Clinics in Surgery

Short Communication
Published: 17 May, 2021

Complications Associated with Dermabond® during Head and Neck Surgery from 2010-2020: MAUDE Study

Esther Lee[1], Alex Chen[2], Catherine Zwemer[1] and Punam G Thakkar[1]*

[1]Division of Otolaryngology-Head and Neck Surgery, George Washington University School of Medicine & Health Sciences, USA

[2]Division of Otolaryngology-Head and Neck Surgery, Medical College of Georgia at Augusta University, USA

Abstract

Dermabond® is a liquid surgical sealant containing 2-octyl-cyanoacrylate that has been widely used during head and neck surgeries. The purpose of this study is to provide a summary of adverse events related to Dermabond® use during head and neck surgery, as reported in the MAUDE database. We identified 32 adverse events and 29 (90.6%) were patient-related events and 3 (9.4%) were operator-related events. Of the patient-related events, CD (20 [69.0%]) was the most common, followed by wound dehiscence (4 [13.8%]). All of the operator-related events were from inadvertent cut injury (3 [100%]). Further studies are needed to establish the causation of contact dermatitis in certain populations.

Keywords: Dermabond; Head and neck; MAUDE; Adverse events

Introduction

Dermabond® is a liquid surgical sealant containing 2-octyl-cyanoacrylate that has been widely used in head and neck surgeries. It provides faster and stronger skin closure compared to traditional suture closure, as well as acting as a barrier to the bacteria [1]. Adverse Events (AEs) related to Dermabond® in the literature are generally attributed to incorrect application and poor wound edge apposition [2]. However, there are several reports of Contact Dermatitis (CD) described occurring in up to 7.0% [3]. This is important to recognize as delayed intervention may lead to severe complications [2,4-6].

The AEs related to medical devices are compiled in the Food and Drug Administration's Manufacturer and User Device Facility Experience (MAUDE) database [7]. The purpose of this study is to provide a summary of AEs related to Dermabond® use during head and neck surgery, as reported in the MAUDE database.

Methods

The MAUDE database search was conducted using a simple search for a combination of "Dermabond" and "thyroid," "parotid," "head," or "neck." Medical Device Reports (MDRs) from January 1st, 2010, to February 1st, 2020, were downloaded for analysis. MDRs involving the use of Dermabond® during head and neck procedures were identified for inclusion in the analysis. Exclusion criteria included non-head and neck procedures or reports with insufficient information. Variables extracted from MDRs included event category, medical intervention, and the root cause of the problem. This study was exempt from review by the Institutional Review Board from the George Washington School of Medicine and Health Sciences.

Results

A total of 130 MDRs were identified and 31 MDRs met inclusion criteria. Of those, a total of 32 AEs were extracted for analysis. AEs by category and medical interventions are summarized in Table 1. Of the 32 AEs, 29 (90.6%) were patient-related events and 3 (9.4%) were operator-related events. Of the patient-related events, CD (20 [69.0%]) was the most common, followed by wound dehiscence (4 [13.8%]). CD was treated with topical cream (13 [56.5%]) and/or oral medications (5 [21.7%]). Wound dehiscence was closed with primary closure (2 [66.7%]) and/or with oral medication (1 [33.3%]). All of the operator-related events were from the inadvertent cut injury (3 [100%]), requiring no further medical intervention (3 [100.0%]).

OPEN ACCESS

Correspondence:
Esther Lee, Division of Otolaryngology-Head and Neck Surgery, George Washington University School of Medicine & Health Sciences, 2300 M. Street NW, 4th floor, Washington, DC 20037, USA, Tel : 607-220-4029; E-mail: estlee@mfa.gwu.edu

Received Date: *15 Apr 2021*
Accepted Date: *10 May 2021*
Published Date: *17 May 2021*

Citation:
Lee E, Chen A, Zwemer C, Thakkar PG. Complications Associated with Dermabond® during Head and Neck Surgery from 2010-2020: MAUDE Study. Clin Surg. 2021; 6: 3173.

Table 1: Adverse events by category and medical intervention (N=32).

			Medical Intervention												
	Category		Total	Oral medication		Topical cream		Wound clean		Primary closure		New Dermabond		No intervention	
	N	%	N	N	%	N	%	N	%	N	%	N	%	N	%
Patient	29	90.60%													
Contact or allergic dermatitis	20	69.00%	23	5	21.70%	13	56.50%	1	4.30%	0	0.00%	3	13.00%	1	4.30%
Wound dehiscence	4	13.80%	3	1	33.30%	0	0.00%	0	0.00%	2	66.70%	0	0.00%	0	0.00%
Reaction to odor	2	6.90%	1	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	100.00%
Infection	1	3.40%	1	1	100.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Inadvertent application	2	6.90%	1	0	0.00%	0	0.00%	1	100.00%	0	0.00%	0	0.00%	0	0.00%
Operator	3	9.40%													
Cut injury	3	100.00%	3	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	100.00%

Oral medication= anti-histamine, steroid, antibiotics; Topical cream= steroid cream, antibiotic cream

Table 2: Causes of adverse events (N=32).

		Patient factor				Operator factor		Device factor			
		Incompatibility		Peel off		Misuse		Broken device		Insufficient closure	
Category	**N**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Patient	29	22	75.9%	1	3.4%	2	6.9%	0	0.0%	4	13.8%
Contact or allergic dermatitis	20	20	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Wound dehiscence	4	0	0.0%	0	0.0%	0	0.0%	0	0.0%	4	100.0%
Reaction to odor	2	2	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Infection	1	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%
Inadvertent application	2	0	0.0%	0	0.0%	2	100.0%	0	0.0%	0	0.0%
Operator	3	0	0.0%	0	0.0%	0	0.0%	3	100.0%	0	0.0%
Cut injury	3	0	0.0%	0	0.0%	0	0.0%	3	100.0%	0	0.0%

If specified, root causes of AEs were categorized based on a patient, operator, or device factor. Most patient-related AEs were caused by the patient factor with patient-device incompatibility (22 [75.9%]). All operator-related AEs were caused by a broken device (3 [100.0%]). The causes of AEs are summarized in Table 2.

MDRs are categorized based on procedure type and are summarized in Table 3. MDRs most commonly occur during unspecified head and neck surgery (12 [37.5%]) followed by thyroidectomy (9 [28.1%]) and laceration repair (7 [21.9%]).

Table 3: MDRs by procedure type (N=32).

	N	%
Total	32	100.00%
Unspecified head and neck surgery	12	37.50%
Thyroidectomy	9	28.10%
Laceration repair	7	21.90%
Hyoid bone removal	2	6.30%
Neck dissection	1	3.10%

Discussion

AEs reported in this study appear to be representative of known AEs in the literature. Our study identified CD as the most common AE (20 [69.0%]). Sensitization to Dermabond® is considered rare due to the rapid polymerization upon contact with the keratin of skin [9]. However, when the epidermal barrier is damaged by lacerations, antigens can bypass the skin and trigger an immune response. Symptoms of CD typically manifest hours after surgery with a few reports of delayed presentation occurring weeks after Dermabond® use [3,10]. This can delay the proper management and lead into systemic allergic reactions requiring high doses of systemic steroids [2]. Our study demonstrates Dermabond®-associated CD in patients with a known allergy to Formaldehyde, a byproduct of Dermabond® polymerization [11-14]. Formaldehyde sensitization has been demonstrated in cases of Dermabond®-associated CD and the frequency of formaldehyde sensitization in the United States is estimated to be 8% to 9% [12,13].

CD can be treated with corticosteroids and antihistamines [14]. Physicians prescribing topical corticosteroids to the head and neck region should be aware that repeated use may lead to AEs such as perioral dermatitis and skin atrophy [3]. Another consideration is that petroleum-based corticosteroids may dissolve Dermabond® [4].

Our study also demonstrated that AEs attributed to Dermabond® frequently occur due to improper usage. Of the four cases of wound dehiscence, three demonstrated improper usage. Reported rates of wound dehiscence are similar between appropriately applied Dermabond® and sutures [15,16]. Dermabond® is approved for clean wounds with easily approximated skin edges. Additionally, maximal strength is achieved by 2.5 min post-application [17]. Following such instruction can minimize wound dehiscence from improper usage. Operator cut injuries (3) also resulted from improper usage. Repeated crushing of the Dermabond® device may cause the inner glass vial to pierce the outer tube, resulting in laceration. Hand lacerations increase the risk of surgical site infection and exposure to blood-

borne pathogens [18]. Thus, physicians should consider compressing the Dermabond® tube using a forcep to avoid repeated compressions.

This study was limited by the small number of AEs recorded and the reporting bias inherent to the voluntary reporting system utilized by the MAUDE database [19]. Additionally, causation cannot be definitively determined for some reported events as conclusive testing such as a patch test is not reported. Further studies are needed to establish the causation of contact dermatitis in certain populations.

Conclusion

The most common AE reported following Dermabond® application for head and neck surgical cases was CD. Physicians should be aware of common adverse events associated with Dermabond® use and take steps to ensure the safe application of Dermabond®.

References

1. Maw JL, Quinn JV, Wells GA, Ducic Y, Odell PF, Lamothe A, et al. A prospective comparison of octylcyanoacrylate tissue adhesive and suture for the closure of head and neck incisions. J Otolaryngol. 1997;26(1):26-30.
2. Ricci JA, Parekh NN, Desai NS. Diffuse cutaneous allergic reaction to Dermabond. Prehosp Disaster Med. 2014;29(5):546-8.
3. Nakagawa S, Uda H, Sarukawa S, Sunaga A, Asahi R, Chi D, et al. Contact dermatitis caused by Dermabond advanced use. Plast Reconstr Surg Glob Open. 2018;6(9):e1841.
4. Perry AW, Sosin M. Severe allergic reaction to Dermabond. Aesthet Surg J. 2009;29(4):314-6.
5. Davis MD, Stuart MJ. Severe allergic contact dermatitis to Dermabond prineo, a topical skin adhesive of 2-octyl cyanoacrylate increasingly used in surgeries to close wounds. Dermatitis. 2016;27(2):75-6.
6. Lefèvre S, Valois A, Truchetet F. Allergic contact dermatitis caused by Dermabond(®). Contact Dermatitis. 2016;75(4):240-1.
7. MAUDE - Manufacturer and User Facility Device Experience. 2021.
8. Lee E, Tong JY, Pasick LJ, Benito DA, Joshi A, Goodman JF, et al. Complications associated with PlasmaBlade TnA during tonsillectomy and adenoidectomy from 2010 to 2020: A MAUDE study. Am J Otolaryngol. 2021;42(1):102826.
9. Sachse MM, Junghans T, Rose C, Wagner G. Allergic contact dermatitis caused by topical 2-octyl-cyanoacrylate. Contact Dermatitis. 2013;68(5):317-9.
10. Asai C, Inomata N, Sato M, Koh N, Goda S, Ishikawa H, et al. Allergic contact dermatitis due to the liquid skin adhesive Dermabond® predominantly occurs after the first exposure. Contact Dermatitis. 2021;84(2):103-8.
11. Parvizi D, Friedl H, Schintler MV, Rappl T, Laback C, Wiedner M, et al. Use of 2-octyl cyanoacrylate together with a self-adhering mesh (Dermabond™ Prineo™) for skin closure following abdominoplasty: An open, prospective, controlled, randomized, clinical study. Aesthetic Plast Surg. 2013;37(3):529-37.
12. de Groot AC, Flyvholm MA, Lensen G, Menné T, Coenraads PJ. Formaldehyde-releasers: Relationship to formaldehyde contact allergy. Contact allergy to formaldehyde and inventory of formaldehyde-releasers. Contact Dermatitis. 2009;61(2):63-85.
13. Hagen SL, Grey KR, Hylwa SA. Allergic contact dermatitis to Dermabond™: A case and review of the literature. Wound Medicine. 2016;14:25-30.
14. Usatine RP, Riojas M. Diagnosis and management of contact dermatitis. Am Fam Physician. 2010;82(3):249-55.
15. Saxena AK, Willital GH. Octylcyanoacrylate tissue adhesive in the repair of pediatric extremity lacerations. Am Surg. 1999;65(5):470-2.
16. Laccourreye O, Cauchois R, EL Sharkawy L, Menard M, De Mones E, Brasnu D, et al. Fermeture cutanée par colle à base d'octylcyanoacrylate (Dermabond) en chirurgie cervicofaciale programmée: étude longitudinale prospective [Octylcyanoacrylate (Dermabond) for skin closure at the time of head and neck surgery: A longitudinal prospective study]. Ann Chir. 2005;130(10):624-30.
17. Summary of Safety and Effectiveness Data. Food and Drug Administration. Accessed March 4, 2021.
18. Misteli H, Weber WP, Reck S, Rosenthal R, Zwahlen M, Fueglistaler P, et al. Surgical glove perforation and the risk of surgical site infection. Arch Surg. 2009;144(6):553-8.
19. Ensign LG, Cohen KB. A Primer to the structure, content and linkage of the FDA's Manufacturer and User Facility Device Experience (MAUDE) Files. EGEMS (Wash DC). 2017;5(1):12.