Mini- or Less-open Sublay Operation (MILOS): A New Minimally Invasive Technique for the Extraperitoneal Mesh Repair of Incisional Hernias

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Objective: Improvement of ventral hernia repair.

Background: Despite the use of mesh and other recent improvements, the currently popular techniques of ventral hernia repair have specific disadvantages and risks.

Methods: We developed the endoscopically assisted mini- or less-open sublay (MILOS) concept. The operation is performed transhernially via a small incision with light-holding laparoscopic instruments either under direct, or endoscopic visualization. An endoscopic light tube was developed to facilitate this approach (EndotorchTM Wolf Company). Each MILOS operation can be converted to standard total extraperitoneal gas endoscopy once an extraperitoneal space of at least 8 cm has been created. All MILOS operations were prospectively documented in the German Hernia registry with 1 year questionnaire follow-up. Propensity score matching of incisional hernia operations comparing the results of the MILOS operation with the laparoscopic intraperitoneal onlay mesh operation (IPOM) and open sublay repair from other German Hernia registry institutions was performed.

Results: Six hundred fifteen MILOS incisional hernia operations were included. Compared with laparoscopic IPOM incisional hernia operation, the MILOS repair is associated with significantly a fewer postoperative surgical complications ($P < 0.001$) general complications ($P < 0.004$), recurrences ($P < 0.001$), and less chronic pain ($P < 0.001$). Matched pair analysis with open sublay repair revealed significantly a fewer postoperative complications ($P < 0.001$), reoperations ($P < 0.001$), infections ($P = 0.007$), general complications ($P < 0.001$), recurrences ($P = 0.017$), and less chronic pain ($P < 0.001$).

Conclusions: The MILOS technique allows minimally invasive transhernial repair of incisional hernias using large retromuscular/preperitoneal meshes with low morbidity. The technique combines the advantages of open sublay and the laparoscopic IPOM repair.

ClinicalTrials.gov Identifier NCT03133000

Keywords: endoscopic retromuscular hernia repair, endoscopic ventral hernia repair, incisional hernia, minimally invasive sublay repair, primary abdominal wall hernia, recurrent abdominal wall hernia, sublay technique, total extraperitoneal preperitoneal repair

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Laparoscopic intraperitoneal onlay mesh (IPOM) repair and open sublay mesh repair are currently the most widely-used techniques for the treatment of primary and recurrent abdominal wall hernias worldwide.[1–7] A systematic review[4] and 2 recently published meta-analyses concluded that lap. IPOM and open abdominal wall hernia repairs are safe procedures with comparable short and long-term outcomes.[1,2] Although the open techniques are burdened with higher infection rates,[1,3,4] the lap. IPOM repair carries an increased risk of intraoperative bowel injury, adhesions, and bowel obstruction.[2,4] Despite progress in mesh technology and development of coated meshes designed to lower risk of adhesion formation, the potential risks associated with an intraperitoneal foreign body has not yet been eliminated[6] and traumatic mesh fixation increases the risk of adhesions, visceral damage, nerve injury, and acute and chronic pain.[5,6] Mobilization of the hernia sac with closure of the hernia defect are difficult with laparoscopic IPOM, and is often omitted leading to higher recurrence rates, eventrations (pseudorecurrences), and seroma formation.[1–3,5] In larger hernias with a diameter of more than 15 cm, the laparoscopic IPOM repair can be very difficult.[5–7]

It is generally accepted that the retromuscular/preperitoneal (= sublay) space is the best option for mesh placement in abdominal wall hernia repair.[1–12] The sublay mesh is pushed against the abdominal wall by the intraabdominal pressure, thus allowing rapid tissue integration without the need for traumatic mesh fixation.[8] The excellent results of laparo-endoscopic inguinal hernia repair have confirmed with the highest level of evidence the success of minimally invasive preperitoneal mesh repair.[10,11] However, cranially to the arcuate line, it is technically very demanding and in many cases impossible to detach the flimsy peritoneum from the posterior rectus sheath. There are only a few reports on minimally invasive sublay repair of abdominal wall hernias in the literature.[12–16,17] The laparoscopic transperitoneal sublay repair of small and medium size ventral eventrations via the left flank is feasible but technically demanding.[12]

To minimize complications and pain in abdominal wall hernia repair, a new minimally invasive technique was developed which permits placement of large sublay meshes via a small transhernial incision, thus avoiding major trauma to the abdominal wall and entering the peritoneal cavity. The current study is the first to describe the novel MILOS technique. The results achieved with the MILOS repair in incisional hernias are compared with the laparoscopic IPOM- and open sublay techniques.

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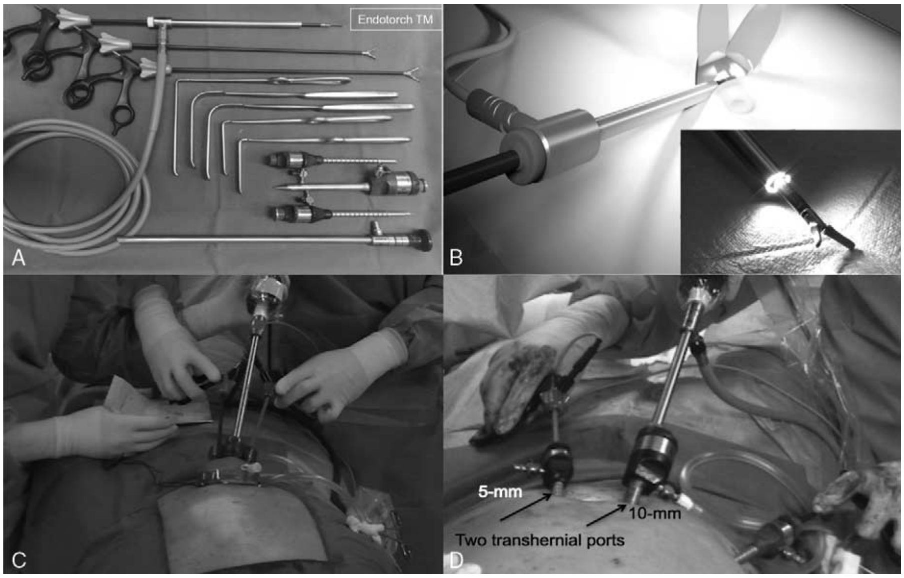

FIGURE 1. MILOS-operation: Instruments, mini-open and endoscopic options. A, MILOS instruments: standard laparoscopic instruments, rectangular retractors and Endotorch TM. B, Transhernial direct view dissection with light armed laparoscopic instruments using the EndotorchTM. C, Endoscopic MILOS operation with standard port total extraperitoneal gas endoscopy: two transhernial ports and one additional transrectus muscle 5 mm port (Option B, ventral hernia TEP). D, Endoscopic MILOS operation with transhernial total extraperitoneal single port gas endoscopy (Option C, single port ventral hernia TEP).

METHODS

Endoscopically Assisted Minimally or Less-open Sublay (MILOS) Repair

Beginning in 2010 all MILOS operations were prospectively registered in the German Hernia Register ''Herniamed.'' Table Supplement 1, http://links.lww.com/SLA/B364 shows the flow chart of patient selection for analysis. Only elective operations were included in the trial. Primary outcome parameters were recurrence after 1 year and chronic pain after 1 year at rest and during physical activity, and chronic pain requiring treatment. Secondary target variables were: intraoperative visceral injury, postoperative bleed, reoperation, infection, prolonged wound healing, and general complications. One year after the operation all patients received a questionnaire. Chronic pain was assessed by numerical rating scale (NRS, 0–10). Mini-open and less-open access were defined as incisions of at most 5 cm and 12 cm, respectively, with a maximum length of less than one-fourth of the longest mesh diameter. Operations with incisions longer than 12 cm were excluded from the trial.

At the start of the operation, the operating surgeon stands on the right side of the patient, the assistant on the left side and the operating-room (OR) technician on the left side near the patient's legs. The laparoscopy tower is located on the right side of the patient. A second video screen opposite the laparoscopy tower is recommended. Because of transhernial circumferential dissection, the operating surgeon has to change position with the assistant several times during the operation. The equipment and instruments of the MILOS operation are described in Table Supplement 2, http://links.lww.com/SLA/B364 and shown in Figure 1A.

All patients received antibiotic prophylaxis with Cefazolin 2 g in 30 minutes preoperatively. Skin disinfection was repeated every 30 minutes. Before mesh implantation gloves were changed and the wound was rinsed with gentamycin solution (80 mg in 100 mL Ringer's solution; 17).

To prevent visceral lesions, operative steps 1 to 3 were always performed carefully and without electrocautery.

Step 1: The MILOS operation starts with a 2 to 12 cm skin incision (2–5 cm = mini-open, 6–12 cm = less open) directly above the center of the hernia defect (Fig. 2A), followed by complete exposure of the hernia sac (Fig. 2B).

Step 2: A small incision of the hernia sac for transhernial laparoscopy is advisable. If necessary, this is followed by laparoscopic or mini-open adhesiolysis. Excessive parts of the hernia sac which pose a risk of bowel obstruction are excised.

Step 3: The border of the hernia defect (hernia ring) is circumferentially exposed and elevated with sharp clamps (Fig. 2C).

Step 4: The peritoneum is detached from the abdominal wall at the edge of the fascia defect with a radius of at least 2 cm (Fig. 2D).

Step 5: The posterior rectus sheath is incised on both sides about 1 cm lateral to the medial border of the rectus muscle (Fig. 3A).

Step 6: The abdominal wall is elevated by the assistant using pairs of narrow retractors of different size (Tab. Supplement 3, http://links.lww.com/SLA/B364; Fig. 3B–D, Suppl 3A, http://links.lww.com/SLA/B364) around the hernia defect.

In the midline, the peritoneum is separated from the linea alba (Fig. 3B). The posterior rectus sheath is extensively mobilized from the rectus muscle with laparoscopic instruments (Fig. 3C).

Dissection is performed circumferentially around the hernia defect either under direct visualization or endoscopic view using laparoscopic instruments armed with a 10-mm light tube which was specifically designed by our working group and Wolf company (Endotorch, Wolf TM, Knittlingen, Germany Fig. 1A, 1B, 3B–D). The Endotorch is a modified 20 cm long and 10 mm diameter laparoscope. Instead of a telescopic rod lens system it has a central canal for the insertion of any 5 mm laparoscopic instrument (Fig. 1A, B). The detailed features of the Endotorch will be described in a separate publication. Before the introduction of the Endotorch in 2014, an endoscopic light cable was attached parallel to a laparoscopic instrument.

The Endotorch gives maximum light at the tip of the light holding laparoscopic instrument, thus automatically pointing to the center of the surgeon's dissection field (Fig. 1B). This allows precise wide range tissue manipulation via mini incisions within the extraperitoneal space. It may also be used for gasless laparoscopy and adhesiolysis. The circumferential dissection range in relation to the skin incision and recommended size of the rectangular retractors are given in Table Supplement 3, http://links.lww.com/SLA/B364. MILOS operations via 2 cm incisions were performed with 3 mm

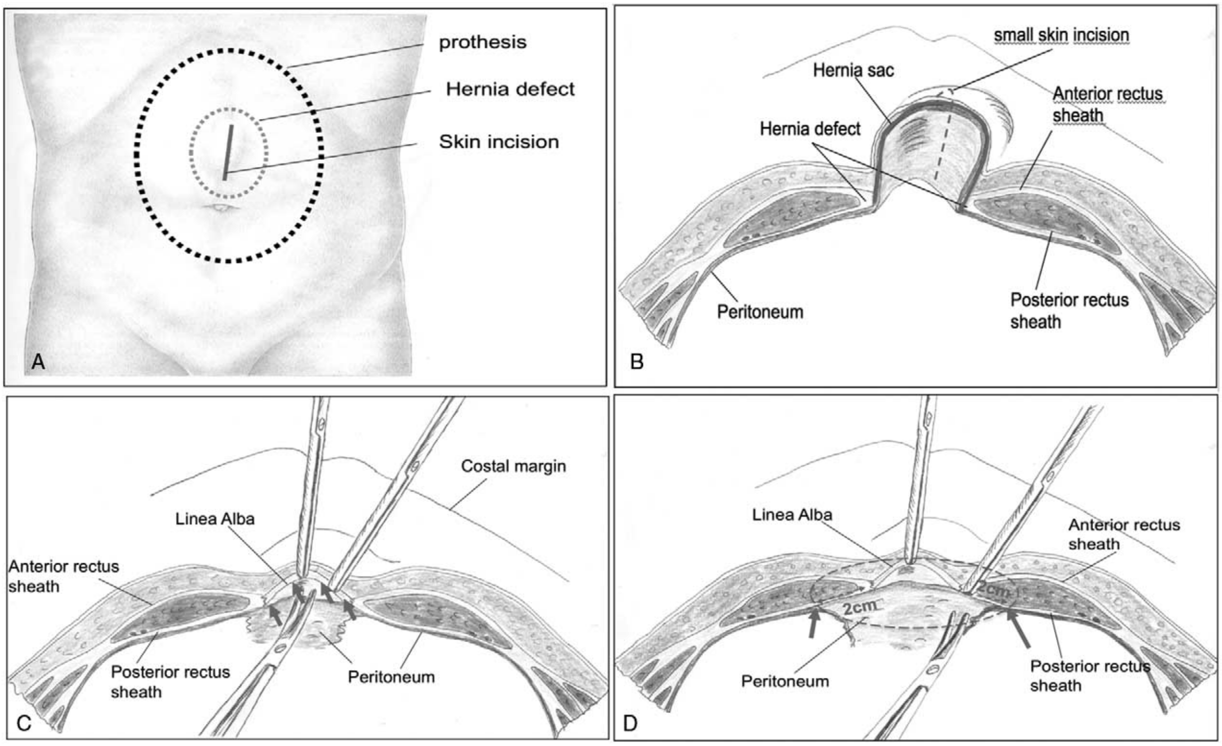

FIGURE 2. Initial MILOS operation steps. A, Small incision above the center of the main hernia defect. B, Complete dissection of the hernia sack. C, The border of the hernia defect is circumferentially exposed and elevated with sharp clamps. D, The peritoneum is circumferentially detached at least 2 cm in all directions from the facia ring.

laparoscopic instruments and a 5 mm laparoscope. Scar tissue formation, especially after previous operation(s) with mesh implantation, may reduce the maximum dissection range and warrant larger incisions.

Step 7: The posterior layer of the rectus sheath is longitudinally incised in all quadrants, about 1 cm lateral to the medial border of the rectus muscle corresponding to the size of the hernia defect and planned alloplastic mesh insertion (Fig. 3D, Suppl 3A,B, http://links.lww.com/SLA/B364).

After creation of an extraperitoneal space of at least 8 cm in diameter and closure of the peritoneum, the operation may be converted to total extraperitoneal gas endoscopy (endoscopic TEP ventral hernia repair). Reusable standard ports (Option B, Tab. Supplement 4, http://links.lww.com/SLA/B364, Fig. 1D) or a transhernial single port technique may be used (Tab. Supplement 4, http://links.lww.com/SLA/B364, Fig. 1C; option C; 18). Option B (Fig. 1D): after temporary hernia defect closure with a running suture one 10 mm optic trocar and one 5 mm working port are inserted via the end points of the suture line without additional skin incisions. After extraperitoneal CO2 application with a maximum pressure of 12 mmHg, a second 5 mm working trocar is inserted through the rectus muscle at least 5 cm lateral to the optic port for better angulation (Fig. 1D). Option C: several different types of disposable and reusable single ports were used. Flexible single ports (ie, Gel port, Applied Medical, Fig. 1C) allow fast conversion to gas endoscopy.

The posterior layer of the rectus sheath is closed if this is possible with low tension. In all other cases, defects of the peritoneum between the cut edges of the posterior rectus sheath are meticulously closed to prevent any contact between alloplastic material and the intestines (Fig. Suppl 3C,D, http://links.lww.com/SLA/B364).

Step 8: A large pore standard alloplastic mesh, preferably polypropylene or polyvinylidenfluoride (PVDF) is double rolled and inserted transhernially with 2 long curved clamps without skin contact and then unfolded with light-armed laparoscopic instruments under direct or endoscopic vision (Fig. Suppl 3D, http://links.lww.com/SLA/B364). The mesh should posteriorly overlap the hernia defect by at least 5 cm (Fig. 2D). The implantation of very large meshes is possible. In most cases, because of large overlap, there is no need for mesh fixation. In the case of subxiphoidal or suprapubic hernia defects, the mesh is secured with absorbable sutures to the paraxiphoidal fascia or Cooper's ligaments. Fascial circumferential lateral mesh fixation with absorbable sutures is only performed if a low tension hernia defect closure is not possible (bridging of the hernia defect). One suction Redon drain (8 Charr.) is inserted into the extraperitoneal space.

Step 9: Additional hernia defects are closed transhernially under direct vision or endoscopically. The main hernia defect is closed with minimal tension above the mesh (Fig. Suppl 3D, http://links.lww.com/SLA/B364). Anatomical reconstruction of the abdominal wall is always the primary goal.

Step 10: Management of subcutaneous tissue and skin: Large hernia sacs are removed, meticulous subcutaneous electrocoagulation is performed and a subcutaneous 8 Char. Redon drain is inserted. If necessary, contracted scar tissue is mobilized and resected, and the umbilicus is reconstructed. The skin is closed with a running subcutaneous suture. Figures Supplement 1 and 2,

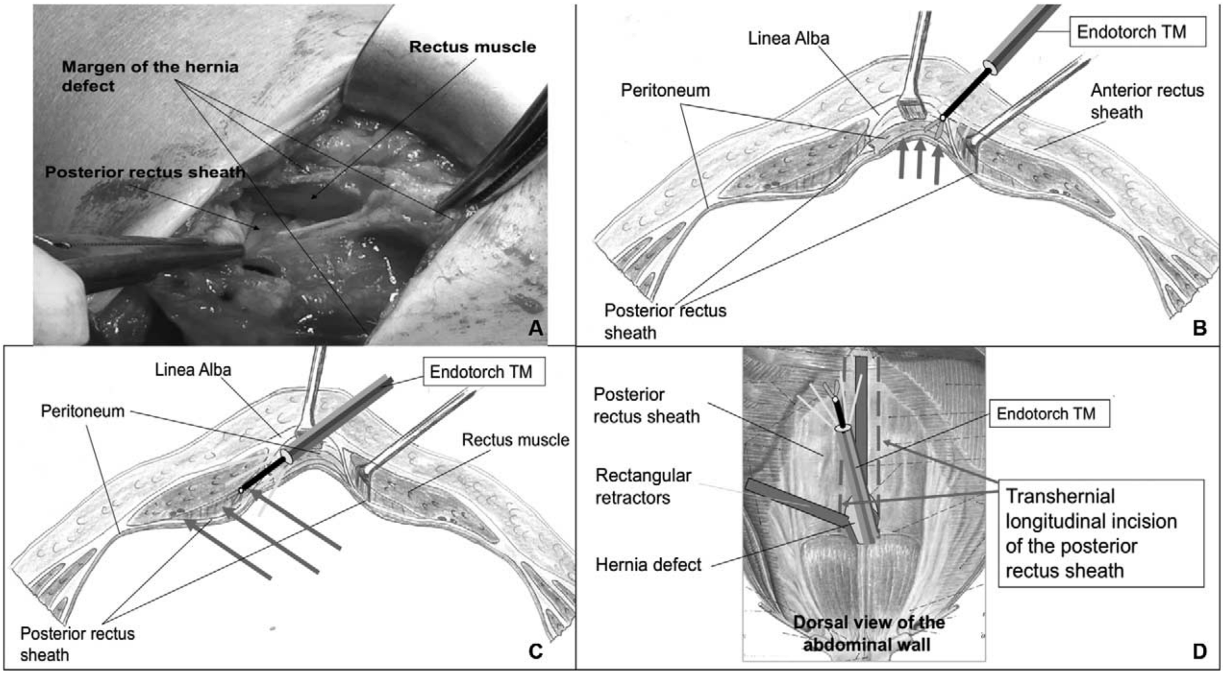

FIGURE 3. MILOS operation steps two. A, The posterior rectus sheath is incised on both sides about 1 cm lateral to the medial border of the rectus muscle. B, The peritoneum and preperitoneal fat are separated from the linea alba cranially and caudally of the hernia defect using laparoscopic instruments with the Endotorch TM. C, The posterior rectus sheath is extensively mobilized from the rectus muscle with light armed laparoscopic instruments. D, Transhernial longitudinal incision of the posterior rectus sheath in all quadrants with direct view using light armed laparoscopic scissors.

http://links.lww.com/SLA/B364 show 2 patients with small scars and corresponding mesh size after MILOS repair of incisional hernias. A video demonstrating the operative steps and technique is available online (https://youtu.be/EXV9qGS5YQc).

The MILOS technique allows: (i) exposure of the entire extraperitoneal rectus compartment from the retroxiphoid to the retropubic region, (ii) additional mini-open or endoscopic assisted posterior component separation/ transversus abdominis release (TAR), (iii) dissection of the complete lateral compartment, and (iv) closure of diastasis recti.

In primary and recurrent lateral hernias, the transhernial dissection is performed in the preperitoneal plane. To obtain sufficient medial mesh overlap the posterior rectus sheath may have to be incised. For the protection of segmental nerves and blood vessels the longitudinal incision should be performed 2 cm medial to the lateral border of the rectus compartment (reversed posterior component separation).

STATISTICS

All analyses were performed with the software SAS 9.4 (SAS Institute Inc., Cary, NY) and intentionally calculated to a full significance level of 5%, that is they were not corrected in respect of multiple tests, and each $P \leq 0.05$ represents a significant result.

The perioperative and 1-year follow-up outcomes for MILOS incisional hernia operations at Gross-Sand Hospital were compared with laparoscopic IPOM and open sublay incisional hernia operations at other institutions participating in the German Hernia Registry ‘‘Herniamed’’ using propensity score matching.[18] Matched samples were analyzed via McNemar’s test. Results are given as nondiagonal elements of the 2×2 frequency table with the corresponding P-value and the odds ratios for paired samples are given.

Propensity score matching was performed using greedy algorithm and a caliper of 0.2 standard deviations. The variables used for matching were: Hernia defect [cm^2], sex, ASA score, primary incisional hernia (yes/no), European Hernia Society (EHS) classification (width W1: 1–4 cm / W2: > 4cm- < 10 cm / W3: > 10 cm), EHS lateral (yes/no), medial (yes/no),[19] body mass index, age, oral anticoagulants (yes/no), platelet inhibitors (yes/no), and mesh size [cm^2]. The balance of the matched sample was checked using standardized differences (also given for the prematched sample) that should not exceed 10% (< 0.1) after matching.

For pairwise comparison of matching parameters between operation methods [for presenting the differences in the original (pre-matched) sample] χ^2 tests and t tests (Satterthwaite) were performed for categorical and continuous variables, respectively. For defect size [cm^2] and mesh size [cm^2] a logarithmic transformation was applied and retransformed mean and range of dispersion are given.

RESULTS

The German Hernia Register identified 5865 laparoscopic IPOM procedures, 5997 open sublay and 615 MILOS incisional hernia operations with complete 1-year follow. One year follow-up rate for the MILOS cohort was 97%. In the first 2 years (2010—2012) all MILOS operations were performed by 2, after 2012 by all 4, specialized hernia surgeons of our department. For the comparison of MILOS repair with laparoscopic IPOM operation and MILOS operation with open sublay repair propensity score matching of 541 (88.0%) and 576 (93.7%) patient pairs was possible, respectively. The cohorts were balanced for all matching parameters. The body mass index (BMI) was > 30 in 40.2% of the MILOS patients.

TABLE 1. MILOS Versus Laparoscopic IPOM: Continuous and Categorical Matching Parameters

A: Standardized Differences of Continuous Matching Parameters Before and After Matching

		MILOS	Laparoscopic IPOM	Standard Difference Matched Sample	Standard Difference Original Sample
Age, yrs	Mean ± STD	60.2 ± 13.1	60.3 ± 13.3	0.004	0.139
BMI	MW ± STD	29.7 ± 6.1	29.6 ± 5.8	0.020	0.064
Defect size, cm^2	MW ± STD	75.6 ± 100.6	78.3 ± 97.8	0.027	0.516
Mesh size, cm^2	MW ± STD	518.2 ± 280.4	532.5 ± 287.0	0.050	0.889

B: Standardized Differences of Categorial Matching Parameters Before and After Matching

	MILOS		Laparoscopic IPOM		Standard Difference	
	n	%	n	%	Matched Sample	Original Sample
Sex: male	295	54.53	295	54.53	0.000	0.121
ASA I	47	8.69	50	9.24	0.019	0.085
ASA II	306	56.56	288	53.23	0.067	0.069
ASA III-IV	188	34.75	203	37.52	0.058	0.124
EHS W1	103	19.04	91	16.82	0.058	0.432
EHS W2	269	49.72	272	50.28	0.011	0.088
EHS W3	169	31.24	178	32.90	0.036	0.542
Preoperative pain	420	77.63	403	74.49	0.074	0.455
No preoperative pain	45	8.32	63	11.65	0.111	0.690
Unknown preoperative pain	76	14.05	75	13.86	0.005	0.170
Primary incisional hernia operation	362	66.91	372	68.76	0.040	0.322
EHS medial	480	88.72	488	90.20	0.048	0.177
EHS lateral	119	22.00	112	20.70	0.032	0.075
Cumarin-medication (Quick/INR not in the normal range)	15	2.77	13	2.40	0.023	0.011
Platelet inhibitors (stopped less than 7 days before surgery	63	11.65	67	12.38	0.023	0.078

ASA indicates American Society of Anesthesiologists; BMI, body mass index; EHS, European Hernia Society; IPOM, intraperitoneal onlay mesh; MILOS, mini- or less-open sublay operation.

The mean defect size in the MILOS cohort before matching was 101.2 ± 115.3 cm^2. Hernia sizes according to the EHS incisional hernia classification W1, W2, and W3 were 103 (16.8%), 282 (45.9%), and 230 (37.4%), respectively. There were 553 medial, 62 lateral, and 76 combined hernias. The mean mesh size was 606.9 ± 352.4 cm^2. The mean skin incision in the MILOS repair was 6.8 cm (range, 2—12 cm). The mean operating times for the MILOS, laparoscopic IPOM, and open sublay operation were 103 (range, 40—332 min), 82, and 95 minutes, respectively. In the first 50 operations the mean skin incision length and average operation time were 9 cm (range, 4–12 cm) and 132 minutes (range, 87–224 min), respectively. Complete defect closure was achieved in 611 cases.

Additional bilateral posterior component separation (TAR) with the MILOS technique was performed in 36 cases of large medial incisional hernias.

In all MILOS operations light-armed laparoscopic instruments were used under direct vision. Mini-open dissection under additional endoscopic visualization was performed in 332 (54.0%) cases (Option A, Tab. Supplement 4, http://links.lww.com/SLA/B364). In 52% of the MILOS operations transhernial laparoscopy was performed. The endoscopic options B (Fig. 1D) and C (Fig. 1C) were used in 63 (10.2%) and 93 (15.1%) of the operations, respectively. Conversion to gas endoscopy was indicated when the mini-open approach gave insufficient exposure of the operative field. There was no difference in complication rates between MILOS operations with or without gas endoscopy ($P = 1.0$) and MILOS operations with single port or standard ports gas endoscopy ($P = 1.0$).

Matched Pair Analysis of MILOS Versus Laparoscopic IPOM Operation

Data of continuous and categorical matching variables of MILOS versus laparoscopic IPOM operation are shown in Table 1. Compared with laparoscopic IPOM incisional hernia operation, the MILOS repair was associated with significantly a fewer postoperative surgical complications [$P < 0.001$; OR 0.23 (0.08, 0.52)], general complications [$P < 0.004$; OR 0.27 (0.09, 0.69)], postoperative seroma with surgical intervention [$P = 0.001$; OR 0.17 (0.03, 0.57)], recurrences after 1 year [$P < 0.001$; OR 0.29 (0.13, 0.61)], less chronic pain after 1 year at rest [$P < 0.001$; OR 0.26 (0.14, 0.45)], during physical activity [$P < 0.001$; OR 0.22 (0.14, 0.34)], and chronic pain requiring therapy [$P < 0.001$; OR 0.29 (0.14, 0.55)]. The MILOS operation was associated with a fewer enterotomies and postoperative bleeding requiring reoperation compared with laparoscopic IPOM repair but these findings were not statistically significant. Data are shown in Table 2.

Matched Pair Analysis of MILOS Versus Open Sublay Operation

Data of continuous and categorical matching variables of MILOS versus open sublay operation are shown in Table 3. After MILOS repair there were significantly a fewer postoperative complications requiring reoperation [$P < 0.001$; OR 0.10 (0.05, 0.19)], hematomas with surgical evacuation [$P < 0.001$; OR 0.16 (0.03, 0.54)], seromas with surgical interventions [$P < 0.001$; OR 0.11 (0.04, 0.29)], postoperative infections [$P = 0.007$; OR 0.15 (0.02, 0.68)], less prolonged wound healing [$P < 0.001$; OR 0.02 (0.001,

TABLE 2. Mini Open Sublay Versus Laparoscopic IPOM: Complications: Direct Comparison of Systematic Deviation Including Adjusted Odds Ratio

	Systematic Disadvantage					OR of Paired Sample		
	MILOS		Laparoscopic IPOM					
	n	%	n	%	P	Adjusted OR	Lower Limit	Upper Limit
General complications	6	1.11	22	4.07	<0.004	0.273	0.090	0.694
Postoperative surgical complications	7	1.29	31	5.73	<0.001	0.226	0.084	0.523
Postoperative seroma with surgical intervention	3	0.55	18	3.33	0.001	0.167	0.031	0.571
Postoperative bleeding	3	0.55	9	1.66	0.146	0.333	0.058	1.336*
Enterotomy	1	0.18	3	0.55	0.625	0.333	0.006	4.151*
Recurrence	10	2.16	34	7.34	<0.001	0.294	0.130	0.609
Chronic pain at rest (1 year postoperative)	17	3.67	65	14.04	<0.001	0.262	0.144	0.451
Chronic pain during physical activity (1 year postoperative)	25	5.40	115	24.84	<0.001	0.217	0.135	0.337
Chronic pain requiring treatment (1 year postoperative)	12	2.22	42	7.76	<0.001	0.286	0.137	0.553

*Statistically no significant difference.
IPOM indicates intraperitoneal onlay mesh; MILOS, mini- or less-open sublay operation; OR, odds ratio.

0.13)], a fewer general complications [$P < 0.001$; OR 0.14 (0.05, 0.33)], recurrences after 1 year [$P = 0.017$; OR 0.40 (0.17, 0.86)], less chronic pain after 1 year at rest [$P < 0.001$; OR 0.28 (0.16, 0.48)], during physical activity [$P < 0.001$; OR 0.21 (0.13, 0.33)], and chronic pain requiring therapy [$P < 0.001$; OR 0.21 (0.10, 0.40)]. Data are shown in Table 4.

DISCUSSION

To improve abdominal wall hernia surgery and overcome the obvious disadvantages of the currently most widely used operations outlined in the introduction, we successfully developed the MILOS technique.

The MILOS operation is the first technique that allows minimally invasive sublay repair of all primary and recurrent abdominal wall hernias, with the exception of giant eventrations. Even in these cases the principles of MILOS repair help to reduce the access trauma to the abdominal wall and facilitate preperitoneal/retromuscular dissection. This study reports on the first large series of minimally invasive sublay repair of incisional hernias.

TABLE 3. MILOS Versus Open Sublay: Continuous and Categorical Matching Parameters

A: Standardized Differences of Continuous Matching Parameters Before and After Matching

				Standard Difference	
		MILOS	Open Sublay	Matched Sample	Original Sample
Age, yrs	MW ± STD	60.4 ± 13.0	60.0 ± 13.4	0.036	0.221
BMI	MW ± STD	29.7 ± 6.1	29.8 ± 6.3	0.016	0.082
Defect size, cm^2	MW ± STD	86.7 ± 112.0	79.2 ± 86.2	0.075	0.367
Mesh size, cm^2	MW ± STD	558.1 ± 315.2	551.4 ± 321.8	0.021	0.874

B: Standardized Differences of Categorial Matching Parameters Before and After Matching

	MILOS		Open Sublay		Standard Difference	
	n	%	n	%	Matched Sample	Original Sample
Sex: male	322	55.90	328	56.94	0.021	0.107
ASA I	47	8.16	44	7.64	0.019	0.082
ASA II	322	55.90	326	56.60	0.014	0.032
ASA III-IV	207	35.94	206	35.76	0.004	0.083
EHS W1	103	17.88	101	17.53	0.009	0.197
EHS W2	276	47.92	285	49.48	0.031	0.181
EHS W3	197	34.20	190	32.99	0.026	0.380
Preoperative pain	451	78.30	425	73.78	0.106	0.419
No preoperative pain	45	7.81	52	9.03	0.044	0.691
Preoperative pain unknown	80	13.89	99	17.19	0.091	0.233
Primary operation	383	66.49	378	65.63	0.018	0.331
EHS medial	514	89.24	518	89.93	0.023	0.199
EHS lateral	127	22.05	114	19.79	0.056	0.059
Cumarin-medication (Quick/INR not in the normal range)	16	2.78	16	2.78	0.000	0.039
Platelet inhibitors (stopped less than 7 days before surgery	72	12.50	65	11.28	0.038	0.003

ASA indicates American Society of Anesthesiologists; BMI, body mass index; EHS, European Hernia Society; MILOS, mini- or less-open sublay operation.

TABLE 4. MILOS Versus Open Sublay: Complications: Direct Comparison of Systematic Deviation Including Adjusted Odds Ratio

	Systematic Disadvantage					OR of Paired Sample		
	MILOS		Open Sublay					
	n	%	n	%	P	Adjusted OR	Lower Limit	Upper Limit
General complications	6	1.04	43	7.47	<0.001	0.140	0.049	0.329
Postoperative infection	2	0.35	13	2.26	0.007	0.154	0.017	0.680
Postoperative bleeding with reoperation	3	0.52	19	3.30	<0.001	0.158	0.030	0.536
Postoperative seroma with surgical intervention	5	0.87	44	7.64	<0.001	0.114	0.035	0.286
Prolonged wound healing	1	0.17	45	7.81	<0.001	0.022	0.001	0.130
Postoperative complications with reoperation	10	1.74	99	17.19	<0.001	0.101	0.047	0.194
Recurrence	10	2.03	25	5.07	0.017	0.400	0.171	0.862
Chronic pain at rest (1 year postoperative)	18	3.65	64	12.98	<0.001	0.281	0.157	0.481
Chronic pain during physical activities (1 year postoperative)	24	4.87	114	23.12	<0.001	0.211	0.130	0.329
Chronic pain requiring treatment (1 year postoperative)	12	2.08	57	9.90	<0.001	0.211	0.103	0.397

MILOS indicates mini- or less-open sublay operation; OR, odds ratio.

Despite the fact that the MILOS operative time is longer, the results of matched pair analysis of incisional hernia operations are very promising. In our hands, the MILOS technique allows minimally invasive transhernial sublay mesh repair of primary and recurrent abdominal wall hernias with low morbidity. The results of MILOS repair in primary abdominal wall repair including repair of diastasis recti are also favorable and will be reported in a separate article. Compared with laparoscopic IPOM and open sublay incisional hernia operations, the MILOS repair is associated with significantly a fewer postoperative surgical complications, general complications, recurrences and less chronic pain at 1 year. There were a fewer enterotomies in the MILOS cohort but the results were statistically not significant. Compared with open sublay repair the MILOS operation was associated with fewer reoperations, prolonged wound healing, and infections. The infection rates after MILOS and laparoscopic IPOM operation are the same. Low infection rates can only be achieved with a maximum of antiseptic discipline. Even before the advent of the MILOS concept, we strictly followed the above-mentioned regimen, which is based on the publication of Maximo Deysine.[20] The low infection rates after MILOS may be related to reduced access trauma and/or our antiseptic policy.

Advantages of the MILOS Operation

Compared with traditional open techniques, access-related trauma is considerably reduced. Except for the posterior rectus sheath, intact structures of the abdominal wall are not compromised. After atraumatic sublay mesh placement with large overlap the hernia defect is closed anatomically, restoring the abdominal wall. The MILOS operation is also suitable for obese patients. Corresponding to the individual situation the incision may have to be enlarged by 1 to 2 cm. In contrast to the laparoscopic IPOM technique where expensive meshes with an adhesion barrier have to be used, standard large pore meshes, can be inserted in the preperitoneal/retromuscular plane without traumatic fixation. This reduces the risk of bowel adhesions, visceral lesions, nerve damage, and acute and chronic pain. Meshes with a circumferential overlap of at least 5 cm reduce the risk of recurrence. If necessary, very large meshes with more extended overlap may be used. Except for laparoscopy and potential laparoscopic adhesiolysis, the abdominal cavity is not broached. Unlike in laparoscopic IPOM repair, only adhesions with a risk of bowel obstruction required adhesiolysis. The hernia sac is always completely mobilized. In most cases, low tension closure of the hernia defect with anatomical reconstruction of the abdominal wall is feasible. The MILOS technique allows repair of large hernias with transverse defect sizes up to 20 cm. If necessary, MILOS posterior component separation is performed. Less-open Incisional hernia operations with incisions larger than 12 cm were excluded from this trial but showed comparably favorable results (data not shown).

MILOS Repair Costs

In contrast to other innovative surgical procedures like robotic ventral hernia repair,[21] the MILOS operation does not require expensive instruments. The reusable Endotorch TM and retractors cost approximately 2.500,-€. Compared with laparoscopic IPOM repair, every MILOS operation represents a saving of at least 1.200,-€ in material costs as no meshes with adhesion barrier and no mesh fixation devices are needed.

Technical Considerations and Teaching of the MILOS Concept

The MILOS technique was developed in a high volume hernia center with extensive experience in the treatment of all variations of complex inguinal and abdominal wall hernias, preferably with sublay mesh placement. The previous development of a transabdominal preperitonal ventral hernia repair technique via the left flank,[12] which is the basis for the recently published robotic sublay approach,[21] was helpful for the better understanding of abdominal wall anatomy and abdominal wall hernia pathology. Key to MILOS operation development were cadaver abdominal wall hernia dissections, gradual reduction of access trauma in open sublay repair by using adequate retractors and the invention of a better light source for laparoscopic instruments (Endotorch TM).

The learning curve for MILOS operations depends on the surgeon's experience of open sublay incisional hernia repair and laparo-endoscopic inguinal hernia operations. To become acquainted with mini-open dissection with light-armed laparoscopic instruments and endoscopic manipulations in the retromuscular space, an experienced hernia surgeon will need approximately 5 to 10 operations.

Cadaver training is helpful. Surgeons should start with easier cases like umbilical and epigastric hernias. The first operations should be performed with a reduced incision instead of a mini-incision. After 50 MILOS incisional hernia operations, the average operation time was reduced from 132 to 103 minutes. In our institution, the MILOS operation of small and medium size ventral hernias has become a training procedure for residents. However, every MILOS operation has to be adapted to the individual anatomical findings and clinical situation. The patient's safety and prevention of enterotomies is of utmost importance. Insufficient exposure and unclear anatomy may require larger incisions.

Mini-open Versus Endoscopic Dissection

The MILOS concept comprises mini-open transhernial dissection under direct or endoscopic vision and after creation of an adequate extraperitoneal space conversion to gas endoscopy (Standard or single port ventral hernia TEP;18; Fig. 1C,D). The introduction of the Endotorch (Wolf TM) facilitates mini-open dissection. In many operations conversion to gas endoscopy is possible but not required. However, when operating on defects that are farther from the mini incision, conversion is indicated. Disposable transparent plastic sheet single ports (ie, Gel port TM, Applied Medical) which adapt to the size of the incision allow the fastest conversion to gas endoscopy (Fig. 1C), but add considerably to material costs. When using standard ports the gastight suture closure of the MILOS incision may be time consuming (Fig. 1D). On the other hand endoscopic tissue manipulation via single port may be difficult. In those cases the use of two additional 5 mm working ports is recommended. The option of earlier conversion to gas endoscopy may be favored by laparoscopic surgeons. Trocar positions may have to be modified according to the specific intraoperative situation. Recently a modified endoscopic MILOS approach with positioning of an additional suprapubic optic port was proposed by Bittner et al.[22]

Limitations of the MILOS Trial

This prospective nonrandomized trial reports 1-year questionnaire follow-up data. The trial does not report on longer term follow-up and recurrences are not assessed by physical examination. There may be a bias because the results of MILOS incisional hernia operations are from a high-volume hernia center as compared with laparoscopic IPOM and open sublay operations data from all institutions participating in the German Hernia registry. Long term follow-up data 5 and 10 years postoperatively will be obtained and a randomized prospective trial is planned. Preliminary 5-year follow-up data of the first 200 MILOS incisional hernia operations reveal a chronic pain at activities rate and recurrence rate of 3.0% and 3.1%, respectively.

CONCLUSIONS

The MILOS repair is the first minimally invasive technique that allows the sublay repair of the vast majority of incisional hernias. Compared with open sublay and lap. IPOM repair the MILOS operation is associated with significantly fewer perioperative complications requiring reoperation, general complications, less chronic pain, and a fewer recurrences after one year, and there were significantly less infections as compared with the open sublay operation. The technique is reproducible, cost effective, easy to standardize, and combines the advantages of open sublay and laparoscopic IPOM repair.

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