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# A Comparative Study between Conventional Sutures, Staples and Adhesive Glue for Clean Elective Surgical Skin Closure

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#### Authors' contributions

This work was carried out in collaboration among all authors. Author KM designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors YRL and Author MY managed the analyses of the study. Author MY managed the literature searches. All authors read and approved the final manuscript.

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Study Protocol

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# ABSTRACT

**Background:** A surgeon's signature is 'scar' [1]. On a regular basis, surgeons face various kinds of wounds which must be healed. The healing process and cosmetic result can be influenced by wound and incision closure techniques.

The Goal of this Research is to Compare 3 Skin Closure Techniques: conventional skin sutures, adhesive glue, surgical stapler. These methods will be used to determine which of them is superior in terms of wound healing and cosmetic outcome in clean elective surgeries. Objectives:

- a. To compare duration between closure by 3 methods.
- b. To compare prices amongst the 3 methods.
- c. A comparison of the cosmetic appearances of the skin after closure.
- d. A comparison of post-operative pain between the 3 methods.
- e. To assess surgical site infections after closure with these 3 methods

**Methodology:** 90 patients, undergoing clean elective surgeries, will be included in this study. 30 patients will be included in every group. Hospitalised under Department of General Surgery in Datta Meghe Institute Of Medical Sciences, Wardha. The study will be conducted between October 2020 to October 2022.

**Results:** The result would be undertaken in SPSS software.

**Conclusion:** Conclusion will be based on findings of study protocol.

Keywords: Skin sutures; adhesive glue; staples; scar; incisions wound.

### 1. INTRODUCTION

A surgeon's signature is 'scar' [1]. On a regular basis, surgeons face various kinds of wounds w hich must be healed. Wound can be described as the severance or break in the continuity of skin, mucous membrane or tissue due by chemical, physical or biological abuse. Whereas, a clean wound is usually an elective surgical incision which includes the following criterias [2]:

- Operative site should be uninfected
- There should be no inflammation
- No break in sterility technique
- Should be closed primarily and, or should be drained via closed drainage
- Respiratory, gastrointestinal and genitorurinary tracts should not be breached.
- Surgical wounds made after nonpenetrating blunt trauma, if the above criteria are fulfilled

Many creative and fascinating practices have said to be implemented in ancient times to hold wounds together. There have been reports from India and in SouthAmerica report ants being motivated to bite across a wound secured close together, after which the body of the ants are rapidly twisted off, leaving the approximated jaws of the creature behind, thereby "stapling" the lesion closed; a pioneer of the surgical stapler used in surgeries [3]

The Masai trbe in East Africa used to place acaciathorns in the skin along the edges of a cut, before securing them together by using plaited plant fibre [4] and thereby, closing the wound.

There was a lot of trialing in the world of surgery by mid 19<sup>th</sup> century. Many different types of materials like aluminum, tendons, arteries, aluminium, silverwire, copper, flex, cotton, hair, hemp, and evencatgut (made

from thesubmucosa ofanimal intestine) were being used. Sutures like polyamide (Nylon), polyglactin 910 (Vicryl) , polydioxanone (PDS) were mass produced by mid-20<sup>th</sup> century that we now find in operation rooms today [5].

During Vietnam War (1955-1975) it was revealed that cyano acrylate glue had an unusual property to grip wounds shut. It polymerized and toughenedwhen left open tomoisture. Ultimately, trauma surgeons or field surgeons begun to spray it on wounds prior to transporting patients to the military hospitals and as a result, many lives were saved [1].

Eventually the Food and Drug Administration granted approval for the usage of adhesive glue in the United States for medical use. Even with various skin closures techniques, the basic doctrine ofskin closure technique has not changed. That is to bring together the edges of skin in an evertedposition and thereby lessening the tension on the wound. The means of woundclosure should ideally be cheap, quick, painless, simple, safe, if possible bactericidal, and should be able to produce the optimal cosmetic result. Closure materials for wounds are categorized into 3 main categories: sutures , surgical staples and adhesive skin glue. Even though the usage of conventional skin sutures is a gold standard practice for wound closure from several years, surgical staples and adhesive tissue glues have shown to be useful as well, in the clinical practice more recently. The conventional skin suturing is lucrative but time taking. Staplers reduced this time length by a huge margin. Modern staplers are either disposable, that is they're made ofplastic or they are made of stainless steel which make them reusable. Surgical Staples carry certain reward of speedy closure, reduced chances of infectivity, better wound eversion with no tissue strangulation, almost zero cross-hatchscarring and reduced foreign

body reaction. It excludes the risk of needlestick injury for doctors and other health care providers when he patient's history is unknown [6].

2-octyl cyanoacrylate has been approved by the FDA ie the Food and Drug Association for closure of skin incisions.

The cyanoacrylates originally gained fame in 1958s, for being marketed as a very strong and a quick drying glue. The widely used skin adhesives come in form of alkyl cyanoacrylates. Octyl-2-cyanoacrylate is now being usedin hospitals across the world, mostlyfor minor surface wound repairs and in places wherein the use of sutures would demonstrate to be unreasonableor tricky [6]. Adhesive tissue glue based on cyanoarcylate have been linked with usage problems and histotoxic reaction in earlier attempts [7].

Now, adhesive glue suits the standard, it supplies a quick, trouble-free, water resistant sealed needle free skin closure which is also cosmetic. It also has anti-microbial properties and hence, requires no added antiseptic bandaging. Reduced pain was noted in post-op period. Patients are able to bathe. The wound disappearsnaturally, leaving no incision mark and no suture or stapler removal is required. Probability of infection of wound with adhesive glue, are less. It also has appropriate features for closure of the wound such as adequate power, barrier proficiency in tissues, and potential to bind in clammy environment [8] Numerous studieshave shown correspondence of cyanoacrylate to 5-0 sutures in facial surgeries and traumatic facial lesion repair [9]. As the pliability of octylcyanoacrylate is superior than oldfashioned cyano acrylate, it can be used on uneven surfaces [10]. Octyl-2- cyanoacrylate use hasbeen linked with a reduced rate of woundinfectivity and has been thought to act asa obstacle for bacteria infecting the wound, especially theGram-positive bacteria [11]. However, there are certain downsides of cyanoacrylates , like their a lesser amount of tensile strength and probability of adhesive discharge if the ends aren't adequately approximated.

In May 1997, Quinn J et al. [12] did the first study of comparing octyl-2cyanoacrylate to

sutures by using a prospective, randomized controlled trial which included 130patients with 136lacerations (mainly facial). Patients were then put in randomized groups and skin closure was done with either monofilamentsutures or octyl-2cyanoacrylate glue. Itwas found that closure with adhesive skin glue was faster (an averageof 3.6 mins for skin glue and 12.4 mins forsutures), and lesspainful (using 100mm visualanalogue pain scale, glue: 7mm, sutures: 18mm, p<0.001).

The second studypublished in 1998 by Toriumi DM et al. [13] with a single surgeon performing elective facial surgeries in 111 randomized patients. The patients were indiscriminately subjected closure either to by interruptedmattress sutures (with 5-0 / 6-0 Nylon), ocyanoacrylate glue. Momentum of wound closure, cosmesis and complication of wound of 100 patients was assessed at the end of 1 year. Itwas again shown that time taken for closure of wound was quicker with skin glue (55 secs) in comparison to that of mattresssutures which took anaverage of 3 minsand57 secs to close. (p < 0.0001). There was no infection or wound dehiscence after accessing at 5-7 davs.

Ridgway et al. [14] published a study in 2007 wherein 30 patients who underwent parathyroid and thyroid surgeries were randomized to skinclosure using adhesive glue orsurgical skinstaples. The time required for wound closurewas considerably abridged with the use of staples. Skin stapler tookan average of 67s +/- 42s less time compared to adhesive glue. According toChibbaro et al. [15], there wasn't any noteworthy difference between skin staples and adhesive glue when used for closing of scalp incisions in neurosurgery.

In the study comparing conventional sutures and staples byRanaboldo et al. [16], the speed of closure for the wound was eight secs/cm with skinstapler and 12.7 secs/cm with conventionalsutures.

Medina dos Santos et al. [17] found less time in staples than suture closure, in his prospective trial. The standard mean time for closure of wound was5 minutes with skin staples and with nylon sutures it, it took 25 minutes. Mastud et al.; JPRI, 33(31A): 90-97, 2021; Article no.JPRI.68580

There was not much difference between the 2 groups inindications for caesarean deliveries or number of previous caesareandeliveries. The rate of complications of wound in the group of was 5.3% and 3.4% in the NBCA group. NBCA maybe useful for closure of skin of Pfannenstiel incisions [18]

All the above mentioned techniques of skin closure vary fromeach other with own merit and demerits.

Hence, this study will be planned towards aiming to compare these three skinclosure modalities after a clean elective surgery, with skin incisions of varying lengths and widths in terms of their potency, cosmesis and costeffectiveness.

# 2. OBJECTIVES

- a. To compare duration between closure by 3 methods.
- b. To compare prices amongst the 3 methods.
- c. Comparison of cosmetic appearances of skin afterclosure by any of the 3 methods.
- d. Comparison of post-operative pain between the 3 methods.
- e. To assess surgical site infections after closure with these 3 methods

# 3. INTERVENTIONS

# 3.1 Materials and Methods

90 patients, undergoing clean elective surgeries, will be included in this comparative prospectivestudy. 30 participants included in every group. Hospitalised under Department of General Surgery in Datta Meghe Institute Of Medical Sciences, Wardha. The study will be conducted between October 2021 to October 2023.

Clean surgical wounds will be given single dose of antibiotic at the time of induction of anesthesia.

**Study design:** Prospective interventional study as the objectives of the study will directly evaluate impacts of treatment

**Study Setting:** In this comparative prospective study 90 patients will be included wherein, 30 in

each group undergoing surgery. Admitted in the Department of General Surgery in Datta Meghe Institute Of Medical Sciences, Wardha. The study will be conducted between October 2021 to October 2023.

#### Groups:

**Group A:** Incisions will be secured with glue (octyl-2- cyanoacrylate).

**Group B:** Incisions will be secured with non-absorbable surgical skin staples.

**Group C:** Incisions will be secured with nonabsorbable conventional nylon sutures. (ethilon 3-0).

Sample Size: 90 GroupA: 30 GroupB: 30 GroupC: 30

### 3.2 Study Participants

#### 3.2.1 Inclusion criteria

- Patients willing to provide informed consent for proposed technique of wound closure, before surgery.
- Patients undergoing skin closure with conventional suturing or surgical stapler or skin glue after undergoing clean elective surgical procedures.
- Incisions ranging between 1-10 cms in cases undergoing clean elective procedures.

#### 3.2.2 Exclusion criteria

- Patients not willing to provide informed consent for proposed technique of wound closure.
- Patients with Hb <10 gm %.
- Skin incisions <1cm or >10 cm.
- Critical cases in need of damage control surgery.
- Patients for whomstomas are needed.
- Patients who won't be able to come forfollow-up on 7<sup>th</sup>or15<sup>th</sup> post-operative days.
- Facial wounds or wounds over bonyprominences and highlymobile areas for surgical staplerclosure.

- Wounds over mucocutaneou sjunctions like lips or sites with high friction like handsandfeet, for adhesive glue application.
- Wounds over anogenital regions.
- Patients with history of DM, scars or keloid formation, immunosuppresion and malignancy

#### 3.2.3 Sample size calculation:

Sample size formula for difference between two means:

$$n = \frac{(Z\alpha + Z\beta)^2 (\delta_1^2 + \delta_2^2 / \kappa)}{\Delta^2}$$

Where,

Zα is the level of significance at 5 % i.e 95% Confidence interval = 1.96 Zβ is the power of test = 80% = 0.84  $\delta_1$  = SD of length of stay in glue group = 0.97  $\delta_2$  = SD of length of stay in staple group = 4.65  $\kappa$  = 1  $\Delta$ = 5.93 – 3.47 = 2.46

$$n = (1.96 + 0.84)^2 (0.97^8 + 4.65^2 - 2.46 = 29.23)$$

n= 30 patient needed in each group

90 healthy patients undergoing lipoma excisions, umbilical hernioplasties, vascular surgeries, open inguinal hernioplasty, splenectomy, thyroidectomy, spine surgeries, c-section will be chosen for the study. After subcutaneous sapproximation to shut dead space and apposing the edges of the wound, patients will be randomly chosen into 3 groups.

In groupA, incision line will be secured with cyanoacrylate tissue glue using propen. Adhesive glue will be applied using propen, in a slim layer over the whole wound with extension of 5-10mm beyond wound edge. The wound will be permitted to dry for 15-20 secs and then 2<sup>nd</sup> and 3<sup>rd</sup> layer will be applied. No additional dressing will bedone. In group B, the incision line will be approximated with non-absorbable surgical skinstaples. It will be applied in one single layer while holding and therefore approximating the margins of the wound together with forceps.

In groupC, lesions will be sutured using ethilon 3-0 that is, non-absorbable nylon suture. After thoroughly examining the patient and routine taking detailed history, blood investigations like complete haemogram, Bleeding time, ClottingTime, blood sugar level, blood urea, serum creatinine, HIV and HBsAg (other investigations if required) will be sent. Injection cefotaxime1gm will bes given intravenously at the time ofinduction of anaesthesia.

Timetaken to close thewound in all three groups, using a particularmethod will be noted and compared using astopwatch timer. The post operativepain will be gauged using a Visual Analog Scale of 1-10. It will be assessed at 12h, 48h, 72h and 7<sup>th</sup> day. 1 being no pain and 10 is worst pain possible. It will be rated by patientthemselves. The outcome of wound will be assessed ranging from 0-10 using the standard wound aspesis scoring system. It will be assessed on 3rd, 5th, 7th postoperative day (POD).

The cosmetic appearance of the wound will be judged using modifiedHollander cosmesisscale of 1-6 on POD 7. A score of 6 will be considered asoptimal while5 or less will be considered suboptimal.

(0 for yes, 1 for no)

- Step off the borders
- Contourirregularities puckering
- Woundmargin separation
- Woundedge inversion
- Excessivewound distortion
- appearance overall (0 poor, 1acceptable)

Post-operative wound infection can be explained as surgical site infection within 0-30 days after surgery, or infection at surgical site till 1 year in cases of implants like mesh, vascular grafts and prosthesis.

Southampton wound grading system will be used to grade the severity of post-operative wound infection, which goes as follows:

# **SOUTHAMPTON WOUND - GRADING SYSTEM**

# (Bailey and love 25<sup>th</sup> edition)

Grade		Appearance
0	Normal healing Normal healing with mild bruising or erythema	
I		
	la	Some bruising
	lb	Considerable bruising
	lc	Mild erythema
11	Erythema plus other signs of inflammation	
	lla	At one point
	llb	Around sutures
	llc	Along wound
	lld	Around wound
	Clear or haemoserous discharge	
	Illa	At one point only (≤ 2cm)
	IIIb	Along wound (>2 cm)
	IIIc	Large volume
	IIId	Prolonged (> 3 days)
IV	Pus	
	Iva	At one point only (≤ 2cm)
	IVb	Along wound (>2 cm)
V	Deep or severe wound infection with or without tissue breakdown; hematoma requiring aspiration	

### 4. RESULTS

**Expected Results:** The comparison between three methods of closure with be monitored for short term and long term outcomes. Comparative evaluation will be done.

#### 5. DISCUSSION

For decades, man has looked for a flawless way to close a wound. Man has left no stone unturned in trying out different ways for closure. War and trauma have provided a continuous supply ofwounds, but it is only recently that surgical incisions have become of importance. Hence, there is a need to find the most appropriate method of closure.

Sources like honey, which are natural were used as antibacterial agents in the pre-historic era. Such old school techniques are still used in modern day managing of the wound.

Ideally, as soon as a wound is closed, it should be strong just like a normal tissue.

However, Douglas and Forester concluded that the maximum strength a tissue can regain after

closure of wound is 80% even after follow up of a year.

Gennari et al. [19] conducted a randomized study which was prospective, in 2004, to explore theusage of skin glue in breast surgeries for superficial woundclosure. 133 patients wererandomized into 2 groups of skin glue monofilament closure(69 patients) or sutureclosure (64 patients). The groups were coordinated forage, incisionlength, type of procedureand length of hospital stay. The results acquired included assessment by blinding the plastic surgeons as well as the patients. The cosmetic appearance was rated after an interval of 6months - 1year. A scale of 1-10 was used, with ten being congruous with optimalcosmetic appearance. Earlyfollow-up was carried out at 5-10 days to gauge erythema of wounds. Economi coutcome was also compared . During follow up, it was evaluated that wounds closed with adhesive glue showed significantly less inflammation and erythema. While assessing patient satisfy action score (on a scale of 1-10, with 10 being optimal), the group where adhesive glue was used appeared to be more satisfied then the group where conventional sutures were used. (9.5 vs. 7.45, p< 0.001). The authors deduced that there wasn't much to choosebetween methods ofclosure based of on out come. Although, economically glue had a upper hand over sutures.

Krishnamoorthy et al. [20], investigated the use of cyanoacrylate glue v/s subcuticularsutures in bridgedsaphenous closing of the vein harvestincisions, for it's use in coronary arterybypass grafting, in 2009. 106 patients were enlisted on the trial and 53 patients were randomized to every group. HWES was used to evaluate the wounds on day 7.Vancouver scar scale was used to evaluate the length of the scar, scar pigmentation and vascularity and pliability at the end of 6 weeks. The vein harvest closure time and total time taken for operation was noted too. The time for veinharvest wound closure lessened significantly, but total time of operation was not greatly lessened. The cosmetic outcome was assessed usina Hollander's scale. The Vancouver scar scale also showed much better results for groups wherein incisions were approximated using glue with regard to scar appearance. (p = 0.001). Patients were significantly more satisfied with their glued group < 0.001).

Knott et al. [21] did a study comparing adhesive glue to conventional sutures for patients undergoingcleft lip, palatecorrection. The study proved that skin adhesives containing cyanoacrylate can be used on the red zone of the lip which is partially keratanized. It gave results similar to that with sutures. Skin adhesive glue was not recommended for internalmucosal closure, as it requires moisture to harden. If glue is used on the internal 'wet' surface , it would result in an ineffective join due to premature hardening.

#### 6. CONCLUSION

The expected conclusion will be to find out which skin closure modality is better after a clean elective surgery, with skin incisions of varying lengths and widths in terms of their potency, cosmesis and cost-effectiveness.

#### CONSENT

As per international standard or university standard, patients' written consent will be taken by the author(s).

#### ETHICAL APPROVAL

As per international standard or university standard written ethical approval will be taken by the author(s).

#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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