Randomized Controlled Study of an Ocular Sealant to Prevent Wound Leak After Cataract Surgery

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

Purpose

To evaluate an ocular sealant (ReSure Sealant, Ocular Therapeutix, Inc.) for preventing incisional leakage from clear corneal incisions (CCIs) with a demonstrated wound leak within the first 7 days following cataract surgery.

Product 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	Naturally occurring essential amino acid which crosslinks the PEG.
FD&C Blue #1	A synthetic, water-soluble colorant which assists with visualization during application and diffuses from the gel within hours.
Water and buffer salts	The hydrogel material is approximately 90% water after polymerization.

The hydrogel sealant is applied as a liquid and gels in less than 30 seconds. Following reepithelialization, the hydrogel sloughs off in the tears, so there is no need for removal of the device.

Preparation and Application

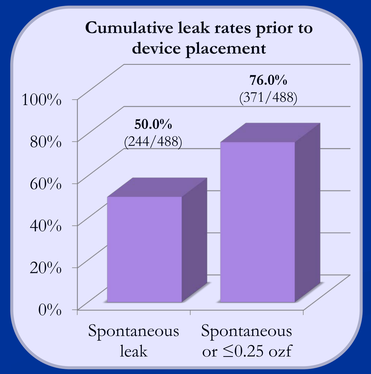
- Use a surgical sponge to thoroughly dry the incision and surrounding tissue.
- Add two drops of diluent solution to the blue deposit in one channeled well.
- Thoroughly mix the solutions for 5 seconds.
- Using the provided applicator(s), apply the material over the entirety of the incision.

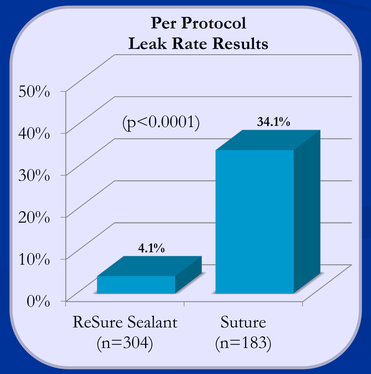
ReSure Sealant is an investigational device that is not commercially available in the United States.

Methods

- 487 eyes were treated in a prospective, parallel arm, controlled multicenter trial.
- Subjects with a demonstrated wound leak were randomized to an ocular sealant or suture and evaluated for 28 days post procedure.
- Following cataract surgery with IOL implantation:
  - **Pre-randomization challenge** conducted with a CFG*:
    - If no leak observed up to 1.0 oz. of force: screen failure
    - If leak observed ≤ 1.0 oz. of force: randomized into study
      - ReSure Sealant or suture applied (randomized 5:3, respectively)
  - **Post-randomization challenge** conducted with a CFG:
    - If leak observed ≤ 1.0 oz. of force: primary endpoint failure
    - If no leak observed up to and including 1.0 oz. of force: successful prevention of fluid egress
- A Seidel test was performed intraoperatively and at 1, 3, 7, and 28 days.

Results





Results

Parameters	ReSure n=304	Suture n=183	p-value
Subjects with AE(s) related to study device	5 (1.6%)	56 (30.6%)	<0.0001
Subjects with at least one AE	69 (22.7%)	83 (45.4%)	<0.0001
Subjects with no AEs	235 (77.3%)	100 (54.6%)	<0.0001

- 94.1% of sealant cases were rated 'easy' or 'very easy' to use.
- No safety concerns were reported.
- Patients were comfortable overall.

Conclusions

A high percentage of clear corneal incisions exhibited some level of wound leakage after cataract surgery and before any intervention. Wounds should be carefully evaluated in the immediate post-operative period, and further preventative measures should be taken to manage wound leaks.

In this trial, the ocular sealant demonstrated superiority over sutures for prevention of wound leaks with significantly fewer adverse events than sutures. The ocular sealant is safe and effective for its intended use in preventing fluid egress.

*Calibrated Force Gauge (CFG): A device which applies quantifiable force to the eye in 0.25 oz. increments. In a previous study, one oz. force using the CFG was found to be adequate for simulating intraocular pressure fluctuations caused by patient manipulation.[1]

1. Masket S, Hovanesian J, et al. Use of a calibrated force gauge in clear corneal cataract surgery to quantify point-pressure manipulation. J Cataract Refract Surg. 2013 Feb 21.