# Comparison of safety and efficacy of drug delivery by topical application versus drug-eluting contact lens in cataract surgery

### Dear Editor,

Ocular drug delivery by topical drops<sup>[1]</sup> may result in draining out of the major part of the drug and poor compliance<sup>[1,2]</sup> leading to low bioavailability and potential for suboptimal outcome.<sup>[3-5]</sup> In the postoperative period of cataract surgery, compliance is important for favorable outcome, but noncompliance is frequent.<sup>[4]</sup> Drug delivery by silicone hydrogel contact lens is a noninvasive method that may eliminate noncompliance<sup>[6,7]</sup> and has been successfully used to deliver antiglaucoma medications in monkeys.<sup>[8]</sup> Though bandage contact lens can safely be used during the postoperative period of cataract surgery,<sup>[9,10]</sup> drug delivery by drug-eluting contact lens in postoperative cataract patients has not been reported in literature to the best of our knowledge.

A nonrandomized, open-label trial approved by the hospital ethics committee and registered with clinical trial registry of India was done to compare the efficacy of drug-eluting contact lens with topical drops in controlling postoperative inflammation in eyes undergoing cataract surgery.

Subjects and Methods: Silicone hydrogel contact lens (Acuvue oasis<sup>R</sup>, Johnson and Johnson, base curve 8.4 mm, diameter 14 mm, power -1.00) was sequentially loaded<sup>[6]</sup> with alcoholic solution of vitamin E 400 mg per 1 ml w/v, dried, and then soaked in commercially available preservative-free eye drop of moxifloxacin 0.5% w/v and dexamethasone phosphate 0.1%w/v (Milflodex<sup>R</sup>, Sun Pharma).

Forty eyes of 40 adult patients undergoing phacoemulsification and hydrophilic foldable intraocular lens implantation surgery under topical anesthesia for uncomplicated cataract were included in the study. Twenty-one patients received the contact lens and constituted the trial group, while 19 were included in the control group.

At the end of uneventful surgery, the trial group received the prepared contact lens and the control group received topical moxifloxacin-dexamethasone drop on the table. In both the groups, the eyes were patched. After removal of patch on the next day, i.e., day 1, the eyes in both groups were examined for signs of inflammation-congestion, anterior chamber (AC) flare, and AC cell. The control group was advised to put moxifloxacin-dexamethasone eye drop, one drop six times daily for 7 days, four times daily from 8<sup>th</sup> to 14<sup>th</sup> day, and two times daily from 15<sup>th</sup> to 21<sup>st</sup> postoperative day. They were followed up on day 1, 7, 14, and 21. The examinations were repeated at each visit up to 21<sup>st</sup> day. Contact lenses were removed on 21<sup>st</sup> day [Fig. 1]. During follow-up from the first postoperative day, the following parameters for assessment of inflammation were recorded and graded.

Grading of ciliary congestion<sup>[9]</sup>: grade 0 = no congestion, 1 = congestion width < 2 mm, 2 = width 2-3 mm, 3 = width > 3 mm but fornix free, and 4 = congestion up to fornix.

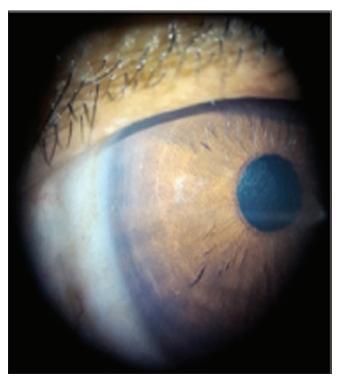


Figure 1: Eye with drug-eluting contact lens on postoperative Day 21

AC flare and AC cells were graded according to grading scheme for AC cells and flare.<sup>[11]</sup> On day 1, 7, 14, and 21, the number of eyes showing different grades of congestion, AC cell, and A C flare of both groups were recorded.

Results were analyzed with descriptive statistics, unpaired *t*-test for age and Chi-square test for categorical variables. Analysis was done using the statistical package  $Medcalc^{R}$  version 19.

Results: The mean age of the patients in trial group who received drug-eluting contact lens was 58.71 ( $\pm$ 10.18 SD) years and that of control group who received eye drops was 60.21 ( $\pm$ 7.92 SD) years. The difference was not statistically significant (*P* = 0.60).

There was no statistically significant difference, between the two groups in clinically observed signs of inflammation on all follow-up days [Table 1]. On day 21, no signs of inflammation were found in any eye of either group.

Discussion: Control of postoperative inflammation and prevention of infection in cataract surgery is conventionally achieved by the topical use of steroid and antibiotic eye drop. Topical application has its limitations including dependence on compliance and low retention time that limits intraocular penetration of the active ingredients.<sup>[2]</sup> Drugs can be released for a longer time by a factor of up to 400 due to the barrier effect of vitamin E-loaded drug-eluting contact lens.<sup>[6]</sup> Although drug delivery to eye by drug-eluting contact lens has been tried as an alternative in laboratory and animal studies,<sup>[6-8]</sup> human studies are lacking. In the present study, safety and efficacy of moxifloxacin-dexamethsone eye drops and a novel vitamin E-loaded moxifloxacin-dexamethasone eluting contact lens was compared in the postoperative management of cataract surgery in an open label design. All patients in both groups

#### Table 1: Comparison of signs of inflammation between two groups

Time	Р		
	Congestion	AC flare	AC cell
Day 1	0.79	0.89	0.74
Day 7	0.05	0.59	0.63
Day 14	0.61	0.75	0.17

achieved the end point of clinical absence of inflammation on 21<sup>st</sup> day. Thus, our study result suggested that drug-eluting contact lens can be a safe, inexpensive, and effective means of controlling postoperative inflammation without repeated application of drops by the patient. Although lack of desired compliance in the control group was an argument in favour of drug-eluting contact lens, our control group seemed to have been reasonably compliant as they were counselled in every visit. Contact lens was well tolerated by the patients and was not necessary to remove before completion of study. However, removal of contact lens may be done if such situation arises.

Vitamin E-loaded drug-eluting contact lens may be an efficient and safe alternative mode of drug delivery following cataract surgery, and this method may be tried in treating intraocular inflammation in other surgeries and uveitis. The role of a similar drug delivery system for glaucoma may be explored by further studies.

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Only hospital equipment and infrastructure used. Some commercially available materials that are not used routinely at the hospital were purchased by the authors from the market.

#### **Conflicts of interest**

There are no conflicts of interest.

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