# Intraoperative and Postoperative Outcomes of Modified Bidirectional Intra-Umbilical Incision versus Infra-Umbilical Incision for Direct Trocar Insertion in Gynaecological Laparoscopy A randomised controlled trial

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ABSTRACT: Objectives: This study aimed to describe a modified, curved, deep, bidirectional, intra-umbilical, vertical incision for primary trocar insertion and prospectively compare its intraoperative and postoperative outcomes with an infra-umbilical incision in gynaecologic laparoscopy. Methods: Between August 2019 and March 2021, 110 patients subjected to the direct trocar insertion technique for laparoscopic intervention were classified into two groups. Group A comprised 55 cases of infra-umbilical incision, whereas group B comprised 55 cases of a modified, curved, longitudinal, deep, bidirectional, intra-umbilical incision. Afterwards, intraoperative and postoperative assessments were performed. *Results:* The increase in the numbers of parity, gravidity and previous caesarean sections was found to be statistically significant; a smaller number of infertility complaints were observed in group B. Similarly, group B expressed a statistically significant less peri-trocar CO<sub>2</sub> leakage (46 [83.6%] patients versus 28 [50.9%] patients) and more tightness of the primary portal entry (45 [81.8%] patients versus 30 [54.5%] patients) when compared to group A throughout the whole operation. After a one-month follow-up, a statistically significant (P = 0.029) decrease in the Observer Scar Assessment Scale and Patient Scar Assessment Scale scores in group B ( $10.4 \pm 4.2$  and  $11.8 \pm 4.3$ , respectively), demonstrating better cosmoses when compared to group A (13.3  $\pm$  5.7 and 16.0  $\pm$  6.8, respectively). Conclusion: Performing a modified, curved, deep, bidirectional, intra-umbilical, vertical incision for the insertion of a primary laparoscopic trocar (i.e. Darwish laparoscopic entry) is a simple and fast step that results in the elimination of intraoperative gas leakage and trocar slippage without the need for any additional sutures. Aesthetically, it results in a better scar with satisfactory cosmoses when compared to an infra-umbilical incision.

Keywords: Laparoscopy; Trocar; Egypt.

#### Advances in Knowledge

- The modified technique of primary trocar umbilical insertion results in less gas leakage and trocar slippage.

- The presented technique is more aesthetical/aesthetically pleasing when compared to other access techniques.

#### Application to Patient Care

Umbilicus cosmoses are particularly important for females.

The proposed method for laparoscopic entry will help preserve umbilicus cosmoses as it is completely intra-umbilical.

APAROSCOPIC SURGERY IS A WELL-ESTABLISHED modern tool for treating many gynaecological disorders as it is characterised by rapid wound healing, a short hospital stay, less postoperative pain and better aesthetic results.<sup>1</sup> The different techniques of laparoscopic entry include Veress needle insertion, open laparoscopy and direct trocar insertion without a statistically significant difference in terms of patient safety.<sup>2</sup> Nevertheless, direct trocar insertion is steadily gaining popularity.<sup>3</sup>

Postoperative umbilical scar cosmoses and appearance are important issues for women. As the umbilicus is an important aesthetic component of the abdomen, surgeons are concerned about how to maintain the cosmetic appearance of the umbilicus. In addition to psychological upsetting, bad scars may result in pain, tenderness and itching.  $^{4-6}$ 

Some studies compared different types of primary portals for gynaecologic laparoscopy;<sup>7,8</sup> however, there is no universal agreement regarding an ideal periumbilical incision for gynaecologic laparoscopy. Moreover, there is a lack of studies that address intraoperative outcomes of different periumbilical incisions. Thus, this study aimed to introduce a modified, curved, deep, bidirectional, intra-umbilical incision for primary trocar insertion and prospectively compare its intraoperative and postoperative outcomes with an infra-umbilical incision in gynaecologic laparoscopy.

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# Methods

This prospective study was performed at the Endoscopy Unit of the Woman's Health University Hospital between August 2019 and March 2021. The participants were women of reproductive age who were subjected to the direct trocar insertion of gynaecologic laparoscopy for different indications and had no history of previous umbilical operation or umbilical hernia. All women consented to participate in this single-blinded randomised, controlled trial (RCT) to enter one of two groups by random allocation. They were assigned according to the 10 mm primary laparoscopic direct trocar entry points (infra or a modified intra umbilical) and incision types (transverse versus curved longitudinal), respectively, using sealed envelopes. The allocated envelopes were opened just before surgery.

The sample size was estimated using Epi Info<sup>™</sup>, Version 7.2.5.0 (Center for Disease Control & Prevention, Atlanta, Georgia, USA) with a 95% confidence interval and a power of 80%, assuming the percent of unexposed with outcome is 5% and the percent of exposed with outcome is 28%. The sample size was estimated at 96. After adding a drop-out rate of 15%, the total sample size was estimated to be 110.9 The 110 allocated cases were then divided into two groups, where group A comprised 55 cases subjected to infra-umbilical 10 mm transverse incision while group B comprised 55 cases of a modified, curved, bidirectional, longitudinal intra-umbilical incision for primary laparoscopic direct trocar insertion. The exclusion criteria included patients scheduled for 5 mm primary trocar insertion, open laparoscopy and Verres needle insertion, as well as patients with

previous abdominal surgery and scars, umbilical hernia, umbilical infection (e.g. pilonidal sinus disease), previous laparoscopy or umbilical surgery and previously burned or hyperpigmented umbilicus.<sup>10</sup> Additionally, prepubertal or postmenopausal patients were also excluded from this study.

In the operating room, the umbilicus was prepared by removing all debris using copious amounts of povidone iodine gauze and cotton swabs. Preoperatively, the surgeon commented on the shape of the umbilicus and any umbilical fascial defect signifying any tiny hernia, tightness of the abdominal muscles and skin laxity [Figure 1].11 To avoid skin disfigurement, clamps were not used in all cases to elevate the abdominal wall, although toothed forceps were used to facilitate delicate skin cuts to avoid the slipping of the scalpel. In group A, a 10 mm infraumbilical transverse incision was made to allow the trocar to be inserted without undue resistance from the skin so that the trocar passed directly through the fascia and the peritoneum with ease. In group B, a 10 mm, right-sided, modified, curved, deep, bidirectional, longitudinal, intra-umbilical incision was made. The technique began by grasping the right edge of the umbilicus with a toothed forceps. Then, a curved vertical incision was made as deep as possible. Afterwards, the trocar was inserted inside the incision till the level of the edge of the sleeve passed the skin. At this moment, the trocar was directed transversely (horizontally) on the right side of the umbilicus for one to 2 cm in the subcutaneous tissue.

The final step was tilting the trocar to the vertical plane to pierce the fascia towards the pelvis [Figure 2]. In this way, the trocar was bidirectional (i.e. has two pathways) until it reached the peritoneal cavity



Figure 1: Different shapes of umbilicus in studied cases: (A) vertical oval umbilicus; (B) transverse funnel-shaped umbilicus; (C) outie belly button projecting umbilicus (looks like a little knot is sticking out); and (D) button-like transverse bulging umbilicus.



Figure 2: Steps of modified intra-umbilical direct trocar insertion: (A) deep curved longitudinal intraumbilical incision, (B) insertion of a 10 mm trocar till the disappearance of the sleeve edge, (C) transverse insertion of the trocar for 1-2 cm in horizontal plane in the subcutaneous tissue and (D) the rotation of the trocar 90 degrees to the vertical plane, followed by the penetration of the fascia.

(horizontally then vertically). In both groups, the inflation of the peritoneal cavity with  $CO_2$  was done

up to a pressure of 12–15 mmHg. Surgical procedures were performed using conventional laparoscopic instruments under vision with a rigid, 0 degree, 10 mm endoscope. Intraoperatively, the surgeon commented on the ease of movement of the trocar and telescope, as well as a reduction of leakage of CO<sub>2</sub> alongside the primary trocar and intraoperative slippage of the trocar during forward and backward movement of the telescope. The operative time varied according to the intraperitoneal laparoscopic procedure. This study did not report the entry site or intraperitoneal complications in either group. In both groups, the skin incision was sutured using a 4-0 Monocryl subcuticular stitch. The patients were offered regular post-laparoscopic surgery care as usual at the institution with on-need analgesics till the time of discharge. Further, they were instructed to take care of the sterile dressings. The patients came back after one week for a check-up and wound dressing. Another follow-up visit was scheduled after one month to properly assess the scar as previously consented by the patients.

Both the Observer Scar Assessment Scale (OSAS) and the Patient Scar Assessment Scale (PSAS) were used in this study to compare the wound with the nearby skin.<sup>12</sup> In both scales, the lower the score, the clinically better the scar. The maximal scores of OSAS and PSAS are 50 and 60, respectively. The patients were clearly asked if they or their partners could see the scar with the naked eye or not to assess the effect

Characteristic		Group A* (n = 55)	Group B* (n = 55)	Stat. test	P value
		Mean ± SD			
Age in years		$28.5\pm7.1$	$29.1\pm 6.8$	T = 0.46	0.643NS
Duration of marriage in years		$7.2 \pm 3.7$	9.0 ± 7.0	MW = 1237.5	0.457NS
Gravidity		$1.4 \pm 1.9$	$2.2\pm1.9$	MW = 1048.5	0.004HS
Parity		$0.8 \pm 1.4$	$1.7 \pm 1.6$	MW = 947	<0.001HS
Abortions		0.6 ± 0.9	$0.5 \pm 0.8$	MW = 1494	0.895NS
Number of Caesarean sections		$0.5 \pm 0.7$	$0.9 \pm 1.2$	MW = 1211	0.038S
Infertility duration		$5.2 \pm 3.2$	$4.5 \pm 3.1$	MW = 464.5	0.351NS
		n (	%)		
Previous operation	No	54 (98.2)	52 (94.5)	$v^2$ 1.02	0.306272
	Yes	1 (1.8)	3 (5.5)	A = 1.05	0.306143
Infertility	No	12 (21.8)	29 (52.7)	$v^2$ 11.0	0.001 HS
	Yes	43 (78.2)	26 (47.3)	A = 11.2	0.001115

 Table 1: Sociodemographic and obstetric data of the study population (N = 110)

SD = standard deviation; T = independent samples t-test; NS = non-significant; MW = Mann-Whitney U test; HS = highly significant; S = significant;  $X^2 = Chi-squared$  test.

\*Group A were cases subjected to infra-umbilical 10 mm transverse incision while group B comprised cases of a modified, curved, bidirectional, longitudinal intra-umbilical incision.

Intraoperative assessment	n (%)		$X^2$	P value
	Group A* (n = 55)	Group B* (n = 55)		
Shape				
Vertical oval	52 (94.5)	47 (85.5)	2.5	0.112NS
Horizontal oval	3 (5.5)	8 (14.5)		
Appearance				
Inverted	48 (87.3)	46 (83.6)	0.29	0.589NS
Everted (protruded)	7 (12.7)	9 (16.4)		
Dimple				
Absent	6 (10.9)	9 (16.4)	0.69	0.405NS
Present	49 (89.1)	46 (83.6)		
Index finger test for hernia				
Negative	55 (100.0)	55 (100.0)		
Abdominal skin laxity				
No	41 (74.5)	29 (52.7)	5.6	0.017S
Yes	14 (25.4)	26 (47.2)		
Abdominal muscles				
Weak	16 (29.1)	32 (58.1)	9.4	0.002HS
Strong	39 (70.9)	23 (41.8)		
Trocar tip				
Conical	55 (100.0)	55 (100.0)		
Umbilical incision				
Transverse	55 (100.0)	0 (0.0)	110	<0.001HS
Longitudinal	0 (0.0)	55 (100.0)		

#### Table 2: Intraoperative assessments of the umbilicus and abdominal wall in both groups (N = 110)

*X*<sup>2</sup> = *Chi-squared test; NS* = *non-significant; S* = *significant; HS* = *highly significant.* 

\*Group A were cases subjected to infra-umbilical 10 mm transverse incision while group B comprised cases of a modified, curved, bidirectional, longitudinal intra-umbilical incision.

Table 3: Comparisons of intraoperative assessments of umbilicus between the studied groups (N = $1$
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Intraoperative assessment	n (%)		$\mathbf{X}^2$	<i>P</i> value		
	Group A* (n = 55)	Group B* (n = 55)				
Easy trocar and telescope movement						
No	6 (10.9)	3 (5.5)	1.09	0.297NS		
Yes	49 (89.1)	52 (94.5)	1.06			
Leakage of CO <sub>2</sub>						
No	28 (50.9)	46 (83.6)	12.4	<0.00HS		
Yes	27 (49.1)	9 (16.4)	13.4			
Tightness						
Tight	30 (54.5)	45 (81.8)	0.4	0.002S		
Loose	25 (45.5)	10 (18.2)	2.4			

 $X^2$  = Chi-squared test; NS = non-significant; HS = highly significant; S = significant.

\*Group A were cases subjected to infra-umbilical 10 mm transverse incision while group B comprised cases of a modified, curved, bidirectional, longitudinal intra-umbilical incision.

of the incision on the aesthetic appearance of the umbilicus. The primary outcome of this study was to assess intraoperative performance using two different periumbilical incisions in terms of ease of surgery,  $CO_2$  leakage, and trocar slippage. The secondary outcomes were observer and couple satisfaction using either incision.

Statistical Package for the Social Science (SPSS) Version 24.0 (IBM Corp., Armonk, New York, USA) was used to analyse the data. The quantitative data were expressed as mean  $\pm$  standard deviation (SD), whereas the qualitative data were expressed as frequency and percentage. Mean (average) refers to the central value of a discrete set of numbers, specifically the sum of values divided by the number of values, while SD is the measure of dispersion of a set of values. A low SD indicates that the values tend to be close to the mean of the set. Conversely, a high SD indicates that the values are spread out over a wider range. The independent samples t-test of significance was used to compare two means for normally distributed data, Mann-Whitney U test was used to compare two means for abnormally distributed data and the Chi-squared test was used to compare non-parametric data. Further, P <0.05 was considered significant, P <0.001 was considered highly significant and P > 0.05 was considered non-significant.

The study was approved by the ethics committee of the Faculty of Medicine (17100792) and was registered at Clinicaltrials.gov (NCT03988348). The authors state that subjects have given their written informed consent. Assiut University Medical School Ethical Review Board approved the study protocol (17100792).

# Results

This study comprised 110 patients subjected to 10 mm direct trocar insertion for gynaecologic laparoscopic surgery, who were divided into two groups, with group A comprising 55 cases of transverse infra-umbilical incision and group B comprising 55 cases subjected to modified, curved, deep, bidirectional, longitudinal, intra-umbilical incision. Between the groups, the differences in age, duration of marriage, history of previous operations, abortion or duration of infertility were found to be insignificant [Table 1]. However, increased numbers of parity, gravidity and previous caesarean sections, as well as a smaller number of infertility complaints, were found to be statistically significant in group B.

Moreover, the indications of laparoscopic surgery were variable in both groups. In group A, the indications were primary infertility in 24 (43.6%) patients, secondary infertility in 19 (34.56%) patients,

haematocolpos and haematometra in one (1.8%) patient, left ectopic pregnancy in one (1.8%) patient, missed intrauterine device (IUD) threads in seven (12.7%) patients, right adnexal cyst in two (3.6%) patients and right ovarian torsion in one (1.8%) patient. On the other hand, in group B, the indications were 1ry infertility in eight (14.5%) patients, 2ry infertility in 16 (29.1%) patients, 2ry amenorrhea in one (1.8%) patient, bilateral endometrioma in one (1.8%) patient, chronic pelvic pain in two (3.6%) patients, Ewing sarcoma for the transposition of ovaries in one (1.8%) patient, undisturbed tubal ectopic pregnancy in 10 (18.1%) patients, missed IUD in six (10.9%) patients, right disturbed ectopic pregnancy in one (1.8%) patient, ovarian cyst in seven (12.7%) patients, adnexal haematoma in one (1.8%) patient and laparoscopic monitoring of hysteroscopic metroplasty of a uterine septum in one (1.8%) patient.

Moreover, the differences between the groups regarding preoperative assessment of the umbilicus, including the presence of dimples, shape, appearance, the index finger test for minute hernia and use of conical trocar end, were found to be insignificant. The most common umbilical shape noted in both groups was vertical (n = 84, 76.3%), followed by transverse umbilicus (n = 21, 19%). However, there was a statistically significant difference between both groups regarding abdominal wall muscle and skin laxity [Table 2].

Group B expressed a statistically significant less peri-trocar  $CO_2$  leakage (46 [83.6%] versus 28 [50.9%] patients) and more tightness of the primary portal entry (45 [81.8%] versus 30 [54.5%] patients) compared to group A throughout the whole operation [Table 3]. On follow-up after one month, a statistically significant (P = 0.029) decrease in OSAS and PSAS scores was observed in group B ( $10.4 \pm 4.2$  and  $11.8 \pm 4.3$ , respectively) compared to group A ( $13.3 \pm 5.7$  and  $16.0 \pm 6.8$ , respectively) [Table 4; Figure 3]. Moreover, in groups A and B, 47 (85.4%) and 23 (41.8%) patients, respectively, reported that they or their partners failed to see the umbilical scar with the naked eye, and they were satisfied by the aesthetic appearance of the umbilicus.

# Discussion

Primary umbilical trocar insertion is a procedural step of critical importance.<sup>13</sup> Despite the widespread use of advanced gynaecologic laparoscopic surgeries, many surgeons give little attention to skin incisions after lengthy and tedious operations, leaving the closing of abdominal wall incisions to the young staff. Most gynaecologic patients are young and very concerned about the aesthetic appearance of their belly. The umbilicus is essential to the aesthetic appearance of the abdomen and umbilical incisions directly affect female cosmoses.<sup>14</sup>

This study included patients of reproductive age with the exclusion of young girls and postmenopausal cases to eliminate age-related factors of wound healing.<sup>15</sup> To minimise study bias, direct trocar insertion was only used in this study with the exclusion of the cases of open laparoscopy and Veress needle insertion. Surgical trocars may be bladed (safety) or bladeless, disposable or reusable and spiral (corrugated) or non-spiral. The trocar end may be pyramidal or conical without a significant difference in the literature. An animal study demonstrated that using conical and pyramidal trocars resulted in similar force, deformation, time and distance of exposed blade if they were of the same size.<sup>16</sup>

In this study, the trocar type was standardised as bladeless, reusable, non-spiral and with a conical end to eliminate the effect of these variables on the incision. Further, the incision sites for the primary trocar insertion may be infra-umbilical, supraumbilical or trans-umbilical.<sup>16</sup> Supraumbilical incision was excluded from this study as it is seldom used by gynaecologists. In a review of laparoscopic practice by general surgeons, approximately half of the laparoscopists preferred the infra-umbilical route for the entry, whereas 35.7% preferred the supraumbilical area.6 Vertical incision is usually preferred for initial intraperitoneal access as it offers superior cosmetic results compared to transverse incision.17 The infra-umbilical incision cuts through the skin, the subcutaneous fat and the fascia. In contrast, the intraumbilical incision is a linear incision from the skin to the fascia, extending only the length of the umbilical ring. An intra-umbilical incision may take less time, is easier to perform and is theoretically less traumatic as only the skin and fascia need to be divided.

At present, the intra-umbilical incision is being used more frequently, as evident from the increasing cases of single-incision laparoscopic surgery, which has recently been proven to be a feasible alternative for conventional laparoscopic surgery with better cosmetic outcomes.<sup>18</sup> In a retrospective comparison of gynaecologic laparoscopy cases, intra-umbilical incision and peri-umbilical incision (longitudinal/ transverse oblique/arc incision according to the belly button natural skin folds) were compared, which concluded that intra-umbilical incision should be promoted in gynaecologic laparoscopy.<sup>19</sup>

Postpartum sterilisation using intra-umbilical skin incision was more efficient regarding aesthetic concerns and operation time in an RCT.<sup>8</sup> What is novel

in the current prospective RCT is the assessment of the impact of modifications of the intra-umbilical incision on intraoperative and postoperative outcomes (i.e. Darwish laparoscopic entry). Making the incision as deep as possible renders it invisible and less liable to cause pain on touch using the maximal benefit of the natural umbilical dimple. Addressing this important point would fulfil the requirements of the aesthetic appearance of the umbilicus as the scar was not seen in 47 (85.4%) patients using this modified technique when compared to 23 (41.8%) patients if the infraumbilical incision was made. Since most human beings' umbilical shape is vertical oval (in this study, it was seen in 84 cases, 76.3%), the vertical incision used in group B was more anatomic than the transverse incision used in group A.

Another additional advantage of the modified technique was making a curved intra-umbilical incision and adapting it to the natural curve of the umbilical dimple [Figure 2]. In this study, the umbilical dimple was present in 95 (86.3%) cases in both groups, so the selection of a curved incision in group B was more anatomic. Notably, the surgeon did not use any instrument to elevate the anterior abdominal wall, unlike others who usually use pointed towel forceps, Kocher forceps or other traumatic instruments that may leave a scar and hyperpigmentation, adding more disfigurement and psychological upset to the patients.<sup>11</sup> Not only is the aggressive elevation of the skin around the umbilical region injurious and nonaesthetic, but it also does not add any surgical benefit because the skin and fascia at the umbilicus are in direct contact, which is why it is the preferred site for primary entry. This proximity can be explained by the absence of subcutaneous fat and muscle at the umbilicus, which makes the midline dissection plane bloodless to the peritoneum.<sup>5</sup>

This modified technique resulted in a better aesthetic appearance of the umbilicus and lower OSAS and PSAS scores (i.e. better cosmoses) when compared to the transverse infra-umbilical incision group. This study incorporated patient impressions and comments on all issues of umbilical incision, including their comments on the visibility of the scar to them or their partners, which is considered one of the best aesthetic evaluation variables. This step is commonly used after liposuction operations, which may affect the appearance and shape of the umbilicus.<sup>20</sup>

There are various intraoperative benefits of the modified intra-umbilical to surgical procedures. The insertion of the trocar, for 1-2 cm horizontally then vertically (i.e. bidirectionally), adds an advantage of maintaining an airtight seal to avoid gas leakages alongside the trocar and trocar slippage throughout

the operation. This is explained by the moving of fascial perforation away from the alignment with the skin incision. Trocar dislodgment occurs frequently during laparoscopic surgery, particularly in women who are lean, have weak anterior abdominal wall muscle or fascia and have lax redundant skin. The best example of this is multiparous or malnourished women.

The results of this study supported these concepts, as the modified bidirectional technique was more successful than the classic infra-umbilical technique even among women with increased parity or gravidity who were prone to weak anterior abdominal wall and lax skin [Table 2].

Frequent slippage of the trocar and abdominal deflation is a distressing problem. Abdominal wall emphysema can occur besides the risky prolongation of the surgical procedure.<sup>21</sup> To overcome this problem, some authors take a stitch at the fascia and encircle the trocar throughout the procedure, whereas others use spiral trocars (whether disposable or reusable).<sup>22,23</sup> Disposable spiral trocars are very expensive compared to reusable trocars and, therefore, cannot be afforded by healthcare authorities in many hospitals, especially in the context of developing countries with limited resources. However, a reusable spiral trocar may require more force for insertion, which may carry a risk of unintentional injury due to repeated resistance to the corrugations along the whole shaft.<sup>24</sup> Besides, despite the lack of sufficient supporting studies, using 10 spiral trocars with force may be a risk factor for subsequent umbilical trocar-site hernia as previously reported due to repeated tears of the fascia.<sup>25</sup> On postoperative follow-up of all cases of this study, which involved the use of ordinary reusable conical 10 mm trocar, no case of trocar-site hernia was observed in either group.

Despite being a prospective RCT, this study has certain limitations, with its small sample size being one such limitation. Moreover, including all types of umbilici in either group would carry a bias as some umbilici are already inverted with a definite dimple while others are protruding, which may affect scar appearance and pain scoring. Furthermore, comments on the ease of movement of trocar and telescope, leakage of CO2 and intraoperative slippage of the trocar were all subjectively assessed. Theoretically, more accurate tools of assessment would be more informative. Nevertheless, in some situations, intraoperative observations, particularly by expert surgeons, would be as accurate and clinically informative as some sophisticated and timeconsuming tests. In modern statistics, subjectivity is respected and is replaced by the awareness of multiple perspectives and context dependence.<sup>26</sup> Thus, a larger sample size and a multicentre study is needed to achieve a definite conclusion in this respect.

# Conclusion

It can be concluded that performing curved, deep, bidirectional, longitudinal, intra-umbilical incision for the insertion of primary laparoscopic trocar (i.e. Darwish laparoscopic entry) is a simple and fast step that results in the elimination of intraoperative gas leakage and trocar slippage without the need of any additional sutures. Aesthetically, it results in a clinically better scar with satisfactory cosmoses compared to infra-umbilical incision.

## AUTHORS' CONTRIBUTION

DA is the principal investigator who conceptualised the study, refined the study protocol, performed many operations and wrote the full paper. TM conceived the idea, wrote the protocol, performed many operations, supervised the candidate and reviewed the thesis and the full paper. GA was the active candidate who conducted the interviews, collected the data and performed all statistical analyses with the aid of a statistician. DD reviewed the paper and made some corrections.

#### CONFLICT OF INTEREST

The authors declare no conflicts of interests.

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