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). 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. 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.

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: