

Randomised Comparison of Nylon versus Stapler for Closure of Class I Surgical Skin Incisions

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Abstract: Background: At present, each surgeon has a plethora of materials available to bring about closure of surgical skin incisions. Till date, many studies have been conducted to compare skin closure materials in varying categories. This study aims to compare nylon and staplers in terms of closure of Class I clean surgical wounds. Materials and Methods: A randomized comparative study was conducted in Department of Surgery in a tertiary care hospital from May 2016 to June 2018 enrolling a total of 102 patients undergoing routine clean surgeries in the age group 15-70 years. Patients were randomized into two groups pre-operatively and were analyzed thereafter in terms of 3 parameters. Pain was documented on Day 1 and at suture removal, wound inflammation was documented in terms of redness, discharge and wound gaping and cosmesis was evaluated from both observers and patient's perspective at 3mths and 6mths. Thereafter, statistical analysis was done by applying t-test and chi-square test to obtain respective p values. Results: Wound complications and pain score were significantly higher in stapler group (p value <0.05). In terms of observer cosmesis sutured wounds scored better however, both stapled and sutured scored equally in terms of satisfaction to the patient. Conclusion: Study findings favour suture over staplers in terms of pain, wound and cosmesis factors although, both stapled and sutured scored equally in terms of satisfaction to the patient.

Keywords: nylon, staplers, cosmesis

1. Introduction

From times immemorial, various methods have been adapted for wound co-aptation. Dating from Paleolithic period Ancient

Greeks, Indians and Egyptians developed various indigenous ways to bring about wound closure using needles made from bone, antler etc and sutures made of natural material like ants, sheep's intestine etc. 19th century saw a leap in wound closure techniques by introducing synthetic materials and the needs for antiseptics. World war taught us the scale of wound infections and the paucity of natural suture materials which led to the revolutionary breakthrough of 'Mersutures'. 20th century saw the advent of spectrum of new sutures, staplers and suture- less closure (tissue glue, topical adhesives etc).

Scar formation is an inevitable consequence of wound healing from either a traumatic or surgical intervention¹. Till date, many studies have been conducted to compare nylon and staplers portraying the advantages and disadvantages of each method respectively. It has been argued that staples are more cost-effective, easier to use, and faster for closing wounds².

Therefore the study aims to compare nylon versus staplers in terms of parameters (pain, cosmesis and wound

inflammation) when it comes to closure of Class I clean surgical wounds.

2. Patients and Methods

A detailed history and routine investigations of patients was done. The randomization of groups was done in the pre-operative room by random list allocation using chits consisting of equal number of staplers and sutures written. In group A, skin was approximated using surgical staplers. In group B, the skin was approximated with nylon. Dressings and other postoperative care standards were followed similarly in both groups. Patients were inspected on the 1st postoperative day, on day of suture or staple removal and 2 weeks after surgery for evidence of wound complications. Scoring of wound complications was done against 3 parameters namely wound redness, discharge and gaping. The measure of pain was according to visual analogue scale. The cosmesis of the scar was rated on 10th day after surgery by the patient and an observer (who is unaware of the method of skin closure used) using the Visual analogue scale and Stony Brooke Scar evaluation scale [SBSES] (Fig 1.) respectively. The SBSES³ is a validated scar scale used in our study with special permission from Adam Singer (Annexure-1). This was followed by the statistical analysis of results so obtained.

The Stony Brook Scar Evaluation Scale (Fig 1.0)

	Scar category	Points
Width	>2 mm	0
	≤ 2 mm	1
Height	Elevated / depressed in relation to surrounding skin	0
	Flat	1
Colour	Darker than surrounding skin	0
	same colour or lighter than surrounding skin	1
Hatch marks/ Suture marks	Present	0
	Absent	1
overall appearance	Poor	0
	Good	1

3. Overview of Literature

Throughout history from ridiculous to ingenious, various materials have been experimented for skin closure. Needles were made of bone or metals such as silver, copper, and aluminum bronze wire. Sutures were made of plant materials (flax, hemp and cotton) or animal material (hair, tendons, arteries, muscle strips and nerves, silk and catgut). The first form of sewing was probably tying together animal skins using thorns and sharpened rocks as needles, with plant material as thread⁴. The year 1860 witnessed a phenomenal shift with Joseph Lister introducing the concept of antisepsis and advocating sterilization. This led to institution of carbolic catgut followed by chromic catgut two decades later. This was in turn followed by development of polymers which were forerunners of new generation of sutures amongst which two of the commonly used materials namely staplers and nylon have been compared in the following paper.

The increasing demand for aesthetically acceptable scars has led to the evolution of increasing number of surgical and non surgical procedures to achieve the same. The review of literature is done hereby to overview the studies comparing factors namely pain, cosmesis and wound inflammation in relation to certain demographic parameters used in our study.

The introduction of surgical staplers has definitely hastened the closure of surgical wound. Literature has reflected a uniform consensus amongst studies conducted in terms of proving the above statement as was shown by Michael et al⁵ who reported in his prospective randomized study of 52 lacerations requiring closure in the emergency department with either stapler or suture that lacerations were closed 2.7 times faster by the stapler method ($p < 0.001$). Similar results were shown by Paras et al⁶, Kanagaye et al⁷.

Chandrashekhar et al⁸ conducted a prospective hospital based study involving a total of 200 patients who underwent abdominal surgery both on an emergency and elective basis. Immediate post operative pain scores were higher with the use of sutures as compared to staples in both elective and emergency cases. Similar line of results was shown by Gaertner et al⁹, BI singh et al¹⁰. Contrasting results were obtained in studies done by Stockley¹¹, Muthukumar¹² whereby higher proportion of patients reported considerable pain with removal of staples.

In terms of patient satisfaction, RJ Khan et al¹³ reported a higher satisfaction rate amongst patients with staplers than

with sutures contrary to findings reported by Gohiya et al¹⁴ who found no significant difference between the two groups.

Lennihan et al¹⁵ compared wound closure using metallic staples and nylon sutures in 150 patients undergoing elective ligation and stripping for varicose vein and found that fewer patients developed complications from the staples however the same was not statistically evaluated. Muthukumar et al¹² in his study of 147 patients reported superiority of staplers over suture in causing less inflammation. Similar results were shown by Ivazzo et al¹⁶, Krunal et al¹⁷ etc.

Toby et al¹⁸ reviewed six papers, and concluded that the risk of developing a superficial wound infection after orthopaedic procedures was over three times greater after staple closure than suture closure. Above findings was also demonstrated by Stockley et al¹¹.

Clayer and Southwood¹⁹ reported that the scars produced by suture closure were significantly thinner than with staples after hip surgery. Veerendra et al²⁰ performed a comparative study on 100 patients undergoing laprotomy and used Modified Hollander score for cosmesis evaluation. The mean score for cosmesis assessment at 1 month and 3rd month for skin staples and suturing group was not statistically significant. Similar ambiguous results were also shown by Meiring et al²¹, Ivazzo et al¹⁶ etc.

4. Results

The results were analyzed from the observations made and are tabulated as follows

The study population analyses showed that majority of patients came under 2 peaks of age group i.e. 15-40 years (50%) and those above 60 years (23.52%). The mean age group in stapler group was 44.13 years and that in suture group 43.80 years. Male contributed to majority of study population in all sub categories taken, except for that of benign breast disease.

Table 1(a): Difference in Pain Levels in two Groups on Day 1

Pain time	Groups	N	Mean Pain Score	Std. Deviation	T	P
POD-1	A	45	2.4667	.89443	0.252	0.80*
	B	57	2.4182	1.03084		

The pain score analysis on POD-1 between the two methods of skin incision closure showed mean score of 2.4667 ± 0.89443 and 2.4182 ± 1.03084 respectively in stapled

and sutured wounds. The differences in the means were statistically insignificant with p value of <0.80 (Table 3a).

Table 1(b): Difference in Pain levels in two groups at suture removal

Pain time	Groups	N	Mean Pain Score	Std. Deviation	T	P
At Suture Removal	A	45	2.8409	1.41328	5.226	0.00**
	B	57	1.7091	.68510		

On the other hand, the pain experienced by the patient at suture removal between the two methods of skin incision closure showed mean score of 2.8409 ± 1.41328 and 1.7091 ± 0.68510 respectively in stapled and sutured wounds. The differences in the means were statistically significant with p value of <0.00 (Table 3).

The sub group analysis showed significantly higher pain score in those with age groups >40yrs, subcutaneous closure and wounds taking >5min for closure.

Table 2: Comparison of different observation b/w group A and group B

Observation	Groups	10th Day		T	P	2 Weeks		T	P
		N	%			N	%		
Redness	A	9	20	2.332	0.022*	0	0		NA
	B	3	6.6			0	0		
Discharge	A	8	17.78	2.453	0.016**	0	0		
	B	2	4.4			0	0		
Gaping	A	5	11.11	1.086	0.280***	4	8.8	1.14	0.256***
	B	3	6.6			2	4.4		

*No. of cases showing redness are significantly greater in group A as compared to group B

** No. of cases showing discharge are significantly greater in group A as compared to group B

*** No significant difference is seen in group A and B with respect to gaping.

The sub group analysis showed significantly higher gaping in stapled wounds with closure taking <2min. On other hand, sub group analysis showed significantly higher wound complications in sutured wounds whose closure took >2 min. No significant association was seen between other parameters and wound closure material.

Table 3: Comparison of patient and observer cosmesis score

Table 3 (a) Cosmesis Scores between two Groups
[Observer cosmesis score was based on Stony Brooke Scar Evaluation Scale whereby biennial score (0 and 1) was given for each of the parameter with minimum score of 0(worst) and maximum of 5(best)

Score	Group	Mean	Std. Deviation	P	Inference
0	Stapler	1.00	.00000	.000*	Stapler group had a significantly larger no of individuals reporting with score
	Suture	.222	.42044		
1	Stapler	.088	.28780	.323	Difference seen among groups was not significant
	Suture	.0667	.25226		
2	Stapler	.6667	.95346	.007*	Suture group had a significantly larger no of individuals reporting
	Suture	.9778	1.01105		

					with score
3	Stapler	.6000	1.21356	.044*	Suture group had a significantly larger no of individuals reporting with score
	Suture	.8667	1.37510		
4	Stapler	.9778	1.73845	.083	Difference seen among groups was not significant
	Suture	.7111	1.54658		

From the above table (Table 3a) we can see that stapled wounds had a significantly higher number of lower (0) observer cosmesis score (p=0.000) whereas sutured group had significantly higher number of scores 2(p value=0.007) and score3 (p value=0.44).

Table 3(b): Showing Comparison Of 3 Month Patient Cosmesis Scores Between Two Groups

[Patient cosmesis score was based on Visual analogue scale whereby scores 1, 2- extremely satisfied, 3- satisfied, 4- neutral, 7-unsatisfied, 10-extremely unsatisfied]

Score	Group	Mean	Std. Deviation	p value	Inference
1	Stapler	.2045	.40803	.013*	Suture group had a significantly larger no of individuals reporting with score
	Suture	.3409	.47949		
2	Stapler	1.0455	1.01052	.007*	Suture group had a significantly larger no of individuals reporting with score
	Suture	1.3636	.94231		
3	Stapler	.7500	1.31406	.323	Difference seen among groups was not significant
	Suture	.6818	1.27175		
4	Stapler	.2273	1.05354	.160	Difference seen among groups was not significant
	Suture	.0000	.00000		

From the above table (Table 3b), we can see that sutured wounds had a significantly higher number of patients with score 1 and 2(p value=0.013 and 0.007) respectively, while there was no significant difference seen between the two groups in terms of score 3, 4 (p value – 0.323 and 0.160) respectively.

Table 3(c) Showing Comparison Of 6 Month Patient Cosmesis Scores Between Two Groups

Score	Group	Mean	Std. Deviation	P	Inference
1	Stapler	.5455	.50369	.000*	Suture group had a significantly larger no of individuals reporting with score
	Suture	.7955	.40803		
2	Stapler	.8636	1.00211	.323	Difference seen among groups was not significant
	Suture	.9091	1.00737		
3	Stapler	.1429	.64662	.160	Difference seen among groups was not significant
	Suture	.0000	.00000		

From the above table, we can see that sutured wounds had a significantly higher number of patients with score 1 (p value=0.000), while there was no significant difference seen between the two groups in terms of score 2 and 3.

5. Discussion

Wound closure material is an important afterthought for majority of surgeons especially with the advancing technology and newer materials in market made available for same. There are a large number of studies comparing sutures versus staplers however on account of presence of heterogeneity of studies, a definite conclusion is yet to be attained. In the following study we compared and reviewed two methods of closure i.e. stapler and suture in terms of patient (pain and cosmesis), observer (cosmesis and wound infection) and general (cost and availability) parameters.

In the current study, study population analyses showed that majority of patients came under 2 peaks of age group i.e. 15-40 years (50%) and those above 60 years (23.52%). Male contributed to majority (73.1%) of study population in all sub categories taken, except for that of benign breast disease.

There was a general consensus regarding the time saved by using staple for wound closure. All the reviewed articles echoed the fact that stapling of wound was quicker and time saving when compared to conventional wound closure methods.²²⁻²⁵ The mean time saving of 80% was possible with stapling devices and was 2.7 times faster than conventional methods.²¹

Pain is a subjective parameter that is dependent on variables varying from age, sex to type of surgery performed, however its assessment is important as it accordingly necessitates standard of care to be provided.

In our study, we found that on pod-1 of surgery no significant difference was seen in pain score between 2 groups compared (Table 3a) in contrast to study done by Veerendra et al²⁰ who found significant differences in VAS score on Day 1 (p value <0.00012), Day 3 (p value <0.0018) and Day 7 (p value <0.00091). Another contrasting yet opposite results were reported by Sagar et al²⁶ in terms of post operative pain over surgical site, where he found wound pain is more in suture group (3rd day 1C4 patients, 7th day 18 patients, 14th day 10 patients) than in stapler group (3rd day 5 patients, 7th day 9 patients, 14th day 3 patients) corroborating with studies done by Ritchie AJ²⁷, D. Gatt et al²⁸.

In contrast to mean scores obtained on pod-1 we found that significantly higher level of pain was reported with stapler removal than suture removal. (As shown in 3b). There was an overall agreement in the fact that staples were associated with more pain and discomfort to patients as was depicted by Krunal et al¹⁷ who studied 162 patients undergoing clean surgery and concluded that VAS score was high in stapler group as compared to subcuticular group and Vertical mattress group. Identical results were also highlighted by studies^{11, 12} showing pain caused due to stapler as more significant than suture.

There was a fraction of studies⁸⁻¹⁰ who reported that suture caused more pain as compared to stapler.

In view of above discordance a meta-analysis was done which compared most of randomized control trials and

made a strong statement in need to incorporate more objective methods for assessment of patient satisfaction in further studies¹⁶.

Muthukumar et al¹² in his sub group analysis showed significant pain score mean differences in incision of length less than 5cm, between 5-10cm, more than 10cm. In contrast to above study, though our subgroup analysis showed significant associations between some of the parameters it was not possible to calculate the statistical difference between both the wound closure materials on account of small sample size.

Table 4: Pain associated with methods of closure in other studies

Study	Subgroup	Results
Our study	Age, subcutaneous closure, type of surgery, sex	Staples were associated with increased pain
Eldrup ²⁹	Not done	
Stockley ¹¹	Not done	
Slade ²²	Not done	
Ivazzo ¹⁶	Not done	
Muthukumar ¹²	Incision of length <5cm, 5-10cm and >10cm, clean and contaminated wounds	Staples associated with reduced pain
Chandrashekhar ⁸	Clean wounds	
Karbhari ³⁰	Not done	
Abdulsalem ²⁵	Not done	Equivocal results
Jitendra ²⁴	Not done	

In terms of wound complications, we have studied 3 parameters that is redness, discharge (Discharge refers to serous/ serosanguinous discharge, didn't encounter any purulent discharge) (p value-0.022) and gaping (p value -0.016) and found that number of cases showing discharge and redness was significantly higher in stapler group, however no such difference was seen in terms of gaping (p value -0.280). Similar studies were reported by Chandrashekhar et al⁸ who concluded that post-operative wound infections were marginally higher (almost comparable) in staples group (13.7%) compared to sutures group (12%) in elective cases; but significantly higher in staples group (38.09%) compared to sutures group (16%) in emergency cases. Also, Toby et al¹⁸ reviewed six papers, in which he reported that the risk of developing a superficial wound infection after orthopaedic procedures was over three times greater after staple closure than suture closure (relative risk 3.83, 95% confidence interval 1.38 to 10.68; P=0.01). Above findings were also demonstrated by Stockley et al¹¹, Tulle et al³¹ etc.

Other studies^{12, 15} demonstrated the superiority of sutures over staples in terms of lesser wound complications. There were also studies^{24, 32} where no difference was found in wound complications in between the two closure methods employed.

The sub group analysis in our study showed significant association between gaping in stapled wounds and closure taking <2min and also between wound complications and sutured wounds whose closure took >5min.

Table 5: Wound complications associated with method of closure in other studies

Study	Subgroup	Results
Our study	Age, subcutaneous closure, type of surgery, sex	Staples associated with More wound complications
Chandrashekhar ⁸	Clean wounds	
Stockley ¹¹	Not done	
Tulle ³¹	Not done	
Toby ¹⁸	Not done	Staples associated with less wound complications
Muthukumar ¹²	Incision of length <5cm, 5-10cm and >10cm, clean and contaminated wounds	
Lennihan ¹⁵	Not done	
Hemming ³²	Not done	
Jitendra ²⁴	Not done	Equivocal results

In our study, in terms of cosmesis we found out that the stapled wounds had a significantly higher number of lower observer cosmesis score (p=0.000) whereas sutured group had significantly higher number of lower (better) which was in line with studies performed by Lindsay et al³³ who showed that women with staples reported worse median cosmetic scores, darker scar color, and more skin marks compared to women with suture closure when using the same Observer cosmesis scale (SBSES).

**Figure 2:** Scar of stapled wound**Figure 3:** Scar of sutured wound

This was in contrast to studies done by Muthukumar et al¹², Karbhari et al³⁰ which showed superiority of stapled over sutured wounds in terms of cosmesis.

Veerendra et al²⁰ Meiring et al²¹, Ivazzo et al¹⁶ on other hand documented unequivocal results with equal scar outlook from both stapler and suture.

Table 6: Observer cosmesis associated with method of closure in other studies

Study	Results
Our study	Sutures had cosmetically superior scar
Lindsay ³⁵	
Karbhari ³⁰	
Muthukumar ¹²	
Ivazzo ¹¹	Equivocal results
Veerendra ²⁴	
Meiring ²¹	

In terms of patient satisfaction score, we can see that sutured wounds had a significantly higher number of patients with score 1 and 2 with p value-0.013 and 0.007 respectively at 3mths, while there was no significant difference seen between the two groups in terms of score 3, 4 with p value 0.323 and 0.160 respectively. The similar observation was reflected even at 6 months; however the percentage of individuals who were satisfied didn't vary between the two groups at both 3 and 6mths. These observations were consistent with studies done by Gohiya et al¹⁴ who found no significant difference between two groups (VAS scores of 8.47 in nylon group and 8.35 in staple group). Similar findings were also reported by Abdu salem et al²⁵, Yuenyongviwat et al²³ demonstrating equivalent results in terms of patient satisfaction. There were few studies like those by R J Khan et al¹³ who showed opposite results i.e. patient being more satisfied with stapler cosmesis than suture.

Table 7: Patient satisfaction associated with method of closure in other studies

Study	Results
Our study	Equivocal results, however for extreme satisfaction sutures superior
Abdu salem ²⁵	
Yuenyongviwat ²³	
Ivazzo ¹⁶	Staples had cosmetically superior scar
R J Khan ¹³	
Krunal ¹⁷	Suture had cosmetically superior scar

In terms of average cost of stapler and suture, most of the studies reviewed showed that staple were indeed more expensive than using conventional closure methods.^{7, 34}

6. Conclusion

Our study was conducted in a tertiary care hospital affiliated to medical school whereby on account of presence of only few such studies that are documented in literature, it can provide a strong platform and valuable resources to future researches. We realized the non acceptance of general population for staplers as wound closure material that comprised 0.6% of the initial study population. Also, we noticed that whereby on one hand the observer cosmesis score hardly managed to fare an average score in handful of patients, majority of patients on other hand were satisfied with their scar.

Small sample size of our study hindered adequate assessment. The scale employed for observer cosmesis i.e.

SBSES was limited by its ability to measure only short term cosmetic outcome. Also, as we employed the scale on Indian patients who are generally dark skinned the evaluation was not fully justified; moreover both stapled and sutured wounds had hatch marks at day 10 of observation which further confounded the result. Hence, future studies will need to be conducted along similar lines that will further clarify and bring out such findings especially in the Indian scenario.

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Annexure-1

