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Synthetic Two-Components Skin Glue (Glubran Tiss) Effectiveness and Suitability in Pediatric Emergency Department

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Abstract

Cyanoacrylate skin glue is increasingly used as a non-invasive alternative to sutures. In pediatric Emergency Department (ED) the use of skin glue for superficial wound closure may offer many advantages over traditional wound closure devices related to reduction of pain, fast and easy application and better aesthetic results.

Objective: To assess effectiveness, suitability and tolerability of n-butyl 2 cyanoacrylate+2 octyl cyanoacrylate (synthetic skin glue Glubran Tiss, GEM, Viareggio, Italy) in selected wound repair in pediatric ED.

Methods: 31 children were enrolled in a prospective observational study on the use of the above skin glue for wound closure by ED operators. Enrolled patients were asked to return for a follow-up visit one week after the procedure.

Results: The skin glue under evaluation for wound closure showed to be effective and easy to use by the operators in all treated patients. No patient experienced pain; 1 patient experienced mild burning sensation after application.

Conclusions: Glubran Tiss skin glue wound closure in pediatric ED has shown to be suitable, effective and well tolerated by patient. This device is a valid alternative to surgical sutures for superficial wound closure in children.

Keywords: Cyanoacrylate skin glue; Pediatric emergency department; Traumatic wounds; Lacerations

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Introduction

Traumatic wounds, including lacerations, are one of the most common reasons for people presenting to the Emergency Department (ED) [1]. More than 12 million patients are evaluated each year for minor laceration repair [2]. Children represent a significant number of these visits. One-third of all injuries in children involve a laceration, making minor wound care an important skill for pediatric care providers [3].

Skin wounds are solutions of continuity of the covering tissues, generally caused by mechanical trauma. Soft tissue injuries, especially with partial thickness and of limited extension, are particularly common in children due to behavioural reasons and sensitivity of the skin to harmful agents in the early years of life. The management of these lacerations involves cleaning the wound and then re-approximating the wound edges until natural healing occurs. Without proper closure, the patient is at increased risk of infection and excessive scar formation, which results in a poor cosmetic outcome [4]. Traditionally, approximation of these lacerations has been accomplished using sutures, which either dissolve after few days, or require another visit for removal. Insertion of sutures requires a local anesthetic agent to reduce the pain associated with the procedure. Infiltration of the wound with a local anesthetic can be quite painful. Small children with lacerations pose further challenges, as they may require sedation to reduce pain, emotional distress and movement during the procedure. This adds time and complexity to the patient's ED visit [5,6]. Other standard wound closure options include staples and adhesive strips. Methods to achieve this in the pediatric population are ideally quick, easy to perform, cause minimum discomfort, and result in a good cosmetic outcome [7]. Usually the type of treatment depends on the characteristics of the

wound (size, depth, location), on its level of contamination, and on how much time has passed since the injury. Methods of skin closure vary in published series and are largely the results of surgeon's choice based upon the need for a rapid, economic, and reproducible technique [8]. Skin glues are widely used to close superficial wounds, thus avoiding the use of more invasive methods such as sutures with needle and thread or staples. In some cases, skin glue is applied in combination with mechanical suturing methods to create a microbial barrier [9].

Many studies showed that tissue adhesive is an acceptable alternative to standard wound closure since it yields similar clinical and aesthetic results, even if early wound dehiscence occurs in the 1% to 5% of cases [10,11]. The adhesive products that have been developed for wound repair belong to the class of compounds called cyanoacrylates. The technology behind cyanoacrylate tissue adhesives was developed more than 50 years ago [12]. Traditional sutures will always have a role in wound repair, however, in selected circumstances, adhesives are an important alternative. Early and effective wound repair helps to restore the protective barrier of the skin. It enhances the healing process and limits the risk of infection. In their studies, Bruns et al. [13], Bozkurt and Saydam [14] reported cosmetic outcome in the cyanoacrylate group to be as good as or better than cosmetic outcome in the suture groups. Quinn et al. [15] Ridgway et al. [8], and Pronio et al. [16] observed no difference between closure with metal clips and closure with tissue glue. The above features are of utmost importance in the Pediatric age group.

One of the few complications evidenced when glues are used for sutures is a burning sensation [17], which is produced by common cyanoacrylate glues during application. This leads to unintentional children's movements with the risk that the suture is not executed perfectly. N-butyl 2 cyanoacrylate+2 octyl cyanoacrylate (Glubran Tiss, GEM, Viareggio, Italy) is a new formulation of synthetic skin adhesive approved as class-II medical device for topical use that fulfils the requirements of EU Directive 93/42 EEC. The composition of Glubran Tiss skin glue, obtained by mixing two different monomers of cyanoacrylate (NBCA - n-butyl 2 cyanoacrylates+OCA – 2 octyl cyanoacrylate), gives the product better elasticity, while maintaining high levels of tensile strength. In fact, international scientific literature shows that the common NBCA is the cyanoacrylate molecule with the greatest tensile strength (34.27 N), and low elasticity [18], while OCA has a lower resistance (11.27 N), but has good elastic properties. Glubran Tiss skin glue has a tensile strength of 27.34 N and, thanks to the presence of OCA, also excellent elasticity. Among its characteristics, this formulation has hemostatic, sealing, bacteriostatic and adhesive properties. Polymerization begins 1-2 seconds after application and completes within 60 seconds. The polymerization reaction generates a temperature of approximately 45°C [19,20], which is lower than that of pure cyanoacrylates [21,22].

The lower polymerization temperature compared to other cyanoacrylate glues seems to reduce or even avoid the burning sensation after application: we think that this might be very useful particularly in pediatric setting. Our pediatric Emergency Department (ED) receives about 44,000 patients a year requiring medical and surgical treatment. About 3 to 4% of these admissions relate to wounds alone. In addition to the previous percentage we see several patients suffering from trauma with associated wounds, amounting to about 10% of total admissions. The purpose of our study is to evaluate the suitability of N-butyl 2 cyanoacrylate+2 octyl cyanoacrylate in our pediatric population in ED setting, to evaluate the effectiveness of the treatment, together with the ease of use and the tolerability in terms of local pain during and after the application.

Methods

Thirty-one children aged between 1 and 14 (median 5 years) in prevalence males (81%) were enrolled in a prospective observational study approved by the Local Ethical Committee. The decision to use skin glue or other methods was taken by experienced ED personnel who evaluated the existence of the appropriateness of its usage. The glue was used for the following type of wounds: recent (within 6 hours), linear or only slightly irregular, superficial (skin and subcutaneous tissue), with undamaged skin margins, little or minimal bleeding, not contaminated. Patients were excluded for known coagulation defects, reported individual reactivity of hypersensitivity to cyanoacrylate and in case of chronic, infected and mucosal wounds and/or with extension greater than 7 cm.

Parents of the enrolled patients were asked to sign an informed consent, which was given in all cases. After routine wound management, the edges of the wounds were held together with either forceps or the operator's fingers before the adhesive was applied. Using the special "Applicator Tip" as a brush, a thin layer of Glubran Tiss was applied on the wound edges which were held together for about one minute (40-60 secs) to enable sufficient polymerization and until the adhesive was dried. Wound dressing with gauze or plasters was allowed. Demographic data and wound characteristics are reported in **Table 1.**

All the enrolled patients were asked to return for a follow-up visit one week after the procedure to check the healing and inflammatory status of the treated wound, skin irritation and simplicity of management during the follow up period.

Effectiveness of the device, ease of use, ease of wound management (at home) and wound healing (after one week) have been evaluated using a discrete scale ranging from 1 (unsatisfactory) to 4 (excellent). Possible side effects (pain, burning sensation and skin irritation) were recorded using usual scale (none, mild, moderate, severe).

Results

The wound closure effectiveness using Gubran Tiss skin glue was considered excellent in 28 (90,32%) and good in 3 (9.68%) patients. Ease of use was considered excellent in 30 (96.77%) and good in one (3.23%) patients. One patient (3.23%) experienced mild burning sensation after application of the glue whereas none experienced pain.

Only 20 (64.5%) patients showed up to the one-week follow up visit. Wound healing was excellent in 15 (75.0%) and good in 5 (25.0%) patients. Examined wounds showed neither signs of

Table 1 Demographics and wound characteristics.

Pt. Number	SEX	AGE (years)	Wound type	Wound lenght (cm)	Wounded area	Time from trauma (Hours)
1	M	4	L.C. Wound	2	Chin	0.5
2	M	11	L.C. Wound	3	Right hand	6
3	M	10	Linear Wound	6	Left Knee*	1.5
4	F	10	L.C. Wound	3	Upper side left foot	1
5	M	13	Linear Wound	2	Right Elbow	4
6	M	5	L.C. Wound	4	Left parieto-occipital	1
7	M	3	L.C. Wound	2	Left eyebrow	1
8	M	1	L.C. Wound	1	Scalp	1.5
9	M	3	L.C. Wound	2	Chin	2
10	M	4	L.C. Wound	2	Forehead	1
11	M	4	Linear Wound	2	Left knee	1
12	M	9	L.C. Wound	2	Scalp	1
13	M	5	Linear Wound	2	Occipital	1
14	M	8	L.C. Wound	1	Right ear	1
15	M	4	L.C. Wound	2	Forehead	1
16	M	2	L.C. Wound	1	Forehead	0.5
17	M	5	Linear Wound	1	Left eyebrow	1
18	F	7	Linear Wound	1	Right eyelid	2
19	F	3	L.C. Wound	1.5	Left ear	1.5
20	M	6	Linear Wound	2	Right eyelid and cheekbone	1
21	F	5	Linear Wound	2	Forehead	1
22	M	4	L.C. Wound	2	Right parietal	1
23	M	2	Linear Wound	1.5	Left eyebrow	1.5
24	M	6	Linear Wound	1.5	Scalp	1.5
25	M	3	Linear Wound	1	Forehead	3
26	M	3	Linear Wound	2	Left eyebrow	3
27	F	2	L.C. Wound	2	Right cheeck	1
28	F	2	L.C. Wound	2	Chin	1
29	M	8	L.C. Wound	2	Scalp	1
30	M	3	L.C. Wound	1	Right eyelid	2
31	M	5	L.C. Wound	1	Right temporal	2

LC Wound: Lacerated and contused wound; *: leg immobilized

inflammation nor skin irritation. During the follow-up, ease of wound management was considered excellent by parents in all patients. 11 (35, 5%) patients did not come back for the follow up visit; for 7 of them (22,6%) it was to get in touch with parents by phone: the reported reasons for missing the follow up visit were: very good healing (4 cases), long distance from hospital together with good wound healing (2 cases) unclear reason (1 case). All parents reached by phone reported very easy wound management at home. The above results are shown in **Tables 2 and 3.**

Table 2 Overall efficacy.

	Excellent	Good	Satisfactory	Unsatisfactory
Effectiveness	28/31 (90,32%)	3/31 (9,68%)	0/31	0/31
Ease of use	30/31 (96,77%)	1/31 (3,23%)	0/31	0/31
Ease of wound management*	27/27 (100%)	0/27	0/27	0/27
Healing of wound**	15/20 (75%)	5/20 (25%)	0/20	0/20

*:reported by parents at follow up visit or by phone; **: evaluated by ED physicians in patients showing up at follow up visit

Discussion

The use of cyanoacrylates as tissue adhesives was described for the first time in 1959 [23]. The original study highlighted how these adhesives offered an alternative to surgical sutures. This concept developed over the years and has now become a very effective weapon in the hands of ED doctors. This is especially true in children, particularly in very young ones, where the use of needles, sutures or staples can be even more upsetting than the wound itself. For this reason, the ideal method for closing a wound in the pediatric population should be painless, fast, easy to perform, safe, with few complications and minimal scarring [24,25].

In our study, we confirmed the possibility to use adhesives to treat pediatric wounds including large ones (up to 7 cm); our results, using a different cyanoacrylate composition, are similar to others reported in literature. We have shown that this formulation

Table 3 Side effects.

	Severe	Moderate	Mild	None
Pain	0/31	0/31	0/31	31/31 (100%)
Burning sensation	0/31	0/31	1/31 (3,23%)	30/31 (96,77%)
Skin irritation*	0/20	0/20	0/20	20/20 (100%)

*: evaluated by ED physicians in patients showing up at follow up visit

does not cause burning sensation probably due to the lower polymerization temperature.

A very good aesthetic result is obtained with the use of Glubran Tiss rather than traditional suturing methods. After 7 days, the wound edges appear well joined, without interruptions, and not inflamed.

The use of cutaneous adhesive is considered very safe due to its low rate of complications [26,27]. The low infection rates have been attributed to the little deposition of foreign bodies into the wound [15] Allergic reactions are rare [28].

Using tissue adhesives makes easier to manage the wound in the following days, and allows cleansing the skin without rubbing. In our study parents of patients reported that managing the wound at home during follow-up was very easy. In addition, there is no need to return to the hospital to remove the stitches or staples. In fact, the film of NBCA+OCA exfoliates spontaneously after about 7 days.

This might also explain the apparently large number of patients (35%) not returning for the follow up visit: the main reason seems to be the good effectiveness of the treatment that in their view does not require further checks. Also in other studies there was a substantial high percentage of patients not returning for follow up visits [7] and the authors did not achieve 100% percent follow-up [29]; in general, as no suture removal is required with this technique, formal follow up is considered unnecessary assuming the parent are aware that they have to return at signs of infection or wound dehiscence [24]. For the above reasons tissue adhesive are considered very practical for patients living a long distance from health facilities or those with limited mobility [30].

The cost of follow-up visits including physician fees and parental lost wages are felt to be the main reason for this increased cost associated with use of standard wound closure [31].

Skin glues seem more cost efficient than alternative treatments considering also that they are faster to apply and requires very simple external dressings. According to Osmond et al. [31], the reduction in cost per patient of switching from the standard non-dissolving sutures was $49.60 for switching to tissue adhesive and $37.90 for dissolving sutures while Karcioglu et al. [32] showed that the costs of 15 patients who were treated with tissue adhesive were lower than $10. In another study, gain of time, few wound complications and cosmetic satisfaction were reported with the use of tissue adhesive [33]. Zempsky et al. mentioned the time for closure of the wound as 3 minutes [34]. It was time-saving as the mean time spent for a patient was 4.6 minutes with additional procedures and generally did not require dressing in our report. Furthermore, in another study tissue adhesive was the preferred method of closure of pediatric facial lacerations [31]. Of those parents surveyed 90% chose tissue adhesive and 10% chose dissolving sutures as their first choice for wound closure. Non-dissolving sutures were ranked third by 29 of 30 parents.

Of course, excellent results require adequate selection of the lesions to be treated and knowledge of the limitations and specific technical aspects of the adhesive in the closure of wounds [35].

Conclusions

Our study clearly shows that the use of the Glubran Tiss skin glue on superficial wounds, whether linear or with irregular edges, is a valid alternative to surgical sutures, since it is easy to apply, is painless, requires minimal training and follow up, decreases the time required for laceration repair and is clearly effective, and therefore can also be used on children. Indeed, the use of this glue is of great help in managing young patients because it allows the operator to work with peace of mind, since children will not resist the treatment because they will feel no discomfort. This does not occur with traditional sutures or other chemical formulations of cyanoacrylate glue producing burning sensation. The effectiveness and absence of side effects is also indirectly testified by the fact that most patients enrolled in the study did not come back for a follow-up, since their parents were apparently satisfied with the procedure and did not feel it was necessary to return to the ED. Finally, perhaps the most important consideration with laceration repair is the final appearance of the wound: several studies comparing the use of adhesives to sutures report equal cosmetic outcome, and in some cases, improved cosmoses with the use of adhesives [12].

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