

# Randomized Trial Comparing a Radially Expandable Needle System with Cutting Trocars

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## ABSTRACT

Sharp trocar insertion for laparoscopic procedures carries with it increased risk for vascular and visceral complications and incisional hernia. In a trial, which randomized 87 patients to treatment with either sharp trocars or a radially expanding needle system with blunt dilator, results showed that with the latter system there was statistically improved patient assessment of pain, a lower complications rate, and shorter procedure time. In the group of patients randomized to treatment with conventional trocars, there were a total of six instrument-related adverse events (6/42): four cases (five incidences) of abdominal wall injuries and one small bowel perforation caused by a Veress needle. Of the 45 patients randomized to the blunt dilator/cannula treatment, there was one adverse event (1/45) that was unrelated to the blunt dilator/cannula system: Veress needle injury to abdominal vasculature. The radially expanding access system demonstrates statistically improved patient postoperative comfort and improved patient safety.

**Key Words:** Laparoscopy, Trocars, Complications, Injury.

## INTRODUCTION

Trocars used in laparoscopic surgery occasionally produce serious complications, such as major vascular injury, abdominal wall bleeding, visceral injury or incisional hernia. Investigators recently reported a study in animals that compared a standard trocar with a device in which the cutting obturator of the standard trocar was replaced by a blunt, radially expanding access device (Step™, InnerDyne, Inc., Sunnyvale, CA).<sup>1</sup> Because the dilator/cannula in the Step device radially expand the tissue tract created by the Veress needle, the defects in the abdominal wall were about 50% narrower ( $p < 0.001$ ), and the incidence of abdominal wall bleeding was considerably less (0% vs. 21%) with the Step devices. Since incisional hernias at trocar sites are known to be related to the size of the abdominal wall defect, it was concluded that the use of radially expanding needle systems should decrease the incidence of this complication. Two other prospective reports suggest that patients have less postoperative pain with the Step devices than with conventional trocars.<sup>2,3</sup> Saville and Woods reported that the incidence of major retroperitoneal vascular injury in a large retrospective series was approximately 0.1%, despite the use of safety-shielded trocars.<sup>4</sup> Further, a 1993 survey conducted by the American Association of Gynecologic Laparoscopists found that trocar-induced bowel injuries occur in up to 1.2% of all laparoscopies.<sup>5</sup> In previous studies, there has not been a single occurrence of bowel, bladder or major vessel injury using the Step system,<sup>2,3,6</sup> and it was suggested that the use of the Step system with its blunt dilators should eliminate these complications in the future.

The following randomized, blinded, prospective clinical study was conducted to investigate the potential benefits of using the Step radially expanding needle compared to conventional trocars and to confirm the findings of the previous studies.<sup>2,3,6</sup> The Step devices are FDA-approved and are commercially available. Further, Step is not an experimental device and is not thought to pose any additional risks to the patient, though IRB/Ethics Committee approval was obtained prior to starting the study.

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## MATERIALS AND METHODS

Various operative and diagnostic laparoscopic procedures were performed by seven different surgeons on 87 consecutive women (age range: 18–54 years) undergoing surgery at the Ernst Moritz Arndt University Hospital in Greifswald, Germany and at the Women's Hospital of Texas in Houston, Texas. The procedures were performed from April 1996 to January 1997.

Patients were randomized to treatment with either the Step device (N = 45) or a conventional trocar/cannula (N = 42). The surgeons documented operative complications and device-related adverse events. Patients were blinded as to which type of instrument was used.

### Devices

The Step device consists of an access-insufflation needle, a radially expandable biocompatible polymeric sleeve, and a tapered blunt dilator/cannula. The surgeon inserts the needle into the abdomen and insufflates. The needle is then removed and reinserted with the sleeve (**Figure 1a**). The surgeon removes the needle, leaving the sleeve in place, and a blunt dilator and cannula is inserted through the sleeve, thereby separating or stretching the tissues along each anatomical plane rather than cutting through tissue layers (**Figure 1b**). The dilator is removed and laparoscopic instruments can then be passed through the cannula (**Figure 1c**). The conventional trocars were either disposable or nondisposable with a stellate cutting stylet. All investigators were experienced laparoscopists who had been trained in the use of the expandable nee-

dle system and had been using it for more than one year. For those patients randomized to trocars, the surgeon used the conventional cutting trocar that was standard for that institution.

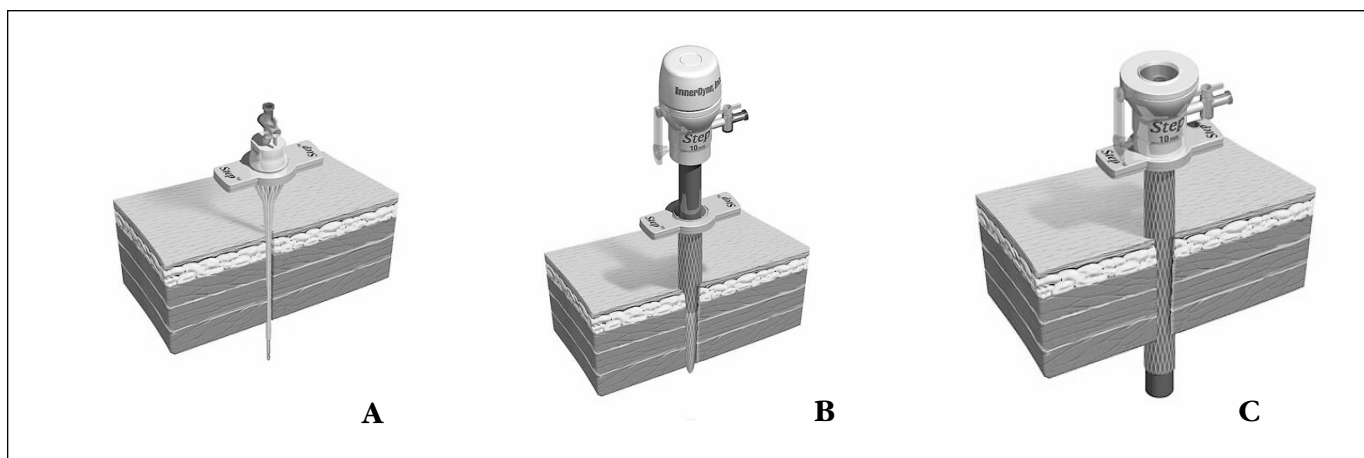
For the purposes of this study, the patients in whom conventional trocars were used had their trocar sites closed for all defects 10 mm or greater. In patients in whom the Step device was used, the intention was not to close any of the fascial defects. Therefore, the intent-to-treat groups were "closure" for the conventional trocars and "nonclosure" for the Step devices. However, it was up to the surgeon to determine if a Step defect needed closure.

### Postoperative Follow-Up

A blinded, trained observer assessed the operative wounds at 4 and 24 hours postoperatively and inquired about the level of the patients' pain using a visual analogue pain scale at 4, 8, 12 and 24 hours. Each evaluation was based on patient assessment of pain as marked on a 100-mm visual analogue pain scale.

### Statistical Methods

Statistical tests of association for categorical variables were performed using either a chi-square analysis or Fisher's Exact Test, depending on the expected cell frequencies. Tests for continuous variables were performed using ordinary t-tests or the Wilcoxon Rank Sum method. All tests were 2-tailed, with a nominal 0.05 alpha level. All statistical analyses were performed using programs and procedures from the Statistical Analysis System (SAS Institute, Cary, NC).



**Figure 1a.** Removal of needle and reinsertion with the sleeve. **Figure 1b.** Insertion of a blunt dilator and cannula. **Figure 1c.** Cannula left in place where laparoscopic instruments can be passed.

**RESULTS**

Forty-two patients in the conventional cannula/trocar group and 45 patients in the Step device group were evaluated during and following 22 different surgical procedures. There were no statistical differences between the groups in terms of age and number of trocar ports used in the study. There was a significant difference in the body-mass index (p-value = 0.0473) and in the mean weights for the two groups (p-value=0.0481) with Step patients being the lower weight.

There was one complication associated with the Step system: insertion of the Veress needle caused an abdominal vessel injury, which was repaired intraoperatively with a suture (**Table 1**). Also, as shown in **Table 1**, there were six device-related adverse events (two incidences in one patient) associated with the conventional trocars. Two were vascular injuries caused by 12-mm trocars inserted into the umbilicus; two vascular injuries occurred in one patient followed by insertion of two 5-mm conventional trocars; another vascular injury occurred in the right lower quadrant during the insertion of a conventional, 5-mm trocar; and, last, one visceral injury involved perforation of the small bowel by the Veress needle insertion at the umbilicus. The latter did not require any management.

The mean sum of pain scores and their corresponding p-values are given in **Table 2**. The Step patients' assessments of pain were significantly lower than those of the conventional trocar patients at 8 (p = 0.0024), 12 (p = 0.0189), and 24 hours (p = 0.0005). At four hours, mean pain scores were lower for the Step group but barely failed to reach significance (p = 0.0639). There was no significant difference in the number of patients in whom analgesics were used postoperatively. Even though it may have been of interest, the type and amount of postoperative analgesics given were not recorded.

The intent-to-treat defect closure results are shown in **Table 3**. All conventional trocar sites 10 mm or larger were closed (100% sutured) using 2-0 or 3-0 Vicryl, full or partial thickness as required. In contrast, all but two of the 10-mm or larger Step device sites were left unsutured (4.17% sutured). One of the two Step defects requiring closure resulted from the enlargement of the defect to allow passage of a bag containing a dermoid cyst. There was no statistically significant difference in the postoperative wound assessments at 4 and 24 hours,

**Table 1.**  
Instrument-related complications.

Instrument complication	Site	Caused By	Management
Step vascular	abdominal	Veress needle	suture
Conventional vascular	umbilical	12-mm trocar	bipolar cauterization
vascular	two abdominal sites	5-mm trocars	bipolar cauterization
vascular	umbilical	12-mm trocar	bipolar cauterization
vascular	right lower quadrant	5-mm trocar	bipolar cauterization
visceral	small bowel	Veress needle	none needed

**Table 2.**  
Visual analog scale pain scores as assessed by patients.

Time Instrument	Mean Pain Score, mm <sup>+</sup>	Wilcoxon 2-Sample Test, p-value
4 Hours		0.0639
conventional	36.05	
Step	27.53	
8 Hours		0.0024*
conventional	24.48	
Step	13.59	
12 Hours		0.0189*
conventional	14.53	
Step	9.79	
24 Hours		0.0005*
conventional	7.97	
Step	2.48	

+Based on a 100-mm scale

\*Statistically significant

**Table 3.**  
Number and percent of 10-mm and 12-mm device defects requiring fascial closure.\*

	Not Closed (%)	Closed (%)	Total†
Conventional	0 (0.00)	50 (100.00)	50
10 mm or greater			
Step	46 (95.83)	2 (4.17)	
10 mm or greater			48
Total	46	52	98

\*p-value = 0.001.

†Frequency missing = 1 case.

nearly all wound sites being unremarkable in appearance.

Two patients, who were randomized to the conventional trocar group, had extensive adhesions, and their procedures necessitated open laparoscopy.

## DISCUSSION

Complications arising from trocar-related injuries were greater by a factor of six in those patients randomized to sharp trocars compared with those in the Step device group (6:1). Though this represents an 83% reduction in complications, this was not statistically significant. The only injury associated with the Step system was caused by Veress needle placement, which could have as easily occurred with the Veress needle before insertion of a sharp trocar. A review of the MEDWatch reports issued over a period of 20 months yielded a total of 92 trocar-related injuries of which 14 resulted in death.<sup>7,8</sup> Chapron et al recently conducted a retrospective review study of major vascular injuries that occurred during gynecologic laparoscopy.<sup>9</sup> In this study, 84.6% of the vascular complications occurred during insertion of the umbilical trocar. Two of these patients died and two more had serious complications.

With the formation of the Laparoscopic Litigation Group, attorneys see gynecologic laparoscopy as a principal target for malpractice suits, and several articles have cited sharp trocars as the leading causes of bowel injuries.<sup>10,11</sup> A recent study from claims data compiled by the

Physician Insurer's Association of America on 306 laparoscopic claims reports 21 vascular injuries in 18 patients, of which there were eight deaths, caused by the introduction of the first trocar. Further, there were 26 gastrointestinal injuries mostly caused by trocars. Mean payments associated with the trocar injuries were \$216,000 ± \$171,000.<sup>12</sup> These legal developments point to the need for gynecologic laparoscopists—and general surgery laparoscopists for that matter—to take precautionary measures when entering the abdomen with insufflation needles and sharp trocars. One report describes the complications associated with 430 laparoscopic procedures performed in 395 children with conventional, sharp trocars.<sup>13</sup> There was a 1.8% incidence of complications related to laparoscopy and the use of sharp trocars. In contrast, Rothenberg reported that not only were there no incidences of complications using the Step system, Step eliminated the need for anchoring and left a smaller wound than conventional trocars.<sup>14</sup>

This study confirms that postoperative incisional pain is significantly less with the Step device compared with conventional trocars. Another study demonstrated the same results when comparing the pain associated with Step devices and conventional trocars regardless of the size of the trocar.<sup>2</sup> In that study, trocars were randomized by sides. Therefore, each patient received at least one of both devices.

The Step device separates, rather than cuts, the tissues, leaving a slit-like defect, which forms along the muscle fibers, as opposed to the cloverleaf defect left by the cutting stylet of a conventional trocar. In addition, because the Step defect is oriented along muscle fibers, the resultant slits in the muscle layers overlap each other in a grid-iron pattern and have been shown to be approximately 50% smaller than defects left by comparably sized sharp trocars.<sup>1</sup> The small, patterned defect implies a reduced risk of incisional hernia. In fact, there were no trocar-site herniations in either the conventional or the Step device group. However, the investigators have experience with fascial closure of 10-mm conventional device defects still resulting in hernia formation. In one case, this resulted in further surgery at an associated hospital cost of \$4,000.<sup>15</sup> In another case, a patient presented with a small bowel obstruction requiring laparotomy and a post-surgical complication of pulmonary embolus.<sup>16</sup> Closure of conventional trocar defects is, therefore, not completely protective. In fact, according to Kadar et al, incisional her-

nias at 10- and 12-mm extraumbilical trocar sites occur up to 3.1% of the time, despite fascial closure.<sup>17</sup>

Operating times for procedures conducted with the Step device were approximately seven minutes shorter on average than those times for procedures conducted with sharp trocars. This was probably due to the need for closure of the fascia in wounds left by the latter instruments. Similar results were obtained in a retrospective study that compared surgical times in 98 patients (43 Step cases, 50 conventional trocar cases)<sup>18</sup> and in a prospective, randomized, multicenter study of 244 patients (119 Step cases, 125 conventional trocar cases).<sup>3</sup> In the prospective study, closure of the fascia was performed in 93% of the patients receiving conventional trocars but was required in only 3% of the patients receiving the Step device. Similarly, in this study, 100% of the patients receiving conventional trocars had fascial closure of the defects, whereas only two of the Step defects (4%) required closure.

The increased adverse events associated with the conventional cutting trocars indicate the relative degree of safety associated with the use of the Step system. Further, the system is easy to use and requires minimal training. In the experience of these surgeons, the Step radially expanding access device demonstrates statistically improved patient comfort, reduced operative time, and improved patient safety. However, further studies that include a larger population with a more similar body mass is recommended.

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