

ORIGINAL ARTICLE

Clinical study of "double diablo" vs. continuous suture for laparotomy closure

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ABSTRACT

Background and Objectives: Incisional hernia is a common complication after abdominal surgery and presents a significant challenge for digestive surgeons. In 2000, we proposed a new suture design, termed "double diablo", which has optimum physical characteristics to ensure that both the thread and the holes are subjected to the least possible tension. We have since tested its effectiveness in theoretical and experimental studies. In the present paper, we demonstrate the effectiveness of this suture at the clinical level. **Methods:** A study was conducted on 100 patients all requiring a laparotomy. The operation was performed by the same surgeon for every case. Two study groups were compared: group A with 50 patients for whom the laparotomy closure was achieved by continuous suture; and group B with 50 patients for whom the laparotomy closure was achieved by double diablo suture. The following parameters were assessed: age, sex, American Society of Anesthesiologists classification, laparotomy size, postoperative (PO) evisceration, PO wound infection, PO hernia, urgent/scheduled surgery, PO hernia duration, PO complications, and follow-up time. **Results:** The double diablo suture group showed a statistically significant reduction in postoperative infections (16% vs. 38%, $P = 0.002$) and a non-statistically significant trend toward reducing postoperative hernias (14% vs. 28%, $P = 0.14$). However, the conclusion regarding "reducing the number of hernias" is unsupported by the results, as statistical significance was not achieved for this outcome. **Conclusion:** The double diablo suture reduces the rate of infection in surgical wounds following laparotomy closure and possibly reduces the number of postoperative hernias, although a statistically significant demonstration of the latter outcome requires further study, with a larger number of patients.

Key words: suture, physical laws, laparotomy, angles

INTRODUCTION

Laparotomy remains the standard method for major abdominal surgery and emergency procedures. However, in recent years, debate has arisen regarding the optimum closure technique and preferred suture material.

An incisional hernia is a common complication following abdominal surgery, with an incidence of 11%–20% in the general surgical population,^[1–4]

although this may rise to 40% in high-risk groups, such as patients with abdominal aortic aneurysm or morbid obesity.^[5–12]

It is therefore essential to perform a laparotomy closure that provides the best possible results. In this respect, preferences and technologies have evolved over time generating the highly sophisticated products that are used in current practice. However, despite the many innovations that have appeared,^[13–16] little progress has

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been made in suturing techniques, and most surgeons continue to use one of the two classical techniques: continuous suturing or simple interrupted suturing (with minor variations).

In 2020, we proposed a new suture design, offering ideal characteristics for laparotomy closure. This design was based on the physical laws that govern the tension in a line that joins two points. The tension of a suture thread joining two surfaces varies in inverse proportion to the angle of the thread with respect to the perpendicular of the surfaces. Therefore, we proposed a “double-diabolo” suturing method in which each point contains eight 45-degree angles (Figure 1), thus distributing and minimizing the suture tension.

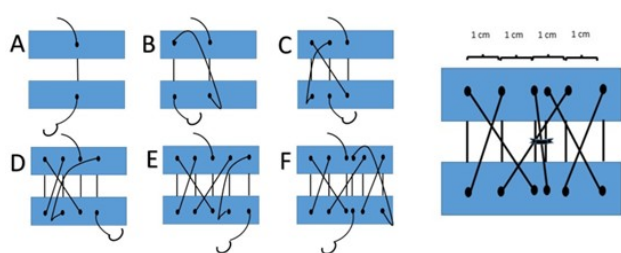


Figure 1. “Double-diabolo” suturing method (each point contains eight 45-degree angles). A: Central stitch; B: Left lateral stitch; C: Left intermediate stitch; D: Right intermediate stitch; E: Right lateral stitch; F: Final central stitch.

In 2021, we published the theoretical physical study,^[17] phase 1 of the process, in which we measured the tension that would be exerted on the thread and the holes of different types of sutures, compared to the double diabolo. Figure 2 summarizes this comparison, when a force of 10 kg is applied to sutures of 10, 20 and 30 cm length.

In 2022, we published the experimental study,^[18] phase 2, in which a device applied tension to each suture to its breaking point. This test showed that the double diabolo suture resists a greater pressure before breaking than traditional sutures.

We now propose a clinical study (phase 3) to compare laparotomy closure with the double diabolo suture vs. the continuous suture that is conventionally used.

MATERIAL AND METHODS

In this study, we test the effectiveness of the double diabolo suture for abdominal closure.

The study population consisted of 100 patients who underwent midline laparotomy at our hospital. In every case, the same surgeon performed the procedure. This

population was divided into two groups: group A, a retrospective study of 50 patients who underwent laparotomy closure with continuous suture; group B, a prospective study of 50 patients who underwent laparotomy closure with the double diabolo suture.

In each group, the sutures were inserted 1 cm from the wall, with a distance of 1 cm between sutures and using the same suture material (absorbable monofilament). The abdominal wall was sutured at the fascial layer ensuring adequate tension and alignment of tissue to minimize the risk of infection and incisional hernia. No additional reinforcement such as mesh was used, adhering to the protocol for both suture techniques.

The following parameters were considered: age, sex, American Society of Anesthesiologists (ASA) classification, laparotomy size, postoperative (PO) evisceration, urgent/scheduled surgery, PO wound infection, PO hernia, PO hernia time, PO complications, follow-up time.

The study was previously approved by the Ethics and Research Committee of the corresponding Health Area.

All patients receive detailed information about the procedure and its scientific basis, and signed the corresponding consent form.

Inclusion criteria:

- Patients with midline laparotomy;
- Age 18–90 years;
- Agree to participate and provide signed consent

Exclusion criteria:

- Patients with non-midline laparotomy;
- Refusal to provide signed consent.

Study variables:

- Dependent variables: PO hernia
- Independent variables: age, laparotomy size, PO wound infection, sex, ASA classification, urgent/scheduled surgery, PO hernia time, PO complications, follow-up time

Schedules for visits and data collection:

Group A:

Retrospective assessment of patients (peri- and postoperative complications in clinical history)

Personalized interview and examination, assessing the size of the wound, whether a hernia has occurred and, if

Table 1: Data for quantitative variables in two independent groups

Variable	Double diabolo suture		Continuous suture		P value	Test
	Mean	SD	Mean	SD		
Age (yr)	61.000	16.883	60.000	17.659	0.773	(a)
Laparotomy size (cm)	18.210	5.826	17.710	5.149	0.650	(a)
Hernia time (months)	13.000	6.000	10.857	5.855	0.442	(a)
Follow up (months)	18.570	6.150	18.850	8.271	0.811	(c)

(a) Student's *t*-test assuming homogeneity of variances. (c) Mann-Whitney-Wilcoxon *U* test. SD: standard deviation

Table 2: Association of the qualitative variables according to group A/group B using Chi square test

		Double diabolo suture		Continuous suture		All		P value
		n	%	n	%	n	%	
Sex	Female	19	38.0	18	36.0	37	37.0	1
	Male	31	62.0	32	64.0	63	63.0	
Urgent/scheduled	Urgent	23	46.0	18	36.0	41	41.0	0.42
	Scheduled	27	54.0	32	64.0	59	59.0	
ASA classification	1	2	4.0	1	2.0	3	3.0	0.23
	2	18	36.0	11	22.0	29	29.0	
	3	30	60.0	38	76.0	68	68.0	
Infection	No	42	84.0	31	62.0	73	73.0	0.02
	Yes	8	16.0	19	38.0	27	27.0	
Hernia	No	43	86.0	36	72.0	79	79.0	0.14
	Yes	7	14.0	14	28.0	21	21.0	

ASA: American Society of Anesthesiologists

so, when (this datum to be included as a complication if it occurred during the first 18 postoperative months).

Group B:

- 1st visit: Preoperative. Explanation of the study and provision of signed consent
- Perioperative assessment: wound complications— infection, evisceration
- 2nd visit: At one month postoperative. Wound review and exploration of possible hernias and other complications
- 3rd visit: At one year postoperative. Wound review and exploration of possible hernias and other complications

ations (if in doubt, request an imaging test)

Statistical analysis

The association between qualitative variables was determined by the chi-square test. The differences between continuous quantitative variables in two independent groups were determined by Student's *t*-test for two independent samples (subject to the condition of normality of the variables in each of the groups compared). In the non-parametric case, the Mann-Whitney-Wilcoxon test was applied.

RESULTS

The diagnoses for the laparotomy cases were categorized as follows:

Group A: colon surgery (36%), bowel obstructions (24%), rectal surgery (14%), gastric resection (12%), anastomotic leakage (4%), and other conditions (10%).

Group B: colon surgery (26%), rectal surgery (20%), bowel obstructions (18%), gastric resection (12%), anastomotic leakage (6%), and other conditions (18%).

Operation modes included urgent procedures in 46% of cases in group A and 36% in group B.

With respect to the study variables age, time of laparotomy, time at which hernia PO recurrence occurred and follow-up time, neither Student's *t* test nor the Mann-Whitney *U* test revealed any significant differences, and therefore the study groups were assumed to be homogeneous (Table 1).

Similarly, the chi square test revealed no significant inter-group differences in terms of the qualitative variables (sex, urgent/scheduled intervention and ASA classification), and so the homogeneity of the groups was maintained in this respect, too (Table 2).

However, there were statistically significant differences ($P = 0.002$) in terms of PO infections, which were less frequent among the patients whose laparotomies were closed using double diabolo sutures (Table 2).

Moreover, there were non-significant differences in terms of PO hernias, which were also less frequent among the patients whose laparotomies were closed using double diabolo sutures ($P = 0.14$). In fact, there were twice as many hernias in the continuous sutures group (Table 2).

DISCUSSION

Laparotomy remains the standard method for major surgery and emergency procedures. In recent years,

		F_t [kg] (tension of the thread)	F_R [kg] (resulting force)
Continuous suture 10 cm		0.5056 kg	0.9342 kg (holes 1 & 2) 0.5056 (holes 3)
Double Diabolo suture 10 cm		0.3807 kg	0.7034 kg (holes A & D) 0.6476 kg (hole B) 0.6477 kg (hole C & E) 0.3807 kg (holes C')
Running X suture 10 cm		0.4353 kg	0.8044 kg (holes 1 & 3) 0.6156 kg (all others)
Zig-Zag suture 10 cm		0.5081 kg	0.9090 kg (all)

Of these sutures, the double diabolo pattern performs best, since both the tension of the thread (TT) and the resulting force on the most unfavorable suture orifice (RFU)* is lower than in the other three cases. Compared to continuous suture, TT and RFU are reduced by 24.7%.

Regarding the Running X suture and the Zig Zag suture, the improvement is also significant. Thus, the double diabolo suture reduces TT by 12,54% and 25,07%, respectively, and RFU by 12,55% and 22,62%, respectively.

*The force exerted on the most unfavorable suture orifice (highlighted in bold): the greatest tension that a suture orifice will withstand and therefore the first one that will tear and cause the suture to fail.

Continuous suture 20 cm		0.2652 kg	0.490 kg (holes 1 & 2) 0,2652 (holes 3)
Double Diabolo suture 20 cm		0.1903 kg	0.3517 kg (holes 1 & 4) 0,3238 kg (hole 2) 0.3238 kg (holes 3 & 5) 0.1903 kg (hole 3')
Running X suture 20 cm		0.2176 kg	0.4022 kg (holes 1 & 3) 0.3078 kg (all others)
Zig-Zag suture 20 cm		0.26 kg	0.4651 kg (todos)

Of these sutures, the double diabolo pattern performs best, since both the tension of the thread (TT) and the resulting force on the most unfavorable suture orifice (RFU)* is lower than in the other three cases. Compared to continuous suture, the TT is reduced by 28,24%, and RFU is 28.22% less.

Regarding the Running X suture and the Zig Zag suture, the improvement is also significant. Thus, the double diabolo suture reduces TT by 12.55% and 26,8%, respectively, and RFU by 12.56% and 24.38%, respectively.

Continuous suture 30 cm		0.1797 kg	0.3321 kg (holes 1–2) 0,1797 (holes 3)
Double Diabolo suture 30 cm		0.1269 kg	0.2344 kg (holes 1 & 4) 0,2159 kg (hole 2) 0.2159 kg (holes 3 & 5) 0.1269 kg (hole 3')
Running X suture 30 cm		0.1451 kg	0.2681 kg (holes 1 & 3) 0.2052 kg (all others)
Zig-Zag suture 30 cm		0.1747 kg	0.3125 kg (todos)

Of these sutures, the double diabolo pattern performs best, since both the tension of the thread (TT) and the resulting force on the most unfavorable suture orifice (RFU)* is lower than in the other three cases. Compared to continuous suture, the TT is reduced by 29.94%, and RFU is 29.42% less.

Regarding the Running X suture and the Zig Zag suture, the improvement is also significant. Thus, the double diabolo suture reduces TT by 12.54% and 27.36%, respectively, and RFU by 12.57% and 24.99%, respectively.

Figure 2. Comparison of continuous, double diabolo, running X and zig-zag sutures when a force of 10 kg is applied to sutures of 10, 20 and 30 cm length

however, a debate has arisen regarding the best closure technique and preferred suture material, as the appearance of incisional hernias after laparotomy remains an extremely common problem and poses a

challenge to all surgeons.

This complication occurs following 11%–50% of all laparotomies,^[19] and an estimated 150,000 to 200,000

patients in the United States require incisional hernia repair each year.^[20]

Numerous proposals have been made to improve suture stability. Thus, Sen *et al.*^[21] proposed an algorithm to minimise the length of the suture and keep the needle at an angle orthogonal to the tissue entry point. In another study, Wieskötter *et al.*^[22] compared different types of suture and assessed the biomechanical stability provided to the tendons in each case. Israelsson *et al.*^[3,23–25] addressed the question of which technique should be used to close laparotomies; from the experimental and clinical data considered, they recommended the short stitch technique. On the other hand, a meta-analysis carried out by Henriksen *et al.*^[26] found no significant differences between the results obtained by interrupted and continuous suture techniques.

Despite the technical advances that have been achieved in producing sutures, our review of the literature did not reveal any detailed study of the physical laws that govern the tensions generated on the threads and holes in the sutures, seeking to optimize the method used. In fact, the techniques used remain practically unchanged, that is, the only suture designs described are either continuous or interrupted patterns (with minor variations).

A Cochrane review published in 2017^[27] concluded that monofilament sutures should be considered for abdominal closure to reduce the risk of incisional hernia, and absorbable sutures to reduce the risk of chronic wound drainage. It has also been reported that the technique currently preferred in elective midline closure is that of the continuous absorbable suture, as advocated by Diener *et al.*^[28] in their 2010 review. Other experimental studies have also recommended the continuous suture technique over the interrupted suture technique.^[29–32] In view of these prior studies, we decided to use absorbable monofilament sutures for both study groups and to take as a control group the patients whose laparotomy closure was performed with continuous sutures.

In this respect, it should be noted that a meta-analysis by Yü *et al.*^[33] concluded that the use of a continuous suture with a suture/wound-length ratio > 4:1 (“small bite”) significantly reduces the rate of laparotomy hernias.

In the double diabolo suture we propose, the sutures are located 1 cm from the wound edge, with a separation of 1 cm between each suture. Obviously, this can be extrapolated to the 4:1 small bites requirement; in other words, the sutures could be given the separation described in the “small bite” design and would continue to enjoy the advantage in terms of the physics in the tension exerted on the suture and the holes (taking into

account that the small bite suture is just a continuous suture with less distance between the points, which is equivalent to reducing the scale of the double diabolo suture).

The direct correlation between suture tension, blood flow and wound healing has been demonstrated experimentally by Höer *et al.*^[30] and is corroborated in subsequent articles by the same author^[29,31,32]. Klink *et al.*^[34] performed an experimental study using a rodent model to demonstrate that non-elastic monofilament sutures rapidly lose tension independently of the sutured tissue. This hypothetical approach towards reducing tissue compression, resulting in less local tissue damage and hence better wound healing, is of fundamental importance to the surgeon’s goal of avoiding postoperative complications.

The greater the tension in the suture, the worse the blood perfusion. This understanding underpins the theoretical model of the proposed double diabolo suture, in which the angles of which it is formed reduce the tension on the thread and holes, thus producing better blood flow within the laparotomy closure. This relationship might explain the fact that, although the rate of infection was high in both study groups (due to the inclusion of many patients requiring urgent surgery), the reduced tension exerted on the suture thread and holes, in the experimental group, meant there was a significantly lower rate of infections than in the continuous suture group.

Regarding the economic impact of reducing the incidence of incisional hernias, Deerenberg *et al.*^[12] reported that the annual cost of incisional hernia repair in the United States was \$3.2 billion. Therefore, if the results of our work are confirmed in the multicentre follow-up study we are now considering, it would be possible to significantly reduce the occurrence of laparotomic hernias, and hence achieve significant financial savings.

In summary, the comparative study of our innovative suture design vs. traditional suture types in laparotomy closure revealed significant differences in a key variable, namely the considerable reduction in postoperative infection rates with the double diabolo suture. Moreover, the incidence of hernias in the patients treated with the latter suture decreased by half, although the study results lacked statistical significance (if the number of patients in the study were increased, significant results would probably be achieved). In the view that this is an essential next step, we are currently designing a prospective randomized multicenter study, with a larger number of patients, to better demonstrate the advantages of using double diabolo *vs.* continuous

sutures for laparotomy closure.

DECLARATIONS

Author contribution

FJ Perez Lara: made a substantial contribution to the concept and design, drafted the article or revised it critically for important intellectual content, approved the version to be published. R. Zubizarreta Jimenez: drafted the article or revised it critically for important intellectual content, approved the version to be published. T. Prieto-Puga: approved the version to be published. M. Pitarch Martínez: approved the version to be published. P. Maldonado Valdivieso: approved the version to be published. R. García Martín: approved the version to be published. P. Fernández Galeano: approved the version to be published.

Informed consent

Informed consent was obtained from all subjects involved in the study.

Conflicts of interest

There is no conflict of interest with any financial support.

Use of large language models, AI and machine learning tools

None declared.

Data sharing statement

No additional data is available.

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