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Liquid Bandage™
as a
Temporary Wound
Barrier
in
Clear Corneal Cataract
Surgery



Cyanoacrylate Adhesives

- Compounds with very high tensile strength that rapidly polymerize on contact with basic substances such as water or blood to form a strong bond
- They are synthetic and non-biodegradable and may stimulate an inflammatory reaction
- They are used mainly in the management of corneal perforations and severe thinning

2-Octyl Cyanoacrylate



2-Octyl Cyanoacrylate

- Specifically formulated to correct some of the deficiencies of its predecessor compounds
- By altering the alkoxycarbonal group (~COOR) group of these molecules different chain lengths can be manufactured

2-Octyl Cyanoacrylate

- Longer chain groups degrade more slowly and may result in lower concentrations of cyanoacrylates in the tissues and thus generate less inflammation
- 2-octyl cyanoacrylate is much more pliable and tissue compatible than its predecessors with 3x the three dimensional breaking strength of its predecessors

Schwade N. Wound adhesives: 2-octyl cyanoacrylate. E medicine article. www.emedicine.com/

Background

- Approximately a decade ago research suggested the incidence of endophthalmitis may be increasing due to the transition from scleral tunnel incisions to clear corneal incisions¹⁻³
- This increased risk of endophthalmitis with sutureless clear corneal wounds has raised questions about the stability of these wounds and their vulnerability to leakage

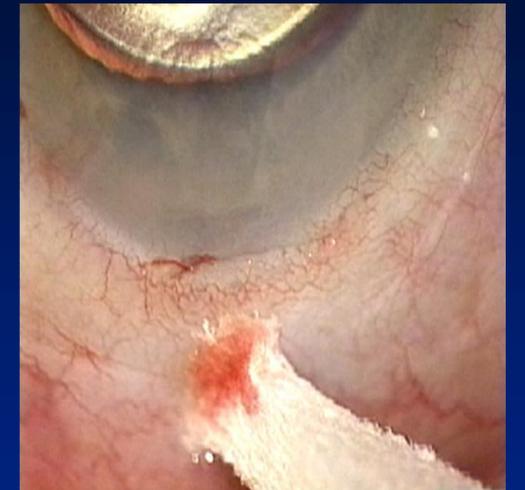
¹Cooper B. AJO 2003

²Lertsumitikul S. Clin Exp Ophthalmol 2001;29:4000-405

³Nagaki Y. Cataract Ref Surg 2003;29:20-26

Background

- McDonnell et al were the first to challenge the assumption, that hydration and stability with gentle manual pressure on the wound lip translates into wound stability and watertightness until epithelialization is complete
- This wound vulnerability may allow an influx of extraocular fluid containing surface bacteria into the eye before wound epithelialization



McDonnell P, Taban M, Sarayba M, et al. Dynamic Morphology of Clear Corneal Cataract Incisions. Ophthalmol 2003;110:2342-2348

Prevention of Infection:Wound Architecture

- Using a laboratory model and Miyake video system they examined incision morphology and leakage of applied India ink particles when varying IOP and manual pressure to the wounds^{1,2}
- Both eye pressure and incision angle affect wound apposition
- Vertical incisions and reductions in IOP tended to allow more India ink particles to enter the wound
- Reductions in IOP to 5-10 mmHg could result in wound separation

¹ McDonnell P, Dynamic Morphology of Clear Corneal Cataract Incisions. Ophthalmol 2003;110:2342-2348

² Taban M, Dynamic Morphology of Sutureless Cataract Wounds-Effect of Incision Angle and Location. Surv of Ophthalmol 49:Supplement 2; March 2004

Prevention of Infection:Wound Architecture

- These wound morphology studies along with the new data on endophthalmitis risks highlight the need and potential benefits of a safe and flexible barrier device to seal a clear corneal cataract wound “watertight”
- The barrier device would serve as an adjunct to prevent the efflux of intraocular fluid out of the eye, as well as, to prevent the influx of potentially contaminated external ocular surface fluid

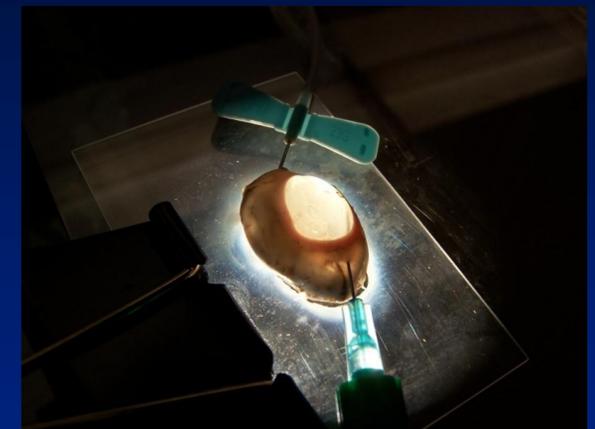
Purpose

- Can IOP fluctuation or wound manipulation cause an influx of fluid through a clear corneal incision?
- Can a wound adhesive or sealant prevent the influx of fluid through a clear corneal wound?
- Can Liquid Bandage™ serve as adequate clear corneal wound sealant?



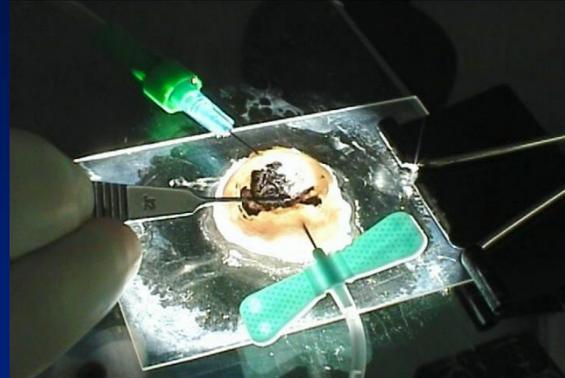
Methods

- Seven human globes prepared for Miyake video microscopy
- 3.0 mm triplanar corneal incision created
- Transcleral cannula inserted connected to bottle of saline
- Butterfly needle connected to manometer to monitor IOP
- Bottle height varied to alter IOP



Methods:

- Droplets of India ink were placed on wound (droplets are the approximate size of bacteria)
- Main outcome measure was influx of India ink into the anterior chamber as viewed through Miyake system with IOP fluctuation or manual manipulation and after application of Liquid Bandage™



Prevention of Infection:Wound Healing

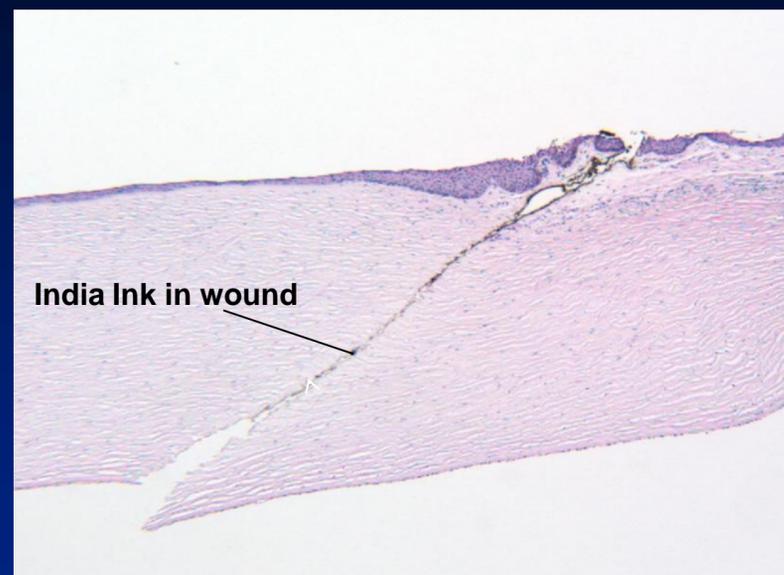
- Miyake video of the influx of India ink on lowering IOP in a clear corneal incision



1. Meskin, Ritterband et al. Miyake video of India ink influx. Human Cornea ASCRS 2005

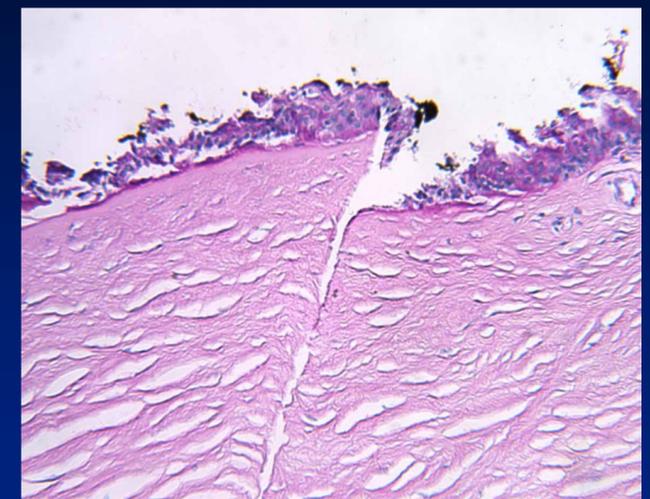
Prevention of Infection:Wound Healing

- Light microscopy with H&E stain confirms influx of India ink within corneal wound on the eye in the previous video



Prevention of Infection:Wound Healing

- Light microscopy with H&E stain confirms no influx of India ink within corneal wound on the eye with Liquid bandage™



Conclusion

- Our laboratory model confirmed the findings of Sarayba et al that clear corneal wounds are vulnerable to fluctuations in IOP or wound manipulation
- It also confirmed that Liquid Bandage™ prevents the influx of ocular surface fluid independent of IOP and manual wound manipulation

Purpose

- To assess the applicability, clinical course, and side effect profile of Liquid Bandage™ as a mechanical barrier and adjunct sealant in the closure of clear corneal cataract wounds



Why Liquid Bandage™ (2- Octyl Cyanoacrylate)?

- Our laboratory study demonstrated its efficacy and applicability as barrier device on clear corneal wounds
- Inexpensive (\$9.00 bottle contains 48 drops, if you estimate 2-3 drops per patient, cost is 40-50 cents/patient)
- 10-0 nylon suture costs \$18.00/package if bought in bulk

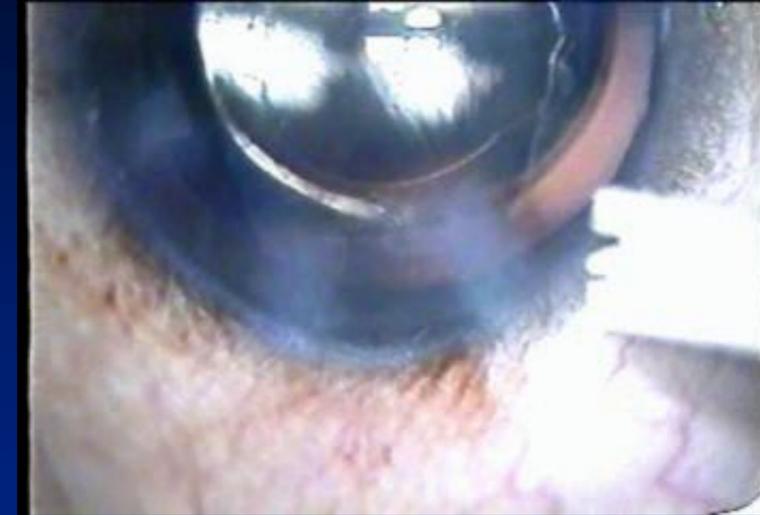
Is Liquid Bandage™ safe for use in cataract surgery?

- 51 eyes of 51 patients undergoing temporal, clear corneal cataract surgery by one surgeon (RSK)
- Informed consent was obtained consistent with the guidelines of the IRB at The New York Eye and Ear Infirmary
- 2.75 mm standard clear corneal tri-planar wound
- Standard phacoemulsification and cortical removal
- Acrylic IOL injected without wound enlargement

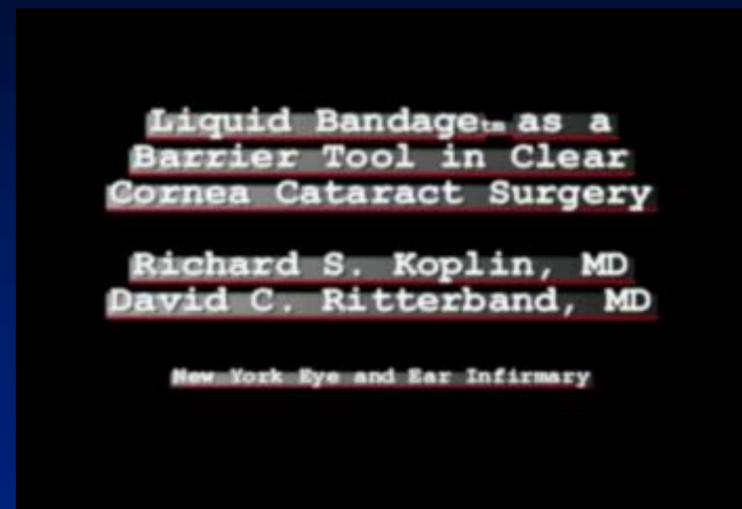
Is Liquid Bandage™ safe for use in cataract surgery?

- Wound was dried with Weck cell sponge
- Two drops of Liquid Bandage™ applied to a modified cellulose sponge
- Liquid Bandage™ was applied to create a sealed barrier across the wound
- *(Video)

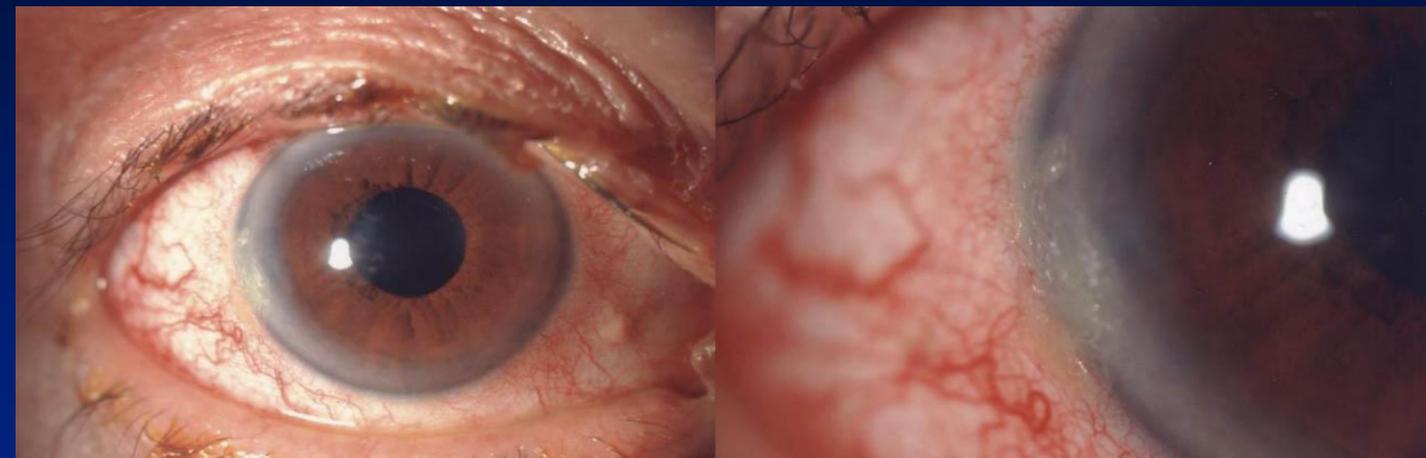
Video



Video #2



Post operative Day #1



Conclusions

- An ideal wound sealant would be easy to apply, nontoxic, efficacious, cost-effective, and degradable at an appropriate time in the early post-operative course
- Our pilot study demonstrates that Liquid Bandage™ as a temporary wound sealant meets some of these ideals
- Improvements and experience with the application technique will likely improve the side effect profile

Conclusions

- Liquid Bandage™ represents a paradigm shift in the thinking concerning wound adhesives in cataract surgery
- The best wound adhesives would function as a barrier to fluid movement and not as an adhesive to provided tensile strength for wound closure

Corneal Adhesives- Future Uses ?

1. Corneal abrasion therapy
2. Prevention of epithelial ingrowth for LASIK flaps
3. Post-operative wound leaks (keratoplasty wounds)
4. Recurrent Erosion Therapy
5. Delivery Device for antibiotics
6. Sclerostomy plug and delivery of medication to vitreous

ReSure™ Sealant

- ReSure Sealant is a synthetic, biocompatible hydrogel that creates a temporary, soft and lubricious surface barrier to protect clear corneal incisions in the immediate post-operative period when wounds are most vulnerable
- A US Food and Drug Administration (FDA) advisory committee panel on 9/19/13 generally endorsed the novel ophthalmic product *ReSure Sealant*
- The 11 members of the FDA's Ophthalmic Devices panel of the Medical Devices Advisory Committee voted 9 yes, 1 no, and 1 abstain to endorse the product's safety; 5 yes, 3 no, 3 abstain for efficacy; and 5 yes, 1 no, 5 abstain with regard to the sealant's benefits outweighing its risks.

