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## TOPICAL DROPS CONTAINING ANDROGEN MAY HELP CLEAR UP DRY EYE SYNDROME

DALLAS – July 12, 2002 – Most days, Paula Hurt's eyes felt irritated, gritty and inflamed. The 45-year-old suffered from dry eye syndrome, a tear deficiency that decreased moisture in her eyes and caused Hurt another inconvenience – frequent trips to her doctor's office.

To alleviate some of her discomfort, Hurt enrolled in a study at UT Southwestern Medical Center at Dallas where ophthalmologists are evaluating whether topical drops containing androgen – a male sex hormone – can help clear up dry eye syndrome, or keratoconjunctivitis.

"I just place drops in my eyes two times a day," said Hurt, who has been participating in the study for the past four months. "The medicine seems to have helped reduce the burning sensation in my eyes."

Dr. James McCulley, chairman of ophthalmology at UT Southwestern, said the most common reason patients visit an ophthalmologist is to relieve dry eye symptoms. One out of every 10 patients complain of the syndrome, he said.

"Tears bathe, lubricate and nourish the surface of the eye," said McCulley, director of the Jean H. & John T. Walter Jr. Center for Research in Age-Related Macular Degeneration. "A person with dry eye has an inadequate function of the tear film that leads to excessive tear evaporation or inadequate tear production. If this condition is left untreated, it can cause scartissue growth, ulcer development or vision impairment."

The tear film is made up of three layers that aid in maintaining a healthy eye surface. A deficiency in any one of the film's layers causes an imbalance, which can lead to reduced tear production or increased tear evaporation.

Researchers have not yet determined the entire etiology of dry eyes, but they have documented the impact certain hormones, specifically androgen, have on the condition and their

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## **DRY EYE SYNDROME - 2**

contributions in maintaining eye health. People most commonly afflicted with this disease are older adults and women.

"Since women produce less quantities of androgen with age, we think this may be the reason they are more susceptible to the development of dry eye," McCulley said. "Oral estrogen, such as birth control pills or hormone-replacement therapy, further compounds the problem for women because it leads to a relative imbalance in already low androgen levels."

McCulley is conducting a phase II clinical trial on ophthalmic drops containing androgen to determine if they are an effective treatment for dry eye syndrome.

To qualify for the study, participants should be 18 or older and have a documented history of dry eye disease. Participants will use an investigational ophthalmic drop two times daily, plus the use of a secondary artificial tears eye drop as needed. They will also be asked to complete electronic diaries and keep all scheduled appointments.

For more information, contact Mike Molai at 214-648-4734.

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