

Multicenter Evaluation of Wound Leakage From Sutured Clear Corneal Cataract Incisions

John A. Hovanesian, MD^{1*}, William J. Flynn, MD², Michael J. Endl, MD³

¹Harvard Eye Associates, San Clemente, CA; ²Rashid, Rice & Flynn Eye Associates, San Antonio, TX; ³Fichte, Endl & Elmer Eye Care, Amherst, NY

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

Introduction:

Sutures have long been considered the 'gold standard' in wound closure following clear corneal cataract surgery. However, a recent study sought to challenge sutured incisions during intraocular pressure fluctuations which normally occur during patient manipulation (eye touching/rubbing) with up to one ounce force using a Calibrated Force Gauge. Leak rates were 36% in single plane incisions (n=11), and 10% in biplane incisions (n=10).¹ A larger study using the same technique was warranted to evaluate leak rates of sutured clear corneal incisions (CCIs) at multiple sites.

Purpose:

To evaluate wound leak rates in sutured, single plane CCIs following cataract surgery. For the purpose of this study, a single plane incision was defined as an incision that extended into the corneal stroma and angled down toward the anterior capsule of the lens.

Methods:

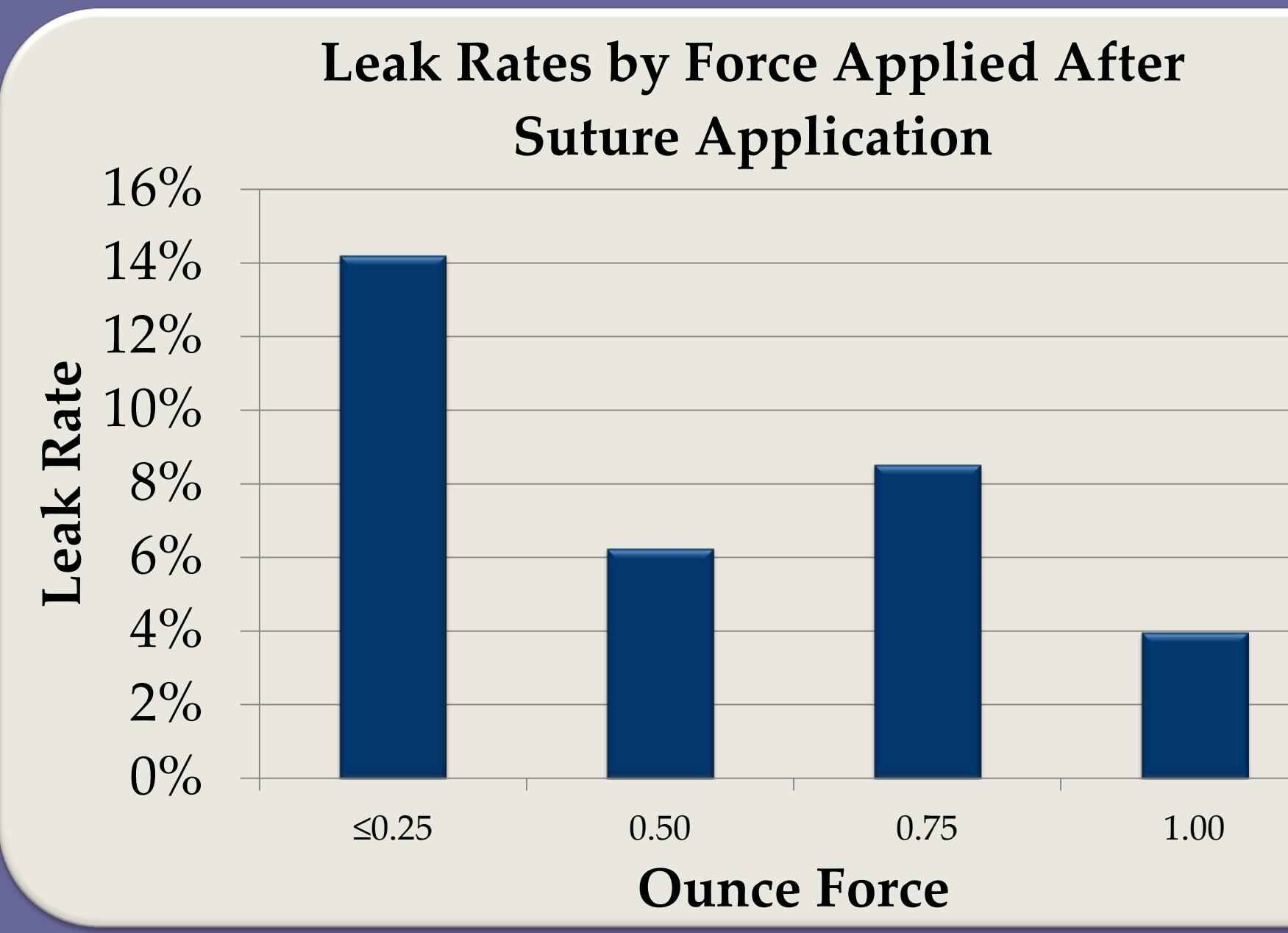
- 183 patients undergoing cataract surgery were enrolled at 23 centers in the United States. Seven patients did not attend all follow-up visits, so the per-protocol population evaluated was 176 eyes.
- Patients were evaluated for fluid egress prior to suture application using a Calibrated Force Gauge (CFG):



- If the wound leaked with ≤ 1.0 ounce of force, a 10-0 nylon suture was applied using a 3-1-1 technique with buried knot.
- Wounds were challenged again using the CFG and evaluated for prevention of fluid egress.
- A Seidel test was also performed at days 1, 3, and 7.
- Sutures were removed at day 28 per physician discretion.

Results:

- 33% (n=58) of patients leaked in the immediate post-operative period with ≤ 1.0 oz. force applied.



- Two additional eyes exhibited leakage within the first seven days post-operatively.
- 30.6% of patients experienced at least 1 device-related adverse event (AE). AEs included:

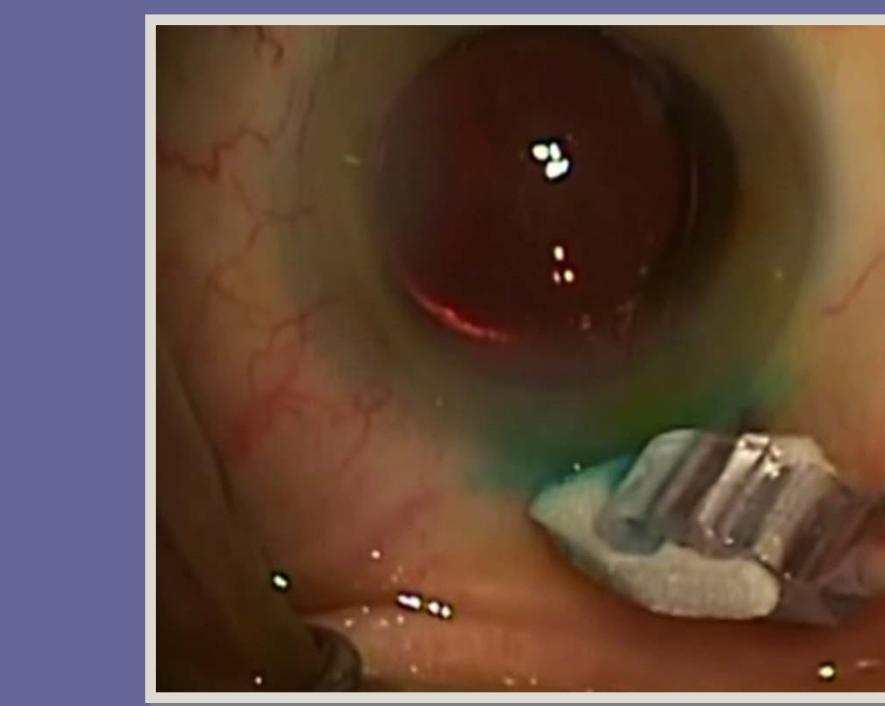
- Subconjunctival hemorrhage
- Induced corneal astigmatism
- Infection
- Corneal edema
- Eye pain, irritation, or discomfort
- Foreign body sensation
- Elevated intraocular pressure
- Other suture-related complications

- 12.6% of patients required premature suture removal due to an AE.
- Incision architecture (incision width/tunnel length) did not influence leak rates.

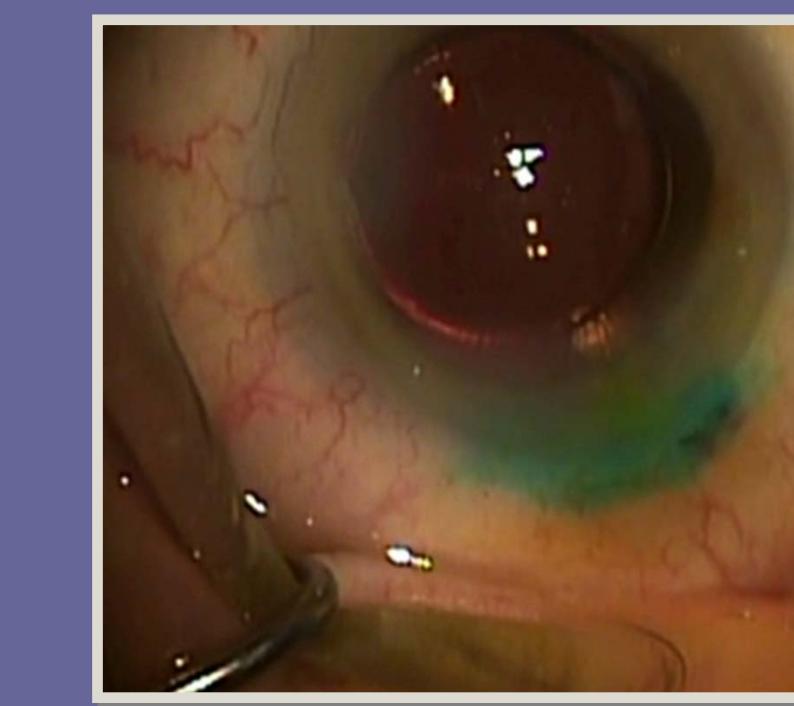
Discussion:

Although CCIs have been considered 'self-sealing', a number of reports in the literature have indicated that this may be overstated.¹⁻⁴ In this study, even when sutured, these incisions still demonstrated a high incidence of leaks and AEs.

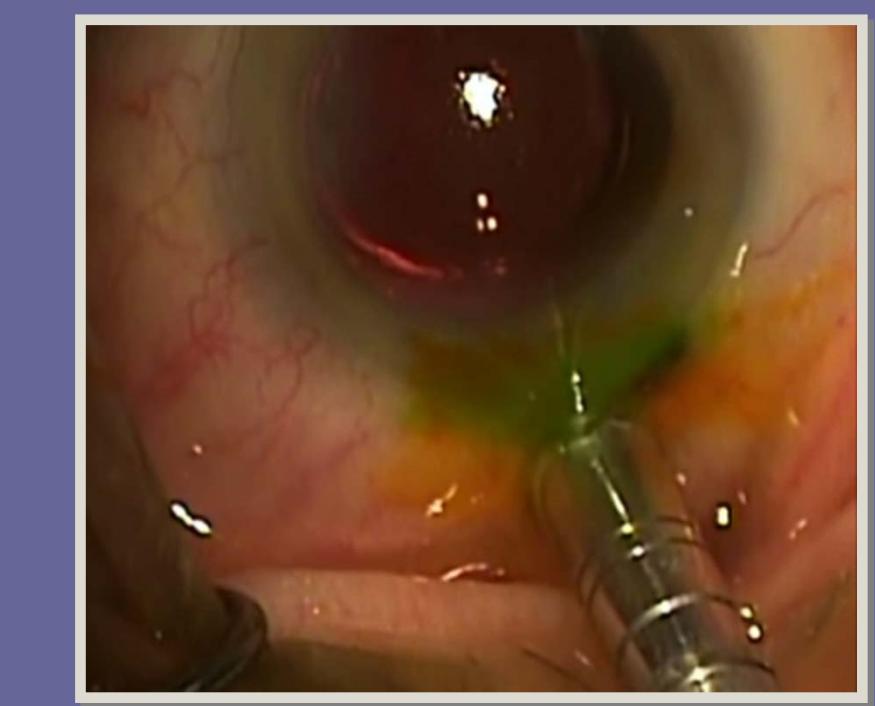
An ocular sealant (ReSure Sealant, Ocular Therapeutix, Inc.) has recently been evaluated in a Pivotal Clinical Trial, where the device effectively prevented wound leaks in 95.9% of cases under the same evaluation with the CFG.



Application



Sealed incision



CFG test – no leak

The sealant is prepared and applied in less than 15 seconds, demonstrated significantly less adverse events than sutures, and does not require removal at a later date as it sloughs off in the tears.

Conclusions:

CCIs are susceptible to leakage even after closure with suture, both spontaneously or when subject to external forces representative of eye touching/rubbing. In the future, ocular sealants may be more effective means of wound closure with less adverse events than sutures.

References:

- Maskit 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.
- Mifflin MD, Kinard, K, et al. Comparison of Stromal Hydration Techniques for Clear Corneal Cataract Incisions: Conventional Hydration versus Anterior Stromal Pocket Hydration. *Journal of Refractive Surgery*. 2012 Jun; 38(6):933-937.
- Herretes S, Stark WJ, et al. Inflow of ocular surface fluid into the anterior chamber after phacoemulsification through sutureless corneal cataract wounds. *American Journal of Ophthalmology*. 2005;140:737-740.
- Chee SP. Clear corneal incision leakage after phacoemulsification—detection using povidone iodine 5%. *Case Report. Int. Ophthalmology* 2005 Aug-Oct;26:175-179.