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 transthoracally 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

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 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 adhesions formation, the potential risks associated with an intraperitoneal foreign body has not yet been eliminated 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.1–7 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.12–17 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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METHODS

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

Beginning in 2010 all MILOS operations were prospectively registered in the German Hernia Register “Herniated.” Table Supplement 1, http://links.lww.com/SLA/B364 shows the flowchart 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). The anterior rectus sheath is incised at the center of the hernia defect (Fig. 2B).

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. 3A, 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
laparoscopic instruments and a 5 mm laparoscope. Scar tissue for-
motion, especially after previous operation(s) with mesh implanta-
tion, may reduce the maximum dissection range and warrant
larger incisions.

Step 7: The posterior layer of the rectus sheath is longitudi-
nally 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 trans-
hernial 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
(i.e., 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 perito-
neum 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://link-
s.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 electrocoagula-
tion is performed and a subcutaneous 8 Charr. 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,
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).

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.

Propensity score matching was performed using greedy algorithm and a caliper of 0.2 standard deviations. The variables used for matching were: Hernia defect \( [\text{cm}^2] \), sex, ASA score, primary incisional hernia \( \text{(yes/no)}, \) European Hernia Society (EHS) classification \( \text{width W1: 1–4 cm / W2: > 4 cm– < 10 cm / W3: > 10 cm)}, \) EHS lateral \( \text{(yes/no)}, \) medial \( \text{(yes/no)}, \) body mass index, age, oral anticoagulants \( \text{(yes/no)}, \) platelet inhibitors \( \text{(yes/no)}, \) and mesh size \( [\text{cm}^2] \).

The balance of the matched sample was checked using standardized differences (also given for the prematched sample) that should not exceed 10% \( (\leq 0.1) \) after matching.

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

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.
The mean defect size in the MILOS cohort before matching was 101.2 ± 115.3 cm². 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 cm². The mean skin incision length of 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 min, 280 min, and 332 min, 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 single port or standard ports gas endoscopy (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).

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

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>MILOS</th>
<th>Laparoscopic IPOM</th>
<th>Standard Difference</th>
<th>Matched Sample</th>
<th>Original Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>Mean ± STD</td>
<td>60.2 ± 13.1</td>
<td>60.3 ± 13.3</td>
<td>0.004</td>
<td>0.139</td>
</tr>
<tr>
<td>BMI</td>
<td>MW ± STD</td>
<td>29.7 ± 6.1</td>
<td>29.6 ± 5.8</td>
<td>0.020</td>
<td>0.064</td>
</tr>
<tr>
<td>Defect size, cm²</td>
<td>MW ± STD</td>
<td>75.6 ± 100.6</td>
<td>78.3 ± 97.8</td>
<td>0.027</td>
<td>0.516</td>
</tr>
<tr>
<td>Mesh size, cm²</td>
<td>MW ± STD</td>
<td>518.2 ± 280.4</td>
<td>532.5 ± 287.0</td>
<td>0.050</td>
<td>0.889</td>
</tr>
</tbody>
</table>

#### B: Standardized Differences of Categorical Matching Parameters Before and After Matching

<table>
<thead>
<tr>
<th>Parameter</th>
<th>MILOS</th>
<th>Laparoscopic IPOM</th>
<th>Standard Difference</th>
<th>Matched Sample</th>
<th>Original Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: male</td>
<td>295</td>
<td>54.53</td>
<td>295</td>
<td>54.53</td>
<td>0.000</td>
</tr>
<tr>
<td>ASA I</td>
<td>47</td>
<td>8.69</td>
<td>50</td>
<td>9.24</td>
<td>0.019</td>
</tr>
<tr>
<td>ASA II</td>
<td>306</td>
<td>56.56</td>
<td>288</td>
<td>53.23</td>
<td>0.067</td>
</tr>
<tr>
<td>ASA III-IV</td>
<td>188</td>
<td>34.75</td>
<td>203</td>
<td>37.52</td>
<td>0.058</td>
</tr>
<tr>
<td>EHS W1</td>
<td>103</td>
<td>19.04</td>
<td>91</td>
<td>16.82</td>
<td>0.058</td>
</tr>
<tr>
<td>EHS W2</td>
<td>269</td>
<td>49.72</td>
<td>272</td>
<td>50.28</td>
<td>0.011</td>
</tr>
<tr>
<td>EHS W3</td>
<td>169</td>
<td>31.24</td>
<td>178</td>
<td>32.90</td>
<td>0.036</td>
</tr>
<tr>
<td>Preoperative pain</td>
<td>420</td>
<td>77.63</td>
<td>403</td>
<td>74.49</td>
<td>0.074</td>
</tr>
<tr>
<td>Unknown preoperative pain</td>
<td>45</td>
<td>8.32</td>
<td>63</td>
<td>11.65</td>
<td>0.111</td>
</tr>
<tr>
<td>Primary incisional hernia operation</td>
<td>76</td>
<td>14.05</td>
<td>75</td>
<td>13.86</td>
<td>0.005</td>
</tr>
<tr>
<td>EHS medial</td>
<td>362</td>
<td>66.91</td>
<td>372</td>
<td>68.76</td>
<td>0.040</td>
</tr>
<tr>
<td>EHS lateral</td>
<td>480</td>
<td>88.72</td>
<td>488</td>
<td>90.20</td>
<td>0.048</td>
</tr>
<tr>
<td>Cumarin-medication (Quick/INR not in the normal range)</td>
<td>119</td>
<td>22.00</td>
<td>112</td>
<td>20.70</td>
<td>0.032</td>
</tr>
<tr>
<td>Platelet inhibitors (stopped less than 7 days before surgery)</td>
<td>103</td>
<td>19.04</td>
<td>91</td>
<td>16.82</td>
<td>0.058</td>
</tr>
</tbody>
</table>

### 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 10.05 (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, 0.52)].

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.
0.13), a fewer general complications \( P < 0.001; \text{OR} 0.14 (0.05, 0.33)\), recurrences after 1 year \( P = 0.017; \text{OR} 0.40 (0.17, 0.86)\), less chronic pain after 1 year at rest \( P < 0.001; \text{OR} 0.28 (0.16, 0.48)\), during physical activity \( P < 0.001; \text{OR} 0.21 (0.13, 0.33)\), and chronic pain requiring therapy \( P < 0.001; \text{OR} 0.21 (0.10, 0.40)\). 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 2.** Mini Open Sublay Versus Laparoscopic IPOM: Complications: Direct Comparison of Systematic Deviation Including Adjusted Odds Ratio

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

*Statistically no significant difference.

IPOM indicates intraperitoneal onlay mesh; MILOS, 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 trans hernial 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 laparoscopy and potential laparoscopic adhesiolysis, the abdominal meshes with more extended overlap may be used. Except for the posterior rectus sheath, intact structures of the abdominal wall are not compromised. 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,\textsuperscript{24} the MILOS operation does not require expensive instruments. The reusable Endotorch TM and retractors cost approximately 2,500,-\textcurrencys. Compared with laparoscopic IPOM repair, every MILOS operation represents a saving of at least 1,200,-\textcurrencys 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 preperitoneal ventral hernia repair technique via the left flank,\textsuperscript{12} which is the basis for the recently published robotic sublay approach,\textsuperscript{27} 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.

\begin{table}
\caption{MILOS Versus Open Sublay: Complications: Direct Comparison of Systematic Deviation Including Adjusted Odds Ratio}
\begin{center}
\begin{tabular}{lccccccc}
\hline
 & \textbf{MILOS} & \textbf{Open Sublay} & \textbf{Adjusted OR} & \textbf{Lower Limit} & \textbf{Upper Limit} \\
 & \textbf{n} & \textbf{\%} & \textbf{n} & \textbf{\%} & \textbf{P} & \textbf{Lower Limit} & \textbf{Upper Limit} \\
\hline
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 & 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 \\
\hline
\end{tabular}
\end{center}
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MILOS indicates mini- or less-open sublay operation; OR, odds ratio.
\end{flushright}
\end{table}
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.

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.

REFERENCES