EVALUATION OF WOUND CLOSURE TECHNIQUES IN LARGE CLEAR CORNEAL INCISIONS

Rajesh K. Rajpal, MD[1*]; John A. Hovanesian, MD[2*]; John Doane, MD[3]; Ferrell Tyson, MD[4]; Sachin D. Rajpal, MS[1]; Josef Tamory, COA[1].

[1]See Clearly Vision Group, McLean, VA; Harvard Eye Associates, San Clemente, CA; [3]Discover Vision Centers, Kansas City, KS; [4]Tyson Eye, Cape Coral, FL.

Study sponsored by Ocular Therapeutix, Inc. **Has financial interest in the company.*

Purpose:

To evaluate sutures versus an FDA approved hydrogel ocular sealant (ReSure® Sealant, Ocular Therapeutix, Bedford, MA) for wound closure in 3.0 mm to 3.5 mm clear corneal incisions following uncomplicated cataract surgery.

Sealant Design:

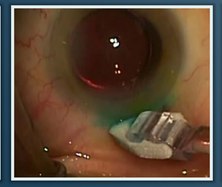
Component	Description
Poly(ethylene glycol) (PEG)	A type of polymer widely used in the pharmaceutical and medical device industries due to its water solubility and inert nature.
Trilysine	A naturally occurring essential amino acid which crosslinks the PEG to form the hydrogel.
FD&C Blue #1	A synthetic, water-soluble colorant which assists with visualization during application and diffuses from the hydrogel within hours.
Water and buffer salts	The hydrogel material is approximately 90% water after polymerization.

Sealant Preparation and Application:

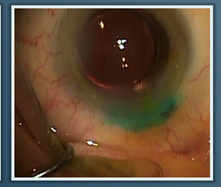
Add two drops of diluent to the blue deposit

Mix components with applicator for 5 seconds

Apply material over entire incision



Incision is sealed in 30 seconds



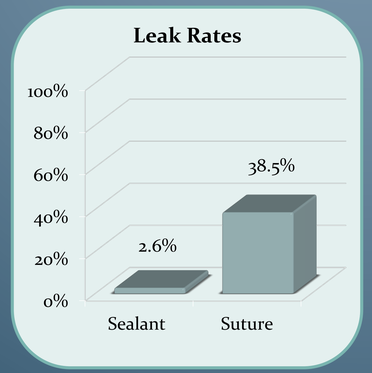
Methods:

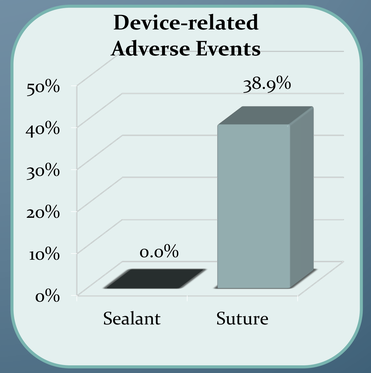
64 cataract patients with a demonstrated wound leak (spontaneous or provoked with up to 1 oz. force using an Ocular Force Gauge) were randomized to a 10-0 nylon suture using a 3-1-1 technique with buried knot (n=26) or the ocular sealant (n=38) in a prospective multicenter study. Following device application, incisions were provoked again using up to 1 oz. force to test for wound leakage. Patients were monitored for Seidel through day 7, and for safety through day 28.

Surgical Characteristics:

Treatment	Incision Width	Tunnel Length	Stromal Hydration Used?
Sealant	3.08 ± 0.10	2.32 ± 0.48	Y=76% | N=24%
Suture	3.06 ± 0.12	2.36 ± 0.62	Y=77% | N=23%

Results:





Results (continued):

- No significant differences in BCVA (logMAR) were noted during the study:

Treatment	Baseline	Day-1	Day-28
Sealant	0.37 ± 0.31	0.16 ± 0.22	0.02 ± 0.19
Suture	0.37 ± 0.29	0.18 ± 0.29	0.08 ± 0.19

- IOP appeared to be slightly more stable in the sealant group at day 1 than the suture group:

Treatment	Baseline	Day-1
Sealant	15.55 ± 2.84	17.58 ± 3.39
Suture	15.58 ± 2.61	18.88 ± 5.03

- No differences in edema, anterior chamber cells, flare, or corneal staining/erosion were noted.

Conclusions:

Large incisions often require additional means of wound closure over stromal hydration to maintain the stability of the anterior chamber and capsular bag. Although sutures have previously been employed in these cases, the adverse events associated with sutures are not ideal, and sutures should be removed on a regular basis to prevent future complications.

In this study, the sealant was more effective in preventing fluid egress in large clear corneal incisions than sutures, with significantly fewer device-related adverse events. Additionally, the sealant sloughs off in the tears within the first post-operative week, so there is no need for device removal.

Based on this evidence, the sealant is an ideal means of wound closure for cases such as premium lens and femtosecond laser patients who pay a premium for the best possible results, complicated cataract surgery cases where additional manipulation to the wound is required, prior radial keratotomy, prior corneal transplant, prior vitrectomy, or cases where a vitrectomy will be necessary later .