ACHES & CLAIMS | *By Laura Johannes*

A Less-Invasive Glaucoma Procedure

A new minimally invasive surgery for glaucoma called **canaloplasty** *is nearly as effective as traditional surgery and has fewer complications, according to a company that sells equipment used in the procedure. Two-year data on canaloplasty look promising, but some physicians warn that little is known about its long-term outcome.*

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Glaucoma is a condition involving progressive damage to the optic nerve that can eventually lead to blindness. There are multiple causes, but one of the most important is elevated eye pressure, which scientists believe is caused by clogging in the trabecular meshwork, tissue that serves as a drainage system for the eye. Glaucoma often occurs with age, and African-Americans are at higher risk.

Glaucoma is often treated with eye drops that reduce the production of fluid in the eye, or help it drain more quickly. However, when the medicines don't work—or when patients can't remember to take them once or more daily—surgery is an option. The traditional surgery is trabeculectomy, in which a portion of the trabecular meshwork is removed, helping to reduce the bottleneck causing elevated eye pressure. Trabeculectomy is considered the gold standard for effectiveness, but can cause infection or other complications serious enough to result in blindness.

In recent years, a number of safer but less-effective alternatives to trabeculectomy have been developed, including laser surgery and trabectome, a minimally invasive surgery that uses an electric probe to remove a portion of the meshwork. Continued medication use may be required after all the surgeries, but it can often be reduced.

Tim Foley

Canaloplasty is one of the newest alternatives and involves forcing open a drainage canal, similar to what cardiologists do to unblock clogged arteries. The procedure is sometimes called "angioplasty for the eye." In canaloplasty, an incision is made in the eye and a thin catheter is inserted into Schlemm's Canal, a tube in the trabecular meshwork. Instead of a balloon, a thick clear gel is injected to open the canal. In addition, a suture, or surgical tie, is placed inside the canal and pulled tight to stretch open the trabecular meshwork, says Richard Lewis, a Sacramento, Calif., eye surgeon who serves as a consultant to iScience Interventional Corp., a Menlo Park. Calif., company that sells the catheter.

The procedure takes about a half hour and can be done under local anesthetic, typically in a hospital or outpatient surgery center with a sedative. The cost—typically $2,500 to $3,500—is covered by many insurers, while others decline payment because they say there isn't yet enough evidence for the procedure's effectiveness. Serious complications are rare, but can include swelling, overly low eye pressure and blood in the eye.

In results of a 14-center study presented by Dr. Lewis at the American Academy of Ophthalmology on Nov. 9 in Atlanta, the average eye pressure in about a hundred patients who received canaloplasty was in the normal range two years after the surgery. The group average at the two-year point was 15.5 millimeters of mercury, a drop of 35%.

The incidence rate for complications, which ranged from minor irritation to blurry vision from blood leaking in their eyes, was 11%. None of the patients suffered serious vision problems caused by the surgery, says Dr. Lewis, who owns stock in iScience.

Independent eye surgeons say canaloplasty is a worthy option, but not necessarily the best choice for many patients. "The results that they've published thus far show great promise," says Douglas Rhee, a glaucoma specialist at the Massachusetts Eye & Ear Infirmary in Boston. "Additional studies need to be done," he adds, including trials that compare it directly to other procedures such as trabeculectomy.

Surgeons agree that canaloplasty is a safer option than the traditional surgery, but some urge caution. "Canaloplasty is still a trip to the operating room that doesn't lower pressure as much as trabeculectomy," Kuldev Singh, a Stanford, Calif., eye surgeon who is chairman of the nonprofit American Glaucoma Society's patient-care committee. Based on current data, he would recommend laser surgery to patients looking for a safer option, and trabeculectomy to patients at serious risk for blindness if their eye pressure isn't lowered significantly.

"We don't know how long canaloplasty lasts," adds Arthur Sit, assistant professor of ophthalmology at the Mayo Clinic in Rochester, Minn. Moreover, he is concerned that scar tissue left from canaloplasty could make a subsequent trabeculectomy less effective. Dr. Sit prefers trabectome, which he says involves a smaller incision that is less likely to impact later surgeries.

Dr. Lewis says that the location of the canaloplasty incision, off to one side of the eye, leaves plenty of room for a trabeculectomy later. Additional trials are now beginning that will compare canaloplasty to trabeculectomy and to medical therapy alone.

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