

ASCRS releases position statement on 2 established ophthalmic practices

The American Society of Cataract & Refractive Surgery (ASCRS) has released an official position statement opposing directives that restrict 2 well-established presurgical ophthalmic practices: the use of diluted povidone-iodine solution for topical infection prophylaxis and the use of multidose topical eye drops on multiple patients. The position statement, developed by the ASCRS Cataract Clinical Committee, comes in the wake of some surgery centers being compelled to cease certain long-accepted topical treatments for preoperative patients.

"Some members reported that surveyors have arbitrarily proscribed these well-established and common practices, without any evidence that they pose greater risk," said **David F. Chang, MD**, ASCRS past president and Cataract Clinical Committee member.

ASCRS position statement

Current literature strongly supports the use of preoperative povidone-iodine solution for cataract (ophthalmic) surgery antisepsis and endophthalmitis prevention. Specifically, instillation of 5% povidone-iodine solution in the conjunctival sac has been shown to be effective for endophthalmitis prophylaxis. This practice has been used almost universally in ophthalmic surgery for decades.

One common method of preparing the 5% solution is by diluting commercially available 10% povidone-iodine (Betadine) with a saline solution. A recent ASCRS survey revealed that 1 in 3 ASCS (ambulatory surgery centers) prepare their surgical prep in this way. This practice has been shown to be safe and effective despite the labeling "Do not use in the eye," present on the 10% Betadine solution. More recently, individually packaged 5% povidone-iodine preps have become commercially available, but at a significant cost premium.

Another well-established practice is the use of multidose eye drops on multiple patients as part of the preoperative surgical protocol (i.e., dilating drops, NSAIDs, etc.). The safety and cost effectiveness

of multidose bottles are well recognized in the clinic and in the surgery setting. Safety guidelines have been established for the safe use of these products including: expiration 28

days after initial use, proper dispensing technique, and discarding of any bottle with suspected tip contamination.

The ASCRS Cataract Clinical Committee strongly supports the current established practice

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Ocular Surgery

DUREZOL® (difluprednate ophthalmic emulsion) 0.05%, a topical corticosteroid, is indicated for the treatment of inflammation and pain associated with ocular surgery.

Endogenous Anterior Uveitis

DUREZOL® Emulsion is also indicated for the treatment of endogenous anterior uveitis.

DOSAGE AND ADMINISTRATION

Ocular Surgery

Instill one drop into the conjunctival sac of the affected eye 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.

Endogenous Anterior Uveitis

Instill one drop into the conjunctival sac of the affected eye 4 times daily for 14 days followed by tapering as clinically indicated.

DOSAGE FORMS AND STRENGTHS

DUREZOL® Emulsion contains 0.05% difluprednate as a sterile preserved emulsion for topical ophthalmic administration.

CONTRAINDICATIONS

The use of DUREZOL® Emulsion, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.

WARNINGS AND PRECAUTIONS

IOP Increase

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, intraocular pressure should be monitored.

Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

Bacterial Infections

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

Viral Infections

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal Infections

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in

any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Topical Ophthalmic Use Only

DUREZOL® Emulsion is not indicated for intraocular administration.

Contact Lens Wear

DUREZOL® Emulsion should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of DUREZOL® Emulsion. The preservative in DUREZOL® Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL® Emulsion.

ADVERSE REACTIONS

Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects; posterior subcapsular cataract formation; secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Ocular Surgery

Ocular adverse reactions occurring in 5-15% of subjects in clinical studies with DUREZOL® Emulsion included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis. Other ocular adverse reactions occurring in 1-5% of subjects included reduced visual acuity, punctate keratitis, eye inflammation, and iritis. Ocular adverse reactions occurring in < 1% of subjects included application site discomfort or irritation, corneal pigmentation and striae, episcleritis, eye pruritus, eyelid irritation and crusting, foreign body sensation, increased lacrimation, macular edema, sclera hyperemia, and uveitis. Most of these reactions may have been the consequence of the surgical procedure.

Endogenous Anterior Uveitis

A total of 200 subjects participated in the clinical trials for endogenous anterior uveitis, of which 106 were exposed to DUREZOL® Emulsion. The most common adverse reactions of those exposed to DUREZOL® Emulsion occurring in 5-10% of subjects included blurred vision, eye irritation, eye pain, headache, increased IOP, iritis, limbal and conjunctival hyperemia, punctate keratitis, and uveitis. Adverse reactions occurring in 2-5% of subjects included anterior chamber flare, corneal edema, dry eye, iridocyclitis, photophobia, and reduced visual acuity.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects

Pregnancy Category C. Difluprednate has been shown to be embryotoxic (decrease in embryonic body weight and a delay in embryonic ossification) and teratogenic (cleft palate and skeletal) anomalies when administered subcutaneously to rabbits during organogenesis at a dose of 1-10 mcg/kg/day. The no-observed-effect-level (NOEL) for these effects was 1 mcg/kg/day, and 10 mcg/kg/day was considered to be a teratogenic dose that was concurrently found in the toxic dose range for fetuses and pregnant females. Treatment of rats with 10 mcg/kg/day subcutaneously during organogenesis did not result in any reproductive toxicity, nor was it maternally toxic. At 100 mcg/kg/day after subcutaneous administration in rats, there was a decrease in fetal weights and delay in ossification, and effects on weight gain in the pregnant females. It is difficult to extrapolate these doses of difluprednate to maximum daily human doses of DUREZOL® Emulsion, since DUREZOL® Emulsion is administered topically with minimal systemic absorption, and difluprednate blood levels were not measured in the reproductive animal studies. However, since use of difluprednate during human pregnancy has not been evaluated and cannot rule out the possibility of harm, DUREZOL® Emulsion should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus.

Nursing Mothers

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when DUREZOL® Emulsion is administered to a nursing woman.

Pediatric Use

DUREZOL® Emulsion was evaluated in a 3-month, multicenter, double-masked, trial in 79 pediatric patients (39 DUREZOL® Emulsion; 40 prednisolone acetate) 0 to 3 years of age for the treatment of inflammation following cataract surgery. A similar safety profile was observed in pediatric patients comparing DUREZOL® Emulsion to prednisolone acetate ophthalmic suspension, 1%.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Difluprednate was not genotoxic *in vitro* in the Ames test, and in cultured mammalian cells CHL/IU (a fibroblastic cell line derived from the lungs of newborn female Chinese hamsters). An *in vivo* micronucleus test of difluprednate in mice was also negative. Treatment of male and female rats with subcutaneous difluprednate up to 10 mcg/kg/day prior to and during mating did not impair fertility in either gender. Long term studies have not been conducted to evaluate the carcinogenic potential of difluprednate.

Animal Toxicology and/or Pharmacology

In multiple studies performed in rodents and non-rodents, subchronic and chronic toxicity tests of difluprednate showed systemic effects such as suppression of body weight gain; a decrease in lymphocyte count; atrophy of the lymphatic glands and adrenal gland; and for local effects, thinning of the skin; all of which were due to the pharmacologic action of the molecule and are well known glucocorticosteroid effects. Most, if not all of these effects were reversible after drug withdrawal. The NOEL for the subchronic and chronic toxicity tests were consistent between species and ranged from 1-1.25 mcg/kg/day.

PATIENT COUNSELING INFORMATION

Risk of Contamination

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the emulsion.

Use of the same bottle for both eyes is not recommended with topical eye drops that are used in association with surgery.

Risk of Secondary Infection

If pain develops, or if redness, itching, or inflammation becomes aggravated, the patient should be advised to consult a physician.

Contact Lens Wear

DUREZOL® Emulsion should not be instilled while wearing contact lenses. Patients should be advised to remove contact lenses prior to instillation of DUREZOL® Emulsion. The preservative in DUREZOL® Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL® Emulsion.

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“We want to defend those facilities that choose to use multiuse bottles or dilute 10% Betadine, based on the best medical judgment of their clinical staff.”

—David F. Chang, MD

This position statement is provided for information and educational use only. It is not intended to establish a standard of care or dictate a particular course of treatment. ASCRS members and other physicians must exercise their independent medical judgment in making treatment decisions for their patients.

“The Cataract Clinical Committee is not recommending or suggesting that there is only one best practice,” Dr. Chang said. “Rather, we want to defend those facilities that choose to use multiuse bottles or dilute 10% Betadine, based on the best medical judgment of their clinical staff.” **EW**

Contact information

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VISION

IMPORTANT SAFETY INFORMATION FOR THE TECNIS® MONOFOCAL 1-PIECE IOL (CONTINUED)

Rx Only

ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information. **WARNINGS:** Do not attempt to disassemble, modify or alter the device or any of its components. Do not use methylcellulose viscoelastics with the device. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the cartridge. Do not push the plunger forward to fully advance the lens until ready for lens implantation. Discard if the lens has been fully advanced for more than 1 minute. The lens should not be placed in the ciliary sulcus. **PRECAUTIONS:** Do not reuse, resterilize, or autoclave. **ADVERSE EVENTS:** In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL included macular edema.

IMPORTANT SAFETY INFORMATION FOR THE TECNIS® MONOFOCAL 1-PIECE IOL WITH TECNIS iTEC PRELOADED DELIVERY SYSTEM

Rx Only

ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information. **PRECAUTIONS:** Do not reuse, resterilize, reprocess, or autoclave the device. Do not store in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F). The recommended temperature for implanting the lens is at least 17°C. Low operating room temperatures combined with high IOL diopter powers may require slower delivery. The use of viscoelastics is required when using the device. The use of balance salt solution alone is not recommended. Do not use if the device has been dropped or if any part was inadvertently struck while outside the shipping case. **WARNINGS:** Do not attempt to disassemble, modify or alter the device or any of its components. Do not use methylcellulose viscoelastics with the device. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the cartridge. Do not push the plunger forward to fully advance the lens until ready for lens implantation. Discard if the lens has been fully advanced for more than 1 minute. The lens should not be placed in the ciliary sulcus. **ADVERSE EVENTS:** The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece IOL was cystoid macular edema, which occurred at a rate of 3.3%.

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ASPHERIC IOL **1**

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ITEC PRELOADED DELIVERY SYSTEM

of utilizing multidose eye drops on multiple patients, when proper protocols are followed. Furthermore, diluting 10% povidone-iodine for surgical prophylaxis remains a common and appropriate option in preparing the surgical prophylaxis.

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