Multicenter evaluation of the safety and efficacy of an ocular sealant after cataract surgery with a premium intraocular lens

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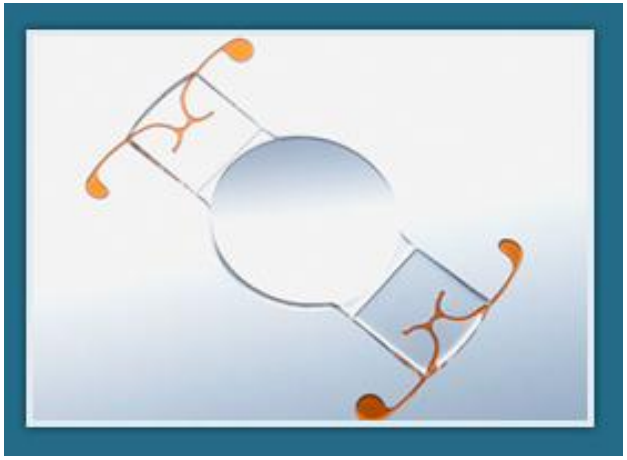
Purpose

To investigate the safety and efficacy of the ReSure® Sealant (Ocular Therapeutix, Inc.) compared to suture after cataract surgery in Crystalens® (Bausch&Lomb) premium intraocular lens patients for prevention of fluid egress following cataract surgery.



Methods

- Uncomplicated cataract surgery with Crystalens premium intraocular lens (IOL) implantation
- 32 patients enrolled:
  - 20 subjects randomized to the ReSure Sealant
  - 12 subjects randomized to receive a single suture (3-1-1 technique with buried knot)
- Wound leads were evaluated using a Seidel test and Ocular Force Gauge (OFG).
- Follow-up visits scheduled at Days 1, 3, 7, 14, 21, and 28. Intraocular pressure and a slit lamp examination were performed at each visit.

Evaluation of Fluid Egress

- A Seidel test was performed to evaluate fluid egress in all patients.
- If spontaneous leak was observed the patient was enrolled into the study.
- If spontaneous leak was not observed, wounds were challenged using an Ocular Force Gauge (OFG)(Ocular Therapeutix, Bedford, MA).

Foot

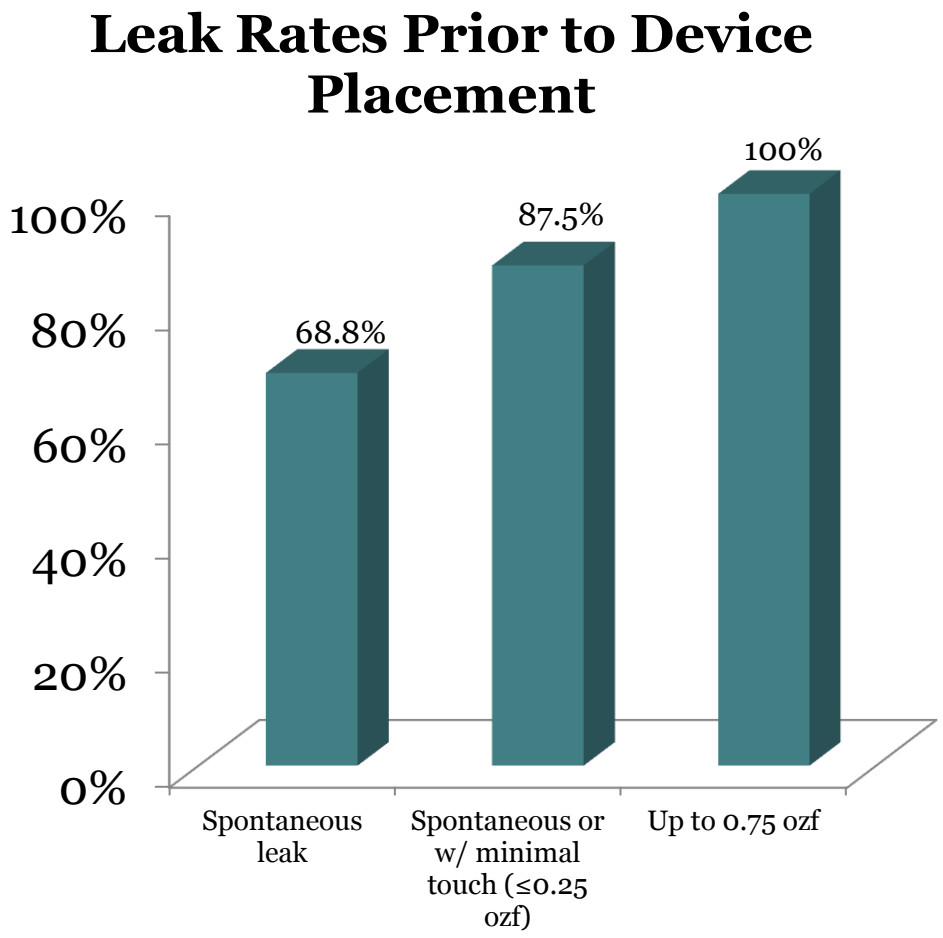
- The foot of the applicator was placed near the CCI on the scleral side of the wound.
- Force was applied until a leak was observed, up to one ounce maximum.* If no leak was observed with up to one ounce force, the patient was not enrolled in the study.

*1.00 oz. force has previously been evaluated to elevate IOP a mean 25.95 mmHg, consistent with light and firm digital pressure application in the literature.[1]

[1]Masket S, Hovanesian J, Raizman M, Wee D, Fram N. Use of a calibrated force gauge in clear corneal cataract surgery to quantify point-pressure manipulation. J Cataract Refract Surg. 2013 Feb 21.

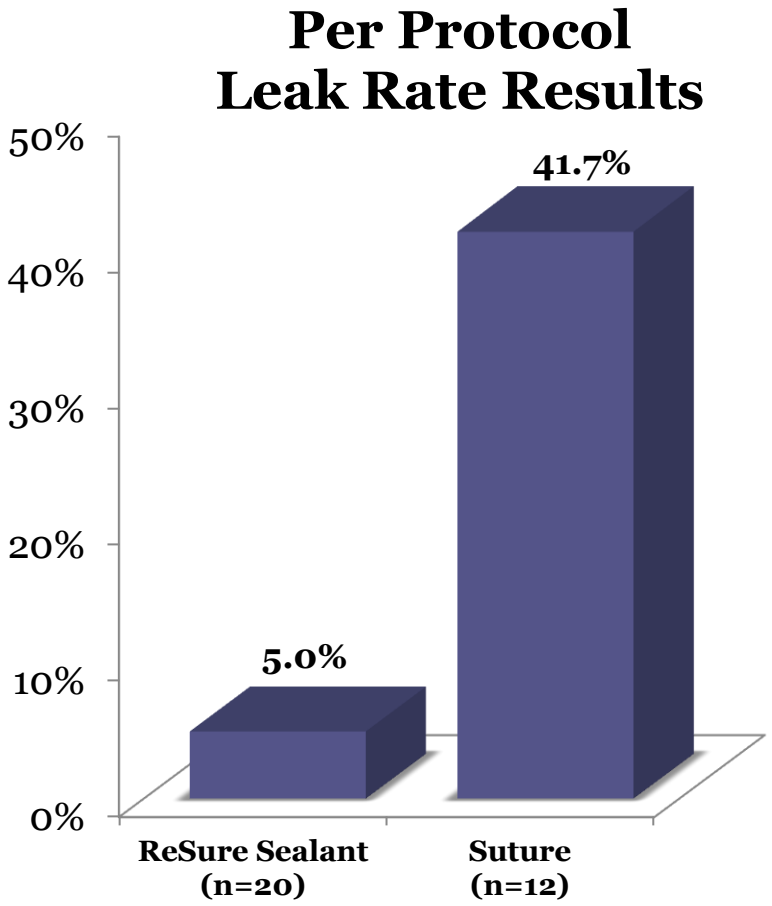
Pre-randomization leak rates

Parameter	mm
Mean Incision Width	2.85 ± 0.19
Mean Tunnel Length	2.27 ± 0.31



Post-randomization leak rates

- ReSure Sealant demonstrated superiority over sutures for prevention of wound leaks (5.0% vs. 41.7%, respectively) (p=0.0070)
- Significantly fewer adverse events in the ReSure group vs. Suture group (10.0% vs. 50.0%, respectively) (p=0.0302)



Additional Results

Mean Intraocular Pressure (mmHg)

	ReSure Sealant	Sutures
Baseline	14.49 ± 2.94	14.92 ± 1.66
Day 1	17.85 ± 3.68	18.67 ± 7.44

- No differences in:
  - Anterior chamber cells
  - Edema
  - Flare
  - Overall wound healing
- No safety concerns were reported
- Patients were comfortable overall

Conclusions

- The incidence of wound leaks and AEs were substantially fewer in the ReSure group after Crystalens implantation.
- There were no significant differences in overall wound healing, intraocular pressure, or edema, flare, or cells.
- Given the larger incision size required for Crystalens patients, the ReSure Sealant may offer a better alternative to wound closure than sutures.