PRESS RELEASE

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Retina Transplants Show Promise in Patients with Retinal Degeneration

Experimental technique yields improved vision in 7 of 10 patients, reports American Journal of Ophthalmology

Philadelphia, 10 July 2008 – Preliminary research shows encouraging results with transplantation of retinal cells in patients with blindness caused by retinitis pigmentosa (RP) and age-related macular degeneration (AMD), according to a report in the July issue of *American Journal of Ophthalmology.*

"This clinical evidence shows the promise of our method to alter progressive vision loss due to incurable degenerative diseases of the retina," comments Dr. Norman D. Radtke of University of Louisville, Ky., lead author of the study.

In the FDA-monitored study, Dr. Radtke and colleagues performed the experimental transplant procedure in ten patients with vision loss resulting from retinal degeneration: six patients with RP and four with the "dry" form of AMD. Although they have different causes, both RP and AMD lead to destruction of the light-receiving (photoreceptor) cells of the retina. There is currently no effective treatment for recovery of visual loss from either condition.

All patients underwent transplantation of fetal retinal cells. The cells were implanted along with their attached retinal pigment epithelium, which plays a key role in nourishing the photoreceptor cells. The concept behind the experimental procedure was that the new cells would grow to replace the damaged photoreceptor cells, connecting to the patient's remaining retina.

Follow-up testing showed visual improvements in seven of the ten patients: three of the patients with RP and all four patients with AMD. Although vision remained in the "legally blind" range for all patients, the gains in vision were significant and measurable.

In one patient with RP, the visual improvement was still present up to six years after surgery, while vision in the opposite (untreated) eye continued to deteriorate. In the same patient, specialized tests showed a 27 percent increase in light sensitivity in the treated eye.

There were no problems with rejection of the transplants by the patients' immune systems, despite the lack of a perfect immunological match between the transplant donors and recipients. This likely reflected the special "immunologic protection" of tissues within the eye.

Two patients also had improved vision in the untreated eyes. The reason for this unexpected result is unknown, but may involve some effect of transplantation on the immune system.

The experimental transplant procedure was designed on the basis of animal studies showing that transplantation of retinal cells can lead to the development of new retinal tissues. Previous "phase I" studies established the safety of the procedure. The new "phase II" trial provides the first evidence of improved vision—the first treatment of any type to restore lost vision in patients with RP or AMD.

Much further research will be needed to determine the potential for retinal transplantation to improve vision in patients with these diseases. "Retinal implants that combine retina and retinal pigment epithelium demonstrated an apparent ability to integrate with host retinas and to re-establish the visual pathways interrupted by disease," adds Dr. Radtke. "What we have learned will help us to refine this method and obtain further evidence that retinal implants may be a viable therapy for retinal degenerative disease."

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