Ultra-small drainage device may replace eye drop medications for some glaucoma patients

November 13 2012

A tiny medical device no larger than an eyelash may significantly reduce eye pressure in glaucoma patients and allow some to stop using eye-drop medications, according to year-one clinical trial results for the device. Results of the HYDRUS I clinical trial, which indicate successful control of eye pressure in all study participants, will be presented today at the 116th Annual Meeting of the American Academy of Ophthalmology, jointly conducted this year with the Asia-Pacific Academy of Ophthalmology.

The Hydrus stent is one of several promising mini-drainage devices now in clinical trials in the United States and other countries. If future trials confirm micro-stents' effectiveness, they could someday help protect millions of glaucoma patients from vision loss or blindness.

Open-angle glaucoma, the most common form of the disease, affects nearly three million people in the U.S and 60 million worldwide. (Click here to see how glaucoma can affect vision.) Though it is a multifactorial disease, currently the only proven way to prevent vision loss is by reducing intraocular pressure (IOP). The treatment choices are effective but less than ideal, as some patients may not use eye drop medications consistently enough to control their IOP, while others simply don't respond to the drugs. Surgical procedures to open blocked drainage channels or implant larger stents, which are used only for patients with advanced glaucoma, carry risks of infection, bleeding, deterioration of other parts of the eye, and vision loss.

In this particular study of 69 patients suffering from mild to moderate open-angle glaucoma, IOP was reduced to acceptable levels in 100 percent of participants after they received minimally invasive stent implant surgery. In 40 patients the stent was placed during cataract surgery, a procedure that also reduces IOP. Twenty-nine patients had the Hydrus stent placed without cataract surgery to assess whether the stent would be effective on its own. No significant complications occurred in either patient group. At the six-month follow up, 85 percent of combined surgery and 70 percent of stent-only patients no longer needed eye drop medications to control their IOP. Reductions in IOP were consistent among all patients and remained stable at the one year follow up.

"So far, mini-stents appear to have important advantages in that they allow us to treat open-angle glaucoma at earlier stages and with lower complication risk," said Thomas W. Samuelson, M.D., a glaucoma specialist with Minnesota Eye Consultants, who served as the HYDRUS I trial's medical monitor. "If the devices can effectively control IOP over many years, it would be a real breakthrough in combating this blinding disease."

Dr. Samuelson cited the experience of an 81- year-old retired neurosurgeon who had tried multiple glaucoma medications, then had a drainage procedure called a trabeculoplasty, but couldn't achieve safe IOP levels. In 2010, the Hydrus was implanted in his right eye during cataract surgery, followed by the same surgery in his left eye a year later. A follow-up exam two months ago, confirmed that his IOP levels remained acceptably low in both eyes, without the use of eye drops.

A number of similar mini-stents, including the MIDI Arrow, Aquecentesis, and Transcend are now in development or clinical trials. The iStent was recently approved by the U.S. Food and Drug Administration for use in conjunction with cataract surgery. All of the

stents work by providing a new drainage channel for the eye's aqueous fluid, circumventing the patient's own clogged or blocked channels. They vary in design, materials and implant site within the eye. Despite encouraging initial results, it will be several years before the long-term safety, efficacy and durability of this treatment approach can be fully confirmed.

Provided by American Academy of Ophthalmology