

# METHOD DEVELOPMENT FOR ASSESSING CLEAR CORNEAL WOUND INTEGRITY

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## INTRODUCTION

Although cataract surgery is well established with low complication rates, clear corneal wound integrity is a frequent topic of concern.<sup>1,2</sup> Wound leaks have been associated with rare but sight-threatening complications, increasing risk of infection up to 44-fold.<sup>3</sup> Previous studies have indicated that fluctuations in intraocular pressure (IOP) may be a culprit of wound leaks. Several factors could be associated with these fluctuations, including eye touching/rubbing, sneezing, and coughing.

## PURPOSE

To develop a standardized and quantitative method to create increases in IOP that simulate patient manipulation following cataract surgery, and to use that method to examine the integrity of clear corneal incisions (CCIs) in the immediate post-operative period.

## METHODS

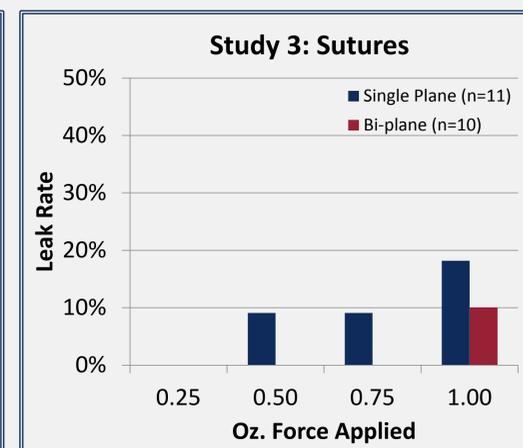
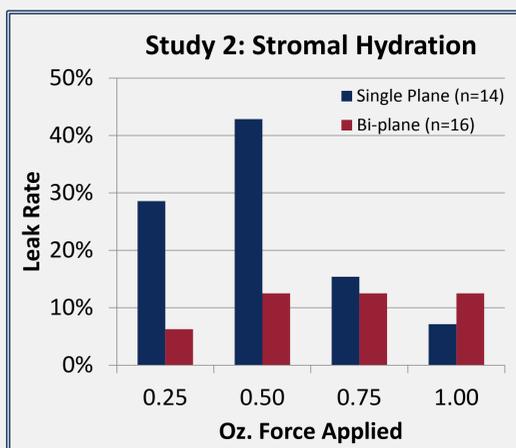
- A Calibrated Force Gauge (CFG) was developed from a Dontrix Gauge (GAC International Inc., Bohemia, NY) with a 3 mm atraumatic tip.



- The device was applied to healthy volunteers not undergoing cataract surgery to examine IOP fluctuations and compare results with existing literature (Study 1).
- Upon determination of the appropriate amount of force to simulate IOP fluctuations consistent with eye touching, the device was then applied to wounds closed with stromal hydration (Study 2) and sutures (Study 3) in both single plane and bi-plane incisions.

## RESULTS

- In Study 1, mean baseline IOP was 17.5 mmHg and rose to 43.4 mmHg upon applying 1.00 oz. force using the CFG. This rise in IOP was comparable to application of light and firm digital forces (27 and 58 mmHg respectively),<sup>4</sup> simulating eye touching.
- In Study 2, a total of 66.7% of all stromally hydrated wounds leaked with application of 1.00 oz. force. Mean incision width was 2.75 mm for single plane incisions, and 2.25 mm for biplane incisions.
- In Study 3, a total of 23.8% of all sutured incisions leaked with application of 1.00 oz. force. Mean incision width was 2.70 mm for single plane incisions, and 2.28 mm for bi-plane incisions. All incisions were stromally hydrated in addition to suture application.



### References:

- Masket S, Belani S. Proper wound construction to prevent short-term ocular hypotony after clear corneal incision cataract surgery. *J Cataract Refract Surg.* 2007; 33(3):383-386.
- Calladine D, Packard R. Clear corneal incision architecture in the immediate postoperative period evaluated using optical coherence tomography. *J Cataract Refract Surg.* 2007; 33(8):1429-1435.
- Wallin T, Parker J, et al. Cohort study of 27 cases of endophthalmitis at a single institution. *J Cataract Refract Surg* 2005; 31:735-741.
- McMonnies CW, Boneham GC. Experimentally increased intraocular pressure using digital forces. *Eye & Contact Lens* 2007; 33(3): 124-129.

## DISCUSSION

Results of this study show that unintended forces caused by patient manipulation may be detrimental to wound integrity. As a result, standardized and routine testing of CCI integrity should be performed routinely.

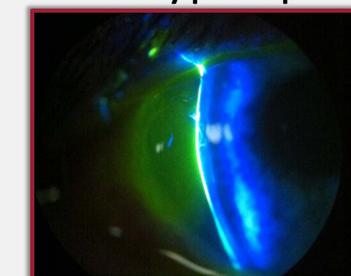
Although sutures appeared to prevent wound leaks in clear corneal incisions better than stromal hydration, the leak rate is still high.

A recent 488 patient study evaluated an ocular sealant (ReSure Sealant, Ocular Therapeutix, Inc.) compared to sutures for prevention of wound leaks in the immediate post-operative period using the same technique described here. In this study, sutures had a leak rate of 31.7%, compared to the sealant at only 3.6%, demonstrating statistical superiority ( $p < 0.0001$ ). The sealant also demonstrated significantly less adverse events than sutures ( $p < 0.0001$ ). The sealant was rated “easy” or “very easy” to use 94.1% of the time.

### Intra-operative



### 1-day post-op



## CONCLUSION

One ounce force using the CFG appeared to be appropriate to simulate forces on the eye which may be caused by eye touching. In these series of studies, a large number of stromally hydrated and sutured wounds exhibited fluid egress upon CFG challenge. If a wound leaks under simulated patient manipulation, further protection, such as an ocular sealant, may be warranted to protect the incision from potential fluid egress.

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