ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 8, Issue – 1, February - 2025, Page No. : 258 – 268

Comparative Study between Novel Zipper Device Versus Sutures For Wound Closure After Surgical Site Incisions

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How to citation this article: Dr.Raiya Gharchar, Dr.Sushil Damor, Dr.Digant Patel, Dr.Saurav Damor, "Comparative Study between Novel Zipper Device Versus Sutures For Wound Closure After Surgical Site Incisions", IJMACR- February - 2025, Volume – 8, Issue - 1, P. No. 258 – 268.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Traditional wound closure techniques, such as sutures, can cause localized trauma, ischemia, and discomfort. Novel zipper devices offer a minimally invasive alternative for surgical wound closure.

Objective: This study aims to compare the effectiveness of zipper devices versus sutures in closing surgical site incisions in clean wounds.

Methods: A prospective cohort study was conducted at SSG Hospital, Baroda, from January to June 2024. A total of 100 patients were randomly divided into two groups: 50 received closure with zipper devices, while 50 underwent closure with sutures. The study compared closure time, postoperative pain, wound complications, and cosmetic outcomes.

Results: The mean closure time was significantly shorter with zipper devices (2.54 ± 0.42 minutes) compared to sutures (6.88 ± 0.56 minutes; $p < 0.00001$). Postoperative pain scores were lower in the zipper group on both Day 1 and Day 3 ($p < 0.0001$). The incidence of surgical site infection (SSI) was slightly lower in the zipper group (6% vs. 8% on Day 10, $p = 0.9$). Wound dehiscence was not observed in either group. Scar assessment favored the zipper device, with 80% of patients achieving good cosmetic outcomes compared to 60% in the suture group ($p = 0.01$).

Conclusion: The use of zipper devices for surgical wound closure significantly reduces closure time and postoperative pain while improving cosmetic outcomes. Although the difference in infection rates was not

statistically significant, the zipper device demonstrated a promising alternative to sutures with potential advantages in patient comfort and recovery. Further studies with larger sample sizes are recommended.

Keywords: Wound Closure, Zipper Device, Sutures, Postoperative Pain, Cosmetic Outcome.

Introduction

Surgical wound closure is a critical step in postoperative care, traditionally performed using sutures, staples, or adhesives. While effective, sutures can cause localized trauma, ischemia, and discomfort, potentially leading to delayed healing and increased infection risk. In contrast, novel zipper devices provide a minimally invasive alternative that applies even pressure across the incision, reducing trauma and enhancing patient comfort. This study compares the effectiveness of zipper devices versus sutures for closing surgical site incisions in clean wounds, evaluating factors such as closure time, postoperative pain, wound complications, and cosmetic outcomes.

Aim

To compare and evaluate the effectiveness of zipper devices and sutures for closure of surgical site incisions of clean wounds.

Objectives

The primary objective:

- To compare the closure time of zipper device and suture for closure of surgical site incisions of clean wounds (counted after taking subcutaneous suture and ending up with complete incision closure)
- To compare the Postoperative pain after using a zipper device and suture for closure of surgical site incisions of clean wounds.

The secondary objectives:

- To compare the development of potential wound complications, such as Seroma, Surgical Site Infection (SSI), and Wound Dehiscence, after using a zipper device and suture to close surgical site incisions of clean wounds.
- To evaluate the cosmetic outcomes after using a zipper device and suture to closesurgical site incisions of clean wounds.

Methodolgy

Study Group: Steps for Clean Surgical Wound Closure Through Zipper Device

Study setting: Department of Surgery, SSG Hospital, Baroda.

Study period: The study was conducted from approval by institutional ethics committee from January 2024 to June 2024 (6 months)

Statistical analysis: The data was double entered in the MS Excel 2019 version and analysed using Medcalc and Epi info 7.1 software. The outcomes were compared with a t-test for quantitative variables and a chi-squared test for qualitative variables. A P-value of less than 0.05 was considered statistically significant.

Study population: The study included 100 patients undergoing surgery with clean surgical wounds.

Inclusion Criteria

- Any patient from Birth to 75 years of age.
- A clean open wound (trauma first aid or war trauma) or a surgical incision that needs to be closed.
- Able to participate in this trial voluntarily and sign the informed consent form.
- The patients undergoing Inguinal Hernioplasty, Epigastric Hernia Repair, Pyelolithitomy/ Ureterolithotomy, Open Cholecystectomy, Lumbar Sympathectomy, Congenital inguinal herniotomy and Flap surgeries for wounds.

Exclusion Criteria

- Patients refused to participate in this study or sign the informed consent form.
- The patients with renal, pulmonary, or other chronic disease requiring ongoing therapy for stabilisation; uncontrolled diabetes mellitus, thyroid disease, or hypertension.
- Patients with a coagulation abnormality.
- All patients with a mental disorder.
- All the critically ill patients cannot accurately evaluate the device's effectiveness and safety.
- All the patients with an infectious incision or a skin disease around the incision.
- Patients with other conditions deemed unacceptable for this trial, as
- scrutinised by the investigators and medical staff.

Sample Size and Sampling Method

This is a time-bound study, so we randomly divided all 100 patients who fit the inclusion criteria into two groups (50 each) over the six- month study period.

Group-A: Patients undergoing skin closure using zipper-like devices. (Study group).

Group B: Patients undergoing skin closure using sutures and staplers. (Control group).

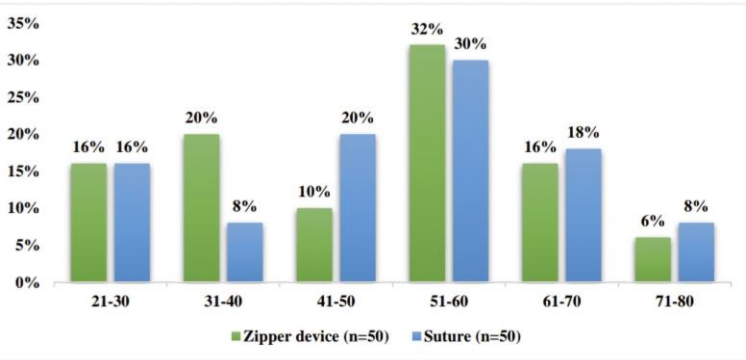
Result

A total of 100 patients were included in this study after taking the informed written consent during the 6 months of study period and were randomly divided into two groups (50 each).The aim of study To compare and evaluate the effectiveness of zipper devices and sutures for closure of surgical site incisions of clean wounds.

Table 1: Age-wise distribution of patients in both groups

	Zipper device (n=50)		Suture (n=50)		
Age (Years)	Frequency	Percentage	Frequency	Percentage	Chi- square test
21-30	8	16%	8	16%	P=0.48
31-40	10	20%	4	8%	
41-50	5	10%	10	20%	
51-60	16	32%	15	30%	
61-70	8	16%	9	18%	
71-80	3	6%	4	8%	

Graph 1:

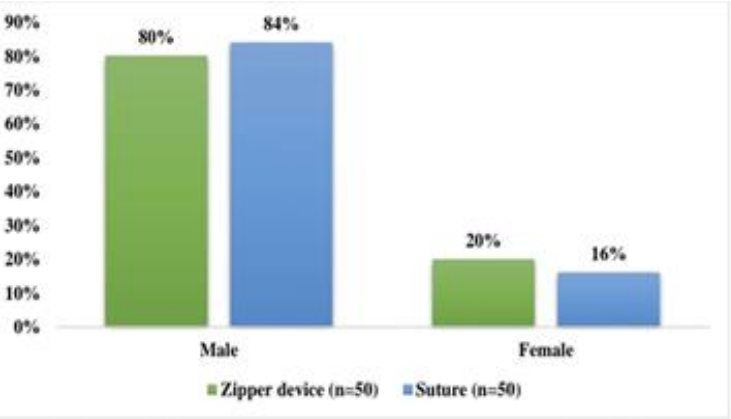


The data shows that the majority of patients in both the Zipper device group and the suture group were from the 51 to 60 years age range, with 32% in the Zipper device group and 30%in the suture group.

Table 2: Gender-wise distribution of patients in both groups

	Zipper device (n=50)		Suture (n=50)		
Gender	Frequency	Percentage	Frequency	Percentage	Chi-square test
Male	40	80%	42	84%	P=0.79
Female	10	20%	8	16%	
Total	50	100%	50	100%	

Graph 2:

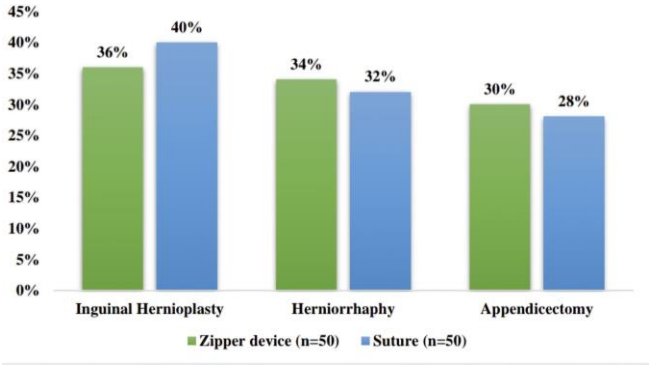


The above table and chart show that 80% and 84% of the patients were male in Zipper device group and Suture group respectively.

Table 3: Distribution of patients in both groups according to the type of surgery

Type of surgery	Zipper device (n=50)		Suture (n=50)		
	Frequency	Percentage	Frequency	Percentage	Chi- square test
Inguinal Hernioplasty	18	36%	20	40%	P=0.92
Herniorrhaphy	17	34%	16	32%	
Appendicectomy	15	30%	14	28%	
Total	50	100%	50	100%	

Graph 3:

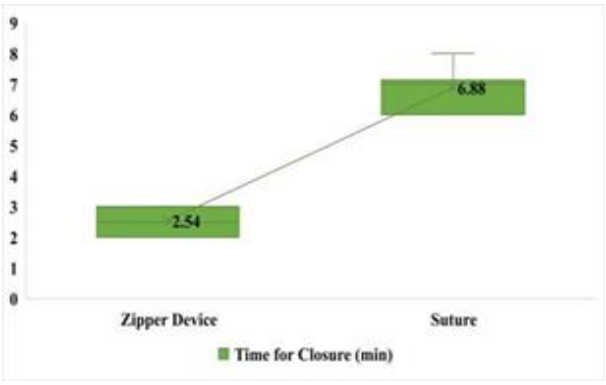


The most common surgery performed in both the Zipper device and suture groups was Inguinal hernioplasty (36% and 40%, respectively), followed by herniorrhaphy (34% and 32%) and appendicectomy (30% and 28%).

Table 4: Comparison of the meantime for closure between both closure techniques

	Zipper device (n=50)	Suture (n=50)	t-test
Closure time in minutes	2.54 ± 0.42	6.88 ± 0.56	P<0.00001

Graph 4:

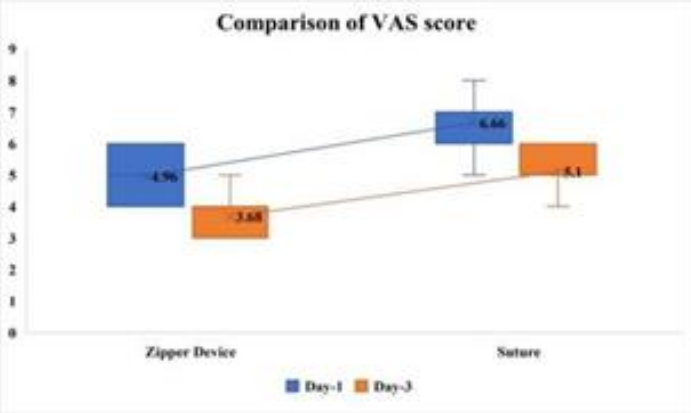


The data shows that the mean time to close a surgical wound using the zipper device was 2.54 ±0.42 minutes, compared to 6.88 ± 0.56 minutes with suture material. The zipper device significantly reduced the closure time compared to the conventional suture method.

Table 5: Comparison of postoperative VAS score for pain between both techniques

VAS score	Zipper device (n=50)	Suture (n=50)	Mann-Whitney test
Post-operative Day-1	5 (4-6)	7 (6-7)	P<0.0001
Post-operative Day-3	4 (3-4)	5 (5-6)	P<0.0001

Graph 5:

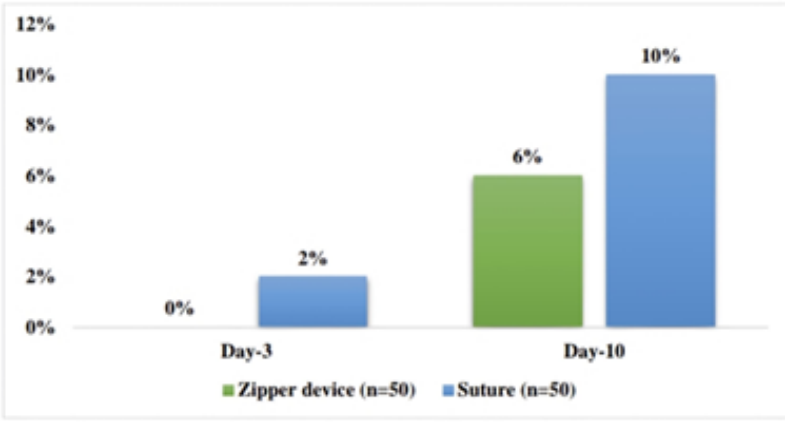


The comparison of median VAS scores showed that patients with wounds closed using the zipper device experienced significantly lower pain. On postoperative day 1, the median VAS score was 5 (4-6) for the zipper device group versus 7 (6-7) for the suture group. On day 3, the median score was 4 (3-4) for the zipper device group versus 5 (5-6) for the suture group.

Table 6: Distribution of patients according to the development of Seroma in both groups

Development of Seroma	Zipper device (n=50)		Suture (n=50)		Chi-square test
	Frequency	Percentage	Frequency	Percentage	
Day-3	0	0%	1	2%	P=1
Day-10	3	6%	5	10%	P=0.71

Graph 6:

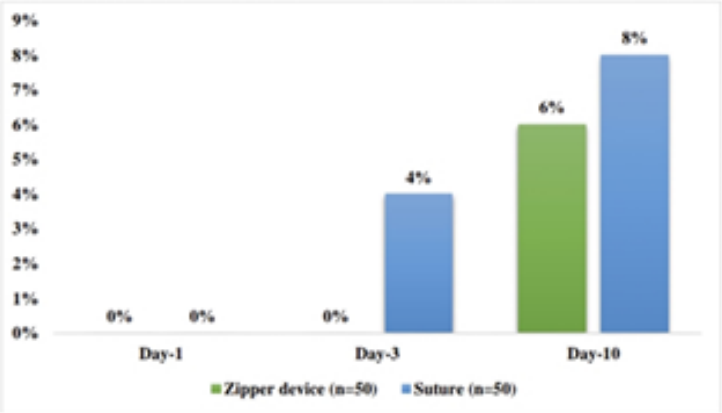


The data indicates that 3% of patients with wounds closed using a zipper device developed seroma by the 10th postoperative day. In contrast, 2% and 10% of patients with wounds closed using the conventional method developed seroma on the 3rd and 10th postoperative days, respectively. However, the difference in proportions was not statistically significant.

Table 7: Distribution of patients according to the development of SSI in patients of both groups

SSI	Zipper device (n=50)		Suture (n=50)		Chi-square test
	Frequency	Percentage	Frequency	Percentage	
Day-1	0	0%	0	0%	-
Day-3	0	0%	2	4%	P=0.48
Day-10	3	6%	4	8%	P = 0.9

Graph 7:



The data shows that 6% of patients with zipper device closures developed surgical site infections (SSI) by postoperative day 10, but none had SSI on days 1 or 3. In comparison, 4% of patients with conventional suture closures developed SSI on day 3, and 8% on day 10. However, the difference in proportions between the two groups was not statistically significant.

Table 8: Distribution of patients according to the development of wound dehiscence in the patients

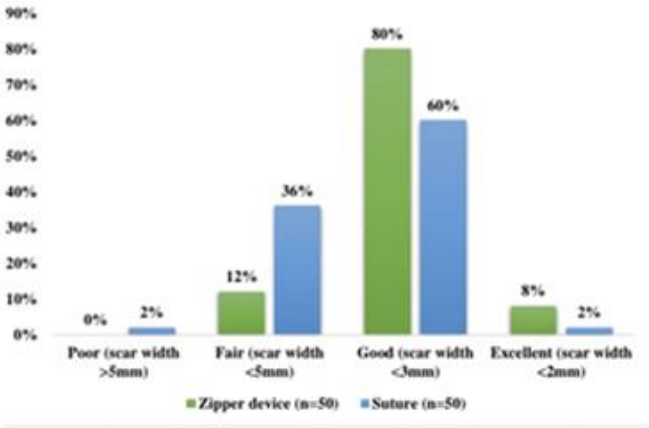
Wound Dehiscence	Zipper device (n=50)		Suture (n=50)	
	Frequency	Percentage	Frequency	Percentage
Yes	0	0%	0	0%
No	50	100%	50	100%
Total	50	100%	50	100%

The above table shows that none of the patients in this study developed wound dehiscence in either group.

Table 9: Comparison of the proportion of patients between both techniques for Scar Assessment

Scar Assessment	Zipper device (n=50)		Suture (n=50)		Chi-square test for trends
	Frequency	Percentage	Frequency	Percentage	
Poor (scar width >5mm)	0	0%	1	2%	P=0.01
Fair (scar width <5mm)	6	12%	18	36%	
Good (scar width <3mm)	40	80%	30	60%	
Excellent (scar width <2mm)	4	8%	1	2%	

Graph 8:



At the end of the study, 80% of patients in the zipper device group had scar widths of less than 3mm (rated as good), with 12% having scars less than 5mm (fair) and 8% having scars less than 2mm (excellent). In the conventional suture group, 60% had scars less than 3mm, with smaller proportions having scars less than 5mm, less than 2mm, and more than 5mm (2% each). A significant difference in scar width proportions was found between the two groups.

Discussion

In our study, 6% of patients in the zipper device group developed surgical site infections (SSI) by postoperative day 10, compared to 12% in the suture/stapler group, with no significant difference between the groups. However, a meta-analysis by Cheng-Xin Xie et al. found that the zipper device reduced SSI incidence compared to sutures. This discrepancy could be due to our study's small sample size. The zipper device may have advantages like being atraumatic and non-invasive, as it avoids the use of needles, reducing the risk of bacterial entry. Additionally, a study by Risnes I et al. noted that bacterial adherence to sutures and their protection from phagocytosis contribute to wound infections, while the zipper device remains closed until removal, minimizing bacterial contamination risks during dressing changes.

Shorter wound closure times can reduce the risk of surgical complications and costs. While suture closure is time-consuming and skill-dependent, zipper closure is easier to apply and requires less advanced surgical skill, reducing technical variability among surgeons and promoting standardization. Patients often seek good cosmetic outcomes, and the zipper device offers precise, adjustable, and tension-free closure, minimizing trauma to the skin and underlying tissues without causing ischemia. This helps improve healing and scarring, making it beneficial for achieving a good cosmetic result. Shorter wound closure times can reduce the risk of surgical complications and costs. While suture closure is time-consuming and skill-dependent, zipper closure is easier to apply and requires less advanced surgical skill, reducing technical variability among surgeons and promoting standardization. Patients often seek good cosmetic outcomes, and the zipper device offers precise, adjustable, and tension-free closure, minimizing trauma to the skin and underlying tissues without causing ischemia. This helps improve healing and scarring, making it beneficial for achieving a good cosmetic result. was that there was no need to remove sutures and bandages, thus causing less pain, further improving patient satisfaction.

Table 10:

Study	Type of Study	Outcome
Cheng-Xin Xie et al.	Meta-analysis	The incidence of surgical site infection was lower with the zipper device than the conventional suture method.
Risnes I et al.	Comparative Prospective study	The wound infection was more common with suture material.
Our study	Comparative Prospective study	The percentage of patients with the development of SSI is more common with suture material than with zipper device
Cheng-Xin Xie et al.	Meta-analysis	The time for wound closure was significantly shorter with the zipper device than with the conventional suture method. The scar assessment score (cosmetic result) was better with the zipper device than the suture material.
Levi et al.	Comparative Prospective study	A zipper device provided greater shielding of the wound from perturbation caused by distraction forces than sutures.
Our study	Comparative Prospective study	The mean closure time for the surgical wound was significantly shorter with Zipper device than suture material. The proportion of patients with good scar was significantly higher with zipper device compared to the suture material.

Summary and Conclusion

This prospective comparative study, conducted in the department of surgery at SSG Hospital, Vadodara, included 100 patients undergoing surgery with clean surgical wounds. All 100 patients were divided into two groups, whose wound closure was performed with conventional suture material and a novel zipper device. The mean age of the patients included in the zipper device group was 47.36, and in the suture group was 50.22. 80% and 84% of the patients were males, respectively, in the zipper group and suture material group, respectively. The most common operative procedure done in this included patients was hernia repair and 2nd most common was inguinal hernia. The mean closure time for the surgical wound was 2.54 ± 0.42 and 6.88 ± 0.56 by using a zipper device and suture material, respectively, and the mean difference was significantly difference between the two groups. That concluded that with the zipper device, the mean closure time for surgical wounds was lesser than the conventional suture material. The median VAS score for pain on post-operative day 1 and day 3 was significantly lesser in the zipper device than the suture material, and it concluded that the efficacy of the zipper device was significantly better than the suture material. The proportion of the patients with good scar was significantly more in zipper device compared to the suture material that concluded that the acceptance of zipper device for cosmetic appearance was far better than the suture material.

Limitation

The main limitation of this prospective comparator study was relatively small sample size (n= 50 in each group) that limits the statistical power and accuracy of the study. This may affect the outcomes of the result and potentially make inconclusive results. This was the single centre study that limits the generalizability of the findings. The results may not apply to other settings with different patient demographics, surgical practices, or healthcare systems. The study has been conducted in a relatively homogenous population, limiting the applicability of the results to more diverse groups with different comorbidities, age ranges, or racial/ethnic backgrounds.

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