ORIGINAL

Are topical steroids essential after an uneventful cataract surgery?

Maki Nishino[*1], Hiroshi Eguchi[*1], Akiko Iwata[*1], Hiroshi Shiota[*1], Mariko Tanaka[*2], and Takeshi Tanaka[*2]

[*1]*Department of Ophthalmology, Institute of Health Biosciences, the University of Tokushima Graduate School ; and* [*2]*Mino Tanaka Hospital, Tokushima, Japan*

Abstract : Purpose : To access the necessity of topical steroids after uneventful cataract surgery, phaco-emulsification/aspiration plus intraocular lens (PEA+IOL) implantation. Design : Single-blind, randomized, prospective study. Participants : Twenty-one patients were prospectively randomized, 11 patients were assigned to the steroid group, and 10 to the non-steroid group. Methods : Between March and September 2007, in Mino Tanaka Hospital in Tokushima Prefecture, Japan, we performed PEA+IOL in 28 eyes of 21 patients and examined the visual acuity, corneal endothelium cell density, and anterior aqueous flare value after dividing all the patients into 2 groups, the topical steroid use and the non-steroid group.
Results : At 1 month postoperatively, no difference was observed between the 2 groups in terms of the outcomes described, and no cystoid macular edema was detected.
Conclusion : Topical steroid medication may not be absolutely essential after uneventful PEA+IOL. J. Med. Invest. 56 : 11-15, February, 2009

Keywords **:** *cataract surgery, topical steroid, topical NSAID*

INTRODUCTION

In recent years, steroidal ophthalmic solutions in addition to topical non-steroidal anti-inflammatory drugs (NSAIDs) such as diclofenac or bromfenac are administered for approximately 1 month after uneventful cataract surgery (phaco-emulsification and aspiration plus intraocular lens implantation, PEA+IOL implantation) in order to reduce an inflammatory reaction. From the perspective of infection prophylaxis, however, postoperative steroidal ophthalmic solutions might be best avoided after internal ocular surgery because these drugs have a non-specific immunosuppressive effect. If it is possible, only NSAIDs ought to be administered after internal ocular surgeries as a postoperative anti-inflammatory medication.

Meanwhile, over more than a decade, the surgical technique of PEA+IOL implantation has been refined dramatically, and sophisticated surgical machines and several types of biocompatible IOLs have been developed. The chance of developing a strong inflammatory reaction such as a fibrin aggregation in the anterior chamber or a widespread corneal edema after a PEA+IOL implantation are low. In this study, we evaluated the necessity of topical steroids in the early postoperative stage following an uneventful PEA+IOL implantation by examining the visual acuity, intraocular pressure (IOP), corneal endothelial cell density and anterior chamber flare value in various perioperative periods.

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Address correspondence and reprint requests to Hiroshi Eguchi, M.D. Ph.D., Department of Ophthalmology, Institute of Health Biosciences, the University of Tokushima Graduate School, Kuramoto-cho, Tokushima, 770-8503, Japan and Fax : +81-88-631-4848.

MATERIALS AND METHODS

1. Materials

A total of 21 patients with age-related cataract (28 eyes) were recruited for this study after obtaining informed consent under the approval of Mino Tanaka Hospital ethics committee. All patients had undergone an uneventful PEA+IOL implantation at Mino Tanaka Hospital in Tokushima Prefecture, Japan between March and September 2007. Patinets with uveitis, glaucoma, exfoliation syndrome, small pupil or poorly controlled diabetes (i.e. hemoglobin A1c value were 8.0% or over) were excluded because of the possible risk of a blood aqueous barrier breakdown. The study included 12 eyes of 8 males and 16 eyes of 13 females, the mean age of participants was 76.2±6.4 years old.

2. Methods

All participants were prospectively evaluated by randomizing into 2 groups : steroid group (12 eyes of 11 patients) and non-steroid group (16 eyes of 10 patients).

1) Perioperative medications

In both groups, 0.3% moxifloxacin (MFLX) and 0.1% chloramphenicol colistin methanesulfonic acid (CP/C) ophthalmic solutions were applied 4 times daily for 3 days prior to surgery, and bromfenac sodium (BF) was applied every 20 minutes 2 hours prior to surgery. From the day after surgery, in the steroid group, patients were adminiseterd 0.1% fluorometholone and BF 4 times and twice daily, respectively, in addition to the same dosage of MFLX and CP/C as administered in the preoperative stage. The non-steroid group patients were administered the above 2 antimicrobial agents and BF were applied 4 times and twice daily, respectively.

2) Surgical procedure

All surgeries were performed in a standardized manner by 3 Japanese ophthalmological specialists in alternate shifts. The pupil was dilated with tropicamide and phenylephrine hydrochloride ophthalmic solutions. The ocular surface was rinsed with 16 times attenuation povidone-iodine. Under the topical 4% oxybuprocaine drops administration, a conjunctival incision was made, and a sub-Tenon's capsule anesthesia with 2 ml of 2% lidocaine hydrochloride was applied. Continuous curvilinear capsulorrhexis and hydrodissection were then performed. This was followd by phaco-emulsification and aspiration via phaco chop methods™ by using Infinity Vision System (Alcon Lab, Fort Worth, Texas, USA), and implantation of acrylic foldable IOLs (SA30AT®, SA60AS®, SN60AT®, SN60WF®, and ZA9003®) implantation through a 2.8 – 3.5 mm sclerocorneal incision using the injector system recommended for each lens. A subconjunctival injection of approximately 0.5 ml phosphoric acid dexamethasone was injected was applied at the end of the surgery in the steroid group.

3) Main outcome measure

For all patients, the best-corrected visual acuity (BCVA), IOP, corneal endothelial cell density, and anterior chamber flare values (photon counts/msec, KOWA, FM-600®) were examined at perioperatively, i.e., from 2 hours before surgery to 1 month after it. We defined visual acuity as "improve" when it recovered up to two phases, "worse" when it decreased to two phases, and "no change" when its value were between the improved and worse visual acuities. Fluorescein fundus angiography was performed only when cystoid macular edema (CME) was suspected to worsen the visual acuity to less than 0.7.

4) Statistical analysis

A student t-test was used for statistical analysis in epidemiological data, corneal endothelial cell density, and anterior chamber flare value.

RESULTS

1. Epidemiological data (Table 1)

Table 1 shows the patient profiles. No significant differences were observed in the age, visual acuity,

Table 1 No significant differences were noted between the 2 groups with regard to any of the parameters. Nuclear sclerosis was determined according to the Emery-Little classification.

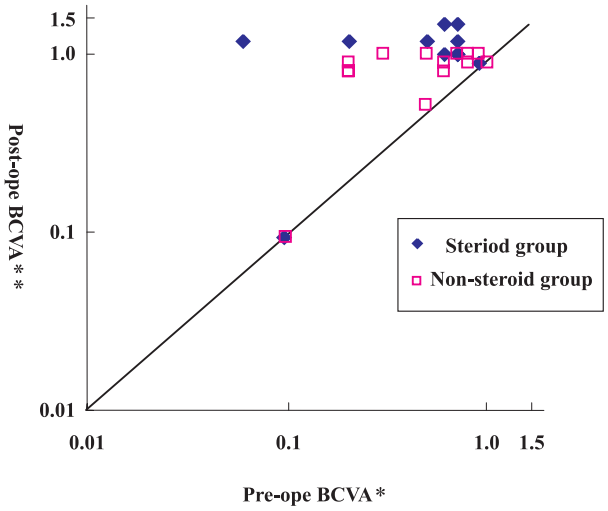
	Steroid group	Non-steroid group	P value
Age (y)	76.7±6.4	76.0±6.1	0.78
Pre-ope BCVA*	0.54±0.27	0.56±0.28	0.86
Pre-ope IOP** (mmHg)	12.3±2.4	12.3±2.9	0.98
Degree of nuclear sclerosis	2.5±0.7	2.3±0.6	0.47
Surgery time (min)	17.5±6.3	14.7±5.8	0.27
PEA time***(s)	35.2±16.6	35.6±19.9	0.95

* : Preoperative best corrected visual acuity
** : Preoperative intra ocular pressure
*** : Phaco-emulsification and aspiration time

IOP, degree of nuclear sclerosis, operation time, and PEA time between the two groups.

2. Visual acuity (Figure 1)

At one month after operation, the BCVA improved in 9 eyes (76%) in the steroid group and 12 eyes (75%) in the non-steroid group, i.e., 21 eyes (75%) in total, improved. The BCVA remained constant in 3 eyes (24%) in the former group and 4 eyes (25%) in the latter group. The BCVA did not deteriorate in any patient.



* : Preoperative best corrected visual acuity
** : Postoperative best corrected visual acuity

Figure 1 BCVA remained unchanged in 3 eyes ; 1 of which had a corneal leukoma and 2 had retinal diseases.

3. IOP

At day 1, 2 weeks and 1 month after operation, the mean IOPs in the steroid group were 14.95, 11.36 and 11.00 mm Hg, respectively, and those in the non-steroid group were 13.31, 11.19, and 9.71 mm Hg, respectively.

4. Corneal endothelial cell density (Figure 2)

At 7 days after operation, the rate of reduction in the corneal endothelial cell density was 11.9% in the steroid group and 8.4% in the non-steroid gruop. Furthermore, no significant difference was noted between the 2 groups with regard to those rate at 1 month after operation (P=0.27), it was 6.7% and 9.6% in the steroid and non-steroid groups respectively.

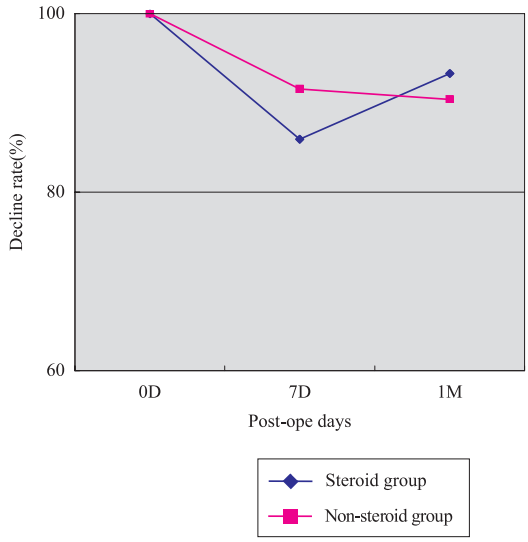


Figure 2 No significant difference was found in the rate of reduction of corneal endothelial cell density between the 2 groups found at 1 month after operation.

5. Anterior chamber flare value (Figure 3)

No significant difference was detected in the anterior chamber flare value between the 2 groups at day 1(P=0.64), days 7(P=0.40), and 1 month (P=0.39) after operation.

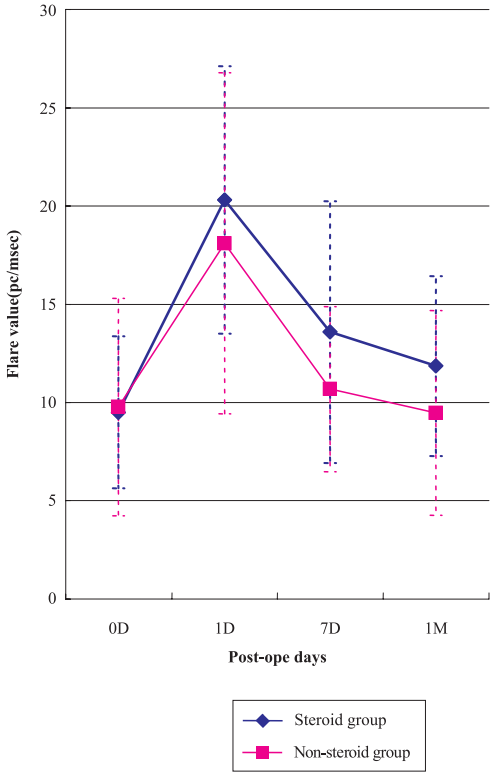


Figure 3 No significant difference was found in the anterior flare values between the 2 groups during every postoperative stages was found.

6. CME

Although the BCVA worsened in 3 eyes of 2 patients, CME was not found in any of patients. In the 2 eyes of the 1 patient, chorioretinal atrophy was considered to be responsible for the deterioration of the BCVA. In 1 eye of another patient, corneal leukoma was related to the deterioration of the BCVA. Therefore, fluorescein fundus angiography was not deemed to be necessary in any of patients.

DISCUSSION

Recently, topical antimicrobials and steroids are commonly used as perioperative medications for internal ophthalmic surgeries in Japan, and the use of steroids has not been questioned. Topical antimicrobials are administered to prevent postoperative infections. Endophthalmitis, although the incident is rare (incidence, 0.048% to 0.36% (1-3)), is one of the most vision-threatening complications that should be avoided after PEA+IOL implantation, because it can cause a rapid visual loss. The causative pathogens are likely to be indigenous gram-positive cocci present on the ocular surface : coagulase-negative *Staphylococcus* (CNS) mainly on *Staphylococcus epidermidis, Staphylococcus aureus, and Enterococcus facealis*. Therefore, fluoroquinolone, chloramphenicol, and cefem antimicrobial ophthalmic solutions are recommended to use as a perioperative medications for the disinfection of the ocular surface prior to cataract surgery. However, it is impossible to completely sterilize the ocular surface during surgery, and bacteria contamination of surgical specimens of the aqueous humour has been reported (4, 5). Additionally, tears can flow into the anterior chamber in the early postoperative stage even if the sclerocorneal incision is well made. Consequently, it seems that the perioperative use of antimicrobial ophthalmic solutions is necessary.

Although topical steroid treatment after intracapsular cataract extraction (ICCE) was reported to be effective against postoperative corneal edema (6), these drugs may induce a secondary glaucoma and delay epithelial wound healing ; additionally, they also have non-specific immunosuppressive effects. From the viewpoint of infection prophylaxis, there is an idea that enough anti-inflammatory effect could be obtained by topical NSAIDs only. Because the surgical trauma after recent small incision of PEA+IOL implantation is less than that caused by older methods of extra capsular cataract extraction and ICCE, the necessity of topical steroids as postoperative anti-inflammatory medication is ought to be reconsidered.

With regard to the anterior chamber flare values after PEA+IOL implantation, some reports (7, 8) have stated that these values do not significantly differ between the patients treated with a single NSAID and those treated with a single steroid during the perioperative periods. Moreover, on comparing of 3 groups ; namely, those administered a combination of steroids and NSAID, a single steroid, and a single NSAID, Kato, *et al* (9). reported that no significant difference existed in the anterior chamber flare values during the periods from the day after the surgery to 3 months after surgery. We believe that the discrepancy in the measurement of the anterior chamber flare value and in the total objects number may have caused the difference results in the results, hence, and the influence of parameter like BCVA, IOP, endothelial cell density, and anterior chamber flare value on each other ought to be considered. Our results that no significant differences exist between the 2 groups with regard to all the criteria measured, as described earlier, provide supportive evidence of similar postoperative anterior chamber flare values in the 2 groups.

With regard to CME following PEA+IOL implantation, Miyake, *et al* (10) reports that CME is less frequent in the group using single NSAID than in the group using a single steroid. They also report that the anterior chamber flare value is higher in patients with CME than the patients without CME. However, in our study, CME cases were not observed in either group. This may be attributed to the decreased surgical trauma inflicted by recent PEA+IOL implantation technique. Additionally, some reports (11-13) described that no significant difference existed in the occurrence of posterior capsular opacification after PEA+IOL implantation among the groups administered a single NSAID, a single steroid, or a combination of these drugs. Although we did not check for posterior capsular opacification in our study because this complication commonly occurs in several years after the operation, it seems that in the long term, the topical NSAIDs are as effective as topical steroids after PEA+IOL implantation.

In conclusion, it is suggested that topical steroidal medication is not absolutely essential after uneventful small-incision PEA+IOL implantation because the postoperative inflammation is very mild.

We believe that non-use of topical steroids during the perioperative periods of intraocular surgery such as PEA+IOL implantation may prevent the occurrence of severe infectious diseases such as endophthalnitis.

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