

Efficacy of Octyl-2-Cyanoacrylate in Type I Tympanoplasty

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Objective: To evaluate the safety and efficacy of octyl-2-cyanoacrylate for type I tympanoplasty.

Methods: This study involved 23 patients (14 females and 9 males) with chronic otitis media who underwent type I tympanoplasty. During surgery, the temporal fascia is placed underlying the eardrum remnant, and octyl-2-cyanoacrylate was dropped over the temporal fascia. The mean air-bone gap (ABG) at the 4 frequencies (500, 1000, 2000, and 4000) was calculated for each patient before and after surgery. These data were compared by Student *t* test.

Results: The mean follow-up was 10 months (range, 6–12 mo). Successful tympanic membrane grafting occurred in 21 patients (91.3%). Graft failure was seen in 2 patients. The mean preoperative ABG of the 23 patients was 19.3 (SD, 5.7) dB, and the postoperative ABG improved to a mean value of 8.2 (SD, 5.9) dB ($P \leq 0.0001$).

Conclusions: Octyl-2-cyanoacrylate is effective and safe in using as a compound on temporalis muscle fascia in type I tympanoplasty and can be used more widely in tympanoplasty.

Key Words: Cyanoacrylate, tympanoplasty, chronic middle ear disease, tissue adhesives

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Cyanoacrylate derivatives used in various surgical operations and interventional radiology were synthesized in 1949 by Ardis.¹ Adhesive properties of the compound were discovered in 1959.² After that, cyanoacrylate was used in human middle ear surgery.^{3,4}

It has been shown in some studies that cyanoacrylate can be toxic to the middle ear, creating an inflammatory reaction and ossicle damage.⁵ In contrast, some other studies using cyanoacrylate for incudostapedial joint disruptions, have reported no evidence of toxicity.⁴ Octyl-2-cyanoacrylate (Dermabond; Ethicon, Inc, Somerville, NJ) is the newest cyanoacrylate formulation. 2-Octyl has been added to the lateral chain.⁶ Dermabond has been available as a skin closure alternative since 1997.⁷

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In this study, we investigated the efficacy and safety of the octyl-2-cyanoacrylate by using the compound on temporalis muscle fascia in type I tympanoplasty.

PATIENTS AND METHODS

The study protocol was approved by the local ethics committee, and written informed consents were obtained from all patients. This study involved 23 patients (14 women and 9 men) with chronic otitis media who underwent type I tympanoplasty. Ages ranged from 20 to 45 years (mean, 32.3 y). Patients who had an air-bone gap (ABG) less than 30 dB and no otorrhea for at least 3 months were included in the study. The audiometric examination comprising vocal and tonal audiograms was done to all patients who presented satisfactory clinical control. All patients underwent nasal endoscopic examination preoperatively. Retroauricular incision and underlay approach was used in all the patients. Reexamination consisted of otoscopy and determination at 4 frequencies (500, 1000, 2000, and 4000). The first audiogram was ordered 6 months after surgery. The mean ABG at the 4 frequencies was calculated for each patient preoperatively and postoperatively. These data were compared with preoperative findings.

Surgical Technique

All procedures were carried out under general anesthesia. Tympanic membrane perforation closure was assessed by the same operating surgeon. After a postauricular approach, a posterior tympanomeatal flap was elevated. After the edges of the perforation were freshened and after removal of tympanosclerotic plaques, longitudinal incision in the meatus at the 6- and 12-o'clock positions was performed, joining the vertical incisions through a transversal incision at 5 to 7 mm away from the tympanic membrane. Detachment and pushover of the tympanic-meatal flap were achieved. The tympanic cavity was filled with sponge, and the temporal fascia is placed underlying the eardrum remnant, adjusting its borders to the inside of the perforation. Octyl-2-cyanoacrylate was dropped over the temporal fascia via an intravenous cannula with butterfly wings (21 gauge) after cutting its wings (Figs. 1 and 2). Any sponge was not used to fill the external acoustic meatus. A piece of the gauze soaked in antibiotic ointment was placed in the external acoustic meatus, and the postauricular incision was closed.

Hospital stay is 1 day, using intravenous analgesic and antibiotics, keeping oral medication for 1 week. Postoperative follow-up occurred with patient returns after 3, 7, 15, 30, 60, and 180 days.

RESULTS

Ten ears (43.5%) of the 23 patients had subtotal perforations, and the remaining ears (13 patients, 56.5%) had large central perforations. It was possible to visualize all the borders of the perforation in all patients. The mean follow-up was 10 months (range, 6–12 mo). Tympanic membrane perforation closure occurred in 21 patients (91.3%). Graft failure was observed in 2 patients (the indication was total perforation for both). Two patients underwent

a second operation. The mean (SD) preoperative ABG of the population of 23 patients was 19.3 (5.7) dB, and the postoperative ABG improved to a mean (SD) of 8.2 (5.9) dB ($P < 0.0001$). A statistically significant difference was found between the preoperative and postoperative values.

DISCUSSION

During the past 2 decades, much has been published on the use of cyanoacrylates in the medical and surgical fields. The use of cyanoacrylates has been well documented in the literature of multiple surgical specialties including otolaryngology.^{3-5,8} Although the short-chain cyanoacrylates (methyl and ethyl) have been associated with tissue toxicity because of rapid degradation, the longer-chain derivatives (octyl-2-cyanoacrylate) have been shown to have minimal toxicity.⁶ Octyl-2-cyanoacrylate is the only derivative currently approved by the US Food and Drug Administration, and it has expanded the clinical options for skin closure in oral, head and neck, hand, and cosmetic surgeries.⁸⁻¹¹ Dermabond, a nonabsorbable topical liquid, forms a thin, occlusive bandage without histotoxicity.¹² It can be applied easily, and no foreign material is left within the skin.¹³ The authors concluded that Dermabond yielded results that were comparable to standard sutured closures with regard to wound infection rates, dehiscence, and long-term cosmetic outcome.^{7,13}

Kerr and Smyth⁵ used Bucrylate (isobutyl-cyanoacrylate) on cat middle ears and found it toxic to the middle ear, causing an inflammatory reaction and damage to the ossicles. Seidentop³ used Histoacryl (2-cyano-butyl-acrylate) to repair incudostapedial joint disruption and showed no evidence of toxicity. Koltai and Eden¹⁴ found that cyanoacrylate was toxic to the promontorium mucosa. Samuel et al⁸ used *n*-butyl cyanoacrylate in myringoplasty and found little inflammation on the middle ear. It was not found to be toxic to the middle ear and ossicles in their study. In our study, we have not seen any toxic sign.

One of the most important things in preventing toxicity is to apply the appropriate dosage in the wanted area. Before application of Dermabond, we prevented the contact of cyanoacrylate with the middle ear by filling the tympanic cavity with sponge. In addition, in our study, we used intravenous cannula to use the appropriate dosage. Because Dermabond was only applied on the graft, no inflammation was seen in the middle ear.

According to Bhat and Ranit,¹⁵ many factors such as age, perforation location, size of the perforation, eustachian tube conditions, status of the middle ear mucosa, type of the graft, and the surgeon experience may influence graft success. Many authors believe that the perforation location plays a more important role in surgery success than perforation size.^{15,16} One of the most important reasons in graft failure is the lack of contact between graft and annulus, especially in the anterior marginal perforations. In such cases, canalplasty can be done to place the graft under the ear canal skin, but this would prolong the operative time and require a lot more

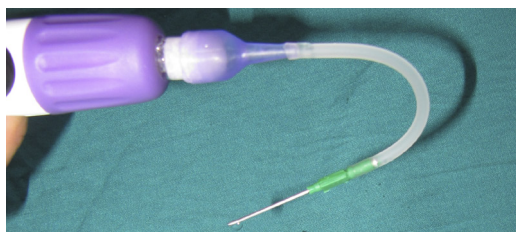


FIGURE 1. Components of the delivery system: Dermabond with intravenous cannula with butterfly wings (21 gauge).

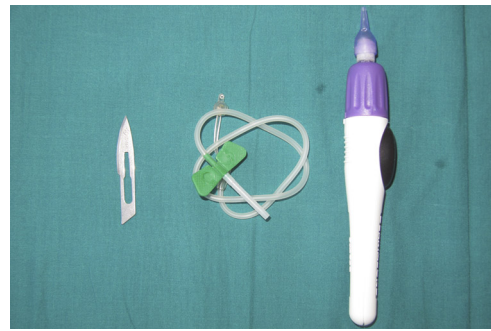


FIGURE 2. Dermabond with intravenous cannula after cutting its wings.

experience. Another way is to use tissue adhesives for adhering the graft, which shortens the operation time and does not require too much experience. In this study, graft failure was seen as central perforations rather than marginal perforations. We have thought this was due to an inadequate blood supply to the graft, which may be caused by octyl-2-cyanoacrylate.

Recent studies have shown that octyl-2-cyanoacrylate is effective as an antimicrobial barrier for the first 72 hours after application.^{17,18} The skin formed by octyl-2-cyanoacrylate is effective against Gram-positive and Gram-negative bacteria, including *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, and *Enterococcus faecium*.¹⁹ Hence, it reduces infection risk. This can be one of the reasons that we have not faced any infection in any patients. In all cases, after 3 weeks of surgery, we have realized that Dermabond has a solid form on the tympanic membrane in the external ear canal.

When we removed this from the external ear canal, we observed the tympanic membrane intact in 21 cases. Because we thought about not only the adhesive effect of the Dermabond but also the pressure applied on the graft, we have not filled any sponge in the external ear canal. The perforations that we have seen in 2 patients were so little. These patients underwent fat graft myringoplasty under local anesthesia. These were repaired successfully.

CONCLUSIONS

In this study, we found that octyl-2-cyanoacrylate is effective by using the compound on temporalis muscle fascia in type I tympanoplasty. Octyl-2-cyanoacrylate presented no toxic signs. It was easy to use in the external ear canal, and it does not require too much experience. Octyl-2-cyanoacrylate can be used more widely in tympanoplasty.

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