Supplement to

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Cataract & Refractive Surgery TODAY

May 2007

SURGICAL THERAPEUTICS

A CLINICAL STUDY REVIEW

A Double-Masked Study of Nepafenac 0.1% and Ketorolac 0.4% for Pain and Epithelial Healing Following PRK

A Double-Masked, Randomized, Single-Dose, Pharmacokinetic Study of Nepafenac Suspension, Ketorolac, or Bromfenac in Human Aqueous Humor

Human Corneal Concentrations of Moxifloxacin and Gatifloxacin in a Penetrating Keratoplasty Model

Placebo-Controlled Trial of NEVANAC Suspension and ACULAR for Treatment of Ocular Pain and Inflammation Following Cataract Surgery

Moxifloxacin and Gatifloxacin MBC90 Values in Relation to VIGAMOX and ZYMAR Solutions Human Aqueous Concentrations

A Comparison of Ocular Penetration and Microbiological Efficacy of Fourth-Generation Fluoroquinolones in Cataract Surgery Patients

This continuing medical education activity is jointly sponsored by

SURGICAL THERAPEUTICS
A CLINICAL STUDY REVIEW

Jointly sponsored by The Dulaney Foundation
and *Cataract & Refractive Surgery Today.*
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STATEMENT OF NEED

Prophylaxis in ophthalmic surgery is an ever-evolving field. Practitioners are continuously presented with new therapeutic agents, updated research findings, and the latest trends in treatment approaches. To keep surgeons abreast of the latest prophylactic developments, The Dulaney Foundation and *Cataract & Refractive Surgery Today* have compiled this educational activity of peer-reviewed research regarding the use of antibiotics and NSAIDs in cataract and refractive surgery.

Presented are data slides from six different studies involving surgical therapeutic agents accompanied by objective information on each study. Subjective perspectives from practitioners about the clinical relevance of the data are also included.

TARGET AUDIENCE

This activity is designed for anterior segment ophthalmic surgeons and other ophthalmologists.

LEARNING OBJECTIVES

Upon successfully completing this learning program, participants should be able to:

- identify the mean human aqueous humor concentrations of various antibiotic drugs and NSAIDs;
- cite the human corneal concentrations of fourth-generation fluoroquinolones;
- explain the effectiveness of particular NSAIDs in treating postoperative pain and inflammation; and
- discuss the need and safety of antibiotics distributed supplementally.

METHOD OF INSTRUCTION

Participants should read the learning objectives and continuing medical education (CME) program in their entirety. After reviewing the material, they must complete the self-assessment test, which consists of a serious of multiple-choice questions. This test is available exclusively online at www.CMEToday.net. Once you register and log in, you can take the test, get real-time results, and print out your certificate. Please e-mail afagan@bmctoday.com or call (484) 581-1824 if you have any questions or technical problems with the Web site.

Upon completing the activity and achieving a passing score of over 70% on the self-assessment test, you can print out a CME credit letter awarding *AMA/PRA Category 1 Credit.*™ The estimated time to complete this activity is 1 hour.

ACCREDITATION

This activity has been planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of The Dulaney Foundation and *Cataract & Refractive Surgery Today.*

The Dulaney Foundation designates this educational activity for a maximum of *1 AMA/PRA Category 1 Credit.*™ Physicians should only claim credit commensurate with the extent of their participation in the activity.

DISCLOSURE

In accordance with the disclosure policies of The Dulaney Foundation and to conform with ACCME and

FDA guidelines, all program faculty are required to disclose to the activity's participants: (1) the existence of any financial interest or other relationships with the manufacturers of any commercial products/devices or providers of commercial services that relate to the content of their presentation/material or the commercial contributors of this activity; and (2) the identification of a commercial product/device that is unlabeled for use or an investigational use of a product/device not yet approved.

FACULTY CREDENTIALS

Eric D. Donnenfeld, MD, is a partner in Ophthalmic Consultants of Long Island and is Co-Chairman of Corneal and External Disease at the Manhattan Eye, Ear, and Throat Hospital in New York. Dr. Donnenfeld may be reached at (516) 766-2519; eddoph@aol.com.

Paul H. Ernest, MD, is Associate Clinical Professor at the Kresge Eye Institute in Detroit. Dr. Ernest may be reached at (517) 782-9436; paul.ernest@tlcmi.com.

Edward J. Holland, MD, is Director of Cornea at the Cincinnati Eye Institute and Professor of Ophthalmology at the University of Cincinnati in Ohio. Dr. Holland may be reached at (859) 331-9000, ext. 3064; eholland@fuse.net.

Stephen S. Lane, MD, is Clinical Professor, University of Minnesota, and is in private practice in Stillwater, Minnesota. Dr. Lane may be reached at (651) 275-3000; sslane@associatedeyecare.com.

Francis S. Mah, MD, is Medical Director, Charles T. Campbell Ophthalmic Microbiology Laboratory, University of Pittsburgh School of Medicine in Pennsylvania. Dr. Mah may be reached at (412) 647-2214; mahfs@upmc.edu.

Terrence P. O'Brien, MD, is Professor of Ophthalmology and Charlotte Breyer Rodgers Distinguished Chair in Ophthalmology as well as Director, Refractive Surgery and Co-Director of Palm Beach Bascom Palmer Eye Institute, Department of Ophthalmology. Dr. O'Brien may be reached at (561) 5151-1544; tobrien@med.miami.edu.

FACULTY DISCLOSURE DECLARATIONS

Eric D. Donnenfeld, MD, is a consultant and performs research for Alcon Laboratories, Inc., Advanced Medical Optics, Inc., and Bausch & Lomb, but he acknowledged no financial interest in the products mentioned herein.

Paul H. Ernest, MD, acknowledged no financial interest in the products or companies mentioned herein.

Edward J. Holland, MD, is a paid consultant for Allergan, Inc., and Alcon Laboratories, Inc., but acknowledged no direct financial interest in the companies or their products.

Stephen S. Lane, MD, is a paid consultant for Alcon Laboratories, Inc, but acknowledged no direct financial interest in any product mentioned herein.

Francis S. Mah, MD, is a consultant for and has received research grants from Alcon Laboratories, Inc., Allergan, Inc., and Ista Pharmaceuticals, Inc..

Terrence P. O'Brien, MD, acknowledged no financial interest in the products or companies mentioned herein.

Contents

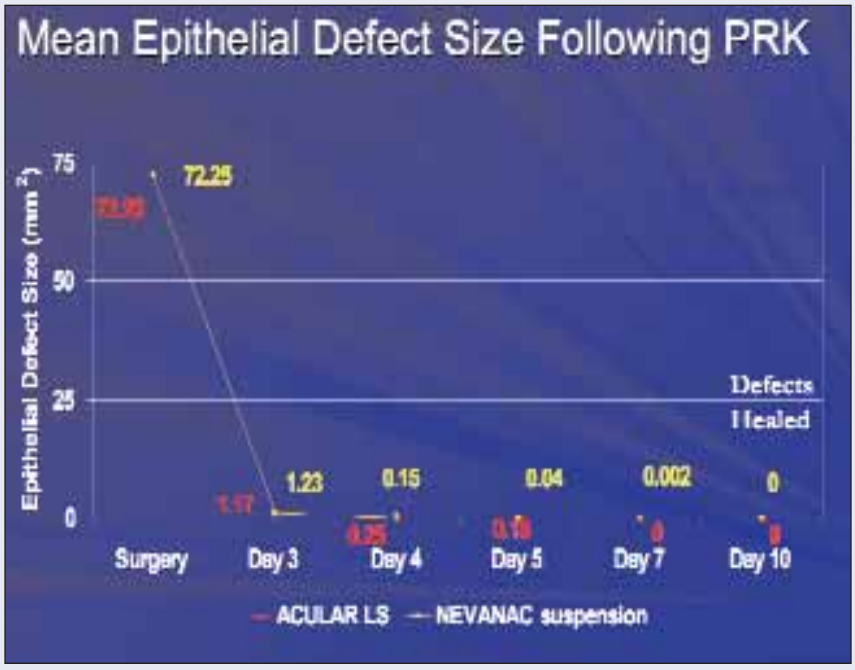
A Double-Masked Study of Nepafenac 0.1% and Ketorolac 0.4% for Pain and Epithelial Healing Following PRK

No Difference Found in Epithelial Healing

BY ERIC D. DONNENFELD, MD

The results of this double-masked, controlled clinical trial of 80 eyes showed no difference in epithelial healing rates between nepafenac 0.1% (NEVANAC suspension; Alcon Laboratories, Inc., Fort Worth, TX) and ketorolac 0.4% (ACULAR LS; Allergan, Inc., Irvine, CA) in epithelial closure rates following PRK. In the study, we investigators administered both the nepafenac 0.1% and the ketorolac 0.4% after placing the contact lens on the cornea—we placed no NSAID onto the corneal bed. We dosed each NSAID t.i.d. for 2 days. I believe that this type of limited dosing schedule is appropriate for epithelial defects after PRK.

The importance of this study is that we found no difference in the healing rates between nepafenac 0.1% and ketorolac 0.4%. Some anecdotal reports had suggested healing problems following PRK surgeries in which nepafenac 0.1% was used, but this series revealed otherwise. However, a larger series is necessary before the true safety of nepafenac 0.1% can be established, whereas the safety of ketorolac 0.4% is well known from its FDA clinical trials.[1]



This graph shows the results for epithelial defect healing. All study patients had an equal initial defect size of 8.50 mm. All patients healed bilaterally by postoperative day 5 except #016, whose right eye did not heal until the 10th postoperative day (the left eye healed in 5 days). No adverse event was reported for this patient. The differences in healing time between the treatment groups are very small, as illustrated in this graph. (Data adapted from Donnefeld ED, Durrie DS, Holland EJ, Raizman MB. A double-masked study of nepafenac 0.1% and ketorolac 0.4% for pain and epithelial healing following PRK. Poster presented at: The AAO Annual Meeting; November 13, 2006; Las Vegas, NV.)

Also, clinicians must remember that the NSAID nepafenac 0.1% should not be placed onto the stromal bed. ■

1. Solomon KD, Donnenfeld ED, Raizman M, et al. Ketorolac Reformulation Study Groups 1 and 2. Safety and efficacy of ketorolac tromethamine 0.4% ophthalmic solution in post-photorefractive keratectomy patients. *J Cataract Refract Surg.* 2004:30:1653-1660.

Human Corneal Concentrations of Moxifloxacin and Gatifloxacin in a Penetrating Keratoplasty Model

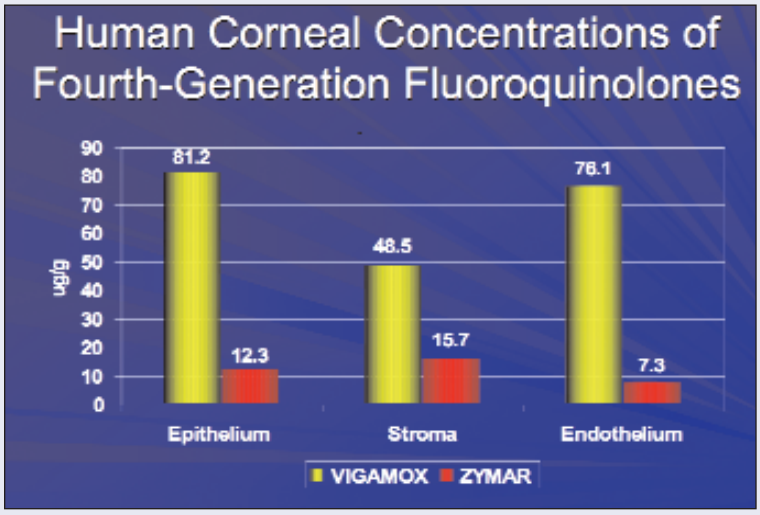
Moxifloxacin Achieves Higher Concentrations Than Gatifloxacin in Human Corneas

BY EDWARD J. HOLLAND, MD

My co-investigators and I conducted a human study to examine the corneal penetration of topical fourth-generation fluoroquinolones and found that levels of moxifloxacin (VIGAMOX ophthalmic solution 0.5%; Alcon Laboratories, Inc., Fort Worth, Texas) were higher in the epithelial, stromal, and endothelial layers of the cornea than levels of gatifloxacin (ZYMAR ophthalmic solution 0.3%; Allergan, Inc., Santa Ana, CA).

The study evaluated two measures of antibiotic corneal penetration: peak concentration levels and the time required to reach these levels. Moxifloxacin achieved a peak stromal concentration of 48.5 µg/g compared with 15.7 µg/g for gatifloxacin. The agents reached these levels within 15 minutes after their application.

The moxifloxacin concentration level achieved in the corneal stroma was high enough to surpass the reported minimum inhibitory concentrations (MICs) for many of the microorganisms that cause infectious keratitis, especially after LASIK surgery. The 15-minute period to reach these peak concentrations is also clinically relevant. Achieving high levels of antibiotic in the corneal stroma soon after dosing would prevent potential bacterial contamination during the creation of the flap and the stromal ablation. Such fast antibiotic action also enables surgeons to begin administering prophylaxis closer to the time of surgery; for example, on the day of surgery as opposed to 2 to 3 days prior.



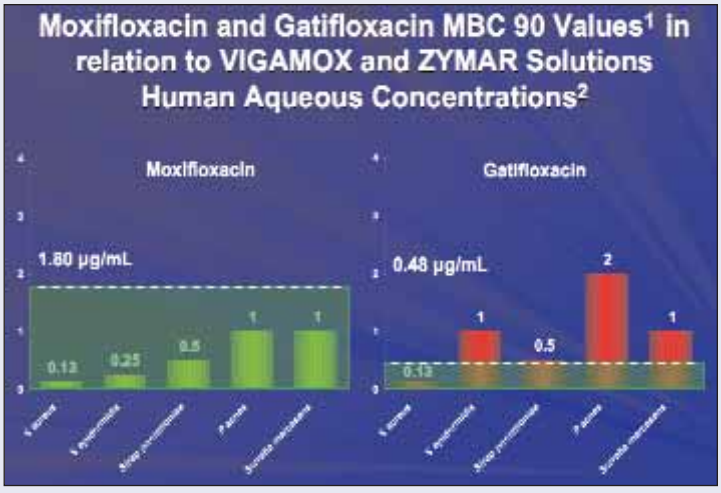
This study analyzed the corneas of 48 patients undergoing penetrating keratoplasty. The controlled, randomized, open-label, multidose study compared the corneal penetration levels of moxifloxacin solution (VIGAMOX; Alcon Laboratories, Inc., Fort Worth, TX) and gatifloxacin (ZYMAR; Allergan, Inc., Irvine, CA). The subject eyes received two drops of either antibiotic 5 minutes apart, with the last dose at 15 minutes, 30 minutes, 1, or 2 hours before the investigators assayed corneal samples for concentrations of moxifloxacin and gatifloxacin. The results depicted in the graph show that the mean peak epithelial level of moxifloxacin was approximately seven times higher than that of gatifloxacin; the mean peak stromal level of moxifloxacin was about three times higher than gatifloxacin; and the mean peak endothelial level of moxifloxacin was approximately 10 times higher than gatifloxacin. These results indicate that moxifloxacin provides superior penetration. These higher tissue concentrations for moxifloxacin would likely translate to greater efficacy against common ocular pathogens associated with keratitis and endophthalmitis. (Data adapted from Holland EJ, Lane S, Kim T, et al. Human cornea and aqueous humor concentrations of moxifloxacin and gatifloxacin following topical ocular dosing with Vigamox solution or Zymar. Poster presented at: The ARVO Annual Meeting; May 3, 2006; Ft. Lauderdale, FL.)

Postoperatively, a t.i.d. or q.i.d. dosing regimen for 5 to 7 days maintains a high level of antibiotic in the cornea that minimizes the risk of infectious keratitis after LASIK. Until this study, clinicians had to rely on animal data to support the comparative penetration of the fourth-generation fluoroquinolones into the cornea. ■

Moxifloxacin and Gatifloxacin MBC90 Values in Relation to VIGAMOX and ZYMAR Solutions Human Aqueous Concentrations

Protective Antibiotic Concentrations in Aqueous Humor With Topical Dosing

BY TERRENCE P. O'BRIEN, MD



This slide shows median minimum bacteriocidal concentrations (MBC) for gatifloxacin and moxifloxacin against a variety of gram-positive organisms compared with the mean aqueous concentration levels achieved by moxifloxacin and gatifloxacin in the study completed by researchers at The Wilmer Eye Institute. These findings are clinically significant, as moxifloxacin penetrated into the aqueous at concentrations that meet and exceed the agent's MBC for the most common endophthalmitis causing susceptible pathogens, whereas gatifloxacin did not. (1. Mather R, Karenchak LM, Romanowski EG, Kowalski RP. Fourth generation fluoroquinolones: new weapons in the arsenal of ophthalmic antibiotics. *Am J Ophthalmol*. 2002;133:4:463-466. 2. Kim DH, Stark WJ, O'Brien TP, Dick JD. Aqueous penetration and biological activity of moxifloxacin 0.5% ophthalmic solution and gatifloxacin 0.3% solution in cataract surgery patients. *Ophthalmology*. 2005;112:11:1992-1996. Epub 2005 Sep 23.)

Ophthalmology is continuing the debate as to the best methods of preventing postoperative endophthalmitis. Currently, the route of prophylaxis has generated much discussion: topical antibiotic eyedrops versus intraocular antibiotic administration. Topical antibiotic eyedrops remain a necessity, but should we supplement them with additional antibiotic delivery methods?

Surgeons must be able to both reduce external ocular surface bacterial contamination as well as to cover any internal ocular contamination in the immediate and early postoperative period. With concentration-dependent antibiotics, such as fluoroquinolones, the higher the concentration achieved in the tissue, the greater the likelihood of success in treatment or prevention of infection.

This slide, from a human study comparing the achieved aqueous concentrations of moxifloxacin versus gatifloxacin, shows that topical dosing of moxifloxacin 0.5% can achieve potentially protective concentrations against the most common organisms that cause endophthalmitis, including those that may be resistant to other antibiotics, whereas the achieved aqueous humor concentration of gatifloxacin 0.3% fell short of potentially protective levels for many common pathogens. Moreover, the concentration achieved with topical moxifloxacin 0.5% exceeded that of gatifloxacin 0.3% by almost fourfold, which is greater than expected based solely on differences in commercial formulation concentrations. This suggests favorable inherent molecular properties of moxifloxacin that enhance solubility and penetration across the corneal epithelial barrier. Thus, topical dosing of a broad-spectrum, bactericidal, biocompatible, self-preserved agent such as moxifloxacin can achieve concentrations that can be protective against infection. Based upon the results of this study, it is my opinion that, with proper perioperative dosing, the need for supplemental intraocular antibiotic administration remains undetermined, as topical dosing alone with the appropriate intervals in the early postoperative window of vulnerability may be adequate with less potential for toxicity. ■

A Double-Masked, Randomized, Single-Dose, Pharmacokinetic Study of Nepafenac Suspension, Ketorolac, or Bromfenac in Human Aqueous Humor

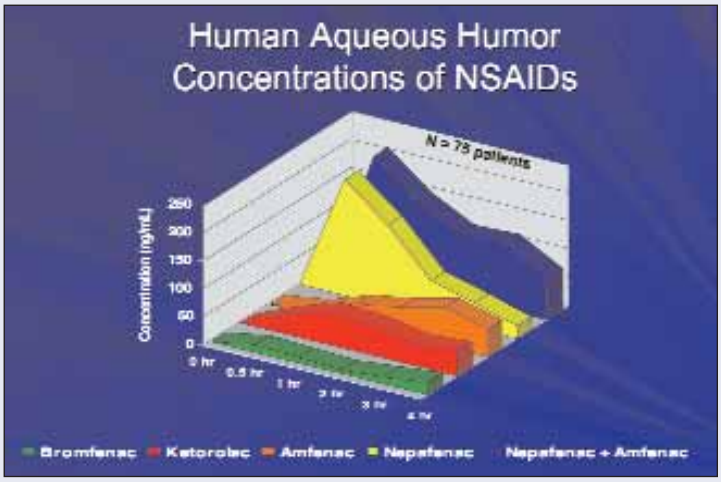
Nepafenac-Amfenac's Aqueous Humor Concentration Is Higher Than That of Other Agents

BY PAUL H. ERNEST, MD

That the NSAID nepafenac suspension 0.1% showed a greater concentration in the aqueous humor compared with ketorolac 0.4% and bromfenac 0.09% is a positive for anti-inflammatory surgical therapy and the treatment of cystoid macular edema (CME). These findings prompt me to consider nepafenac suspension as my NSAID of choice.

I use NSAIDs on every cataract and refractive lens exchange patient. I prescribe these drugs for 1 month t.i.d. after surgery, a strategy that I believe has kept the incidence of CME among my patients very low. I also use them preoperatively in certain eyes, such as those of patients with diabetes, who are more prone to CME. I also use nepafenac after a YAG laser capsulotomy on eyes implanted with an apodized refractive IOL to make sure the macula remains pristine.

I have been using ketorolac; the reason I will consider switching is because nepafenac suspension penetrates the ocular tissues better. Also, I have not heard any complaints about nepafenac's comfort from patients, whereas I have had a few reports of stinging with other drugs I have used. ■



Mean aqueous humor concentrations. This study[1] evaluated concentrations in the aqueous humor of commercially available nepafenac 0.1% (NEVANAC suspension; Alcon Laboratories, Inc., Fort Worth, TX), ketorolac 0.4% (ACULAR LS; Allergan, Inc., Irvine, CA), and bromfenac 0.09% (XIBROM; Ista Pharmaceuticals, Inc., Irvine, CA) after topical administration. Seventy-five patients were randomized to receive one drop of the drugs at 30, 60, 120, 180, or 240 minutes before their surgery. The investigators collected aqueous humor samples at the time of the paracentesis.

They found that one drop of nepafenac suspension provided better bioavailability and duration in the aqueous chamber across all time points tested than the other two agents. Nepafenac's ability to act as a reservoir for continued amfenac formation makes it available to further suppress inflammation longer than other NSAIDs.[2] Suppressing inflammation in the anterior segment over time is important to preventing sight-threatening complications later in the postoperative healing process. Nepafenac is primarily metabolized throughout the vascular tissues, beginning in the cornea, more so in the iris/ciliary body, and to the highest degree in the retina/choroid.

1. Walters TR, Raizman M, Ernest P, et al. A double-masked, randomized, single-dose, pharmacokinetic study of nepafenac, amfenac, ketorolac, and bromfenac in human aqueous humor following topical administration of Nevanac, Acular LS, or Xibrom. Submitted to *Invest Ophthalmol Vis Sci.* 2007.
2. Ke TL, Graff G, Spellman JM, Yanni JM. Nepafenac, a unique nonsteroidal prodrug with potential utility in the treatment of trauma-induced ocular inflammation. II. In vitro band permeation of external ocular barriers. *Inflammation.* 2000;24:4:371-384.

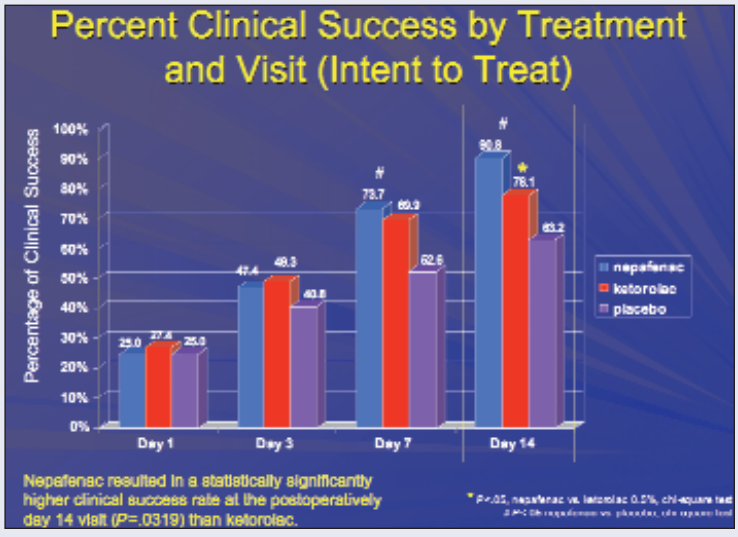
Placebo-Controlled Trial of NEVANAC Suspension and ACULAR for Treatment of Ocular Pain and Inflammation Following Cataract Surgery

Strengthening the Case for Using NSAIDs After Cataract Surgery

BY STEPHEN S. LANE, MD

This study[1] shows that both ketorolac and nepafenac are superior to placebo at controlling inflammation after cataract surgery. This conclusion strengthens my belief that the postoperative use of NSAIDs has clinical benefits and should be included in my postcataract medication regimen. Using NSAIDs after cataract surgery also decreases the amount and duration of topical steroids needed and therefore limits these agents' potential side effects.

There are three noteworthy findings from this study. First, patients in the nepafenac group had less pain and second, they experienced less discomfort upon instillation compared with the ketorolac and placebo groups. Third and most importantly, this study demonstrated statistically significant efficacy for nepafenac over ketorolac and placebo at 14 days postoperatively. Based on these results, surgeons considering prescribing an NSAID after cataract surgery to reduce inflammation can conclude that nepafenac is the more efficacious agent. Nepafenac's greater success in controlling inflammation may be due to its unique prodrug chemical structure, which makes the drug more bioavailable in the anterior chamber. ■



A European double-masked, randomized, placebo- and active-controlled parallel group study compared nepafenac 0.1% (NEVANAC suspension; Alcon Laboratories, Inc., Fort Worth, TX) to ketorolac 0.5% (ACULAR; Allergan, Inc., Irvine, CA) and placebo for the prevention and treatment of ocular inflammation and pain associated with cataract surgery. The study enrolled 227 patients; each group received one drop of its respective agent t.i.d.† for an average of 23 days, and no steroid was used.

Statistically, nepafenac showed a significantly higher clinical success rate (defined as 0 to 5 cells, no flare) at the 14th postoperative day compared with ketorolac and placebo. Patients in the nepafenac group also had less pain on postoperative day 3 and experienced significantly better comfort upon instillation compared with ketorolac on day 7.

†(Note: Acular's package inserts distributed in Europe recommend t.i.d. dosing, although the drug's inserts distributed in the US recommend q.i.d. dosing postcataract. Nevanac's package inserts in the US suggest t.i.d. dosing postcataract.)

1. Nardi M, Cunliffe I, Cano J, et al. Nepafenac 0.1% compared to ketorolac 0.5% and placebo in cataract surgery. Poster to be presented at: The 2007 ARVO meeting (E-Abstract B684); May 6-7 2007; Fort Lauderdale, FL.

A Comparison of Ocular Penetration and Microbiological Efficacy of Fourth-Generation Fluoroquinolones in Cataract Surgery Patients

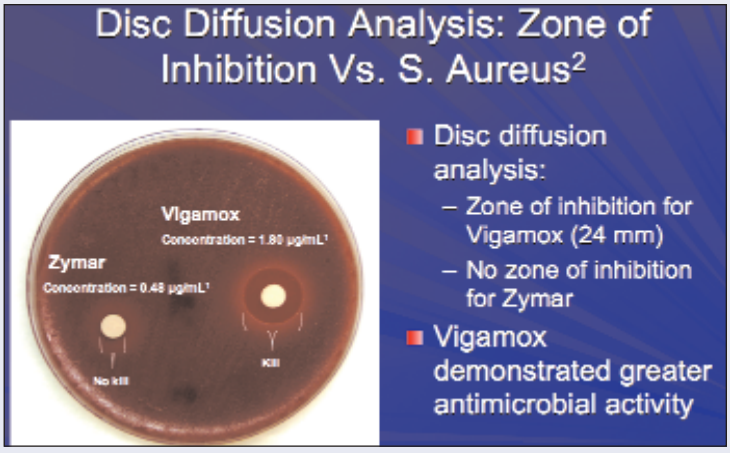
Interesting Findings in Antibiotic Efficacy

BY FRANCIS S. MAH, MD

Two criteria predict a flouroquinolone's efficacy in tissue. One criterion evaluates the level of antibiotic in the blood and tissues, and the other determines the drug's mean inhibitory concentration (MIC). First, we look at the amount of drug in the tissue over time after a dose. Then, we draw the therapeutic area (the area under the concentration curve but above the MIC level). The ratio between the drug's concentration in the tissues and its MIC will predict efficacy against infection 100% of the time. The only way to truly predict therapeutic efficacy is the C-MAX-to-MIC ratio, or the area under the inhibitory curve. Each antibiotic has a different ratio that predicts its efficacy against each isolate of bacteria; for flouroquinolones, that ratio is 1:10.

HIGHER CONCENTRATION NEEDED

Interestingly, the MIC of the bacteria used in this study is 0.19 for both drugs, so it is very sensitive to both antibiotics. Although gatifloxacin's concentration on the disc diffusion was greater than 0.19, it was not high enough to prevent the growth of bacteria. This finding proves the point that a concentration above the MIC must be present in order to inhibit bacteria. In other words, an antibiotic's concentration sufficiently higher than the MIC of the bacteria would inhibit an infection in the anterior chamber. This is the likely scenario for moxifloxacin's zone of inhibition in the disc diffusion. ■



This figure shows a disc-diffusion analysis comparing moxifloxacin 0.5% ophthalmic solution (VIGAMOX; Alcon Laboratories, Inc., Fort Worth, TX) with gatifloxacin 0.3% ophthalmic solution (ZYMAR; Allergan, Inc., Irvine, CA) on a plate of *Staphylococcus aureus*. The concentration data are from a study conducted at the Wilmer Eye Institute, Johns Hopkins University School of Medicine in Baltimore by Kim et al[1] that measured the aqueous penetration of the antibiotics in 50 cataract surgery eyes. The group found that the 25 eyes pretreated with moxifloxacin 0.5% had, on average, 1.8 µg/mL of antibiotic in the anterior chamber, and the 25 eyes pretreated with gatifloxacin 0.3% had, on average, 0.48 µg/mL of that drug. Investigators then placed diffusion discs of each antibiotic in their respective concentrations on a plate of endophthalmitis-causing *S. aureus*.[2] The disc with 1.8 µg/mL of moxifloxacin 0.5% was able to create a zone of inhibition that the *S. aureus* could not penetrate. In contrast, the bacteria grew right up to the disc with 0.48 µg/mL of gatifloxacin 0.3%, indicating that there was no zone of inhibition of the *S. aureus*.

(1. Kim DH, Stark WJ, O'Brien TP, Dick JD. Aqueous penetration and biological activity of moxifloxacin 0.5% ophthalmic solution and gatifloxacin 0.3% solution in cataract surgery patients. *Ophthalmology*. 2005;112:1992-1996. 2. O'Brien TP, Stroman DW. A comparison of ocular penetration and microbiological efficacy of fourth generation fluoroquinolones in cataract surgery patients. Presented at: The Ocular Microbiology and Immunology Group Meeting; October 15, 2005; Chicago, IL.)

CME QUESTIONS

To answer these questions online and receive real-time results, you must visit www.CMEToday.net.
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E-mail afagan@bmctoday.com if you have any problems accessing the site or taking the test online.

1. What was the important finding of the study "A Double-Masked Study of Nepafenac 0.1% and Ketorolac 0.4% for Pain and Epithelial Healing Following PRK" regarding the safety of topical NSAIDs?
a. The investigators found a clinically significant difference between the healing rates of nepafenac 0.1% and ketorolac 0.4%.
b. The investigators found no difference in the healing rates between nepafenac 0.1% and ketorolac 0.4%.
c. The study's results supported anecdotal reports of healing problems when nepafenac 0.1% was used after PRK.
d. The investigators found nepafenac 0.1% to have a better healing rate than ketorolac 0.4%.

2. The study "Human Corneal Concentrations of Moxifloxacin and Gatifloxacin in a Penetrating Keratoplasty Model" found that moxifloxacin maintained higher concentrations in the epithelial, stromal, and endothelial layers of the cornea compared with gatifloxacin.
a. True
b. False

3. Which antibiotic achieved concentration levels in the corneal stroma within 15 minutes that surpassed the MICs for many of the microorganisms that cause infectious keratitis, especially after LASIK surgery?
a. Moxifloxacin
b. Gatifloxacin
c. Ofloxacin

4. In the study "Moxifloxacin and Gatifloxacin MBC90 Values in Relation to VIGAMOX and ZYMAR Solutions Human Aqueous Concentrations," by what degree did moxifloxacin's human aqueous concentrations surpass those of gatifloxacin?
a. Twofold
b. Threefold
c. Fourfold
d. Fivefold

5. What is Dr. O'Brien's opinion about the need for the intraoperative dosing of antibiotics?
a. It is clearly necessary.
b. It is clearly unnecessary.
c. It is at the surgeon's discretion.
d. It remains undetermined.

6. The study "A Double-Masked, Randomized, Single-Dose, Pharmacokinetic Study of Nepafenac Suspension, Ketorolac, or Bromfenac in Human Aqueous Humor" suggests that a higher concentration of drug leads to a longer supression of inflammation.
a. True
b. False

7. Nepafenac 0.1% is metabolized by what ocular structure?
a. The cornea
b. The retina/choroid
c. The iris/ciliary body
d. All of the above

8. In the European study "Placebo-Controlled Trial of NEVANAC Suspension and ACULAR for Treatment of Ocular Pain and Inflammation Following Cataract Surgery," at which day did nepafenac show a statistically significant clinical success rate compared with ketorolac?
a. Day 1
b. Day 7
c. Day 14
d. Day 28

9. In the study "A Comparison of Ocular Penetration and Microbiological Efficacy of Fourth-Generation Fluoroquinolones in Cataract Surgery Patients," the aqueous penetration levels were:
a. higher for moxifloxacin
b. higher for gatifloxacin
c. equal

10. The C-MAX-to-MIC ratio is not a reliable way to predict an antibiotic's efficacy.
a. True
b. False

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