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Prospective randomized study comparing single-incision laparoscopic versus multi-trocar laparoscopic totally extraperitoneal (TEP) inguinal hernia repair at 2 years

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Abstract

Background Inguinal hernia repair via multi-trocar laparoscopy (MTL) has gained an increasing popularity worldwide. Single-incision laparoscopy (SIL) has been introduced to reduce the port-related complications and to improve the cosmetic results. The authors report a prospective randomized study comparing SIL versus MTL totally extraperitoneal (TEP) inguinal hernia repair.

Methods Between January 2013 and May 2015, 113 versus 97 patients were prospectively randomized between SILTEP and MTLTEP. Perioperative, short-term, and mid-term outcomes have been assessed. The primary endpoint was the mid-term outcomes (late postoperative complications, late inguinal hernia recurrence, surgical and cosmetic satisfactions). Secondary endpoints were perioperative outcomes (operative time, mesh fixation, operative complications, postoperative pain, and hospital stay) and short-term outcomes (early postoperative complications, early inguinal hernia recurrence, and days to return to normal activities).

Results After a mean follow-up of 27 ± 8 months, a statistically significant difference was found between the two groups in terms of mean operative time for both unilateral and bilateral inguinal hernia repair ($p = 0.016$; $p = 0.039$) and cosmetic satisfaction ($p = 0.003$).

Conclusion Perioperative, short-term, and mid-term outcomes were comparable between the two groups. At 2-year follow-up, a significant shorter operative time after MTLTEP and a greater cosmetic satisfaction after SILTEP have been found.

Keywords Single-incision laparoscopy · TEP · Inguinal hernia · Laparoscopy · Mid-term outcomes

The first laparoscopic inguinal hernia repair has been reported by Ger et al. [1]. Since that time, the laparoscopic hernioplasty has gained an increasing popularity worldwide [2, 3]. Compared to open techniques, laparoscopic treatment has been reported in favor of less postoperative pain, faster recovery, early return to daily activities, and enhanced cosmetic results [4–6]. The next step in minimally invasive techniques for inguinal hernia repair has been via single-incision laparoscopy (SIL). The first SIL totally extraperitoneal repair (SILTEP) was reported by Filipovic-Cugura et al. [7]. Since that time, SILTEP has been reported as feasible and safe [7–9]. However, despite the promising initial reports, SILTEP clinical advantages over conventional multi-trocar laparoscopic TEP (MTLTEP)—besides the improved cosmetic outcomes—have not been clearly defined [10]. The aim of this study was to randomly compare the perioperative, short-term, and mid-term outcomes of SILTEP versus MTLTEP inguinal hernia repair.

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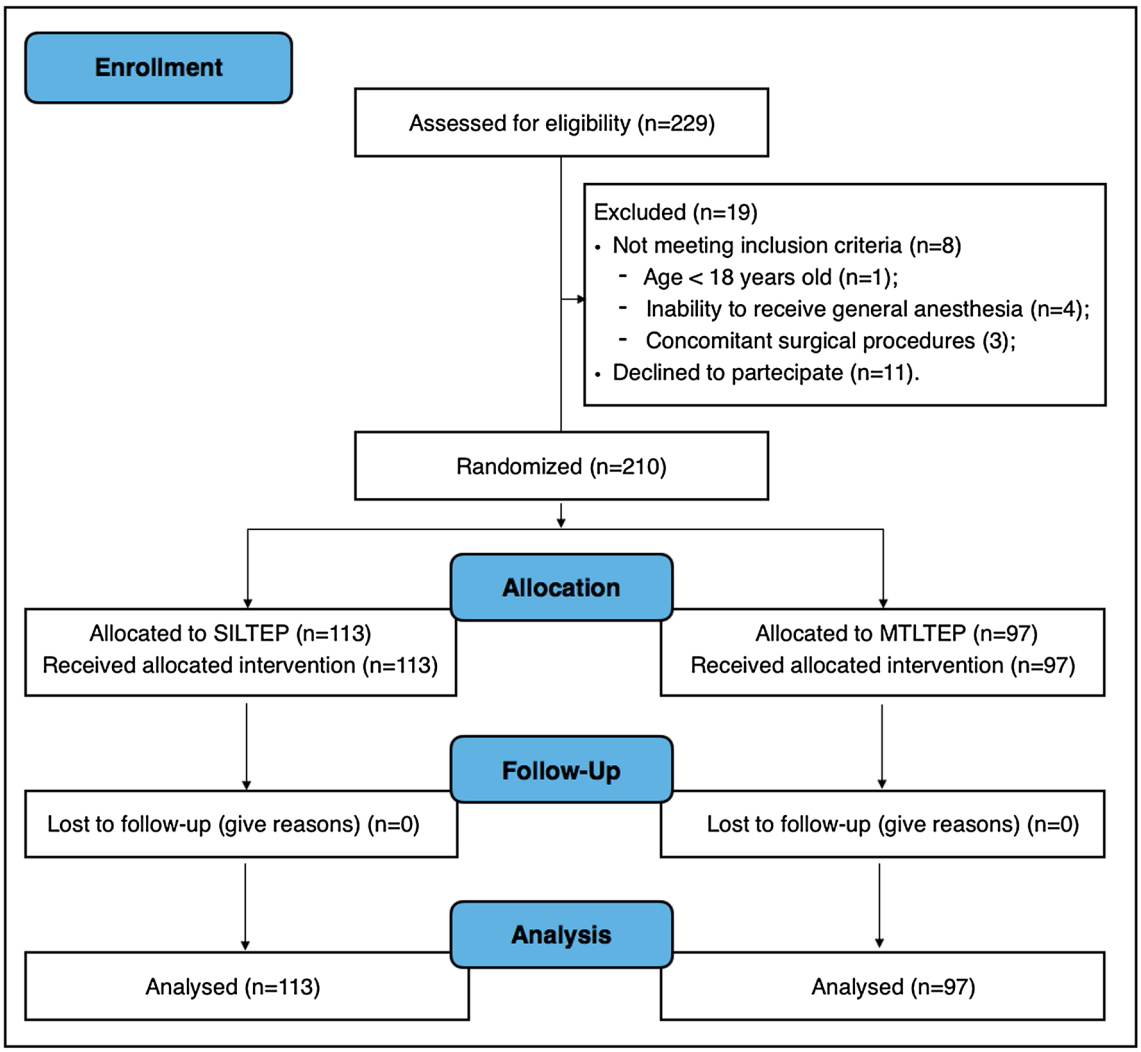


Fig. 1 Consort flow diagram

Patients and methods

Protocol

Between January 2013 and May 2015, 229 patients with inguinal hernia were assessed for study eligibility. Figure 1 shows the trial profile according to the CONSORT statement (Fig. 1). Eight patients did not meet the inclusion criteria and 11 withdrew consent. A total of 210 consecutive patients were prospectively and randomly enrolled in the study. All patients were properly informed and gave their consent to the procedures. The trial was registered at ISRCTN (International Standard Randomised Controlled Trial Number) registry with this reference number: https://doi.org/10.1186/ISRCTN63754528.

Inclusion criteria were adult patients (aged 18 years or more), unilateral or bilateral inguinal hernia requiring surgical treatment, and patient's approval. Exclusion criteria were patient refusal to participate in the study, inability to receive general anesthesia, and concomitant surgical procedures besides hernia repair. Randomization was performed by using computer-generated randomized numbers in sealed envelopes.

Patients were randomized into two groups: SILTEP and MTLTEP. 113 patients were allocated to the SILTEP group and 97 patients to the MTLTEP group. The two techniques were performed by two different surgeons (GD, JB) with high-level experience in conventional abdominal laparoscopy.

The study was designed as a pilot study; therefore, the required sample size was not outlined a priori. The primary

endpoint was the mid-term outcomes (late postoperative complications, late inguinal hernia recurrence, surgical and cosmetic satisfactions). Secondary endpoints were perioperative outcomes (operative time, mesh fixation, operative complications, postoperative pain, and hospital stay) and short-term outcomes [early postoperative complications, early inguinal hernia recurrence, and days to return to activity of daily living (ADL)].

Baseline patient characteristics [demographics, body mass index (BMI), American Society of Anesthesiologists (ASA) risk group, morbidities, previous abdominal surgery] and hernia characteristics (number, site, type, clinical presentation, and surgical indication) were recorded. Patients enrolled in the study, who presented a recurrent inguinal hernia, had been previously treated by open hernioplasty in other institutions.

Operative data, including operative time, mesh fixation, conversions, and major perioperative complications [vascular injury, peritoneal tear, and conversion to transabdominal preperitoneal (TAPP) repair] were recorded. Operative time was calculated from skin incision to fascial closure.

Postoperative pain was assessed according to a visual analogue scale (VAS) from 0 (no pain) to 10 (worst imaginable pain) at 6 (VAS-6), 12 (VAS-12), 18 (VAS-18), and 24 (VAS-24) hours after surgery.

All patients were assessed for early postoperative complications at office consultation on day 7 and 30 from surgery. Late postoperative complications (after 30 days), inguinal hernia recurrences, and days to return to ADL were recorded too.

During follow-up, patients were contacted and consulted by telephone questionnaire. Surgical and cosmetic satisfactions were evaluated. Surgical satisfaction was assessed according to a numerical rating scale (NRS) from 1 (extremely dissatisfied) to 5 (extremely satisfied). Cosmetic satisfaction was considered according to the "score of access-site satisfaction & consideration" questionnaire on a scale from 1 to 10, where 1 was "extremely dissatisfied," 5 "neither satisfied nor dissatisfied," and 10 "extremely satisfied."

Surgical techniques

Patients were placed under general anesthesia in supine position with both legs straight. In bilateral hernia cases, the surgeon stood to the patients' left side first. The monitor was placed at the foot of the operating table, while the surgeon stood on the opposite side of the hernia to be treated. Prophylactic antibiotics were given to patients before the operation. In both techniques, a 0-degree, standard length, rigid scope was adopted. No balloon device was introduced for the dissection of preperitoneal space. The main landmarks were identified—including the pubic bone, inferior epigastric vessels, and Cooper's ligaments. The preperitoneal space was laterally freed toward the anterior superior iliac spine. In both techniques, the triangle of Doom, triangle of pain, and Hasselbach's triangle were dissected and identified. Following the reduction of the hernia sac, a 15 cm (latero-lateral) by 10 cm (craniocaudal) polypropylene mesh was introduced through the trocar and positioned to cover the inguinal orifice. In bilateral hernias, the contralateral hernia sac was reduced before the introduction of both meshes. The mesh was fixed to the pubic bone by a tack device, if necessary. At the end of the procedure, the pneumopreperitoneum was desufflated under mesh vision.

SILTEP

A 1.5-cm umbilical incision was created in the region opposite the hernia to be treated, and the anterior rectus fascia was opened. A fascial purse-string suture using Vicryl 1 was placed starting at 9 o'clock position. An 11-mm reusable rigid trocar was introduced behind the rectus muscle into the preperitoneal space. The 0-degree regular scope was advanced into the 11-mm trocar, and the preperitoneal space was insufflated. The space was dissected from medial to lateral side by using the optical system. At the time of hernia sac retraction, a DAPRI reusable monocurved grasping forceps (Karl Storz—Endoskope, Tuttlingen, Germany) was introduced inside the purse-string suture, at 9 o'clock position and parallel to the 11-mm trocar. The hernia sac was reduced, the peritoneal sheet was retracted, and the spermatic elements were skeletonized. A 15 cm by 10 cm polypropylene mesh was introduced through the 11-mm trocar. The mesh was adequately positioned using the monocurved umbilical grasper, placing the lateral corner anteriorly to the peritoneal sheet and the medial corner under the pubic bone.

MTLTEP

The operation started with an infraumbilical vertical incision approximately 1.5–2 cm long, and the rectus fascia on the opposite side of hernia was opened. A space was created slightly off the midline behind the rectus muscle and in front of the posterior rectus sheath. Subsequently, an 11-mm reusable rigid trocar was introduced behind the rectus muscle into the preperitoneal space. The 0-degree regular scope was advanced into the 11-mm trocar and used for blunt dissection of the areolar tissue in the preperitoneal space using a gentle sweeping motion. Under direct vision, two other 6-mm trocars were placed. In unilateral hernias, the first 6-mm trocar was placed through the midline between the umbilicus and the pubis, while the second 6-mm trocar was placed through the horizontal umbilical line, 3 cm internal

Table 1 Patient demographics and hernia characteristics

	SILTEP ($n=113$)	MTLTEP ($n=97$)	p Value
Gender[a]			
Male	102 (90.27)	91 (93.81)	0.347°
Female	11 (9.73)	6 (6.19)	
Age (years)[b]	49 (18–89)	55 (19–88)	**0.011**[#]
BMI (kg/m^2)[b]	24.85 (17.36–36.29)	24.55 (18.52–44.92)	0.544[#]
ASA score[a]			
1	57 (50.44)	39 (40.21)	0.286*
2	47 (41.59)	50 (51.55)	
3	9 (7.96)	7 (7.22)	
4	0 (0)	1 (1.03)	
Comorbidities[a]			
High blood pressure	19 (16.81)	21 (21.65)	0.870°
Cardiovascular disease	12 (10.62)	8 (8.25)	
Chronic obstructive pulmonary disease	8 (7.08)	6 (6.19)	
Diabetes mellitus type 2	9 (7.96)	8 (8.25)	
Obesity	9 (7.96)	6 (6.19)	
Previus abdominal surgery[a]	43 (38.05)	44 (45.36)	0.284°
Total hernia repair[a]	142 (54.62)	118 (45.38)	
Number of hernia[a]			
Unilateral	84 (74.34)	76 (78.35)	0.496°
Bilateral	29 (25.66)	21 (21.65)	
Site of hernia[a]			
Left	37 (32.74)	31 (31.96)	0.726°
Right	47 (41.59)	45 (46.39)	
Bilateral	29 (25.66)	21 (21.65)	
Type of hernia[a]			
Direct	39 (27.46)	33 (27.97)	**0.002***
Indirect	64 (45.07)	76 (64.41)	
Inguino-scrotal	16 (11.27)	5 (4.24)	
Femoral	2 (1.41)	0	
Direct + indirect	17 (11.97)	4 (3.39)	
Inguino-scrotal + femoral	1 (0.70)	0	
Direct + femoral	1 (0.70)	0	
Indirect + femoral	2 (1.41)	0	
Clinical presentation[a]			
Bulging	84 (74.34)	85 (87.63)	**0.029***
Pain or disconfort	27 (23.89)	12 (12.37)	
Irreducible	2 (1.77)	0	
Indication for surgery[a]			
Primary repair	108 (95.58)	87 (89.69)	**0.024***
Recurrent	3 (2.65)	10 (10.31)	
Incarcerated	2 (1.77)	0	

Bold values indicate the results with a statistically significant difference between the two groups ($p<0.05$)

SILTEP single-incision laparoscopic totally extraperitoneal, *MTLTEP* multi-trocar laparoscopic totally extraperitoneal, *BMI* body mass index, *ASA* American Society of Anesthesiologists

°Chi-square test

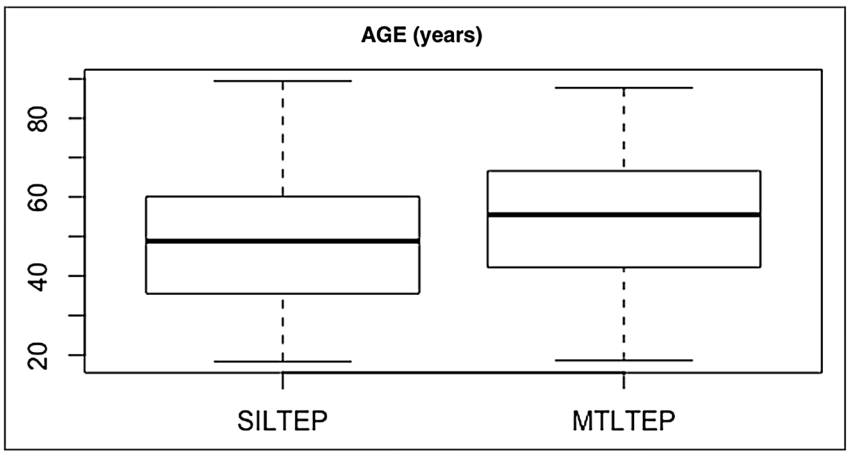
*Fisher's exact test

[#]Student's *T* test

[a]Qualitative variables are presented as absolute frequencies and percentages in brackets

[b]Quantitative variables are expressed as mean and range in brackets

Fig. 2 Patient age



SILTEP Single-incision laparoscopic totally extraperitoneal, MTLTEP Multitrocar laparoscopic totally extraperitoneal

Table 2 Operative data

	SILTEP ($n=113$)	MTLTEP ($n=97$)	p Value
Operative time (min)[a]			
Unilateral hernia	50.98 (24–99)	44.92 (24–91)	**0.016**[#]
Bilateral hernia	72.31 (30–115)	62.57 (38–94)	**0.039**[§]
Mesh fixation[b]	40 (35.40)	30 (30.93)	0.619°
Operative complications[b]	28 (24.78)	25 (25.77)	0.868°
Peritoneal tear repair	26 (23.01)	24 (24.74)	
Epigastric vessels injury	1 (0.88)	0	
Corona mortis bleeding	1 (0.88)	0	
Conversion to TAPP	0	1 (1.03)	

Bold values indicate the results with a statistically significant difference between the two groups ($p<0.05$)

SILTEP single-incision laparoscopic totally extraperitoneal, *MTLTEP* multi-trocar laparoscopic totally extraperitoneal, *TAPP* transabdominal preperitoneal

°Chi-square test

[#]Student's *T* test

[§]Median test

[a]Quantitative variables are expressed as mean and range in brackets

[b]Qualitative variables are presented as absolute frequencies and percentages in brackets

to the ipsilateral anterior superior iliac spine. In bilateral hernias, two 6-mm trocars were inserted through the horizontal umbilical line, 2–3 cm internal to the anterior superior iliac spines. Two atraumatic grasping forceps were used to isolate and reduce the hernia sac, to retract the peritoneal sheet and to skeletonize and accurately identify all spermatic cord structures. A 15 cm by 10 cm polypropylene mesh was appropriately placed.

Statistical analysis

The analysis included descriptive statistical methods: calculation of mean and range for continuous variables, and contingency tables for categorical variables. Patient characteristics between the two groups were compared using the Chi-square or Fisher's exact test (when the expected frequencies were <5) for categorical variables, and the Student's t or Median test (when the sample size was smaller than 30) for continuous outcomes. A p value <0.05 was considered as statistically significant.

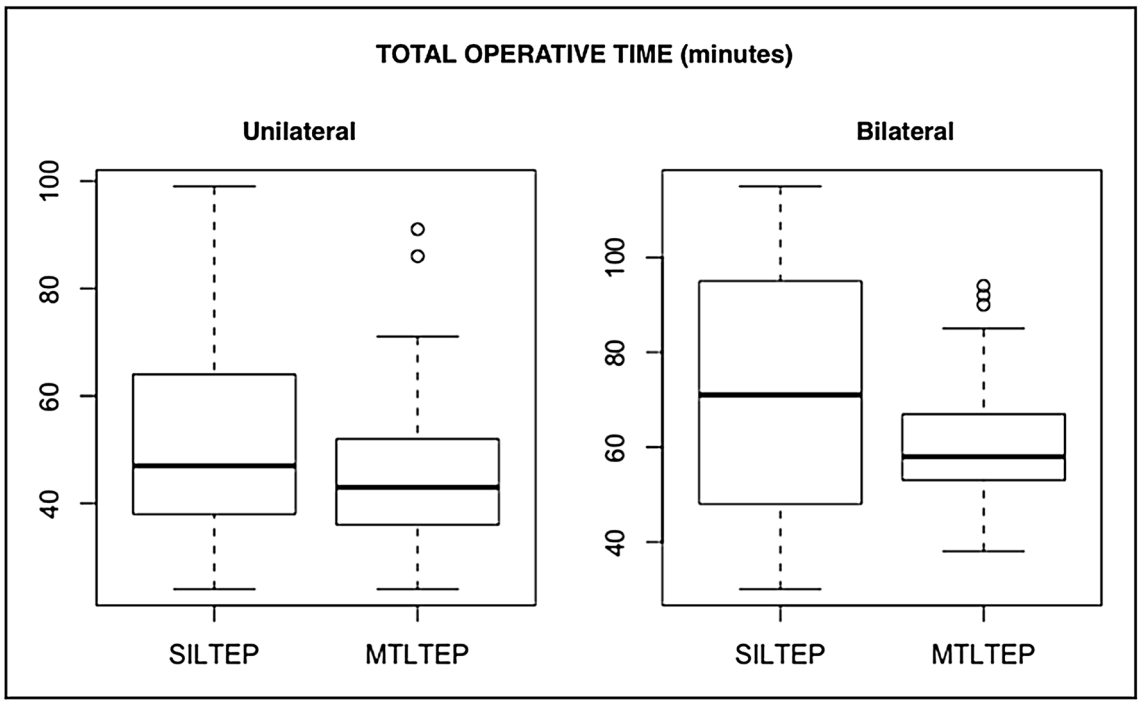
Results

Patient demographics and hernia characteristics are shown in Table 1. There were statistically significant differences between the two groups in terms of mean age ($p=0.011$) (Fig. 2), type of hernia ($p=0.002$), clinical presentation ($p=0.029$), and indication for surgery ($p=0.024$).

Perioperative data are summarized in Table 2. There were statistically significant differences between the two groups in terms of mean operative time for both unilateral and bilateral inguinal hernia repair ($p=0.016$; $p=0.039$) (Fig. 3).

Data regarding mean postoperative pain and length of hospital stay are given in Table 3. There were no statistically significant differences between the two groups in terms of mean postoperative pain (Fig. 4) and length of hospital stay (Fig. 5).

Postoperative complications and days to return to ADL are shown in Table 4. There were no statistically significant differences between the two groups in terms of postoperative complications and mean days to return to ADL (Fig. 6).



SILTEP Single-incision laparoscopic totally extraperitoneal, MTLTEP Multitrocar laparoscopic totally extraperitoneal

Fig. 3 Total operative time

Table 3 Postoperative pain and hospital stay

	SILTEP ($n=113$)	MTLTEP ($n=97$)	p Value
Postoperative pain score (VAS)[a]: unilateral			
At 6 h after surgery (VAS-6)	5.85 (0–9)	5.14 (0–9)	0.187[#]
At 12 h after surgery (VAS-12)	3.57 (0–6)	3.47 (0–9)	0.673[#]
At 18 h after surgery (VAS-18)	3.88 (0–6)	3.29 (0–6)	0.114[#]
At 24 h after surgery (VAS-24)	2.24 (0–6)	2.63 (0–6)	0.395[#]
Mean VAS (VAS/24)	3.88 (1–6.75)	3.63 (0–6.75)	0.236[#]
Postoperative pain score (VAS)[a]: bilateral			
At 6 h after surgery (VAS-6)	5.00 (0–9)	5.86 (2–9)	1[§]
At 12 h after surgery (VAS-12)	4.00 (0–6)	3.52 (2–6)	0.481[§]
At 18 h after surgery (VAS-18)	4.00 (0–6)	4.10 (2–6)	1[§]
At 24 h after surgery (VAS-24)	1.93 (0–6)	1.62 (0–6)	1[§]
Median VAS (VAS/24)	3.50 (0–6.75)	3.75 (2–5.75)	0.675[§]
Hospital stay (days)[a]	1.12 (0.5–2)	1.10 (0.5–3)	0.784[#]

SILTEP single-incision laparoscopic totally extraperitoneal, *MTLTEP* multi-trocar laparoscopic totally extraperitoneal, *VAS* visual analogue scale

[#]Student's *T* test

[§]Median test

[a]Quantitative variables are expressed as mean and range in brackets

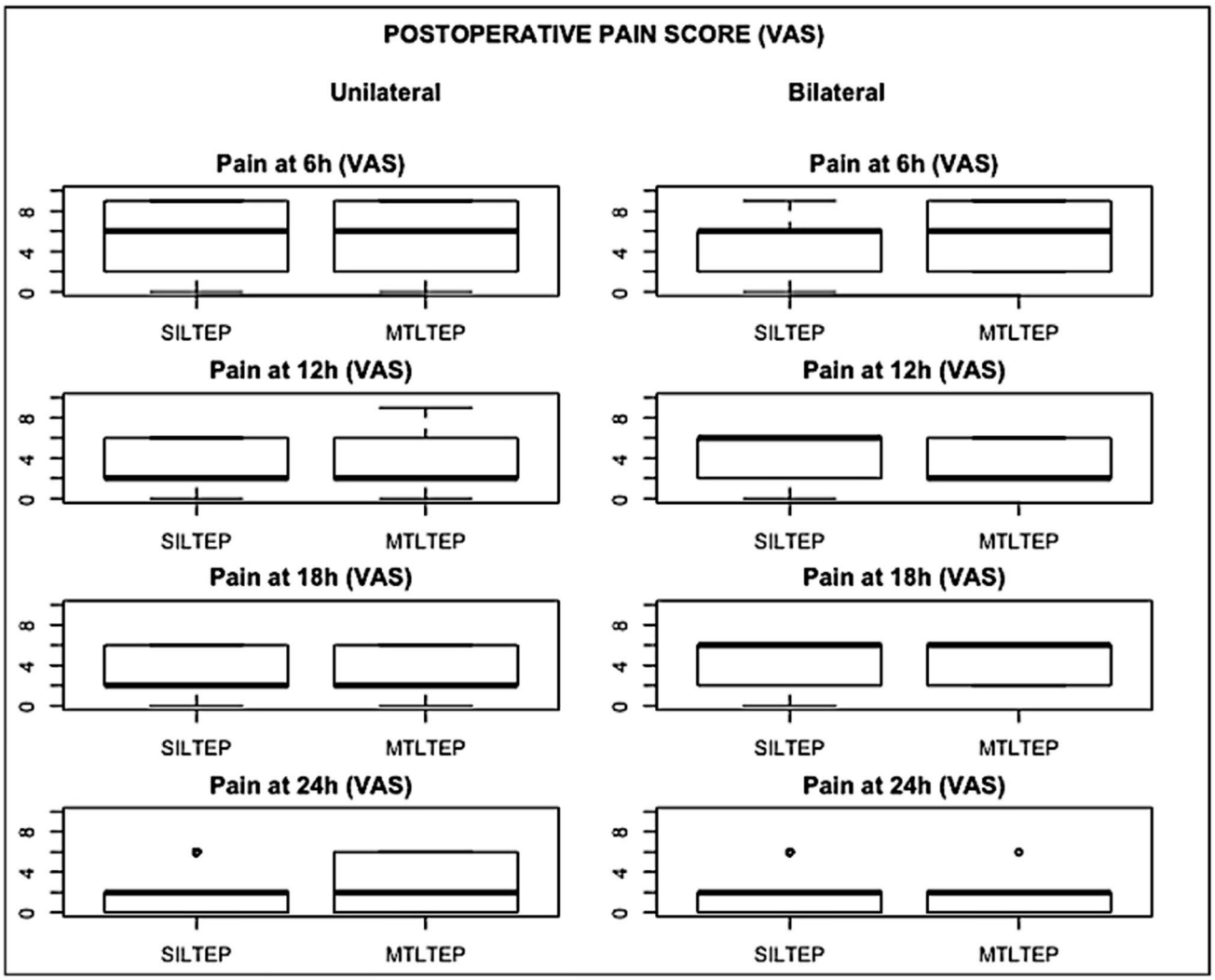
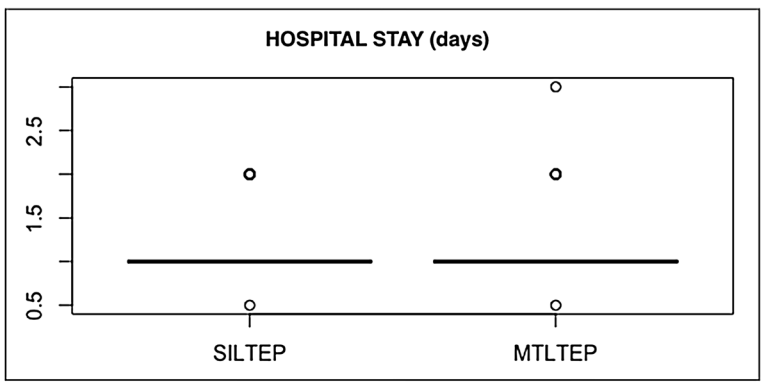


Fig. 4 Postoperative pain score

Fig. 5 Hospital stay



SILTEP Single-incision laparoscopic totally extraperitoneal, MTLTEP Multitrocar laparoscopic totally extraperitoneal

Table 4 Postoperative complications and mean days to return to activity of daily living (ADL)

	SILTEP ($n=113$)	MTLTEP ($n=97$)	p Value
Total consultation complications (at 7 days)[a]	20 (17.70)	21 (21.65)	0.514°
Consultation complications (at 7 days)[a]			
Umbilical hematoma	7 (6.19)	5 (5.15)	0.315*
Inguinal hematoma	7 (6.19)	5 (5.15)	
Inguinal seroma	5 (4.42)	10 (10.31)	
Umbilical infection (abscess)	1 (0.88)	0	
Urinary retention	0	1 (1.03)	
Total early complications (< 30 days)[a]	6 (5.31)	7 (7.22)	0.568°
Early complications (< 30 days)[a]			
Umbilical hematoma	3 (2.65)	2 (2.06)	0.650*
Inguinal hematoma	3 (2.65)	2 (2.06)	
Inguinal hernia recurrence	0	1 (1.03)	
Testicular atrophy	0	2 (2.06)	
Total late complications (> 30 days)[a]	5 (4.42)	5 (5.15)	0.804°
Late complications (> 30 days)[a]			
Umbilical hematoma	3 (2.65)	0	0.190*
Inguinal hematoma	2 (1.77)	1 (1.03)	
Inguinal hernia recurrence	0	1 (1.03)	
Testicular atrophy	0	1 (1.03)	
Chronic pain	0	2 (2.06)	
Days to return to ADL[b]	6.76 (1–30)	8.11 (1–30)	0.116[#]

SILTEP single-incision laparoscopic totally extraperitoneal, *MTLTEP* multi-trocar laparoscopic totally extraperitoneal, *ADL* activity of daily living

°Chi-square test

*Fisher's exact test

[#]Student's *T* test

[a]Qualitative variables are presented as absolute frequencies and percentages in brackets

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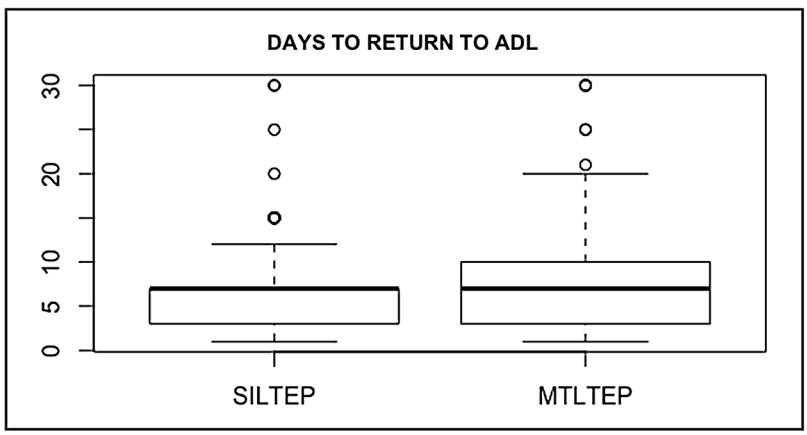


Fig. 6 Days to return to ADL

SILTEP Single-incision laparoscopic totally extraperitoneal, MTLTEP Multitrocar laparoscopic totally extraperitoneal

Table 5 Surgical and cosmetic satisfactions at 2-year follow-up

	SILTEP ($n=113$)	MTLTEP ($n=97$)	p Value
Follow-up (months)[a]	28.37 (13–41)	26.42 (13–41)	0.097[#]
Mean surgical satisfaction (1–5)[a]	4.43 (1–5)	4.20 (1–5)	0.090[#]
Surgical satisfaction (1–5)[b]			
Very satisfied (5)	74 (65.49)	52 (53.61)	0.073*
Satisfied (4)	19 (16.81)	26 (26.80)	
Average satisfied (3)	16 (14.16)	11 (11.34)	
Not satisfied (2)	3 (2.65)	2 (2.06)	
Extremely dissatisfied (1)	1 (0.88)	6 (6.19)	
Cosmetic satisfaction (1–10)[a]			
Preoperative	6.38 (1–10)	6.70 (4–10)	0.125[#]
Postoperative	7.51 (2–10)	6.93 (3–10)	**0.003**[#]

Bold value indicates the results with a statistically significant difference between the two groups ($p<0.05$)

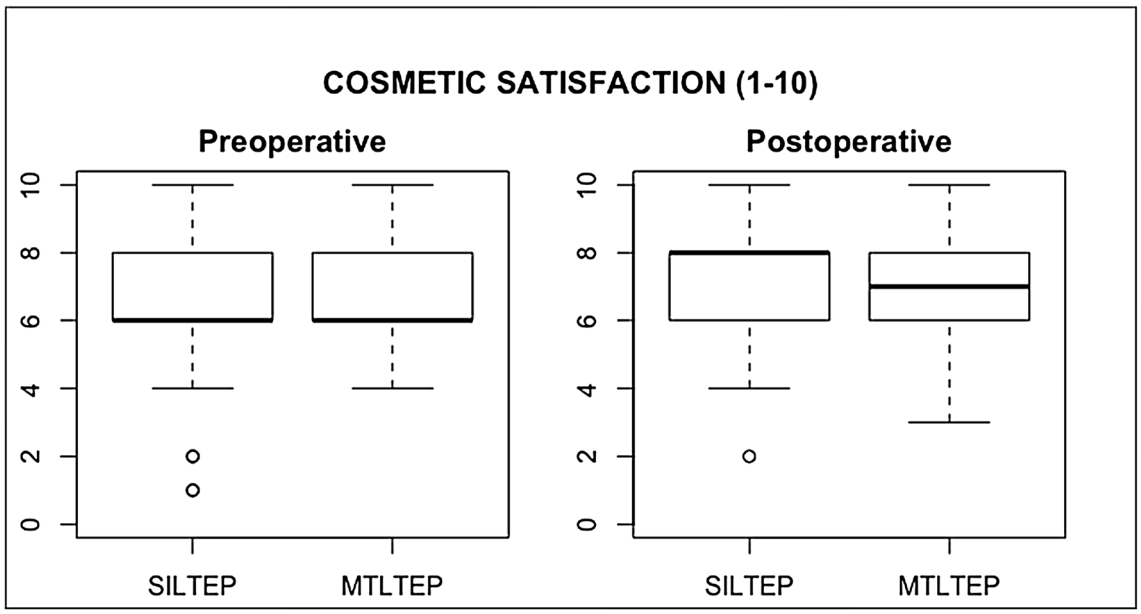
SILTEP single-incision laparoscopic totally extraperitoneal, *MTLTEP* multi-trocar laparoscopic totally extraperitoneal

*Fisher's exact test

[#]Student's *T* test

[a]Quantitative variables are expressed as mean and range in brackets

[b]Qualitative variables are presented as absolute frequencies and percentages in brackets



SILTEP Single-incision laparoscopic totally extraperitoneal, MTLTEP Multitrocar laparoscopic totally extraperitoneal

Fig. 7 Cosmetic satisfaction

The results of surgical and cosmetic satisfactions are summarized in Table 5. There was a statistically significant difference between the two groups regarding the cosmetic satisfaction in favor of SILTEP ($p=0.003$) (Fig. 7).

Discussion

This study confirmed that SILTEP and MTLTEP had comparable surgical efficacy, hospital stay, mean days to return to ADL, conversion rate, and postoperative complications at

both short-term and mid-term follow-ups.

The mean operative time in SILTEP for unilateral inguinal hernia repair was 6 min longer than MTLTEP. It was 10 min longer for bilateral hernia repair, as well. This difference in operative time between the two techniques was similar to that previously reported by other authors [10–13]. In a prospective randomized clinical trial comparing SILTEP with MTLTEP, Tsai et al. reported a longer operative time in the single-site TEP approach [10]. The authors related this result to the extra-time required for setting up the single-access platform for TEP repair. Likewise, in a recent review comparing 595 SILTEP versus 514 MTLTEP, a significant longer operative time was found in unilateral inguinal hernia repair after SILTEP [8]. The authors related these data to the limited surgeons' experience in SILTEP. In our institution, SILTEP was started in November 2011 [14] and, in this randomized study, SILTEP was performed after achieving an experience of just 50 cases. Hence, like Lo et al. [8], in this study, the recorded differences in operative time were probably associated to the limited experience of the surgeon in performing SILTEP.

According to the "update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia" by the International Endohernia Society [15], in our study, the mesh was fixed when a large direct inguinal hernia defect was found. The association between the mesh fixation and chronic pain has been widely debated in literature. In a recent meta-analysis [16], Sajid et al. reported no difference between non-fixation versus mechanical fixation for both early and chronic pain. Moreover, the randomized controlled trial of Garg et al. [17], published after this meta-analysis, confirmed the same results. In their second meta-analysis [18], Sajid et al. reported a significant difference between glue fixation and mechanical fixation for chronic pain. However, this result has not been confirmed by the four subsequent studies [19–22]. Reduced postoperative pain after SILTEP could be due to the fewer number of scars and trocars' introduction. However, in our study, this hypothesis has not been confirmed like in another randomized study where no statistically significant difference was found [23]. Therefore, the results of our study confirmed that SILTEP repair is comparable with MTLTEP repair in terms of postoperative and chronic pain.

In this study, the perioperative, early, and late complications resulted similar in both groups. These results were consistent with those already reported by other authors [10, 11, 23] and by a recent meta-analysis [8].

The cosmetic outcomes after SIL have been enhanced in several randomized studies [24–26], but a recent review and meta-analysis [8] did not show a superiority of SILTEP over MTLTEP. So far, five studies compared the cosmetic results after SILTEP versus MTLTEP inguinal hernia repair: three of them reported no statistically significant differences between the two techniques [10, 11, 23]; one showed higher cosmesis after SILTEP [27], and one concluded that, even if SILTEP offered less visible scars, no statistically difference was found over MTLTEP [28].

In our study, we evaluated the surgical and cosmetic satisfactions between the two groups, after a mean follow-up of 27 months. We noticed a higher cosmetic satisfaction in the SILTEP group, with an increased satisfaction score from 6.38 (pre-surgery) to 7.51 (after 27 months from surgery). In the MTLTEP group, the cosmetic satisfaction score remained stable: 6.70 (pre-surgery) and 6.93 (after 27 months from surgery).

In this study, the surgical satisfaction score was positive in both groups. Indeed, 96 and 92% of patients undergoing SILTEP and MTLTEP inguinal hernia repair, respectively, stated to be satisfied with the surgical procedure received. Moreover, at consultation and telephone follow-up, patients highly recommended both surgeries to future candidates.

Conclusions

Perioperative, short-term, and mid-term outcomes were comparable between the two groups. At 2-year follow-up, a significant shorter operative time after MTLTEP and a greater cosmetic satisfaction after SILTEP have been found.

Compliance with ethical standards

Disclosures Giovanni Dapri is a consultant for Karl Storz-Endoskope, Tuttlingen, Germany. Luca Cardinali, Claudia Hannele Mazzetti, Anny Cadenas Febres, Deborah Repullo, Jean Bruyns have no conflicts of interest or financial ties to disclose.

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