Visualization in Vitrectomy Procedures

FDA-approved injectable triamcinolone acetonide is formulated for intraocular use.

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In February, triamcinolone acetonide injectable suspension (Triesence, Alcon Laboratories, Inc.) became available for use by ophthalmologists. It is the first injectable steroid approved for use in the eye by the US Food and Drug Administration (FDA).

The triamcinolone acetonide injectable suspension is a preservative-free synthetic corticosteroid that is FDA-approved for visualization of the vitreous during vitrectomy and for the treatment of ocular inflammatory conditions that are unresponsive to topical corticosteroids.

IMPROVED VISUALIZATION WITHOUT TOXICITY

Surgeons have been using triamcinolone acetonide for years to enhance the visualization of vitreous and pathologic membranes during vitrectomy surgery. Studies have shown that triamcinolone acetonide effectively facilitates key surgical maneuvers during vitrectomy, and it has been used to visualize clear vitreous body, posterior vitreous base, internal limiting membrane (Figure 1), and associated epiretinal membranes.

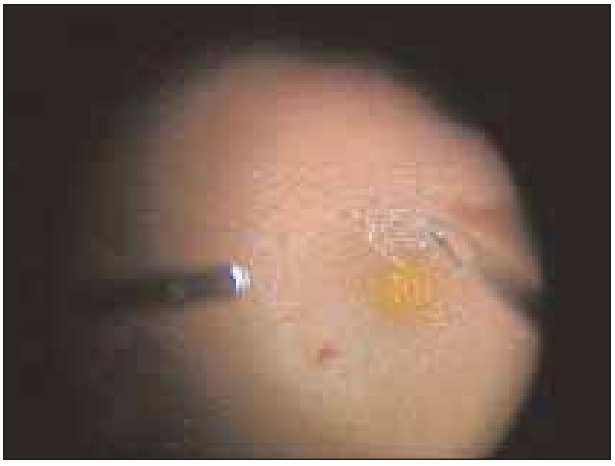

Figure 1. Triamcinolone acetonide injectable suspension applied for an internal limiting membrane peeling procedure.

Retina specialists have been using triamcinolone intravitreally to treat a variety of inflammatory conditions because corticosteroids given as drops, given systemically, or injected into the subconjunctival or sub-Tenon's space often do not reach high enough concentrations to be effective. Additionally, with the prolonged use of systemic corticosteroids, there is a risk of systemic side effects.

There has been concern regarding the toxicity of preserved triamcinolone formulations, specifically with benzyl alcohol, which has been associated with retinal toxicity and inflammatory phenomena. The triamcinolone acetonide formulation from Alcon is preservative-free, which eliminates the potential for the preservative to cause ocular inflammation. Additionally, it is terminally sterilized and comes in a vial with a sterile exterior, making it ideal for use in the operating room (Figure 2).

Preservative-free triamcinolone acetonide effectively provides intraoperative visualization for various conditions, such as peeling cortical vitreous, epiretinal membranes, or the internal limiting membrane.

The particle size of the preservative-free triamcinolone acetonide formulation was optimized to provide excellent visualization of vitreous and membranes without obscuring the retina, and the formulation is injectable through a 30-gauge needle (Figure 3). In our experience, preservative-free triamcinolone acetonide should be diluted with balanced salt solution before injection for visualization. For optimal visualization we recommend preservative-free triamcinolone acetonide diluted to balanced salt solution in a 1:8 ratio.

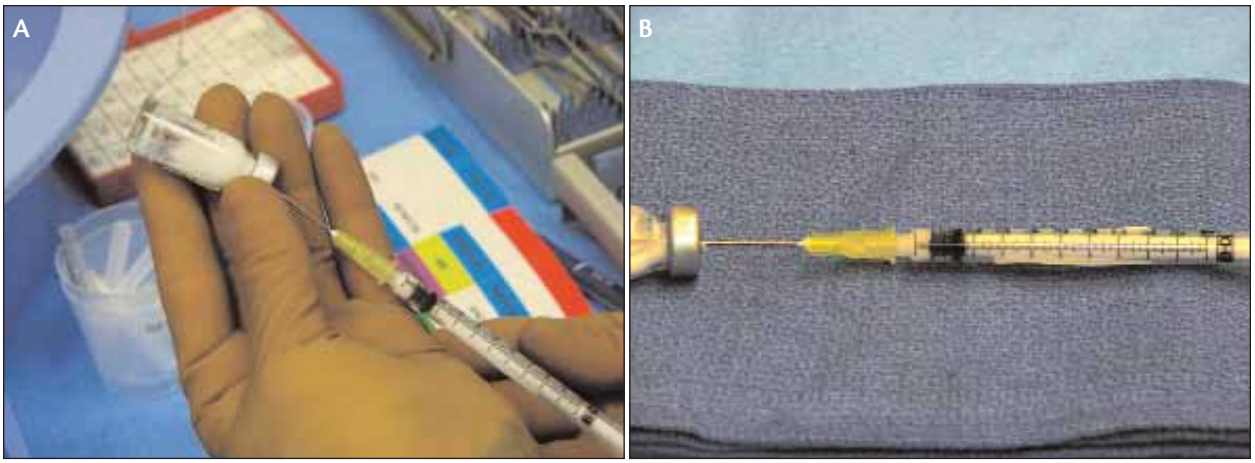

Figure 2. Triamcinolone acetonide injectable suspension is terminally sterilized (A) and comes in a vial with a sterile exterior, making it ideal for operating room use (B).

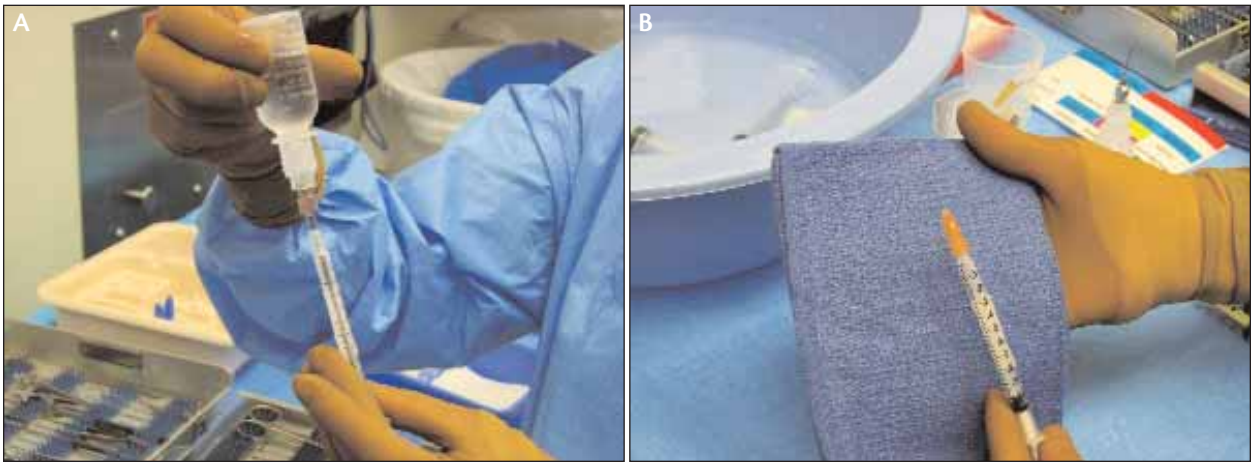

Figure 3. A 30-gauge needle is inserted into the sterile container (A) and is used to administer triamcinolone acetonide injectable suspension (B).

To dilute preservative-free triamcinolone acetonide in the operating room for use in visualization the surgeon combines it with balanced salt solution in a syringe. Then, some sterile air is pulled into the syringe to ensure enough room for thorough mixing. Preservative-free triamcinolone acetonide should be injected into the eye immediately after dilution and mixing. One should not allow the suspension to settle. In the office, however, we have injected preservative-free triamcinolone acetonide without dilution for therapeutic indications.

Figures 4 through 6 show preservative-free triamcinolone acetonide utilized in the anterior chamber.

SAFETY AND EFFICACY

A phase 3 study found that preservative-free triamcinolone acetonide is safe and effective for improving visualization during pars plana vitrectomy with or without membrane removal.[1] The multicenter, observer-masked study included 60 patients who were scheduled to undergo pars plana vitrectomy. Forty-three patients underwent 25-gauge surgery, 12 patients underwent 23-gauge surgery, and five patients underwent 20-gauge surgery. In 59 of the 60 cases, the masked observers' scores for visualization of posterior segment structures were higher after the instillation of preservative-free triamcinolone acetonide. Observers rated the visibility on a scale of 0 to 4 (0=not visible and 4=clearly delineated). The mean visualization score was 0.5 before the instillation of preservative-free triamcinolone acetonide and 3.7 after the instillation of preservative-free triamcinolone acetonide.

ADDITIONAL USES AND REIMBURSEMENT

In addition to using preservative-free triamcinolone acetonide for visualization during surgery, it can also be used to treat uveitis and other inflammatory conditions

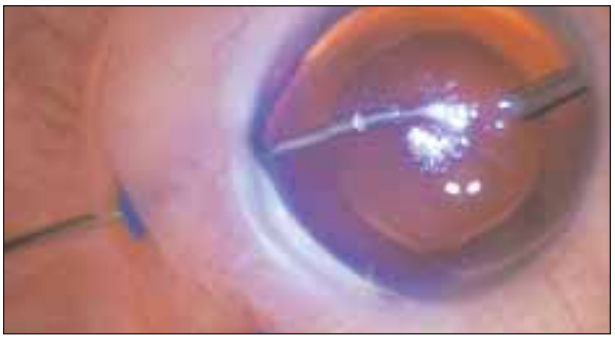

Figure 4. Triamcinolone acetonide injectable suspension 5% disperses behind the IOL.

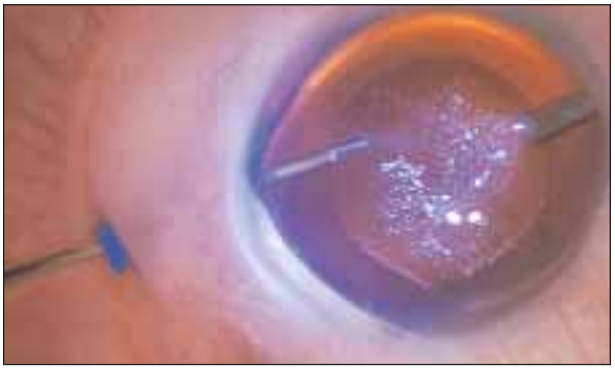

Figure 6. Triamcinolone acetonide injectable suspension 5% is injected into the anterior vitreous. A circular pattern results as it is injected.

that are unresponsive to topical corticosteroids.

Because preservative-free triamcinolone acetonide is FDA-approved for use in the eye, surgeons can be reimbursed for its use. Although specific coding does not currently exist to report the use of preservative-free triamcinolone acetonide, facilities can use a miscellaneous code (C9399) to report the drug. Like Medicare, for private payers and Medicaid reimbursement, preservative-free triamcinolone acetonide must be reported using miscellaneous code J3490. For in-office injection, we have used the miscellaneous code J3490 to report preservative-free triamcinolone acetonide along with the intravitreal injection procedure code 67028.

When billing with miscellaneous codes, on the claim form, it will be important to list the product name, National Drug Code number, and vial size (Triesence, 00065-0543-01, 40 mg/mL).

Because of its advantages over triamcinolone formulations that contain preservatives and are not approved for use in the eye, in our opinion, preservative-free triamcinolone acetonide is a valuable addition to retina specialists' armamentarium. ■

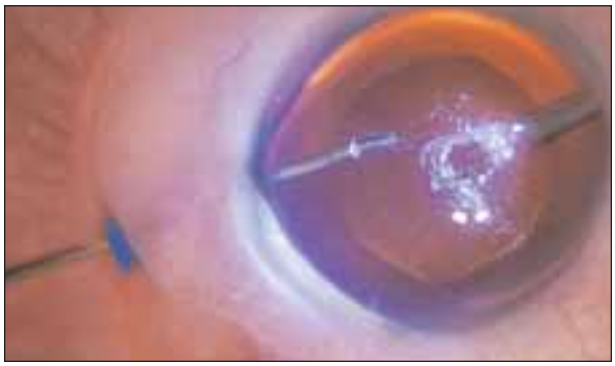

Figure 5. Triamcinolone acetonide injectable suspension caught in the anterior vitreous superiorly. The triamcinolone falls away because there is no vitreous behind the inferior half of the IOL.

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1. Bochow T, Callanan D, Dyer D, et al. Clinical evaluation of the safety and efficacy of Triesence (triamcinolone acetonide injectable suspension) 40 mg/mL for visualization of vitreous and membranes in pars plana vitrectomy. Presented at: 2008 annual Association for Research and Vision in Ophthalmology meeting; April 27-May 1, 2008; Fort Lauderdale, FL.