



General Surgery

COMPARATIVE STUDY OF STAINLESS STEEL STAPLES CLOSURE OF SKIN WOUND VERSUS 3-0 ETHILON CLOSURE

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ABSTRACT **BACKGROUND:** The choice of wound closure after surgery, whether major or minor procedure, there always exist lot of questions in many concerns. One of those concerns is how fast and comfortable will be the recovery. A new technology is surgical staples, easier to use with minimal tissue reactivity. The Objectives of the study: To compare the post operative pain ,cosmetic appearance of skin closure by two observe any complications in the two methods of skin closure.

Methods: This is a comparative study conducted on 70 patients in two groups, done at Department of General Surgery, ASRAMS, Eluru. Cases undergoing clean elective surgical procedure and skin closure with suturing or with staples under same antibiotic coverage for same duration from October 2016 to September 2018. In both the groups, the post-operative pain is assessed at 0hours, 12 hours, 24hours, 36 hours, 48hours, 72hours, and 7th day using VAS of 0 to 100, as rated by patient themselves. The outcome of wound is assessed at 3rd, 5th, 7th post-operative days using ASEPSIS score and Any complications,.

Results: There is significant less post-operative pain. Maximum number of complication is noted in Skin Suturing group of 34% (12 cases). In Skin staples group 20% (7 cases) of complications are observed. Wound separation is 0.06% (2cases) in Skin staples Group and 0.06% (2 cases) in Skin Suturing Group which is of equivalent outcome. The early results are in favour of Skin staples group and the Cosmesis at 1st month, 3rd month and 6th month is good with Skin staples group is of great significant.

KEYWORDS : Skin staples, Wound ASEPSIS Score, Wound Cosmesis Score, Visual Analog Scale.

INTRODUCTION

The goal of surgery is to achieve healing by such means with minimal oedema, no serous discharge or infection, without separation of the wound edges and with minimal scar formation. After any surgical procedure (assuming there are no tension and a good blood supply) careful approximation of the tissues will allow healing by primary intention. Principles of wound closure focus on relieving tension on the wound and bringing the skin edges together in an everted orientation. If sutures are tied too tight or left in too long, they may leave permanent suture tracts and removed before adequate healing, the lack of wound tensile strength may result in wound dehiscence or a widened scar. Wound closure includes ensuring a clean wound with satisfactory vascularity and haemostasis and apposition without wound tension. Surgical Site Infection (SSI) is the most common nosocomial infections reported in the hospital patients.. A closure that penetrates the epidermis and dermis only serves to auto inoculate the wound of the patient, driving surface flora deep into the subcutaneous tissue. Suture closure also is a potential source of foreign body reaction within the susceptible subcutaneous tissue. The type of suture material for skin closure is also reported to influence postoperative wound complications. Skin staples give a neat scar with good wound eversion and minimal cross hatching effect. They can be placed faster than sutures and have a lower predisposition to infection because they do not penetrate entirely through the wound and do not produce a complete track from one wound to the other.

AIMS AND OBJECTIVES

1. To compare the incidence of post operative wound infection between skin staples and conventional sutures in elective surgeries.
2. To compare the cosmetic outcome of stapled closure with conventional sutures.
3. Cost-effectiveness.

INDICATIONS for use of staplers:

The Skin Stapler has application for routine skin closure in a wide variety of surgical procedures.

CONTRAINDICATIONS:

When it is not possible to maintain at least a 5 mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated. Wounds that are to be closed with tension Known allergy to nickel or chromium.

ADVANTAGES

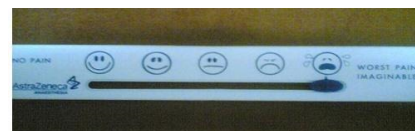
Time, Cosmesis, Prevention of needle prick injury

DISADVANTAGES

Cost, Pain, Requires an second operator for wound eversion

METHODOLOGY

In both the groups, the post-operative pain is assessed at 0hours, 12 hours, 24hours, 48hours, 72hours, and 7th day using Visual Analogue Scale of 0 to 100. 0 being no pain and 100 is worst pain possible as rated by patient themselves.

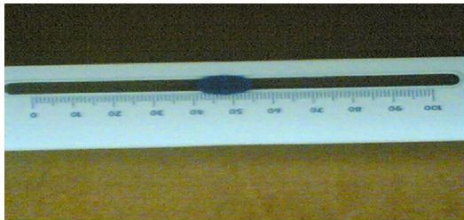


The outcome of wound is assessed at 3rd, 5th, 7th post-operative days using ASEPSIS score. Wound is scored from 0 to 10, according to the proportion of wound involved and presence of serous collection, erythematous changes, purulent exudate exudates, and separation of deep tissues.

ASEPSIS wound score	Proportion of wound affected					
	0	<20	20-39	40-59	60-79	>80
Wound characteristic	0	<20	20-39	40-59	60-79	>80
Serous exudate	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudate	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

The wound is assessed for Cosmesis on 7th post-operative day using Modified Hollander Cosmesis Scale. which has 6 clinical variables as step-off borders, edge inversion, contour irregularities, excess inflammation, wound margin separation, and good overall appearance. A total cosmetic score was derived by adding the scores of variables. A score of 1 is given to each variable if not present in the wound, so a score of 6 was considered as optimal while 5 or less as sub-optimal. Any complications/infections, if present are also observed in both the groups.

On the follow-up at 1st month and 3rd month, the Wound Cosmesis is assessed by independent blinded observer and wound scoring is done using VAS of 0 to 100.



Visual Analog Scale markings

INCLUSION CRITERIA:

Cases undergoing clean elective surgical procedure and skin closure with suturing or with Stainless Skin Staples under same antibiotic coverage for same.

EXCLUSION CRITERIA:

Cases not undergoing primary closure, patients with diabetes, tuberculosis, anemia, jaundice, malnutrition, chronic immunosuppressive therapy & steroids, not agreeing for Skin Staples closure.

Method of Statistical Analysis:

- The following methods of statistical analysis have been used in this study.
- The results were averaged (mean + standard deviation) for continuous data and number and percentage for dichotomous data are presented.

Univariate analyses of the dichotomous variables encoded was performed by means of the Chi-Square test.

OBSERVATIONS AND RESULTS

The present study is done to compare the efficacy between traditional skin suturing and Skin Staples closure in clean elective surgeries. A total of 70 patients were recruited in the study from October 2016 to September 2018. The patients were randomly included in either Skin Suturing group or Skin Staples group and of same antibiotic for same duration. In no case, in any group, any irritation of skin or any hypersensitivity reaction was observed. No generalized reaction was noted either. No toxicity was observed in any case in either of the groups.

The patients in both the groups were selected randomly shows there were 57 males and 13 females in the present study and percentage of gender distribution of 81.43% males and 18.57% of females in our study. There were 27(38.5%) males and 8(11.4%) females out of 35 total cases in Skin Staples group, In suturing group there were 30 males(42.8%) and 5(7.1%) females out of 35 total cases. It is observed mean age ± SD of the age for Skin Staples group was 39.86±15.57 years and that for Skin Suturing group was 41.91±18.01 years. Nevertheless, this marginal difference in the age between the two categories were statistically not significant (p>0.609). The diagnosis and nature of surgeries were variable in each case in each group. All cases were clean and elective surgeries.

Distribution of Surgeries according to type of material used

SURGERIES	Type of Material used		Total
	Skin Staples	Skin Suturing	
Open Appendectomy	2 2.86%	3 4.29%	5 7.14%

Laparoscopic Cholecystectomy	2 2.86%	3 4.29%	5 7.14%
Excision of Fibroadenoma Lt breast	1 1.43%	1 1.43%	2 2.86%
Excision of Fibroadenoma Rt breast	2 2.86%	1 1.43%	3 4.29%
Bilateral Lichtenstein s Tension Free Mesh Hernioplasty	3 4.29%	5 7.14%	8 11.43%
Left Lichtenstein s Tension Free Mesh Hernioplasty	7 10%	10 14.2%	17 24.28%
Right Lichtenstein s Tension Free Mesh Hernioplasty	11 15.7%	8 11.43%	19 27.14%
Left Orchidectomy	0 0.00%	1 1.43%	1 1.43%
Lipoma Excisions	5 7.14%	1 1.43%	6 8.57%
Sebaceous Cyst Excisions	2 2.86%	2 2.86%	4 5.71%
Total	35 50%	35 50%	70 100%

POST OPERATIVE PAIN SCORE

The Post-operative pain is measured in both the groups using Visual Analog Scale by patients themselves. Visual Analog Scale (VAS) is calibrated from 0 to 100.0 is marked for being no pain and 100 being sense of worst pain. The pain score is observed at 0 hours, 12 hours, 36 hours, 24 hours, 48 hours, 72 hours, and 7th day. The Post Operative pain VAS at 0 hours after surgery. The mean in Skin is 84.57±14.82 and that of skin suturing is 97.14±7.10. This difference is of great significance with p value of <.0001 confidence. At 12 hours after surgery the mean in Skin Staples VAS is 69.43±14.13 and that of skin suturing is 84.71±9.54. This difference is of great significance with p value of <.0001 confidence. At 24 hours after surgery is as follows; mean in Skin Staples is 54.00±13.97 and that of skin suturing is 68.57±11.67. This difference is of great significance with p value of <.0001 confidence. At 36 hours after surgery is as follows; mean in Skin Staples group is 36.57±17.48 and that of Skin suturing is 53.71±13.08. This difference is of great significance with p value of <.0001 confidence. At 48 hours after surgery the mean in Skin Staples is 24.86±15.02 and that of skin suturing is 34.71±9.62. This difference is of great significance with p value of <.0017 confidence. At 72 hours after surgery, mean in Skin Staples is 12.57±8.52 and that of skin suturing is 19.43±8.02. This difference is of great significance with p value of <.0009 confidence. At 7th day after surgery, mean in Skin Staples is 3.82±4.93 and that of skin suturing is 7.94±5.92. This difference is of less significance with p value of <.0027 confidence.

WOUND ASEPSIS SCORE:

The outcome of wound is assessed at 3rd, 5th, 7th post-operative days using ASEPSIS score. Wound is scored from 0 to 10, according to the proportion of wound involved and presence of serous collection, erythematous changes, Purulent exudates, and separation of deep tissues. The overall complication rates in both the groups maximum number of complication is noted in Skin Suturing group of 34% (12 cases). In Skin Staples group 20% (7 cases) of complications are observed. There are 3 seromas, 2 Purulent exudate and 2 wound separation observed in Skin Staples group while in Skin Suturing 6 seromas, 3 Purulent exudates, 1 erythema and 2 wound separation were observed in the present study. Wound separation is 0.06% (2 cases) in Skin Staples Group and 0.06% (2 cases) in Skin Suturing Group which is of equivalent outcome in both groups.

WOUND COSMESIS SCORE

Patients in both the groups were followed up at time of suture removal usually 7 days, 1st month, and 3rd month and the wound is assessed for Cosmesis on 7th post-operative day using Modified Hollander Cosmesis Scale which has 6 clinical variables as step-off borders, edge inversion, contour irregularities, excess inflammation, wound margin separation, and good overall appearance. A total cosmetic score was derived by adding the scores of variables. A score of 1 is given to each variable if not present in the wound, so a score of 6 was considered as optimal while 5 or less as sub-optimal. Any complications/infections, if present are also observed in both the groups. On the 1st month, 3rd month and 6th month Wound Cosmesis is assessed by independent blinded observer and wound scoring is done using VAS of 0 to 100.

Score at 7th post-operative day using Modified Hollander Cosmesis Scale and Skin Suturing group has a maximum score of 6 and a minimum of 4 in 2 patients and score of 5 in 1 patient. In Skin Staples group maximum score is 6 and minimum is 5 in 2 patients. These early results are more in favour of Skin Staples. At 1 month, Skin Suturing group has a minimum score is 10 and maximum is 100 with a mean of 86.57±13.92. In Skin Staples group, maximum score is 100 and minimum is 70 with a mean of 98±7.19. This difference is of great significance with a P value of <.0001 confidences. At 3 months, Skin Suturing group has a minimum score is 10 and maximum is 100 with a mean of 88.29±13.82. In Skin Staples group, maximum score is 100 and minimum is 80 with a mean of 98.86±4.71. This difference is of great significance with a P value of <.0001 confidences.

At 6 months, Skin Suturing Group has a score of 100 and that of Skin Staples is also the same and the final outcome is equivalent in both the groups.

DISCUSSION

In our study, 70 patients underwent elective surgical procedure. Out of the 70, 35 underwent closure of skin with skin staples while the remaining 35 patients had their skin closed with non-absorbable sutures.

The comparison of these two groups were done in relation to: Post Operative Pain, wound Asepsis Score, wound Cosmesis Score

In both the groups, the post-operative pain is assessed at 0 hours, 12 hours, 24 hours, 36 hours, 48 hours, 72 hours, and 7th day using Visual Analogue Scale of 0 to 100, as rated by patient themselves. The present study shows significant less post-operative pain during early and 7 days post-operatively. In the present study there is significant less pain in Skin Staples Group up to first 72 hours following surgery and the 7th day post-operative pain is of less pain in Skin Staples is of no significance. This may be due to random selection of procedures in Skin Staples group.

The outcome of wound is assessed at 3rd, 5th, 7th post-operative days using ASEPSIS score. Maximum number of complication is noted in Skin Suturing group of 34% (12 cases). In Skin Staples group 17% (6 cases) of complications are observed. There are 3 seromas, 2 Purulent exudate and 1 wound separation observed in Skin Staples group while in Skin Suturing 6 seromas, 3 Purulent exudates, 1 erythema and 2 wound separation were observed. In the Present Study Wound separation is 0.06% (2 cases) in Skin Staples Group and 0.06% (2 cases) in Skin Suturing Group which is of equivalent in significance. There is a uniform agreement that skin wounds closed by staples exhibit a superior resistance to infection than skin wounds contaminated by the least reactive suture. The superior resistance of stapled wounds to infection as compared with the resistance of sutured wounds was confirmed by the experimental study of Stillman and colleagues. In contaminated wounds in mice, stapled wounds displayed a lower incidence of infection than wounds approximated by either percutaneous sutures (4-0 silk, 4-0 monofilament nylon, and 4-0 polyglycolic acid suture) or subcuticular sutures (4-0 polyglycolic).

Patients in both the groups were followed up at time of suture removal usually 7 days, 1st month, and 3rd month and the wound is assessed for Cosmesis on 7th post-operative day using Modified Hollander Cosmesis Scale. Further, in the follow-up of 1st month and 3rd month, the Wound Cosmesis is assessed by a blinded independent observer and was scored in VAS from 0 to 100. In the present study, the early results on 7th day is in favour of Skin Staples Group and the later follow up at 1st month, 3rd month and 6th month shows significant difference and Skin Staples group had got good Cosmesis as compared with Skin Suturing.

Thus in comparison with criteria of, the Post Operative Pain, the Cosmetic Appearance between Skin Staples group and Skin Suturing Group of the present study with earlier studies proves that Skin Staples is significantly better than the traditional Skin Suturing Skin closure.

Skin staples have several advantages over conventional sutures. They are quick and easy to use. Cosmetically, they produce good wound eversion and have a minimal crosshatch scar. Skin staples are relatively inert and can be left in situ for a longer period of time without any complications and in addition, patient can take a bath in the early postoperative period

CONCLUSION

Cosmesis is an important aspect in this day and age. A cosmetic scar not only gives patient satisfaction but also mental ease to the surgeon. Several methods of skin closure are available to close the skin incisions in place of sutures like staples, clips and glue adhesives. In our study, comparison of skin closure between stainless skin staples and sutures was done. We found that the use of skin staples in low tension incision is easy, less time consuming, associated with low incidence of wound complications, provides a good cosmetic outcome and thus recommend its use more frequently than it is being used presently.

SUMMARY

Skin staples give faster, comfortable and easier skin closure. So Skin staples are effective and reliable skin closure in clean elective surgeries

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