

Appendix 1

Questionnaires at T0 (preoperatively on admission)

T0
Postoperative Questionnaire
 PD Dr. med. Eckhard Löhde
 Laparoscopic.oesophago.hiatal.deltamesh.enforcement (LOEHDE)

1. If you take your advised medication regularly: do you suffer from the following complaints?

(Please note: All the time = daily often = 2-3x/week on and off = 1x/week rarely = 1x/month never = does not occur)

1. Do you suffer from **acid reflux** ?
 All the time often on and off rarely never
2. Do liquids or foods come back into **your mouth when bending over** ?
 All the time often on and off rarely never
3. Do you suffer from **pain** in the upper abdomen or chest?
 All the time often on and off rarely never
4. Do you suffer from problems while **swallowing**?
 All the time often on and off rarely never
5. Do you suffer from **hoarseness, frequent throat clearing, or a stuffy nose** ?
 All the time often on and off rarely never
6. Do you suffer from **sore throat**?
 All the time often on and off rarely never
7. Do you **feel stuffed or bloated** in the upper abdomen?
 All the time often on and off rarely never
8. Do you suffer from **cough attacks at night**?
 All the time often on and off rarely never
9. Do you suffer from **frequent air belching**?
 All the time often on and off rarely never
10. Do you suffer from a **sick gastric feeling or nausea** ?
 All the time often on and off rarely never
11. Do you have to observe a **special diet** to prevent worsening of your complaints ?
 All the time often on and off rarely never
12. Do you sleep with **your chest raised** ?
 All the time often on and off rarely never
13. Do you eat **fast**?
 All the time often on and off rarely never
14. Do you feel a **painful pressure** in your chest?
 All the time often on and off rarely never
15. Do you have **breathing difficulties** causing **physical restrictions** ?
 All the time often on and off rarely never
16. Do you suffer from **sudden palpitation or arrhythmia**?
 All the time often on and off rarely never

T0
Preoperative Questionnaire

PD Dr.med.Eckhard Löhde
Laparoscopic.oesophago.hiatal.deltamesh.enforcement (**LOEHDE**)

2. If you take your advised medication: Do you feel intolerance referring to the following food products?

(Please underline all appropriate points)

Coffee, sparkling wine, sparkling water, fruit juice, red wine, white wine

Sweets, cake, chocolate, tomato products

Others:.....

No restrictions

3. Which medication do you take to ease your complaints? (Please underline)

.....mg Nexium mg Omeprazol mg Omep mg Pantozol,

.....mg Rifun mg Pariet mg Maloxan mg Sodium bicarbonate

Others:

4. If you take your advised medication properly: How do you feel?

(Visick score)

(Please mark the most appropriate point)

- = No complaints with my medication
- = Mild complaints and doctor visits are rare
- = Moderate complaints and doctor visits are often
- = No improvement by my medication

5. How long have you been suffering from the symptoms?

..... years

6. Because of your complaints, how often did you have the following examinations?

..... Consultation of my doctor

..... MRI or CT scan

..... Gastroscopy

..... Stress or 24 h EKG

..... Coloscopy

..... Intracardiac catheter

..... X-ray examination

..... Admission to a hospital for examination

T0
Preoperative Questionnaire
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Laparoscopic.oesophago.hiatal.deltamesh.enforcement (Loe.h.d.e.)

7. If you **DO NOT** take your advised medication regularly: do you suffer from the following complaints?

(Please note: All the time=daily often=2-3x/week on and off=1x/week rarely=1x/month never=does not occur)

1. Do you suffer from **acid reflux**?

All the time often on and off rarely never

2. Do **liquid or foods come back into your mouth when bending over**?

All the time often on and off rarely never

3. Do you suffer from **pain** in the upper abdomen or chest?

All the time often on and off rarely never

4. Do you suffer from problems while **swallowing**?

All the time often on and off rarely never

5. Do you suffer from **hoarseness, frequent throat clearing, or a stuffy nose**?

All the time often on and off rarely never

6. Do you suffer from **sore throat**?

All the time often on and off rarely never

7. Do you **feel stuffed or bloated** in the upper abdomen?

All the time often on and off rarely never

8. Do you suffer from **cough attacks at night**?

All the time often on and off rarely never

9. Do you suffer from **frequent air belching**?

All the time often on and off rarely never

10. Do you suffer from a **sick gastric feeling or nausea**?

All the time often on and off rarely never

11. Do you have to observe a **special diet** to prevent worsening of your complaints?

All the time often on and off rarely never

12. Do you sleep with your **chest raised**?

All the time often on and off rarely never

13. Do you eat **fast**?

All the time often on and off rarely never

14. Do you feel a **painful pressure** in your chest?

All the time often on and off rarely never

15. Do you have **breathing difficulties** and **physical restrictions**?

All the time often on and off rarely never

16. Do you suffer from **sudden palpitation or arrhythmia**?

All the time often on and off rarely never

T0
Preoperative Questionnaire
PD Dr.med.Eckhard Löhde
Laparoscopic.oesophago.hiatal.deltamesh.enforcement (l.o.e.h.d.e.)

8. **NOW: If you DO NOT take your advised medication:**

Would you feel intolerance referring to the following food products?

(Please underline all appropriate points)

Coffee, sparkling wine, sparkling water, fruit juice, red wine, white wine

Sweets, cake, chocolate, tomato products

Others:.....

No restrictions

9. **What were your doctors' suggestions?**

(Please mark all appropriate points)

Continue medication!

Try a special diet!

Increase the dosage!

Consider an operation!

Change your medication!

Don't go for an operation!

Change your daily habits!

Others:

10. **What are the worst of your complaints?**

.....
.....

11. **Were you a premature baby or twin?**

Yes No

12. **Do you have spinal scoliosis or a torsion?**

Yes No

13. **Are there other members in your family suffering from reflux?**

Yes No

(children, father, mother, uncle, grandparents)

If Yes: **Who?**.....

Thank you very much for accurately answering the questions!

Dr. med. Eckhard Löhde

Appendix 2

Questionnaires at T1 (1 year postoperatively)

T1
Postoperative Questionnaire
PD Dr. med. Eckhard Löhde
Laparoscopic.oesophago.hiatal.deltamesh.enforcement (**LOEHDE**)

1. One year after the **LOEHDE procedure**: do you suffer from the following complaints?

(Please note: All the time=daily often=2-3x/week on and off=1x/week rarely=1x/month never=does not occur)

- | | | | | | |
|---|--------------|-------|------------|--------|-------|
| 1. Do you suffer from acid reflux ? | All the time | often | on and off | rarely | never |
| 2. Do liquids or foods come back into your mouth when bending over ? | All the time | often | on and off | rarely | never |
| 3. Do you suffer from pain in the upper abdomen or chest? | All the time | often | on and off | rarely | never |
| 4. Do you suffer from problems while swallowing ? | All the time | often | on and off | rarely | never |
| 5. Do you suffer from hoarseness, frequent throat clearing, or a stuffy nose ? | All the time | often | on and off | rarely | never |
| 6. Do you suffer from sore throat ? | All the time | often | on and off | rarely | never |
| 7. Do you feel stuffed or bloated in the upper abdomen? | All the time | often | on and off | rarely | never |
| 8. Do you suffer from cough attacks at night? | All the time | often | on and off | rarely | never |
| 9. Do you suffer from frequent air belching ? | All the time | often | on and off | rarely | never |
| 10. Do you suffer from a sick gastric feeling or nausea ? | All the time | often | on and off | rarely | never |
| 11. Do you have to observe a special diet to prevent worsening of your complaints? | All the time | often | on and off | rarely | never |
| 12. Do you sleep with your chest raised ? | All the time | often | on and off | rarely | never |
| 13. Do you eat fast ? | All the time | often | on and off | rarely | never |
| 14. Do you feel a painful pressure in your chest? | All the time | often | on and off | rarely | never |
| 15. Do you have breathing difficulties causing physical restrictions ? | All the time | often | on and off | rarely | never |
| 16. Do you suffer from sudden palpitation or arrhythmia ? | All the time | often | on and off | rarely | never |



T1
Postoperative Questionnaire
PD Dr. med. Eckhard Löhde
Laparoscopic.oesophago.hiatal.deltamesh.enforcement (**LOEHDE**)

2. Do you feel intolerance referring to the following food products?

(Please underline all appropriate points)

- Coffee, sparkling wine, sparkling water, fruit juice, red wine, white wine
- Sweets, cake, chocolate, tomato products
- Others:.....
- No restrictions

3. As to your quality of life (QoL) referring to daily life, nourishment, sports, mood, and so forth.

To which answer would you agree most likely? *(Please mark the most appropriate point)*

- = Yes, my QoL is much better at any rate. I am so glad about it.
- = Yes, my QoL is better. I am satisfied.
- = No, my QoL has not changed very much. I am not really satisfied.
- = No, my QoL is even worse. I am disappointed.

4. How long did it take to recover after the surgery?

..... weeks

5. Which were your complaints in the first few weeks after the surgery?

.....

.....

.....

6. Would you choose the LOEHDE procedure again to treat your complaints retrospectively?

(Please mark the appropriate point)

- = Definitely
- = Probably yes
- = Probably no
- = No, certainly no!

T1
Postoperative Questionnaire
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7. From today's point of your experience: How would you score the different therapies?

(School grading: 1=very good 2=good 3=satisfying 4=sufficient 5=inadequate)

Medical treatment (PPI medication) Score ()

Operative treatment (**LOEHDE** procedure) Score ()

8. How do you feel now after surgery referring to your former complaints?

(Please mark the most appropriate point)

(Visick score)

- = No complaints
- = Mild complaints and doctor visits are rare
- = Moderate complaints and doctor visits are often
- = No improvement by the operation

9. Important! Did you have relevant problems related to the hiatal hernia surgery?

(Please mark all appropriate points and do not hesitate to contact the team at any time!)

I had to contact my doctor Yes No

I had a gastroscopy Yes No

I have to take PPI medication again! Yes No

I had another hiatal hernia operation Yes No

What kind of problems emerged?

.....
.....

10. Do you have any notes, thoughts, or recommendations? Do you wish to have the doctors contact?

Please write down freely!

.....
.....

Thank you very much for accurately answering the questions!

Appendix 3

Questionnaires at T5 (5 years postoperatively)

T5
Postoperative Questionnaire
PD Dr. med. Eckhard Löhde
Laparoscopic.oesophago.hiatal.deltamesh.enforcement (**LOEHDE**)

1. Five years after the **LOEHDE procedure**: do you suffer from the following complaints?

(Please note: All the time=daily often=2-3x/week on and off=1x/week rarely=1x/month never=does not occur)

- | | | | | | |
|---|-------|------------|--------|-------|--|
| 1. Do you suffer from acid reflux ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 2. Do liquids or foods come back into your mouth when bending over ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 3. Do you suffer from pain in the upper abdomen or chest? | | | | | |
| All the time | often | on and off | rarely | never | |
| 4. Do you suffer from problems while swallowing ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 5. Do you suffer from hoarseness, frequent throat clearing, or a stuffy nose ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 6. Do you suffer from sore throat ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 7. Do you feel stuffed or bloated in the upper abdomen? | | | | | |
| All the time | often | on and off | rarely | never | |
| 8. Do you suffer from cough attacks at night? | | | | | |
| All the time | often | on and off | rarely | never | |
| 9. Do you suffer from frequent air belching ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 10. Do you suffer from a sick gastric feeling or nausea ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 11. Do you have to observe a special diet to prevent worsening of your complaints? | | | | | |
| All the time | often | on and off | rarely | never | |
| 12. Do you sleep with your chest raised ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 13. Do you eat fast ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 14. Do you feel a painful pressure in your chest? | | | | | |
| All the time | often | on and off | rarely | never | |
| 15. Do you have breathing difficulties causing physical restrictions ? | | | | | |
| All the time | often | on and off | rarely | never | |
| 16. Do you suffer from sudden palpitation or arrhythmia ? | | | | | |
| All the time | often | on and off | rarely | never | |

T5
Postoperative Questionnaire
PD Dr. med. Eckhard Löhde
Laparoscopic.oesophago.hiatal.deltamesh.enforcement (**LOEHDE**)

2. Do you feel intolerance referring to the following food products?

(Please underline all appropriate points)

Coffee, sparkling wine, sparkling water, fruit juice, red wine, white wine

Sweets, cake, chocolate, tomato products

Others:.....

No restrictions

3. As to your quality of life (QoL) referring to daily life, nourishment, sports, mood and so forth.

To which answer would you agree most likely? *(Please mark the most appropriate point)*

= Yes, my QoL is much better at any rate. I am so glad about it.

= Yes, my QoL is better. I am satisfied.

= No, my QoL has not changed very much. I am not really satisfied.

= No, my QoL is even worse. I am disappointed.

4. Would you choose the LOEHDE procedure again to treat your complaints retrospectively?

(Please mark the appropriate point)

= **Definitely**

= Probably yes

= Probably not

= No, certainly not!

5. How would you score the different therapies retrospectively?

(School grading: 1=very good 2=good 3=satisfying 4=sufficient 5=inadequate)

Medical treatment (PPI medication) Score ()

Operative treatment (LOEHDE procedure) Score ()

T5
Postoperative Questionnaire
PD Dr. med. Eckhard Löhde
Laparoscopic.oesophago.hiatal.deltamesh.enforcement (**LOEHDE**)

6. How do you feel now after surgeryreferring to your former complaints?

(Please mark the most appropriate point)

(Visick score)

- = No complaints
- = Mild complaints and doctor visits are rare
- = Moderate complaints and doctor visits are often
- = No improvement by the operation

7. Important! Did you have relevant problems related to the hiatal hernia surgery?

(Please mark all appropriate points and do not hesitate to contact the team at any time!)

- I had to contact my doctor Yes No
- I had a gastroscopy Yes No
- I have to take PPI medication again!** Yes No
- I had another hiatal hernia operation Yes No

What kind of problems emerged?

.....

.....

8. Do you have any notes, thoughts, or recommendations? Do you wish to have the doctors contact?

Please write down freely!

.....

.....

Thank you very much for accurately answering the questions!

Dr. med.Eckhard Löhde

Symptom score Proportion of scores

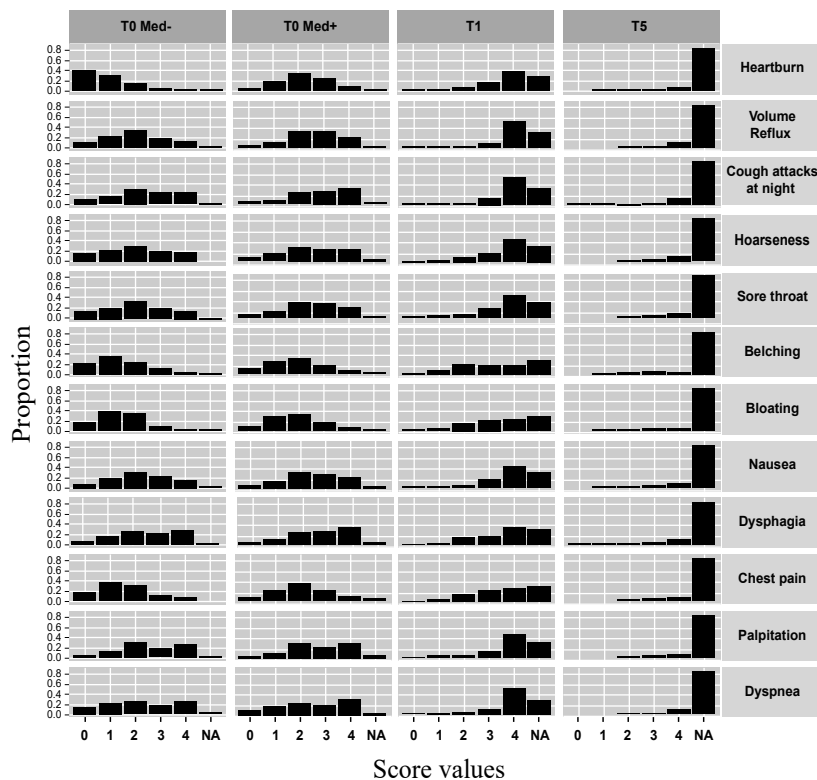


Figure S1 Symptom scores split into proportions of scoring values. Proportions confirm that without PPI medication (T0Med-) patients report a wide range of complaints occurring daily and during a week (Predominant scores 1–2). PPI treatment (T0Med+) shows an alleviating effect, especially for heartburn, but many complaints persist (Predominant scores 2–3). Cure of patients is only achieved at T1 and T5, as symptom scores predominantly improve to 3–4.

Symptom score: 0 = all the time (daily); 1 = often (2–3x/week); 2 = on and off (1x/week); 3 = rarely (1x/month); 4 = never (does not occur); NA = not available. T0Med- = preoperative without PPI; T0Med+ = preoperative with PPI; T1 = 1 year postoperatively; T5 = 5 years postoperatively.

Table S1 Symptom score frequencies

Observation point	Frequency total	Missing data	Valid total
T0Med+	n=1351	n=59	n=1292 (100%)
T1	n=1351	n=424	n=927 (100%)
T5	n=1351	n=1151	n=200 (100%)

Valid total values were used to describe frequencies and proportions of symptoms such as such heartburn, volume reflux, cough attacks at night, hoarseness, sore throat, belching, bloating, nausea, dysphagia, chest pain, palpitation, and dyspnoea. T0Med- = preoperative without PPI; T0Med+ = preoperative with PPI; T1 = 1 year postoperatively; T5 = 5 years postoperatively. To note: Due to the end of the study after 10 years, the observation point T1 could only be reached by 1287/1351 patients and observation point T5 by 529/1351 patients.

Table S2 Food intolerance frequencies

Observation point	Frequency total	Missing data	Valid total
T0Med-	n =1351	n=192	n=1159 (100%)
T0Med+	n=1351	n=50	n=1301 (100%)
T1	n=1351	n=484	n=867 (100%)
T5	n=1351	n =1151	n=200 (100%)

Valid total values were used to describe frequencies and proportions of food intolerances for critical drinks such as white wine, sparkling wine, red wine, fizzy drinks, fruit juices, and coffee, as well as food such as sweets, cakes, chocolate, and tomatoes. T0Med- = preoperative without PPI; T0Med+ = preoperative with PPI; T1 = 1 year postoperatively; T5 = 5 years postoperatively. To note: Due to the end of the study after 10 years, the observation point T1 could only be reached by 1287/1351 patients and observation point T5 by 529/1351 patients.

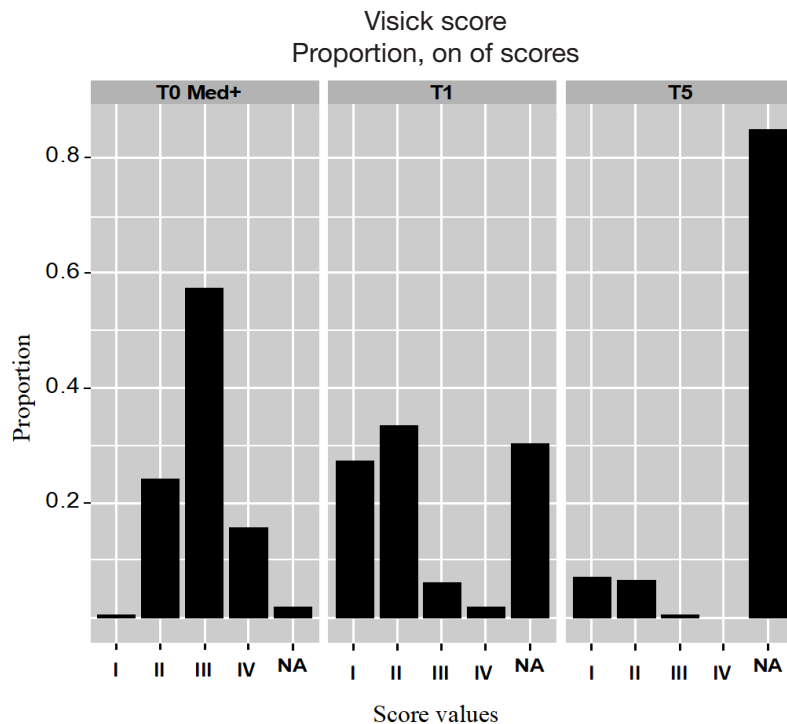


Figure S2 Visick scores split into proportions of scoring values. Proportions confirm that despite optimised PPI medication at T0Med+, almost no patient felt cured preoperatively and continued doctor visits were required. The Visick score that best described the state of health was III. Postoperatively, at T1 and T5, patients predominantly attributed their condition to Visick score I-II. Visick score: I = no complaints; II = mild complaints relieved by care and doctor visits are rare; III = moderate complaints not relieved by care and doctor visits are often; IV = no improvement. NA = not available. T0Med+ = preoperative with PPI; T1 = 1 year postoperatively; T5 = 5 years postoperatively.

Table S3 Visick score frequencies

Observation point	Frequency total	Missing data	Valid total	Visick I	Visick II	Visick III	Visick IV
T0Med+	n=1351	n=50	n=1301 (100%)	n=9 (0,7%)	n=322 (24,8%)	n=760 (58,4%)	n=210 (16,1%)
T1	n=1351	n=431	n=920 (100%)	n=364 (39,6%)	n=446 (48,5%)	n=82 (8,9%)	n=28 (3%)
T5	n=1351	n=1151	n=198 (100%)	n=98 (49,5%)	n=90 (45,4%)	n=10 (5%)	n=0 (0%)

Valid total values were used to describe frequencies and proportions of the Visick score. T0Med+ = preoperative with PPI; T1 = 1 year postoperatively; T5 = 5 years postoperatively.

Visick score: I = no complaints; II = mild complaints relieved by care and doctor visits are rare; III = moderate complaints not relieved by care and doctor visits are often; IV = no improvement. To note: Due to the end of the study after 10 years, the observation point T1 could only be reached by 1287/1351 patients and observation point T5 by 529/1351 patients.

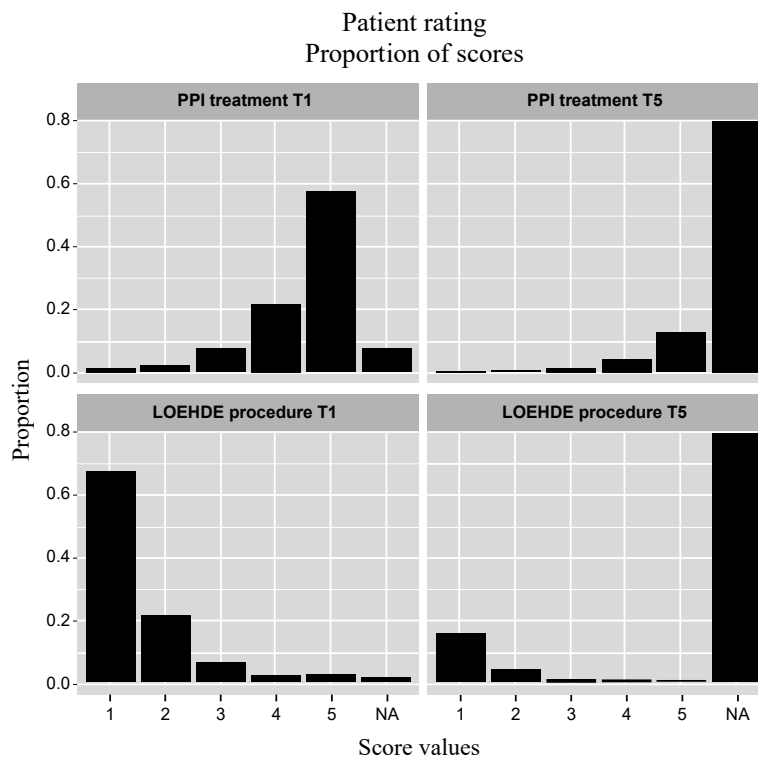


Figure S3 Patient ratings of therapeutic efficacy split into proportions of scoring values retrospectively. Retrospective evaluation of the therapeutic efficacy at T1 and T5. PPI medication was inversely assessed in favour of LOEHDE. Rating score: 1 = excellent; 2 = good; 3 = satisfying; 4 = sufficient; and 5 = poor; NA = not available. T1 = 1 year postoperatively; T5 = 5 years postoperatively.

Table S4 Patient rating frequencies

Treatment	Frequency total	Missing data	Valid total	Score 1	Score 2	Score 3	Score 4	Score 5
T1 PPI med.	n=1351	n=506	n=845 (100%)	n=17 (2%)	n=23 (2,7%)	n=73 (8,6%)	n=202 (23,9%)	n=530 (62,7%)
T5 PPI med.	n=1351	n=1166	n=185 (100%)	n=4 (2,2%)	n=7 (3,8%)	n=15 (8,1%)	n=40 (21,6%)	n=119 (64,3%)
T1 LOEHDE	n=1351	n=449	n=902 (100%)	n=610 (67,6%)	n=193 (21,3%)	n=57 (6,3%)	n=20 (2,2%)	n=22 (2,4%)
T5 LOEHDE	n=1351	n=1158	n=193 (100%)	n=142 (73,6%)	n=36 (18,6%)	n=7 (3,6%)	n=5 (2,6%)	n=3 (1,5%)

Valid total values were used to describe frequencies and proportions of the patient ratings. Patient rating: 1 = excellent; 2 = good; 3 = satisfying; 4 = sufficient; and 5 = poor. T1 = 1 year postoperatively; T5 = 5 years postoperatively. To note: Due to the end of the study after 10 years, the observation point T1 could only be reached by 1287/1351 patients and observation point T5 by 529/1351 patients.

Appendix 4

Delta Mesh background and Technical notes

Introduction

Stable hiatal reconstruction is mandatory for successful hiatal hernia surgery. However, postoperative stability is challenged by significant axial- and bilateral-acting tensile forces, tender and vulnerable muscles without fascial envelopes, and variations of the specific three-dimensional angular composition of the esophageal hiatus in the sagittal and frontal planes. Various techniques of onlay-mesh application have not shown a transparent breakthrough compared to conventional hiatal hernia surgery.

These results led to a fundamentally new closure concept that does not aim to cover the defect, but to induce stable internal reinforcement of the crura. Therefore, a new type of mesh was developed that is specifically adapted to the three-dimensional anatomy of the hiatus and its specific functional requirements.

Innovation

The underlying principle of the DM is the anatomical and functional reconstruction of the disrupted esophageal hiatal unit against the background of its crucial importance for CODIS. Central requirements for the DM were avoidance of an intra-abdominal position, exclusive contact only with the targeted crura, muscle shielding from adjacent abdominal organs, induction of a stable three-dimensional muscle-mesh complex, constructional resistance to the prevailing axial and bilateral tensile forces, safe and easy mesh fixation, small size and simple handling in laparoscopic procedures.

Results

Shape and material

The DM is V-shaped, 30x40x11 mm in size. It is based on the three-dimensional principle of a T-profile, which creates two longitudinal compartments for stable embedding of the left and right crus. This creates a three-dimensional, bi-angular adhesion system with an enlarged integration surface for the muscle tissue. The DM is made of polyvinylidene fluoride, which best matches the natural consistency of the crura and facilitates surgical adjustment to the individual anatomy.

Centrefold

The centerfold arises vertically along the longitudinal midline of the wings and determines the decisive three-dimensional structure of the DM. It creates the two compartments of the T-profile for comprehensive muscle embedding and provides an active edge-to-edge

interlocking of the crura. The DM height is limited to 11 mm, which thus allows for complete coverage by the crura. The centerfold supports the longitudinal and torsional stability of the DM and always ensures its standardized exact concentric positioning in the hiatal midline.

Bilateral wings

Both wings unfold autonomously retrocrurally due to the construction and elasticity of the DM. They have a maximum width of 30 mm at the base to provide intensive muscle integration in this area of maximum axial and bilateral tensile forces and to create a stable retrocrural back shield to protect the crura from the transecting forces of the straining hiatal sutures. As the tensile forces in the hiatus decrease towards the posterior, the DM can taper towards the tip without losing stability. The resulting delta shape of the DM significantly facilitates retrocrural positioning of the wings behind the crura.

Location

The DM is placed in the widened esophageal hiatus, inverted, with the base up and the tip down directly below the esophagus. When the threaded first hiatal suture is closed, the DM is automatically positioned concentrically, covered by both crura and shielded from the abdominal cavity.

Fixation

The DM fixation and hiatal closure are simultaneously achieved by the reverse closure technique. The crucial first suture (0-Prolene 0.9m, CT-2 Plus; PROLENE™, Ethicon® Endo-Surgery Inc., USA) takes 8–10 mm of the left crus directly below the esophagus, is threaded extracorporeally along the DM base, and after insertion of the DM through an 11 mm trocar, the right crus is correspondingly grasped in a horizontal line. Closure is performed with a tight locking suture in the extracorporeal technique under tension. This first suture neutralizes all bilaterally acting forces. Therefore, all other 1-2 sutures further below only capture both crura and the base of the centerfold and provide the final closure of the hiatal defect. Additional fixation is not required.

Discussion

Onlay-mesh techniques in common hernia surgery focus on the simple but successful approach to cover a defect by an attached flat mesh. However, these techniques require a large mesh-tissue contact area, reliable structures for mesh fixation, the absence of sensitive adjacent hollow organs and predominant axial instead of bilateral tensile forces. All those prepositions are absent in the hiatal area. In particular, hiatal hernia repair is not about somehow closing a defect,

Hiatal closure concepts

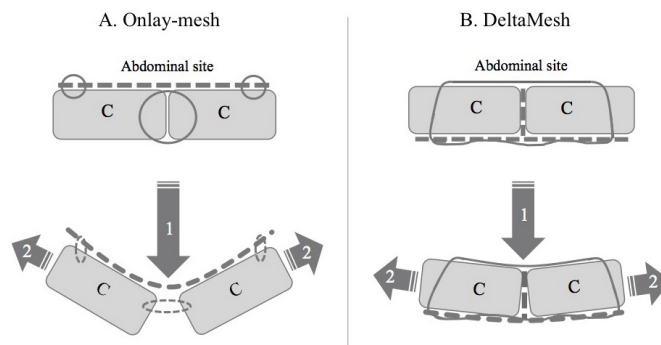


Figure S4 Comparison of hiatal closure concepts. (A) Despite the hiatal coverage by an intraabdominal onlay-mesh, axial force vectors ① continuously strain the sutures between the crura (C) and bilateral forces ② additionally pull the muscles apart underneath the mesh. (B) In DeltaMesh implantation the axial forces support the firm pressing of the crura into its retroabdominal compartments and the bilateral forces are resisted by the edge-to-edge integration of the crura with the centerfold.

but about restoring a fundamental functional structure that is part of the interacting organ system CODIS.

Therefore, the specific architecture of the hiatus was transferred to a corresponding three-dimensional composition of the DM, matching the requirements of inner hiatal enhancement. The T-profile is designed to activate stable edge-to-edge interlocking of the crura and to achieve high joint stability in a bi-angular fusion system. These constructional advantages exceed the stability of common single-angular systems with flat, surface-covering onlay-meshes (*Figure S4*).

Due to its retrocrural position, the DM is shielded from abdominal organs and contact is focused almost exclusively on the targeted crura. Despite its small size, the three-dimensional structure seems to provide sufficient surface area for deep muscle integration.

The easy handling of the DM is based on the small size, elasticity, and ease of grasping the centerfold for positioning. Fast and reliable DM anchoring is obtained by integration into the regular sutures of the hiatoplasty, thus providing a time-saving simplification in laparoscopic procedures. The DM construction and the reverse closure technique ensure that the centerfold is always exactly in the intercrural midline after closure and both wings are retrocrurally unfolded, regardless of hernia size, tissue quality, or surgical variations.

The DM length is intraoperatively adjusted to the size of the defect. The reverse closure technique neutralizes all tensile forces already by the first suture. Therefore,

all further sutures can be positioned quickly, tension-free and at a wide distance. This not only saves time, but also helps to preserve the crucial blood supply to the crura. The developed proportions of the DM are suitable for the vast majority of hiatal hernia patients. However, a ready-made DM in different sizes and design could be an important option in the future and may expand indication for the three-dimensional closure technique of i.e. incisional hernias.

The DM concept seems to eliminate various disadvantages of common two-dimensional onlay meshes as the great variability in terms of size, shape, type, placement, fixation, and surgical assessment. Furthermore, during laparoscopic positioning of a flat onlay-mesh, the diaphragm is straightened and stretched by the CO₂ pressure. However, CO₂ venting inevitably causes the diaphragm to fall back to its normal anatomical angles, leading to uncontrolled folding of the fixed onlay mesh with the risk of undefined mesh-tissue adhesion complexes found at recurrency surgery.

Conclusions

The new three-dimensional DM provides the stable bi-angular crura closure for hiatal hernia patients. The newly described technique of reverse closure is simple, time-saving, and integrates cruroplasty and DM fixation without the need for additional sutures. The three-dimensional DM closure concept is standardized, reproducible, and independent of the shape or size of the hiatal hernia.