

New Sealant's Many Uses After Cataract Surgery

The ReSure Sealant offers multiple benefits over traditional sutures.

BY CYNTHIA MATOSSIAN, MD

During the past 2 decades, there has been an evolution from larger, sutured incisions for cataract surgery to smaller nonsutured incisions. Surgeons pay meticulous attention to constructing incisions that will not leak at the end of the cataract surgery case to avoid endophthalmitis or possible rotation of toric IOLs. Preexisting ocular comorbidities, poor wound architecture, larger sizes, and iatrogenic causes, such as wound burn, are among the many factors that can contribute to leaking incisions.

Obviously, if there is a leak, or if the surgeon has any doubt about the integrity of the wound at the end of the case, a suture is recommended. At times, even when the incision is well constructed and appears to be watertight with no leakage detected on testing with a Weck-Cel sponge (Beaver-Visitec International) and pressurized dabbing at the incision site, there may be instances when the surgeon may want an additional safety net and may consider placing a sealant over the incisions.

ALTERNATIVE TO SUTURES

The ReSure Sealant (Ocular Therapeutix) can effectively manage wound leaks and prevent fluid egress after cataract surgery, and it is a promising alternative to sutures under certain circumstances.

The sealant is a hydrogel composed of polyethylene glycol, trilycine, buffering salts, and more than 89% water. It is applied to a dry surface as a liquid and polymerizes into an adherent hydrogel in less than 30 seconds. It contains FD&C Blue #1, which aids visualization for accurate placement and observation and dissipates within hours of application, leaving a clear sealant on the eye. FD&C Blue #1 is a synthetic, water-soluble colorant approved for use in medical devices, drugs, and cosmetics; how-

ever, the product should not be used on patients who are allergic to this colorant.

The pliable nature of this hydrogel allows it to conform to the corneal tissue, creating a smooth surface so as not to induce astigmatism or create foreign-body sensation. Some ophthalmologists have used cyanoacrylate glue off label to temporarily seal a wound leak, but the results have not been ideal. Cyanoacrylate dries into a very hard and brittle structure that often requires the placement of a bandage contact lens on the eye to address the associated patient discomfort. The ReSure Sealant was comfortable for patients in the pivotal clinical trial without the use of a bandage contact lens.

APPLYING THE SEALANT

The device is packaged as a mixing tray, diluent dropper, and two foam-tipped applicators. Two drops of the diluent are added to a blue deposit in one well, and the components within that well are then reconstituted by the physician for approximately 5 seconds. The surgeon must apply the sealant within the next 7 seconds after mixing, or the hydrogel material will begin to polymerize. The physician should then wait another 15 seconds to ensure the device has completely gelled on the ocular surface.

If the first application is not adequate, or if the application was compromised due to movement by the patient, etc., a second well is provided in the mixing tray for an additional application. I prefer to use both applications on each patient to ensure that I have complete coverage of the incision.

HOW THE SEALANT ADHERES

When applied, the hydrogel molds around the irregularities of the de-epithelialized tissue and adheres via "lock and key," instead of binding chemically to the

THE FUTURE OF CATARACT WOUND CLOSURE?

Another measure of security for surgeons.

BY JOHN A. HOVANESIAN, MD

After cataract surgery, stromal hydration is the most common method of “sealing” clear corneal incisions. It is not a perfect solution to wound closure, however, because the effects are transient and inconsistent with respect to endurance. After cataract surgery, wounds are likely to leak with little to no provocation. In a clinical study, 48.8% of eyes experienced spontaneous leakage, and incisions in 97.6% of eyes leaked with the application of 1 ounce of pressure or less to the ocular surface.¹ Although hydration increases the IOP to close the wound internally, it does not provide a physical barrier that protects against fluid egress and ingress, which has the potential to introduce harmful bacteria into the wound once the IOP drops some hours later.

NOT MANY OPTIONS

To date, the gold standard for sealing incisions has been suturing, although sealants like cyanoacrylates and fibrin glues have generated some interest. All of these options, however, expose the patient to potential complications and discomfort. Sutures sometimes induce astigmatism, and their removal requires a separate procedure. Furthermore, patients may worry about the quality of their surgery when a suture is used—something their peers undergoing cataract surgery probably did not require.

Cyanoacrylates and fibrin glues have been used off label for wound closure, because they provide a physical barrier. These two options have a number of serious drawbacks. It is well known that cyanoacrylates are extremely uncomfortable for patients, because they cause foreign body sensation. Fibrin glues are not an option for many patients and practices due to their high cost and the preparation required. In addition to

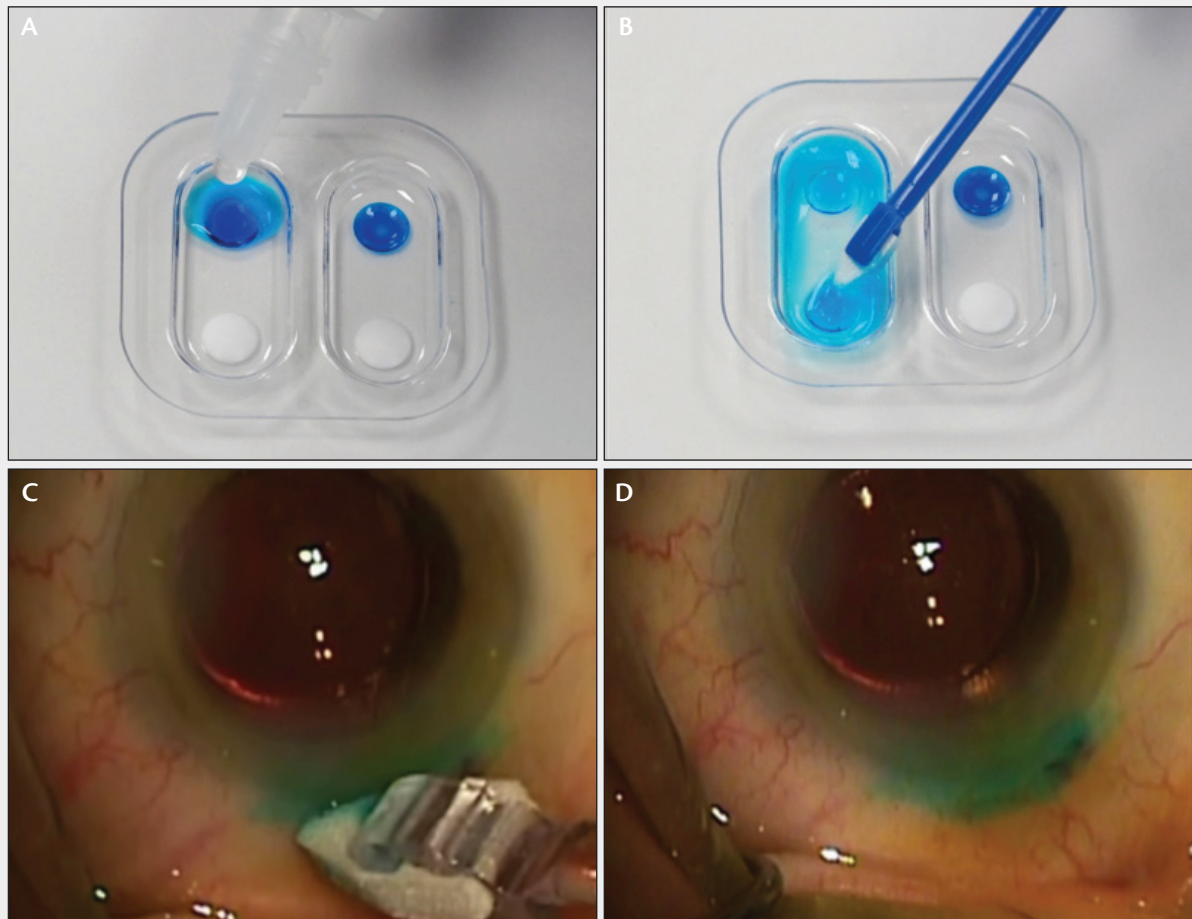


Figure. Two applications' worth of product are included in each disposable kit. Add two drops of diluent (A). Mix for 5 seconds (B). Apply over the entire incision (C). The incision is sealed in 30 seconds (D).

THE FUTURE OF CATARACT WOUND CLOSURE? (CONTINUED)

its leak-preventing superiority, a hydrogel sealant offers some advantages for patients and surgeons.

FIRST SEALANT APPROVED

ReSure Sealant (Ocular Therapeutix) is the first FDA-approved sealant for wound closure. It is composed of polyethylene glycol, a large biocompatible molecule frequently used in eye drops. ReSure begins as a liquid and forms a soft hydrogel, adherent as it polymerizes. In the phase 3 FDA trial of this device, the sealant demonstrated superiority to sutures for preventing wound leakage. Of eyes in the sealant group, 4.1% leaked after provocation with 1 ounce of pressure compared with 34.1% in the suture group.¹ Additionally, the sealant better prevented device-related adverse ocular events than sutures (1.6% in the sealant group vs 30.6% in the suture group).

To prepare and apply the sealant takes about 30 seconds. The product contains a blue colorant that aids in visualization during application and fades away in about 1 hour. Because the sealant is then clear and flexible, it is also comfortable for the patient. In 94.1% of cases in the trial, the surgeon rated the sealant as “easy” or “very easy” to use. The product sloughs off in the tears during re-epithelialization in the first week after surgery, so there is no need for removal.

FLUID EGRESS HAPPENS

Even well-constructed, clear corneal and femtosecond laser-created incisions are prone to fluid egress when external pressure is applied, as happens during manipulation by the patient or the instillation of eye drops, for example. When the wound's integrity is questionable, and it may be vulnerable to leakage, the application of a hydrogel sealant can provide security. For example, enlarged incisions

and phaco burns can compromise wound integrity, as can increased manipulation in eyes with dense cataracts, intraoperative floppy iris syndrome, or additional procedures such as the use of a trabecular microbypass stent. In these situations, surgeons may wish to consider closing the incision with a hydrogel sealant.

The hydrogel can increase safety in cases of perfectly constructed wounds and also provide added security for patients with a medical history of concern. For example, patients who have had previous ocular surgery are at increased risk of developing complications. Similarly, those with diabetes or compromised immune systems who heal at a much slower rate could benefit from the sealant. The additional security would also help monocular patients, who must avoid adverse events.

CONCLUSION

The cost of the ReSure Sealant may limit its initial use. The benefits it can provide, however, should earn the device a place in every surgeon's toolkit. The reduced rate of adverse events and enhanced wound closure compared with the preexisting options may well outweigh the sealant's cost for select cataract cases.

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ocular surface. In the days following surgery, the product selectively adheres to the de-epithelialized tissue without any chemical reaction or toxicity. It is important to note, however, that the incision should not be further de-epithelialized in order for the product to adhere.

The ReSure Sealant's selective adherence means that it persists on de-epithelialized tissue and clears from re-epithelialized tissue. The product therefore does not require removal.

The pivotal study showed that the sealant typically stays on for 1 to 3 days, depending on the patient, which coincides with the time the epithelium heals after cataract surgery (S. Masket et al, unpublished data, 2014). The sealant therefore remains on the wound in the immediate postoperative period when wounds are most vulnerable to leaks.

SAFE AND EFFECTIVE

In a recent study evaluating the safety and effectiveness of the sealant compared with sutures to prevent fluid egress from clear corneal incisions in the immediate postoperative period following uneventful cataract surgery, 488 of 500 eyes exhibited leakage at the time of cataract surgery (S. Masket et al, unpublished data, 2014). Of these, 48.8% experienced spontaneous leakage, and an additional 25.4% had leaks with minimal touch pressure using a calibrated force gauge.¹

The study was conducted at 24 ophthalmic clinical practices in the United States and included 500 healthy eyes that were undergoing uncomplicated clear corneal cataract surgery. The 488 eyes that demonstrated leakage were randomized to receive either the sealant or a nylon

suture at the main incision site. Incisional leakage was re-evaluated at 1, 3, 7, and 28 days postoperatively.

After randomization and treatment, 12 of 295 eyes in the sealant group (4.1%) versus 60 of 176 eyes in the suture group (34.1%) exhibited wound leakage with provocation, a difference that was shown to be statistically significant ($P < .0001$), with the sealant demonstrating superiority to sutures for preventing wound leakage as tested. The overall incidence of adverse ocular events reported for patients treated with the sealant was significantly lower than for patients treated with sutures ($P < .0001$).

WHEN TO USE THE SEALANT

There are several scenarios in which I previously employed sutures but now use ReSure.

Monocular Patients

If a patient is monocular and is undergoing cataract surgery on the sighted eye, I now use the sealant for that additional safety net and peace of mind.

Immunocompromised Patients

If a patient is immunocompromised from preexisting systemic issues, there is a greater risk of infection for him or her at the time of surgery. Although the wound appears not to leak, I like the added protection of having a sealed incision.

Patients Undergoing Chemotherapy During Cataract Surgery

Some chemotherapeutic agents and/or the concomitant use of steroids in the prescribed regimens exacerbate cataract formation. When the chemotherapy treatments are stretched out over months, patients with visually significant cataracts may benefit from cataract surgery. If the cataract surgery occurs during the patient's chemotherapy treatment, I always use additional protection over the corneal incision.

Long-Term Use of Steroids

Steroids delay wound healing. If patients are on steroids long term for systemic illnesses, the corneal incision's healing may be delayed. I like the added security over the cataract incision.

Cases That Require Additional Manipulation at the Time of Surgery

Some cases are complex, requiring many additional maneuvers in the eye with the insertion and removal of different instruments through the corneal incision(s). Additional manipulation of the incision may make it less

stable with a potential for leaking. The ReSure Sealant may be of benefit in these types of challenging cases.

Enlarged Incisions

At times, the incision has to be enlarged for a variety of reasons. With the increased use of intraoperative aberrometry to obtain real-time refractive power readings, the exchange of an IOL may be required. Depending on the IOL model and material, it may require the enlarging of the main incision for the IOL exchange. The sealant may help secure the slightly larger incision.

Patients With Methicillin-Resistant *Staphylococcus Aureus*

Given the high risk of postoperative complications in methicillin-resistant *S aureus*-positive patients following cataract surgery, I now use the ReSure Sealant to ensure my wounds are watertight in the early postoperative period.

TIME SAVINGS

I recently timed the tying of a 10-0 Vicryl suture (Ethicon) on an eye with a Crystalens (Bausch + Lomb). It took 2 minutes and 34 seconds using a standard 3-1-1 technique with a buried knot. OR time costs have been reported to be between \$46 and \$60 per minute.^{2,3} The sealant offers substantial time and cost savings, considering the device takes less than 30 seconds to prepare and apply, and it also saves clinic time by avoiding the necessity of suture removal.

CONCLUSION

In a case with a toric IOL, there was some conjunctival ballooning near the incision. I used the ReSure Sealant to avoid any potential rotation of the toric IOL by ensuring chamber stability.

In summary, the ReSure Sealant offers multiple benefits over traditional sutures and is a significant advance for the protection of wounds after cataract surgery. ■

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