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Office of Medical Information Office of Medical Information The University of Texas Southwestern Medical Center at Dallas ****UT Southwestern ophthalmologist develops time-release implant for CMV retinitis

DALLAS -- Time-release capsules are commonly used to treat colds and allergies. Now Dr. Rajiv Anand, assistant professor of ophthalmology at The University of Texas Southwestern Medical Center at Dallas, is using time-release technology to deliver medication inside the eye.

During recently completed phase I clinical trials using an implantable device that releases medication slowly, he achieved a 90 percent success rate in healing a viral eye infection in 22 patients (30 eyes) at the AIDS Clinic at Parkland Memorial Hospital, UT Southwestern's largest teaching hospital.

Cytomegalovirus (CMV) retinitis is a viral infection of the retina, which can develop in people who have AIDS or those on longterm immunosuppressant drugs. Nearly 25 percent of patients with AIDS develop with CMV retinitis, and this number is likely to increase as patients with AIDS live longer because of new drug therapies.

The cytomegalovirus can be contracted by close personal contact. People with normal immune systems are able to ward off infection, but in people with impaired immunity the virus can cause progressive destruction of tissues. CMV infection of the retina causes progressive destruction of the light-sensitive tissue at the back of the eye and leads to permanent loss of vision.

Assisted by UT Southwestern faculty member Dr. Steven Nightingale, Anand and polymer researchers in Kentucky and Massachusetts have developed an implantable device--a permeable polymer pellet that releases ganciclovir inside the infected eye over a period of four to six months. Once the device is empty, it can be replaced with a fresh one.

Ganciclovir released from the implanted pellet does not reach the high levels typical during intravenous administration, does not affect the untreated eye and does not produce toxic effects on the rest of the body, said Anand.

Anand is working on an implant that will release the drug over a 12-month period. The phase II trial, beginning shortly, will compare the effectiveness of the two devices.

The implant typically produces results within a short time. "Within two weeks we see regression of the infection and complete eradication of the virus within six to eight weeks," the researcher said.

Implant surgery is done on an outpatient basis and takes 30 to 45 minutes.

Anand hopes to use similar devices for use in delivering antiinflammatory drugs, drugs to increase the success of glaucoma surgery, and drugs to prevent scarring after surgery for retinal detachment. "This device has very promising implications for a number of other eye problems," he said.

Until recently, accepted therapy for CMV retinitis was intravenous administration of ganciclovir. Since the drug needs to be given on a long-term basis, an intravenous line for regular administration

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usually is surgically inserted into a neck or a chest vein. There are two major complications with this treatment, said Anand. Up to 50 percent of patients develop an intolerance to highly concentrated doses of ganciclovir, and 12 percent develop resistance to the drug. Some also develop infections at the site of the implanted line. In addition, Anand said AIDS patients undergoing intravenous administration of ganciclovir cannot take the drug AZT, which helps to slow the progression of the HIV infection.

The National Institutes of Health has recently announced the results of a study that compared a newly approved drug, foscarnet, and ganciclovir. It appears that foscarnet may be the better drug to treat widespread CMV infection associated with AIDS because it may have an effect on the AIDS virus as well. Patients who received foscarnet therapy survived longer although foscarnet is associated with kidney toxicity, said Anand.

"The therapy for a newly diagnosed case of AIDS-associated CMV retinitis should henceforth be intravenous foscarnet. If the patient has impaired kidney function, however, he should be started on intravenous ganciclovir. In patients with CMV retinitis and no associated lung or bowel infection, our ganciclovir device offers unique advantages," said Anand.

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NOTE: The University of Texas Southwestern Medical Center at Dallas comprises Southwestern Medical School, Southwestern Graduate School of Biomedical Sciences, Southwestern Allied Health Sciences School, affiliated teaching hospitals and outpatient clinics.