)	2.2 (1.6–2.7)	4.3‡ (4.1–4.6)
T_r	NA	NA	0.70 (0.6–1.1)	1.11 (0.6–1.2)	0.10 (0.04–0.2)	0.70 (0.6–0.8)	0.05 (0.02–0.15)	0.17 (0.07–0.70)

Values are medians with 95% confidence interval.
*$p < 0.05$ compared with BNR #2.
†$p < 0.05$ compared with BRs #1, #2, and #4.
‡$p < 0.05$ compared with needle without sheath.
F_d, total drive force (newtons); F_f, force needed to go through fascia (newtons); F_p, force needed to go through peritoneal lining (newtons); F_l, loss of drive force after entering the peritoneum (newtons); L_d, the amount of tissue deformation (cm); L_t, the length of trocar exposed in the abdomen after the peritoneum retracts (cm); NA, not applicable; T_d, time to drive the trocar into the abdomen (sec); T_r, duration of blade exposed unprotected (sec).

Table 2. Force and Blade Parameters at 10 mmHg

	Bladed nonretractile (BNR)		Bladed retractile (BR)				Needle (N)	
Parameter	**#1**	**#2**	**#1**	**#2**	**#3**	**#4**	**Without sheath**	**With sheath**
F_d	114.8* (108.2–125.3)	80.9 (74.5–95.7)	34.8 (30.2–40.1)	96.9 (91.5–112.3)	35.6 (34.84–42.34)	41.7 (40.4–52.9)	17.7 (16.0–19.0)	28.0 (24.0–31.0)
F_f	38.50* (28.5–47.5)	67.5 (47.5–70.0)	30.5 (29.2–34.0)	35.0 (30.5–45.0)	34.8 (31.3–35.1)	36.0 (32.0–40.0)	18.1 (17.7–18.6)	14.5 (14.0–15.0)
F_p	67.5* (57.5–75.0)	50.0 (28.5–55.0)	6.5 (6.0–7.5)	65.0 (62.5–67.5)	6.0 (4.5–11.0)	26.0 (21.0–33.5)	1.8 (1.3–3.5)	13.5 (10.5–16.0)
F_l	80.0 (65.0–85.0)	67.0 (48.5–78.5)	22.5 (16.0–27.5)	20.0 (13.5–26.5)	6.5 (6.0–12.5)	19.5 (18.5–20.0)	4.0 (3.8–5.5)	12.5 (11.3–14.0)
T_d	4.0 (4.0–4.3)	3.8 (3.5–4.0)	4.5 (4.3–4.5)	5.0 (5.0–5.0)	4.3 (4.0–4.8)	3.8 (3.5–4.0)	1.6 (1.4–1.7)	2.7 (2.3–2.8)
L_d	1.8 (1.5–2.1)	1.4 (1.3–4.0)	1.6 (1.5–1.7)	1.2 (1.1–1.5)	1.2 (1.2–1.3)	1.1 (0.9–1.4)	1.4 (1.2–1.5)	1.4 (1.3–1.4)
L_t	4.0 (3.9–4.1)	3.9 (3.1–4.3)	4.4 (3.8–4.8)	3.6 (3.4–3.8)	2.8 (2.7–3.0)	4.2 (3.9–4.4)	1.9 (1.7–2.0)	1.7 (1.1–1.7)
T_r	NA	NA	1.3 (1.2–1.3)	1.1 (1.1–1.2)	0.6 (0.5–0.7)	1.2 (1.2y–1.3)	0.26 (0.20–0.36)	0.14 (0.13–0.20)

Values are medians with 95% confidence interval.
*$p < 0.05$ compared with BNR #2.
F_d, total drive force (newtons); F_f, force needed to go through fascia (newtons); F_p, force needed to go through peritoneal lining (newtons); F_l, loss of drive force after entering the peritoneum (newtons); L_d, the amount of tissue deformation (cm); L_t, the length of trocar exposed in the abdomen after the peritoneum retracts (cm); NA; not applicable; T_d, time to drive the trocar into the abdomen (sec); T_r, duration of blade exposed unprotected (sec).

Table 3. Force and Blade Parameters Grouped by Trocar Design

Parameter	BNR system (BNR #1 + #2)		BR1 system (BR #1 + #2)		BR2 system (BR #3 + #4)		N1 system (needle without sheath)		N2 system (needle with sheath)	
	0 mmHg	10 mmHg	0 mmHg	10 mmHg	0 mmHg	10 mmHg	0 mmHg	10 mmHg	0 mmHg	10 mmHg
F_d	109.0* (95.6–125.2)	100.9* (90.3–117.8)	77.5 (64.9–90.2)	69.4 (40.5–92.4)	44.1 (31.9–57.2)	43.9 (34.1–62.6)	8.4 (7.4–27.1)	17.7 (16.0–19.0)	44.1 (30.6–60.8)	28.0 (24.0–31.0)
F_f	82.1 (62.5–93.5)	48.4 (30.6–56.3)	44.9 (37.2–52.9)	35.3 (28.8–43.5)	41.1 (29.7–50.9)	34.3 (29.5–40.0)	6.7 (5.8–26.1)	18.1 (17.7–18.6)	23.5 (21.0–37.5)	14.5 (14.0–15.0)
F_p	26.3 (18.6–33.3)	54.0 (30.5–69.2)	34.8 (30.2–38.9)	35.9 (17.5–52.4)	15.6† (8.5–23.1)	18.0 (7.5–24.3)	3.3 (2.3–4.5)	1.8 (1.3–3.5)	13.5 (9.5–26.0)	13.5 (10.5–16.0)
F_l	62.5 (57.5–68.3)	69.3 (60.1–75.3)	34.4 (26.6–41.3)	20.8 (11.2–26.4)	11.7 (7.6–14.2)	14.7 (7.4–18.2)	3.8 (3.3–19.5)	4.0 (3.8–5.5)	14.5 (9.5–22.0)	12.5 (11.3–14.0)
T_d	3.7 (3.5–3.9)	3.2 (3.0–3.5)	3.8 (3.5–4.0)	4.7 (4.0–5.0)	3.5 (3.0–3.8)	4.1 (3.8–4.8)	2.8 (2.5–3.3)	1.6 (1.4–1.7)	2.9 (2.4–3.5)	2.7 (2.3–2.8)
L_d	5.1‡ (4.7–5.6)	2.0 (1.7–2.3)	3.1‡ (2.1–4.2)	1.4 (1.2–1.5)	3.5‡ (2.5–3.7)	1.2 (1.1–1.6)	1.8 (1.4–2.3)	1.4 (1.2–1.5)	3.6‡ (2.9–4.1)	1.4 (1.3–1.4)
L_t	5.7 (5.2–5.9)	5.2 (4.9–5.5)	4.9 (3.5–5.6)	4.0 (3.4–4.3)	4.5 (3.6–5.3)	3.5 (2.8–4.1)	2.2 (1.6–2.7)	1.9 (1.7–2.0)	4.3 (4.1–4.6)	1.7 (1.1–1.7)
T_r	N/A	N/A	1.0 (0.8–1.3)	1.2 (1.1–1.3)	0.4 (0.1–0.6)	0.9 (0.5–1.3)	0.05 (0.02–0.15)	0.26 (0.20–0.36)	0.17 (0.07–0.70)	0.14 (0.13–0.20)

Values are means with 95% confidence interval.
*$p < 0.05$ compared with all other groups of trocar designs.
†$p < 0.05$ compared with BR1.
‡$p < 0.05$ comparing 0 mmHg with 10 mmHg.
BNR, bladed nonretractile; BR, bladed retractile; F_d, total drive force (newtons); F_f, force needed to go through fascia (newtons); F_p, force needed to go through peritoneal lining (newtons); F_l, loss of drive force after entering the peritoneum (newtons); L_d, the amount of tissue deformation (cm); L_t, the length of trocar exposed in the abdomen after the peritoneum retracts (cm); NA, not applicable; T_d, time to drive the trocar into the abdomen (sec); T_r, duration of blade exposed unprotected (sec).

at our institution,[12] we similarly observed a 1.6% complication rate related to access, with similar incidence in open and closed techniques. So, placement of the access system blindly remained widely practiced because of a lack of safety data precluding its use. Despite the relatively low complication rate, access-related injuries are still potentially catastrophic for the patient. When extrapolating the vast amount of laparoscopic operations performed here and elsewhere, the actual number of injuries is not insignificant and can be quite large, despite the small percentage. Any preventive measure to reduce such injury is necessary. Many of the preventative measures that physicians and hospital staff routinely perform may be for rare events or complications, but nonetheless, these routines are beneficial to the patient and have become part of the standard of care.

Currently, there is an overwhelming number of different access systems available on the market, all claiming to be superior in safety. Given the large number of different types of trocar and needle systems and the relatively low associated complication rate, it would be difficult to compare the safety of various access system designs based solely on the reported complication rates. The choice of access system depends on a multitude of factors including ease of use, cost, and surgeon's personal preference, in addition to safety data, about which the surgeon should be cognizant. This study illustrates an adjunctive method of evaluating the safety of access systems. We demonstrated that the force required to insert trocar and needle access devices can be objectively quantified. All access systems had a reproducible and characteristic force profile required to pass the device through the anterior abdominal wall fascia (F_f) and the peritoneum (F_p). Although it was expected that the amount of force required to insert the systems through the thick fascia of the anterior abdominal wall would be considerable, it was surprising to observe that passing the systems through the thin peritoneal lining also required a significant amount of force. This finding is seen clinically (Fig. 7) and it is not uncommon to observe during laparoscopy that the peritoneal lining greatly deforms as the trocar is inserted. So, additional force is needed to drive the trocar through this last layer of resistance. In addition, all the access systems had a reproducible and characteristic immediate loss of resistance after the trocars or needles enter the abdomen. Within 200 to 300 milliseconds, the force required to move the trocar or needle dramatically dropped from loss of resistance once the peritoneum was punctured. This loss of driving pressure (F_l) is an important determinate of safety because the more drastic the change in force after the access system enters the peritoneum, the more likely a trocar or needle will be advanced deeper into the

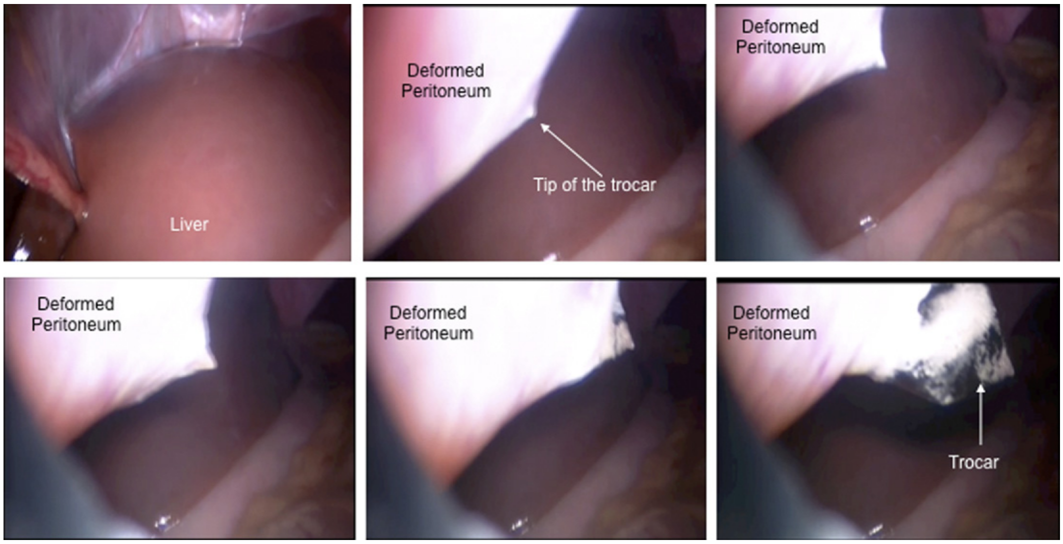

Figure 7. Deformation of the peritoneum observed when a trocar was inserted at 10 mmHg of intraabdominal pressure in an 8-year-old child undergoing laparoscopic pyeloplasty. Note the progressive amount of deformation until the blade pierced the peritoneal layer.

abdominal cavity, resulting in inadvertent injury to surrounding structures such as bowel and blood vessels.

When comparing the various designs, we observed that the needle system required 5- to 10-fold less insertion force compared with the other trocar access systems, and there was less tissue deformation, a shorter length of trocar inside the abdomen, and a shorter time for blade retraction. These parameters suggest a potential safety benefit of the needle access system in reducing trocar-related injury. This finding is not surprising because the needle is much smaller in diameter than the other systems tested. Interestingly, we also observed that the presence of the nylon sheath on the needle system negatively affected its force profile, making it comparable with those of the bladed retractile systems; the sheath provided additional resistance by catching on the fascial layer of the abdominal wall. All needle access system complications in our review were associated with the presence of the nylon sheath.[12] Based on these findings, we have recently switched to placing the needle system without the sheath first to insufflate the abdomen, then reintroducing the needle system with a sheath, through which we then place a blunt trocar. Anecdotally, we noted that with this technique, access into the abdomen was more controlled and required less effort.

When comparing bladed trocars, the BR system required less force for insertion through the fascia and peritoneal layers compared with the BNR system. This is primarily because the blades of the BR system were much sharper than those of the BNR system. Because it could be inserted with less force, the BR system had a more favorable loss of resistance profile and tissue deformation parameters. Despite requiring a blade to pierce the peritoneum, this system required less force to insert, so it may be safer to use. The sharp edge on the blade of a BNR system, in combination with the great amount of force needed to insert the system and the large degree of change in driving force after the system enters the peritoneum, may make these trocars less desirable from a safety standpoint. In evaluating the blade design of the BR system, we observed that trocars with a diamond-shaped blade (BRs #3 and #4) had a more favorable force profile than those with a spear-shaped blade (BRs #1 and #2). This makes intuitive sense because the diamond-shaped blade had more edges than the spear-shaped blade, allowing it to separate the fascia and peritoneal layers more easily.

It has been claimed that retractable bladed trocars and needles are a much safer design because the blade or sharp point of the needle, which facilitates tissue separation of the abdominal wall, rapidly retracts to prevent inadvertent injury. We observed that different systems had different retraction times, ranging from 0.05 to 1.2 seconds. The mechanism that triggers blade retraction or coverage of the needle tip varies between designs. We observed that in some devices, the sheath that drops over the blade to protect it after passing through the peritoneum was stuck on the abdominal wall fascia or peritoneal layers until additional force was applied to push the sheath through. The length of time in which the blade is exposed, in combination with the rapid loss of driving force, can allow the sharp edges or point to be advanced deep into the abdominal cavity and can result in serious bowel or vascular injury.

For all systems tested, the mean total driving force was not significantly different at 0 mmHg versus 10 mmHg of intraabdominal pressure. Independent of the system used, the mean total driving force ranges were found to be 8.4 to 109.0 newtons and 17.7 to 100.0 newtons at 0 and 10 mmHg of intraabdominal pressure, respectively. Contrary to traditional teaching, creation of the pneumoperitoneum did not reduce the amount of force needed to drive the trocar into the peritoneum, even though the layers of the abdominal wall were placed under tension by the pneumoperitoneum. In addition, the pneumoperitoneum did not significantly reduce the change in the amount of force loss after the trocar entered the peritoneum. Consequently, the risk for inadvertent injury to surrounding structures (from the amount of force applied and the rapid loss of force on entering the peritoneum) may not be decreased with the abdomen insufflated. But the amount of tissue deformation (T_d) for all systems tested was significantly reduced at 10 mmHg compared with 0 mmHg of intraabdominal pressure. This finding suggested that the pneumoperitoneum did allow the abdominal wall to be more rigid, resulting in less tissue deformation when the trocar was pushed into the abdomen. In combination with the observation that the increased intraabdominal pressures result in an increased distance between the abdominal and surrounding structures,[13] a pneumoperitoneum can help to minimize potential injury. These safety considerations are of particular importance in pediatric laparoscopy, where the presence of a thinner abdominal wall and the limited size of the intraabdominal space magnifies the risk for injury to surrounding structures, including a relatively large liver and spleen, a more horizontally oriented stomach, and an intraabdominal bladder.

Interestingly, we observed that for the BNR system, although the total driving force was not different at 0 and 10 mmHg, the force needed to go through the fascial layers at 10 mmHg was reduced although the force needed to go through the peritoneal lining was increased. The pneumoperitoneum helped the BNR trocars enter the fascial layers more easily but not the peritoneal layer. It may be speculated that the pneumoperitoneum allowed the more rigid fascial layer to be placed at greater tension than the more pliable peritoneal layers, allowing the trocars to pass through the former more easily than the latter.

There were several limitations to our study. First, the device used to measure the force of insertion was not designed to measure the rotational force; consequently, the method of insertion did not incorporate a twisting motion typically used to facilitate trocar placement. Several access systems, in particular, the bladed designs, rely on the edges of the introducer to separate the tissue. By inserting the trocar with a twisting motion, it is expected that less force is required to push the trocar into the peritoneum. It is technically difficult to measure rotational and transitional force simultaneously. We are currently attempting to develop devices that will be able to accomplish this task, allowing us to quantitate these forces in future studies. Second, in this study we did not take into account other parameters such as the positioning of the patient (ie, Trendelenberg), the angle of insertion, or lifting the abdominal wall during entry. It has been suggested in the literature that these parameters may affect trocar insertion efficacy and safety.[11,14] Third, we were not able to obtain high-speed images of the trocar in a closed abdomen at 10 mmHg because of insufficient lighting, which prevented parameters other than force from being obtained using swine. Alternatively, we developed a plastic model to replicate the abdominal wall insufflated to 10 mmHg to obtain these parameters. Fourth, the force parameters and blade characteristics could not be directly correlated with specific design specifications such as the design of the blade, the blade cover, and the ridges on the outer sheath. In future studies, we plan to create a generic trocar to which each specification can be added one at a time to see how they each affect the studied parameters. Finally, the measured parameters in this study were not correlated with clinical outcomes. Future studies will incorporate animal models for bowel and vascular injuries to determine the amount of force required to produce these complications.

In conclusion, by defining the forces required to place trocars and needles, loss of resistance, and characteristics of the blade or needle exposure, we developed an objective and reproducible method of evaluating the characteristics of laparoscopic access systems. These force and blade characteristics may help to identify risk factors for access-related complications. Based on our findings, the needle system appeared to have the most favorable force profile and blade characteristics. Placement of the access system with the abdomen insufflated to 10 mmHg did not reduce the amount of force required for insertion but did decrease the amount of tissue deformation, potentially reducing the risk of injuring underlying organs and vessels. Additional studies that incorporate rotational force measurement and animal models for bowel and vascular injury will help to characterize the safety profile of the various access system designs.

Author Contributions

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Analysis and interpretation of data: C Passerotti, Leite, Antunes, Nguyen
Drafting of manuscript: C Passerotti, Penna, Nguyen
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