



# Mentorship Programs in Bariatric Surgery Reduce Perioperative Complication Rate at Equal Short-Term Outcome—Results from the OPTIMIZE Trial

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Published online: 5 September 2018

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## Abstract

**Objectives** The aim of this study was to determine the efficacy of coaching on outcome in low volume centers of excellence and to evaluate the influence of mentorship programs on the center development.

**Background** The number of bariatric procedures has increased steadily in the last years. Providing nationwide bariatric care on a high professional level needs structures to train and guide upcoming centers and ensure high quality in patient care.

**Methods** A prospective multicentered, observational study including laparoscopic sleeve gastrectomies (SG) and Roux-en-Y gastric bypass (RYGB) procedures was performed. Twelve emerging bariatric centers were coached by five experienced bariatric centers. Surgeons of the mentor centers gave guidance on pre- and postsurgical management of their patients including complications and proctored the first interventions. The results were compared regarding operative outcomes, percentage of excess weight loss, complications, and resolution of comorbidities.

**Results** A total of 214 of 293 patients (73.0%) completed the study. The most frequently reported complications were wound infection (4.4%), disorder of emptying stomach/new reflux (2.4%), anastomotic leaks, intra-abdominal secondary hemorrhage, and dumping syndrome (2.0% each). The mortality rate was zero. We found no difference in overall complication rates or resolution of obesity-related comorbidities when comparing experienced surgeons with less experienced surgeons.

**Conclusions** Our results suggest that under the conditions of the practices of this study, coaching and mentoring were associated with comparable outcomes both in experienced and emerging centers. In addition, mentorship programs ensure equal outcome quality in terms of improvement of obesity-associated comorbidities.

**Trial Registration** NCT Number: [NCT01754194](https://clinicaltrials.gov/ct2/show/study/NCT01754194).

**Keywords** Obesity · Bariatric surgery · Mentorship · Learning curve · Outcome

## Introduction

Obesity has become one of the major health risks in western society. In Germany, the prevalence of obesity, defined as a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>, is more than 22% [1].

Obesity is accompanied by several severe comorbidities such as type II diabetes (T2DM), hypertension, sleep apnea, or non-alcoholic steatohepatitis (NASH). The surgical treatment of obese patients in general, orthopedic and cardiac surgery is associated with higher complication rates [2–4]. Nevertheless, surgical treatment is the most effective option to improve comorbid conditions like T2DM in morbid obese patients [5] and providing long-term weight loss [6]. Consequently, the volume of bariatric surgery in Germany and worldwide has increased steadily in the last years [7, 8]. As a result, bariatric surgery is in great demand, and a high number of experienced surgeons and bariatric/metabolic centers are needed to provide comprehensive health care.

The introduction of laparoscopy to gastric bypass surgery in 1994 [9] led to a reduction of overall complication rates [10], but also increased the technical complexity of these

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procedures. Sleeve gastrectomy was believed to be less demanding, but shows comparable complication rates in several studies [11]. In conclusion, bariatric surgery especially laparoscopic Roux-en-Y gastric bypass (LRYGB) can be a technically challenging procedure, and surgeons must have the technical skill set to provide safe surgery and to ensure long-term success. As in other procedures, surgeons must overcome a demanding learning curve before mastering LRYGB. Previous studies reported a learning curve including 100 cases for reaching a significant reduction in morbidity [12]. Experience in advanced laparoscopy may shorten this learning curve for LRYGB [13]. In treating these high risk, obese patients, hospital as well as surgeon volume are modifiable risk factors for bariatric surgery [14, 15].

As a result, accredited centers for bariatric surgery perform the majority of bariatric procedures. Against the background of centralization, requirements for establishing new bariatric centers are high. Health care insurance approval is a prerequisite before performing bariatric procedures in Germany. Therefore, the financial uncertainty in planning and development of an obesity treatment center and provision of the necessary resources represent a major challenge for hospital operators. Mentorship programs could minimize the dilemma of a raising need for bariatric centers in times of higher requirements for accredited centers.

The aim of this study was to evaluate the influence of mentorship programs in establishing high-quality bariatric surgeons and to observe differences in outcome between established and emerging centers.

## Material and Methods

A prospective multicentered, observational, non-interventional study stratified for laparoscopic sleeve gastrectomies (SG) and Roux-en-Y gastric bypass (RYGB) procedures was performed. A total of 17 investigational centers recruited patients. Five centers were experienced bariatric referral centers (hereafter referred to as mentor centers) with at least 500 bariatric procedures over the last years performed. The remaining 12 centers had performed less than 50 procedures each and were considered emerging centers (hereafter referred to as mentee centers).

The sites consisted of a mix of experienced mentor centers and emerging bariatric referral mentee centers. The surgeons at the mentee centers had experience in advanced laparoscopic surgery with several years of performing upper abdominal laparoscopic surgery, but had minor experience in bariatric surgery. The aim was to provide structured procedure guidelines and training and therefore facilitating procedural adoption. Surgeons of the mentor centers trained, coached, and mentored the less experienced centers both on surgical as well as medical management of their bariatric patients. At mentee sites, the whole team was trained, while one surgeon was

instructed in bariatric surgery. A protocol was developed to ensure equal surgical technique as well as perioperative treatment. Also, mentors consulted the surgeons with less experience on pre and postsurgical management of their patients including complications and live proctoring at least the first six interventions, consisting of three laparoscopic sleeve gastrectomies and three Roux-en-Y gastric bypass cases. The indications were discussed in advanced by telephone. The investigator monitored the occurrence of intra- and postoperative complications for each patient during the course of the clinical evaluation or at time of major complications. In addition, a 24-h emergency cell phone line was set up by the coordinating center for additional daily support and direct reporting of serious complications, leading to guidance in the management of postoperative complications. Any event/experience that could be associated with the operative procedure was to be considered a complication and reported as such.

The target population included adult patients who were eligible for SG or RYGB weight loss surgery and had appropriate insurance approval status following the German Guidelines for Bariatric Surgery [16]. Target enrolment was 275 eligible patients from 17 sites within Germany.

For each patient, the study consisted of three phases: screening/baseline, surgery, and post-operative care for at least 12 months of follow-up. Data were gathered at each of the three study phases. The balance of the study was naturalistic and did not influence clinical practice in management of patients who had undergone bariatric surgery.

The inclusion criteria were as follows: Patients were aged from 18 to 65 years, with a body mass index (BMI) of  $> 40 \text{ kg/m}^2$  or a BMI  $> 35 \text{ kg/m}^2$  with additional weight-related comorbidities such as type II diabetes, hypertension, obstructive sleep apnea, or weight-bearing osteoarthropathy. As one of the objectives was the learning curve of less experienced centers, complex bariatric patients and patients featuring a BMI  $> 55 \text{ kg/m}^2$  were not the target group of this study. Patients were excluded from this study when planned for a two-stage procedure, when prior bariatric procedures had been performed (including gastric banding), when featuring mental or physical comorbidities at the discretion of the investigator, or when insurance approval was rejected. More complex bariatric patients were usually referred to the nearest mentor.

The study protocol, all study protocol amendments, written study patient information, informed consent form (ICF), and any other appropriate study-related information were reviewed and approved by an Independent Ethics Committee (IEC) or Institutional Review Board (IRB) at each study site. The study was also conducted with scientific purpose, value, and rigor and followed generally accepted research practices such as the International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines. Compliance with

these requirements also constitutes conformity with the ethical principles of the Declaration of Helsinki.

## Statistics

The statistical analyses were performed in accordance with ICH E9 guidelines. Analysis was performed using SAS® Software, Version 9.2 or higher. All analyses were performed for all patients in the study by type of surgical procedure. Appropriate methodology to control for the heterogeneous nature of the patients enrolled in this study and the practice patterns of investigators was used.

The data were summarized with respect to demographic and baseline characteristics and surgical observations and measurements. Categorical variables were summarized by absolute and relative frequencies. Continuous variables were summarized by descriptive statistics (number of valid and missing observations, mean, standard deviation [SD], median, minimum and maximum, and 95% confidence interval). All statistical tests were carried out at a significance level of  $\alpha = 0.05$  (two-sided). No adjustments for multiplicity of endpoints or within-subgroup comparisons were used in the analyses.

## Results

Of 304 patients who were screened, 293 were considered eligible for the study and included in the full analysis population (124 patients in the bypass group and 169 patients in the sleeve group). Eleven patients failed inclusion/exclusion criteria either before entry into the study or were subsequently found to have failed after they had entered the study. For details on patient demographics see Tables 1 and 2. Groups were comparable regarding BMI, age, sex, and comorbidities.

A total of 214 of 293 patients (73.0%) completed the study at 1-year follow-up (78.2% in the bypass group and 69.2% in the sleeve group). A total of 79 patients (27.0%) were withdrawn from the study (21.8% in the bypass group; 30.8% in the sleeve group). The most common reason for withdrawal was lost to follow-up (53 patients [18.1%]), followed by refusal to participate (7 patients [2.4%]), and inability to participate (1 patient [0.3%]). A reason was not specified for 16 patients (5.5%) of subjects, and 2 patients (0.7%) were withdrawn for other reasons (deployment to another country).

The overall incidence of intra-operative complications was low (1.7%; 4 of 241 observed patients): three patients in the bypass group with significant staple-line bleeding and one patient with an intraoperative insufficiency of the gastrojejunostomy stapler. Mortality rate was zero in both groups.

Comparing perioperative data, total operation time was significantly lower in mentor hospitals (mean: 118.87 min  $\pm$  SD 45.00 min) compared to mentee hospitals (mean

163.87 min  $\pm$  SD 47.86 min) in the RYGB group. Also operation time for sleeve gastrectomies was significantly lower in the mentor group (mean 74.18 min  $\pm$  SD 26.96 min) compared to mentee group (mean 92.24 min  $\pm$  SD 36.84 min). In the RYGB group, duration of hospital stay in days differs significantly in mentor group (mean 5.83 days  $\pm$  SD 4.03 days) vs. mentee group (mean: 7.9 days  $\pm$  SD 3.89 days). In Sleeve group, however, duration of hospital stay did not differ on a statistically significant level (mentor mean: 6.11 days  $\pm$  SD 4.27 days vs. mentee mean 7.29 days  $\pm$  SD 4.78 days). ICU duration time did not differ in mentor group neither in the RYGB group (mean 1.16 days  $\pm$  SD 0.125 days) vs. mentee (mean 1.21 days  $\pm$  SD 0.123 days) nor in the sleeve gastrectomy group (mentor mean 1 day  $\pm$  SD 0.00 days vs. mentee mean 1.26 days  $\pm$  SD 0.63 days).

All centers were required to record all post-surgery events whether they were surgical complications or not. After the final analysis, the Clavien-Dindo classification [17] was applied to differentiate the severity of complications. Recorded events which featured a Clavien-Dindo-score < III were considered to be “minor events,” whereas recordings which featured a Clavien-Dindo score  $\geq$  III were considered to be “major complications.”

Comparing mentor and mentee sites’ patients, major complication rates did not differ on a statistical significant level. In fact, the mentor sites featured a major complication rate of 10.1% while the mentee sites featured a complication rate of 9.7%. Also, the rates of minor events were about the same in both mentor (12.6%) and mentee sites (13.4%) and again, did not differ on a statistically significant level. Post-operative adverse events within 30 days of surgery were observed in 62 patients. The most frequently reported complications were wound infection (4.4% [13 patients]), also disorder of emptying stomach, new reflux (2.4% [7 patients]), anastomotic leaks, intra-abdominal secondary hemorrhage, and dumping syndrome (2.0% each [6 patients]).

Complications with a difference in reporting rate of  $\geq 10\%$  between Roux-en-Y gastric bypass and sleeve gastrectomy groups were anastomotic/staple line leaks (RYGB 14.3% vs. SG 3.1%) and disorder of emptying stomach/increased, new reflux (RYGB 2.9% vs. SG 18.8%). The most common measures taken were a re-laparoscopy (6.1%), gastroscopy (2.7%), or other unspecified measure (17.4%), such as nutritional advice, wound care, medications, and diagnostic tests.

The most notable difference between subgroups in any individual complication was for wound infection, which was reported by a higher percentage of patients in the mentee subgroup (6.7% [9 of 134 total patients]) than the mentor subgroup (2.5% [4 of 159 patients]). Other complications with a difference between subgroups of more than 10.0% were dumping syndrome (mentee 3.7% [5 of 134 total patients], mentor 0.6% [1 of 159 patients]), and urinary tract infection

**Table 1** Patient demographics

	Gastric bypass			Gastric sleeve			Total procedures		
	Mentor centers ( <i>n</i> = 77)	Mentee centers ( <i>n</i> = 47)	Total centers ( <i>n</i> = 124)	Mentor centers ( <i>n</i> = 82)	Mentee centers ( <i>n</i> = 87)	Total centers ( <i>n</i> = 169)	Mentor centers ( <i>n</i> = 159)	Mentee centers ( <i>n</i> = 134)	Total centers ( <i>n</i> = 293)
Age (years)									
Mean (SD)	44.4 (11.0)	42.1 (12.1)	43.5 (11.4)	42.3 (10.3)	44.9 (9.5)	43.6 (10.0)	43.3 (10.7)	43.9 (10.5)	43.6 (10.6)
Median	44.0	42.0	44.0	42.5	45.0	44.0	43.0	45.0	44.0
Min, max	21, 65	21, 62	21, 65	22, 63	20, 62	20, 63	21, 65	20, 62	20, 65
Height (cm)									
Mean (SD)	170.2 (9.4)	168.9 (9.1)	169.7 (9.3)	172.7 (9.1)	170.9 (9.7)	171.7 (9.4)	171.5 (9.3)	170.2 (9.5)	170.9 (9.4)
Median	170.0	169.0	169.5	172.0	169.0	170.0	171.0	169.0	170.0
Min, max	152, 204	153, 195	152, 204	155, 202	150, 196	150, 202	152, 204	150, 196	150, 204
Weight (kg)									
Mean (SD)	133.5 (19.8)	130.3 (20.8)	132.3 (20.2)	142.0 (21.0)	139.6 (20.3)	140.8 (20.6)	137.9 (20.8)	136.3 (20.9)	137.2 (20.8)
Median	131.5	128.0	129.6	142.5	140.0	141.0	134.2	134.5	134.2
Min, Max	94, 192	92, 183	92, 192	106, 198	99, 202	99, 202	94, 198	92, 202	92, 202
Body mass index (kg/m <sup>2</sup> )									
Mean (SD)	46.0 (5.0)	45.5 (4.9)	45.8 (5.0)	47.5 (4.4)	47.7 (4.9)	47.6 (4.6)	46.8 (4.8)	46.9 (5.0)	46.8 (4.9)
Median	46.1	45.0	45.5	47.0	47.9	47.6	46.6	46.6	46.6
Min, max	36.7, 54.5	37.4, 54.9	36.7, 54.9	36.7, 55.0	36.0, 54.9	36.0, 55.0	36.7, 55.0	36.0, 54.9	36.0, 55.0
Gender, <i>n</i> (%)									
Male	19 (24.7)	9 (19.1)	28 (22.6)	27 (32.9)	29 (33.3)	56 (33.1)	46 (28.9)	38 (28.4)	84 (28.7)
Female	58 (75.3)	38 (80.9)	96 (77.4)	55 (67.1)	58 (66.7)	113 (66.9)	113 (71.1)	96 (71.6)	209 (71.3)

(mentee, no patients; mentor 2.5% (4 of 159 patients] (Table 3).

The percentage of patients with post-operative complications after 30 days of surgery was similar across mentor and mentee subgroups within each surgical group. There were no marked differences between subgroups for individual complications. It should be noted that the number of patients within the subgroups who were reported with major complications 30 days after surgery were extremely small with 0.6%. We observed one patient with pulmonary embolism in the mentee subgroup and one patient with a late onset leakage in the mentor subgroup.

Excess weight loss (EWL) increased over the 12 months after surgery in both surgical groups. Adjusted mean AUC at month 12 in the bypass group was 169 (SD 5.9) and in the sleeve group was 168 (SD 6.0) compared with month 1 when the adjusted mean AUC was 9 (SD 0.8) and 9 (SD 1.3), respectively. Adjusted mean AUC for all patients at month 12 was 168.17 (SD 5.969) (Tables 4 and 5). No difference between mentor and mentee subgroup regarding EWL and decrease of BMI was observed (Fig. 1).

Diabetes remission after 1 year of follow-up was observed in 44.3% of all diabetic patients. The percentage of patients with diabetes remission was similar across mentor and mentee subgroups within each surgical group. No differences were observed regarding remission of hypertension and obstructive sleep apnoea (Table 6). Improvement in low-density lipoprotein (LDL) was better in the Roux-en-Y gastric bypass subgroup (*p* 0.001), but did not differ between mentor and mentee subgroup. There was no difference between groups regarding high-density lipoprotein (HDL) or triglycerides.

## Discussion

Our results suggest that bariatric surgery can be performed safely in emerging bariatric centers under the supervision of experienced surgeons with comparable complication rate. This is the first study demonstrating that interhospital mentorship programs and network building in bariatric surgery are useful in the development of bariatric programs and lead to similar results regarding outcome and weight loss.

**Table 2** Preoperative comorbidities

Comorbidities, <i>n</i> (%)	Gastric bypass ( <i>n</i> = 124)	Gastric sleeve ( <i>n</i> = 169)	Total ( <i>n</i> = 293)
Arthrosis	86 (69.4)	124 (73.4)	210 (71.7)
Arterial hypertension	71 (57.2)	97 (57.4)	168 (57.3)
Diabetes mellitus 2	49 (50.5)	48 (49.4)	97 (33.1)
Depression	32 (25.8)	35 (20.7)	67 (22.9)
Obstructive sleep apnoea (OSA)	27 (21.7)	24 (14.2)	51 (17.4)
Hypothyroidism	33 (26.6)	33 (19.5)	66 (22.5)
Gastroesophageal reflux	29 (23.4)	31 (18.3)	60 (20.5)
Dyspnoea, exertional	27 (21.8)	31 (18.3)	58 (19.8)
Bronchial asthma	18 (14.5)	25 (14.8)	43 (14.7)
Lymphoedema	22 (17.7)	9 (5.3)	31 (10.6)
COPD (chronic obstructive pulmonary disease)	9 (7.3)	7 (4.1)	16 (5.5)
Coronary heart disease	1 (0.8)	10 (5.9)	11 (3.8)
Cholelithiasis	2 (1.6)	8 (4.7)	10 (3.4)
Dyspnoea, resting	4 (3.2)	5 (3.0)	9 (3.1)
Cardiac insufficiency	2 (1.6)	5 (3.0)	7 (2.4)
Cardiac arrhythmia	2 (1.6)	4 (2.4)	6 (2.0)
Hyperthyroidism	2 (1.6)	2 (1.2)	4 (1.4)
Peripheral arterial disease	1 (0.8)	0 (0.0)	1 (0.3)

Fellowship programs in advanced laparoscopy are a result of the complexity of laparoscopic procedures and the steady need for bariatric centers in the USA [18]. There are no formal training programs in bariatric surgery in Germany or in other European countries. Bariatric training is mostly done through short training courses and mini-fellowships over a period of days or weeks. Previous studies have shown that these short training courses are not adequate for independent performance of laparoscopic bariatric surgery [19]. Adoption of these new procedures in the hospital of the less experienced bariatric surgeon is even more difficult. Some studies suggested that the complication rate can be reduced by the attendance of an experienced bariatric surgeon but were always surveyed in an established bariatric program [20, 21]. There is an increasing interest in educational strategies for physicians in the actual practice setting [22, 23]. Our aim was to introduce experienced laparoscopic surgeons to bariatric surgery and accompany surgical departments in safely building a bariatric program. Data on mentorship programs for experienced surgeons are lacking. In times of lifelong learning and accelerated development of new surgical techniques, new teaching methods are needed for surgeons throughout their whole career.

Mentorship programs in medicine are uncommon in Germany. Several concerns about mentoring and coaching exist especially in surgical professions. Data from an interview-based study with experienced surgeons reported concerns about whether coaching would risk portraying an image of incompetence or would restrict the surgeons autonomy and control [24].

Public and professional concerns about the quality of surgical outcomes associated with the rapid growth in bariatric surgery over the past decade led to the development of accredited centers. Data from the German bariatric surgery database reported a rise in bariatric procedures from 596 procedures in 2005 to 5824 procedures in 2012 [8]. Providing nationwide bariatric care on a high professional level needs structures to train and guide upcoming centers and ensure high quality in patient care. Building a network could raise new centers while maintaining requirements for the treatment of bariatric patients.

We found no difference in overall complication rate when comparing experienced surgeons with less experienced surgeons. In the present study, mortality rate was zero. Nguyen et al. showed data that low volume hospitals have a higher in-hospital mortality (1.2%) than high volume hospitals with more than 100 cases per year (0.3%). It was proposed that the improved outcomes observed at hospitals performing a high-volume of bariatric surgery may be a reflection of the presence of appropriate structural characteristics and formalized processes of care [14]. For the first sleeve gastrectomy cases included in the German bariatric surgery database between 2006 and 2007, the mortality rate was up to 1.4% [25]. Adoption of procedures as well as surveillance and guidance in case of major complications could have contributed to the better outcome in our study. We observed a slightly higher major complication rate in mentor sites (10.1% vs. 9.7% overall and 15.6% vs. 10.6% in RYGB) while it did not differ on a statistically significant level. A possible explanation could be

**Table 3** Postoperative complications within 30 days of surgery

	Gastric bypass		Gastric sleeve		Total procedures	
	Mentor centers ( <i>n</i> = 77)	Mentee centers ( <i>n</i> = 47)	Mentor centers ( <i>n</i> = 82)	Mentee centers ( <i>n</i> = 87)	Mentor centers ( <i>n</i> = 159)	Mentee centers ( <i>n</i> = 134)
Any postoperative complications within 30 days of surgery, <i>n</i> (%)						
Major complications (Clavien-Dindo Score > III)	12 (15.6)	5 (10.6)	2 (2.4)	5 (5.7)	14 (8.8)	10 (7.5)
Minor events (Clavien-Dindo Score < III)	7 (9.1)	11 (23.4)	11 (13.4)	9 (10.3)	18 (11.3)	20 (14.9)
Events observed total	19 (24.7)	16 (34.0)	13 (15.9)	14 (16.1)	32 (20.1)	30 (22.4)
If yes, specify postoperative complications within 30 days of surgery <sup>a</sup> , <i>n</i> (%)						
Secondary hemorrhage, endoluminal (grade III)	1 (1.3)	0	0	0	1 (0.6)	0
Secondary hemorrhage, intra abdominal (grade III)	2 (2.6)	0	0	4 (4.6)	2 (1.3)	4 (3.0)
Urinary tract infection (grades I–II)	2 (2.6)	0	2 (2.4)	0	4 (2.5)	0
Pneumonia (grades I–II)	0	0	1 (1.2)	0	1 (0.6)	0
Acute renal failure (grade I)	0	0	0	1 (1.1)	0	1 (0.7)
Sepsis (grade I)	1 (1.3)	0	0	0	1 (0.6)	0
Pulmonary embolism (grade I)	0	1 (2.1)	1 (1.2)	0	1 (0.6)	1 (0.7)
Intra abdominal abscess (grade III)	3 (3.9)	0	0	0	3 (1.9)	0
Wound infection (grade II)	2 (2.6)	5 (10.6)	2 (2.4)	4 (4.6)	4 (2.5)	9 (6.7)
Anastomotic leak (grade III)	4 (5.2)	1 (2.1)	0	1 (1.1)	4 (2.5)	2 (1.5)
Mechanical ileus (grade III)	1 (1.3)	0	0	0	1 (0.6)	0
Anastomotic stenosis (grade III)	1 (1.3)	1 (2.1)	0	0	1 (0.6)	1 (0.7)
Disorder of emptying stomach/increased, new reflux (grade II)	1 (1.3)	0	4 (4.9)	2 (2.3)	5 (3.1)	2 (1.5)
Hernia, internal (grade III)	0	1 (2.1)	0	0	0	1 (0.7)
Hernia, external (grade III)	0	1 (2.1)	0	0	0	1 (0.7)
Pancreatitis (grades I–II)	0	0	0	1 (1.1)	0	1 (0.7)
Symptomatic cholelithiasis (grades I–II)	1 (1.3)	1 (2.1)	0	0	1 (0.6)	1 (0.7)
Dumping syndrome (grade II)	0	4 (8.5)	1 (1.2)	1 (1.1)	1 (0.6)	5 (3.7)
Anastomotic ulcer (grade III)	0	0	1 (1.2)	0	1 (0.6)	0
Infected hematoma (grade III)	0	0	1 (1.2)	0	1 (0.6)	0
Leak small gut (grade III)	0	1 (2.1)	0	0	0	1 (0.7)
Death	0	0	0	0	0	0
Measures taken based on complications, <i>n</i> (%)						
Gastroscopy	2 (2.6)	3 (6.4)	1 (1.2)	1 (1.1)	3 (1.9)	4 (3.0)
Re-laparoscopy	8 (10.4)	4 (8.5)	2 (2.4)	4 (4.6)	10 (6.3)	8 (6.0)
Re-laparotomy	2 (2.6)	1 (2.1)	0	0	2 (1.3)	1 (0.7)
Sonographic controlled puncture	1 (1.3)	0	0	0	1 (0.6)	0

<sup>a</sup> Percentages may total to greater than 100% since more than one complication or measure may have occurred during surgery

that experienced centers treated higher risk patients than the emerging centers.

We observed a leak rate of 2.5% in mentor sites and 1.5% in mentee sites, which is comparable to the data of the nationwide registry. In the time of formation of several new bariatric centers, data from the German bariatric surgery database reported leak rates of 3.3% for RYGB in 2008 and 7.0% for sleeve in 2007 [8]. Our results show comparable low leakage rates in experienced as well as in less experienced centers and can also be a result of procedural adoption.

Major complication rate for RYGB was 15.6% in mentor sites and 10.6% in mentee sites. In comparison, major complication rate for sleeve gastrectomy was 2.4% in mentor sites and higher in mentee sites with 5.7%. These findings are different than other studies [11]. A possible reason is that other studies mainly analyzed cases performed by experienced bariatric surgeons. Some authors described a learning curve of 100–150 procedures in Roux-en-Y gastric bypass, with a high rate of major complications (12.5%) in the first 70 procedures [26]. Another study about the learning curve of a skilled

**Table 5** Excess weight loss (EWL)—by surgery type in mentee sites

Month post-surgery	Gastric bypass ( <i>n</i> = 49)				Gastric sleeve ( <i>n</i> = 88)			
	Unadjusted		Adjusted <sup>a</sup>		Unadjusted		Adjusted <sup>a</sup>	
	EWL (%)	AUC	EWL (%)	AUC	EWL (%)	AUC	EWL (%)	AUC
<b>Month 6</b>								
Observed	34	34	49	49	63	63	88	88
Mean (SD)	49 (15.5)	128 (40.5)	48 (1.2)	122 (1.6)	47 (15.9)	122 (39.9)	47 (1.8)	122 (3.3)
Median	48	122	48	122	47	125	48	122
Min, max	(25.8, 96.2)	(71.7, 247.9)	(45.0, 53.8)	(117.4, 131.3)	(8.0, 83.3)	(12.0, 205.3)	(38.0, 52.4)	(107.0, 135.3)
<b>Month 12</b>								
Observed	32	32	49	49	52	52	88	88
Mean (SD)	61 (17.2)	176 (50.9)	58 (2.8)	169 (8.6)	56 (20.4)	162 (59.7)	58 (2.5)	168 (5.8)
Median	62	176	58	169	59	170	58	169
Min, max	(34.6, 97.9)	(100.6, 310.3)	(50.0, 73.4)	(144.9, 215.9)	(1.3, 107.1)	(11.4, 310.0)	(48.6, 65.4)	(147.8, 183.0)

For unadjusted (raw) values, the number of observations at each month corresponds to the number of patients completing the assessment at that timepoint. For adjusted values, the number of observations corresponds to the number of patients

*SD* standard deviation, *AUC* area under the curve

<sup>a</sup> Values adjusted using propensity score method

laparoscopic surgeon, the rate of major complications was reduced significantly from 13% in the first 75 RYGB to 3% in the next 75 procedures [27]. Our data suggest better peri-operative outcome after sleeve gastrectomy even in less experienced centers. One should consider incorporating sleeve gastrectomies in bariatric surgery programs due to its technical less challenging performance and a stepwise approach in bariatric surgery training.

The most common complication in our cohort were wound infections which were more common in patients operated by less experienced surgeons. These findings are similar with other studies on surgical site infections in other procedures than bariatric surgery, where patients operated by surgeons with a low operation volume seem to have a higher risk of developing an infection [28]. Another complication with a difference between subgroups was the occurrence of a

**Table 4** Excess weight loss (EWL)—Gastric bypass by surgery type in mentor sites

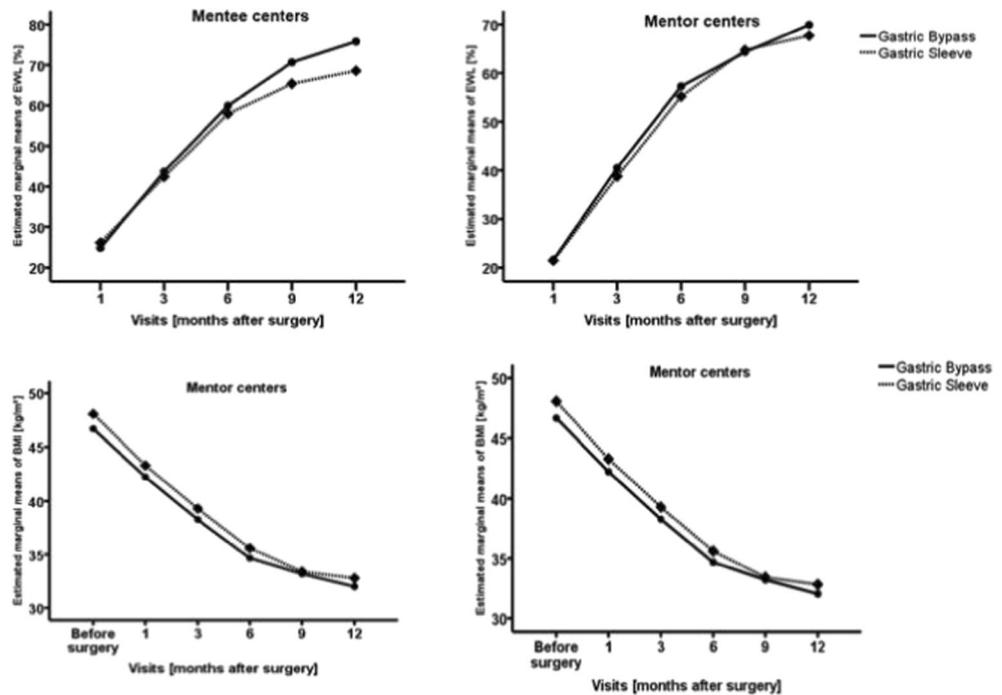
Month post-surgery	Gastric bypass ( <i>n</i> = 80)				Gastric sleeve ( <i>n</i> = 82)			
	Unadjusted		Adjusted <sup>a</sup>		Unadjusted		Adjusted <sup>a</sup>	
	EWL (%)	AUC	EWL (%)	AUC	EWL (%)	AUC	EWL (%)	AUC
<b>Month 6</b>								
Observed	57	57	80	80	66	66	82	82
Mean (SD)	49 (11.9)	124 (27.8)	47 (1.1)	122 (4.0)	46 (11.1)	117 (26.8)	47 (1.6)	122 (2.4)
Median	48	122	48	122	47	118	48	122
Min, max	(25.5, 84.1)	(72.2, 181.2)	(44.0, 53.6)	(116.4, 154.3)	(21.1, 70.3)	(54.7, 176.8)	(35.2, 50.8)	(103.5, 126.9)
<b>Month 12</b>								
Observed	56	56	80	80	58	58	82	82
Mean (SD)	60 (15.4)	170 (45.5)	58 (1.3)	169 (3.3)	56 (15.6)	162 (44.9)	58 (2.1)	167 (6.2)
Median	58	161	58	169	56	163	58	169
Min, max	(21.1, 96.4)	(81.2, 290.6)	(52.3, 66.9)	(152.6, 183.0)	(19.7, 88.8)	(62.1, 263.0)	(45.7, 62.1)	(143.0, 181.8)

For unadjusted (raw) values, the number of observations at each month corresponds to the number of patients completing the assessment at that timepoint. For adjusted values, the number of observations corresponds to the number of patients

*SD* standard deviation, *AUC* area under the curve

<sup>a</sup> Values adjusted using propensity score method

**Fig. 1** Excess weight loss (EWL) and BMI improvement in mentor and mentee centers. EWL and BMI showed no difference between surgical groups



dumping syndrome that was more common in mentee sites. The rate in mentee sites was 3.7% which is much lower than in other studies [29].

Excess weight loss showed no difference between mentor and mentee sites as well as between both types of surgery after 1 year. Remission of comorbidities was common in all groups. Comparing laparoscopic sleeve gastrectomies and Roux-en-Y gastric bypass (RYGB) procedures, we found no difference

regarding remission of type II diabetes, hypertension, or obstructive sleep apnea. Decrease of low-density lipoprotein was the only significant serum marker differing between RYGB and sleeve gastrectomy. This is comparable to other studies and maybe a consequence of an assumable better, metabolic effect of RYGB [30]. Remission of type II diabetes (T2DM) did not differ between mentor and mentee sites and between sleeve gastrectomy and RYGB after 1 year. This is the first

**Table 6** Remission of comorbidities—by surgery type in mentor and mentee sites

			<i>n</i>	Procedure		Total	<i>p</i> value
				Gastric bypass	Gastric sleeve		
Mentee	Type II diabetes status 1-year follow-up	Type II diabetes remission	11	14	25	n.s.	
		%	21.6	27.5	49.0		
Mentor		Type II diabetes remission	14	4	18	n.s.	
		%	30.4	8.7	39.1		
Total		Type II diabetes remission	25	18	43	n.s.	
		%	25.8	18.6	44.3		
Mentee	Hypertension status 1-year follow-up	Hypertension remission	14	17	31	n.s.	
		%	16.9	20.5	37.3		
Mentor		Hypertension remission	19	13	32	n.s.	
		%	22.4	15.3	37.6		
Total		Hypertension remission	25	18	43	n.s.	
		%	60.9	39.1	100.0		
Mentee	OSAS status 1-year follow-up	OSAS remission	5	4	9	n.s.	
		%	18.5	14.8	33.3		
Mentor		OSAS remission	5	3	8	n.s.	
		%	20.8	12.5	33.3		
Total		OSAS remission	10	7	17	n.s.	
		%	19.6	13.7	33.3		

study demonstrating that bariatric surgery mentored by less experienced surgeons is comparably efficient as compared to surgery by experienced surgeons in the improvement of type 2 diabetes. In our study, type II diabetes remission was observed in a total of 49.0% of the patients who underwent LSG or RYGBP mentee subgroup as compared with 39.1% of those who underwent surgery by experienced surgeons. These rates are somewhat lower as compared to the results of previous trials on short-term type II diabetes remission after bariatric surgery reporting of diabetes remission rates around 63% [31]. These differences may be due to differences in the study design including patient characteristics such as age, sex, BMI, or duration of diabetes. Another reason can be differences in decision-making by mentor and mentee surgeons regarding the indication for sleeve gastrectomy or RYGB. More follow-up data is needed to compare the experience of the surgeon with long-term weight loss and resolution of comorbidities.

Our study has several other limitations. More data on long-term outcome is needed to evaluate the influence of this mentorship program on weight loss and resolution of comorbidities. As an observational study, a selection bias cannot be excluded. In addition, we observed a follow-up rate of 73% after 1 year, which seems relatively low but is higher than the national average of less than 50% [32]. One of the weaknesses in evaluating the experience–outcome relationship is the limited use of risk adjustment. Nevertheless, one advantage of this study is the observational study design, producing “real-life” data and describing for the first time, the situation of bariatric training and center building in Germany and the feasibility of mentorship programs in bariatric surgery.

## Conclusion

Our results show that bariatric surgery under guidance of experienced bariatric surgeons can be provided with equal complication rates at emerging bariatric centers. The development of bariatric surgery with a high standard of care and with low complication and mortality rates allows the increase of bariatric surgical centers under the supervision of experienced mentors. Furthermore, there was no significant difference in terms of resolution of obesity-related comorbidities based on experience in this study. Building a network between bariatric centers led to an active exchange between mentor and mentees. A mentorship program for experienced surgeons can be a useful tool in the further development of emerging bariatric centers.

**Acknowledgments** The authors like to thank the participating hospitals for their commitment: Krankenhaus Bad Cannstatt, Stuttgart, Germany; Bundeswehr Krankenhaus Berlin, Berlin, Germany; Franziskus Hospital Bielefeld, Bielefeld, Germany; Klinikum Bremerhaven-Reinkenheide, Bremerhaven, Germany; Amperklinikum Dachau, Dachau, Germany; Kreiskrankenhaus Emmendingen, Emmendingen, Germany;

Universitätsklinik Hamburg Eppendorf, Hamburg, Germany; Ev. Krankenhaus Herne, Herne, Germany; Klinikum Itzehoe, Itzehoe, Germany; Marienkrankenhaus Kassel, Kassel, Germany; Krankenhaus Luebbecke, Luebbecke, Germany; Sana Klinikum Lübeck, Lübeck, Germany; Diakoniekrankenhaus Mannheim, Mannheim, Germany; Krankenhaus Hetzelstift Neustadt/Weinstraße, Neustadt, Germany; Thüringen-Kliniken “Georgius Agricola”, Saalfeld, Germany; Schwarzwald Baar Klinikum Villingen, Villingen-Schwenningen, Germany; and Krankenhaus Winsen, Winsen (Luhe), Germany.

**Funding** Medtronic MITG supported the study.

## Compliance with Ethical Standards

The study protocol, all study protocol amendments, written study patient information, informed consent form (ICF) and any other appropriate study-related information were reviewed and approved by an Independent Ethics Committee (IEC) or Institutional Review Board (IRB) at each study site. The study was also conducted with scientific purpose, value, and rigor and followed generally accepted research practices such as the International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines. Compliance with these requirements also constitutes conformity with the ethical principles of the Declaration of Helsinki

**Conflict of interest** The authors have no financial support or commercial associations that may be a conflict of interest in relation to this article.

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