

Tear duct implant effective at reducing pain and inflammation in cataract surgery patients

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The first tear duct implant developed to treat inflammation and pain following cataract surgery has been shown to be a reliable alternative to medicated eye drops, which are the current standard of care, according to a study presented today at AAO 2014, the 118th annual meeting of the American Academy of Ophthalmology. The device, known as a punctum plug, automatically delivers the correct amount of postoperative medication in patients, potentially solving the issue of poor compliance with self-administering eye drops.

After [cataract surgery](#), most patients are prescribed topical [eye drops](#) to reduce ocular inflammation that often occurs after surgery, but many do not or are not able to comply with the recommended dosing regimen. To potentially eliminate the issue of compliance, patients who had received cataract surgery from four ophthalmology practices across the United States were selected to participate in this phase 2 study. The researchers tested punctum plugs designed to deliver a sustained release anti-inflammatory pain medication (dexamethasone) to the [eye](#) over a period of 30 days following the removal of cataracts. After 30 days, the plug softens, liquefies and is cleared through the tear duct without the need for removal. The researchers concluded that when compared to a placebo, the dexamethasone punctum plug provides sustained reductions of inflammation and pain for up to one month following cataract surgery.

The 60 participants were randomly split into two groups, with one group of 30 patients receiving a placebo vehicle punctum plug and the other group of 30 patients receiving a dexamethasone-medicated punctum plug. At various points throughout the 30 days following cataract surgery the researchers assessed the number of patients in both groups with ocular inflammation (measured by the presence of anterior chamber cells in the treated eye) and pain.

They found that the medicated plug group had significantly less pain throughout the 30 days. On day one, the placebo group reported a mean ocular pain score more than three times higher than the medicated plug group. By day 14, the placebo group reported a mean ocular pain score 11 times higher than the medicated plug group, remaining at this level through the conclusion of the study.

Ocular inflammation in the medicated plug group was also significantly less than the placebo group throughout the 30 days. By day 14, more than 30 percent of patients in the medicated plug group showed no ocular inflammation, compared to just 3 percent in the placebo group. By day 30 of the study, over 60 percent of the patients in the medicated plug group had no signs of inflammation compared to 13 percent of patients in the placebo group.

Significantly fewer patients in the medicated plug group required additional anti-inflammatory medications compared to those in the [placebo group](#). Furthermore, a lower percentage of the medicated plug group reported experiencing light sensitivity compared with placebo patients at day 1 (44.8 percent vs. 65.5 percent) and day 4 (37.9 percent vs. 56.7 percent).

"Most people who have cataract surgery are older and may have a difficult time adhering to a post-operative eye drop regimen for various reasons," says Thomas Walters, M.D., an ophthalmologist at Texan Eye

in Austin, Texas and lead researcher for the study. "Getting eye drops onto the eye can be difficult for anybody, especially those who might have trouble holding the bottle or targeting the drops onto the eye. The punctum plug eliminates those variables and will make recovering from surgery far easier for cataract patients."

Based on the results of this study, the product is being evaluated further in phase 3 clinical trials. This study was supported by Ocular Therapeutix, which developed the dexamethasone punctum plug.

Provided by American Academy of Ophthalmology

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