

Humalog KwikPen
To help answer your customers' questions about the prefilled Humalog[®] KwikPen[™].

SAFETY INFORMATION
The safety and effectiveness of Humalog in patients less than 3 years of age have not been established. There are no adequate and well-controlled clinical studies of the use of Humalog in pregnant or nursing women.

ModernMedicine ModernMedicine Community

Welcome back, Dr. Chang [Edit Your Profile](#) / [Log Out](#)



Enter your keyword

ModernMedicine Recommended Medical Sites

[Home](#) [Clinical Perspectives](#) [Business Perspectives](#) [Patient Care](#) [Learning](#) [Community](#) [Products](#) [Careers](#) [About Us](#)

HOT TOPICS: [Cardiometabolic Disorders & Weight](#) · [Liability & Risk Management](#) · [Health Care IT](#)
[E-mail Alerts](#) [RSS Feeds](#)

FDA adds warning to tamsulosin labeling

New information meant to alert patients and physicians about risks with cataract surgery

Publish date: Jan 1, 2006
 By: Cheryl Guttman

[Email](#) | [Print](#) | [Share](#) | [Save](#) | [License](#)



Chicago—This past October, the FDA issued a labeling change for the drug tamsulosin HCl (Flomax, Boehringer Ingelheim) warning of the possibility of intraoperative floppy iris syndrome (IFIS), stating "The patient's ophthalmologist should be prepared for possible modifications to their surgical technique."

That labeling change comes as the result of the astute observations and studies conducted by John R. Campbell, MD, and David F. Chang, MD, who postulated there was a connection between IFIS and tamsulosin and then confirmed that association in retrospective and prospective clinical trials.

Dr. Chang did not indicate any financial interest in any of the products mentioned. Phone: 650/948-9123 E-mail: dceye@earthlink.net

Tamsulosin, an alpha-1 blocker, is the most commonly prescribed medication for treating benign prostatic hyperplasia (BPH). By relaxing the smooth muscle in the bladder neck and prostate, the patient's urinary outflow symptoms are improved. Boehringer Ingelheim, the manufacturer, also sent a "dear doctor" letter to every ophthalmologist, urologist, and primary-care physician notifying them about IFIS.

Patients at risk

"Awareness of this new syndrome and identification of patients at risk is important because it allows surgeons to undertake appropriate small-pupil management strategies," explained Dr. Chang. "IFIS has been associated with a high rate of posterior capsule rupture when the surgeon did not anticipate it. Now, by eliciting a history of alpha-blocker use, cataract surgeons can predict in advance when this problem may occur," said Dr. Chang, clinical professor at the University of California, San Francisco. Dr. Chang spoke about IFIS in the Spotlight on Cataract Surgery 2005 session held during the annual meeting of the American Academy of Ophthalmology in Chicago.

The condition is characterized by the clinical triad of billowing and floppiness of the iris in response to normal irrigation currents in the anterior chamber, repeated iris prolapse to the incisions, and progressive miosis. In many cases, the pupil dilates poorly preoperatively.

Dr. Chang credited Dr. Campbell with first suspecting tamsulosin as a cause for IFIS. To investigate that link further, Dr. Campbell undertook a retrospective study reviewing cataract surgery cases that he and his partner had performed during the previous year. In reviewing the operative reports for 706 eyes (511 patients), a floppy iris was identified as occurring in 16 eyes (2.3%) of 10 (2.0%) patients, all of whom were taking tamsulosin. Another six patients were found to have been taking tamsulosin without any mention of floppy iris in the operative report. Other systemic alpha-1 blockers, including terazosin HCl (Hytrin, Abbott), doxazosin mesylate (Cardura, Pfizer), and prazosin HCl (Minipres, Pfizer), were being used by 11 patients, but none of them were recorded as having a floppy iris.

Characterizing the syndrome

In his attempt to characterize the features, incidence, and causes of IFIS, Dr. Chang undertook a prospective study of 900 consecutive eyes of 741 cataract patients whom he operated on while being masked to each individual's medication history. In that series, IFIS also occurred in

[Sign-up Today!](#)

Customized Email Alerts

Get the information you want... When you want it.

Get Email Newsletters

Practice Tools

ICD-9 CODING COUNSELOR
Simple and accurate ICD-9 code search. [START HERE](#)

POPULAR ARTICLES

- [Weight-based dosing: Extended-release minocycline efficient, predictable](#)
- [FDA warns Allergan on Aczone promotion](#)
- [Exit Accutane: Derms' reactions mixed as Roche pulls long-standing remedy](#)
- [Gaining control: Birth control pills, spironolactone first-line treatments for hormonal acne](#)
- [Getting to the root: Look below the surface for cause of hyperandrogenic symptoms](#)

MORE POPULAR ARTICLES

Featured Jobs

[More Jobs](#)

SPONSORED MEDIA

- [OTLA Video Player](#)
 - [Multimedia: Why Patients Considering an IUC May Say YES to ParaGard](#)
- SPONSORED
- [sponsored multimedia Promiseb A non steroidal topical cream for managing seborrheic dermatitis](#)

MORE MEDIA

about 2% of cases whether considering the number of eyes (21/900; 2.3%) or patients (16/741; 2.2%). Of the 16 affected patients, 15 were found to have a history of current or prior tamsulosin use. Among the 725 patients who did not manifest IFIS, none had a history of tamsulosin treatment.

Importantly, a relatively high risk for posterior capsule (PC) rupture was also identified. In Dr. Campbell's study, the PC rupture rate was 12.5% among the 16 cases of IFIS. No posterior capsular ruptures occurred in Dr. Chang's series, but he noted that two of the patients with IFIS had a history of PC rupture in the fellow eye operated on previously at another center. Drs. Chang and Campbell's companion studies were published in the April 2005 issue of the *Journal of Cataract and Refractive Surgery* [Chang DF, Campbell JR. Intraoperative floppy iris syndrome associated with tamsulosin (Flomax). *J Cataract Refract Surg* 2005;31:664-673].

1 2 3 [Next »](#)

POST A COMMENT

Please complete the form below to post your comment.

Bold = Required

Email Address _____ Your email address will NOT be published.

Display Name _____ appears with your comment

City _____

State _____

Country _____

Remember me: Yes No

Comment _____ read our [privacy policy](#)

Note: does not support HTML
All comments submitted are subject to review, and may be delayed before posting. We reserve the right not to post comments.

[Submit Now >>](#)

LATEST PRACTICE NEWS

[Rural Residents More Likely to Have Total Joint Replacement](#)

[Uninsured Show Higher Risk for Death Following Trauma](#)

[Medicaid Enrollment Common Among Overdose Deaths](#)

[Uninsured Children May Be More Likely to Die in the Hospital](#)

[SNS: Web Surfing Linked to Brain Function in Older Adults](#)

[→ More](#)

LATEST DRUG NEWS

[Cetuximab Linked to Resection of Liver Metastases](#)

[H1N1 Influenza Rates Drop in Many States](#)

[Zegerid OTC Approved for Frequent Heartburn](#)

[Observing Antiretroviral Therapy Yields Little Benefit](#)

[Morphologic Changes Gauge Liver Cancer Therapy Response](#)

[→ More](#)

Clinical Perspectives

- [Acne](#)
- [Adolescent Medicine](#)
- [Allergy & Immunology](#)
- [Alzheimer's Disease](#)
- [Asthma](#)
- [BPH](#)
- [Breast Cancer](#)
- [Cardiology](#)

Business Perspectives

- [Coding Counselor](#)
- [Liability & Risk Management](#)
- [Health Care Information Technology](#)
- [Practice Management](#)
- [Business Operations](#)
- [Human Resources](#)
- [Health Law & Policy](#)

Popular Topics

- [CME/CE](#)
- [Coding Counselor](#)
- [eNewsletters](#)
- [Patient Education Center](#)
- [Blogs](#)
- [Discussions](#)
- [ModernMedicine Radio](#)
- [Syndication](#)



[Home](#) | [About Us](#) | [ModernMedicine Team](#) | [Editorial and Advertising Policy](#) | [Our Publications](#) | [Terms & Conditions](#) | [Contact Us](#) | [Medical News](#) | [Medical Articles](#) | [CME Center](#) | [Patient Education](#) | [Practice Management](#) | [All Content](#) | [Privacy Policy](#) | [Terms of Use](#) | [Linking and RSS Policy](#)

© 2009 Advanstar Communications, Inc. All rights reserved.
Reproduction in whole or in part is prohibited.
Please send any technical comments or questions to our webmaster.