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Original Research Article

A randomized clinical study comparing Trupler skin stapler and Trulon polyamide suture in post-surgical skin closure during orthopaedic and open abdominal surgeries

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ABSTRACT

Background: The increasing demand for accelerated rehabilitation and shorter hospital stays emphasizes the importance of effective post-surgical skin closure techniques. Orthopaedic and open abdominal surgeries commonly use metal staples or polyamide sutures for wound closure. Surgical site infections (SSIs) remain a significant concern, impacting patient outcomes and healthcare costs.
Methods: This prospective, randomized, single-centre trial aimed to compare clinical outcomes in 140 adult patients, randomized between Trupler skin stapler and Trulon polyamide sutures, undergoing orthopaedic and open abdominal surgeries. The primary endpoint was the incidence of SSI according to CDC criteria. Secondary outcomes included wound complications, post-operative pain, patient satisfaction, cosmetic appearance, time taken for closure, ease of use, and safety of the interventions.
Results: The primary endpoint did not show any significant difference in the number of SSIs between the two groups. Both groups experienced wound complications, but the stapler group showed less severe outcomes. The stapler group demonstrated improved time efficiency and ease of closure, leading to reduced post-operative pain and higher patient satisfaction. Cosmetic outcomes were superior in the stapler group. Adverse events were reported in both groups, with a slightly higher incidence in the suture group.
Conclusions: The Trupler skin stapler demonstrated advantages over Trulon polyamide sutures for wound closure. Despite similar SSI rates, the stapler group experienced improved time efficiency, lower post-operative pain, higher patient satisfaction, and superior cosmetic outcomes. The study supports the preference for Trupler skin stapler for wound closure in orthopaedic and open abdominal surgeries.

Keywords: Abdominal surgery, Orthopaedic surgery, Trulon polyamide suture, Trupler skin stapler

INTRODUCTION

The advancement of accelerated rehabilitation has created a demand for shorter hospital stays, placing increased emphasis on the post-surgical skin closure techniques.[1,2] The main objective of effective wound closure is to facilitate the healing process of the skin and achieve an aesthetically pleasing result, while minimizing the risk of complications such as wound dehiscence or infection.[3,4]

In orthopaedic and open abdominal surgeries, the two commonly utilized methods for skin closure are metal staples and polyamide sutures.[1,3] These techniques are employed to bring skin edges together during the healing phase. Metal staples are often favoured over sutures due to their perceived benefits of speed and ease of use.[2]

SSI is a significant and undesirable complication that can arise from surgical procedures. Identifying the risk

factors associated with SSI offers several advantages, including managing patient expectations and improving clinical outcomes. The national nosocomial infections surveillance (NNIS) system, established by the center for disease control and prevention (CDC), categorizes SSI as the third most commonly reported type of nosocomial infection among inpatients.[5]

Indeed, SSIs makeup approximately 16% of all nosocomial infections in hospitalized patients and can account for as much as 38% of infections specifically in surgical patients.[6] Despite advancements in surgical techniques, the implementation of modern technologies in the operating room, and preventive measures such as perioperative intravenous antibiotics and preoperative skin antiseptic, SSIs remain a persistent challenge in surgical settings.

SSIs pose significant risks to patient health, leading to increased morbidity and mortality rates, as well as imposing substantial economic burdens. In the realm of orthopaedic procedures alone, it is estimated that between 31,000 and 35,000 cases of SSIs occur annually.[7] Furthermore, abdominal surgery carries a significantly higher risk of SSI compared to other types of surgeries. Multiple prospective studies have consistently demonstrated that the incidence of SSI in abdominal procedures ranges from 15% to 25%, depending on the degree of contamination at the surgical site.[8-11] It is essential to focus on understanding and addressing SSI prevention in orthopaedic and open abdominal surgeries to enhance patient outcomes and reduce healthcare-associated costs.

Numerous authors have conducted comparative analyses to evaluate the clinical outcomes of staple and suture closure methods in orthopaedic and open abdominal surgeries.[12-13] However, despite these endeavours, the optimal approach for skin closure remains uncertain.

To address the existing uncertainty, we conducted a randomized clinical trial involving both orthopaedic and open abdominal surgeries. The objective of our study was to investigate whether there are any noticeable distinctions in clinical outcomes, specifically regarding SSI, wound complications, cosmetic appearance, and patient and surgeon feedback when utilizing either staples or sutures for skin closure in adult patients undergoing orthopaedic and open abdominal surgical procedures.

METHODS

Study design and study setting

This study is a single-centre, prospective, two-arm, parallel-group, randomized (1:1) trial conducted at the Department of Orthopaedics and Department of General Surgery, Burdwan Medical College and Hospital, between September 3, 2022, and June 5, 2023. The primary objective of the study was to compare the rate of SSI between the two groups: Trupler skin stapler and Trulon polyamide sutures. The secondary objectives included the evaluation of wound complications, post-operative pain, patient satisfaction, cosmetic appearance of the wound, time taken for skin closure, ease of use, and safety of the two interventions.

Ethical approval

The study received approval from the Institutional Ethics Committee of Burdwan Medical College and Hospital. Additionally, it was prospectively registered in the clinical trial registry of India on August 29, 2022, under the reference number CTRI/2022/08/045018.

Study participants

The study included adult patients (both males and females) aged between 18 and 70 years, who were scheduled to undergo orthopaedic or open abdominal surgeries at the study site and provided informed consent. However, certain criteria were applied for the exclusion of patients. Those excluded from the study were patients with uncontrolled diabetes (HbA1c >10%), hemoglobin levels below 7 gm/dl, a body mass index (BMI) exceeding 35 kg/m^2, a history of previous surgical incision at the same site as the current planned surgery, a systemic infection that was not controlled by antibiotic treatment, or a topical infection present at the planned incision site.

Interventions

The Trupler skin stapler from Healthium Medtech Limited was used as the intervention group in the study. This skin stapler is made of pre-loaded stainless-steel staples and is designed for approximating the skin during surgical procedures across various indications.

In the comparator group, the Trulon monofilament polyamide non-absorbable suture from Healthium Medtech Limited was utilized. This sterile suture is composed of a synthetic, monofilament material prepared from a copolymer 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 participants in the study underwent predetermined open abdominal surgeries or orthopaedic surgeries according to the standard practice at the institution. Following the surgical procedure, the choice of post-surgery skin closure method, either the Trupler skin stapler or Trulon polyamide suture, was determined based on randomization. This randomization process aimed to minimize allocation bias and ensure an unbiased comparison between the two groups.

Study outcomes

The primary endpoint of the study was to compare the incidence of SSI between the two groups, using the criteria set by the centers for disease control and prevention (CDC).

The secondary endpoints included a comparison of various wound complications such as skin disruption, wound dehiscence, sinus formation, seroma, and hematoma. Post-operative pain and pain experienced during staple or suture removal were assessed using a 100-point visual analog scale (VAS). Analgesic usage was also recorded. Patient satisfaction was evaluated using a scale of 1 to 100. The cosmetic appearance of the wound was assessed using the Modified Hollander scale. The time taken for skin closure, measured in seconds, was recorded. The ease of use of the two interventions was assessed using a 5-point scale. Any adverse events or serious adverse events (AE/SAE) that occurred in either group were also documented.

During the screening visit, comprehensive data including demographics, vital signs, medical history, surgical history, orthopaedic and abdominal history, as well as physical examination findings, were recorded for all patients. The operating surgeon's opinion regarding the device used was documented on day 0 of the study.

During the follow-up reviews, which took place on day 7-14±2, 42±7, and 84±7, the investigator noted their opinion on various characteristics of the wound. This assessment provided insights into the healing process and any potential complications.

Sample size

According to Kathare et al 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, a superiority trial's sample size calculation formula was used for the study with a power of 95% and a significance level of 0.05 ($\alpha=0.1$). The sample size was estimated to be 122. Taking into account randomisation failure and failure to follow up among 12% of subjects, the sample size was increased to 140, with 70 subjects in each group.

Randomisation

All participants in the study were randomly assigned to either the Trupler skin stapler or the Trulon polyamide suture in a 1:1 ratio. The randomization sequence was created independently using computer-generated randomization. To ensure balance and prevent potential biases, block randomization was utilized with block sizes of 4, 6, and 8. The randomization details were concealed within opaque envelopes, which were only opened in the operation theatre on the day of surgery. Separate block randomization was performed for orthopaedic and open abdominal surgeries. As a result, 35 patients from each group received the Trupler skin stapler, while the remaining 35 received the Trulon polyamide suture, following the generated randomization sequence.

Statistical analysis

Continuous variables in the study were analysed using the ANOVA test to assess extreme reactions. The results were reported as the mean and standard deviation, where applicable. Categorical variables were evaluated using Pearson's chi-square test. A confidence interval of 95% was used for calculations, and a $p\leq0.05$ was considered statistically significant. All statistical analyses were conducted using the statistical package for the social sciences (SPSS) software, version 28.0.

RESULTS

A total of 140 adult patients were screened for the study between September 3, 2022, and January 31, 2023. These patients were then randomly assigned to either the stapler or suture group. All participants from both groups received the designated interventions as per the randomization. The follow-up period for the last recruited subject was completed on June 5, 2023, indicating the conclusion of the study. In total, there were 140 subjects who were randomized into the two groups, with 70 participants in each group (Figure 1).

Table 1: Base line demographics and vital characteristics of patients in both groups.

Parameters	Trupler skin stapler, (n=70)	Trulon polyamide suture, (n=70)	P value (ANOVA test)
Age (in years)	44.47±13.95	41.80±14.49	0.27
Height (cm)	165.23±6.22	165.74±7.34	0.66
Weight (kg)	59.24±7.75	60.16±7.09	0.47
BMI (kg/m^2)	21.71±2.46	21.88±2.04	0.66
Systolic (mm of Hg)	122.46±9.72	121.09±7.53	0.35
Diastolic (mm of Hg)	78.10±8.08	79.71±4.99	0.16
Pulse (BPM)	83.07±5.63	83.74±4.28	0.43
Temperature (°F)	96.68±0.39	96.70±0.46	0.81
Respiratory rate (BPM)	16.24±1.07	16.30±1.17	0.76

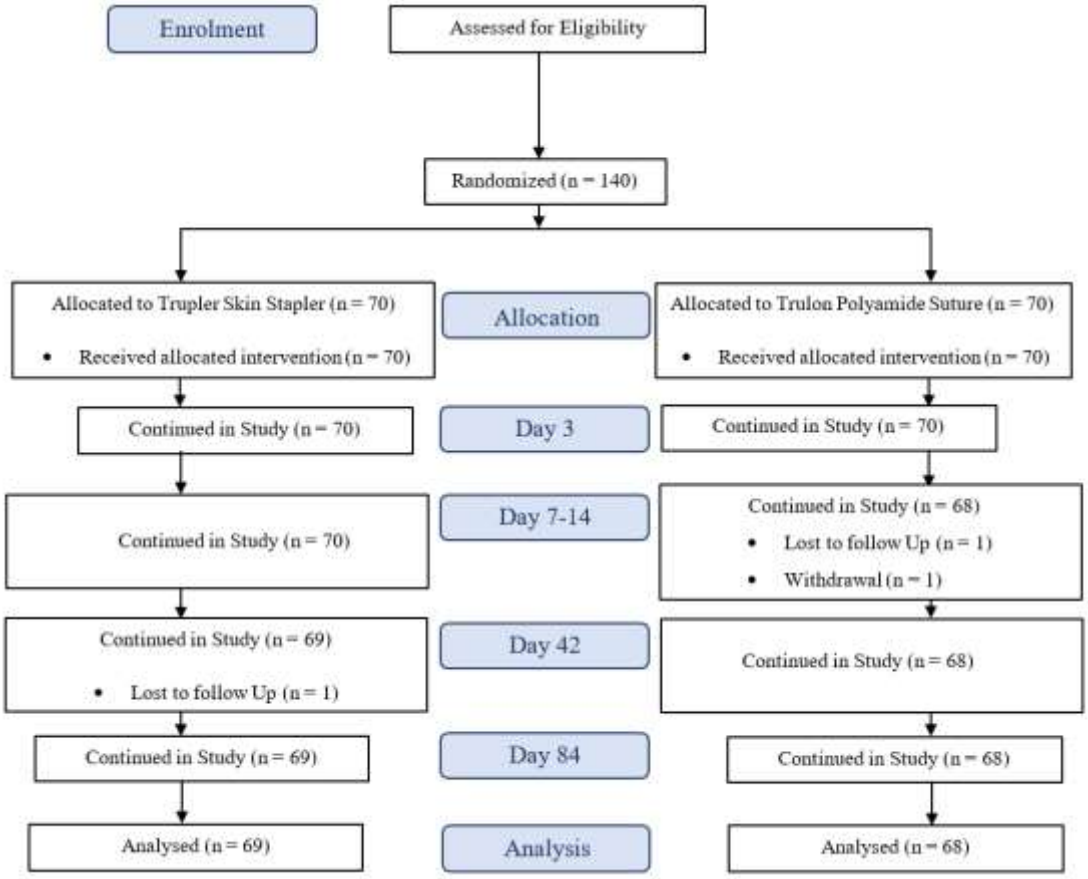

Figure 1: CONSORT 2010 flow diagram.

Baseline demographic parameters and vital characteristics were comparable between the two groups (Table 1).

Primary endpoint analysis

SSIs as per CDC criteria were detected in 4 patients within both the stapler and suture groups with no significant difference. The incidence rate of these infections in each group was determined to be 5.71%.

Secondary endpoint analysis

Intraoperative profile

All patients included in the study received antimicrobial prophylaxis prior to surgery, and general anaesthesia was administered as per standard institutional practice (p=1.00). Two instances of misfiring were reported with the Trupler skin staplers, with one occurring in orthopaedic wound closure and the other in open abdominal wound closure. No dysfunction related to sutures was reported. The mean length of incision was 23.74±6.40 cm in the stapler group and 19.86±6.86 cm in the suture group. The characteristics of stapler and suture techniques varied significantly, making direct comparison challenging. More details on these characteristics can be found in Table 2. The time taken for the closure of the incision site was 157.97±70.02 seconds in the stapler group and 522.36±150.23 seconds in the suture group, as indicated in Table 2 and Figure 2. The difference in closure time between the two groups was found to be statistically significant (p<0.0001).

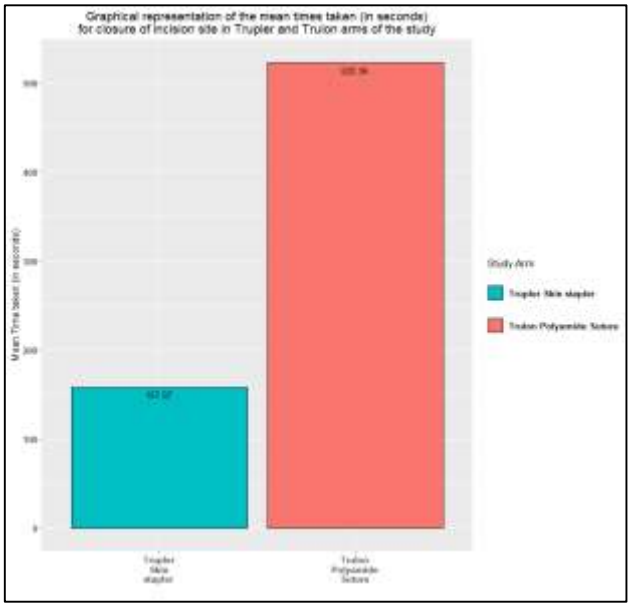

Figure 2: Schematic representation of meantime (seconds) taken for closure of incision site in stapler and suture arms of the study.

Table 2: Intraoperative characteristics of stapler and suture evaluated by operating surgeon.

Parameters	Mean±SD
Trupler skin stapler, (n=70)	
Ease of handling stapler	4.86±0.39
Ease of stapling	4.53±0.65
Ease of stapler release	4.04±0.65
Staple pin shape after firing	4.14±0.52
Satisfaction with skin closure	4.79±0.56
Time in seconds	157.97±70.02
Trulon polyamide suture, (n=70)	
Ease of passage	3.33±0.79
Knot holding	3.09±0.81
Knot security	2.97±0.82
Knot tie down smoothness	2.87±0.80
Stretch capacity	2.73±0.83
Memory	2.84±0.75
Suture fraying	2.66±0.66
Satisfaction with skin closure	2.71±0.82
Time in seconds	522.36±150.23

Regarding the satisfaction score of operating surgeons for skin closure, the stapler group had a score of 4.79±0.56, while the suture group had a score of 2.71±0.82 (on a scale of 1 to 5, with 1 representing the least satisfaction and 5 representing the highest satisfaction). The difference in satisfaction scores between the two groups was statistically significant (p<0.0001).

Wound complications

Throughout the duration of the study, a total of four cases of wound complications were recorded. Among these instances, two were observed in the stapler group. These two cases included seroma in the patients who also had SSI as mentioned in the primary endpoint. It is noteworthy that no incidents of wound dehiscence, sinus formation, hematoma, and skin disruption or the need for re-stapling were reported within this particular group.

In contrast, the Trulon group also encountered two cases of wound complications. These complications consisted of two occurrences of skin disruptions that required re-suturing, in the patients who also had SSI as mentioned in the primary endpoint. There were no other incidents of wound dehiscence, sinus formation, hematoma, and Seroma reported within this particular group. For a more comprehensive comparison of these outcomes, additional information can be found in Table 3.

Post-operative pain

Post-operative pain was assessed at all visits from day 0 to day 84. The highest pain scores were reported on day 0 after the effects of anaesthesia wore off, followed by a gradual decrease in pain scores during subsequent visits. By day 84, the reported mean score was 0.48±2.31 in stapler and 0.74±2.62 in suture group.

During the removal of either a suture or stapler, subjects experienced mild pain, which was also one of the secondary endpoints measured. The mean pain score during device removal was 24.99±9.19 for the stapler group and 36.07±11.36 for the suture group. Pain was measured using the 100-point VAS for both scenarios. Comparative pain scores can be found in Table 3 and Figure 3.

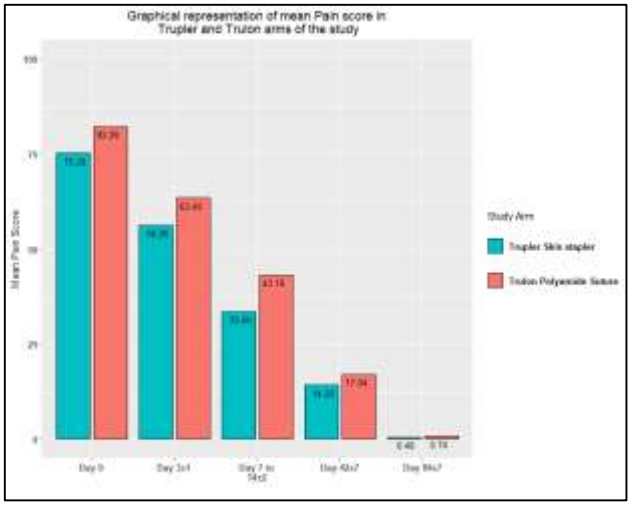

Figure 3: Mean pain score among patients in stapler and suture arms of the study during each visit.

Use of analgesics

The post-surgical use of analgesics is a common practice to alleviate pain following surgical procedures. On day 0, the highest usage of analgesics was observed, which gradually decreased as the days progressed. After day 14±2, there was minimal usage of analgesics reported (Table 3).

Table 3: Comparative analysis of secondary endpoints in both groups.

Point of analysis	Parameters	Trupler skin stapler, (n=70)	Trulon polyamide suture, (n=70)	P value (Chi-square test)
Wound complications	Seroma	2	0	<0.0001
	Skin disruption requiring restapling /resuturing	0	2	<0.0001
	Wound dehiscence	0	0	-
	Sinus formation	0	0	-

Continued.

Point of analysis	Parameters	Trupler skin stapler, (n=70)	Trulon polyamide suture, (n=70)	P value (Chi-square test)
	Hematoma	0	0	-
Analgesics used	Day 0	2.41±0.77	2.31±0.67	0.58
	Day 3±1	2.11±0.86	2.01±0.79	0.48
	Day 7-14±2	1.04±0.46	1.01±0.47	0.73
	Day 42±7	0.28±0.48	0.40±0.49	0.15
	Day 84±7	0.03±0.17	0.09±0.29	0.14
Skin closure	Ease of skin closure	4.69±0.58	1.96±0.91	<0.0001
	Time taken for skin closure (secs)	157.97±70.02	522.36±150.23	<0.0001
Pain score	Day 0	75.20±5.66	82.26±7.57	<0.0001
	Day 3±1	56.26±9.69	63.40±10.02	<0.0001
	Day 7 to 14±2	33.56±10.14	43.16±11.07	<0.0001
	Day 42±7	14.22±6.08	17.04±4.69	<0.0001
	Day 84±7	0.48±2.31	0.74±2.62	0.48
Pain during removal	Day 7-14±2	24.99±9.19	36.07±11.36	<0.0001
Modified Hollander score	Day 7 to 14±2	0.19±0.57	2.01±0.92	<0.0001
	Day 42±7	0.03±0.24	0.91±0.77	<0.0001
	Day 84±7	0.00±0.12	0.12±0.32	0.01

Skin closure

The study findings indicate a correlation between the ease of skin closure and the time taken for the procedure. The mean time in seconds for skin closure was 157.97±70.02 in the stapler group and 522.36±150.23 in the suture group. This significant difference in time between the two groups is supported by a p<0.0001, as shown in Figure 2. The data suggests that the easier the skin closure method, the less time it takes to complete the procedure.

Modified Hollander scale

The modified Hollander scale was completed by the investigator on day 7-14±2, day 42, and day 84 to assess the cosmetic appearance of the wound. Over time, there was a gradual improvement observed in the wound and its cosmetic appearance. The values in Table 3 and Figure 4 represent the scores on a scale of 0 to 6, where 0 indicates the closest proximity to normal appearance and 6 represents the farthest deviation from normal appearance. The data suggests that the wounds showed a trend toward improved cosmetic outcomes as the study progressed.

Patient satisfaction score

The patient satisfaction score was recorded during the visit on days 7-14 when the skin closure device was removed. In the stapler group, the mean satisfaction score of patients was 81.59±10.83. On the other hand, in the suture group, the mean satisfaction score of patients was 62.99±9.41. The satisfaction score was assessed on a scale of 1 to 100, where 1 represented least satisfaction and 100 represented the highest satisfaction. The data suggests that patients in the stapler group had higher satisfaction scores compared to those in Trulon group.

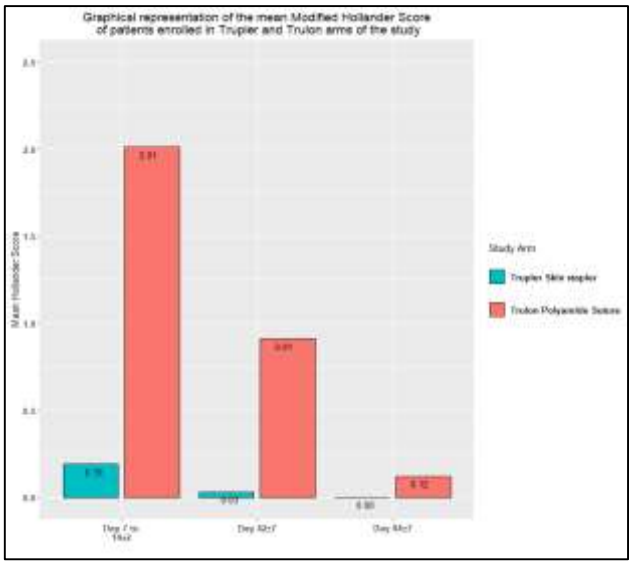

Figure 4: Mean total modified Hollander score among patients in stapler and suture arms of the study.

Adverse events

Both the stapler and suture groups experienced non-serious and SAEs during the study.

Among the four SAEs that were reported, two of them were associated with the stapler group, while two were linked to the suture group. The two SAEs in the stapler group were attributed to readmissions caused by post-operative wound complications such as seroma and SSI. Patients were treated with antibiotic medications and wounds were dressed with silver colloidal solution. As for the suture group, the two SAEs were also attributed to the readmission for more than 24 hours due to re-suturing in two cases as a result of SSI and skin disruption. All

these 4 events were found to be unrelated to the study devices but were attributed to factors like lack of hygiene, poor general health and patient awareness regarding wound care.

Furthermore, there were a total of 8 non-SAEs reported. In the stapler group, two patients experienced seasonal flu. In the suture group, six patients encountered various AEs such as fever, abdominal pain, seasonal flu, nausea, vomiting, and post-surgical orthopaedic pain. These AEs were considered non-serious and were not directly related to the study device.

It's important to note that all adverse events, both serious and non-serious, were monitored and documented during the study to ensure participant safety and to evaluate any potential risks or complications associated with the interventions.

DISCUSSION

Several factors are considered important when choosing wound closure methods after orthopaedic and open abdominal surgery. These factors include ease and speed of closure, patient comfort, complication rate, final cosmetic outcome, and cost.[2] In the past, early studies indicated that using staples for wound closure could potentially reduce the incidence of wound infections due to their fixation mechanism. Krishnan et al referenced the work of researchers such as Johnson and Stillman who suggested that skin stapling might cause less damage to the wound's defences compared to non-absorbable sutures.[14] Their reasoning was based on the concern that foreign materials could compromise immune response.

Another hypothesis, proposed by Pickford and referenced by Oswal et al suggested that staples crossing the incision site without penetrating the skin could potentially reduce the introduction of foreign materials into the wound.[15] Despite this study reporting an equal number of wound complications in both groups, our study's findings support the hypothesis put forth by Johnson, Stillman, and Pickford. This validation is attributed to the fact that the severity of wound complications was comparatively lower in the stapler group as opposed to the suture group. Although the overall count of reported complications remained consistent across the two groups, the suture group experienced more intense complications, leading to skin disruptions that required re-suturing in two patients. In contrast, the stapler group did not encounter any instances necessitating re-stapling. These results emphasize that while the total occurrence of wound complications may not show a significant difference, the nature and intensity of these complications align with the hypothesis endorsed by Johnson, Stillman, and Pickford. The stapler technique's ability to mitigate the severity of wound-related issues contributes to the support of their proposed mechanism.

In a study by Huda et al no significant difference in wound infection was observed between the two groups.[16] Similarly, in a multicentric study involving 1080 patients with open gastrointestinal wounds, Pandey et al found no statistically significant difference in wound infection rates between subcuticular sutures and skin staplers.[17] Similarly, the present study's results align with this pattern, as the occurrence of SSI was noted in 4 cases within both the stapler group and the suture group. In a study by Kathare et al 3 cases of wound complications were reported in the stapler group compared to 4 cases in the suture group, which is consistent with the present study that reported 2 complications in each group.[18]

All comparative studies unanimously indicate that staplers offer the advantage of time over sutures in skin closure.[13,16] Kathare et al reported a skin closure time of 11 seconds/cm in the stapler group compared to 45 seconds/cm in the suture group.[18] The mean incision length in that study was 7 cm, whereas, in the present study, it was 23.74±6.40 cm for stapler arm and 19.86±6.86 for suture arm respectively. The present study reported a mean skin closure time of 6.65 seconds/cm seconds in the stapler group and 26.30 seconds/cm seconds in the suture group. Ease of skin closure was also statistically more significant in the stapler group (4.69±0.58 vs 1.96±0.91).

Both groups experienced post-operative pain to varying degrees, necessitating the use of analgesics. The present study reported decreased post-operative pain in the stapler group compared to the suture group (35.94 vs 41.32), with no significant difference in analgesic use (1.17 vs 1.16). These results align with those of Parameshwara et al where a visual analogue scale was used to assess post-operative pain, showing that the suture group had a pain score three times higher than the stapler group.[13] Initially, when staplers were first used in surgeries, pain during their removal was believed to be higher than during suture removal. However, in recent years, it has been thought to be similar, as reported by Huda et al and Oswal et al.[15,16] The present study also confirms this observation.

Liu et al referenced Kanegaye et al study on paediatric scalp lacerations, which found less pain during removal and a more cosmetically appealing scar in the stapler group.[19] The present study reports a slightly better cosmetic appearance of the wound at the 42-day follow-up visit in the stapler group (0.01 vs 0.10). This coincides with the findings of Huda et al and Kathare et al.[16,18]

In our study, we found that 98.55% of patients in the stapler group had a good scar, while only 27.94% of patients in the suture group had a good scar ($p<0.0001$). These findings are consistent with the study conducted by Malle et al which demonstrated that the cosmetic result of staples is comparable to, if not better than, polyamide sutures.[20] Similarly, Feng et al compared stapled and sutured abdominal wound closure and found nearly equal cosmetic scores for vertical wounds.[21] They also observed

that wounds closed with staplers were cosmetically superior in 80% of the cases.

Both stapler and suture groups in our study reported AEs, including SSI and wound complications, which aligns with findings of Cochetti et al.[22]

Limitations

The present study was conducted in a single centre with a relatively small patient population, which limits the generalizability of the results. If the study had been conducted in a multi-centre setting, involving different hospitals and a larger patient pool, the findings would have provided a more generalized perspective. Conducting research across multiple centres allows for greater diversity in patient characteristics, surgical techniques, and healthcare practices, enhancing the external validity and applicability of the study's results to a broader population.

CONCLUSION

The study's outcomes highlight multiple advantages of the Trupler skin stapler in contrast to the Trulon polyamide sutures. The primary study endpoint, which focused on the incidence of SSI, revealed an equal number of cases in both groups. Although the frequency of wound complications was comparable between the two groups, distinctions in the severity of these complications emerged. Particularly noteworthy is that none of instances in stapler group required re-stapling, while in contrast, 2 cases in suture group necessitated re-suturing.

Furthermore, the Trupler skin stapler demonstrated improved time efficiency and ease of closure. This led to reduced post-operative pain and discomfort during the removal of the device. Additionally, higher patient satisfaction and superior cosmetic outcomes were reported in stapler group in comparison to suture group.

The comprehensive findings of this study substantiate the conclusion that employing the Trupler skin stapler yields superior results compared to the Trulon polyamide sutures for wound closure in both orthopaedic and open abdominal surgeries. These outcomes strongly advocate for the preference of the Trupler skin stapler for wound closure in these surgical contexts over the use of Trulon polyamide sutures.

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