

# Laparoscopic clips can be a safe buttressing method for the sleeve gastrectomy operations: An experimental study on resected sleeve gastrectomy specimens

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**Ethics Committee Approval**

Ethics Committee approval was taken from the Ethics Committee of Keçiören Training and Research Hospital (B.10.4.ISM.4.06.68.49/2015, date: 11.03.2015).

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

**Conflict of Interest**

No conflict of interest was declared by the authors.

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**Abstract**

**Background/Aim:** Laparoscopic sleeve gastrectomy has been accepted in obesity surgery, as it provides rapid weight loss and has low mortality rates. However, because of the long staple line, leakage is a significant problem for these patients. Buttressing methods can be used to reduce the leakage. The aim of this study was to evaluate the efficacy of clips for buttressing the staple line on resected sleeve gastrectomy patients.

**Methods:** The study included 20 patients aged 18–60 years who underwent laparoscopic sleeve gastrectomy surgery in our clinic. Any patients with connective tissue disease or with the removed stomach tissue not intact were excluded from the study. The age, gender, height, weight, and additional disease data were recorded. A manual manometer and inflation mechanism was created, and when the pressure suddenly dropped and a bubble was observed from the staple line, this value was recorded as the leakage pressure. By measuring the leakage pressure in the staple line by inflating the resected and removed stomach, leakage pressure and leakage location were recorded as no-clip leakage pressure. Then, the observed area of leakage was buttressed with laparoscopic clips, and the leakage pressure was measured once more by inflating the stomach; this value was recorded as the clipped leakage pressure.

**Results:** The first pressure value observed had a mean of 43.8mmHg (range, 35–55 mmHg); after application of the clips, the mean was 43.8 mmHg (range (40–50 mmHg) ( $P = 0.20$ ). The leakage was located in the upper section in 14 (70%) cases, in the mid-section in 5 (25%) cases, and in the lower section in 1 (5%) case. Micro-leakage was observed in 15 (75%) cases, 1-mm leakage in 1 (5%) case, 2-mm leakage in 2 (10%) cases, and 3-mm leakage in 2 (10%) cases.

**Conclusion:** Leakage is the most significant complication following sleeve gastrectomy surgery. The use of laparoscopic clips was described as a buttressing method, but no positive effect of metal clips on leakage pressure was observed in our study. Clarification of the effect of the buttressing with metallic clips is required using *in vivo* and *ex vivo* experiments.

**Keywords:** Obesity, Sleeve gastrectomy, Leakage

## Introduction

Laparoscopic sleeve gastrectomy was first applied as a part of biliopancreatic diversion operations [1]. Over time, it came into use in obesity surgery due to its low mortality rates and the provision of rapid weight loss [2]. However, because of the long staple line, leakage is a significant problem in these operations. To prevent this problem, tissue adhesives, sutures, and laparoscopic clips are used to buttress the staple line; however, their efficacies have not been proven [3–5]. This study examined the maximum pressure that the gastric resection staples could withstand. Then, we evaluated whether reinforcing clips applied to leakages in the staple line were useful in preventing leakage.

## Materials and methods

The study was conducted at Keçiören Training and Research Hospital. Approval for the study was granted by the Ethics Committee of Keçiören Training and Research Hospital (B.10.4.ISM.4.06.68.49/2015), and informed consent was obtained from all of the voluntary participants. Power analysis was calculated using G\*Power 3 (Faul, Erdfelder, Lang, & Buchner, 2007) to test the difference between two independent group means using a two-tailed test, with a medium effect size ( $d = 0.50$ ) and an alpha of 0.05. The results revealed that a total sample size of 20 participants was required to achieve a power of 80 [6]. The study included selected patients aged 18–60 years who presented at the General Surgery Obesity Clinic and for whom sleeve gastrectomy surgery was planned. Any patients with connective tissue disease or with the removed stomach tissue not intact were excluded from the study. The age, gender, height, weight, and additional disease data were recorded. After removal of stomach tissue, the stomach dimensions were measured as length and upper 1/3 width, mid-1/3 width, and lower 1/3 width, and recorded. The width measurements were made in the mid-section of the area being measured. The stomach corpus level was opened with a 0.5-cm incision from the staple line. By applying purse sutures around this area, a Foley probe was advanced from here and inflated. A manual manometer and inflation mechanism was created over the Foley probe. By inflating the stomach, the leakage pressure in the staple line was measured, and this value and the leakage location were recorded (Figure 1). The stomach was inflated and the maximum pressure the stapler line could withstand was recorded. Then the leak point was reinforced with the clip and the pressure was measured again (Figure 2).

### Statistical analysis

Statistical analyses were performed using SPSS software version 18. The variables were investigated using analytical methods to determine whether the variables are normally distributed. The paired Student's *t*-test was used to compare the measurements at two time points (first leakage/without clips, after clips). A *P*-value of less than 0.05 was considered to show statistical significance.

Figure 1: Micro-leakage in mid-1/3 width.



Figure 2: Buttressing the staple line with laparoscopic clip.



## Results

The study included evaluations of stomach tissue removed from 20 patients following laparoscopic sleeve gastrectomy. The sample comprised 7 (35%) males and 13 (65%) females, with a mean age of 39.3 years (range, 21–54 years) and a mean BMI of 46.4 (range: 38.5–58.4). In 9 (45%) patients, there was a history of chronic disease (Table 1). The mean operative time was 52 minutes, and 5 out of the 20 patients were smokers.

Table 1: Demographic characteristics and leakage information

	n = 20
Age*	39.3 (21–54)
Gender – female, n(%)	13 (65)
BMI*	46.4 (38.5–58.4)
Comorbid disease	9 (45)
Smoking	5 (25)
Leakage, n(%)	
Upper section	14 (70)
Mid-section	5 (25)
Lower section	1 (5)
Leakage pressure value	
First observed*	45.3 (35–60) mmHg
After the application of the clips*	42.3 (30–55) mmHg

\* median (IQR: interquartile range)

The measurements of the removed stomach tissue were as follows: mean length 24.2 cm (range, 15–32 cm), upper third width 4.8 cm (4–7 cm), mid-third width 4.6 cm (3–6 cm), and lower third width 3.8 cm (3–5 cm). The mean first pressure value of the observed leakage was 45.3 mmHg (range, 35–60 mmHg); after application of the clips, the mean was 42.3 mmHg (range, 30–55 mmHg) ( $P = 0.20$ ).

After the application of the clips, 20 (100%) of the leakages occurred under the clips. The mean maximum pressure

applied to the stomach tissue was 187 mmHg (range, 150–200 mmHg). The leakage was in the upper section in 14 (70%) cases, in the mid-section in 5 (25%), and in the lower section in 1 (5%) case. Micro-leakage was observed in 15 (75%) cases, 1-mm leakage in 1 (5%) case, 2-mm leakage in 2 (10%) cases, and 3-mm leakage in 2 (10%) cases.

## Discussion

One of the most important problems following sleeve gastrectomy operations is leakage. The long staple line makes locating the leakage difficult. Previous studies have touched on the challenges of determining the leakage size and location [7, 8]. In this study, there were difficulties in locating the leak since the leaks caused by the application of pressure were generally at the micro level. Therefore, liquid soap was used to locate the leak. As it is difficult to determine the leakage location in an experimental environment, it is even more difficult in clinical environments. Clinicians have opted for using low-pressure contrast or dye to minimize contamination at the leakage site, as such contamination increases the difficulty of clinical diagnosis.

Leakages occurring after sleeve gastrectomy surgery are as serious a problem in diagnosis as in treatment. Although there is not a complete algorithm for treatment, the priority must be stabilization of the patient, followed by percutaneous drainage. Furthermore, endoscopic procedures should be applied prior to surgery [7]. In the current study, the defects occurring after pressure were millimetric. If there is no tissue bleeding or distal obstruction, a fistula of this size can be expected to be closed with non-operative techniques.

In clinical observations, staple line leakages following gastrectomy are generally near the gastro esophageal junction. This can be due to surgical technical difficulties, anatomical, physiological, or physical reasons [2]. In the current study, the leakages were determined to be in the mid-section in 14 (70%) cases and in the upper section in 5 (25%) cases. No leakage was observed in the end sections. Leakages occurred associated with millimetric tears of the tissue from the staples, due to the tension of the staple line. The reasons for more leakages in these areas can be explained by Pascal's Law. In areas where the radius is greater, areas of greater surface tension are formed, and leakages occur due to the staple cut.

Leakage pressures in stomach tissue removed after sleeve gastrectomy have been previously researched. López-Monclova et al. [9] determined a mean leakage pressure of 35 mmHg in the staple line, using a special mechanism. In the current study, the mean value of the leakage pressure was 45.3 mmHg (range, 35–60 mmHg). The differences in these pressures could be due to the differences in methodologies used.

There are many methods to buttress the staple line during sleeve gastrectomy operations, such as oversewing, or using biomaterials or metallic clips; however, the utility of such methods in sleeve gastrectomy operations has been a matter of debate. Specifically, clinical research showed that there is no difference between the buttressed and non-buttressed groups. On the other hand, experimental studies revealed that the buttressed group had better outcomes than the non-buttressed group [3, 5, 10–12]. Our study revealed that buttressing with metallic clips did not result in better outcomes.

In our previous study, we studied the same pressure model on resected sleeve gastrectomy specimens in three groups. It revealed that, in the sutureless group, the knotless suture group and the knotted suture group, the pressure levels causing leakage were 42.7 (1), 98.7 (3.9), and 97.7 (4.1) mmHg, respectively. Buttressing with sutures increased the bursting pressures significantly [11]. However, in our recent study, buttressing with metallic clips had the same bursting pressure as the nonbuttressed group (42.3 mmHg). It should be noted that we calculated our sample size with the pressure level of the other buttressing techniques. More samples are needed to make inferences with such similar pressure values.

In their prospective randomized clinical study, Yiğit et al. [12] concluded that buttressing the staple line with metallic clips was effective in terms of leakage. However, in our study, we could not observe any positive effect of metallic clips to support the staple line. This discrepancy indicates that leakage after sleeve gastrectomy operations depends not only on pressure, but also on other, complex factors. In the current study, the pressure level that the clip-supported regions can withstand was found to be 42.3 mmHg (range: 30–55 mmHg). All of the leaks occurred in areas where clips were placed. The leaks in areas where the clips were placed occurred through the sliding of the clip due to the tension created by the stomach inflation. This evidence suggests that buttressing the staple line with metallic clips may not be safe.

## Limitations

The most important limitation of this study was its reliance exclusively on mechanical factors. Physiological etiopathogenetic factors, which play important roles in leakage mechanisms, were not investigated. We calculated our sample size with the pressure level of the other buttressing techniques. More studies are needed to make inferences with such similar pressure values, which will enable us to better understand the complex etiopathogenesis of these leakages.

## Conclusion

Leakage is the most significant complication following sleeve gastrectomy surgery. Buttressing methods can be used to prevent this complication. Although there are few studies that argue that metal clips can be a reinforcement method, no positive effect of metal clips on leakage pressure was observed in our study. Clarification of the pathophysiology is required to be able to overcome difficulties in diagnosis and treatment.

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