Hernia
https://doi.org/10.1007/s10029-023-02847-3

ORIGINAL ARTICLE

Mini- or less-open sublay (E/MILOS) operation vs open sublay and laparoscopic IPOM repair for the treatment of incisional hernias: a registry-based propensity score matched analysis of the 5-year results

W. Reinpold[1] · C. Berger[1] · D. Adolf[2] · F. Köckerling[3]

Received: 22 February 2023 / Accepted: 19 July 2023

Abstract

Background Open sublay and laparoscopic IPOM repair have specific disadvantages and risks. In recent years, this evidence led to a paradigm shift and induced the development of new minimally invasive techniques of sublay mesh repair.

Methods Pioneering this trend, we developed the endoscopically assisted mini- or less-open sublay (MILOS) concept. The operation is performed trans-hernially via a small incision with light-holding laparoscopic instruments either under direct, or endoscopic visualization. After dissection of an extra-peritoneal space of at least 8 cm, port placement and CO_2 insufflation, each MILOS operation can be continued endoscopically (EMILOS repair).

All E/MILOS operations were prospectively documented in the Herniamed Registry with 1- and 5-year questionnaire follow-ups. Propensity score matching of incisional hernia operations comparing the results of the E/MILOS operation with the laparoscopic intraperitoneal onlay mesh operation (IPOM) and open sublay repair from all other institutions participating in the Herniamed Registry was performed. The results with perioperative complications and 1-year follow-up have been published previously.

Results This paper reports on the 5-year results. The 5-year follow-up rate was 87.5% (538 of 615 patients with E/MILOS incisional hernia operations). Comparing E/MILOS repair with laparoscopic IPOM and open sublay operation, propensity score matching analysis was possible with 448 and 520 pairs of operations, respectively.

Compared with laparoscopic IPOM incisional hernia operation, the E/MILOS repair is associated with significantly fewer general complications ($P=0.004$), recurrences ($P<0.001$), less pain on exertion ($P<0.001$), and less chronic pain requiring treatment ($P=0.016$) and tends to result in fewer postoperative complications ($P=0.052$), and less pain at rest ($P=0.053$). Matched pair analysis with open sublay repair revealed significantly fewer general complications ($P<0.001$), postoperative complications ($P<0.001$), recurrences ($P=0.002$), less pain at rest ($P=0.004$), less pain on exertion ($P<0.001$), and less chronic pain requiring treatment ($P=0.014$). A limitation of this analysis is a relative low 5-year follow-up rate for laparoscopic IPOM and open sublay.

Conclusions The E/MILOS technique allows minimally invasive trans-hernial repair of incisional hernias using large standard meshes with low morbidity and good long-term results. The technique combines the advantages of sub-lay repair and a mini- or less-invasive approach.

Trial registration ClinicalTrials.gov Identifier NCT03133000.

Keywords Endoscopic retro-muscular hernia repair · Endoscopic ventral hernia repair · Incisional hernia · Minimally invasive sub-lay repair · Abdominal wall hernia · Recurrent abdominal wall hernia · Sub-lay technique · Total extra-peritoneal pre-peritoneal repair

Extended author information available on the last page of the article

Published online: 21 August 2023

Introduction

The open sublay mesh operation and the laparoscopic intraperitoneal onlay mesh (IPOM) repair are still the most widely used procedures for the treatment of primary and recurrent abdominal wall hernias worldwide [6–8]. However, both techniques have specific disadvantages and problems: the open techniques are burdened with larger wounds and higher rates of SSO and SSI. The laparoscopic IPOM repair with obligatory traumatic mesh fixation carries an increased risk of intraoperative bowel injury, adhesions, bowel obstruction, nerve injury, and acute and chronic pain [1–9]. Today, it is generally accepted, that the pre-peritoneal/retro-muscular (= sublay) plane is the best option for permanent mesh placement in hernia repair [6–9]. The last years have been characterized by a shift of paradigm in ventral and incisional hernia repair. Due to several publications with promising short-term results, the new minimally invasive techniques with extra-peritoneal mesh repair are becoming more and more popular [10–20]. Pioneering this trend, we started early to look for new techniques of minimal-invasive ventral hernia repair [11, 13–15, 18, 19]. For the reduction of complication rates and improvement of quality of life after ventral and incisional hernia repair, we developed the endoscopically assisted mini- or less-open sublay (E/MILOS) concept [13, 15, 18, 19].

Materials and methods

Endoscopically assisted (MILOS) and endoscopic mini- or less-open sublay (EMILOS) repair

Beginning in 2010, all MILOS and EMILOS (E/MILOS) incisional hernia operations were prospectively registered in the Herniamed Registry. The perioperative complication rates and 1-year follow-up data of this registry-based analysis were published in 2018 [18]. Figure 1 shows the flow chart of patient inclusion for the 5-year follow-up analysis. Only elective operations were included in the analysis. Mini-open and less-open access were defined as incisions of up to 5 cm and 12 cm, respectively, with a maximum incision length of less than one-fourth of the longest mesh diameter. Operations with incisions longer than 12 cm and/or an incision length/mesh diameter ratio of > 1/4 were excluded from the analysis. Small incisional hernias (< 1.5 cm defect diameter) had a suture repair. Primary outcome parameters were recurrence, pain at rest, pain on exertion, and chronic pain requiring treatment after 5 years. Secondary outcome variables were postoperative surgical complications and general complications. 5 years after the operation, all patients and the general practitioners received a questionnaire. If the patient and/or the general practitioner reported about any problem after the operation, the patient could be requested to attend clinical examination or radiologic tests. Pain was assessed by numerical rating scale (NRS, 0–10). The 5-year follow-up outcomes of E/MILOS incisional hernia operations at Gross-Sand Hospital were compared with laparoscopic IPOM and open sublay incisional hernia repair at all other institutions participating in the Herniamed Registry using propensity score matching [18, 22]. Only E/MILOS operations that had been included in the 1-year follow-up analysis [18] were eligible for the 5-year analysis.

A detailed description of the technical steps and perioperative management of the MILOS and endoscopic MILOS (= EMILOS) operation has already been published [13, 18, 19]. The MILOS operation is performed via a small skin incision trans-hernially with light-armed laparoscopic instruments either under direct vision or endoscopically assisted with gasless endoscopy [13, 18, 19]. After transhernial mini-open dissection of a small extraperitoneal space transhernial insertion of an optic port device, and CO_2 insufflation, the procedure can be continued endoscopically (EMILOS) [13, 18, 19]. In lateral incisional hernias, the transhernial dissection is performed in the preperitoneal plane. In large hernias where after retromuscular dissection, a defect closure is not possible. An additional E/MILOS m. transversus abdominis release (TAR) is performed according to the principles of the open TAR procedure [23].

Statistics

All analyses were performed with the software SAS 9.4 (SAS Institute Inc., Cary, NC, USA) 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 the 5-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 all other institutions participating in the Herniamed Registry' using propensity score matching [18, 22].

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 (I/II/III–IV), primary incisional hernia (yes/no), European Hernia Society (EHS) classification (width W1: 1–4 cm/W2: > 4 cm– < 10 cm/W3: > 10 cm), EHS lateral (yes/no), EHS medial (yes/no) [22], body mass index, age, oral anticoagulants (yes/no), platelet inhibitors (yes/no), preoperative pain (yes/no/unknown), and mesh size [cm^2].

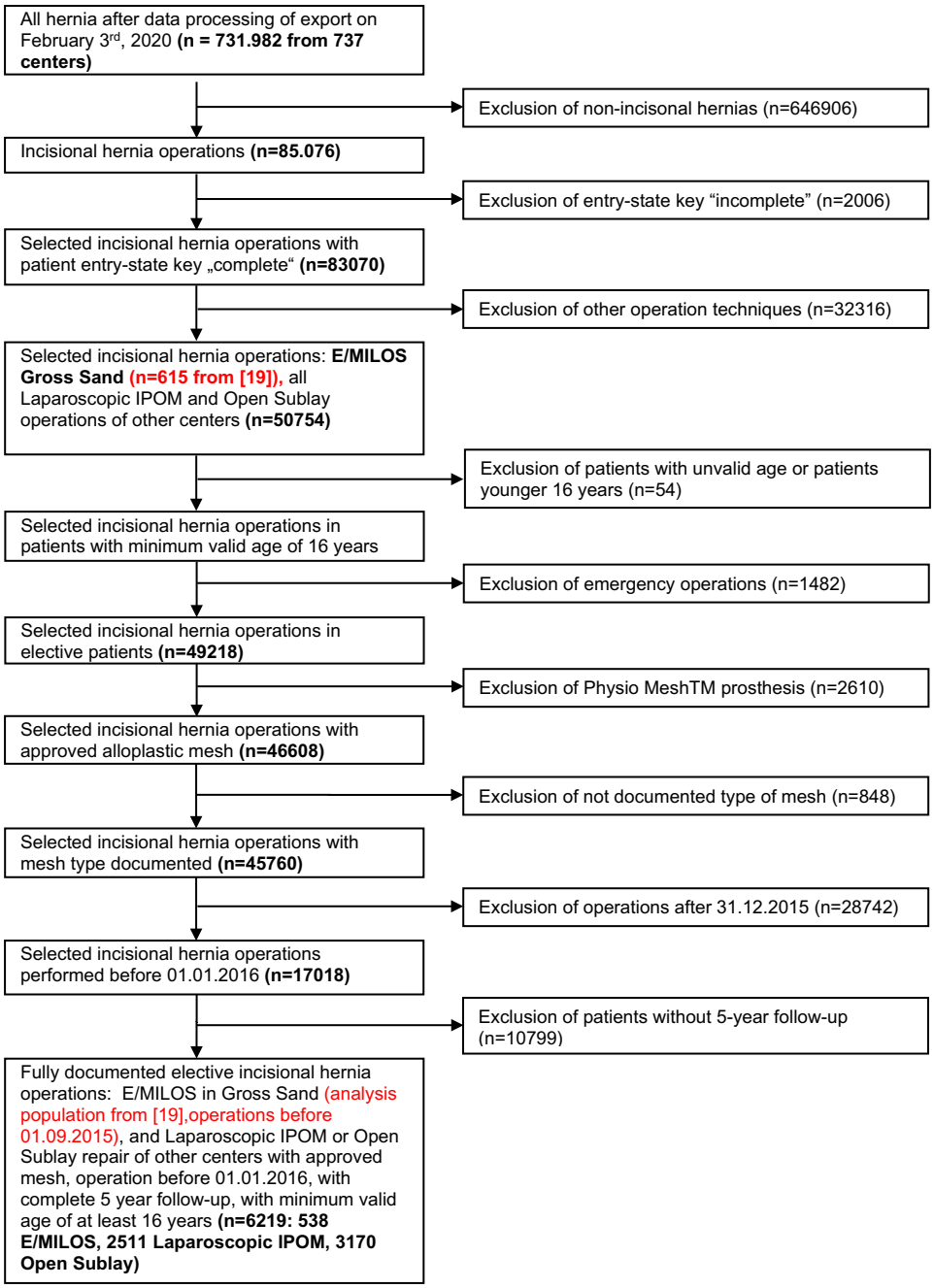

Fig. 1 Flow Chart for patient inclusion of analysis (Herniamed registry)

The balance of the matched sample was checked using standardized differences (also given for the pre-matched 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], x^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.

Matched samples were then analyzed for perioperative and 5-year follow-up outcomes (intra- and postoperative complications, complication-related reoperations, pain at rest and on exertion, pain requiring treatment, and recurrences) via McNemar's test. The results obtained are presented as the non-diagonal elements of the 2×2 frequency table, the corresponding p values, and the odds ratio (OR) estimates for matched samples with 95% confidence interval.

Results

In the Herniamed Registry 2511 laparoscopic IPOM procedures, 3170 open sub-lay and 538 E/MILOS incisional hernia operations with complete 5-year follow-up could be identified (Fig. 1), of which 138 (25.7%) were EMILOS operations. Eight patients had died within 5 years after surgery due to causes not related to E/MILOS repair. The E/MILOS cohort had a 5-year follow-up rate of 87.5%. For the comparison of E/MILOS repair with laparoscopic IPOM operation and E/MILOS operation with open sublay repair, propensity score matching analysis of 448 (83.3%) and 520 (96.7%) patient pairs was possible, respectively. The cohorts were well balanced for all matching parameters (Figs. 2 and 3).

Matched pair analysis of E/MILOS versus laparoscopic IPOM operation

Continuous matching parameters:

The descriptive statistics of age, BMI, defect sizes, and mesh sizes of the E/MILOS versus laparoscopic IPOM cohort before matching are given in Table 1.

Mean defect sizes of the E/MILOS and laparoscopic IPOM cohort with complete 5-year follow-up are 44.6 cm^2 (range 40.4–48.7 cm^2) and 21.7 cm^2 (range 18.0–25.3 cm^2), respectively.

Mean mesh sizes E/MILOS, and laparoscopic IPOM are 494.2 cm^2 (range 492.2–496.1 cm^2), and 279.3 cm^2 (range 277.4–281.2 cm^2), respectively.

Categorical matching parameters:

The descriptive statistics of gender, ASA score distribution, hernia size and location according to the EHS incisional hernia classification, patients with preoperative pain, primary incisional hernia operations, and rate of operations performed under anticoagulation medication of the E/MILOS versus laparoscopic IPOM cohort before matching are shown in Table 2.

In the E/MILOS cohort, there were 412 (76.6%) medial, 56 (10.4%) lateral, and 70 (13.0%) combined hernias. The number of W1, W2, and W3 incisional hernias was 93 (17.3%), 246 (45.7%), and 199 (37.0%), respectively.

Propensity score matching:

Propensity score matching was performed using greedy algorithm and a permitted caliper width of 0.2 standard deviations for the 538 E/MILOS and the 2511 laparoscopic

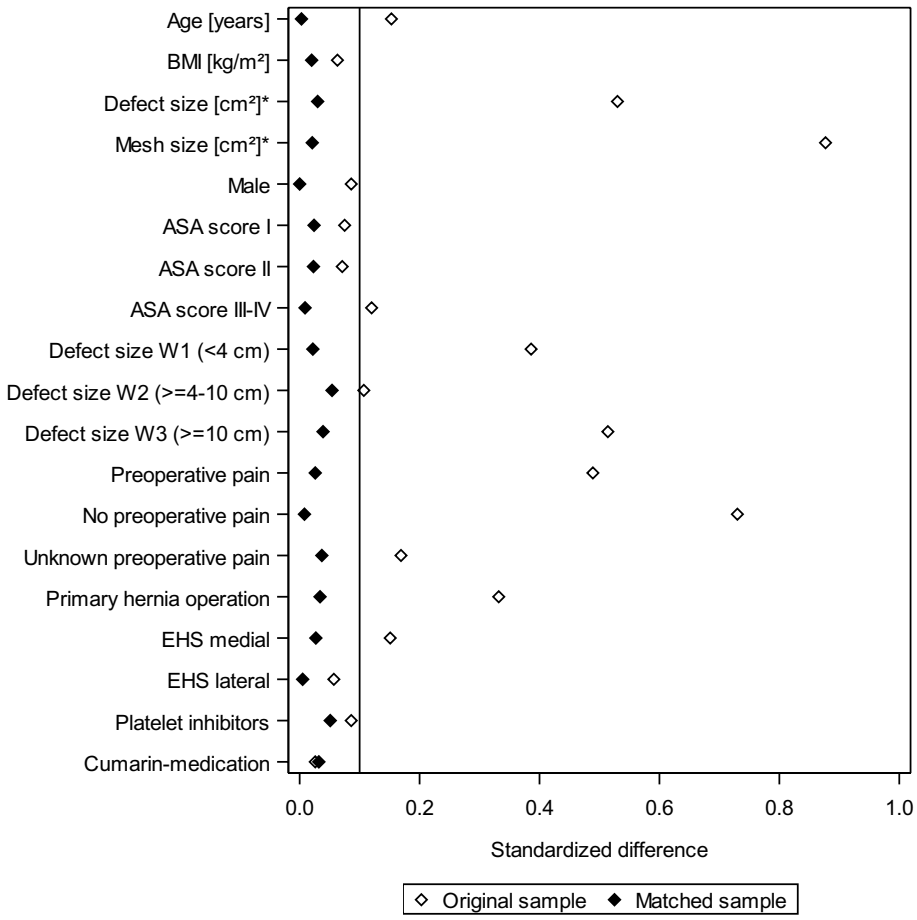

Fig. 2 E/MILOS versus Laparoscopic IPOM operation: Scatter Plot: Standardized differences for matching variables both before (original sample) and after matching (matched sample)

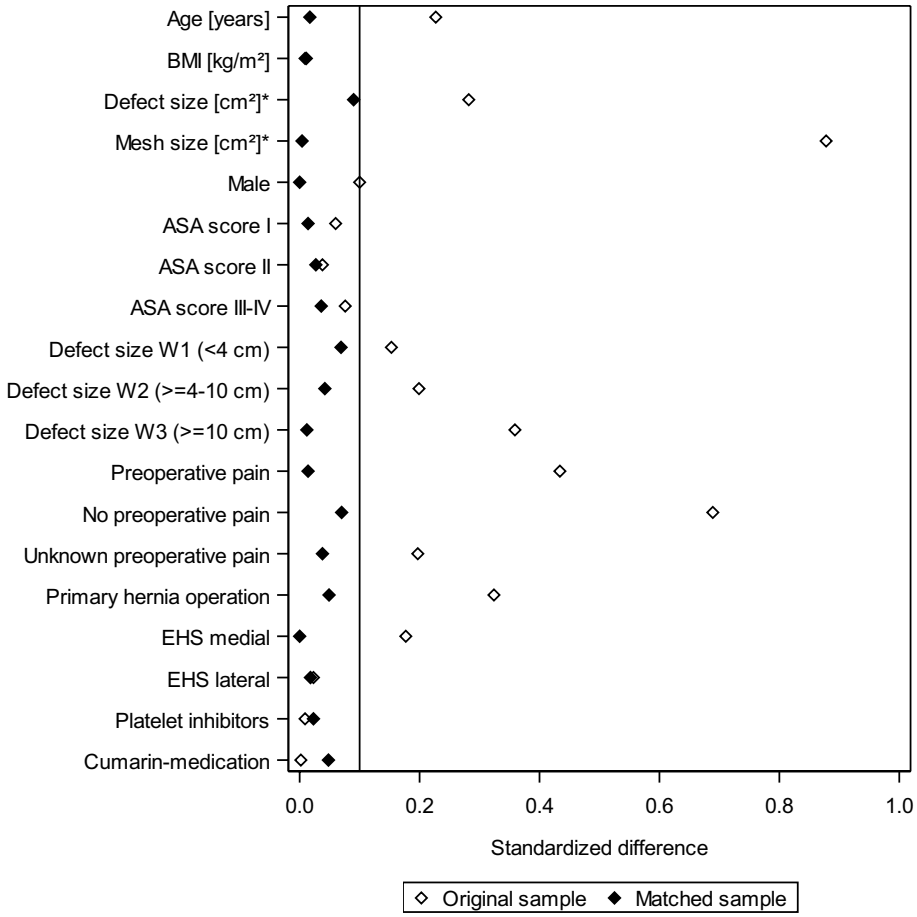

Fig. 3 E/MILOS versus Open sublay Operation: Scatter Plot: Standardized differences for matching variables both before (original sample) and after matching (matched sample)

Table 1 E/MILOS versus Laparoscopic IPOM operation: summary of descriptive statistics and results of the unadjusted tests for homogeneity between comparison groups for the continuous matching variables before matching

	Surgical method		*P*
	Mini-open sublay	Lap. IPOM	
Age [years]			
N/Mean ± SD	538/60.8 ± 12.7	2511/62.8 ± 12.8	0.001
BMI [kg/m^2]			
N/Mean ± SD	538/29.7 ± 6.1	2510/30.2 ± 9.0	0.132
Defect size [cm^2][a]			
N/Mean [Range]	538/44.6 [40.4; 48.7]	2511/21.7 [18.0; 25.3]	< 0.001
Mesh size [cm^2][a]			
N/Mean [Range]	538/494.2 [492.2; 496.1]	2511/279.3 [277.4; 281.2]	< 0.001

[a]Logarithmic transformation: Illustration of the back-transformed mean values and ranges (mean value ± SD)

IPOM patients. Matching was successfully performed for n = 448 (83.3%) patients.

Figure 2 shows the standardized differences between the matching variables both before (original sample) and after (matched sample) matching.

That difference was well below 10% for all matching variables, attesting a good balance between the groups for the variables included in the model.

Compared with laparoscopic IPOM incisional hernia operation, the E/MILOS repair was associated with fewer postoperative surgical complications [1.8% vs 4.2%, $P = 0.052$; OR = 0.421 (0.159, 1.007)], significantly fewer general complications [0.7% vs 3.6%, $P = 0.004$; OR = 0.187 (0.035, 0.655)], significantly less recurrences after 5 years [0.9% vs 5.6%, $P < 0.001$; OR = 0.160 (0.040, 0.463)], including cumulative recurrences after 1 year and 5 years

Table 2 E/MILOS versus laparoscopic IPOM operation: summary of descriptive statistics and results of unadjusted tests for homogeneity between comparison groups for the categorical matching variables before matching

	Surgical method				*P*
	Mini-open sublay		Lap. IPOM		
	n	%	*n*	%	
Gender					
Male	299	55.58	1288	51.29	0.071
Female	239	44.42	1223	48.71	
ASA					
I	45	8.36	265	10.55	0.024
II	290	53.90	1442	57.43	
III/IV	203	37.73	804	32.02	
Defect size (EHS classification)					
I (< 4 cm)	93	17.29	849	33.81	< 0.001
II (4–10 cm)	246	45.72	1282	51.06	
III (> 10 cm)	199	36.99	380	15.13	
Preoperative pain					
No	38	7.06	879	35.01	< .001
Yes	419	77.88	1393	55.48	
Unknown	81	15.06	239	9.52	
Primary hernia operation					
No	186	34.57	502	19.99	< 0.001
Yes	352	65.43	2009	80.01	
EHS medial					
No	56	10.41	388	15.45	0.003
Yes	482	89.59	2123	84.55	
EHS lateral					
No	413	76.77	1866	74.31	0.235
Yes	125	23.23	645	25.69	
Platelet inhibitors					
No	471	87.55	2266	90.24	0.061
Yes	67	12.45	245	9.76	
Cumarin medication					
No	522	97.03	2447	97.45	0.576
Yes	16	2.97	64	2.55	

[2.7% vs 8.9%, $P < 0.001$; OR = 0.300 (0.143, 0.583)], less chronic pain at rest after 5 years [2.9% vs 5.8%, $P = 0.053$; OR = 0.500 (0.236, 1.009)], significantly less chronic pain on exertion [2.9% vs 10.7%, $P < 0.001$; OR = 0.271 (0.135, 0.508)], and significantly less chronic pain requiring therapy [1.8% vs 4.9%, $P = 0.016$; OR = 0.364 (0.140, 0.848)]. Results are shown in Table 3.

Matched pair analysis of E/MILOS versus open sublay operation

Continuous matching parameters:

The descriptive statistics of age, BMI, defect sizes, and mesh sizes of the E/MILOS versus open sublay cohort before matching are shown in Table 4:

Mean defect sizes of the E/MILOS and open sublay cohort with complete 5-year follow-up are 44.6 cm^2 (range 40.4–48.7 cm^2), and 30.5 cm^2 (range 27.0–34.1 cm^2), respectively.

Mean mesh sizes the E/MILOS and open sublay cohort are 494.2 cm^2 (range 492.2–496.1 cm^2) and 250.1 cm^2 (range 247.8–252.5 cm^2), respectively.

Categorical matching parameters:

The descriptive statistics of gender, ASA score distribution, hernia size and location according to the EHS incisional hernia classification, patients with preoperative pain, primary incisional hernia operations, and rate of operations performed under anticoagulation medication of the E/MILOS versus open sublay cohort before matching are given in Table 5.

Table 3 Mini-Open sublay versus Laparoscopic IPOM: Results of matched pair analysis of incisional hernia repair (448 matched pairs)

	Disadvantage					OR for matched samples		
	E/MILOS		Lap. IPOM					
	N	(%)	*N*	(%)	*P*-value	OR	Lower limit	Upper limit
General complications	3	(0.67)	16	(3.57)	0.004	0.187	0.035	0.655
Postoperative complications	8	(1.79)	19	(4.24)	0.052	0.421	0.159	1.007
Recurrence on 5-year follow-up	4	(0.89)	25	(5.58)	< 0.001	0.160	0.040	0.463
Recurrence on 5-year follow-up (cumulative)[a]	12	(2.67)	40	(8.92)	< 0.001	0.300	0.143	0.583
Pain on exertion on 5-year follow-up	13	(2.90)	48	(10.71)	< 0.001	0.271	0.135	0.508
Pain at rest on 5-year follow-up	13	(2.90)	26	(5.80)	0.053	0.500	0.236	1.009
Pain requiring treatment on 5-year follow-up	8	(1.79)	22	(4.91)	0.016	0.364	0.140	0.848

[a]Inclusive recurrence information from the previous visit (if available)

Table 4 E/MILOS versus open sublay operation: summary of descriptive statistics and results of the unadjusted tests for homogeneity between comparison groups for the continuous matching variables before matching

	Surgical method		*P*
	Mini-open sublay	Open sublay	
Age [years]			
N/Mean ± SD	538/60.8 ± 12.7	3170/63.7 ± 12.5	< 0.001
BMI [kg/m^2]			
N/Mean ± SD	538/29.7 ± 6.1	3169/29.6 ± 12.3	0.802
Defect size [cm^2][a]			
N/Mean [Range]	538/44.6 [40.4; 48.7]	3170/30.5 [27.0; 34.1]	< 0.001
Mesh size [cm^2][a]			
N/Mean [Range]	538/494.2 [492.2; 496.1]	3170/250.1 [247.8; 252.5]	< 0.001

[a]Logarithmic transformation: Illustration of the back-transformed mean values and ranges (mean value ± SD)

Propensity score matching:

Propensity score matching was performed using greedy algorithm and a permitted caliper width of 0.2 standard deviations for the 538 E/MILOS and the 3170 open sublay patients. Matching was performed for $n = 520$ (96.7%) patients. Figure 3 shows the standardized differences between the matching variables both before (original sample) and after (matched sample) matching.

That difference was well below 10% for all matching variables, attesting a good balance between groups for the variables included in the model.

After E/MILOS repair, there were fewer postoperative complications [2.1% vs 16.5%, $P < 0.001$; OR = 0.128 (0.062, 0.240)], fewer general complications [1.0% vs 5.2%, $P < 0.001$; OR = 0.185 (0.056, 0.488)], less recurrences after 5 year [1.0% vs 3.5%, $P = 0.011$; OR = 0.278 (0.081, 0.776)], less cumulative recurrences after 1 year and 5 years [2.7% vs 7.1, $P = 0.002$; OR = 0.378 (0.189, 0.717)], less chronic pain after 5 year at rest [3.1% vs 7.3%, $P = 0.004$; OR = 0.421 (0.219, 0.773)], on exertion [3.9% vs 12.3%, $P < 0.001$; OR = 0.313 (0.179, 0.523)], and less chronic pain requiring therapy [2.5% vs 5.8%, $P = 0.014$; OR = 0.433 (0.207, 0.856)]. All differences were statistically significant. Results are shown in Table 6.

Discussion

Incisional hernia repair is among the most frequent operations in general and abdominal surgery [8]. The most widely used techniques are still open retro-muscular mesh and laparoscopic IPOM repair [8], but the new minimal-invasive techniques with extra-peritoneal mesh placement are gaining popularity [8, 10–20].

To our knowledge, this is the first trial reporting on long-term results of the new minimal-invasive extra-peritoneal mesh repair techniques (E/MILOS, eTEP, TARM, laparoscopic TAPP, and robotic-assisted variants).

The short-term results with one-year follow-up of this prospective Herniamed registry trial revealed significantly less perioperative complications, recurrences, and chronic pain after E/MILOS vs laparoscopic IPOM and open Sub-lay repair [18]. The promising early results are confirmed by our

Table 5 E/MILOS versus Open sublay operation: Summary of descriptive statistics and results of unadjusted tests for homogeneity between comparison groups for the categorical matching variables before matching

	Surgical method				*P*
	E/MILOS		Open sublay		
	n	%	*n*	%	
Gender					
Male	299	55.58	1604	50.60	0.033
Female	239	44.42	1566	49.40	
ASA					
I	45	8.36	320	10.09	0.178
II	290	53.90	1769	55.80	
III/IV	203	37.73	1081	34.10	
Defect size					
I (< 4 cm)	93	17.29	743	23.44	< 0.001
II (4—10 cm)	246	45.72	1763	55.62	
III (> 10 cm)	199	36.99	664	20.95	
Preoperative pain					
No	38	7.06	1052	33.19	< 0.001
Yes	419	77.88	1842	58.11	
Unknown	81	15.06	276	8.71	
Primary hernia operation					
No	186	34.57	644	20.32	< 0.001
Yes	352	65.43	2526	79.68	
EHS medial					
No	56	10.41	521	16.44	< 0.001
Yes	482	89.59	2649	83.56	
EHS lateral					
No	413	76.77	2403	75.80	0.630
Yes	125	23.23	767	24.20	
Platelet inhibitors					
No	471	87.55	2785	87.85	0.840
Yes	67	12.45	385	12.15	
Cumarin medication					
No	522	97.03	3077	97.07	0.959
Yes	16	2.97	93	2.93	

5-year follow-up propensity score matching analysis: there are significantly less recurrences, less cumulative recurrences (includes recurrences in 1-year follow-up), late postoperative complications, and patients suffering from chronic postoperative pain after E/MILOS operations compared to open Sub-lay and laparoscopic IPOM repair (Figs. 2 and 3; Tables 3 and 6).

In this propensity score matching trial, the long-term cumulative recurrence rates after laparoscopic IPOM and open Sub-lay repair are 8.9% and 7.1%, respectively.

We detected 12 trials with long-term follow-up (48–84 months) after incisional hernia repair: one RCT, two register trials, and 9 retrospective cohort trials. The evidence of most of these studies is low [8, 32–38]. The only long-term RCT reported on incisional hernia repair, compared suture with open retro-muscular mesh repair. There were more recurrences (63% vs 32%; $P < 0.001$) and more chronic abdominal pain after suture repair (36% vs 20%; $P = 0.01$) indicating the superiority of mesh repair [32].

Nine publications with long-term follow-up after open retro-muscular mesh repair with a total of 2.376 patients reported recurrence rates between 5 and 34% [32–35]. A retrospective cohort trial from Sweden found a recurrence rate of 8.1% 7 years after open retro-muscular mesh repair, which is in accordance with our results. The trial also investigated long-term quality of life. The authors concluded that hernia recurrence and chronic postoperative pain have the highest impact on the hernia-related quality of life [34].

The long-term (54 to 78 months of follow-up) recurrence rates after laparoscopic IPOM incisional hernia repair in three cohort trials ranged between 4.5 and 20%. [36–38].

A long-term prospective register study of the Danish Hernia database which included all 3242 elective incisional hernia operations in Denmark from 2007 to 2010 with a median follow-up period of 60 months and 100% follow-up rate reported recurrence rates after open mesh and laparoscopic IPOM repair of 12.3% and 10.6%, respectively. The mesh-related complication rates after open mesh and laparoscopic mesh repair were 5.6% and 3.7%, respectively

Table 6 Mini-Open sublay versus Open sublay: Results of matched pair analysis of incisional hernia repair (520 matched pairs)

	Disadvantage				*P*-value	OR für matched samples		
	E/MILOS		Open sublay			OR	Untere Grenze	Obere Grenze
	N	(%)	*N*	(%)				
General complications	5	(0.96)	27	(5.19)	< 0.001	0.185	0.056	0.488
Postoperative complications	11	(2.12)	86	(16.54)	< 0.001	0.128	0.062	0.240
Recurrence on 5-year follow-up	5	(0.96)	18	(3.46)	0.011	0.278	0.081	0.776
Recurrence on 5-year follow-up (cumulative)[a]	14	(2.69)	37	(7.12)	0.002	0.378	0.189	0.717
Pain on exertion on 5-year follow-up	20	(3.85)	64	(12.31)	< 0.001	0.313	0.179	0.523
Pain at rest on 5-year follow-up	16	(3.08)	38	(7.31)	0.004	0.421	0.219	0.773

[a]Inclusive recurrence information from the previous visit (if available)

[33]. In contrast to this finding, there were no reports of late mesh-related complications, bowel obstructions, mesh infections, fistulae, and mesh-related reoperations in the 5-year follow-up after E/MILOS operation. In our series, two large chronic subcutaneous seromas after repair of large midline incisional hernias were successfully treated in mini-open technique. There were no reoperations related to chronic pain in our cohort.

The evidence of long-term chronic pain after incisional hernia repair in the literature is very low [8, 32–38].

Only one register trial had a higher long-term follow-up rate than 87.5% in our E/MILOS cohort [33] and only two register trials included more patients in the long-term follow-up than our study [33, 34]. All previous long-term trials on incisional hernia repair reported higher recurrence and chronic pain rates compared to our results after E/MILOS operations [32–38]. Due to the heterogeneity of trials, these findings should be interpreted carefully.

Even though very large incisional hernias were excluded and operated on with an open sublay repair, the E/MILOS cohort of this propensity score matching analysis included a considerable percentage of incisional hernias which can be considered as difficult or complex: There were more than two thirds recurrent incisional hernias, 37% large incisional hernias (W3 EHS classification), and 23.2% lateral or combined (EHS classification: L, LM) incisional hernias, Tables 2 and 5). Moreover, in our cohort, 40.2% of the patients had BMI > 30, indicating that the E/MILOS operation is also suitable for obese patients. In obese patients, the incision may have to be one to two cm larger, compared to normal weight patients. In this study, we performed an EMILOS repair in one-quarter of the cases. Detailed indications and results of MILOS and EMILOS operations, including E/MILOS TAR operations were published previously [18]. In the first phase of this trial, there was no difference in outcomes between MILOS and EMILOS repair [18]. Because of this finding, we did not perform a subgroup analysis between MILOS and EMILOS operations after 5 years. In 79.3% of our cases, video endoscopy was used. Those operations can be considered as hybrid operations [18].

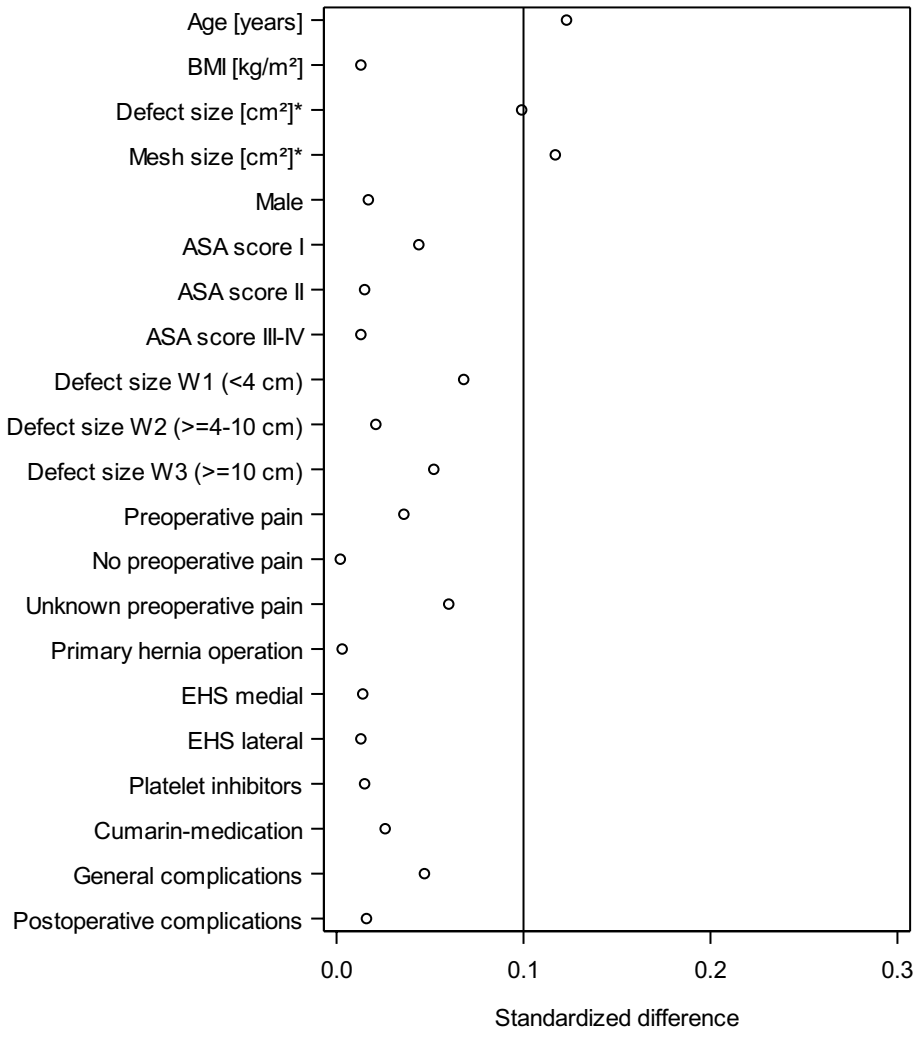

Fig. 4 Standardized differences of the infuencing factors and the perioperative outcomes between patient collectives with and without follow-up

The mini-open transhernial approach avoids damage of intact structures of the abdominal wall, allows extended dissection in the retromuscular/preperitoneal plane, implantation of large standard meshes with a wide defect overlap (Table 1 and 4) without traumatic mesh fixation, facilitates hernia sac manipulations, defect closure and skin/scar corrections. This reduces the risk of recurrences, bulging, visceral adhesions, bowel lesions, nerve damage with acute and chronic pain.

Since long-term results of the other new MIS techniques have not been published, a comparison with E/MILOS data is not yet possible. Compared to the new pure laparoendoscopic techniques (ventral hernia eTEP, TARM, TAPP, and robotic variants), the mini-open transhernial approach may allow easier dissection of large hernia sacs (especially if bowel or omentum is incarcerated), easier mesh insertion, defect closure, skin and scar corrections, and umbilical reconstruction. Pure laparoendoscopic closure of large defects without mini- or less-open skin and scar corrections may result in ugly folding and bulging of the skin.

The E/MILOS operation is associated with a low number of short-term SSOs and SSIs [18, 19]. In this analysis, there were no late infections detected.

The finding that infection rates after laparoscopic IPOM and E/MILOS repair are in the same low range [18, 19] is in accordance with other recent publications that compared new hybrid MIS techniques of ventral and incisional hernia repair with pure laparoendoscopic and open procedures [22–31].

In contrast to other innovative surgical procedures like robotic ventral hernia repair, the E/MILOS operation does not require expensive instruments and devices. The reusable light source for laparoscopic instruments (Endotorch TM, Fa. Richard Wolf, Knittlingen) and retractors cost approximately 2.500,-€. Compared with laparoscopic IPOM repair, every E/MILOS operation saves about 1.200,-€ in material costs as no meshes with adhesion barrier and no mesh fixation devices are needed. Discussing operation costs, a disadvantage of the E/MILOS operation in this trial must be mentioned: the operation time was 8 and 21 min longer compared to open sublay and laparoscopic IPOM repair, respectively [18].

Limitations of this trial: For 1- and 5-year follow-up, a questionnaire is sent to the patient and general practitioner, asking both about any recurrence, bulging, pain at rest, pain on exertion, and chronic pain requiring treatment. If recurrence or chronic pain is reported by the general practitioner or patient, patients could be requested to attend clinical examination or radiologic tests. Nevertheless, asymptomatic recurrences may be missed. There is a bias because the results of E/MILOS incisional hernia operations are from a high-volume referral hernia center as compared with laparoscopic IPOM and open sublay operations data from all institutions participating in the German Hernia registry.

The low 5 years of follow-up rate after laparoscopic IPOM and open sublay operation is a further limitation of this study. At least, we can quantify the differences between those patients with a 5-year follow-up ($n = 6219$) and those without ($n = 10{,}799$): the standardized differences between those two groups are below 10% (as a role of thumb) for general and postoperative complications as well as for all matching variables except for age and mesh size. Here, patient groups differ by 1.6 years and 24 cm^2, respectively. Thus, matching variables and perioperative outcomes are quite balanced between patients with and without a 5-year follow-up so that we conclude that we have no relevant bias in the analysis population (Fig. 4).

In 2017 after the end of patient enrollment of this trial, we modified the EMILOS technique to allow a faster begin of the endoscopic operation phase, using flexible wound protection devices with a cap and opening for standard camera ports. Technical details were published previously [19]. Since 2017, our EMILOS technique is unchanged and now used in two-third of our incisional hernia operations.

This prospective register trial with propensity score matching shows that hernia registries may play an important role in the development, evaluation, and successful implementation of new surgical techniques.

Conclusion

The E/MILOS repair allows the minimal-invasive sublay repair of almost all incisional hernias with low long-term morbidity. Compared with open sublay and laparoscopic IPOM repair, the E/MILOS operation is associated with significantly fewer long-term complications, less chronic pain, and less recurrences after five years. In our hands, the technique is reproducible, easy to standardize, and combines the advantages of open sublay and laparoscopic IPOM repair. Our favorable results have to be confirmed by future high-quality register trials and multicenter RCTs.

Data availability Not applicable.

Declarations

Conflict of interest Dr. Köckerling reports grants to fund Herniamed from Johnson & Johnson, Norderstedt, Karl Storz, Tuttlingen, pfm medical, Cologne, Dahlhausen, Cologne, B Braun, Tuttlingen, MenkeMed, Munich, Bard, Karlsruhe, and personal fees from Bard, Karlsruhe, outside the submitted work. All other authors have nothing to disclose.

Ethical approval Only cases of routine hernia surgery were documented in the Herniamed Registry and all patients have signed a special

informed consent declaration agreeing to participate. The Herniamed Registry has ethical approval (BASEC Nr 2016–00123, 287/2017BO2).

Human and animal rights This article does not contain any study with animals performed by any of the authors.

Informed consent All patients with routine hernia surgery documented in the Herniamed Registry have signed an informed consent declaration agreeing to participate.

References

1. Stoppa R, Petit J, Abourachid H et al (1973) Original procedure of groin hernia repair: interposition without fixation of Dacron tulle prosthesis by subperitoneal median approach. Chirurgie 99:119–123
2. Rives J, Pire JC, Flament JB et al (1977) Treatment of large eventrations (a propos of 133 cases). Minerva Chir 32:749–756
3. Sauerland S, Walgenbach M, Habermalz B et al (2011) Laparoscopic versus open surgical techniques for ventral or incisional hernia repair. Cochrane Database Syst Rev 16:CD007781
4. Al Chalabi H, Larkin J, Mehigan B et al (2015) A systematic review of laparoscopic versus open abdominal incisional hernia repair, with meta- analysis of randomized controlled trials. Int J Surg 20:65–74
5. Awaiz A, Rahman F, Hossain MB et al (2015) Meta-analysis and systematic review of laparoscopic versus open mesh repair for elective incisional hernia. Hernia 19:449–463
6. Arita NA, Nguyen MT, Nguyen DH et al (2015) Laparoscopic repair reduces incidence of surgical site infections for all ventral hernias. Surg Endosc 29:1769–1780
7. Liang MK, Holihan JL, Itani K et al (2017) Ventral hernia management: expert consensus guided by systematic review. Ann Surg 265:80–89
8. Bittner R, Bain K, Bansal VK, Berrevoet F, Bingener-Casey J, Chen D, Chen J, Chowbey P, Dietz UA, de Beaux A, Ferzli G, Fortelny R, Hoffmann H, Iskander M, Ji Z, Jorgensen LN, Khullar R, Kirchhoff P, Köckerling F, Kukleta J, LeBlanc K, Li J, Lomanto D, Mayer F, Meytes V, Misra M, Morales-Conde S, Niebuhr H, Radvinsky D, Ramshaw B, Ranev D, Reinpold W, Sharma A, Schrittwieser R, Stechemesser B, Sutedja B, Tang J, Warren J, Weyhe D, Wiegering A, Woeste G, Yao Q (2019) Update of Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS))-Part A. Surg Endosc 33(10):3069–3139. https://doi.org/10.1007/s00464-019-06907-7. (**Epub 2019 Jun 27PMID: 31250243**)
9. Köckerling F, Hoffmann H, Mayer F, Zarras K, Reinpold W, Fortelny R, Weyhe D, Lammers B, Adolf D, Schug-Pass C (2021) What are the trends in incisional hernia repair? Real-world data over 10 years from the Herniamed registry. Hernia 25(2):255–265
10. Miserez M, Penninckx F (2002) Endoscopic totally preprepreperitoneal ventral hernia repair. Surg Endosc 16(8):1207–1213. https://doi.org/10.1007/s00464-001-9198-z
11 Schroeder AD, Debus ES, Schroeder M, Reinpold WM (2013) Laparoscopic transperitoneal sublay mesh repair: a new technique for the cure of ventral and incisional hernias. Surg Endosc 27(2):648–654. https://doi.org/10.1007/s00464-012-2508-9. (**Epub 2012 Sep 6**)
12. Abdalla RZ, Garcia RB, da Costa RI, Abdalla BM (2013) Treatment of midline abdominal wall hernias with the use of endo-stapler for midline closure. Arq Bras Cir Dig 26(4):335–337
13. Reinpold W (2015) Endoscopic total extraperitoneal transhernial Sublay ventral hernia repair in single port technique. In: Schumpelick V, Arlt G, Conze J, Junge K (eds) Hernien, 5th edn. Thieme, Stuttgart, pp 301–304
14. Köckerling F, Botsinis MD, Rohde C, Reinpold W (2016) Endoscopic-assisted linea alba reconstruction plus mesh augmentation for treatment of umbilical and/or epigastric hernias and rectus abdominis diastasis—early results. Front Surg 13(3):27
15. Schwarz J, Reinpold W, Bittner R (2017) Endoscopic mini/less open sublay technique (EMILOS)-a new technique for ventral hernia repair. Langenbecks Arch Surg 402(1):173–180. https://doi.org/10.1007/s00423-016-1522-0. (**Epub 2016 Oct 20**)
16. Warren JA, Cobb WS, Ewing JA et al (2017) Standard laparoscopic versus robotic retromuscular ventral hernia repair. Surg Endosc 31:324–332 (**Epub 2016 Jun 10**)
17. Belyansky I, Daes J, Radu VG, Balasubramanian R, Reza Zahiri H, Weltz AS, Sibia US, Park A, Novitsky Y (2018) A novel approach using the enhanced-view totally extraperitoneal (eTEP) technique for laparoscopic retromuscular hernia repair. Surg Endosc 32(3):1525–1532. https://doi.org/10.1007/s00464-017-5840-2. (**Epub 2017 Sep 15**)
18. Reinpold W, Schröder M, Berger C, Stoltenberg W, Schröder A, Nehls J, Hukauf M, Adolf D, Bittner R, Köckerling F (2019) Mini- or Less Open Sublay Operation (MILOS)—a new minimally invasive technique for the extraperitoneal repair of incisional hernias. Ann Surg 269(4):748–755 (**Epub Feb 1, 2018**)
19. Reinpold W, Schröder M, Berger C, Stoltenberg W, Köckerling F (2019) MILOS and EMILOS repair of primary umbilical and epigastric hernias. Hernia 23(5):935–944. https://doi.org/10.1007/s10029-019-02056-x. (**Epub 2019 Sep 30.PMID: 31571064**)
20. Mohan R, Yeow M, Seng Wong J, Syn N, Wijerathne S, Lomanto D (2021) Robotic versus laparoscopic ventral hernia repair: a systematic review and meta-analysis of randomized controlled trials and propensity score matched studies. Hernia 25(6):1565–1572 (**Epub 2021 Sep 23**)
21. Muysoms FE, Miserez M, Berrevoet F et al (2009) Classification of primary and incisional abdominal wall hernias. Hernia 13:407–414
22. Lonjon G, Porcher R, Ergina P et al (2017) Potential pitfalls of reporting and bias in observational studies with propensity score analysis assessing a surgical procedure: a methodological systematic review. Ann Surg 265:901–909
23 Novitsky YW, Elliott HL, Orenstein SB, Rosen M (2012) Transversus abdominis muscle release: a novel approach to posterior component separation during complex abdominal wall reconstruction. J Am J Surg 204(5):709–716
24. Abdu R, Vasyluk A, Reddy N, Huang L-C, Halka JT, DeMare A, Janczyk R, Iacco A (2018) Hybrid robotic transversus abdominis release versus open: propensity-matched analysis of 30-day outcomes. Hernia 25(6):1491–1497 (**Epub 2020 Jun 30**)
25. Halka TJ, Vasyluk A, DeMare A, Janczyk RJ, Iacco A (2018) Robobtic and hybrid robotic transversus abdominis release may be performed with low length of stay and wound morbidity. Am J Surg 215(3):462–465 (**Epub 2017 Nov 13**)
26. Halka JT, Vasyluk A, DeMare A, Iacco A, Janczyk R (2019) Hybrid robotic-assisted transversus abdominis release versus open transversus abdominis release: a comparison of short-term outcomes. Hernia 23(1):37–42 (**Epub 2018 Nov 19**)
27. Ahonen-Sirrtola M, Nevala T, Vironen J, Kössi J, Pinta T, NIemeläinen S, Rauti T (2020) Laparoscopic versus hybrid approach for treatment of incisional ventral hernia: a prospective randomized multicentre study, 1-year results. Surg Endosc 34(1):88–95 (**Epub 2019 Apr 2**)
28. Kudsi OY, Chang K, Bou-Ayash N, Gokcal F (2021) Hybrid robotic hernia repair for incisional hernias: perioperative and

patient-reported outcomes. J Laparoendosc Adv Surg Tech A 31(5):570–578 (**Epub 2020 Nov 4**)
29. Addo A, Lu R, Broda A, George P, Reza Zahiri H, Belyansky I (2021) Hybrid versus open retromuscular abdominal wall repair: early outcomes. Surg Endosc 35(10):5593–5598 (**Epub 2020 Oct 9**)
30. Van den Dop LM, De Smet GH, Kleinrensink G, Hueting W, Lange JF (2021) (2021) Hybrid operation technique for incisional hernia repair: a systematic review and meta-analysis of intra- and postoperative complications. Hernia 25(6):1459–1469 (**Epub 2021 Sep 18**)
31. Sharma A, Sinha C, Baijal M, Soni V, Khullar R, Chowbey P (2021) Hybrid approach for ventral incisional hernias of the abdominal wall: a systematic review of the literature. J Minim Access Surg 17(1):7–13
32. Burger J, Luijendijk R, Hop W, Halm J, Verdaasdonk E, Jeekel J (2004) Longterm follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg 240(4):578–585
33 Kokotovic D, Bisgaard T, Helgstrand F (2016) Long-term recurrence and complications associated with elective incisional hernia repair. JAMA 316(15):1575–1582
34. Rogmark P, Smedberg S, Montgomery A (2018) Long-term follow-up of retromuscular incisional hernia repairs: recurrence and quality of life. World J Surg 42(4):974–980
35 Hawn M, Snyder C, Graham L, Gray S, Finan K, Vick C (2010) Long-term follow-up of technical outcomes for incisional hernia repair. J Am Coll Surgeons 210(5):648–655 (**655-7**)
36. Lavanchy J, Buff S, Kohler A, Candinas D, Beldi G (2019) Long-term results of laparoscopic versus open intraperitoneal onlay mesh incisional hernia repair: a propensity score-matched analysis. Surg Endosc 33(1):225–233
37. Chelala E, Baraké H, Estivenart J, Dessily M, Charara F, Allé J (2016) Long-term outcomes of 1326 laparoscopic incisional and ventral hernia repair with the routine suturing concept: a single institution experience. Hernia 20(1):101–110
38. Gomez-Menchero J, Andrea B, Ana C, Morales-Conde S (2022) Primary closure of the midline abdominal wall defect during laparoscopic ventral hernia repair: analysis of risk factors for failure and outcomes at 5 years follow-up. Surg Endosc 36(12):9064–9071

Authors and Affiliations

W. Reinpold[1] · C. Berger[1] · D. Adolf[2] · F. Köckerling[3]

✉ W. Reinpold
w.reinpold@hernie.de

C. Berger
c.berger@hernie.de

D. Adolf
daniela.adolf@statconsult.de

F. Köckerling
ferdinand.koeckerling@vivantes.de

[1] Department of Abdominal Wall Surgery, Hamburg Hernia Center, Helios Mariahilf Hospital Hamburg, Stader Strasse 203c, 21075 Hamburg, Germany

[2] Institute for Statistics, Otto-Von-Guerike-University, Magdeburg, Universitätsplatz 2, 39106 Magdeburg, Germany

[3] Center of Hernia Surgery, Vivantes Humboldt-Klinikum, Am Nordgraben 2, 13509 Berlin, Germany