Single center results from safety and efficacy evaluation of sustained release dexamethasone after cataract surgery

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Study Sponsored by Ocular Therapeutix, Inc.

Purpose

To evaluate the safety and efficacy of OTX-DP (Ocular Therapeutix, Inc.) as a sustained release drug (dexamethasone) product placed in the canaliculus of the eyelid for the treatment of ocular inflammation and pain in subjects who have undergone cataract surgery.

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OTX-DP Product Design

- Polyethylene glycol-based hydrogel punctum plug
- Provides a sustained and tapered release of dexamethasone to the ocular surface for up to 30 days
- One-time administration at the conclusion of surgery
- Illuminates under blue light and yellow filter for retention monitoring
- Absorbs and exits the nasolacrimal system following therapy without need for removal

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Methods

- Prospective, multi-center, randomized, double-masked Phase II study.
- Thirty subjects (n=30) were randomized (1:1) to receive OTX-DP or a placebo vehicle control punctum plug (PVPP) after cataract extraction with intraocular lens implantation.
- Subjects were evaluated at postoperative Days 1, 4, 8, 11, 14 and 30 and every 15 days after the Day 30 visit until the punctum plug was no longer present in the canaliculus.
- Assessments included ocular pain and photophobia, BCVA, slit lamp biomicroscopy, punctum examinations, IOP measurements, and dilated fundus examinations.

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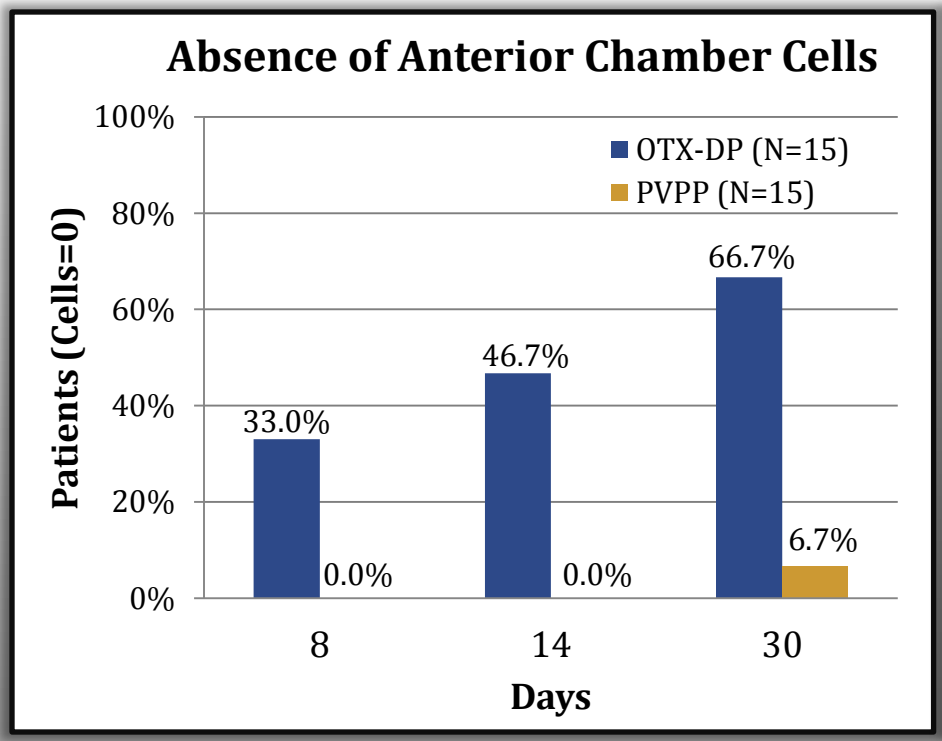
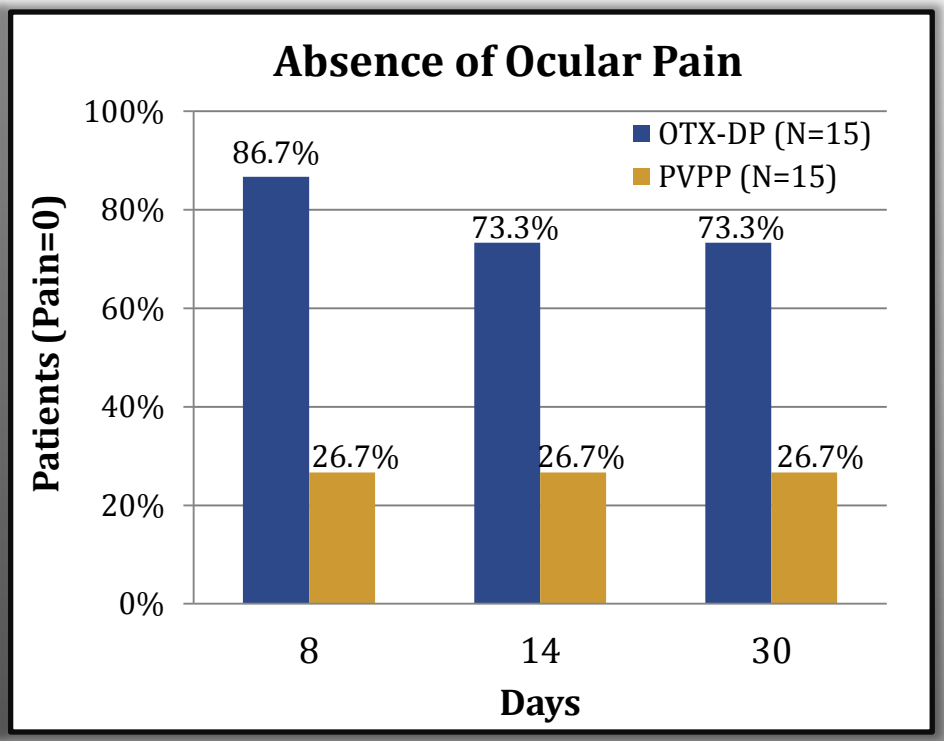
Results





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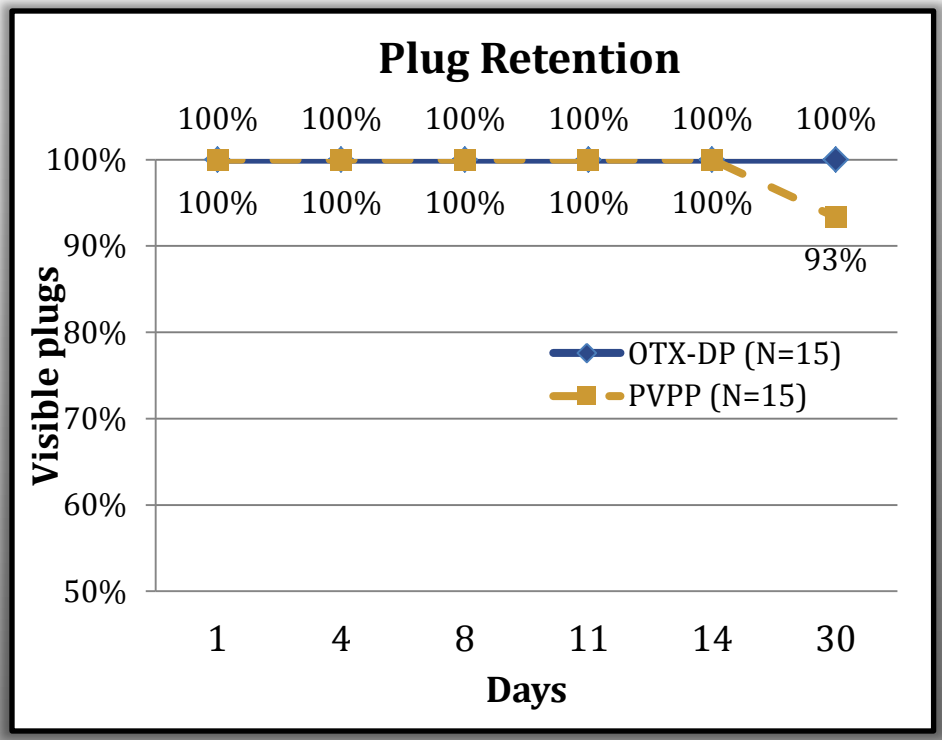
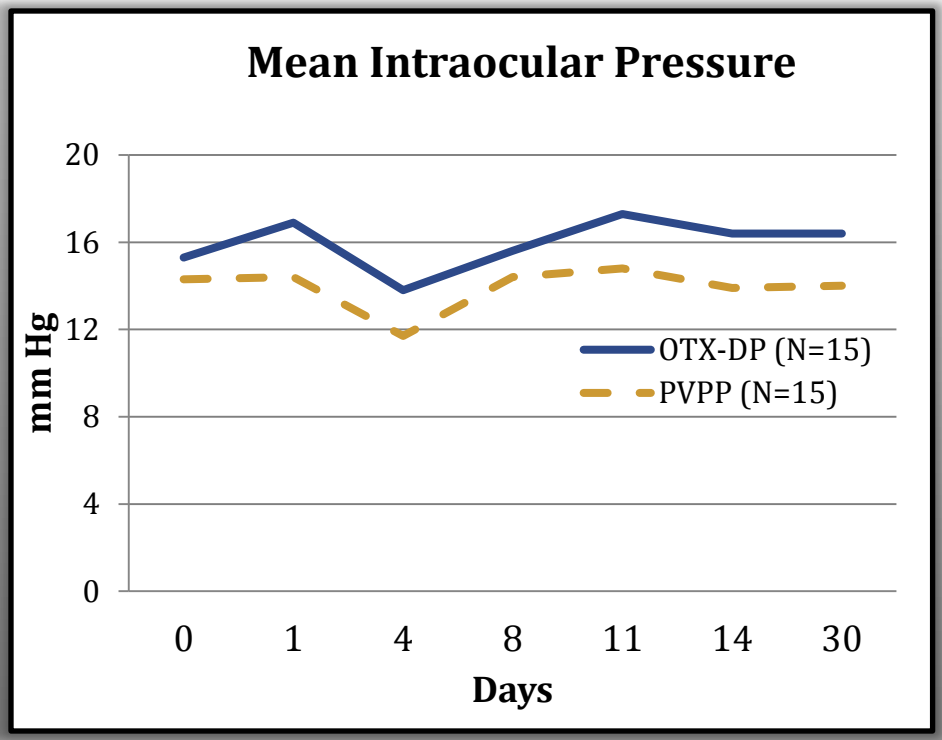
Results





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Results

- The OTX-DP group demonstrated superiority over placebo for absence of anterior chamber cells at days 8, 14, and 30.
- The OTX-DP group was statistically superior for absence of pain at days 8, 11, 14, and 30.
- Plugs were easily visualized by investigators.
- No long-term IOP spikes were experienced in either group.
- The OTX-DP group experienced less corneal edema, photophobia, and bulbar conjunctival injection.
- No OTX-DP related adverse events were noted in the study.
- Patients were comfortable overall.

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Summary

- OTX-DP effectively reduced ocular inflammation and pain in the study, without any unwanted side effects.
- Sustained dosing over time may enhance post-operative results while reducing patient burden.
- Further studies are warranted to examine the full benefits and use of this product.

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