

Surgiplier Skin Stapler versus Trulon Polyamide Suture in Post-surgical Open Abdominal Wound Closure: A Randomised Clinical Trial

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ABSTRACT

Introduction: Surgical wound closure is the process of closing incised skin to facilitate rapid wound healing with a low risk of complications and an appealing cosmetic outcome. The method and material for wound closure are influenced by the type of surgery, the anatomical site of the wound, and the length of the incision. It must serve both functional and aesthetic purposes with fewer complications.

Aim: To compare the rate of Surgical Site Infection (SSI) between skin staplers and polyamide sutures among patients undergoing open abdominal surgeries.

Materials and Methods: The present study was a single-centre, prospective, two-arm, parallel-group, randomised (1:1) clinical study conducted at the Department of General Surgery, IPGMER-SSKM Hospital, Kolkata, West Bengal, India, between July 19, 2022, and January 31, 2023. A total of 134 eligible adult patients (18-70 years) undergoing open abdominal surgeries were screened, enrolled, and randomised to the Surgiplier skin stapler (n=67) and Trulon polyamide suture (n=67). Patients were followed up for 84 days. The primary objective

was to compare the rate of SSI between the two groups. The secondary objectives were evaluation of wound complications, postoperative pain, patient satisfaction, cosmetic appearance of the wound, time taken for skin closure, ease of use, and safety of the two interventions. The statistical analysis was performed using the Analysis of Variance (ANOVA) test for continuous variables. A p-value <0.05 was considered significant.

Results: The Surgiplier skin stapler performed better than the Trulon polyamide suture in postoperative wound closure of open abdominal surgeries, based on the percentage of SSI (2.98% vs. 4.47%), skin closure time (387.99±116.40 vs. 578.57±139.22 seconds), patient satisfaction score (4.20±0.53 vs. 2.69±0.57), the overall Patient and Observers Scar Assessment Scale (POSAS) observers score (1.17±0.39 vs. 2.44±0.69), and the overall POSAS patient score (1.24±0.47 vs. 2.50±0.76) at the end of the study. All parameters had a statistically significant p-value <0.0001.

Conclusion: The present study concludes that the Surgiplier skin stapler performed better than the Trulon polyamide suture in postoperative wound closure in open abdominal surgeries.

Keywords: Cosmetic appearance, Patient and observers scar assessment scale, Patient satisfaction, Surgical site infection, Wound complication

INTRODUCTION

Surgical wound closure is the process of closing skin flaps to facilitate rapid healing with a low risk of complications while achieving an appealing cosmetic outcome [1]. The choice of wound closure method and material is influenced by the type of surgery, anatomical site of the wound, and the length of the incision [2].

Suturing is the most commonly used technique for closing the incision site. The practice of sewing surgical sites using animal sinews, braided horsehair, and vegetable fibers dates back to 600 Before Christ (BC), as mentioned in the Sushruta Samhita, an ancient Sanskrit text on surgery [2]. What began with catgut, silk, and cotton has now expanded to include antibiotic-coated and knotless suture materials. There is approximately 5,269 suture materials available, which can be natural or synthetic, absorbable or non-absorbable, monofilament or braided. The suturing technique can be continuous or interrupted [3].

However, sutures have the disadvantage of increased application time and can result in a cosmetically inferior scar [4]. Sutures can also increase the chances of Surgical Site Infections (SSI) due to the potential ischaemia of wound flaps, which delays the normal healing process. SSI remains the most common cause of postsurgical readmission [5] and can lead to increased morbidity and mortality [6-8]. The Centres for Disease Control and Prevention (CDC) classified SSI into three types in its 2017 guideline for prevention: superficial

incisional, deep incisional, and organ/space SSI [9]. Superficial SSI is often attributed to the different methods of skin closure used [10].

The concept of wound closure using staplers originated from ancient Hindus who used insect mandibles to close skin wounds [11]. Skin staplers were first developed in the Soviet Union and introduced by Sreichen and Ravitch in 1973 in the United States of America (USA), as mentioned by Rabha P et al., [12]. The technique of skin closure aims to minimise postoperative wound complications such as infections, pain, scarring, and keloid formation, while achieving optimal skin approximation and adequate healing. Various factors, including the indication for surgery, location, and intra/postoperative complications, influence the outcome of surgical wound closure [13].

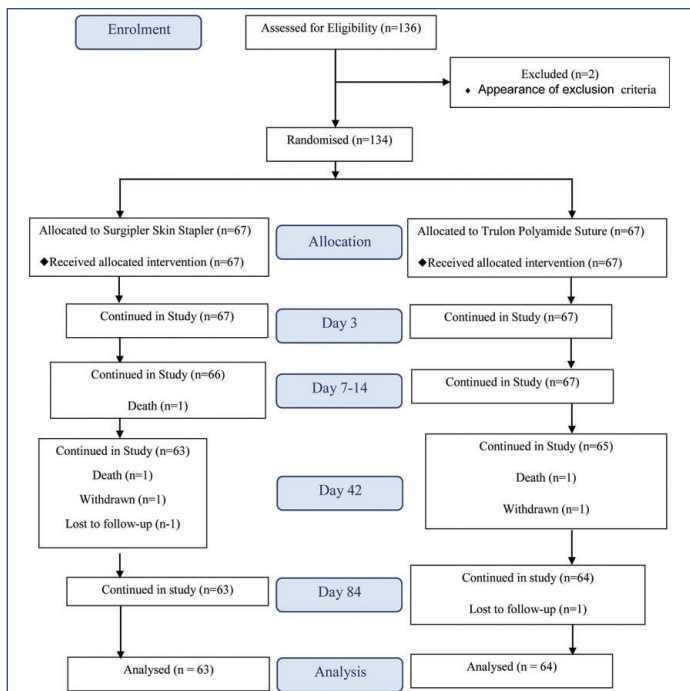
Surgeons consider several factors when choosing a skin closure technique, including cost-effectiveness, time efficiency, and patient satisfaction by maximising wound cosmesis [13]. The aesthetics of the resulting scar are a significant factor that impacts the patient's quality of life during the postoperative period. Therefore, the skin closure material must serve both functional and aesthetic purposes [14]. The advancement of skin closure techniques has revolutionised modern surgical outcomes. Staples are preferred over conventional suture materials due to their disposable nature, reduced wound closure time, lower risk of contamination [15], and improved cosmetic appearance [4].

In present randomised clinical trial, the authors compared the Surgipler skin stapler and Trulon polyamide suture for open abdominal wound closure. This comprehensive analysis represents the first of its kind to compare these devices.

MATERIALS AND METHODS

This was a single-centre, prospective, two-arm, parallel-group, randomised (1:1) clinical study conducted at the Department of General Surgery, Institute of Postgraduate Medical Education and Research, and Seth Sukhlal Karnani Memorial (IPGMER and SSKM) Hospital, Kolkata, West Bengal, India between July 19, 2022, and January 31, 2023. The study received approval from the Institutional Ethics Committee (IPGME&R/IEC/2022/296) and was registered prospectively in the Clinical Trial Registry of India on July 12, 2022, with reference number CTRI/2022/07/043924.

A total of 136 adults were screened for the study between July 19, 2022, and October 3, 2022, and were randomly assigned to two groups: Surgipler and Trulon. As one patient from each group met the exclusion criteria after consenting, they were not included and did not receive any intervention. The follow-up of the last recruited subject was completed on January 31, 2023. In total, 134 subjects were randomised into two groups: 67 in the Surgipler group and 67 in the Trulon group [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram.

According to Kathare SS and Shinde ND, the stapler method was found to be more acceptable among patients due to less pain and better cosmetic results ($p < 0.0001$) [13]. Based on this evidence, the sample size calculation formula for a superiority trial was used, with a power of 95% and a significance level of 0.05 ($\alpha = 0.1$). The estimated sample size was 122. Considering potential randomisation failures and a 10% failure to follow-up rate, the sample size was increased to 136, with 68 subjects in each group.

Inclusion and exclusion criteria: Adults (both male and female) in the age group of 18-70 years undergoing open abdominal surgeries at the study site and who provided informed consent were included in the study.

Patients with uncontrolled diabetes (HbA1c >10%), haemoglobin <7 g/dL, Body Mass Index (BMI) > 35 kg/m², a history of surgical incision at the same site as the currently planned surgery, systemic infection not controlled by antibiotic treatment, or topical infection at the planned incision site were excluded from the study.

Randomisation: All patients who participated in the study were randomly assigned in a 1:1 ratio to either the Surgipler skin stapler or the Trulon polyamide suture. The randomisation sequence was independently created using computer-generated randomisation, with blocks of 4, 6, and 8 being used. The details were concealed in opaque envelopes, which were only opened in the operation theater on the day of surgery. Blinding was not implemented in the study as all participants had the ability to observe whether patients were assigned to the stapler or suture arm. Patients were informed about the skin closure device once they regained consciousness following surgery.

Interventions:

1. Surgipler skin stapler, Healthium Medtech Limited (Intervention Group): This device consists of preloaded stainless-steel staples used for approximating the skin in general surgery for various indications. Skin staples were removed using the X-Tract disposable sterile skin staples remover.
2. Trulon monofilament polyamide non-absorbable suture, Healthium Medtech Limited (Comparator group): This sterile, synthetic, monofilament, non absorbable surgical suture is prepared from a co-polymer of Polyamide 6 (Nylon 6) and Polyamide 6/6 (Nylon 6/6). It is intended for use in general soft tissue approximation and/or ligation, as well as in cardiovascular, ophthalmic, and neurological tissues.

Study Procedure

All subjects included in the study underwent designated open abdominal surgeries following standard institutional practice. All surgeries were elective and performed on haemodynamically stable patients. For postsurgery skin closure, either the Surgipler skin stapler or Trulon polyamide suture was used according to randomisation to avoid allocation bias.

Study outcomes: The primary endpoint was to compare the incidence of SSI between the two groups using CDC criteria [15]. The secondary endpoints included the comparison of wound complications (skin disruption, wound dehiscence, sinus formation, seroma, and haematoma), postoperative pain, pain during staple or suture removal using a 100-point Visual Analogue Scale (VAS), analgesic usage, patient satisfaction using a 5-point scale, cosmetic appearance of the wound using the Patient and Observers Scar Assessment Scale (POSAS) [16], time taken (in seconds) for skin closure, ease of use of the two interventions using a 5-point scale, and Adverse Events/Serious Adverse Events (AE/SAE) between the two groups [Table/Fig-2].

[Table/Fig-2]: Scales used in the study: (a) Details of removal of skin closure material; (b) Pain score (100 point VAS scale); (c) Subject satisfaction scale.

Demographic information, vital signs, medical and surgical history, abdominal history, and physical examination data of all patients were recorded during the screening visit. The operating surgeon's assessment of the device was recorded on day 0. The investigator's opinion about various characteristics of the wound was noted during follow-up reviews on day 7-14±2, 42±7, and 84±7. Participants were interviewed on day 7-14±2 on the day of suture or stapler removal to calculate patient satisfaction scores and POSAS scale, and on day 42±7 and day 84±7 for the POSAS scale only.

STATISTICAL ANALYSIS

Continuous variables were assessed using the Analysis of Variance (ANOVA) test for extreme reactions, and the results were reported as mean and standard deviation, where applicable. Categorical variables were assessed using Pearson's Chi-square test. Calculations were performed with a 95% confidence interval, and a p-value ≤0.05 was considered statistically significant. All statistical analyses were conducted using Statistical Package for the Social Sciences (SPSS) software version 28.0.

RESULTS

Baseline demographic parameters and vital characteristics were comparable between the two groups [Table/Fig-3].

Parameters	Surgiplier skin stapler (n=67)	Trulon polyamide suture (n=67)	p-value (ANOVA test)
Age (years)	49.28±11.03	47.91±12.49	0.50
Height (cm)	162.35±5.94	163.93±6.92	0.16
Weight (kg)	60.93±9.09	61.63±9.21	0.66
BMI (kg/m ²)	23.04±2.61	22.87±2.60	0.70
Systolic (mm of Hg)	122.38±1.30	121.54±1.17	0.27
Diastolic (mm of Hg)	79.39±0.86	79.03±0.79	0.48
Pulse (bpm)	83.19±0.70	82.16±0.65	0.02
Temperature (°C)	97.49±0.24	97.53±0.17	0.76
Respiratory rate (bpm)	17.98±0.162	18.03±0.163	0.61

[Table/Fig-3]: Base line demographics and vital characteristics of patients in both groups.

Primary Endpoint Analysis

Surgical site infections (SSIs) as per CDC criteria were observed in two patients (2.98%) from the Surgiplier group, while the Trulon group reported 3 (4.47%) cases. The p-value was <0.0001, determined using the Moses test of extreme reaction.

Secondary Endpoint Analysis

Intraoperative profile: All patients enrolled in the study received antimicrobial prophylaxis prior to surgery and were given general anaesthesia as part of standard institutional practice (p-value=1.00). All surgeries were elective and performed on haemodynamically stable patients. Surgeries were conducted on the gastrointestinal system (23 in the Surgiplier group vs 26 in the Trulon group) and the hepatopancreaticobiliary system (44 in the Surgiplier group vs 41 in the Trulon group). Two misfired Surgiplier staplers were reported, while no suture-related dysfunction was observed. The mean length of the incision was 12.47±5.05 cm in the Surgiplier stapler group and 11.50±4.12 cm in the Trulon suture group. The characteristics of the stapler and suture techniques varied significantly and are described in [Table/Fig-4]. The satisfaction score for skin closure was 4.22±0.57 in the Surgiplier group and 3.01±0.44 in the Trulon group (on a scale of 1 to 5, with 1 being least satisfied and 5 being most satisfied), with a significantly different p-value (<0.0001).

Wound complications: A total of nine wound complications were reported in the Surgiplier group and 11 in the Trulon group. Superficial serous discharge was observed in seven patients in the Surgiplier group and five patients in the Trulon group, but they did

Surgiplier skin stapler (n=67)	Mean score
Ease of handling stapler	4.52±0.61
Ease of stapling	4.42±0.60
Ease of stapler release	4.25±0.70
Staple pin shape after firing	4.19±0.74
Satisfaction with skin closure	4.22±0.57
Trulon polyamide suture (n=67)	Mean score
Ease of passage	3.15±0.58
Knot holding	3.00±0.78
Knot security	3.27±0.57
Knot tie-down smoothness	3.18±0.62
Stretch capacity	3.52±0.56
Memory	2.73±0.62
Suture fraying	3.15±0.52
Satisfaction with skin closure	3.01±0.44

[Table/Fig-4]: Intraoperative characteristics of Surgiplier and Trulon evaluated by operating surgeon.

not meet the criteria for SSI as suggested by CDC guidelines. Skin disruption and wound dehiscence were observed in two patients in the Surgiplier group and three patients in the Trulon group. Therefore, two instances of restapling were noted in the Surgiplier group compared to three instances of re-suturing in the Trulon group [Table/Fig-5].

Point of analysis	Parameters	Surgiplier Skin Stapler (n=67)	Trulon Polyamide Suture (n=67)	p-value (Chi-square test)
Wound complications	Serous discharge	7	5	NA
	Seroma	0	2	
	Deep incisional SSI	0	1	
	Skin disruption and wound dehiscence leading to Resuturing/ Restapling	2	3	
Analgesics used	Day 0	1.49±0.53	1.52±0.50	0.6
	Day 3±1	0.75±0.70	0.87±0.60	0.11
	Day 7-14±2	0.32±0.47	0.31±0.48	0.57
	Day 42±7	0.00±0.00	0.09±0.52	0.23
	Day 84±7	0.00±0.00	0.00±0.00	1
Skin closure	Ease of skin closure	3.87±0.50	2.14±0.98	<0.0001
	Time taken for skin closure (secs)	387.99±116.40	578.57±139.223	<0.0001
Pain score	Day 0	84.64±4.54	85.40±3.46	0.28
	Day 3±1	62.57±7.21	70.82±5.62	<0.0001
	Day 7 to 14±2	43.20±8.33	46.13±9.181	0.04
	Day 42±7	14.48±5.63	16.14±8.16	0.18
Pain during removal	Day 7-14±2	17.86±6.92	29.52±7.79	<0.0001

[Table/Fig-5]: Comparative analysis of secondary endpoints in both groups.

Postoperative pain: Postoperative pain was assessed at all visits from day 0 to day 84, with the highest pain reported on day 0 after the effects of anaesthesia wore off. Pain scores gradually decreased during subsequent visits, and no pain was reported on day 84 in either group. The mean pain experienced during device removal was 17.86±6.92 in the Surgiplier group and 29.52±7.79 in the Trulon group. Pain was measured using the 100-point VAS for both scenarios [Table/Fig-5].

POSAS scale: The POSAS scale was completed by both the investigator and the patient on day 7-14±2, day 42, and day 84.

Parameters	Observers opinion					
	Day 7-14±2		Day 42±7		Day 84±7	
	Surgiplier skin stapler (n=66)	Trulon polyamide suture (n=67)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=65)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=64)
Vascularity	3.73±0.78	4.66±1.14	2.52±0.69	3.28±0.92	1.38±0.49	2.41±0.71
Pigmentation	3.39±0.82	4.30±1.31	2.16±0.57	3.00±1.13	1.30±0.50	2.27±0.90
Thickness	3.45±0.88	4.70±1.26	2.37±0.66	3.42±1.20	1.63±0.58	2.56±0.92
Relief	3.47±0.82	3.58±1.32	2.21±0.60	3.26±1.17	1.29±0.49	2.42±0.79
Pliability	3.33±0.81	4.46±1.42	2.21±0.65	3.18±1.11	1.33±0.51	2.38±0.88
Surface area	3.53±0.76	4.81±1.16	2.37±0.63	3.35±0.99	1.59±0.61	2.64±0.82
Overall opinion	3.48±0.71	4.58±1.10	2.30±0.46	3.29±0.98	1.17±0.39	2.44±0.69
Parameters	Patient's opinion					
	Day 7-14±2		Day 42±7		Day 84±7	
	Surgiplier skin stapler (n=66)	Trulon polyamide suture (n=67)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=65)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=64)
Has the scar been painful in the past few weeks?	3.76±0.88	5.06±1.14	2.63±0.68	3.52±1.08	1.48±0.53	2.47±0.78
Has there been itching in the scar area in the past few weeks?	2.97±0.94	3.97±1.60	2.35±0.93	3.28±1.38	1.51±0.69	2.47±1.00
Is the colour of the scar colour different from your normal skin colour at present?	3.95±0.90	5.19±0.99	2.70±0.63	3.60±1.02	1.60±0.56	2.47±0.76
Is the stiffness of the scar different from your normal skin at present?	3.79±1.00	4.94±1.19	2.71±0.72	3.46±1.13	1.35±0.48	2.38±0.97
Is the thickness of the scar different from your normal skin at present?	3.88±0.97	5.06±1.04	2.52±0.69	3.40±1.17	1.41±0.56	2.50±1.01
Is the scar more irregular when compared to your normal skin at present?	3.88±0.92	5.15±0.99	2.51±0.61	3.54±1.11	1.51±0.56	2.48±0.88
What is your overall opinion of the scar compared to normal skin?	3.86±0.86	5.21±0.88	2.49±0.56	3.57±0.95	1.24±0.47	2.50±0.76

[Table/Fig-6]: Comparison of observers and patient POSAS scale on all visits for both groups. The p-value (Chi-square test) was <0.0001 for all parameters in all visits

Classification	Patient's opinion					
	Day 7-14±2		Day 42±7		Day 84±7	
	Surgiplier skin stapler (n=66)	Trulon polyamide suture (n=67)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=65)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=64)
Total score	26.09±5.07	34.58±6.90	17.92±3.23	24.37±7.09	10.10±2.39	17.27±5.11
≤18	4 (6.06%)	0	39 (61.90%)	6 (9.23%)	63 (100%)	39 (60.93%)
19-24	24 (36.36%)	4 (5.97%)	21 (33.33%)	36 (55.38%)	0	20 (31.25%)
≥ 25	38 (57.57%)	63 (94.02%)	3 (4.76%)	23 (35.38%)	0	5 (7.81%)
Classification	Observers opinion					
	Day 7-14±2		Day 42±7		Day 84±7	
	Surgiplier skin stapler (n=66)	Trulon polyamide suture (n=67)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=65)	Surgiplier skin stapler (n=63)	Trulon polyamide suture (n=64)
Total score	24.39±4.38	32.09±7.91	16.13±2.80	22.78±6.73	9.70±2.05	17.11±4.84
≤18	7 (10.60%)	1 (1.49%)	49 (77.77%)	17 (26.15%)	63 (100.00%)	39 (60.93%)
19-24	25 (37.87%)	8 (11.94%)	14 (22.22%)	26 (40.00%)	0	21 (32.81%)
≥25	34 (51.51%)	58 (86.56%)	0	22 (33.84%)	0	4 (6.25%)

[Table/Fig-7]: Comparison of total score of observers and patient POSAS scale on all visits for both groups and its classification. p-value (Chi-Square test) was <0.0001 for all parameters during all visits.

Gradual improvement in the wound and its cosmetic appearance were observed, as shown in [Table/Fig-6]. The values are given on a scale of 1 to 10, where one represents the closest and 10 represents the farthest from normal. The results indicate that Surgiplier outperformed Trulon based on this scoring system and classification [Table/Fig-7].

Patient satisfaction score: The patient satisfaction score was recorded during the visit on days 7-14, when the skin closure device was removed. The mean satisfaction score for the Surgiplier group patients was 4.20±0.53, while that for the Trulon group patients was 2.69±0.57. The satisfaction score was assessed on a scale of 1 to 5, with 1 representing the least satisfied and 5 representing the most satisfied.

Adverse events: Both groups experienced non serious and serious adverse events. The total number of Serious Adverse Events (SAEs)

was eight, with three patients from the Surgiplier group and five from the Trulon group. There were three reported deaths among the study patients: two in the Surgiplier group and one in the Trulon group. The deaths in the Surgiplier group were caused by acute respiratory distress leading to cardiac failure in patients with adenocarcinoma in the small intestine. They underwent duodenectomy and Whipple's procedure (pancreaticoduodenectomy) and received four and two units of blood, respectively, to manage postoperative complications. The patient in the Trulon group, who underwent subcostal gastrectomy and loop gastrojejunostomy, succumbed to septicemia resulting from bloodstream infection and lower respiratory tract infection. None of these patients reported any wound-related complications.

There were a total of five non-serious adverse events, which included one patient in the Surgiplier group with seasonal flu, nausea, and

vomiting, and one patient in the Trulon group with abdominal pain, seasonal flu, and nausea and vomiting.

DISCUSSION

The primary goal of postsurgical tissue repair is to achieve rapid strength regain and minimise tissue damage and inflammation, while also ensuring a cosmetically appealing scar [12]. Many factors, including the choice of wound-closing material, can influence this outcome [15].

Huda F et al., reported no significant difference in wound infection rates between the stapler and suture groups [17]. Similarly, in a multicentre study of open gastrointestinal wounds involving 1080 patients, Pandey ND et al., found no statistical difference in wound infection rates between subcuticular sutures and skin staplers [18]. However, the findings of the current study differ, as it observed slightly lower rates of SSIs in the Surgipler skin stapler group compared to the Trulon polyamide suture group (2.98% vs. 4.47%). A meta-analysis of 42 trials comparing staplers and sutures among 1671 patients reported that sutures had slightly lower overall infection rates (4.9% vs. 6.75%) than staplers [1].

Kathare SS and Shinde ND reported three cases of wound complications in the stapler group compared to four cases in the suture group, which is consistent with the present study's findings of nine complications in stapler group and eleven complications in suture group [13]. However, Cochetti G et al., did not find any significant difference between the stapler and suture groups in subcuticular wound closure for open abdominal GI surgeries [1].

All comparative studies unanimously agree that staplers have the advantage of time over sutures in skin closure [4,13,16]. Kathare SS and Shinde ND reported a skin closure time of 11 seconds/cm in the stapler group compared to 45 seconds/cm in the suture group [13]. However, it's important to note that the mean length of incision in their study was 7 cm, whereas in the current study, it was 12 cm. In the present study, the mean time of skin closure was reported as 387.99 seconds in the stapler group and 578.57 seconds in the suture group. The ease of skin closure was also statistically more significant in the stapler group.

Postoperative pain was experienced in both groups with varying intensities, leading to the use of analgesics. The present study reports decreased postoperative pain in the stapler group rather than the suture group, along with no significant difference in the use of analgesics. These results match those of Parameshwara CM and Karthik B, who used a visual analogue scale to assess postoperative pain and reported that the suture group had a pain score three times higher than that of the stapler group [4]. Initially, when staplers began to be used in surgeries, it was believed that pain during stapler removal was higher than suture removal [18,19]. However, recent studies by Huda F et al., and Oswal S et al., have suggested that the pain is similar [17,20]. The present study also supports this observation. Liu Z et al., referenced Kanegaye et al., who conducted a study on paediatric scalp lacerations and observed less pain during removal and a more cosmetically appealing scar in the stapler group [21]. The present study reports a marginally better cosmetic appearance of the wound at the 84-day follow-up visit in the stapler group, which coincides with the findings of Kathare SS and Shinde ND and Huda F et al., [13,17].

Sureshkumar S et al., reports a similar total score in the POSAS scale for stapler and suture in inguinal hernia surgery, but overall opinion favours sutures [22]. However, in the current study, the POSAS scale indicates that the stapler is better for wound management and scar health. Most patients' skin appeared to be close to normal during the day 84 visits. Both the total score and overall opinion favour the stapler. Huda F et al., used the Stony Brook Scar Evaluation Scale during the one-month follow-up and did not find any significant difference in scar status [17].

Both groups reported Adverse Events (AEs), including SSI and wound complications, similar to the study by Cochetti G et al., [1]. The Trulon group reported more AEs than Surgipler in the present study, which aligns with the published literature by Kathare SS and Shinde ND [13].

Limitation(s)

The study was conducted in a single centre. The findings of the study could have had broader applicability if it had been conducted across multiple centres, including diverse hospitals and patient populations, instead of being limited to a single centre.

CONCLUSION(S)

The present study concludes that the Surgipler skin stapler performed better than Trulon polyamide sutures in postoperative wound closure in open abdominal surgeries. It achieved a lower incidence of SSI and wound complications, better time efficiency and ease of closure, less postoperative and device removal pain, higher patient satisfaction, and a better cosmetic outcome.

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REFERENCES

- [1] Cochetti G, Abraha I, Randolph J, Montedori A, Boni A, Arezzo A, et al. Surgical wound closure by staples or sutures?: Systematic review. *Medicine (Baltimore)*. 2020;99(25):e20573. Doi: 10.1097/MD.00000000000020573. PMID: 32569183; PMCID: PMC7310845.
- [2] Kumar R, Hastir A, Goyal S, Walia RS. Sutures versus staplers for skin closure of midline incision in laparotomy patients and their outcome. *Int J Surg Med*. 2017;3(4):211-15. Doi: 10.5455/ijsm.sutures-versus-staplers-for-skin-closure.
- [3] Mohit Biswas DA, Jagadamba Sharan D. Comparative study of staplers vs simple interrupted vs sub-cuticular method of skin closure of surgical wounds. *Eur J Mol Clin Med*. 2022;9(3):1926-33.
- [4] Parameshwara CM, Karthik B. A comparative study between skin staples and skin suture materials in abdominal surgical wound closure. *MedPulse-Int Med J*. 2015;2(12):903-05.
- [5] Merkow RP, Ju MH, Chung JW, Hall BL, Cohen ME, Williams MV, et al. Underlying reasons associated with hospital readmission following surgery in the United States. *JAMA*. 2015;313(5):483-95. Doi:10.1001/jama.2014.18614.
- [6] Tolcher MC, Whitham MD, El-Nashar SA, Clark SL. Chlorhexidine-alcohol compared with povidone-iodine preoperative skin antisepsis for Cesarean delivery: A systematic review and meta-analysis. *Am J Perinatol*. 2015;26(2):118-23. Doi:10.1055/s-0038-1669907.
- [7] Artinyan A, Orcutt ST, Anaya DA, Richardson P, Chen GJ, Berger DH. Infectious postoperative complications decrease long-term survival in patients undergoing curative surgery for colorectal cancer: A study of 12,075 patients. *Ann Surg*. 2015;261(3):497-505. Doi:10.1097/SLA.0000000000000854.
- [8] Dencker EE, Bonde A, Troelsen A, Varadarajan KM, Sillesen M. Postoperative complications: An observational study of trends in the United States from 2012 to 2018. *BMC Surg*. 2021;21(1):393. Published 2021 Nov 6. Doi:10.1186/s12893-021-01392-z.

- [9] Berríos-Torres SI, Umscheid CA, Bratzler DW, Leas B, Stone EC, Kelz RR, et al. Centers for disease control and prevention guideline for the prevention of surgical site infection. 2017 [published correction appears in JAMA Surg. 2017;152(8):803]. JAMA Surg. 2017;152(8):784-91. Doi: 10.1001/jamasurg.2017.0904.
- [10] Tomita K, Chiba N, Ochiai S, Yokozuka K, Gunji T, Hikita K, et al. Superficial surgical site infection in hepatobiliary-pancreatic surgery: Subcuticular suture versus skin staples. J Gastrointest Surg. 2018;22(8):1385-93. Doi: 10.1007/s11605-018-3754-5.
- [11] Batra J, Bekal RK, Byadgi S, Attresh G, Sambyal S, Vakade CD. Comparison of skin staples and standard sutures for closing incisions after head and neck cancer surgery: A double-blind, randomized and prospective study. J Maxillofac Oral Surg. 2016;15(2):243-50. Doi: 10.1007/s12663-015-0809-y.
- [12] Rabha P, Srinivas S, Bhuyan K. Closure of skin in surgical wounds with skin stapler and conventional sutures: A comparative study. Int Surg J. 2021;9:66. Doi: 10.18203/2349-2902.isj20215132.
- [13] Kathare SS, Shinde ND. A comparative study of skin staples and conventional sutures for abdominal skin wound closures. Int Surg J. 2019;6:2168-72. Doi:10.18203/2349-2902.isj20192387.
- [14] Misha G, Chelkeba L, Melaku T. Incidence, risk factors and outcomes of surgical site infections among patients admitted to Jimma Medical Center, South West Ethiopia: Prospective cohort study. Ann Med Surg. 2021;65:102247. Doi:10.1016/j.amsu.2021.102247.
- [15] The Association of Surgeons of India: Guidelines for surgical emergencies. 2015 Available: <https://asiindia.org/wp-content/uploads/guidelines-for-surgical-emergencies.pdf>.
- [16] Lenzi L, Santos J, Raduan Neto J, Fernandes CH, Faloppa F. The Patient and Observer Scar Assessment Scale: Translation for portuguese language, cultural adaptation, and validation. Int Wound J. 2019;16(6):1513-20. Doi: 10.1111/iwj.13228. Epub 2019 Oct 9. PMID: 31599117; PMCID: PMC7949325.
- [17] Huda F, Gajula B, Singh S, Kumar S, Lokavarapu MJ, Sowmya D. Staples versus sutures for skin closure in standard four port laparoscopic cholecystectomy: A prospective cohort study. Cureus. 2021;13(3):e13725. Doi: 10.7759/cureus.13725.
- [18] Pandey ND, Singh AK, Choudhary AK, Jina G, Thakare A, Supe NB. Comparative evaluation of efficacy of skin staples and conventional sutures in closure of extraoral surgical wounds in neck region: A double-blind clinical study. Natl J Maxillofac Surg. 2022;13(3):449-56. Doi:10.4103/njms.njms_305_21.
- [19] Krishnan R, MacNeil SD, Malvankar-Mehta MS. Comparing sutures versus staples for skin closure after orthopaedic surgery: Systematic review and meta-analysis. BMJ Open. 2016;6(1):e009257. Doi: 10.1136/bmjopen-2015-009257.
- [20] Oswal S, Borle R, Bhola N, Jadhav A, Surana S, Oswal R. Surgical staples: A superior alternative to sutures for skin closure after neck dissection-A single-blinded prospective randomized clinical study. J Oral Maxillofac Surg. 2017;75(12):01-06. Doi: 10.1016/j.joms.2017.08.004.
- [21] Liu Z, Liu B, Yang H, Zhao L. Staples versus sutures for skin closure in hip arthroplasty: A meta-analysis and systematic review. J Orthop Surg Res. 2021;16(1):735. Doi: 10.1186/s13018-021-02870-z.
- [22] Sureshkumar S, Jubel K, Ali MS, Vijayakumar C, Amaranathan A, Sundaramurthi S, et al. Comparing surgical site infection and scar cosmesis between conventional linear skin closure versus purse-string skin closure in stoma reversal-A randomized controlled trial. Cureus. 2018;10(2):e2181. Doi: 10.7759/cureus.2181.

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