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Prospective randomized controlled trial of the closure of gastrojejunal anastomosis in RYGB with absorbable and inabsorbable thread

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Abstract

Introduction: The Roux-en-Y gastric bypass (RYGB) is, currently, the most performed technique in Brazil. Suture threads are classified according to their degradation properties. **Objective:** To analyze the influence on the size of the gastrojejunal anastomosis performed in Roux-en-Y gastric bypass surgery, as well as the main complications with the use of absorbable or inabsorbable thread. **Methods:** This study followed a prospective and randomized clinical trial, initially with 40 participants, with only 37 participants being duly selected, 19 of whom underwent gastrojejunostomy closure with an absorbable (Abs) polydioxanone suture (PDS II®) and 18 with the inabsorbable (Inb) ETHIBOND®. Statistical analysis was performed using the ANOVA and logistic regression tools ($p<0.05$ significant). **Results:** General complications and Upper Digestive Endoscopy (UDE) were less frequent at the end of 12 months in both groups. At the end of twelve months, the number of complications of the Inb thread decreased considerably, while the number of complications of the Abs thread showed an increase in other complications, including marginal ulcer and intrusive thread. Despite this, there was no significant difference between groups in terms of total weight loss. There was no statistically significant difference between the final values of the anastomotic diameter. The percentage of weight loss over the 12 months was 33.77 ± 6.97% for the Inb group and 36.10 ± 4.89% for the Abs group ($p<0.05$). **Conclusion:** Both suture threads (Inb and Abs) presented similar complications and did not present significant differences between the values of weight, gastrojejunal anastomosis, and pouch.

Keywords: Roux-en-Y gastric bypass. Gastrojejunal anastomosis. Absorbable thread. Inabsorbable thread. Complications.

Introduction

Obesity represents a multifactorial disease that causes serious public health problems **[1]**. There are 2.0 billion overweight and obese people in the world **[1,2]**, and Brazil is in fifth place in the world ranking **[3]**. The prevalence of patients with morbid obesity is increasing worldwide. In Brazil, there was an increase of approximately 7.1% in the frequency of obese patients. Accompanying this growth, the number of bariatric surgeries performed also increased, registering 100 thousand operations in 2016 **[3]**.

In this context, RYGB is currently the most performed technique in Brazil **[4]**. The main reason for this preference is given by the fact that the metabolic mechanism that the surgery promotes, associated with restrictive and disabsorptive factors. Long-term weight regain is observed in approximately 20% to 30% of patients **[5]**. Of these, approximately 58.9% present dilatation of the gastrojejunal anastomosis (GJA) **[6,7]**. In this sense, GJA directly influences the restrictive factor of bariatric surgery for delaying the progression of food, but its size is still controversial **[7]**. In this context, little has been documented about the type of

thread used to close this anastomosis, to the increase in postoperative diameter **[8-10]**.

In this scenario, suturing is a technique that has been used for at least 4,000 years, has evolved in terms of the materials chosen. Organic materials are destroyed by proteolysis, in contrast to synthetics that undergo hydrolysis and which are therefore associated with less inflammatory reactions. Currently, most natural materials have been replaced by synthetic materials although silk, despite being a natural material, is still widely used **[11]**.

In this respect, configuration, handling, tension strength, and tissue reaction are inherent properties of sutures. The configuration refers to the number of layers that make up a thread, which can be formed by monofilaments that are associated with less infectious risk and less tissue trauma, or multifilaments with greater tensile strength, more flexible, easier to handle and the coated ones are more suitable for intestinal procedures **[12]**.

Sutures are classified according to their degradation properties. Sutures that undergo rapid tissue degradation, losing their traction strength within 60 days, are considered absorbable sutures. Sutures that generally maintain their tensile strength for longer than 60 days are non-absorbable **[13]**. Thus, absorbable sutures can be used to hold the wound edges in approach temporarily, until they have healed enough to withstand tissue stress. These sutures are prepared from either mammalian collagen or synthetic polymers. Some are absorbed quickly, while others are chemically treated to increase the absorption time. They can also be impregnated or coated with agents that improve their handling and have an FDA-approved coloring to increase fabric visibility **[14]**.

Also, absorbable natural sutures are digested by body enzymes that can degrade the suture thread. Absorbable synthetic sutures are hydrolyzed, causing the polymer to break. Hydrolysis results in a lower degree of tissue reaction after implantation during the first phase of the absorption process, yet the tensile strength decreases gradually, almost linearly. This occurs during the first few weeks after implantation **[15]**.

The second phase follows with considerable overlap, characterized by loss of suture mass. Both steps exhibit leukocyte cell responses that serve to remove cellular debris and tissue suture material. A suture can lose tensile strength quickly and still be absorbed slowly, or it can maintain adequate tensile strength through wound healing, followed by rapid absorption. In any case, the yarn is eventually completely dissolved. Although they offer many advantages, absorbable sutures also have certain inherent limitations **[14,15]**.

In that sense, if a patient has a fever, infection, or protein deficiency, the suture absorption process can accelerate, causing a very rapid decline in traction force. Also, if the sutures become wet or damp during handling, before being implanted in the tissue, the absorption process can begin prematurely **[13]**. Regarding non-absorbable sutures, they are not degraded by enzymes or hydrolyzed in the tissue body. They are made from a variety of non-biodegradable materials and are encapsulated or blocked by the body's fibroblasts. Non-absorbable sutures usually remain in the same location within the tissues and are composed of single or multiple filaments **[15]**.

As an example of absorbable thread, the suture thread made of polyester (p-dioxanone, PDS II®) is a monofilament that presents softness, flexibility, and durability for up to 6 weeks. It causes only a slight tissue reaction **[16]**. This material is suitable for many types of soft tissue approach, including cardiovascular, pediatric, orthopedic, gynecological, ophthalmic, plastic, digestive, and colonic surgery. Approximately 70% of the traction force remains for 2 weeks post-implantation, 50% in 4 weeks, and 25% in 6 weeks. Absorption is minimal until about 3 months after surgery and ends in 6 months. However, the safety and efficacy of PDS II® in microsurgery, neural and cardiovascular tissue has not been established. PDS II® sutures are available transparent or dyed violet to improve visibility **[16]**.

The sutures performed by the ETHIBOND EXCEL® polyester thread are uniformly coated with polybutylene, being a biologically inert, non-absorbable compound that adheres to the braided polyester fiber cord. The coating facilitates the passage of the braided filaments through the fabric and provides excellent flexibility, handling qualities, and smooth tying with each toss of the knot. Sutures cause minimal tissue reaction and retain their strength in vivo for long periods. ETHIBOND EXCEL® sutures are used mainly in cardiovascular surgery, for anastomosis and placement of prosthetic materials **[16]**.

Therefore, the present study aimed, through a prospective and randomized study, to analyze the influence on the size of gastrojejunal anastomosis performed in Roux-en-Y gastric bypass surgery, as well as the main complications with the use of absorbable sutures. or non-absorbable, correlating the possible increase in the anastomotic diameter with the weight regain and analyze whether the complications are related to the weight regain and increase in the anastomotic diameter.

Methods

Study design and sample size

This study is a prospective and randomized clinical trial with 40 participants who were duly selected based on the inclusion and exclusion criteria, with 19 being randomized to the procedure with the closure of gastrojejunostomy with absorbable polydioxanone suture (PDS II®) and 18 with suture non-absorbable Polyester ETHIBOND® (ETHICON, INC., PO BOX 151, SOMERVILLE, NJ 08876-0151) **[15]**, with a total of 37 participants. Three participants were excluded for other reasons. The rules of the CONSORT Platform (The clinical research, available at http://www.consort-statement.org/) were followed.

Eligibility

Inclusion criteria

A patient who underwent Roux-en-Y gastric bypass surgery, according to the CFM bariatric surgery indication criteria, according to resolutions 2,131/2015 and 2,172/2017 **[17,18]**. Operations performed at the Hospital from 03/05/2018 until completing 60 cases for later selection.

Exclusion Criteria

Patients who had an adverse reaction to anesthesia during surgery, requiring interruption of the surgical procedure, a gastric pouch made with more than less than 3 staples, leakage of Methylene Blue during the intraoperative test, and there is a need to reinforce the closure of the gastrojejunostomy, either with absorbable or non-absorbable thread, regardless of the reason.

Randomization

37 identical and sealed envelopes were made, 19 of which were for the PDS II® group and 18 were for the ETHIBOND® group. All envelopes were deposited in a box stored at the Hospital's Surgical Center. During anesthetic induction, a drawing was carried out by the surgical team and then the material described in the drawn envelope was used. After that, the data were collected and the envelope was discarded.

Groups

Absorbable Thread Group (Abs)

Formed by 19 participants who underwent gastrojejunostomy closure with absorbable Polydioxanone thread (PDS II®).

Inabsorbable Thread Group (Inb)

Formed by 18 participants who underwent gastrojejunostomy closure with non-absorbable polyester ETHIBOND® thread.

Location and Procedures

The surgeries were performed at the Hospital. Postoperative follow-up and upper gastrointestinal endoscopy exams were performed at the Hospital Dia. Data were prospectively collected during routine follow-up visits in the pre-and postoperative period, during hospitalization, and during surgery. The outpatient postoperative follow-up and upper gastrointestinal endoscopy exam were performed in the periods of one, six, and twelve months after the operation. At each consultation, the data were recorded in an electronic spreadsheet, or a paper protocol and then delivered to a professional responsible for inserting them in the spreadsheet. The evaluation of the diameter of the gastrojejunal anastomosis and, also, of the gastric pouch, was performed via upper digestive endoscopy by a professional experienced in bariatric endoscopy, using the method published by de Quadros, et al. (2017, BMC Res Notes) **[19]**.

Outcomes

Primary Outcome

It was to identify the influence of the type of absorbable and non-absorbable thread on the size of the gastrojejunostomy up to one year after surgery.

Secondary outcome

It was expected to establish a correlation of complications with gastrojejunal anastomosis and gastric pouch and for weight loss or regain.

Ethical Aspects

The present research project was submitted to the Ethics and Research Committee being approved under number 2.551.515. After that, the patients' medical records were analyzed in strict compliance with this study protocol. The data were kept confidential by the ethical principles contained in resolution 466/12 of the National Health Council. Patients provided a free and informed consent form, with the possibility of giving up the registration at any time, free of charge for follow-up.

Procedures and Interventions

Before surgery, anthropometric data were collected from each patient and compared after 1 year of surgery. Upper Digestive Endoscopy was performed to measure the size of the anastomosis using the method of de Quadros, et al. (2017, BMC Res Notes) **[19]**, which is performed in 3 stages, in the postoperative returns of 1 month, 6 months, and 12 months.

Data were collected at each return, and then correlated and defined whether or not there was an influence on the type of yarn used, also observing the appearance of any complications and other determinants that influence weight loss or regain.

Statistical Analysis

The data were collected using a table previously built-in Excel, containing the dates of collection, the variables that were collected, and the number of the medical record. The variables were presented in the form of a percentage, average, and standard deviation. Depending on the Gaussian distribution (Normality test), the comparisons of the variables were performed using the Person Test and One-Way ANOVA Test (Tukey) between the variables of the present study, considering $p<0.05$ with statistical significance, in the 95% CI. Logistic regression analysis was also carried out to analyze the association of the diameter of the gastrojejunal anastomosis with complications, considering $p <0.05$ with significant statistical influence, in the 95% CI. Statistical analysis was performed using the Minitab 18® program (version 18, Minitab, LLC, State College, Pennsylvania, USA) **[20]**.

Results

Clinical data from a total of 37 participants (18 Inb and 19 Abs) showed that there was a prevalence of females, with n = 29 (78.38%), non-hypertensive patients, with n = 25 (67.57%), of non-diabetic, with n = 32 (86.49%), non-hypothyroidism, with n = 37 (100%), general non-complications (1 month), with n = 33 (89.19%), non-complications UDE (1 month), with n = 29 (78.38%), with no general complications (6 months), with n = 17 (68.00%), with 12 lost cases. Regarding Upper Digestive Endoscopy (UDE) complications (6 months), there were 9 cases lost and the number of complications was n = 14 (50.00%). General complications (12 months) were absent in n = 18 (85.71%), with 10 cases lost, and UDE complications (12 months) were absent in n = 12 (63.16%), with 16 cases lost.

The clinical data between the groups were homogeneous, showing that there was a prevalence of females in both groups, as well as a higher prevalence of non-hypertensive, non-diabetic, non-hypothyroidism, non-general complications (1 month), non-complications UDE (1 month), and general non-complications (6 months). Regarding UDE complications (6 months), there was a higher prevalence of complications in the Inb group with 10 cases (62.50%). Finally, general complications and UDE (12 months) showed a higher prevalence of non-complications in both groups.

Besides, it was observed that the number of general complications with the use of both suture threads (Inb and Abs) was equal in the first month after the operation. In the sixth month, the Inb thread had a higher number of complications than the Abs thread. In twelve months, the number of complications of the Inb thread decreased considerably, as well as the number of complications of the Abs thread. However, it is noteworthy that the number number of participants lost for analysis with the Abs thread was considerably large to the Inb thread.

Also, it was observed that the number of UDE complications with the use of the Inb thread was higher in the first postoperative month than in the Abs thread. In the sixth month, the Inb thread also had a higher number of complications regarding the Abs thread, with emphasis on the increase of marginal ulcer, intruder thread, and esophagitis B in the Inb group and increase of marginal ulcer in the Abs group. In twelve months, the number of complications of the Inb thread decreased considerably.

The number of complications of the Abs thread showed an increase in other complications, including marginal ulcer and intrusive thread. However, it is noteworthy that the number of participants lost for analysis of both Inb and Abs threads over 12 months was significant. In the Abs group, in the sixth month, he had a greater loss of participants than the Inb group for the analysis of complications.

Table 1 gathered the general data on weight (kg), BMI (kg/m2), GJA (mm), Pouch (cm) and percentage of weight loss before, 1 month, 6 months and 12 months postoperatively. According to this Table, the mean value of total weight before surgery was 119.41 ± 19.52 kg (minimum = 91.80 and maximum = 174.00), after 1 month it was 106.71 ± 17, 59 kg (minimum = 79.95 and maximum = 149.00), after 6 months it was 87.15 ± 15.46 kg (minimum = 64.00 and maximum = 120.00) and after 12 months it was 77, 78 ± 13.80 kg (minimum

= 60.00 and maximum = 102.00).

Also, Table 1 also shows that the average of the GJA group values was 9.514 ± 1.742 mm (minimum = 3,000 and maximum = 14,000) in 1 month, 15,655 ± 3,921 mm (minimum = 10,000 and maximum = 25,000) in 6 months and 15.667 ± 3.838 mm (minimum = 10,000 and maximum = 28,000) in 12 months. The percentage of weight loss over the 12 months was 34.69 ± 6.22% (minimum = 18.64 and maximum = 47.58).

Table 1. General data on weight (kg), BMI (kg/m2), GJA (mm), Pouch (cm), and percentage of weight loss before, 1 month, 6 months, and 12 months postoperatively.

Variables	*Total (N)*	*N* (Lost)*	*Mean*	*StDev*	*Min*	*Max*
WEIGHT_Before	37	0	119.41	19.52	91.80	174.00
BMI_ Before	37	0	43.099	5.377	35.342	56.090
WEIGHT _1 Month	37	0	106.71	17.59	79.95	149.00
BMI_1 Month	37	0	38.508	4.880	32.180	51.145
WEIGHT LOSS (%)_1 Month	37	0	10.638	2.232	5.085	14.602
GJA (mm)_ 1 Month	37	0	9.514	1.742	3.000	14.000
POUCH (cm)_ 1 Month	37	0	4.6351	0.5851	3.0000	6.0000
WEIGHT _6 months	31	6	87.15	15.46	64.00	120.00
BMI_6 meses	32	5	30.52	6.97	0.00	43.82
WEIGHT LOSS _6 months	32	5	29.78	14.61	0.00	100.00
GJA (mm)_ 6 months	37	8	15.655	3.921	10.000	25.000
POUCH (cm)_ 6 months	37	8	4.621	0.728	3.000	6.000
WEIGHT _12 months	25	12	77.78	13.80	60.00	102.00
BMI_12 meses	29	8	28.424	3.934	22.862	37.578
WEIGHT LOSS _12 months	29	8	34.69	6.22	18.64	47.58
GJA (mm)_ 12 months	22	15	15.667	3.838	10.000	28.000
POUCH (cm)_ 12 months	22	15	4.619	0.740	3.000	6.000

Figure 1 shows the weight loss curves (kg), in the moments before, 1 month, 6 months, and 12 months postoperatively to the use of the Inb and Abs threads. The average value of weight loss over 12 months for the Inb and Abs groups respectively was 79.84 ± 14.41 kg (minimum = 60.00 and maximum = 98.00), with a percentage of total weight loss of - 33.78%, and 74.90 ± 13.06 kg (minimum = 65.00 and maximum = 102.00), with a percentage of total weight loss of - 36.10%.

Figure 1. The curve of average values and percentage of weight loss (kg) over 12 months with the use of **Inb and Abs threads**.

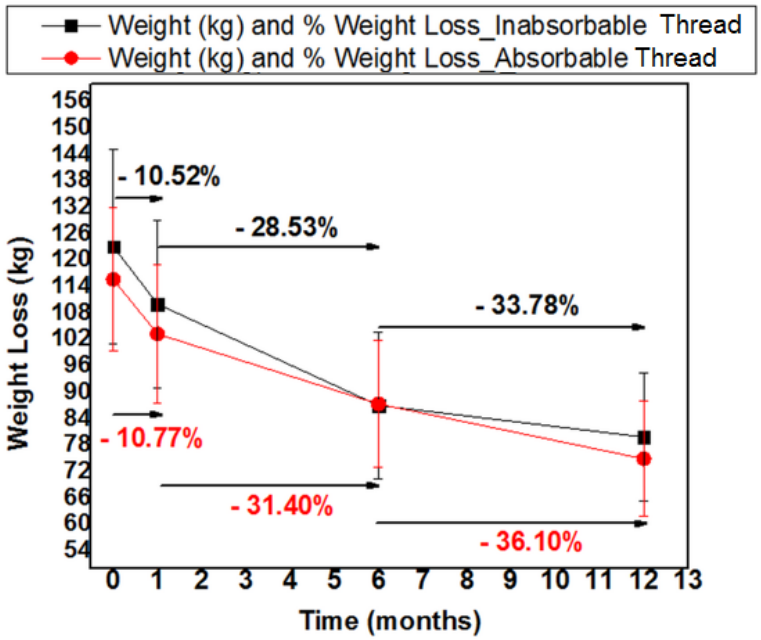
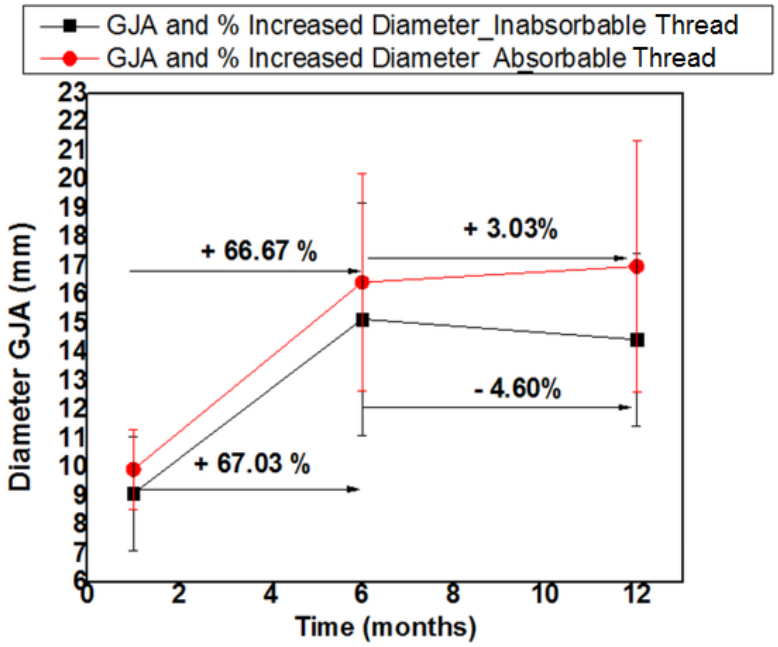


Figure 2 shows that the average of the GJA values of the Inb and Abs groups over 12 months was 14.455 ± 3.012 mm (minimum = 10,000 and maximum = 18,000), respectively, with an increase percentage of + 67.03% up to 6 months and decay of - 4.60% from 6 months to 12 months, and 17,000 ± 4,350 mm (minimum = 14,000 and maximum = 28,000), with an increase of + 66.67% up to 6 months and a further increase of + 3.03% from 6 months to 12 months.

Figure 2. The curve of mean values and percentage of increase in the diameter of the gastrojejunal anastomosis (mm) over 12 months using the Inb and Abs threads.



To the Inb group, the BMI values (kg/m2) in the periods before, 1, 6 and 12 months were, respectively, 44.68 (4.97), 39.98 (4.50), 31.70 (4.53), and 29.08 (3.68). The pouch values (cm) in the periods before, 1, 6 and 12 months were 4.50 (0.60), 4.55 (0.70) and 4.45 (0.69), respectively. To the Abs group, the BMI values (kg/m2) in the periods before, 1, 6 and 12 months were, respectively, 41.43 (5.41), 36.96 (4.91), 28, 99 (9.20), and 27.41 (4.31). The pouch values (cm) in the periods before, 1, 6 and 12 months were 4.78 (0.55), 4.73 (0.79) and 4.8 (0.79), respectively.

Figure 3 below shows the trend of increasing GJA in both groups Inb and Abs. In group Inb, it was observed that from 1 month to 6 months there was a considerable increase in the diameter of GJA, from 9.056 mm to 14.88 mm. However, from 6 months to 12 months GJA slightly decreased the diameter to 14.45 mm. In the Abs Group, it was observed that from 1 month to 6 months there was a considerable increase in the diameter of GJA, from 9,056 mm to 16.45 mm, and from 6 months to 12 months, it was from 16.45 mm to 17.00 mm. By the same Figure, between 6 and 12 months, it was deduced that the probability in the Inb group of maintaining the anastomotic diameter until the measurement of 15.00 mm was around 55% and to the Abs group it was around 33%.

Besides, **Figure 4** represents Tukey's statistical analysis to the Inb group, showing that there was a statistically significant difference between the mean GJA diameters at 1 and 6 months and 1 and 12 months, as the measurement range of both comparisons did not cross the dashed line at zero (0.0), with $p < 0.05$. The comparison between the mean values of the anastomotic diameter between 6 and 12 months showed no statistically significant difference, since the measurement range crossed the dashed line at zero (0.0), with $p > 0.05$.

Also, **Figure 5** represents Tukey's statistical analysis of the Abs group, showing that there was a statistically significant difference between the mean GJA diameters at 1 and 6 months and 1 and 12 months, as the measurement range of both comparisons was not crossed the dashed line at zero (0.0), with $p < 0.05$. The comparison between the mean values of the anastomotic diameter between 6 and 12 months showed no statistical difference, since the measurement range crossed the dashed line at zero (0.0), with $p > 0.05$.

Figure 3. Graph showing the tendency to increase gastrojejunal anastomosis over 12 months to the Inb and Abs groups.

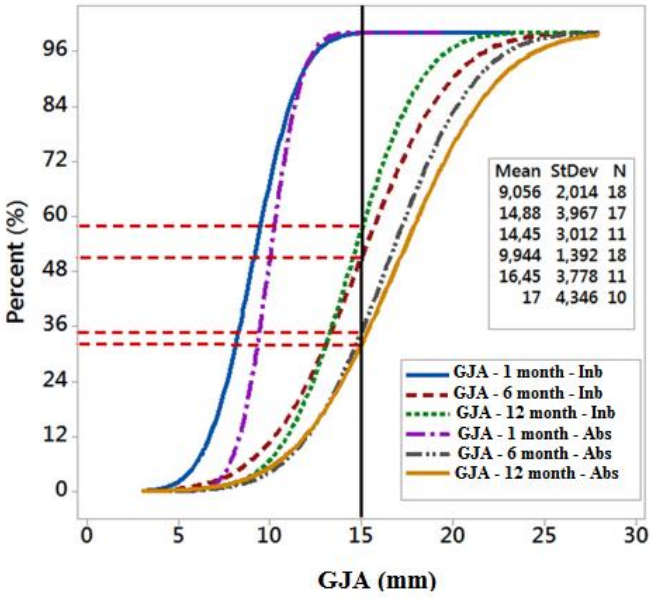


Figure 4. Tukey analysis showing the comparison between the mean and confidence intervals of the GJA of the Inb group, 95% CI.

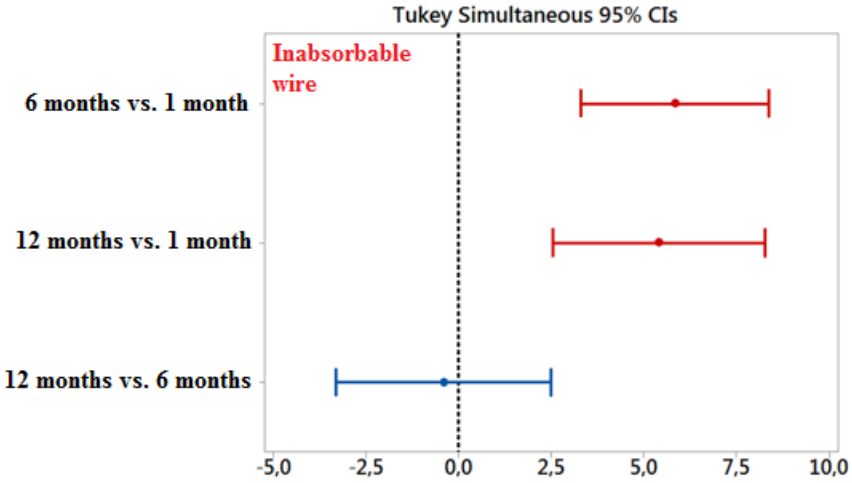
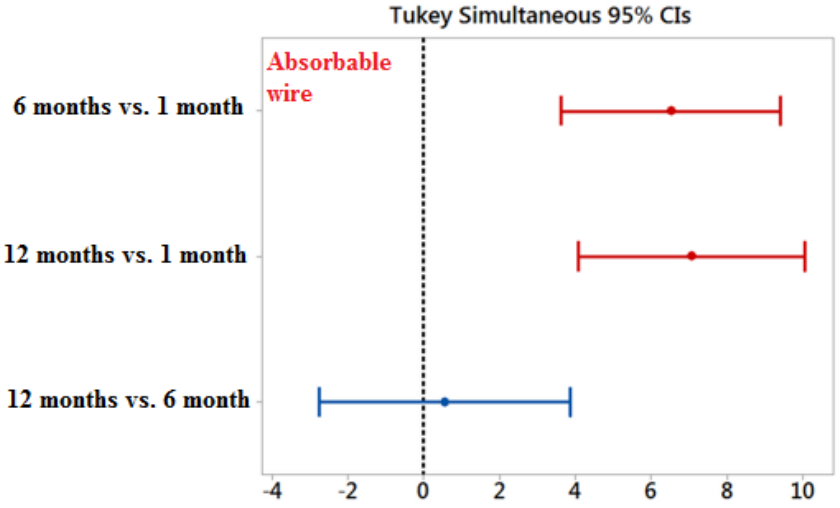


Figure 5. Tukey analysis showing the comparison between the means and confidence intervals of the GJA of the Abs group, 95% CI.



Tables 2 and **3** showed that there was no statistically significant difference in the comparison between the Inb and Abs groups to the mean values of the anastomotic diameter and weight in the paired times of 1, 6, and 12 months between each group, with p> 0, 05.

Tables 4 and **5** show the statistical correlations between the variables "weight", "GJA", "pouch" with the variables "general complications", and "UDE complications" at 1, 6, and 12 months after the operation. These Tables were presented because they were the only ones that showed results of statistical significance, representing as an example the other statistical correlations. In Table 4, there was statistical significance only between the variable "GJA" and "UDE complications" in the Inb group at 1 month, with p = 0.003 <0.05. In Table 5, there was statistical significance only between the variable "weight" and "complications UDE" in the Abs group at 6 months, with p = 0.003 <0.05. In the other analysis, no statistical significance was observed, with p> 0.05. Also, no significant statistical correlations were found between the size of the pouch and the complications, weight, and GJA variables, with p> 0.05 for all analysis.

Table 2. Tukey's test for the differences in the means of the intergroup GJA (Inb vs. Abs), with p> 0.05 without statistically significant difference, with a 95% CI.

Difference of Levels	Difference of Means	SE of Difference	95% CI*	T-Value	Adjusted p-value
GJA (mm)_1 months	0.889	0.577	(-0.284; 2.062)	1.54	0.133
GJA (mm)_6 months	1.57	1.51	(-1.53; 4.67)	1.04	0.307
GJA (mm)_12 months	2.55	1.62	(-0.84; 5.93)	1.57	0.132

**Individual confidence level = 95,00%*

Table 3. Tukey's test for the differences in the means of the intergroup GJA (**Inb** vs. **Abs**), with p> 0.05 without statistically significant difference, with a 95% CI.

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
WEIGHT_before	-4.59	5.85	(-16.47; 7.30)	-0.78	0.438
WEIGHT _1 months	-4.60	5.46	(-15.69; 6.49)	-0.84	0.405
WEIGHT _6 months	2.09	5.49	(-9.15; 13.34)	0.38	0.706
WEIGHT _12 months	-4.94	5.75	(-16.85; 6.98)	-0.86	0.400

**Individual confidence level = 95,00%*

Table 4. Statistical correlations between the variables "weight", "GJA", "pouch" with the variables "general complications" and "UDE complications" at 1 month after surgery, with p <0.05 with a statistical difference for Pearson, with 95% CI.

CORRELATIONS* (Month 1) Group Inb	GENERAL COMPLICATIONS	UDE COMPLICATIONS	WEIGHT Inb	GJA (mm)
WEIGHT_Inb	0.082	0.095		
	0.747	0.708		
GJA (mm)__Inb	0.281	0.651	-0.034	
	0.259	0.003	0.895	
POUCH (cm)_Inb	-0.017	0.076	0.129	-0.288
	0.948	0.764	0.609	0.246

**Cell Contents:*
Pearson correlation
P-Value

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Table 5. Statistical correlations between the variables "weight", "GJA", "pouch" with the variables "general complications" and "UDE complications" in the 6-month postoperative period, with p <0.05 with a statistical difference for the Pearson, with 95% CI.

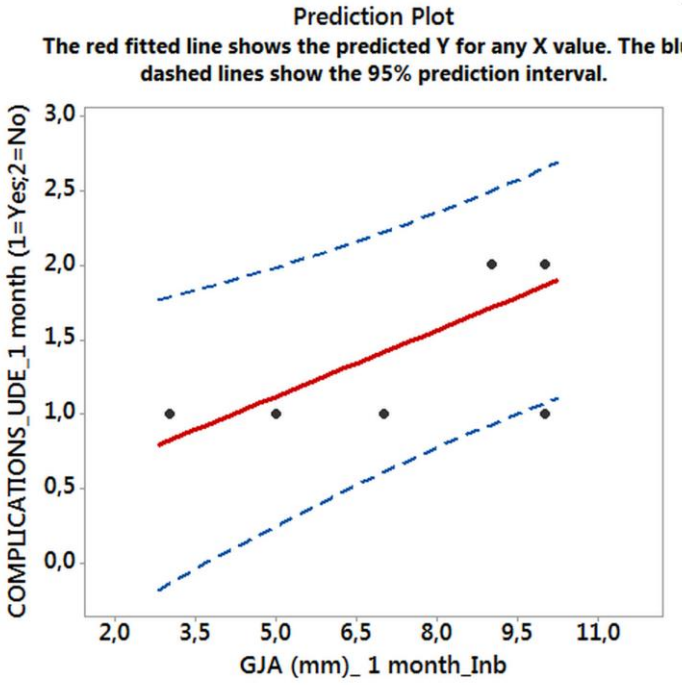
CORRELATIONS* (Month 6)

Group Abs	GENERAL COMPLICATIONS	UDE COMPLICATIONS	Abs WEIGHT	GJA (mm)
WEIGHT_Abs	0.478	-0.836		
	0.162	0.003		
GJA (mm)_Abs	-0.131	0.077	-0.347	
	0.737	0.821	0.326	
POUCH (cm)_Abs	0.109	0.322	-0.347	0.383
	0.780	0.335	0.326	0.246

**Cell Contents:*
Pearson correlation
P-Value

Figure 6 described, through logistic regression analysis, the predictive behavior of the possible increase in GJA in association with the events of complications to the result obtained in Table 4, as an example, as there was statistical significance between the variable "GJA" and " complications UDE "in the Inb group at 1 month, with p = 0.003 <0.05. The results of this regression analysis showed that as complications decrease, there is a tendency to increase the diameter of the GJA.

Figure 6. Logistic regression analysis the predictive behavior of the possible increase in GJA in association with the events of complications, with p <0.05 with a statistical difference for Pearson's Test, with 95% CI.



	X Predicted Y	95% PI
2,8	0,78969	(-0,18387; 1,7632
3,11	0,83590	(-0,12106; 1,7929
3,42	0,88211	(-0,05882; 1,8230
3,73	0,92832	(0,002807; 1,853
4,04	0,97454	(0,063806; 1,885
4,35	1,0207	(0,12414; 1,9174)
4,66	1,0670	(0,18378; 1,9501)
4,97	1,1132	(0,24269; 1,9837)
5,28	1,1594	(0,30084; 2,0179)
5,59	1,2056	(0,35820; 2,0530)
5,9	1,2518	(0,41473; 2,0889)
6,21	1,2980	(0,47041; 2,1256)
6,52	1,3442	(0,52520; 2,1633)
6,83	1,3905	(0,57908; 2,2018)
7,14	1,4367	(0,63202; 2,2413)
7,45	1,4829	(0,68400; 2,2818)
7,76	1,5291	(0,73499; 2,3232)
8,07	1,5753	(0,78499; 2,3656)
8,38	1,6215	(0,83396; 2,4091)
8,69	1,6677	(0,88191; 2,4535)
9	1,7139	(0,92883; 2,4990)
9,31	1,7602	(0,97471; 2,5456)
9,62	1,8064	(1,0196; 2,5932)
9,93	1,8526	(1,0634; 2,6418)
10,24	1,8988	(1,1062; 2,6914)

Discussion

According to the results of the present study in relation to the use of non-absorbable and absorbable threads, the clinical data of the Inabsorbable (Inb) and Absorbable (Abs) groups showed that there was a prevalence of females in both groups, as well as a higher

prevalence in both groups. the groups of participants without clinical problems such as hypertension, diabetics, hypothyroidism, as well as the absence of general complications (1 month), Upper Digestive Endoscopy (UDE) complications (1 month), and general complications (6 months). Regarding UDE complications (6 months), there was a higher prevalence of complications in the Inb group with 10 cases (62.50%). General complications and UDE (12 months) were less frequent at the end of 12 months in both groups.

It was also observed that the number of complications with the use of the Inb thread was higher in the first and sixth postoperative month to the Abs thread, with emphasis on the increase of marginal ulcer, intrusive thread, and esophagitis B in the Inb group and increase in marginal ulcer in the Abs group. However, at the end of twelve months, the number of complications of the Inb thread decreased considerably, while the number of complications of the Abs thread showed an increase in other complications, including marginal ulcer and intrusive thread.

Also, according to this Table 4, the average weight value over 12 months for the Inb and Abs groups was 79.84 ± 14.41 kg and 74.90 ± 13.06 kg, respectively, with no thus significant difference between groups in terms of total weight loss.

Still, Tables 4 and 5 showed that the mean of the GJA values of the Inb and Abs groups over 12 months was 14.455 ± 3.012 mm and 17,000 ± 4.350 mm, respectively, however, despite this difference between the means (2,55 mm at the end of 12 months), there was no statistically significant difference between the final values of the anastomotic diameter. Still, the percentage of weight loss over the 12 months was 33.77 ± 6.97% for the Inb group and 36.10 ± 4.89% for the Abs group, also not implying a significant difference.

Besides, however, according to Figure 3, between 6 and 12 months, it was deduced that the probability of the Inb group to maintain the anastomotic diameter up to the measurement of 15.00 mm was around 55% and to the Abs group was around 33%. Table 4 showed that there was statistical significance only between the variable "GJA" and "UDE complications" in the Inb group at 1 month, with $p = 0.003 < 0.05$, suggesting that as complications decrease, there may be a tendency to increase the diameter GJA due to the greater food consumption by the participants. In the same analysis, in Table 5 there was statistical significance only between the variable "weight" and "complications UDE" in the Abs group at 6 months, with $p = 0.003 < 0.05$, thus pointing to a possible relationship between reduction of complications with an increase of weight. However, these findings need to be better confirmed in later studies with a larger number of participants.

From the results of the complications found in this study, it is explained that the tissue reaction occurs whenever foreign materials are implanted in the organism **[11,12]**. The tissue reacts with an inflammatory process for two to seven days, depending on the material used, and can be complicated by infection, allergy, or trauma. The ideal suture can be used in any intervention, it is malleable and flexible to facilitate its handling, allows secure knots, arouses little tissue reaction, has uniform characteristics and predictable behavior, and is easily and absorbed once unnecessary. It is essential to adapt the properties of the suture to the local needs of the wound **[13-15]**.

In this context, a study showed the feasibility of a method with less use of mechanical sutures. 63 patients were operated on in 2 university hospitals, 12 men and 51 women (81%), with an average age of 33.5 years and an average BMI of 43. The average operative time was 5.5 hours. Early complications were fistula in the esophageal-gastric angle (1.6%), stenosis (1.6%) and fistula in the gastrojejunal anastomosis (1.6%), and torsion of the intestinal anastomosis (1.6%). The stenosis was treated by endoscopic dilation and the other complications through 3 re-operations (2 laparoscopic and 1 laparotomy). The length of hospital stay ranged from 2 to 20 days, with an average of 4 days, with no death **[25]**.

Another study reported the technical aspects of surgical systematization and results of simplified laparoscopic gastric bypass. A total of 12,000 patients (72% women) were included, with a mean age of 43 years (14-76) and a mean BMI of 44.5 (35-90 kg / m2). The average total operative time was 72 minutes (36-270) and the average hospital stay was 36 hours. With the use of non-absorbable suture (2-0 Ethibond®), a rate of stenosis requiring endoscopic dilation of almost 4% was observed. To increase weight loss, over the next two years (2003 and 2004), gastroenterostomy continued to be performed with the same non-absorbable sutures, but now calibrated with a 15 mm diameter. The result was an improvement in weight loss, but the rate of stenosis requires endoscopy and the dilation doubled, reaching 7.9%. In a third phase, gastroenterostomy started to be performed with absorbable suture (PDS 3-0) and calibrated to less than 15 mm. The rate of stenosis requiring dilation decreased to 0.8% and the results of weight loss were satisfactory. Currently, the stapler is closed with a 15-20 mm linear extension, with continuous seromuscular suture with absorbable sutures (3-0 Caprofyl®) and strengthening

the three angles with non-absorbable suture (2-0 Ethibond®), to decrease the tension in the anastomosis and collaborate with maintaining the gauge of the gastroenterostomy in the long term **[26]**.

In this sense, another study prospectively compared two methods of closing the alba line after restrictive gastric operations performed to treat morbid obesity. During 6 years, 229 patients were randomized to close the midline fascia using a PDS II ® suture placed continuously or Ethibond® suture. Two of the 109 patients who had closure with Ethibond® experienced acute midline fascia dehiscence versus no case of fascial dehiscence in the PDS II ® group. There were no wound infections in either group. There were 20 late incisional hernias (18%) in the Ethibond® group vs 11 late hernias (10%) in the PDS II ® group (p <ou = 0.04). Also, the mean closing time in the Ethibond® group was 13.3 vs 9.1 minutes in the PDS II ® group (p <0.0001). Therefore, this study concluded that when PDS II ® is placed continuously, it provides a safer and more economical closure of the midline fascia in patients with morbid obesity than Ethibond® **[27]**.

Also, another study analyzed, after Roux-en-Y gastric bypass surgery, the occurrence of marginal ulcers through the use of non-absorbable sutures, given that the literature shows that the incidence of this complication is about 3 to 23% of patients. Marginal ulcers can occur secondary to the use of non-absorbable sutures to create gastrojejunostomy. The suture can cause a foreign body reaction that exposes it to the gastric lumen, irritating the mucosa. Surgical removal is mandatory when medical therapy does not resolve the problem. Since endoscopic removal would be less invasive than laparotomy, a technique for endoscopic suture removal was developed. Six (6) female patients who underwent laparoscopic RYGB had to remove the endoscopic stitches. These women had a mean age of 57 years, an average initial body mass index of 55 kg/m2, and had undergone laparoscopic RYGB on average 18 months before presentation. At 6 months of follow-up, all patients were symptom-free and had normal results on upper gastrointestinal endoscopy. The results showed that the removal of the endoscopic suture is a viable and effective means of treating epigastric pain and preventing marginal ulcers induced by the suture after RYGB **[28]**.

According to the reported literature, gastrojejunostomy strictures in 3-31% and ulcerate in 1-16% of cases. Thus, a retrospective study using absorbable and non-absorbable sutures from a database collected prospectively for 315 patients with primary Roux-en-Y gastric bypass. Statistically fewer gastrojejunostomy complications were found in the absorbable suture group (4.7%) than in the nonabsorbable suture group (19.9%). Subgroup analysis showed that anastomotic strictures were less common in the absorbable suture group, but the difference was below statistical confirmation. The use of absorbable sutures resulted in statistically fewer marginal ulcers (2.3%) compared to the non-absorbable suture (13.4%) **[29]**.

Still, another retrospective study with 3,285 laparoscopic Roux-en-Y gastric bypass operations analyzed the incidence of marginal ulcers in the postoperative period with the use of non-absorbable versus absorbable sutures. The incidence of marginal ulceration after Roux-en-Y gastric bypass decreased significantly from 2.6% to 1.3% after the change from nonabsorbable to absorbable suture to the inner layer of the gastrojejunal anastomosis. The incidence of visible suture adjacent to the ulcer at endoscopy was also significantly reduced (64.3% vs 3.4%). When the results were corrected for the duration of the follow-up, the difference in the incidence of ulcers within 1 year of surgery remained significant between the two groups **[30]**. However, the present study found that the number of complications of the Abs thread showed an increase in other complications, including marginal ulcer and intrusive thread at the end of 12 months.

Limitations

It is noteworthy to note that the number of participants lost for analysis with the Abs thread was considerably large to the Inb thread. Also, the number of participants lost for analysis of both Inb and Abs threads over 12 months was considerable. In the Abs group in the sixth month, there was a greater loss of participants than the Inb group for the analysis of complications. Still, the number of participants was small in each group analyzed.

Conclusion

General and UDE complications were less frequent at the end of 12 months in both groups. At the end of twelve months, the number of complications of the Inb thread decreased considerably, while the number of complications of the Abs thread showed an increase in other complications, including marginal ulcer and intrusive thread. Despite this, there was no significant difference between groups in terms of total weight loss. There was no statistically significant difference between the final values of the anastomotic diameter, and there was no significant difference in the percentage of weight

loss at the end of 12 months. General and UDE complications were less frequent at the end of 12 months in both groups. At the end of twelve months, the number of complications of the Inb thread decreased considerably, while the number of complications of the Abs thread showed an increase in other complications, including marginal ulcer and intrusive thread. Despite this, there was no significant difference between groups in terms of total weight loss. There was no statistically significant difference between the final values of the anastomotic diameter, and there was no significant difference in the percentage of weight loss at the end of 12 months.

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Not applicable.

Ethics approval
This study was analyzed and approved by the Research Ethics Committee (CEP) according to a substantiated opinion number 2.551.515, and obtaining the patient's consent through the Informed Consent Form (TCLE) according to CNS/CONEP Resolution 466/12.

Informed consent
The participants signed the consent form.

Data sharing statement
No additional data are available.

Conflict of interest
The authors declare no conflict of interest.

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References
1. WHO-World Health Organization. Available in: https://www.who.int/topics/obesity/en/ - 62k. Accessed September 25, 2019.
2. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity among adults and youth: United States, 2015–2016. NCHS data brief, no 288. Hyattsville, MD: National Center for Health Statistics. 2017.
3. IBGE- Instituto Brasileiro de Geografia e Estatística. Disponível em: < http://www.ibge.gov.br>. Acessado em julho de 2019.
4. Sociedade Brasileira de Cirurgia Bariátrica e Metabólica, "Número de cirurgias bariátricas no Brasil cresce 7,5% em 2016," SBCBM, 24 Janeiro 2017. [Online]. Available: https://www.sbcbm.org.br/numero-de-cirurgias-bariatricas-no-brasil-cresce-75-em-2016/. [Acesso em 06 Dezembro 2017].
5. Almby K, Edholm D. Anastomotic Strictures After Roux-en-Y Gastric Bypass: a Cohort Study from the Scandinavian Obesity Surgery Registry. Obes Surg. 2019 Jan; 29(1):172-177 [doi: 10.1007/s11695-018-3500-9].
6. Docimo S Jr, Svestka M. Endoscopic Evaluation and Treatment of Postoperative Bariatric Surgery Complications. Surg Innov. 2017 Dec;24(6):616-624. DOI: 10.1177/1553350617736651. Epub 2017 Oct 26.
7. Abu Dayyeh BK, Lautz DB, Thompson CC. Gastrojejunal stoma diameter predicts weight regain after Roux-en-Y gastric bypass. Clin Gastroenterol Hepatol. 2011 Mar;9(3):228-33. doi: 10.1016/j.cgh.2010.11.004. Epub 2010 Nov 17. PMID: 21092760; PMCID: PMC3043151.
8. Bures Claudia, Seika Philippa, Denecke Christian, Pratschke Johann, Zorron Ricardo. Routine use of v-lock® suture for bariatric anastomosis is safe: comparative results from consecutive case series. ABCD, arq. bras. cir. dig. [Internet]. 2019 [cited 2020 Aug 10] ;32(3):e1452. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102720201900030040 1&lng=en. Epub Oct 21, 2019. https://doi.org/10.1590/0102-672020190001e1452.
9. Ministério da Saúde, "Vigitel Brazil 2016: Surveillance of Risk and Protective Factors for Chronic Diseases by Telephone Survey," MS/CGDI, Distrito Federal, 2016.
10. Joo MK. Endoscopic Approach for Major Complications of Bariatric Surgery. Clin Endosc. 2017 Jan;50(1):31-41. doi: 10.5946/ce.2016.140. Epub 2016 Dec 23.

11. Espinet Coll E, Nebreda Durán J, López-Nava Breviere G, et al. Efficacy and safety of transoral outlet reduction via endoscopic suturing in patients with weight regain after a surgical Roux-en-Y gastric bypass. Rev Esp Enferm Dig. 2018;110(9):551-556. doi:10.17235/reed.2018.5419/2017.
12. Jiang HP, Lin LL, Jiang X, Qiao HQ. Meta-analysis of hand-sewn versus mechanical gastrojejunal anastomosis during laparoscopic Roux-en-Y gastric bypass for morbid obesity. Int J Surg. 2016;32:150-157. doi:10.1016/j.ijsu.2016.04.024.
13. Abellán I, López V, Lujan J, et al. Stapling Versus Hand Suture for Gastroenteric Anastomosis in Roux-en-Y Gastric Bypass: a Randomized Clinical Trial. Obes Surg. 2015;25(10):1796-1801. doi:10.1007/s11695-015-1638-2.
14. Ruiz de Adana JC, Hernández Matías A, Hernández Bartolomé M, et al. Risk of gastrojejunal anastomotic stricture with multifilament and monofilament sutures after hand-sewn laparoscopic gastric bypass: a prospective cohort study. Obes Surg. 2009;19(9):1274-1277. doi:10.1007/s11695-009-9897-4.
15. Stavropoulos SN, Modayil R, Friedel D. Current applications of endoscopic suturing. World J Gastrointest Endosc. 2015;7(8):777-789. doi:10.4253/wjge.v7.i8.777.
16. Dunn DL. Wound Closure Manual. Ethicon, inc. Johnson & Johnson Company PRISCO R. Acta Urológica Instrumental Laparoscópico, October 2002 October: 11-20.
17. Conselho Federal de Medicina, Resolução CFM N°2.131/2015, Seção I ed., Diário Oficial da União, 2016, p. 66.
18. Conselho Federal de Medicina, Resolução CFM N° 2.172/2017, Seção I ed., Diário Oficial da União, 2017, p. 205.
19. Quadros LG, Galvão Neto MP, Campos JM, Kaiser Junior RL, Grecco E, Flamini Junior M, Santana MF, Zotarelli Filho IJ e Alexandre AATVA. Validation of a new method for the endoscopic measurement of post-bariatric gastric outlet using a standard guidthread: an observer agreement study," BMC Research Notes, p. 10:13, 2017.
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21. Toh et al, "The National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study Cohort: Rationale, Methods, and Baseline Characteristics," JMIR Res Protoc, 2017.
22. Quadros LG, Junior RLK, Neto MdPG., Campos JM., Santana MF e Ferraz AAB. Long-Term Postoperative Endoscopic Findings After Gastric Bypass Procedure: a co-occurrence analysis," Arq Gastroenterol, vol. 53, nº 4, p. 273:277, 2016.
23. Hedberg HM, Trenk A, Kuchta K, Linn JG, Carbray J, Ujiki MB, "Endoscopic gastrojejunostomy revision is more effective than medical management alone to address weight regain after RYGB," Surgical Endoscopy, vol. 32, nº 3, pp. 1564-1571, 2018.
24. Abdeen G, Roux, Mechanism Underlying the Weight Loss and Complications of Roux-en-Y Gastric Bypass. Review. Obes Surg, pp. 401-421, 2016.
25. Josemberg CM, Paiva GE, Teixeira SL, Lobato ELF, Souza VC, Bandeira FA et al . Bypass gástrico laparoscópico com uso reduzido de suturas mecânicas. ABCD, arq. bras. cir. dig. [Internet]. 2008 June [cited 2020 Aug 05] ; 21(2): 73-76. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102-67202008000200007&lng=en. https://doi.org/10.1590/S0102-67202008000200007.
26. Ramos AC, Silva AC, Ramos MG, et al. Simplified gastric bypass: 13 years of experience and 12,000 patients operated. Arq Bras Cir Dig. 2014;27 Suppl 1(Suppl 1):2-8. doi:10.1590/s0102-6720201400s100002.
27. Brolin RE. Prospective, randomized evaluation of midline fascial closure in gastric bariatric operations. Am J Surg. 1996;172(4):328-331. doi:10.1016/S0002-9610(96)00194-8.
28. Frezza EE, Herbert H, Ford R, Wachtel MS. Endoscopic suture removal at gastrojejunal anastomosis after Roux-en-Y gastric bypass to prevent marginal ulceration. Surg Obes Relat Dis. 2007;3(6):619-622. doi:10.1016/j.soard.2007.08.019.
29. Vasquez JC, Wayne Overby D, Farrell TM. Fewer gastrojejunostomy strictures and marginal ulcers

with absorbable suture. Surg Endosc. 2009;23(9):2011-2015. doi:10.1007/s00464-008-0220-6.

30. Sacks BC, Mattar SG, Qureshi FG, et al. Incidence of marginal ulcers and the use of absorbable anastomotic sutures in laparoscopic Roux-en-Y gastric bypass. Surg Obes Relat Dis. 2006;2(1):11-16. doi:10.1016/j.soard.2005.10.013.