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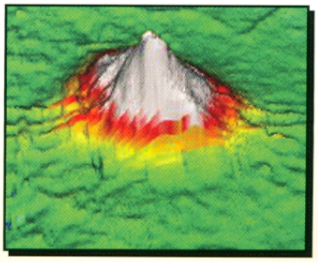
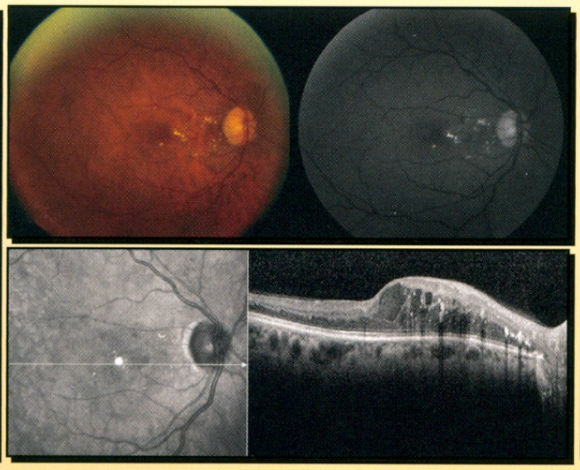
RETINA TODAY

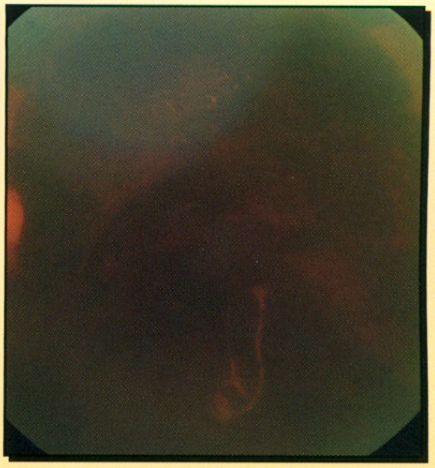
September 2009 • Volume 4, No. 6

Updates on Treating



Diabetic Eye Disease





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VITREORETINAL SURGERY • MEDICAL RETINA • INJECTING THE NEW STEROID IMPLANT

RETINA NEWS

Volume 4, No. 6 • September 2009

Intraarterial Chemotherapy for Retinoblastoma Pioneered at Wills, Jefferson

Physicians at the Wills Eye Hospital and Jefferson Hospital for Neuroscience in Philadelphia are treating retinoblastoma with intraarterial chemotherapy, according to a news release. Intraarterial chemotherapy delivers high doses of chemotherapy directly to the affected eye.

Carol Shields, MD, the Co-Director of the Ocular Oncology Service at Wills Eye Hospital and Thomas Jefferson University, and Robert Rosenwasser, MD, Chair of the Department of Neurological Surgery at Jefferson Medical College of Thomas Jefferson University, are the second team in the United States to treat retinoblastoma patients with this form of targeted chemotherapy. A microcatheter is inserted into an artery in the child's body and threaded to the artery leading to the eye. Chemotherapy agents are then injected into the tube and delivered directly into the eye. Later, reassessment with laser treatment to the cancer is performed by Dr. Shields.

"Intraarterial chemotherapy is a promising new technique for treatment of selective cases of retinoblastoma and allows for a higher local dose of chemotherapy to the eye with minimal side effects to the body as compared to the more traditional intravenous method," Dr. Shields said in the news release. "This high dose of chemotherapy delivered to the eye accelerates regression of the tumor without adversely affecting other healthy organs. While the long term outcome of these patients is still unknown, this new delivery system may reduce the need for the surgical removal of some patients' eyes," she said.

FDA Steps up Actions Against Misconduct in Drug and Device Development

The US Food and Drug Administration (FDA) recently fine-tuned its procedures for the debarment and disqualification of noncompliant investigators participating in new product development. The purpose of these steps is to better protect participants in clinical studies, help ensure that the sponsors of clinical studies do not unknowingly involve individuals who may be debarred or disqualified by the FDA, and guarantee the safety and effectiveness of medical products marketed to the American public, according to the FDA.

Under the current law, the FDA can ban or debar individuals who have broken the law from working for companies with approved or pending drug applications at the FDA. The agency can also disqualify researchers who have not followed rules intended to protect study subjects. Further, the agency can disqualify a clinical investigator who manipulated data and inaccurately reported study findings.

According to a news release, "the revamped debarment and disqualification procedures, which include increased staffing and centralized coordination, ensure that more rapid, transparent, and consistent actions are taken." Since the inception of these new measures, debarment actions have increased, and the length of time for resolving both disqualification and debarment actions have been reduced significantly, the news release said.

The FDA has also reportedly taken steps to provide sponsors involved in the testing and development of new medical products with access to information about the agency's debarment and disqualification actions. All pending and completed disqualification and debarment proceedings can be found on the FDA's Web site.

Pediatric Retinal Imaging System To Be Used in Two ROP Clinical Trials

Clarity Medical Systems announced that the RetCam Digital Imaging System (Clarity Medical Systems, Inc.,