Bromfenac Ophthalmic Solution 0.07% Dosed Once Daily for Cataract Surgery

Results of 2 Randomized Controlled Trials

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Purpose: To evaluate the efficacy and ocular safety of bromfenac ophthalmic solution 0.07% (Prolensa) dosed once daily for the treatment of ocular inflammation and pain in subjects who underwent cataract surgery with posterior chamber intraocular lens implantation.

Design: Two phase 3, randomized, double-masked, placebo-controlled, multicenter clinical trials.

Participants: Four hundred forty subjects (440 study eyes: 222 in the bromfenac group and 218 in the placebo group).

Methods: Two phase 3, prospective, randomized, double-masked, placebo-controlled clinical trials were conducted at 39 ophthalmology clinics in the United States. Subjects 18 years of age or older were randomized to receive either bromfenac 0.07% or placebo dosed once daily beginning 1 day before cataract surgery, on the day of surgery, and continuing for 14 days after surgery (for a total of 16 days). Subjects were evaluated on days 1, 3, 8, 15, and 22 after surgery. The primary efficacy end point was cleared ocular inflammation, as measured by the summed ocular inflammation score of zero (anterior chamber cell count = 0 and absence of flare) by day 15. Secondary end points included cleared ocular inflammation at day 15 and the number of subjects who were pain free at day 1. The data from the 2 clinical trials were integrated for analyses.

Main Outcome Measures: Summed ocular inflammation score and ocular pain.

Results: A significantly higher proportion of subjects treated with bromfenac 0.07% achieved complete clearance of ocular inflammation by day 15 and at day 15 compared with placebo ($P < 0.0001$). A statistically significantly higher proportion of subjects in the bromfenac 0.07% group were pain free at all study visits compared with those in the placebo group ($P < 0.0001$). Fewer subjects in the bromfenac group (3.2%) discontinued investigational product early because of a lack of efficacy than in the placebo group (23.9%; $P < 0.0001$). The incidence of adverse events was significantly lower in the bromfenac 0.07% group compared with the placebo group ($P = 0.0041$).

Conclusions: Bromfenac ophthalmic solution 0.07% dosed once daily was clinically safe and effective compared with placebo for the treatment of ocular inflammation and pain in subjects who had undergone cataract surgery and may be a beneficial addition to the current standard of care, which commonly includes ophthalmic antibiotics and corticosteroids. *Ophthalmology 2014;121:25-33 © 2014 by the American Academy of Ophthalmology.*

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Cataracts are the leading cause of blindness in the United States and worldwide.[1] Although approximately 10 million cataract surgeries are performed annually worldwide, untreated cataract-associated blindness is increasing by approximately 1 million people per year, and those with cataracts leading to a visual acuity of worse than 6/60 is increasing by 4 to 5 million annually.[2] By 2020, more than 30 million people in the United States will have a cataract.[3] Numerous population-based studies have shown that age and female gender are leading factors for the onset of cataract[3–7]; the incidence of a nuclear cataract has been estimated to occur in 40% of United States adults older than 75 years.[8] Buch et al[9,10] noted that cataract surgery can reduce a patient's visual impairment by more than one third. Different medications have been developed to reduce inflammation after cataract surgery, including corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs).

Ophthalmic NSAIDs are used to reduce ocular pain and inflammation in patients after cataract surgery, and in the United States, it is becoming more prevalent to begin NSAID dosing anywhere from 1 to 2 days before surgery.[11] Nonsteroidal anti-inflammatory drugs inhibit cyclooxygenase enzymes that synthesize prostaglandins via the arachidonic acid pathway.[12–15] Prostaglandins have a crucial

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role in the onset of postoperative pain and inflammation. Bromfenac, a well-studied NSAID, has been shown to be a potent inhibitor of cyclooxygenase.[16] The United States Food and Drug Administration (FDA) has approved several NSAIDs for the reduction of postoperative inflammation after cataract surgery.[17]

Bromfenac sodium is designated chemically as sodium 2-amino-3-(4-bromobenzoyl) phenylacetate sesquihydrate.[18] The additional bromine atom increases the absorption into ocular tissue and increases the duration of effect.[19–21] In a preclinical[14] study in New Zealand White rabbits, bromfenac was detected in all ocular tissues 24 hours after a single dose of the 0.09% concentration.[22] Bromfenac has been studied extensively in the Untied States and Japan and has demonstrated effectiveness as a topical agent.[23–30] In 2000, bromfenac sodium hydrate ophthalmic solution 0.1% (Bronuck; Senju Pharmaceuticals Co, Osaka, Japan) was approved by the Japanese Ministry of Health, Labour and Welfare and currently is approved for twice-daily use in Japan as a treatment for blepharitis, conjunctivitis, scleritis, and postoperative inflammation.[31] Bromfenac ophthalmic solution 0.09% (Xibrom; ISTA Pharmaceuticals, Inc, Irvine, CA) was approved by the United States FDA in 2005 for twice-daily dosing in the treatment of ocular inflammation after cataract surgery with posterior chamber intraocular lens (IOL) implantation and in 2006 for the treatment of postoperative ocular pain with no predosing and twice-daily administration.[32] The Japanese and United States versions of bromfenac 0.09% are identical; in computing concentrations, the Japanese formulation is labeled as the sodium salt (0.1%), whereas the United States formula is labeled as the free acid concentration (0.09%).

The pivotal studies on which the FDA based the approval of bromfenac ophthalmic solution 0.09% (Xibrom) were 2 randomized, double-masked, vehicle-controlled United States clinical trials evaluating bromfenac 0.09% instilled twice daily for 14 days; the results indicated that bromfenac 0.09% had a significant effect on reducing intraocular inflammation after cataract surgery (62%–66%, compared with 40%–48% in the placebo group). Eighty percent of bromfenac-treated subjects reported no ocular pain on postoperative day 1; the bromfenac group also had a statistically significant difference in median time to resolution of ocular pain of 2 days compared with 4 days for the placebo group.[32]

Once-daily dosing has the potential benefits of both improved patient compliance and limited ocular exposure to the active ingredient.[33] After the FDA approval of bromfenac ophthalmic solution 0.09%, researchers conducted dose-ranging studies including bromfenac 0.09% dosed once daily. Four randomized, double-masked, placebo- or active-controlled clinical trials then were conducted to evaluate bromfenac 0.09% dosed once daily for the same indications as its twice-daily counterpart.[26] As a result of those clinical trials, a once-daily version of bromfenac 0.09% (Bromday; Bausch and Lomb, Irvine, CA) was approved in the United States in 2010 for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction.[18]

Researchers then reassessed the 0.09% once-daily formulation to determine if a lower concentration of bromfenac ophthalmic solution would be effective in the treatment of postoperative pain and inflammation associated with cataract surgery. Bromfenac ophthalmic solution 0.07% was formulated using a more physiologic pH (7.8), which has been shown to improve penetration into ocular tissues.[23] Limiting the ocular exposure to a medication may result in decreased adverse events (AEs), which is important because, historically, ocular NSAID use has resulted in small numbers of corneal erosions or melts.[34–37] We hypothesized that bromfenac 0.07% dosed once daily would be safe and effective as a treatment for ocular inflammation and pain in subjects who underwent cataract surgery with posterior chamber IOL implantation.

Methods

Patients

These 2 multicenter, prospective, randomized, double-masked, placebo-controlled clinical trials received approval from an institutional review board (Sterling Institutional Review Board, Atlanta, Georgia). These clinical trials were conducted in accordance and adherence with the Declaration of Helsinki (Edinburgh 2000), the Code of Federal Regulations, and the International Conference on Harmonisation, including the maintenance of patient confidentiality and compliance with the United States Health Insurance Portability and Accountability Act. Both clinical trials were registered with ClinicalTrials.gov (accessed July 2, 2013) with the single identifier of NCT01367249. Written informed consent was received from each subject at each of the 39 study sites across the United States.

Study Design

The FDA requires that phase 3 clinical trials in this therapeutic area be properly controlled by including a placebo control group. This phase 3 trial was inclusive of 2 pivotal studies that were conducted under the same protocol. Study S00124-ER (ER) enrolled United States clinical sites east of the Mississippi River and study S00124-WR (WR) enrolled United States clinical sites west of the Mississippi River. The sample size was determined based on previous studies[26] assessing the use of bromfenac ophthalmic solution 0.09% with identical study designs in which 27.4% of subjects in the control group and 51.1% of subjects in the bromfenac group achieved complete clearance of ocular inflammation by day 15. Separate randomization sequences were used in each study, and each of the 4 groups (ER bromfenac, ER placebo, WR bromfenac, and WR placebo) enrolled at least 75 subjects to generate sufficient data to demonstrate statistical significance. A sample size of 75 subjects per treatment arm would provide 80% power to detect a treatment effect, and the calculation was based on a 2-sided Fisher exact test of independent proportions conducted with $\alpha = 0.05$ and was performed using PASS version 2005 (NCSS Statistical Software, Kaysville, UT). To account for a potential dropout rate of 30%, the required sample size was increased to 200 subjects, 100 per group. A total of 220 subjects were enrolled in the ER study and 220 in the WR study and were included in the intent-to-treat group; 416 subjects received at least 1 dose of either bromfenac 0.07% or placebo and are included in the safety analysis.

Study Protocol

All subjects were enrolled between May 2011 and July 2011. All subjects were screened anywhere from 1 to 8 days before study enrollment; subjects who signed the informed consent and met all inclusion and exclusion criteria were randomized to receive either bromfenac 0.07% or placebo. The enrolled subjects were assigned sequentially according to a computer-generated randomization list to receive either bromfenac ophthalmic solution 0.07% or placebo in a 1:1 ratio. The study investigators, staff, and subjects were appropriately masked to the identity of the investigational product (IP). Subjects were exposed only to the IP that they were provided. Dosing began 1 day before surgery, continued on the day of surgery, and then continued for 14 days after surgery (for a total of 16 days). The subjects were instructed to instill one drop of the IP into the lower conjunctival cul de sac of the study eye. Concomitant medications (i.e., ophthalmic antibiotics) were allowed per the investigators' postoperative standard of care with the exception of those listed in the exclusion criteria. Although ophthalmic corticosteroids commonly may be used in the management of pain and inflammation after cataract surgery, their use was not allowed to assess the effect of the IP properly compared with placebo. Follow-up was at days 1, 3±1, 8±1, and 15±1 after surgery. Subjects then were seen on day 22 (+3) after cataract surgery or, if the subject prematurely discontinued the test agent, on day 7 (+3) after the subject's last dose. The IP could have been discontinued because of an AE, lack of efficacy, the use of disallowed medications, or other reasons (i.e., cataract surgery did not occur, informed consent was withdrawn before the first dose, etc.). For subjects in whom the IP was discontinued, attempts were made to have the subject return for a safety follow-up visit. Rescue medications consisted only of ophthalmic NSAIDs, corticosteroids, or both and were given only after the subject discontinued because of an AE or because of lack of efficacy.

Outcome Measures

Efficacy. The primary efficacy outcome was cleared intraocular inflammation, defined as the proportion of subjects who achieved a summed ocular inflammation score (SOIS) of grade 0 by day 15 (Table 1). The SOIS was assessed by adding the subject's anterior chamber cells and flare grades with the minimum score of 0 and a maximum score of 8; this protocol has been described previously.[26,28]

A secondary end point was the proportion of subjects who achieved complete clearance of ocular inflammation (SOIS = 0) at day 15. The difference between the "at" and "by" day results is that the "at" day results included only the subjects who were observed to have complete clearance at that visit. Another secondary efficacy outcome was ocular pain as evaluated by the ocular comfort grading assessment (OCGA) reported in the subjects' diaries. Subjects recorded their ocular pain as none, mild, moderate, or severe at screening and throughout all study days. Subjects completed their assessment of the 7 symptoms (eye pain, tearing, itching, foreign body sensation, photophobia, eye discharge, and haziness) within 1 hour after instilling the drop into the study eye. A subject was considered to be pain free at a particular visit if there was a score of none on the pain scale of the OCGA in the subject diary at that visit. The end point determined the proportion of subjects who were pain free at day 1. Only the ocular pain data from the OCGA was integrated from the 2 trials.

Other secondary efficacy outcomes included the proportion of subjects who achieved an SOIS of grade 0 by and at day 1, day 3, and day 8, and the proportion of subjects who achieved an ocular pain score of none at day 3, at day 8, and at day 15.

Table 1. Ocular Inflammation Grading Scale for the Calculation of the Summed Ocular Inflammation Score

Anterior Chamber Cells*		Anterior Chamber Flare†	
Grade	*Cell Count*	*Grade*	*Flare Count*
0	0	0	Complete absence
0.5	1–5 cells (trace)		
1	6–15	1	Very slight (barely detectable)
2	16–25	2	Moderate (iris and lens clear)
3	26–50	3	Marked (iris and lens hazy)
4	>50	4	Intense (fibrin clot)

The summed ocular inflammation score was calculated by adding the subject's anterior chamber cells and flare grades with the minimum score of 0 indicating the absence of inflammation and a maximum score of 8. A subject could not be enrolled in the trial if there was the presence of cell or flare at the screening visit in either eye.

*To evaluate, investigators were instructed to use the following methods: slit-lamp biomicroscope, use ×16 magnification; 1×1-mm oblique high-intensity beam; aim central cornea in pupillary axis; focus in anterior aqueous humor; at plane of focus, perform first count of cells; do not focus on multiple planes; move focus to central cornea; refocus in anterior aqueous humor; at plane of focus, perform second count of cells; convert each cell count to a grade (see grading scale above); sum the 2 grades, divide by 2 to determine the average final cell score; try to score white blood cells only.

†To evaluate, investigators were instructed to use the following methods: slit-lamp biomicroscope, use ×16 magnification; 1×1-mm oblique high-intensity beam; aim central cornea in pupillary axis; focus in anterior aqueous humor; single determination; convert flare analysis to grade (see grading scale above); record the flare grade.

Safety. The safety for these clinical trials was assessed by the incidence and frequency of ocular and systemic AEs using the MedDRA version 14.0 (MedDRA MSSO, McLean, VA). The ophthalmologic evaluations included visual acuity, slit-lamp examination, intraocular pressure (IOP) assessment, and dilated funduscopic examination. The OCGA also was used.

Inclusion Criteria

After completion of the informed consent process, male and female subjects 18 years of age or older were eligible for participation in the clinical trial if they were scheduled for unilateral cataract surgery (phacoemulsification or extracapsular cataract extraction) with posterior chamber IOL implantation without other ophthalmic surgical procedures (such as limbal relaxing incisions, iridectomy, or conjunctival excisions). At clinical trial entry, baseline medical and ophthalmic histories were obtained. The key inclusion criteria were visual acuity of 0.6 logarithm of the minimum angle of resolution units or better in the nonstudy eye; no ocular, topical, or systemic NSAIDs within 1 week of investigational product initiation; no ocular, topical, inhaled, or systemic corticosteroids within 15 days of the IP initiation; and an IOP between 5 and 22 mmHg in the study eye at screening. For women of childbearing potential, a negative urine pregnancy test result and agreement to use a medically acceptable form of birth control for the study period, including 1 week before and 1 week after completion of the clinical trial, was necessary.

Exclusion Criteria

Subjects were excluded at the screening visit if they had a known hypersensitivity to bromfenac or any component of the investigational products, procedural medications, salicylates, sulfites, or

other NSAIDs; had extraocular or intraocular inflammation (i.e., any cells or flare in the anterior chamber as assessed using slit-lamp examination) in either eye at screening, including ongoing, unresolved uveitis; had ocular pain (greater than none) on the pain scale of the OCGA in either eye at the screening visit; had any active or chronic or recurrent ocular or systemic disease that was uncontrolled and was likely to affect wound healing; had an uncontrolled systemic disease including a bleeding disorder; or had taken anticoagulants within 7 days of initiating dosing for this study. Additional exclusion criteria included the use of ocular, topical, or systemic NSAIDs or gentamicin within the 7 days before initiation of dosing with IP or throughout the study; any use of opioid, narcotic, or other pain-relieving medication that could bias study results (with the exception of up to 4000 mg/day of acetaminophen or use of an opioid during surgery within 7 days before initiation of dosing with the IP or throughout the study); the use of immunomodulators such as topical cyclosporine 0.05% within 7 days before initiation of dosing with the IP or throughout the study; the use of any corticosteroid within 15 days before initiation of dosing with the IP or throughout the study; the use of tamsulosin, silodosin, afluzoxin, or finasteride; or the use of any medication within 7 days before initiation of dosing with the IP or throughout the study that could have interfered with normal lacrimation.

Exclusionary eye pathologic features included any active corneal pathologic feature in either eye at screening that was nonstable or worse than mild or that would compromise assessment of the safety or efficacy of treatment (with the exception of superficial punctate keratitis in the nonstudy eye), or use of anterior capsule staining for capsulorrhexis. Subjects also were excluded if they had undergone corneal transplantation or corneal refractive surgery in the study eye within the 2 years before study enrollment.

Study Medications

All study participants were instructed to self-instill 1 drop once daily into their study eye for a maximum total of 16 days (day before surgery, day of surgery, and 14 days after surgery). All IPs were provided by the study sponsor (ISTA Pharmaceuticals, Inc) and included bromfenac 0.07% and vehicle-controlled ophthalmic solution (placebo; Bausch and Lomb, Inc). These solutions were formulated identically, with the exception that the vehicle did not include bromfenac. Bromfenac sodium is a yellow to orange crystalline powder that may have caused a slight difference in color between the active and the placebo solutions; all other characteristics of the solutions were indistinguishable. All drops were supplied in identical bottles with trial-specific labels, and each of the bottles was placed into a tamper-evident carton. Both the bottles and the cartons were masked to all study participants.

Adverse Event Reporting

Adverse events included the incidence and frequency of both ocular and systemic events and were collected by the study investigators. Event information was collected for any subject who had instilled at least 1 dose of the IP. MedDRA version 14.0 was used to standardize reporting of the AEs.

Data Analysis and Statistical Methods

All randomized subjects were included in the intent-to-treat population. If a subject missed a follow-up appointment, the investigators used the last observation carried forward for efficacy outcomes. The safety population included all randomized subjects who had instilled at least 1 dose of the IP. All data from the bromfenac 0.07% groups were pooled for the integrated analyses, as were all data from the placebo groups. All data in this summary analysis are based on the pooled data. The bromfenac 0.07% treatment group and the placebo group were compared using the chi-square or Fisher exact test for dichotomous or nonordered categorical response measures and the *t* test or Wilcoxon rank-sum test for continuous variable and ordered categorical response measures.

Results

Demographics and Treatment Allocation

In the 2 clinical trials, a total of 440 subjects were randomized to bromfenac ophthalmic solution 0.07% (n = 222 subjects) or to placebo (n = 218; Fig 1). Overall, approximately two-thirds of subjects in each group were female and approximately three-quarters were white (Table 2). The proportion of subjects in the intent-to-treat population who completed treatment (defined as receiving 16 doses of either the bromfenac 0.07% or placebo) was significantly higher in the bromfenac 0.07% group than in the placebo group in the pooled data (64.4% [143/222] v. 45.9% [100/218]; $P = 0.0001$). The mean proportion of patient compliance, calculated as the number of doses received multiplied by 100 and divided by 16, also was significantly higher in the bromfenac 0.07% group compared with the placebo group (91.2% vs. 76.0%, respectively; $P < 0.0001$).

Efficacy End Points

The primary efficacy end point, the proportion of subjects who achieved complete clearance (SOIS of 0) of ocular inflammation by day 15, was significantly higher in the bromfenac 0.07% group (48.6% [108/222]) than in the placebo group (24.3% [53/218]; $P < 0.0001$; Fig 2). The proportion of subjects who had cleared ocular inflammation as determined by an SOIS score of 0 was significantly greater in the bromfenac 0.07% group than in the placebo group by day 8 (29.7% [66/222] vs. 11.9% [26/218], respectively; $P < 0.0001$), and this continued through the remaining study visits. A significantly higher proportion of subjects in the bromfenac 0.07% group, compared with those in the placebo group, also achieved complete clearance (SOIS of 0) at day 8 (27.0% [60/222] vs. 10.1% [22/218], respectively; $P < 0.0001$) and at day 15 (45.5% [101/222] vs. 20.6% [45/218], respectively; $P < 0.001$; Fig 3). A secondary efficacy outcome was the proportion of subjects who were pain free at each study visit. A significantly greater proportion of subjects were pain free in the bromfenac 0.07% group than in the placebo group at day 1 (78.8% [175/222] vs. 49.5% [108/218], respectively; $P < 0.0001$), and this continued through the remaining follow-up visits (Fig 4). The mean pain scores in the bromfenac 0.07% group were significantly lower than those in the placebo group at all follow-up visits ($P < 0.0001$ for all comparisons).

Safety End Points

Of the 440 subjects enrolled in these clinical trials, 416 subjects received at least 1 eye drop and were included in the safety analysis.

Adverse Events

A total of 148 (35.6%) of 416 subjects included in the safety analysis experienced an AE. There were a total of 276 AEs reported, 170 of which were unique (i.e., excluding repeated reports by of the same AE by a subject). The incidence of AEs was significantly lower in the bromfenac 0.07% group (28.8% [61/212]) than in the placebo group (42.6% [87/204]; $P = 0.0041$). Overall, 31.3% of subjects (n = 130) experienced an AE affecting

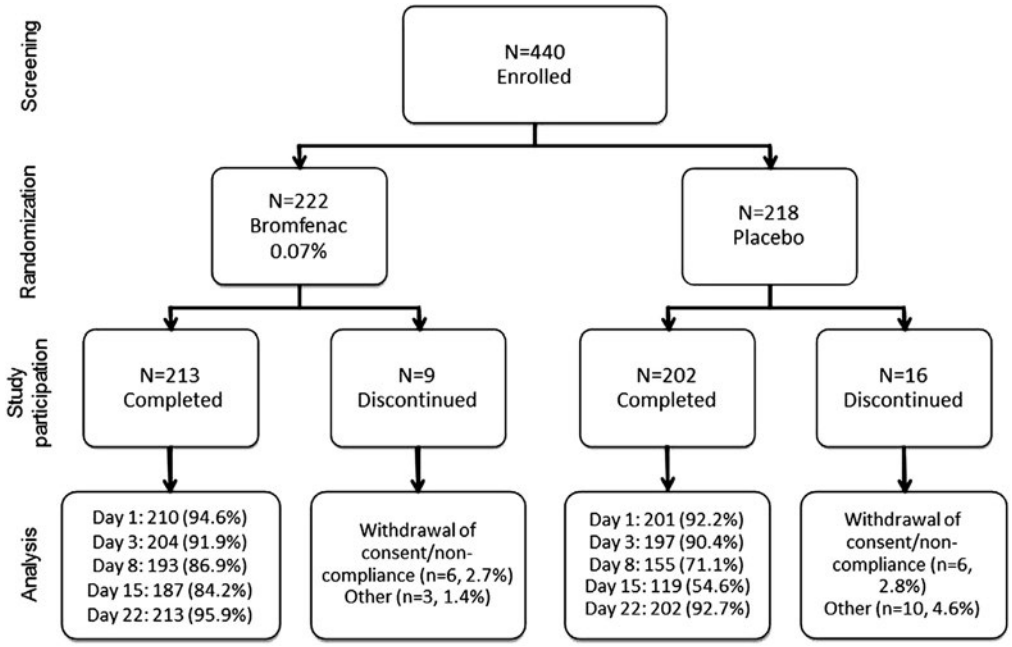

Figure 1. Subject disposition flow diagram (consolidated standards of reporting trials [CONSORT]).

the study eye. The incidence of AEs affecting the study eye by subjects in the bromfenac 0.07% group (22.6% [48/212]) was significantly lower than in the placebo group (40.2% [82/204]; $P = 0.0001$). Three subjects in the bromfenac 0.07% group (1.4%) and 4 subjects in the placebo group (2.0%) experienced a serious AE. The number of subjects who experienced an AE related to the instilled eye drop was lower in the bromfenac 0.07% group (7.1% [15/212]) than in the placebo group (21.6% [44/204]).

Among the subjects treated with bromfenac 0.07%, eye pain, anterior chamber inflammation, and foreign body sensation were the most frequently reported AEs in the study eye (5.7%, 4.7%, and 3.3%, respectively). Among the placebo-treated subjects, eye pain, anterior chamber inflammation, conjunctival hyperemia, photophobia, and corneal edema were the most frequently reported AEs in the study eye (9.8%, 8.8%, 7.4%, 5.4%, and 4.9%, respectively). Other reported AEs in the bromfenac 0.07% group included blurred vision and photophobia (each 1.9%); conjunctival hyperemia, increased IOP, and pruritus (each 1.4%); and corneal edema and increased lacrimation (each 0.9%). Other reported AEs in the placebo group included foreign body sensation (3.9%); increased lacrimation (3.4%); ocular hyperemia (2.9%); vitreous floaters (2.5%); and blurred vision, ocular pruritus, and increased IOP (each 2.0%).

Overall, 5.3% (22/416) of subjects experienced a systemic AE. The bromfenac 0.07% group and the placebo treatment group did

Table 2. Subject Demographics

Parameter	Pooled Bromfenac 0.07%	Pooled Placebo
Intent-to-treat population, no. of subjects	222	218
Age (yrs)		
Mean (standard deviation)	68.4 (10.70)	68.5 (9.68)
Gender, n (%)		
Male	81 (36.5)	72 (33.0)
Female	141 (63.5)	146 (67.0)
Race, n (%)		
American Indian or Alaska Native	1 (0.5)	0 (0%)
Asian	4 (1.8)	8 (3.7)
Black/African American	22 (9.9)	17 (7.8)
White	167 (75.2)	162 (74.3)
Other	28 (12.6)	31 (14.2)
Iris color (study eye), n (%)		
Black	0 (0)	0 (0)
Blue	57 (25.7)	65 (29.8)
Brown	109 (49.1)	93 (42.7)
Gray	1 (0.5)	5 (2.3)
Green	24 (10.8)	21 (9.6)
Hazel	31 (14.0)	33 (15.1)
Other	0 (0)	1 (0.5)

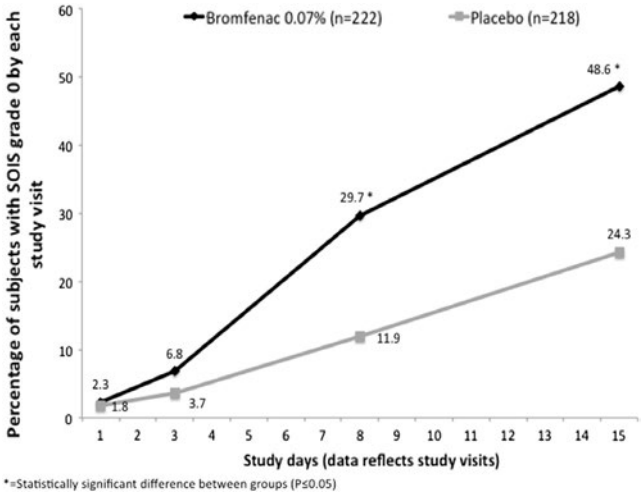

Figure 2. Graph showing the percentage of subjects with summed ocular inflammation score (SOIS) of grade 0 by each study visit.

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