# Results of a prospective, uncontrolled, single-arm study of 1,351 patients with hiatal hernia operated on exclusively with DeltaMesh hiatal reconstruction over a 10-year period

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**Background:** Surgical gastroesophageal reflux disease (GERD) therapy is conceptually based on the hypothesis of a deficient lower oesophageal sphincter (LES). Consequently, the focus is on a variety of internal or external oesophageal constrictions, with Nissen and Toupet surgery considered the gold standard. However, clinical outcomes still show wide variations in terms of recurrence and complications and, in particular, there are still unresolved fundamental inconsistencies regarding the function and actual existence of the LES. In this work, a new surgical procedure, laparoscopic oesophagohiatal DeltaMesh enhancement (LOEHDE), was used, based on the emerging pathophysiological suggestion that reflux is instead significantly controlled by a complex cardioesophageal pumping system that decisively depends on the intact hiatal architecture. Accordingly, the surgical focus was solely on the anatomical correct reconstruction of the oesophagohiatal unit without any fundoplication or other conventional anti-reflux measures.

**Methods:** In a 10-year prospective clinical single arm cohort study from January 2007 to December 2016, all consecutively admitted patients with symptomatic hiatal hernia who met the inclusion criteria underwent the DeltaMesh enhanced oesophagohiatal reconstruction. Patients follow-up was recorded by standardised questionnaires given preoperatively on admission (T0; 43 questions), postoperatively at 1 year (T1; 24 questions) and 5 years (T5; 22 questions). There was no randomisation and no control group, as all patients refused any other form of surgery, especially fundoplication.

**Results:** A total of 1,351 patients were included and operated on. The follow-up rate was 96% at T0 (1,297/1,351), 68.6% at T1 (927/1,351), and 14.8% at T5 (200/1,351). The Visick score, symptom score, and patient rating significantly improved postoperatively at T1 and T5 (P<0.0001) compared with the situation under medical treatment at T0 in all symptom categories: A (reflux, heartburn); B (hoarseness, coughing); C (palpitation, dyspnoea); and D (belching, nausea). Recurrence was observed in 91 of the 1,351 (6.7%) patients. DeltaMesh penetration was observed in the oesophagus (n=2) and stomach (n=3). Mortality (n=1) was 0.07%.

**Conclusions:** Anatomical reconstruction of the oesophagohiatal unit alone resulted in significant restoration of oesophageal function without fundoplication, confirming the new pathophysiological approach. LOEHDE proved to be a safe, efficient, and standardisable procedure for symptomatic hiatal hernia.

**Keywords:** Hiatal hernia; reflux surgery; fundoplication; DeltaMesh; laparoscopic oesophagohiatal DeltaMesh

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enhancement (LOEHDE)

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## Introduction

In recent decades, hiatal hernia, gastroesophageal reflux disease (GERD) and extraoesophageal symptoms have become the most common gastrointestinal disorder worldwide, with a pooled prevalence ranging from about 13% to more than 25% in various countries. The public health dimension may be reflected in the fact that GERD has become the most common gastrointestinal symptom in outpatient diagnosis, with nearly 9 million visits in the United States already in 2009 (1,2).

For years, the therapeutic guidelines for these patients have focused on the administration of proton pump inhibitors (PPIs) in various modalities, although up to 50% of patients report persistence of various symptoms (3-5). The therapeutic gap is widened by the fact that any kind drug therapy can only achieve symptom relief and not a cure, and the unlimited use of medication for decades must be viewed increasingly critically (6-8). Therefore, the therapeutic goal in the future must undoubtedly be successful causal surgical treatment.

This points to the crucial question of what is "causal". The conventional pathophysiological hypothesis considers a diseased and opened LES to be causally responsible for GERD, despite persistent conceptual inconsistencies, which are being tried to be explained by a long list of hypothesised genetic, neurological, hormonal, and environmental cofactors, flaps, valves, and flap valves (9-11). Consequently, the common surgical anti-reflux approach focuses on a variety of therapeutic internal or external oesophageal strictures such as gastric wrapping from 90° to 360°, oesophageal wall destruction and scarring, magnetic closure, division of short gastric vessels, and all forms of mesh implantation in addition (12-18).

However, even after decades, there is still no conceptual breakthrough, fundoplication, with all its shortcomings, is widely accepted as the surgical "gold standard" for anti-reflux therapy, and practically gastroenterologists and general practitioners still consider surgery as the last option, not least because of the rather limited good surgical results in their patients.

New MRI data may open up a crucial new pathophysiologic concept. It is assumed that reflux control does not occur through a hypothetical LES, but through a complex cardio-oesophago-diaphragmatic interacting system (CODIS) that is determined by a continuous downward rollout movement of the heart onto the ventral wall of the oesophagus, which is more or less only passively involved in the system. However, the position of the oesophagus and the three-dimensional hiatal architecture proved to be crucial but vulnerable to the functioning of this system (19). Based on these new findings, the technique of laparoscopic oesophagohiatal DeltaMesh enhancement (LOEHDE) was developed, which focuses exclusively on the correct anatomical reconstruction of the oesophagohiatal unit. Fundoplication or other anti-reflux procedures were strictly omitted in all patients. For long-term stabilisation of the hiatus, a new three-dimensional DeltaMesh was applied, which is specifically designed to meet the special requirements of a destructed hiatus and efficiently neutralises the axial and tensile acting forces. We present the following article in accordance with the STROBE reporting checklist (available at https://ls.amegroups.com/article/view/10.21037/ls-22-1/rc).

## Methods

### *Study design*

This study was conducted as a prospective uncontrolled single-arm cohort study over a 10-year period, from January 2007 to December 2016. All patients consecutively admitted with symptomatic type I–IV hiatal hernias from Germany and other EU countries who met the inclusion criteria underwent surgery according to LOEHDE using DeltaMesh in all cases. No other anti-reflux surgery was performed. Surgeries were carried out by two surgeons and successively in two hospitals in Berlin, Germany: the Parksanatorium Dahlem, D-14199 (2007-2013, presently closed) and the DRK-Klinikum Westend, D-14050 (2014-2017). This study had no control group and was not randomised, as all patients specifically wanted to be operated on with LOEHDE only without fundoplication or other techniques. This was respected and, for ethical reasons, patients were not persuaded to undergo fundoplication instead.

### *Ethics approval*

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Ethics Commission of the Ärztekammer Berlin, Friedrichstr. 16, D-10969 Berlin, Germany (approval number: Eth-56/20), and listed in the German Clinical Trial Register DRKS (registered number: DRKS00024357) being accepted by the WHO and the International Committee of Medical Journal Editors (ICMJE). All included patients specifically asked for LOEHDE. Nevertheless, they were extensively informed about the common fundoplication being the accepted "gold standard" in anti-reflux surgery. All patients provided signed informed consent, agreed on the 5-year follow-up, consented to further scientific utilisation of their anonymised data, and were instructed to keep close contact in case of any irregularity.

### *Inclusion criteria*

All type I–IV hiatal hernias were included. The definition of "symptomatic" was based on the following four symptom categories: (A) fluid reflux such as heartburn, bending forward reflux, nocturnal cough, and a need for diet; (B) aerosol reflux such as hoarseness, throat clearing, globus sensation, sinus swelling, and posterior laryngitis; (C) core symptoms such as chest pain, feeling of incarceration, cardiac sensations, back pain, and dyspnoea; (D) functional disorders such as dysphagia, belching, fast eating, and bloating.

The inclusion criteria for the entire study period were as follows: (I) age ≥15 years (mandatory); (II) increasing symptoms in categories A, B, C, and D with significant impairment of daily life (mandatory); (III) endoscopic findings of an incompetent cardia or hiatal hernia, irrespective of size (mandatory) (IV) oesophagitis with a Savary–Miller grade ≥2 or Los Angeles classification grade ≥B (20,21); (V) histopathological findings of oesophagitis or Barrett's metaplasia or dysplasia; (VI) ineffectiveness of PPIs or adverse effects; and (VII) pathological findings of pH measurement, manometry, X-ray contrast swallow evaluation, computed tomography (CT), or magnetic resonance imaging (MRI). Patient's physical status was classified by the physical status classification system of the American Society of Anesthesiologists (ASA) (22).

The exclusion criteria were age <15 years, suspected achalasia or malignancy, comorbidities that did not justify surgical treatment, and a doubt about diagnosis.

### *Patient-reported outcome*

Basic data were collected from the patient records. Outcome data were collected by means of questionnaires through direct contact with patients by post, mail or telephone at 4 observation time points: (I) T0Med− = preoperative status, if PPIs were not administered; (II) T0Med+ = preoperative status, if PPIs were administered; (III) T1 = postoperative status, 1 year postoperatively without PPIs; (IV) T5 = postoperative status, 5 years postoperatively without PPIs. Forty-three standardised and open questions were asked preoperatively at T0Med− and T0Med+, and 24 and 22 questions were asked postoperatively at T1 and T5, respectively. The questionnaires contained various questions on symptoms, medical history, nutrition, quality of life, medication, examinations performed, postoperative problems, and therapy evaluation (Appendixes 1-3).

The following scores were integrated:

- ❖ The symptom score was redesigned based on patients' empirically frequently reported complaints to specifically detail the outcome of A-D classified symptoms postoperatively. The symptom score has not yet been validated. It was recorded at all four observation points on a scale of 0–4, reflecting "well-being" with regard to a specific symptom at a high score: 0 = complaints all the time (daily); 1 = often (2–3×/week); 2 = on and off (1×/week); 3 = rarely (1×/month); and 4 = never (does not occur). These time intervals were chosen to help patients describe the frequency of their complaints in a structured and comparable way (Appendixes 1-3).
- ❖ The Visick score I-IV, which is commonly used to assess the patient's general well-being, was recorded at all four observation time points, reflecting "well-being" at a low 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 (Appendixes 1-3).
- ❖ The patient rating score was introduced to capture the patients assessment of surgical success compared to the recalled effectiveness of PPI treatment preoperatively. The assessment was made at T1 and

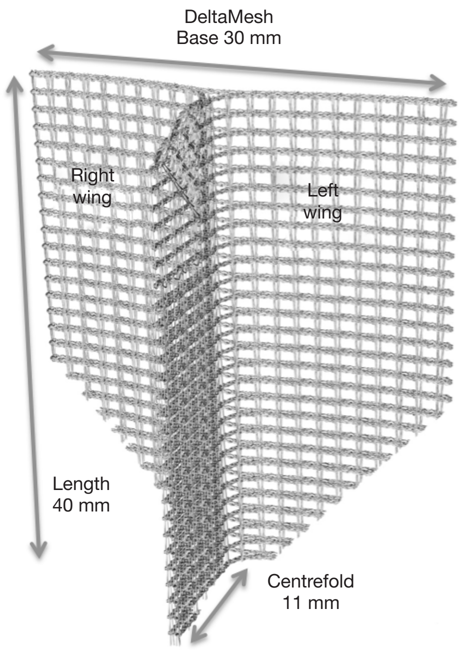


**Figure 1** DeltaMesh diagonal front view. At the base, in the area of the strongest tensile forces, the largest surface area of the wings is kept ready for muscle integration. The three-dimensional structure of the T-profile results from the vertically rising centrefold.

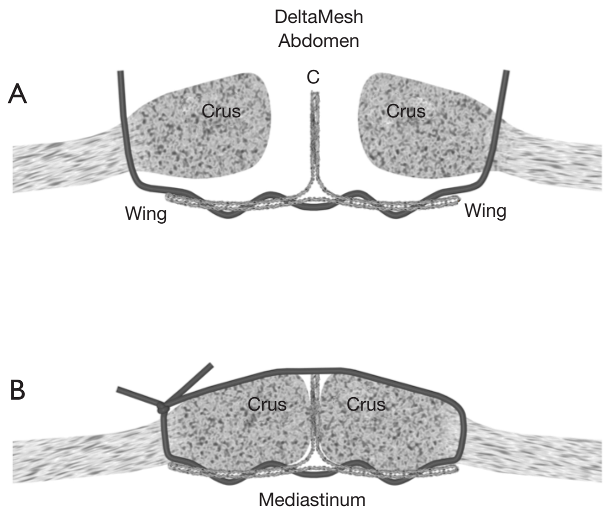


**Figure 2** DeltaMesh cross-section. (A) The wings are placed retrocrurally with the C in the midline. The suture is threaded in the base. (B) During closure, the suture presses both crura into its compartments of the T-profile and ensures tight integration of muscle and mesh. C, centrefold.

T5 on a scale of 1–5, reflecting "great success" at a low score: 1 = excellent; 2 = good; 3 = satisfying; 4 = sufficient; and 5 = poor. The patients' ratings were based on the German school grading system to help patients classify their rating in a familiar system (Appendixes 2,3).

❖ Food intolerances were recorded at T0, T1 and T5 to capture their progression with respect to the empirically most commonly reported 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 (Appendixes 1-3).

### *DeltaMesh*

The DeltaMesh is a V-shaped, 30×40×11 mm, three-dimensional polyvinylidene fluoride mesh designed to target the specific anatomy of the hiatus. The two wings and the vertical lengthwise rising central fold form two compartments that adapt the principle of a three-dimensional T-profile (*Figure 1*). This allows for tight intermuscular bi-angular embedding of the crura. The DeltaMesh is designed for the retroperitoneal position, and the contact is almost exclusively limited to the crura. The DeltaMesh does not require additional fixation but is integrated into regular hiatus sutures (*Figure 2*). (DynaMesh®-DELTA by FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH, Aachen, Germany, and approved in Germany by TÜV Süd, referring to the guidelines of the European Union 93/42/EWG and 2007/47/EG, certificate number: G1 107055 0001 Rev.02. The DeltaMesh has not yet been approved by the US Food and Drug Administration in the USA).

### *LOEHDE*

The procedure involved a 5-trocar technique (1×10 mm; 1×11 mm; 3×5 mm) with the patient in the reverse Trendelenburg position and insertion of a 30 Ch. gastric tube. First, an incision was made in the minor omentum and ventral peritoneal lining of the hiatus. The oesophagus and the posterior vagal nerve branch were exposed and the herniated organs were predominantly repositioned without resection of the hernia sac. The shortened dorsal meso-oesophagus was released to allow for the necessary oesophagus ascent, and the posterior sides of both crura were exposed to ensure free spreading of the DeltaMesh

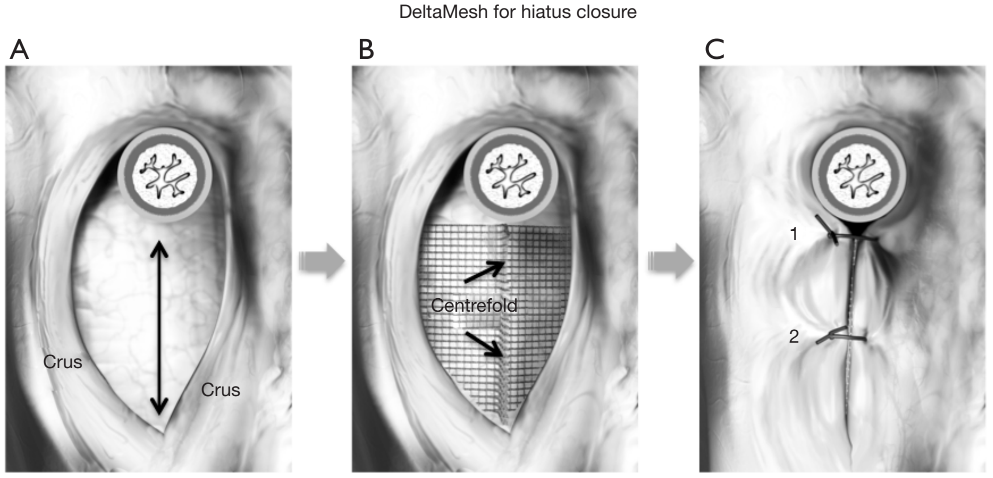


**Figure 3** Schematic illustration of hiatus closure with DeltaMesh. (A) Measurement of the hiatal defect after oesophageal repositioning (double arrow). (B) Position of the adapted DeltaMesh with the base up and the tip down. The wings are unfolded retrocrurally and the centrefold rises in the midline (arrows). (C) Reverse closure of the hiatus, starting with the upper suture ①. Completion of the closure by the second suture ②, ensuring homogeneous longitudinal expansion of the DeltaMesh.

wings retrocrurally.

The left hiatal circumference was dissected while preserving the anterior vagal nerve branch. Finally, the oesophagus was relocated to its correct ventral position. Hernia size was estimated as the distance between the dorsal oesophageal wall and posterior confluence of the crura after complete repositioning. The hiatus was closed in a reverse closure procedure:

For this, the crucial first suture (0-Prolene 0.9m, CT-2 Plus; PROLENE™, Ethicon® Endo-Surgery Inc., USA) was placed directly below the oesophagus, taking 8–10 mm of the left crus. After extracorporeal threading of the DeltaMesh base the right crus was correspondingly grasped in a horizontal line. The hiatus was firmly closed around the oesophagus with an immediate tight locking suture using an extracorporeal knot technique under tension allowing a smooth run of the controlling 30 Ch gastric tube. Adequate longitudinal expansion of the DeltaMesh and complete hiatus closure were ensured by one or two downward sutures. Additional DeltaMesh fixation or anti-reflux procedures were not required (*Figure 3*).

In cases of recurrence after the Nissen/Toupet procedure or other procedures, fundoplication was reset as far as possible occasionally with fundus resection, if necessary, followed by LOEHDE. In cases of recurrence after LOEHDE, the procedure was repeated with an additional small DeltaMesh, leaving the first one in place. Fundoplication or other procedures were not performed in any case.

### *Recurrence*

Recurrence was primarily defined as patients complaining of persistent symptoms, requiring PPIs and dietary changes for relief, and ruling out of other causes. Clinical suspicion was always confirmed by endoscopy, and in cases of doubt, by pH measurement or other methods. Each patient was offered a re-do surgery.

### *Statistical analysis*

Data from questionnaires were transferred to Excel and consecutively analysed using SPSS® (IBM SPSS Statistics, RRID: SCR_019096 version, Armonk, NY, USA) and R version 3.5.0. (R Project for Statistical Computing, RRID: SCR_001905, R Core Team 2018, R Foundation for Statistical Computing, Vienna, Austria, URL: http://www.R-project.org.) Regression models were fitted using the ordinal [Christensen RHB (2019), Ordinal-Regression Models for Ordinal Data, R package version 2019.12-10. https://CRAN.R-project.org/] and brms packages (23).

Data are presented as standard descriptive statistics including frequencies, proportions, means, medians, and quartiles. The Visick score, symptom score, and patient ratings were analysed using hierarchical ordered logistic regression models. Separate models were constructed for each score type. Fixed effects (indicator variables) for measurement occasions were included in all models, and a therapy indicator was included in the model for patient rating. Treatment-time interaction was initially tested and omitted from the final model based on a likelihood ratio test of the interaction term. All models included random intercepts grouped by patients.

To test the overall time effect on symptoms, a model including all symptom types was used, with random effects grouped by symptom type. Random effects for individuals and symptom types were assumed to be independent. Likelihood ratio tests were employed to test for fixed effects. Food intolerance was coded as a dichotomous variable and modelled using a mixed-effects logistic regression model with fixed effects for measurement occasions and random intercepts grouped by individuals and food types, respectively. The likelihood ratio test was used to test the overall differences across measurement occasions (T0Med+, T1, and T5).

Incomplete and missing data are marked as not available in the graphical presentations in figures and tables of frequency in the supplementary.

## Results

### *Patient characteristics*

A total of 1,351 patients were included, of which 1303 (96.4%) had primary hernia and 48 (3.6%) had recurrence or re-recurrence after preceding surgery using Nissen (n=22), Toupet (n=19), Thal (n=2), or other procedures (n=5), partially re-enforced by onlay mesh. All I–IV types of hernias were included but not differentiated in detail, with type I clearly predominating. The patients were 55.9% male and 44.1% female, with a median age of 45 years (range, 15–83 years). Disease persisted <5 years in 50.1% of patients, and 6–10, 11–15, 16–20, and >21 years in 25.7%, 11.2%, 7.3% and 5.8% of patients, respectively.

The regular PPI medication used by 97.4% of patients were pantoprazole, omeprazole, esomeprazole, and rabeprazole, in descending order. The diagnostic measures on the patients by their doctors included stress or 24-h electrocardiography (41.6%), X-ray contrast swallow evaluation (36.5%), MRI/CT (28.8%), and cardiac catheter examination (6.4%). Patients had estimated 10 visits (median, 1–50) to their general practitioner and three gastroscopies (median, 1–12) before surgery. The patients reported 4555 doctors' recommendations for further therapy. Continued medication, changes in diet, increase in PPI dosage, changes in general behaviour, or change in type of medication were recommended 1,143, 731, 686, 576, and 369 times, respectively (n=3,505). 585 recommendations considered an operation, 465 were explicitly against it. 97.1% patients were classified as ASA1 or ASA2, 2.9% as ASA3.

The patients were operated by two surgeons and all surgeries were completed laparoscopically. DeltaMesh enhancement was successful irrespective of the hernia size or previous surgery. The hernia size was 1–2 cm in 5.1% of 451 patients and 2–4, 4–6, and 6–8 cm in 69.2%, 22.2%, and 3.5%, respectively. An enlarged DeltaMesh was used when required. The number of hiatal hernia surgeries per year increased from 73 in 2007 to 196 in 2016.

The follow-up rate of the 1,351 operated patients within the 10-year period from January 2007 to December 2016 was 96% at T0 (1,297/1,351), 68.6% at T1 (927/1,351), and 14.8% at T5 (200/1,351).

Due to the end of the study after 10 years, observation point T1 could only be reached by 1,287 patients and the questionnaire response rate was 72% (927/1,287). Observation point T5 could be reached by 529 patients and the questionnaire response rate was 37.8% (200/529). The continuous follow-up of the patients ended in December 2019.

### *Patient-reported outcomes*

#### Symptom score

A comparison of T0Med– and T0Med+ confirmed that median symptom scores improved by one point from 1 to 2 or 2 to 3 with PPI treatment for heartburn, nightly cough attacks, belching, bloating, nausea, chest pain, palpitation, and dyspnoe, indicating relief but not cure. Median scores for other factors, such as volume reflux, sore throat, dysphagia, and hoarseness, remained largely the same.

The comparison of optimised PPI treatment (T0Med+) *vs.* LOEHDE showed increased scores at T1 and T5 for all symptoms except dysphagia (*Figure 4*). The symptom score increased from 2 to 4 after surgery especially for the main complaints such as heartburn, volume reflux, hoarseness, and sore throat. An additional improvement of the symptom score from 3 to 4 was seen for palpitation, dyspnoea, cough attacks at night, and nausea. Only minor improvements from 2 to 3 were seen for belching, bloating, and chest pain. The low response rate for T5 must be considered. The outcome was comprehensively confirmed by the proportion and distribution of symptom scoring values (Table S1,

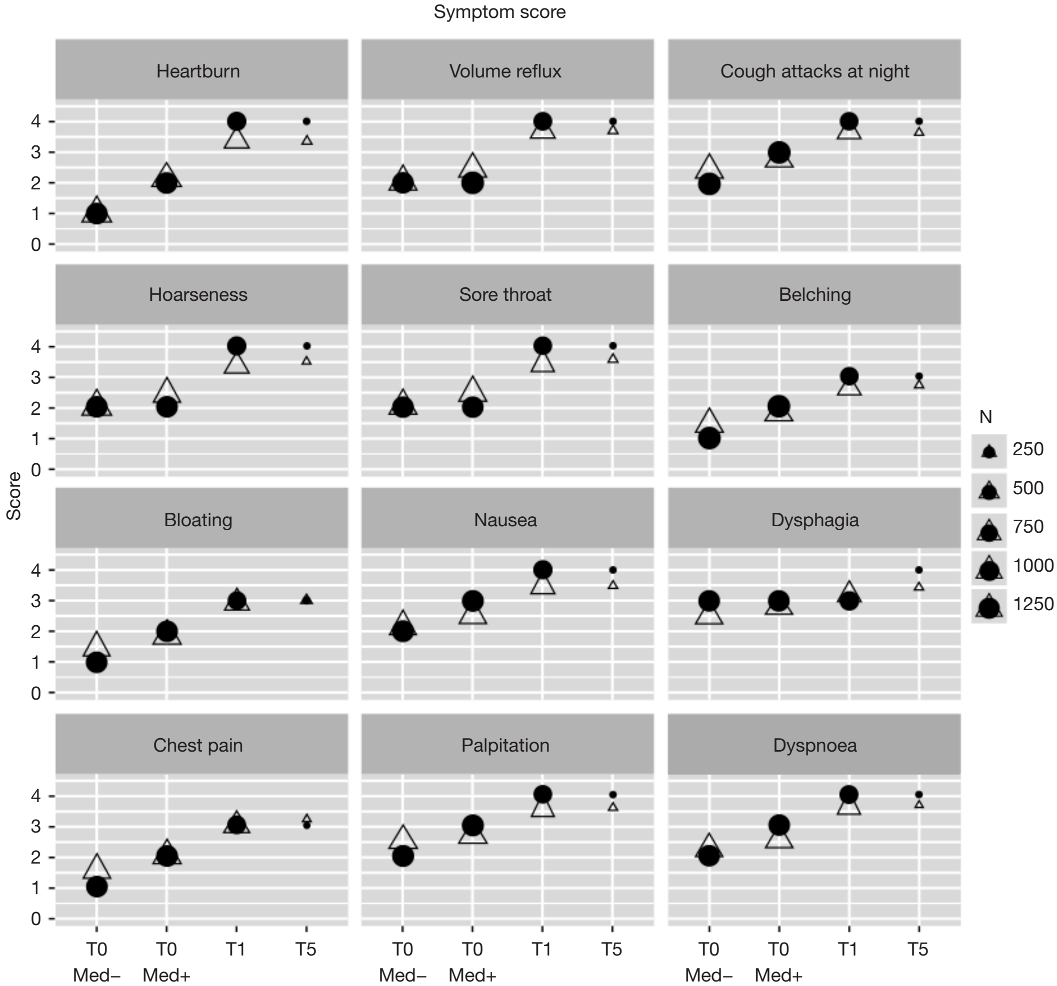


**Figure 4** Symptom scores at T0Med−, T0Med+, T1, and T5. Compared to the situation without PPI medication (T0Med−), PPI medication (T0Med+) provided some improvement, especially for heartburn. After LOEHDE at T1 and T5, the highest symptom scores were achieved in almost all categories. Dots represent medians and triangles represent means. Size of the mark corresponds to the number of patients (N). PPI, proton pump inhibitor; LOEHDE, laparoscopic oesophagohiatal DeltaMesh enhancement.

Figure S1). The test of the overall time effect on symptom scores in the regression model suggested differences in symptom scores across the different time points (Likelihood ratio statistic: 5262; df: 2; $P=2.2\times10^{-16}$ or $P<0.0001$). Based on hierarchical ordered logistic regression, a joint model could be generated for the prediction of symptom scores at T1 and T5, thus predicting the probability of the postoperative course and probable scores for each symptom (data not shown).

### Food intolerance

The comparison of T0Med− and T0Med+ showed that the complaints triggered by critical drinks and foods were only slightly alleviated by PPI. Patients still had to adhere to a diet. In contrast, after surgery at T1 and T5, all critical foods were significantly better tolerated. (*Figure 5*). (LR test: 3778, df: 2, $P<2\times10^{-16}$ or $P<0.0001$). Frequencies and missing data are shown in the supplement (Table S2).

### Visick score

At T0Med+ preoperatively, most patients reported “moderate complaints and frequent doctor visits” despite optimised PPI therapy reflecting the median Visick score of III (range, I–IV). Conversely, at T1 and T5, patients predominantly attributed their improved condition to the median Visick score of II (range, I–IV). The low response

 

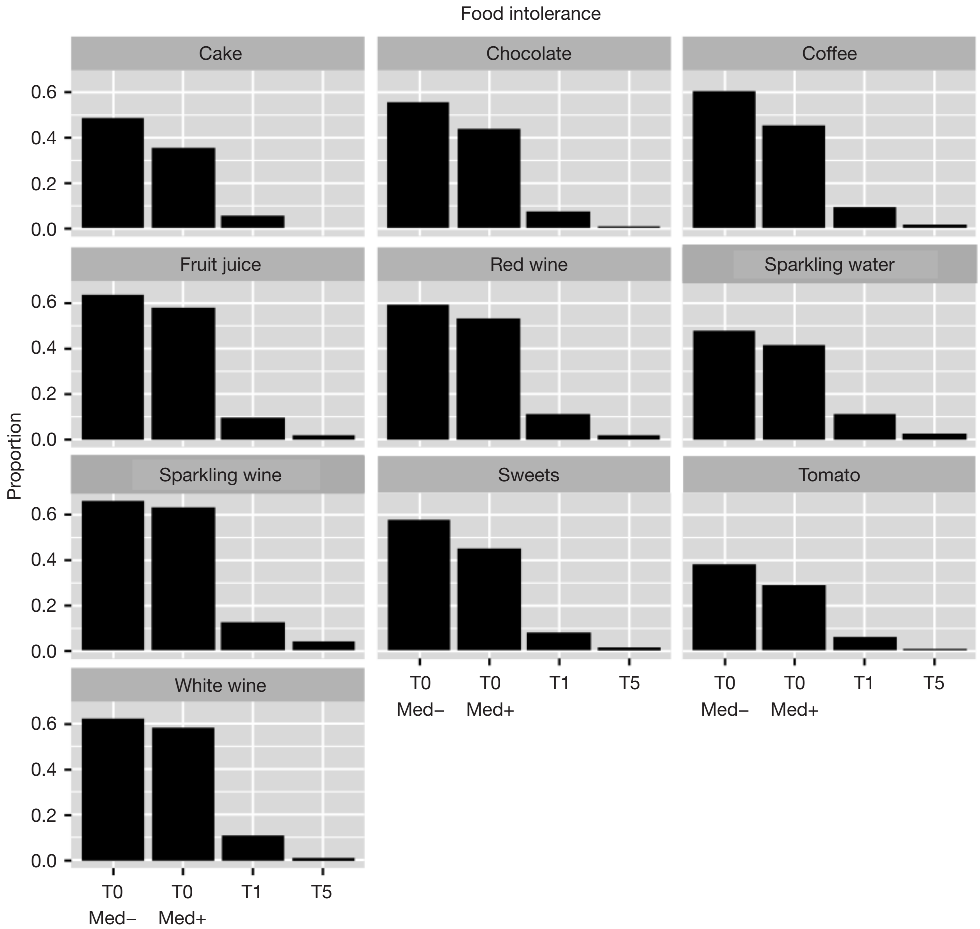


**Figure 5** Preoperatively, critical food was poorly tolerated without treatment (T0Med–). PPI medication showed an improvement especially for heartburn, while other complaints were only slightly alleviated (T0Med+). After LOEHDE at T1 and T5, there were almost no restrictions for the patients. PPI, proton pump inhibitor; LOEHDE, laparoscopic oesophagohiatal DeltaMesh enhancement.

rate for T5 must be considered (*Figure 6*). (LR test: 1329, df: 2, $P<2.2\times10^{-16}$ or P<0.0001). This was comprehensively confirmed by the proportion of Visick scoring values and frequencies (Figure S2, Table S3).

**Patient rating**

Retrospectively, PPI treatment was concordantly rated poorly at T1 and T5 with the median score of 5 (range, 1–5). Inversely, LOEHDE was rated excellent with the median score of 1 at both T1 and T5 (range, 1–5). The low response rate for T5 must be considered (*Figure 7*). (LR test: 1963, $P<2.2\times10^{-16}$ or P<0.0001). This assessment was confirmed by the proportion of scoring values and frequencies (Figure S3, Table S4).

Correspondingly, the question at T1 as to whether patients would re-take their decision to have surgery was answered as definitely, probably yes, probably no, and definitely no, by 82.3%, 13.2%, 3.6%, and 0.9% of patients (n=863), respectively.

***Clinical observation***

The regular postoperative course was that symptoms such as heartburn, volume reflux, chest tightness, and dyspnoea should disappear immediately. Heart symptoms and respiratory symptoms such as hoarseness and sore throat subsided within 1 week. Regular food intake was achieved after 1–3 weeks. Burping was generally not a problem for patients postoperatively. PPI medication was discontinued immediately or gradually. The ability to vomit was not explicitly asked in the questionnaires, but was casually confirmed by a few patients. However, patients did not

 

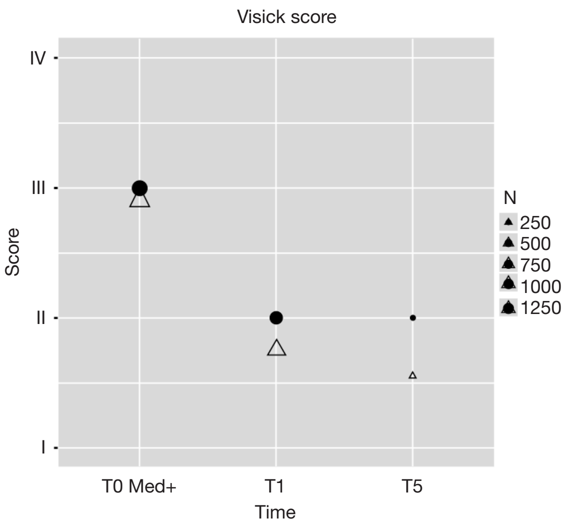


**Figure 6** Visick scores at T0Med+, T1, and T5. Despite optimized PPI treatment, patients reported moderate complaints with frequent doctor visits with a median Visick score of III (range, I–IV). After LOEHDE at T1 and T5, the score was downgraded to mild complaints and a median Visick score of II (range, I–IV). Dots represent median and triangles represent means. Size of the mark corresponds to the number of patients (N). PPI, proton pump inhibitor; LOEHDE, laparoscopic oesophagohiatal DeltaMesh enhancement.

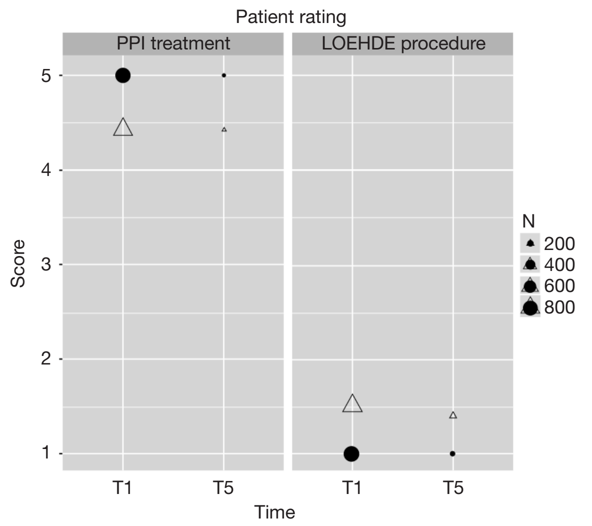


**Figure 7** Patient rating of treatment efficacy in hindsight at T1 and T5. With the experience of both therapies, patients rated the PPI treatment as sufficient and poor with the median of 5 (range, 1–5), while LOEHDE was rated as good and excellent with a median score of 1 (range, 1–5). Dots represent medians and triangles represent means. Size of the mark corresponds to the number of patients. PPI, proton pump inhibitor; LOEHDE, laparoscopic oesophagohiatal DeltaMesh enhancement.

mention problems in the general questions at T1 and T5, nor did they contact the team in any other way.

### *Recurrence*

Recurrences were continuously recorded and observed in 91/1,351 (6.7%) patients during the observation period from January 2007 to December 2016. Recurrence occurred primarily within the first 2 years (58%) postoperatively and decreased continuously in the following years (*Figure 8*). During reoperation, the DeltaMesh proved to be firmly ingrown in the hiatus, but the ventral area around the oesophagus showed hiatal instability. All patients experienced re-displacement of the oesophagus and additional DeltaMesh enhancement, with the first one remaining in place. No procedure such as fundoplication or other was performed.

The recurrence rates of LOEHDE for primary hernia and fundoplication were 6.7% (87/1,303) and 8.3% (4/48), respectively. Among the 91 patients with recurrence, 19 continued conservative treatment, and 72 underwent re-do LOEHDE. Re-recurrence after re-do LOEHDE was detected in 5/72 (6.9%) of patients (*Table 1*).

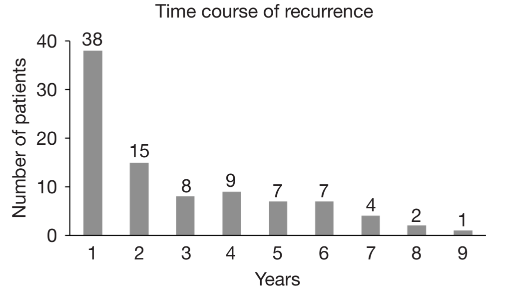


**Figure 8** Time course of recurrences (n=91). More than 50% of the recurrences after LOEHDE emerged within the first 2 years followed by increasing long-term stability. LOEHDE, laparoscopic oesophagohiatal DeltaMesh enhancement.

Six women reported their pregnancy after surgery, of which five had no problems in and after pregnancy and one had a recurrence after the second birth 6 years postoperatively and was operated on again.

### *Morbidity and mortality*

Full recovery from surgery was retrospectively reported

 

**Table 1** Recurrence rate after LOEHDE

| | LOEHDE operation, n | Recurrence diagnosed, n (%) | Recurrence operated, n | Re-recurrence diagnosed, n (%) |
|---|---|---|---|---|
| Total | 1,351 | 91 (6.7) | 72 | 5 (6.9) |
| On primary hernia | 1,303 | 87 (6.7) | 68 | 4 (5.9) |
| On fundoplication recurrence | 48 | 4 (8.3) | 4 | 1 (25.0) |

LOEHDE, laparoscopic oesophagohiatal DeltaMesh enhancement.

at T1 after a median of 4 weeks (range, 1–32 weeks). Cumulatively, 22.4% of patients felt recovered after 3 weeks, 80% after 6 weeks, 90.9% after 9 weeks, and 97.5% after 12 weeks (n=835).

Major postoperative complications developed in 62/1,351 (4.6%) patients, of whom 46 (74.2%) had complications due to re-surgery and 16 (25.8%) required other conservative care or endoscopic intervention. The primary reason for re-surgery was dysphagia (35 patients). In 26 patients re-surgery was performed within the first 3 weeks postoperatively at day 6 (median, range day 1–21). Nine patients were initially treated conservatively, but underwent re-surgery 5 months postoperatively (median, month 1–12).

Other patients showed a subhepatic abscess that did not affect the DeltaMesh (one patient), a gastric perforation that did not affect the DeltaMesh (one patient), severe fungal sepsis of unknown origin with DeltaMesh removal as a precaution (one patient), and haemorrhage (two patients). Mortality was observed in one (0.07%) of the 1,351 patients due to poorly managed bleeding complications not associated with the DeltaMesh.

DeltaMesh-associated complications emerged in five patients. In two patients, the DeltaMesh penetrated the distal oesophagus (22 and 26 months after surgery), causing pain and dysphagia. In these two patients, the DeltaMesh was removed by endoscopy, and the defect healed without further complications. In three patients, asymptomatic penetration of a DeltaMesh edge into the stomach was incidentally observed by control endoscopy after a mean of 48.3 months postoperatively with no need for further intervention to date. Notably, DeltaMesh penetration occurred exclusively in patients who had already undergone one or more Nissen or other surgeries with severe hiatal scarring.

## Discussion

The study design has definite methodological limitations. First, no control group was formed because the patients who came refused fundoplication or any operation other than the LOEHDE procedure mostly due to critical patient reports on the internet or opposition from their doctors. Although this methodological deficiency could not be avoided, it clearly forces caution in the interpretation of these data.

Second, the origin of the patients from different parts of Germany and the EU, different health insurance companies, cost structures, lack of interest or the refusal of treating doctors to schedule further examinations without medical indication prevented a standardised follow-up, for example, by pH-metrics and endoscopy. This form of follow-up could only be carried out in patients with Barrett's metaplasia. However, the carefully conducted analysis of the patient reports proved to be highly informative and clearly outperformed apparative diagnostics, especially in assessing outcome, detecting recurrence, and deciding whether to operate again (24,25).

In this context, it should be noted that, surprisingly, many of the preoperative reports of the patients admitted from various clinics and specialists proved to be unreliable, incomplete, and even false compared to the intraoperative findings including endoscopy (26,27). For the patients, this frustrating diagnostic workup, combined with the persistent complaints, means increasing exhaustion, which is answered by doctors prescribing antidepressants or admitting them to psychiatric institutions (28,29). The observed diagnostic misjudgements raise the fundamental question of how a methodologically reliable and comparable pre- and postoperative diagnostic assessment can be achieved for hiatal hernia patients.

Third, the score systems used are criticisable. The Visick score is considered an established tool for evaluating surgical success in anti-reflux therapy (30). However, the Visick score is undifferentiated and only represents the severity of general complaints in a grossly simplified way (31).

The symptom score was newly invented and not validated. The redesign of the symptom score was necessary because the aim was not only to measure the outcomes of well-being, quality of life, reflux and recurrence, but also to determine in detail which of the various preoperative symptoms of categories A-D and to what extent can be influenced by the reconstruction of the oesophagohiatal unit. This should make it possible to infer the detailed functions of the oesophagus that are directly related to the hiatal architecture and CODIS. This approach for this study is not adequately covered by common scores such as Visick score, Quality-of-life in Reflux and Dypepsia (QOLRAD), Gastrointestinal Symptom Rating scale (GSRS), SF-36 Health Survey, or GERD–HRQL (32-35).

The patient rating score must not be equated with an objective success of the operation. Nevertheless, it is important for the evaluation of this new surgical procedure to know whether or not patients are still basically satisfied with the operation performed, even years later (36).

Forth, the common guidelines for comprehensive preoperative diagnostics such as upper endoscopy, barium oesophagram, pH testing, and manometry, oropharyngeal pH testing, multichannel, and intraluminal impedance, in the context of patient selection for fundoplication, were not fully adopted in the indication concept of this study (37). However, these procedures serve to gain preoperative insights into the multifactorial pathogenesis of reflux disease and the disturbed functionality of the oesophagus in order to decide, whether and how fundoplication should be tailored to the individual's oesophagus function against the background of known side effects such as gas bloating, severe dysphagia, difficult belching, impossibility of vomiting, or whether these risks should not be taken at all.

It should be noted, however, that LOEHDE is a completely different surgical approach of sole anatomic reconstruction without wrapping, constriction or even suturing of the oesophagus. Since no definite histomorphological disease of the oesophagus was ever detectable, but only functional disturbances of the system, the oesophagus should be considered a priori as a healthy organ even in reflux patients.

This points to the central point of this study, which shows that stable repositioning of the oesophagus in the oesophagohiatal unit alone appears to restore all the various impaired functions. This clinically found interdependence of oesophagus position and function seems to confirm a new perspective on the oesophagus. These results are in full accordance with recent findings from cine-MRI and X-ray contrast swallow studies that the oesophagus might be a passive part of an interacting cardioesophageal peristaltic pump system. Data show the heart acting as the central pump that triggers rapid clearance and functional reflux control by a downward rollout impulse along the oesophagus, referred to CODIS (19). Correspondingly, data showed that the function of the system crucially depends on the exact position of the oesophagus in the three-dimensional set-up of the system, which is controlled by the oesophagohiatal unit (38). In this respect, endosonography of the oesophagus may become a promising diagnostic tool in future. These new pathophysiological findings seem to explain the successful recovery of the systems functionality after LOEHDE, which in fact focuses exclusively on the required three-dimensional repositioning of the oesophagus.

This observation clearly contradicts the common hypothesis of a diseased LES or entire oesophagus in reflux patients. It is also in marked contrast to studies showing that hiatoplasty alone is usually not sufficient to predictably cure patients without fundoplication (39). However, it must be considered that the usual surgical approach to hiatoplasty in the fundoplication procedure is only to close a hole in the diaphragm and not to restore function by reconstructing the crucial position of the oesophagus. Therefore, this part is commonly underestimated, and a variety of different techniques are used, such as dorsal, ventral, or both sutures, sutures too close together, jeopardising crural circulation, and still intracorporeal knotting techniques, which are not suitable to overcome the increasing traction forces in the upper part of the hiatus, so that just crura narrowing is often considered sufficient.

Several randomised trials that specifically dealt with crural closure have reported poor methodological quality. Studies have shown that a detailed technical description of this important surgical part is completely omitted from the methodology or is often casually dismissed as a mere routine posterior hiatus repair. However, if described at all, the crura are only approximated, leaving gaps as wide as 1–2 cm, so that the oesophagus may remain unstable in an incorrect dislocated position and the pathological opening between the abdominal and thoracic compartment persists (39-41). This procedure is clearly different from the stable reconstruction of the oesophagohiatal unit targeted by LOEHDE.

Undoubtedly, fundoplication as the common "gold standard" in reflux surgery can restore reflux control. The success of the fundoplication procedure has generally been attributed to gastric wrapping for the external support of the hypothetical LES. Surprisingly, however, the data do not show major differences in outcomes between 90°, 180°, 270°, and 360° fundoplication, which would undoubtedly be expected with such fundamentally different surgical procedures (42-44).

In view of the identified crucial importance of oesophageal ventralisation in the hiatus, the remarkable success of these various forms of fundoplication could be explained by the fact that the dorsal pull-through of the gastric cushion eventually pushes the oesophagus into its required elevated position in the hiatus, resulting in healing despite a possibly inadequate hiatoplasty. In this respect, a 90° or 360° wrapping should indeed be of secondary importance as demonstrated, rather than the actual volume of the gastric cushion, which in principle might give some more advantage in Nissen and Toupet procedures.

This suggests gastric wrapping thus seems to be more important to compensate for a potential inadequate hiatus reconstruction. Therefore, in the case of an anatomically correct rearrangement of the oesophagus from the outset, as in LOEHDE, fundoplication should be superfluous. Accordingly, the complete release of the cuff had no negative effect on any of the 48 operated fundoplication recurrences when followed by stable oesophageal repositioning according to LOEHDE and hiatal instability was proved to be the most important factor and main cause of recurrency in the other studies as well (45-47).

In this context, the unresolved question raises of why different types of hernia can cause different symptoms so that even different therapeutic approaches are discussed (48,49). With regard to the pathophysiological concept of CODIS, axial displacement of the stomach in type I hernia can easily compromise the cardiooesophageal junction, resulting in loss of reflux control. However, when the stomach slides strictly para-oesophageal in particular dorsal to the oesophagus, without pushing the oesophagus out of the cardiac pressure zone as in type II hiatal hernia, Patients have various symptoms such as incarceration, pain, dyspnoea, etc., but little or no symptoms related to CODIS function, e.g., reflux control. CODIS is still functional.

However, if the cardioesophageal junction becomes increasingly compromised, as in a type III mixed hiatal hernia, there will inevitably be a loss of reflux control as well.

The different symptoms of the different hernia types may therefore be explained by their different impact on CODIS. The correct anatomical reconstruction by LOEHDE therefore healed all patients in the same way regardless of the hernia type. However, the exact distribution of hernia types was not routinely recorded in this study, not least because in practice the pre- and intraoperative distinction between type I and III or type II and III in particular is imprecise. Para-oesophageal hernia was not found to be a risk factor for recurrence or other complications.

To achieve the crucial goal of long-term stability of the oesophagohiatal unit, the DeltaMesh was designed specifically for the requirements of a destructed hiatus (Appendix 4). The laparoscopic application of DeltaMesh has proven to be simple, effective and standardisable and significantly facilitates and accelerates hiatus closure. However, in this study, a total of 91/1,351 (6.7%) patients had a recurrence, including all hernia sizes, re-do surgeries, and postoperative risks in the everyday life of patients (*Table 1*). The recurrence rate during continuous follow-up increased to 7.2%, with seven additional recurrences observed between January 2017 and December 2019. Recurrence after LOEHDE was associated with renewed hiatus weakness and displacement around the oesophagus, while the DeltaMesh was still firmly integrated downwards into the crura in all patients. Re-LOEHDE in the weakened area caused the symptoms to disappear again.

Often no specific reason for the recurrence could be identified. However, risk factors were found to be long-lasting coughing, strong spontaneous pressing in the anaesthetic recovery phase during surgery, hiatus anatomy and the angle of crura insertion in the diaphragm, surgical misjudgement during reconstruction, impaired crura innervation presumably due to transcrural sutures, and crude postoperative endoscopy. Risk factors such as obesity, scoliosis, type of hernia, and heredity did not play a role in the emergence of recurrence.

It is still too early to examine the comparability of these results in the literature, given the wide range of different types of operations, major methodological differences in terms of indication, surgical technique, and definition and detection of recurrence, or lack of such information (41). Therefore, a methodologically standardised study protocol for hiatal hernias still seems necessary for reliable significance and comparability (36,50).

However, it is worth mentioning that re-operation after a previous fundoplication showed a comparable low recurrence rate of 8.3%. This success and the absence of intraoperative complications are probably due to the surgical focus being solely on re-stabilising the oesophagohiatal unit rather than risking re-fundoplication or other modified solutions (51-54).

As the worst DeltaMesh-associated complication, five patients experienced the penetration of the DeltaMesh into hollow organs even though the DeltaMesh was conceptually designed exclusively for extra-abdominal use to avoid such risks (55-57). Intervention was necessary in two cases of oesophagus penetration. The small size of the DeltaMesh clearly facilitated complication management and allowed purely endoscopic mesh removal and defect closure with fibrin glue. DeltaMesh penetration was an observed but rare complication that occurred only in patients after re-do or re-re-do surgeries with a heavily scarred intraoperative situation. These risks seemed acceptable to justify DeltaMesh use to improve the long-term results in hiatal hernia patients. However, the low follow-up rate of 14.8% and questionnaire response rate of 37.8% at T5 does not allow a conclusive statement.

## Conclusions

These clinical data from 1,351 patients treated with LOEHDE and the ongoing surgical experience demonstrate that reconstruction of the three-dimensional architecture of the oesophagohiatal unit alone can predictably restore reflux control and other impaired oesophageal functions. These data confirm the new pathophysiological finding that dysfunction of the oesophagus is due to its malposition in CODIS. The correct three-dimensional reconstruction of the oesophagohiatal unit thus seems to be the key to restoring all functions of the system. These results clearly contradict the common LES hypothesis.

The use of the DeltaMesh has proven to be a safe, efficient, and time-saving surgical tool for stable hiatus closure. These new findings can hopefully open a new approach to the pathophysiology of oesophageal function and new ways for diagnostics and therapy in the future.

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## Footnote

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Commission of the Ärztekammer Berlin, Friedrichstr. 16, D-10969 Berlin, Germany (approval number: Eth-56/20), and listed in the German Clinical Trial Register DRKS (registered number: DRKS00024357) being accepted by the WHO and the International Committee of Medical Journal Editors (ICMJE). Written informed consent was obtained from the patients for publication.



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