

in the wake of the new vitamin E study, recommends an individualized approach to continuing on the high-dosage regimen, based upon consultation with a physician.

(A copy of the NIH letter to AREDS participants may be found at <http://spitfire.emmes.com/study/areds>.)

In the meantime, Dr. Chew will advise her patients

to keep taking the supplement. "I feel strongly enough that I will continue to say that you need to take this for your eyes," she said.

"I don't think we're killing

patients with our formulation," Dr. Chew said.

—Miriam Karmel

1 Miller, E. R. et al. *Ann Intern Med* 2005;142(1):37-46.

Cornea

Fetal Tissue Transplant Saves One Woman's Sight

Objectively, Elizabeth Bryant of Louisville, Ky., sees better than she did before a 1.5 x 3.1 millimeter sheet of fetal neural retina was transplanted to her left eye as a treatment for retinitis pigmentosa. However, the jury is still out on the technique.

And—conscious of the skeptical reception that earlier retinal transplants received—the ophthalmologists involved in this pioneering research are being careful

not to overstate their case.

"We've done 13 patients, and we've had one very successful patient and one that appears she's going to be successful as well," said Norman Radtke, MD, of the Retina Vitreous Resource Center at Norton Audubon Hospital in Louisville. "But the other 11 patients had little or no effect from the transplant. Just one patient may be a fluke—but this patient is definitely seeing better."

At her exam two years and

two months after surgery, the 65-year-old Mrs. Bryant's ETDRS (Early Treatment Diabetic Retinopathy Study) visual acuity had held steady at 20/200 for more than a year, compared with 20/800 before the implant, Dr. Radtke said. The other patient, who has the dry form of AMD, improved from 20/640 preoperatively to 20/240 six months later.

In Ms. Bryant, visual improvement first became measurable six months after surgery, according to one-year results that Dr. Radtke and colleagues published last summer in the *Archives of Ophthalmology*.¹ The researchers speculated that the transplant succeeded because of a trophic effect on host cones, or because of local synaptic connections between the transplant and the host retina.

Unlike previous retinal transplant efforts, the Louisville team's work is part of an FDA-supervised trial. The procedure inserts intact fetal neural retina, with its adjacent retinal pigment epithelium, into the subretinal space under the fovea, between the neurosensory retina and retinal pigment epithelium. It uses a custom instrument with a flat plastic nozzle tip at a 130-degree angle. Tissue donation is sought only from women who already have decided to terminate pregnancy.

The fetal retinal sheets carry both the structure and

natural biochemistry of the retina, bypassing a key barrier to using stem cells for treating retinal diseases: understanding the complex molecular signals they would need to be used therapeutically.

(Recently, it was shown that throughout life the human retinal ciliary margin contains stem cells that can differentiate into any retinal cell type.²)

But research using fetal tissue can't be done with federal funds, and insurance companies won't pay for experimental surgeries. Luckily for the Louisville team, an anonymous benefactor is paying for all the pre- and postoperative testing as well as the surgeries, Dr. Radtke said.

The other 11 patients in whom the surgeons saw little or no visual improvement had, at best, light-perception vision before surgery, Dr. Radtke said. To see if results improve in eyes that aren't so severely affected, the FDA is allowing the trial to be extended into 20/400 eyes, and the researchers hope to lower that threshold further to 20/200.

"I don't think this procedure should be widely done until we have an effect in six or seven patients on a consistent basis," he said.

1 *Arch Ophthalmol* 2004;122(8):1159-1165.

2 Coles B. L. et al. *Proc Natl Acad Sci USA* 2004;101(44):15772-15777. Epub 2004 Oct 25.



Mrs. Bryant now sees 20/200, well enough to read large print, sew and paint ceramics. Her vision was 20/800.