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ORIGINAL ARTICLE

To Evaluate the Efficacy and Effectiveness of N-butyl-2-cyanoacrylate glue (TRU SEAL) in Closure of Oral and Maxillofacial Laceration and Surgical Incisions

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Abstract
Introduction Effective wound closure is critical for minimizing wound complications and preventing wound dehiscence. The various wound closure techniques include staples, traditional nylon and skin sutures, subcuticular sutures, and skin adhesives. Currently topical skin adhesives are frequently being used. It offers countless advantages: short application time, easy execution as well as possessing hemostatic character. N-butyl-2-cyanoacrylate is bacteriostatic and biodegradable and exhibits suitable tensile strength.
Materials and Methods Under nasoendotracheal intubation, the reduction in fracture and plating was done. In 80% of the patients, subcutaneous sutures were placed. Skin closure was done with N-butyl-2-cyanoacrylate glue.
Results In this study, REEDA scale was used to assess healing. Redness, edema, and ecchymosis were seen in all 10 patients, which subsided by the second week postoperatively. None of the patients had discharge from surgical site on the first postoperative day but was noted in two patients the first week postoperatively. There was evidence of wound gaping in one patient on the first postoperative day and two patients at end of the first week postoperatively. Stony Brook Scar Evaluation was used to evaluate postoperative cosmesis. No significant cosmetic impairment was found in all patients at the end of the study.
Conclusion The study reflects qualitative assessment of cyanoacrylates which is simple to use and proper application which resulted in uniform and everted closure of wound. It is cost-efficient as compared to other wound closure materials.

Keywords N-butyl-2-cyanoacrylate glue · Tissue adhesive · Surgical incisions · Lacerations

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Introduction

Effective wound closure is critical for minimizing wound complications and preventing wound dehiscence. Incision is a basic step for surgical procedures. Suitable closure and optimal maintenance of the surgical area are the most important factors that affect proper wound healing and surgical success. The conventional method of wound closure causes trauma during the needle penetration while passing through the tissues and provides a "wick down" through which bacteria can gain access to the underlying tissues and it has been proved that the presence of suture material itself increases the susceptibility to infection. It may also lead to complications like stitch abscess, epithelial inclusion cysts, and railroad track scar due to the invasion of underlying epithelial layer. Moreover, the

wound approximation by suture is time-consuming and leads to more amount of scar formation [1].

The various wound closure techniques include staples, traditional nylon and skin sutures, subcuticular sutures, and skin adhesives. Over the last decade, there has been an increase in the use of noninvasive wound closure devices aimed at reducing the pain of wound closure and the need for device removal. These noninvasive devices include the topical skin adhesives octyl-cyanoacrylate and butyl-cyanoacrylate, as well as surgical adhesive tapes such as Steri-Strip™ Adhesive Skin Closures (3 M, St. Paul MN) [2]. Currently, topical skin adhesives are being frequently used. Most of the adhesives used are cyanoacrylates short and longer-chain (butyl- and isobutyl-cyanoacrylate) derivatives. Among them, N-butyl-2-cyanoacrylates are least histotoxic and have been widely used owing to its potential advantages. Cynoacrylate glue is easy to apply and can save considerable time and effort [3].

N-butyl-2-cyanoacrylate glue has been used in many ways since it was introduced 40 years ago. Cyanoacrylates were first synthesized by "Ardis" in 1949. Coover in 1959 described their possible use as surgical adhesives [4]. Since then a variety of tissue adhesives have been under trial in surgery. One of the major drawbacks of the earlier adhesives was their lack of tissue compatibility and extensive inflammatory reactions. The adhesiveness is maximized by spreading the monomer in a very thin film. The adhesion properties of the adhesive are determined by the presence of polar CN and ester groups that interact with amino and carboxyl groups of protein molecules of tissues freed of moisture [5].

Cyanoacrylates produce tissue adhesion by secondary inter-molecular forces such as hydrogen bonding aided by mechanical interlocking of irregular and porous surfaces. Haematosis on surface oozing blood results from the adhesive thrombogenic property. Almost all solids have sufficient adsorbed water to initiate polymerization. The cyanoacrylate adhesives are free flowing liquids which spread readily into a very thin layer and then polymerize in place to form strong bond. Polymerization occurs extremely rapidly so that strong bonds are formed in few seconds. It occurs within 4 s in the spray form and within 10 s in droplet form [1].

All cyanoacrylate adhesives eventually degrade into formaldehyde and cyanoacetate. Although formaldehyde is known to be a histotoxic irritant, any significant degradation occurs long after the adhesives have sloughed off the skin and these breakdown products do not contribute to any toxicity when cyanoacrylate adhesives are used topically [6].

The material can be spread easily, readily wets the surface to which it is applied and, in thin film, produces very little heat. Rather than instilling the adhesive into the base of the wound, it is applied onto the epidermal surface ("spot welding") of the fully approximated edges of the wound [7]. When choosing a tissue adhesive for wound closure, the clinician must be confident that the adhesive is strong enough to hold the wound edges together, thus minimizing the risk of dehiscence [8]. The spontaneous dehiscence rate has been between 0.7 and 8.1% [9]. Swabs, gloves, and instruments should be kept clear of adhesive or they stick to the tissue. The material can then be removed from instruments with acetone. Eliminated products occur in the urine, feces, and expired air. This process starts several minutes after glueing. The product of cyacryn degradation accumulates partially in different organs for period up to 10 months [1].

The adhesive is approved for gluing fresh and smooth skin wounds. Not approved is the use in internal organs, brain surface, central nervous system, and blood vessels. N-butyl-2-cyanoacrylate has been used in various clinical situations and can also be used as an alternative bone graft fixation material [10]. Despite this limited range of approved applications, there are reports which discuss a bonding of soft tissue. Thus, Histoacryl® is used with variable success for gluing facial bone fractures, ossicles, and hemostasis in the area of esophageal varices and bleeding gastric ulcers as well as gluing microvascular anastomoses [11]. N-butyl-2-cyanoacrylate has been tried since it exhibited advantages like achieving immediate hemostasis, and apart from being easy to use it also processed bacteriostatic properties and rapid adhesion to hard and soft tissues [12]. N-butyl-2-cyanoacrylate tissue adhesive has been used extensively in wound closure after soft tissue injuries to the face, elective otological surgery, and hand surgery [13].

Properties of Cyanoacrylate Glues

Cyanoacrylates are synthesized by condensation of cyanoacetate with formaldehyde in the presence of a catalyst. The resultant CA monomer is refined and augmented with stabilizers, plasticizers, and other proprietary additives by manufacturers. It is then packaged and distributed in liquid form. The cyanoacrylates are formed by the condensation of cyanoacetate and formaldehyde in the presence of heat and vacuum [14]. Some of these characteristics include (Figs. 1, 2, 3, 4).

Wetting, Spreading, and Polymerization

Wetting and spreading are terms commonly used to describe the interactions of CAs with their binding surface. They are indicative of the affinity and strength between the adhesive and substrate. On non-proteinaceous surfaces, the reverse was found; lower homologs wet, spread, and

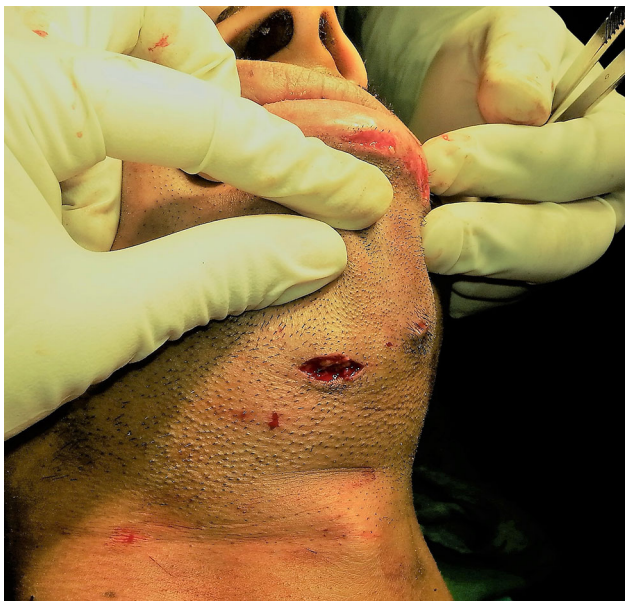

Fig. 1 Intra operative incision

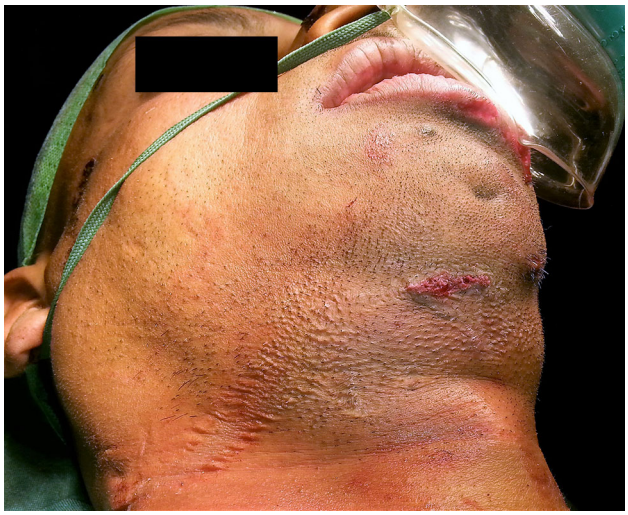

Fig. 2 Intra operative closure using TRU SEAL

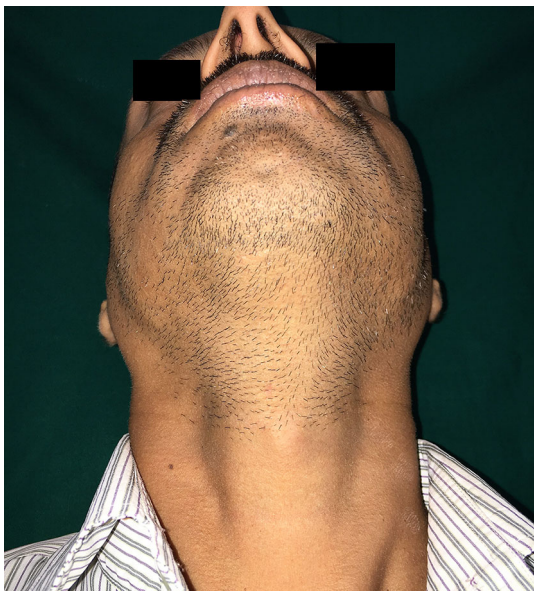

Fig. 3 Post operative - 3 months

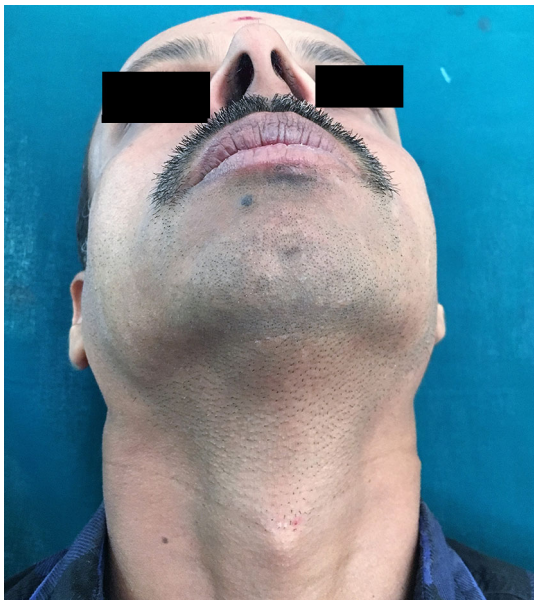

Fig. 4 Post operative - 6 months

polymerize at faster rates. Although this is true of unadulterated CAs, manufacturers have optimized polymerization speeds to better suit their intended purpose. It can be slowed by including a polymerization inhibitor, or sped up by exposing it to an initiator as found in the foam applicator tip of a Dermabond ProPen (2-octyl-cyanoacrylate). Wetting and spreading are characteristics indicative of an affinity between the adhesive and the substrate and contribute to the strength of the adhesive bond [15].

Liquid cyanoacrylate consists of cyanoacrylate monomers, which polymerize into long chains in the presence of hydroxyl ions. Water containing human tissue activates the polymerization of cyanoacrylate monomers and is bonded together as the glue rapidly sets. The property of nearly instantaneous bonding makes cyanoacrylates an effective hemostatic agent and tissue adhesive [16]. The higher n-alkyl a-cyanoacrylate homologs had been previously found to wet, spread, and rapidly polymerize on tissue substrates whereas the lower homologs do not wet and polymerize slowly [17]. It has been reported that the higher homologs wet, spread, and instantaneously polymerize on tissue substrates and are thereby more effective than the lower homologs in inducing hemostasis [18].

Stability

During extended travel, it is important that the CA continues to function in extreme environments. Freezing or heat exposure might render the glue useless, while a low flashpoint and high combustibility might allow it to serve as an improvised fire starter [19]. Leonard et al. thought that the longer-chain cyanoacrylate derivatives (R = C4H,, butyl) degrade at a slower rate, thereby permitting the degradation products to be more safely metabolized with evocation of a less intense inflammatory response. In 1968, Matsumoto et al. showed that N-butyl-2-cyanoacrylate had a much less intense inflammatory response when compared with methyl- and ethylcyanoacrylate [20].

Antimicrobial Effects

Early investigations demonstrated that CA films confer antimicrobial properties and that increased growth inhibition was found among the shorter alkyl chains. Shortly afterward, a pattern displaying increased bacteriotoxicity against gram-positive vs gram-negative organisms was revealed. This discovery has led investigators to postulate that the polymerization with hydroxyl groups found in bacterial cell walls is likely responsible for the observed bacteriostatic activity. Thus, the outer lipopolysaccharide capsule surrounding the cell wall of gram-negative microorganisms may impede this action (Tables 1, 2, 3, 4).

Adverse Effects

Not long after their discovery and subsequent application to medicine, adverse side effects to the short-chain CAs were observed. Histotoxicity, tissue necrosis, and their related sequelae caused the original short-chain alkyl CAs to fall from favor, particularly with the innovation of higher homologs. Cyanoacrylate polymers degrade by hydrolytic scission, resulting in formaldehyde and alkyl-cyanoacetate. Earlier research work proposed that CA adhesives may generate lipid hydroperoxides, which activate prostaglandin and thromboxane biosynthesis. CA has also been shown to oxidize and lyse cell membranes [21]. It is the first cyanoacrylate adhesive to pass all ISO (International Standards Organization) standards and has been classified as a nontoxic medical device, thus its designation as a medical-grade adhesive. A paint-on formulation of this cyanoacrylate has been approved by the Food and Drug Administration (FDA) for external use as a topical wound closure device [22].

Cost

As outlined above, FDA-approved tissue adhesives have many properties that make them a good alternative to more established medical procedures. The upfront cost may be more expensive than most suture, but the vast majority of studies maintain that CA repairs, using ECA or FDA-approved tissue adhesives, are more cost-effective than their equivalent non-CA substitutes. Cost reduction is further attributed to a decreased need for supplemental materials such as suture kits, and revision secondary to infection or dehiscence [23].

The use of tissue adhesives as an alternative to, or replacement for, sutures in wound closure has long been an area of interest. The primary purported advantages of using tissue glue for laceration repair include the lack of required anesthesia prior to wound closure, the lack of need of subsequent suture removal [24]. Cyanoacrylates have a wide range of applications in surgery and are supposed to offer some advantages such as effective and immediate homeostasis, ease of application, bacteriostatic properties, and rapid adhesion to hard and soft tissues. It has wide range of application in surgery such as repair of organs, vessels, skin and mucosa grafts, closure of lacerations, and incisions post-extraction dressings.

Materials and Methods

Surgical Technique

Under nasoendotracheal intubation, skin preparation was done with povidine iodine. Skin incision for each procedure was placed in the standard location. Then reduction in

Table 1 Relevant clinical parameters for healing based on REEDA scale

	Redness	Edema	Ecchymosis	Discharge	Approximation
0	None	None	None	None	No separation
1	Within 0.25 cm of incision	< 1 cm	Within 0.25 cm bilaterally or 0.5 cm unilaterally	Serum	Skin separation 3 cm or less bilaterally from incision
2	Within 0.5 cm of incision bilaterally	1–2 cm from incision	0.25–1 cm bilaterally or 0.5–2 cm unilaterally	Sero-sanguineous	Skin and subcutaneous separation
3	Beyond 0.5 cm of incision bilaterally	> 2 cm from incision	> 1 cm bilaterally or 2 cm unilaterally	Bloody or purulent	Skin, subcutaneous fat, and facial separation

Table 2 Relevant clinical parameters for scarring based on Stony Brook Evaluation Scale

	Scar category	Points
Width	> 2 mm	0
	≤ 2 mm	1
Height	Elevated/depressed in relation to surrounding skin	0
	Flat	1
Color	Darker than surrounding skin	0
	Same color or lighter than surrounding skin	1
Overall appearance	Poor	0
	Good	1

Table 3 Relevant clinical parameters for healing based on REEDA scale

No.	Name of patient	Redness	Edema	Ecchymosis	Discharge	Approximation	Total score
First postoperative day							
1.	MANJUNATH	1	3	2	0	0	6
2.	LIBIN MICHAEL	2	2	1	0	0	5
3.	PRATHAP M.B	1	2	1	0	0	4
4.	KOUSHIK C.	2	2	1	0	0	5
5.	CHIKKAMAHADEVA	1	2	2	0	0	5
6.	GOWRAMMA	1	3	2	0	1	7
7.	ASHOK S.	1	2	1	0	0	4
8.	NAVEEN HR	1	2	1	0	0	4
9.	SUBHASH HN.	1	2	2	0	0	5
10.	MAHESHA	1	3	1	0	0	5
First week postoperative							
1.	MANJUNATH	0	1	0	0	0	1
2.	LIBIN MICHAEL	1	1	1	0	0	3
3.	PRATHAP M.B	0	0	0	0	0	0
4.	KOUSHIK C.	0	0	0	0	0	0
5.	CHIKKAMAHADEVA	0	0	0	0	0	0
6.	GOWRAMMA	0	1	0	1	2	4
7.	ASHOK S.	0	0	0	0	0	0
8.	NAVEEN HR	0	0	0	1	1	2
9.	SUBHASH HN.	0	0	0	0	0	0
10.	MAHESHA	0	1	0	0	0	1
Second week postoperative							
1.	MANJUNATH	0	0	0	0	0	0
2.	LIBIN MICHAEL	0	0	0	0	0	0
3.	PRATHAP M.B	0	0	0	0	0	0
4.	KOUSHIK C.	0	0	0	0	0	0
5.	CHIKKAMAHADEVA	0	0	0	0	0	0
6.	GOWRAMMA	0	0	0	0	1	1
7.	ASHOK S.	0	0	0	0	0	0
8.	NAVEEN HR	0	0	0	0	1	1
9.	SUBHASH HN.	0	0	0	0	0	0
10.	MAHESHA	0	0	0	0	0	0

Table 4 Relevant clinical parameters for scarring will be based on Stony Brook Evaluation Scale

No.	Name of patient	Width	Height	Color	Overall appearance	Total point
1 month postoperative						
1.	MANJUNATH	0	0	0	1	1
2.	LIBIN MICHAEL	0	0	1	1	2
3.	PRATHAP M.B	0	0	0	1	1
4.	KOUSHIK C.	0	0	0	1	1
5.	CHIKKAMAHADEVA	0	0	1	1	2
6.	GOWRAMMA	0	0	0	1	1
7.	ASHOK S.	0	1	1	1	3
8.	NAVEEN HR	0	0	1	1	2
9.	SUBHASH HN.	0	0	1	1	2
10.	MAHESHA	0	0	1	1	2
3 months postoperative						
1.	MANJUNATH	0	0	1	1	2
2.	LIBIN MICHAEL	0	1	1	1	3
3.	PRATHAP M.B	0	0	1	1	2
4.	KOUSHIK C.	0	0	1	1	2
5.	CHIKKAMAHADEVA	0	0	1	1	2
6.	GOWRAMMA	0	1	1	1	3
7.	ASHOK S.	0	1	1	1	3
8.	NAVEEN HR	0	0	1	1	2
9.	SUBHASH HN.	0	0	1	1	2
10.	MAHESHA	0	0	1	1	2
6 months postoperative						
1.	MANJUNATH	0	0	1	1	2
2.	LIBIN MICHAEL	1	1	1	1	4
3.	PRATHAP M.B	0	0	1	1	2
4.	KOUSHIK C.	0	0	1	1	2
5.	CHIKKAMAHADEVA	0	0	1	1	2
6.	GOWRAMMA	1	1	1	1	4
7.	ASHOK S.	1	1	1	1	4
8.	NAVEEN HR	0	0	1	1	2
9.	SUBHASH HN.	0	0	1	1	2
10.	MAHESHA	0	0	1	1	2

fracture and plating was done. In 80% of the patients, subcutaneous sutures were placed. Skin closure was done with N-butyl-2-cyanoacrylate glue. Pressure dressing was placed in the usual manner for 24-h postoperatively.

Results

In this study, REEDA scale was used to assess healing. Redness, edema, and ecchymosis was seen in all 10 patients, which subsided by the second week postoperatively. None of the patients had discharge from surgical site on the first postoperative day but was noted in two patients the first week postoperatively. There was evidence of wound gaping in one patient on the first postoperative day and two patients at the end of the first week postoperatively.

Stony Brook Scar Evaluation was used to evaluate postoperative cosmesis in this study. No significant cosmetic impairment was found in all patients at the end of the study. Patients were highly satisfied with the excellent cosmetic results.

In this study, no adverse inflammatory reactions were encountered. The surgical glue has the characteristic of being rapidly transferred from a liquid to a solid state that occurs at room temperature without the need of catalysts, solvents, or application of pressure.

Discussion

Ideally, a wound closure device should be easy to use, rapid, painless, result in excellent cosmesis, not require device removal, and be cost-effective. Although none of the currently available closure devices meet all of these needs, the topical cyanoacrylate tissue adhesives offer many of the characteristics of this ideal wound closure device.

Suturing is the method most commonly employed for closure of lacerations. Factors enhancing utilization of tissue adhesives are: easy and fast application, usage without local anesthesia and suturing equipment, fewer complications, and good cosmetic appearance, no need of referral for suture removal, and bacteriostatic and bactericidal effect against Gram(+) microorganisms.

In this study, REEDA scale was used to assess healing. Redness, edema, and ecchymosis were seen in all 10 patients which subsided by the second week postoperatively. None of the patients had discharge from surgical site on the first postoperative day but was noted in two patients the first week postoperatively. There was evidence of wound gaping in one patient on the first postoperative day and two patients at end of the first week postoperatively.

Stony Brook Scar Evaluation was used to evaluate postoperative cosmesis in this study. No significant cosmetic impairment was found in all patients at the end of the study. Patients were highly satisfied with the excellent cosmetic results.

In this study, no adverse inflammatory reactions were encountered and it is relevant to a study conducted by Ahmed Habib et al. The surgical glue has the characteristic of being rapidly transferred from a liquid to a solid state that occurs at room temperature without the need of catalysts, solvents, or application of pressure.

The cost factor plays a pivotal role in certain geographic locations where affordable and holistic health care is the prime policy of healthcare provider.

Conclusion

The study reflects qualitative assessment of cyanoacrylates which is simple to use and with proper application resulted in uniform and everted closure of the wound. It is cost-efficient as compared to other wound closure materials.

The properties of cyanoacrylate glue were appreciated clinically as it showed excellent results with respect to the closure time, postoperative healing, and patient comfort.

The quantitative data as reiterated from results make us conclude that cyanoacrylate glue performed excellently and showed similar cosmetic results when scarring evaluation was done.

It is noteworthy that within the limitations of this study, which includes, less sample size and short duration for evaluation, this material showed excellent results and future studies in larger sample size can overcome the above stated limitations.

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