Viscocanalostomy and Canaloplasty

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Aetna considers canaloplasty medically necessary for the treatment of primary open-angle glaucoma (POAG).

Aetna considers canaloplasty experimental and investigational for all other indications (e.g., for use in corticosteroid-induced glaucoma, glaucoma gene therapy and uveitic glaucoma) because its effectiveness for indications other than the one listed above has not been established.

Aetna considers viscocanalostomy (including phacoviscocanalostomy) experimental and investigational for the treatment of primary open-angle glaucoma or any other indications because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of this procedure.

Aetna considers combined phacoemulsification and viscocanalostomy with Ologen implant for co-existing cataract and POAG experimental and investigational because the effectiveness of this approach has not been established.
Background

Glaucoma is an irreversible group of conditions/diseases involving death of the nerve cells in front of the optic nerve. It was once thought that glaucoma was generally due to increased intra-ocular pressure (IOP); however, the condition is also found in individuals with normal or low eye pressure. Therefore, diagnosis of glaucoma does not rely on increased IOP and may be related to optic nerve damage. Glaucoma is one of the leading causes of blindness with loss of peripheral vision being a hallmark sign of glaucoma.

Medication, in the form of eye drops, pills or both, is the most common early treatment for glaucoma. There are numerous medications available for treating glaucoma; all of which must be taken regularly. If medication fails, other interventions may be recommended.

Current standard surgical treatments for glaucoma include trabeculectomy or trabeculoplasty (incisional or laser). Iridotomy, iridectomy or iridoplasty may be necessary for angle-closure glaucoma.

Viscocanalostomy is an ophthalmic surgical procedure that has been developed as an alternative to trabeculectomy. In some cases, viscocanalostomy has been used in conjunction with cataract removal via phaco-emulsification. Viscocanalostomy is similar to canaloplasty in that tissue flaps are cut in the conjunctiva and the sclera. The creation of these flaps exposes a portion of the drainage (Schlemm’s) canal into which a high-viscosity elastic gel is injected. The injected material opens and enlarges the canal to allow increased fluid flow out of the anterior chamber. The tissue flaps are then closed.
Although there are a variety of viscocanalostomy techniques, the procedure basically involves production of superficial and deep scleral flaps, excision of the deep scleral flap to create a scleral reservoir, and unroofing of Schlemm's canal. A high-viscosity viscoelastic, such as sodium hyaluronate, is used to open the canal and create a passage from a scleral reservoir to the canal. The superficial scleral flap is then sutured water tight, trapping the viscoelastic until healing takes place. However, the peer-reviewed published medical literature reveals that viscocanalostomy has only been studied in a relatively small number of patients at a few centers. There are no published peer-reviewed data on long-term outcomes of viscocanalostomized patients, and what few clinical studies have been published directly comparing viscocanalostomy with trabeculectomy show that trabeculectomy is more effective at lowering intraocular pressure (IOP).

Randomized controlled multi-center clinical trials directly comparing viscocanalostomy with trabeculectomy are needed before viscocanalostomy can be accepted as an established alternative to trabeculectomy. As one of the leading investigators of viscocanalostomy in North America commented: "As with all glaucoma studies, long term follow-up evaluation will be required to prove its [viscocanalostomy's] real efficacy. In addition, randomized studies which would compare viscocanalostomy and phacoemulsification with other combined glaucoma procedures are also in order" (Henahan, 1998).

In a technology assessment on non-penetrating glaucoma surgery, the American Academy of Ophthalmology (AAO, 2001) stated that non-penetrating glaucoma surgery (viscocanalostomy is one of the 2 major variations of this procedure) has the potential to reduce IOP while minimizing the risk of post-operative relative hypotony and the complications associated with hypotony. The authors found, however, that the majority of the published literature on non-penetrating glaucoma surgery contains information from case
series, which are not randomized and lack a control group. The authors concluded that randomized clinical trials (RCTs) are needed to assess these procedures and to determine their role in the clinical management of glaucoma patients.

The AAO's practice guideline on the management of primary open-angle glaucoma (2005) recognized viscocanalostomy as being a non-penetrating surgery used by some physicians as an alternative to trabeculectomy, but it stated that the precise role of non-penetrating surgeries (i.e., viscocanalostomy and non-penetrating deep sclerectomy) has yet to be determined.

Shaarawy and associates (2003) studied prospectively the success rate and complications of viscocanalostomy in patients with medically uncontrolled primary and secondary open angle glaucoma (n = 57). These investigators concluded that viscocanalostomy appears to be a promising modification of filtering surgery.

Randomized controlled clinical studies comparing viscocanalostomy with trabeculectomy in glaucomatous patients have shown that trabeculectomy is more effective in lowering IOP than viscocanalostomy. In a RCT (n = 20) comparing viscocanalostomy and trabeculectomy for the treatment of patients with open angle glaucoma, Jonescu-Cuypers et al (2001) found that trabeculectomy was more effective than viscocanalostomy in lowering IOP in glaucomatous eyes of such patients. This is in agreement with the finding of Luke et al (2002) who examined the IOP-lowering effectiveness and the post-operative complication profile of viscocanalostomy versus trabeculectomy in a prospective randomized trial (n = 60). The authors concluded that in eyes with open-angle glaucoma, viscocanalostomy is less effective in reducing IOP than standard filtering surgery. However, post-operative complications are less frequent after viscocanalostomy. In a prospective clinical study, Kobayashi and colleagues (2003) compared the IOP-lowering effect and safety of viscocanalostomy and trabeculectomy with mitomycin
C in patients with bilateral primary open-angle glaucoma (n = 25). The eyes of each patient were randomly assigned to receive viscocanalostomy in 1 eye and trabeculectomy with mitomycin C in the other eye. The patients were followed-up for 12 months. These researchers reported that trabeculectomy with mitomycin C may be more effective than viscocanalostomy in lowering IOP in patients with primary open-angle glaucoma, while eyes undergoing viscocanalostomy experience a lower incidence of complications, and they stated that further investigation of more cases is needed.

In a single-masked, parallel-group, prospective, randomized 24-month trial, Carassa et al (2003) compared the effectiveness and safety of viscocanalostomy and trabeculectomy in adults with uncontrolled open-angle glaucoma (n = 50). Eyes were assigned randomly to either viscocanalostomy (group 1) or trabeculectomy (group 2) with no intraoperative anti-fibrotics in the study eye. In group 1, no further intervention was allowed, whereas trabeculectomy eyes could receive subconjunctival 5-fluorouracil (5-FU) injections or laser suture lysis after surgery. It was found that viscocanalostomy is an effective IOP-lowering procedure in adults affected by open-angle glaucoma. Trabeculectomy with post-operative 5-FU can probably provides lower IOPs, but, with more numerous complications, greater discomfort, and more intensive post-operative management. The authors concluded that large, multi-center controlled studies are needed to define the role of viscocanalostomy in the surgical management of glaucoma.

An assessment prepared for the Cochrane Collaboration comparing surgical and medical management of glaucoma found no studies comparing viscocanalostomy with medical management (Burr et al, 2004). The assessment noted that although viscocanalostomy may have fewer complications than trabeculectomy, viscocanalostomy may have limited effectiveness at lowering IOP.
Guidelines from the Royal College of Ophthalmologists (2004) conclude that "at the present time there is insufficient evidence from prospective studies that these operations [viscocanalostomy and deep sclerectomy] have a lower incidence of long-term complications while maintaining good IOP control to advocate their use in routine glaucoma practice."

In a prospective randomized 1-year study, Kobayashi and Kobayashi (2007) compared the IOP-lowering effect of combined viscocanalostomy and phaco-emulsification and combined trabeculectomy and phaco-emulsification with mitomycin C in eyes with primary open-angle glaucoma. A total of 40 consecutive patients (40 eyes) with primary open-angle glaucoma and cataract were enrolled in this study. Eyes were assigned randomly either to trabeculectomy with mitomycin C or to viscocanalostomy in combination with phaco-emulsification and intra-ocular lens implantation. Mean baseline IOP was 24.0 +/- 2.0 mm Hg in the viscocanalostomy group and 23.7 +/- 2.6 mm Hg in the trabeculectomy group (p = 0.7). Mean post-operative IOP was 13.7 +/- 2.2 mm Hg at 3 months, 14.8 +/- 3.3 mm Hg at 6 months, and 14.9 +/- 3.0 mm Hg at 12 months in the viscocanalostomy group and 12.1 +/- 4.0 mm Hg at 3 months, 13.8 +/- 4.7 mm Hg at 6 months, and 14.1 +/- 4.4 mm Hg at 12 months in the trabeculectomy group. There was no significant difference in the mean IOP between the groups at any time. At 12 months, 17 patients (85 %) in the viscocanalostomy group and 16 patients (80 %) in the trabeculectomy group achieved an IOP of 20 mm Hg or less without medication (p = 0.7). Complications included 2 cases (10 %) of flat/shallow anterior chamber and 4 cases (20 %) of hypotony in the trabeculectomy group, whereas intra-operative microperforation of Descemet's membrane occurred in 3 cases (15 %) in the viscocanalostomy group. The authors concluded that there was no significant difference in IOP reduction between viscocanalostomy and trabeculectomy with mitomycin C in combination with phaco-emulsification and intra-ocular
lens implantation in patients with primary open-angle glaucoma. They also stated that future study of a large population is needed to verify these observations.

In a long-term, prospective, randomized study, Gilmour et al (2007) compared the lowering effects of viscocanalostomy and trabeculectomy without anti-metabolite on IOP. The results of this study showed that at 40-month follow-up, trabeculectomy was more likely to achieve IOP levels below 18 mm Hg than viscocanalostomy. The study enrolled 21 primary open angle glaucoma patients who underwent trabeculectomy and 22 who underwent viscocanalostomy by a single surgeon familiar with both procedures. The mean pre-operative IOP was 25 mm Hg, and the trabeculectomies were performed without anti-metabolite intra-operatively, although some patients received 5-FU in the post-operative period. The follow-up period was 4 years, and the post-operative treatment was similar in both groups.

Survival analysis suggested that patients who underwent trabeculectomy had a 42% chance of experiencing lower IOP compared to a 21% chance in the viscocanalostomy group at 40 months. Success was defined as IOP below 18 mm Hg, and qualified success was IOP below 18 with medications. The trabeculectomy group, however, had more complications, and interventions such as needling and 5-FU injections were needed in the early post-operative period. Although the trabeculectomy group was less likely to need glaucoma medications to control IOP in the post-operative period, IOP with medication was well-controlled in the viscocanalostomy group. Of interest, only 1 patient required goniopuncture in the viscocanalostomy group compared to other studies in the literature where goniopuncture was required for around 30% of patients. It is unclear how this might have influenced the results.
The authors stated that the findings of this study confirmed previous reports that the likelihood of obtaining lower IOP over the long-term with viscocanalostomy is lower than that with a standard trabeculectomy. The re-introduction of canal based surgery in adults has generated intense interest in the glaucoma community to develop new approaches to improve filtration through the trabecular and other pathways. They noted that prospective, randomized, long-term, clinical trials will hopefully provide some insight as to which of these new procedures might be most beneficial to glaucoma patients.

More recently, a glaucoma canaloplasty (enhanced viscocanalostomy) has been introduced, which involves modification of the viscocanalostomy procedure. Canaloplasty uses viscoelastic and a specialized microcatheter (e.g., iScience Surgical Ophthalmic Microcannula, Menlo Park, CA) to forceably open the Schlemm’s canal. The procedure is intended to restore the natural drainage of fluid from the eye, thus reducing IOP in persons with glaucoma.

Canaloplasty is a surgical procedure in which tissue flaps are cut in the conjunctiva and the sclera to expose the drainage area (Schlemm’s canal). Canaloplasty attempts to open the entire drainage area surrounding the anterior chamber (360°) instead of just a portion of it, as in viscocanalostomy below. A very small catheter is placed in the opening and used to inject the high-viscosity elastic gel into the entire drainage area forming a ring around the anterior chamber. A suture loop is left in the canal to help maintain tension and keep the canal open. The canal is expanded by the injection to promote better fluid drainage.

Similar to the viscocanalostomy, canaloplasty is completed under a scleral flap. The canal is identified then intubated with a flexible microcatheter which has a lighted tip to identify its location as it passes through the Schlemm’s canal. The microcatheter also has a lumen to allow for the passage of high viscosity sodium hyaluronate for dilation of the canal.
Once the cannula has passed the full length (360° through) of the Schlemm's canal, a suture is tied to the cannula and as the cannula is withdrawn the suture is tied off and left in place. The intracanalicular suture cinches and stretches the trabecular meshwork inwards and permanently opening the Schlemm's canal. The scleral flap is tightly closed as well as the conjunctiva. Before, during and after the surgery, a special ultrasound imaging system is used to help identify the canal and the instrumentation in the canal.

An important difference between viscocanalostomy and canaloplasty is that canaloplasty aims at opening the entire length of the Schlemm's canal, not just one section of it. Canaloplasty is currently under investigation. Several trials are currently underway to further support the benefits and safety of this technique.

Although a relatively new procedure, canaloplasty seems effective in lowering IOP when used in glaucoma patients as an alternative to trabeculectomy. The choice between these procedures relates to the degree of IOP lowering required by a patient as well as the patient's risk factors for complications. Canaloplasty will likely be used most often in earlier stages of glaucoma and in patients in whom bleb infection and leakage would put them at higher risk for infection-associated blindness (endophthalmitis). This procedure may also be indicated in patients who may not need IOP-lowering to the degree that is achievable with trabeculectomy. Canaloplasty and other procedures that lower IOP without creating an aqueous filtering hole in the eye with a conjunctival bleb may have an increasing role in the surgical management of patients with glaucoma because of their potentially improved safety profile.

In an international multi-center prospective study (14 sites in Germany and in the United States of America), Lewis et al (2007) assessed the safety and effectiveness of circumferential viscodilation and tensioning of the inner wall of
Viscocanalostomy and Canaloplasty for the treatment of open-angle glaucoma (OAG). Adult patients having glaucoma surgery, patients with qualifying pre-operative IOP of at least 16 mm Hg or higher and open angles were eligible. Evaluation was performed at baseline and 1 day, 1 week, and 1, 3, 6, and 12 months post-operatively. After a non-penetrating dissection technique to expose Schlemm's canal was performed, a flexible microcatheter was used to dilate the full circumference of the canal by injecting sodium hyaluronate 1.4 % during catheterization. A suture loop was placed in the canal to apply tension to the trabecular meshwork. High-resolution ultrasound imaging was used to evaluate Schlemm's canal and anterior segment angle morphology, including distension of the trabecular meshwork caused by the tensioning suture. Data analysis was performed in 2 groups: Group 1, in which patients met all inclusion criteria, and Group 2, made up of Group 1 patients who had successful suture placement. Group 1 comprised 94 patients and Group 2, 74 patients. The mean baseline IOP in Group 1 was 24.7 mm Hg +/- 4.8 (SD) on a mean of 1.9 +/- 1.0 medications per patient. In Group 2 (patients with sutures), the mean IOP was 16.1 +/- 4.7 mm Hg 3 months post-operatively, 15.6 +/- 4.0 mm Hg at 6 months, and 15.3 +/- 3.8 mm Hg at 1 year. Medication use dropped to a mean of 0.6 +/- 0.9 per patient at 12 months. Suture tensioning was an apparent contributing factor in achieving surgical success. Patients with measurable trabecular meshwork distension from suture tension had a mean IOP of 15.9 +/- 5.2 mm Hg at 6 months and 14.5 +/- 3.0 mm Hg at 12 months. Surgical and post-surgical adverse events were reported in 15 of 94 patients (16 %) and included hyphema (n = 3), elevated IOP greater than 30 mm Hg (n = 3), Descemet's tear (n = 1), hypotony (n = 1), choroidal effusion (n = 1), and exposed closure suture with eyelid edema and erythema epiphora (n = 1); 4 patients were subsequently converted to trabeculectomy. The authors concluded that canaloplasty was a safe and effective procedure to reduce IOP in adult patients with OAG. The major drawbacks of this study included the lack of randomization and a control group, as well
as the learning curve associated with performance of the procedure. Other limitations include the small, heterogeneous patient group, short-term follow-up, and the number of patients lost to follow-up.

Shingleton et al (2008) evaluated the safety and effectiveness of canaloplasty combined with clear corneal phaco-emulsification and posterior chamber intraocular lens (IOL) implantation in treating OAG. This international multi-center prospective study comprised adult patients with OAG having combined glaucoma and cataract surgery. Patients with qualifying treated pre-operative IOP of at least 21 mm Hg or higher and open angles were eligible. Evaluation was performed at baseline and 1 day, 1 week, and 1, 3, 6, and 12 months post-operatively. Intra-operative and post-operative high-resolution ultrasound imaging was used to assess Schlemm canal and anterior segment angle morphology, including distension of the trabecular meshwork due to the tensioning suture. Data from 54 eyes that had combined glaucoma and cataract surgery performed by 11 surgeons at 9 study sites were analyzed for this interim analysis. The mean baseline IOP was 24.4 mm Hg +/- 6.1 (SD) with a mean of 1.5 +/- 1.0 medications per eye. In all eyes, the mean post-operative IOP was 13.6 +/- 3.8 mm Hg at 1 month, 14.2 +/- 3.6 mm Hg at 3 months, 13.0 +/- 2.9 mm Hg at 6 months, and 13.7 +/- 4.4 mm Hg at 12 months. Medication use dropped to a mean of 0.2 +/- 0.4 per patient at 12 months. Surgical complications were reported in 5 eyes (9.3 %) and included hyphema (n = 3, 5.6 %), Descemet tear (n = 1, 1.9 %), and iris prolapse (n = 1, 1.9 %). Transient IOP elevation of more than 30 mm Hg was observed in 4 eyes (7.3 %) 1 day post-operatively. The authors concluded that canaloplasty combined with clear corneal phaco-emulsification and posterior chamber IOL implantation was a safe and effective procedure to reduce IOP in adult patients with OAG.
The National Institute for Health and Clinical Excellence (NICE, 2008) stated that canaloplasty for the treatment of primary OAG should be used only in the context of research or formal prospective data collection. It noted that current evidence on the safety and effectiveness of canaloplasty is inadequate in quality and quantity. Specialist advisors to NICE considered theoretical adverse events to include anterior chamber perforation, tearing of Descemet’s membrane resulting in corneal opacification or retinal damage, intraocular inflammation caused by the suture, cataract formation, sustained increases in IOP, hypotony, and bleb formation or suture exposure with endophthalmitis.

In a meta-analysis, Hondur and colleagues (2008) evaluated the effectiveness of non-penetrating glaucoma surgery for OAG with respect to target IOP and severity of glaucoma. Studies encompassing only combined glaucoma and cataract surgery were excluded. Measurement of effectiveness was determined on the basis of achievement of target IOP. Data related to post-operative goniopuncture and needling with anti-metabolite application were noted. The percentage of cases achieving less than or equal to 21 mm Hg was 48.6 % after primary deep sclerectomy (DS), 68.7 % after DS with implant, 67.1 % after DS with anti-metabolite, 51.1 % after primary viscocanalostomy, and 36.8 % after viscocanalostomy with anti-metabolite or implant. Visual field parameters were almost exclusively not available; whereas cup/disk ratio and target IOP lower than 21 mm Hg were available in very few reports. With lower set IOP targets, the rates of success varied between 35 % and 86 % for DS, and between 10 % and 67 % for viscocanalostomy. The mean follow-up of the studies were mostly in the range of 3 years. The authors concluded that non-penetrating glaucoma surgery seems to provide IOP reduction into the high teens. Its potential to achieve lower target IOPs seems to be low. They stated that longer-term studies, with data related to glaucoma severity and proper target IOPs are needed.
Mendrinos et al (2008) noted that non-penetrating glaucoma surgeries have been developed in recent years in order to improve the safety of conventional filtering procedures. The goal of non-penetrating filtering procedures is to reduce IOP by enhancing the natural aqueous outflow channels, while reducing outflow resistance located in the inner wall of the Schlemm's canal and the juxta-canalicular trabecular meshwork. In the last few years, viscocanalostomy and DS with external trabeculectomy have become the most popular non-penetrating filtering procedures. Both involve removal of a deep scleral flap, the external wall of Schlemm's canal and corneal stroma behind the anterior trabeculum and Descemet's membrane, thus creating an intrascleral space. The aqueous humour leaves the anterior chamber through the intact trabeculo-Descemet's membrane into the scleral space, from where it will egress into different pathways. The technique is associated with a long learning curve. Published clinical trials comparing non-penetrating glaucoma surgery to full-thickness trabeculectomy have a consensus on the superior safety profile of non-penetrating glaucoma surgery but are not in agreement when it comes to efficacy, where conflicting results have been found.

Lewis and colleagues (2009) assessed 2-year post-surgical safety and efficacy of canaloplasty (circumferential viscodilation and tensioning of the inner wall of Schlemm canal) to treat OAG. This international prospective study comprised adult OAG patients having glaucoma surgery or combined glaucoma-cataract surgery. Qualifying pre-operative IOP was at least 16 mm Hg and historical IOP, at least 21 mm Hg. The full circumference of the canal was viscodilated and a trabecular tensioning suture placed with a micro-catheter. Primary outcome measures included IOP and glaucoma medication use. At 24 months, all 127 eyes (127 patients) had a mean IOP of 16.0 mm Hg +/- 4.2 and mean glaucoma medication use of 0.5 +/- 0.8 (baseline values 23.6 +/- 4.8 mm Hg and 1.9 +/- 0.8 medications). Eyes with canaloplasty alone had a mean IOP of 16.3 +/- 3.7 mm Hg and...
0.6 +/- 0.8 medications (baseline values 23.2 +/- 4.0 mm Hg and 2.0 +/- 0.8 medications). Eyes with combined glaucoma-cataract surgery had a mean IOP of 13.4 +/- 4.0 mm Hg and 0.2 +/- 0.4 medications (baseline values 23.1 +/- 5.5 mm Hg and 1.7 +/- 1.0 medications). The IOP and medication use results at all time points were statistically significant versus baseline (p < 0.001). The late post-operative follow-up identified 3 patients with elevated IOP. No other serious ocular or non-ocular complications were reported. The authors concluded that canaloplasty was safe and effective in reducing IOP in adult patients with OAG. These are "interim" results of an ongoing clinical study; the clinical value of canaloplasty awaits the completion and final analyses of results.

Griesbacher et al (2010) reported on a prospective study evaluating 32 consecutive eyes that had canaloplasty and at least 1 year of follow-up. The mean pre-operative IOP (with medications) of 27.3 +/- 5.6 mm Hg improved to a mean post-operative IOP (without medications) of 12.8 +/- 1.5 mm Hg at 12 months. The success rate where the IOP reached less than 21, less than 18, and less than 16 mm Hg was 93.8 % (95 % confidence interval[CI]: 0.86 to 1.0), 84.4 % (95 % CI: 0.73 to 0.98), and 74.9 % (95 % CI: 0.61 to 0.92) at 12 months, respectively.

Minckler and Hill (2009) described the rationales and initial clinical outcomes in studies to date on Glaukos iStent, iScience (canaloplasty), Solx (supra-choroidal shunt), and Trabectome, which are newly developed surgical technologies for the treatment of OAG. These new approaches to angle surgery have been demonstrated in preliminary case series to safely lower IOP in the mid-teens with far fewer complications than expected with trabeculectomy and without anti-fibrotics. Trabectome and iStent are relatively non-invasive, aim to improve access of aqueous to collector channels and do not preclude subsequent standard surgery. Canaloplasty,
modified from viscocanalostomy, is thought to improve trans-trabecular flow. Solx potentially offers an adjustable aqueous outflow into the supra-choroidal space.

In a prospective and non-randomized study, Chakib and colleagues (2010) evaluated the short-term clinical results and complications of viscocanalostomy. A total of 107 consecutive eyes of 67 patients who underwent viscocanalostomy were analyzed. The surgeon conducted post-operative care. The minimal follow-up was 1 year, with a mean follow-up of 13.1 months (range of 12 to 18 months). The criteria for success were defined as IOP less than 21 mm Hg without treatment. The mean pre-operative IOP was 28.3 mm Hg while the mean post-operative IOP was 5.4 mm Hg on the first day and 10.2 mm Hg at 13 months. The rate of patients who had IOP below 21 mm Hg with or without treatment was 98 % at 13 months. The complete success rate without treatment was 80 % at 13 months. Seven cases of ocular hypotony lasting more than 1 month were noted. The authors concluded that viscocanalostomy is a promising procedure because in the short-term it provides good tonometric results in glaucomatous patients without the complications of trabeculectomy. However, it remains a technique with a learning curve.

Tian and Kaufman (2013) stated that since the inner wall of Schlemm’s canal (SC) is directly in contact with the trabecular meshwork (TM) for 360 degrees and the catheter device used in canaloplasty allows viscoelastic to be injected into the entire length of SC, canaloplasty might also be used to perform SC/TM-targeted delivery of transgene vectors for glaucoma gene therapy. This hypothesized new method for transgene delivery may give the transgene access to the entire inner wall of SC and the whole juxta-canalicular region of the TM and allow the transgene to be expressed in both the TM and SC without affecting the cornea, iris and ciliary body. The authors concluded that this strategy might have a greater trabecular outflow resistance-decreasing effect than either the genetic or surgical approach alone.
Aktas et al (2014) noted that SC inner wall is adjacent to the juxta-canalicular TM over their entire circumference. These researchers attempted to transfer reporter and therapeutic genes to these outflow-modulating tissues via canaloplasty surgery in live monkeys. A standard canaloplasty surgical approach was performed in cynomolgus monkeys using flexible canaloplasty catheters, modified for monkey eyes with a 175-μm outer diameter and an LED-lighted tip. A 6-0 prolene suture was used for the exact localization of SC. Trypan blue was injected during catheter withdrawal to document catheter placement within SC and to determine ease of injecting fluid into SC. Before, during, and after the injection, the position of the catheter and the anatomic details were video-captured with an externally positioned non-contact endoscopic imaging system and 50 mHz ultrasound biomicroscopy (UBM). A 360-degree catheterization and injection of dye into SC was achieved. Suture, catheter, and trypan blue were imaged with the endoscope camera system and the catheter was also visualized with UBM. Trypan blue was seen in the SC over 5 clock hours after a 1 clock-hour insertion of the catheter. The authors concluded that a modified canaloplasty catheter device might be used for gene delivery to the SC/TM area without circumferential catheterization. Moreover, they stated that further studies comparing different delivery methods of the vector/transgene into the SC using canaloplasty are needed.

The AAO Preferred Practice Pattern on primary open angle glaucoma (AAO, 2015) states that the precise role of canaloplasty in the management of open-angle glaucoma remains to be determined. The AAO states that “The safety and efficacy of canaloplasty alone and combined with phacoemulsification was described in a nonrandomized multicenter clinical trial through 3 years of follow-up [citing Lewis, et al., 2011]. No randomized clinical trial comparing trabeculectomy and canaloplasty exists. A retrospective case series found lower postoperative IOP with trabeculectomy compared with canaloplasty [citing Ayyala, et al, 2011]."
An AAO's clinical practice guideline on “Primary open-angle glaucoma” (AAO, 2010) as well as an AAO report on “Novel glaucoma procedures” (Francis et al, 2011) did not mention phacoviscocanalostomy as a therapeutic option. Furthermore, in an UpToDate review on “Open-angle glaucoma: Treatment” (Jacobs, 2014), viscocanalostomy and phacoviscocanalostomy are not mentioned as therapeutic options.

In a prospective, non-randomized case-series study, Moradian et al (2013) evaluated the safety and effectiveness of viscocanalostomy in the management of medically uncontrollable primary OAG (POAG) in a developing country. A total of 14 consecutive eyes with medically uncontrollable POAG were subjected to viscocanalostomy. The main outcome measure was success rate based on the IOP level achieved post-operatively. The procedure was considered a complete success if IOP was less than 21 mmHg without any anti-glaucoma medication. Qualified success was defined as IOP of less than 21 mmHg with anti-glaucoma medication. All patients had a regular follow-up of at least 12 months. Overall, IOP was reduced from a mean baseline value of 27.9 ± 7.3 mmHg (range of 21 to 40 mmHg) to a mean final value of 16.0 ± 2.7 mmHg (range of 13 to 22 mmHg), which was statistically highly significant (p < 0.005). The mean number of pre-operative anti-glaucoma medications was 3.0 ± 0.4 (range of 2 to 4), which was reduced significantly (p < 0.0001) to 0.3 ± 0.6 (range of 0 to 2) at the last follow-up visit. One year post-operatively, complete success was achieved in 71% and qualified success was observed in 21.4% of patients, summing up to an overall success rate of 92.4%. There were no major complications in any of the patients. The authors concluded that viscocanalostomy could be performed effectively and safely for control of POAG in developing countries. Moreover, they stated that “A larger number of patients and a longer follow-up period are warranted for the further evaluation of this relatively novel procedure in developing countries. In addition, comparing the future
surgical cases of the same surgeon would show the learning curve of viscocanalostomy more precisely. However, we believe that the high success rate and low complication rate in these initial 14 cases are highly encouraging to suggest popularization of non-penetrating glaucoma procedures in developing countries”.

In a Cochrane review, Eldaly and colleagues (2014) compared the effectiveness of non-penetrating trabecular surgery with conventional trabeculectomy in people with glaucoma. These investigators searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2013, Issue 8), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to September 2013), EMBASE (January 1980 to September 2013), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to September 2013), the metaRegister of Controlled Trials (mRCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). They did not use any date or language restrictions in the electronic searches for trials. They last searched the electronic databases on September 27, 2013. This review included relevant RCTs and quasi-RCTs on participants undergoing standard trabeculectomy for OAG compared to non-penetrating surgery, specifically viscocanalostomy or deep sclerectomy, with or without adjunctive measures. Two review authors independently reviewed the titles and abstracts of the search results. They obtained full copies of all potentially eligible studies and assessed each one according to the definitions in the “Criteria for considering studies” section of this review. They used standard methodological procedures expected by The Cochrane Collaboration. These researchers included 5 studies with a total of 311 eyes (247 participants) of which 133 eyes (participants) were quasi-randomized. A total of 160 eyes that had trabeculectomy were compared to 151 eyes that
had non-penetrating glaucoma surgery (of which 101 eyes had deep sclerectomy and 50 eyes had viscocanalostomy). The CI for the odds ratio (OR) of success (defined as achieving target eye pressure without eye drops) does not exclude a beneficial effect of either deep sclerectomy or trabeculectomy (OR 0.98, 95 % CI: 0.51 to 1.88). The odds of success in viscocanalostomy participants was lower than in trabeculectomy participants (OR 0.33, 95 % CI: 0.13 to 0.81). These investigators did not combine the different types of non-penetrating surgery because there was evidence of a subgroup difference when examining total success. The OR for achieving target eye pressure with or without eye drops was imprecise and was compatible with a beneficial effect of either trabeculectomy or non-penetrating filtration surgery (NPFS) (OR 0.79, 95 % CI: 0.35 to 1.79). Operative adjuvants were used in both treatment groups; more commonly in the NPFS group compared to the trabeculectomy group, but no clear effect of their use could be determined. Although the studies were too small to provide definitive evidence regarding the relative safety of the surgical procedures, these researchers noted that there were relatively fewer complications with non-filtering surgery compared to trabeculectomy (17 % and 65 %, respectively). Cataract was more commonly reported in the trabeculectomy studies. None of the 5 trials used quality of life measure questionnaires. The methodological quality of the studies was not good. Most studies were at high risk of bias in at least one domain and for many, there was lack of certainty due to incomplete reporting. Adequate sequence generation was noted only in 1 study. Similarly, only 2 studies avoided detection bias. These investigators detected incomplete outcome data in 3 of the included studies. The authors concluded that this review provided some limited evidence that control of IOP is better with trabeculectomy than viscocanalostomy. For deep sclerectomy, they could not draw any useful conclusions. This may reflect surgical difficulties in performing non-penetrating procedures and the need for surgical experience. This review has highlighted the lack of use of quality of life outcomes and
the need for higher methodological quality RCTs to address these issues. Since it is unlikely that better IOP control will be offered by NPFS, but that these techniques offer potential gains for patients in terms of quality of life, the authors felt that such a trial is likely to be of a non-inferiority design with quality of life measures.

Ghate and Wang (2015) stated that primary congenital glaucoma (PCG) manifests within the first few years of a child's life and is not associated with any other systemic or ocular abnormalities. Primary congenital glaucoma results in considerable morbidity even in developed countries. Several surgical techniques for treating this condition, and lowering the IOP associated with it, have been described. These investigators compared the safety and effectiveness of different surgical techniques for PCG. They searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2014, Issue 6), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to June 2014), EMBASE (January 1980 to June 2014), (January 1982 to June 2014), PubMed (January 1946 to June 2014), the metaRegister of Controlled Trials (mRCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov), the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en).

They did not use any date or language restrictions in the electronic searches for trials. They last searched the electronic databases on June 23, 2014. These researchers included all randomized and quasi-randomized trials in which different types of surgical interventions were compared in children less than 5 years of age with PCG. The authors used standard methodological procedures specified by The Cochrane Collaboration. A total of 6 trials (4 randomized and 2 quasi-randomized) with 102 eyes in 61 children were included in this analysis. Two trials were conducted in the USA and 1 trial each in Egypt, Israel, Lebanon and Saudi Arabia. All trials included children aged younger than 1 year
when diagnosed with PCG, and followed them for periods ranging from 6 months to 5 years. No 2 trials compared the same pair of surgical interventions, so these investigators did not perform any meta-analysis. One trial compared trabeculotomy versus goniotomy; a 2nd trial compared combined trabeculectomy-trabeculotomy with mitomycin C versus trabeculectomy-trabeculotomy with mitomycin C and deep sclerectomy; a 3rd trial compared combined trabeculotomy-trabeculectomy versus trabeculotomy; a 4th trial compared 1 goniotomy versus 2 goniotomies; a 5th trial compared trabeculotomy versus viscocanalostomy; and the 6th trial compared surgical goniotomy versus neodymium-YAG laser goniotomy. For IOP change and surgical success (defined by IOP achieved), none of the trials reported a difference between pairs of surgical techniques. However, due to the limited sample size for all trials (average of 10 children per trial), the evidence as to whether a particular surgical technique is effective and which surgical technique is better still remains uncertain. Adverse events, such as choroidal detachment, shallow anterior chamber and hyphema, were reported from 4 trials. None of the trials reported quality of life or economic data. These trials were neither designed nor reported well overall. Two trials were quasi-randomized trials and judged to have high risk of selection bias; 4 trials were at unclear or high risk for performance bias and detection bias; and these researchers judged 1 trial to have high risk of attrition bias due to high proportions of losses to follow-up. Due to poor study design and reporting, the reliability and applicability of evidence remain unclear. The authors concluded that no conclusions could be drawn from the trials included in this review due to paucity of data. They stated that more research is needed to determine which of the many surgeries performed for PCG are effective.

Tan and colleagues (2016) stated that childhood glaucoma is known to be one of the most challenging conditions to manage. Surgical management is more complicated than in
adults because of differences in anatomy from adults along with variations in anatomy caused by congenital and developmental anomalies, wide-ranging pathogenetic mechanisms, a more aggressive healing response, and a less predictable post-operative course. Challenges in post-operative examination and management in less co-operative children and the longer life expectancies preempting the need for future surgeries and re-interventions are also contributing factors. Angle surgery is usually the 1st-line treatment in the surgical management of primary congenital glaucoma because it has a relatively good success rate with a low complication rate. After failed angle surgery or in cases of secondary pediatric glaucoma, options such as trabeculectomy, glaucoma drainage devices, or cyclodestructive procedures can be considered, depending on several factors such as the type of glaucoma, age of the patient, and the severity and prognosis of the disease. Various combinations of these techniques have also been studied, in particular combined trabeculotomy-trabeculectomy, which has been shown to be successful in patients with moderate-to-advanced disease. Newer non-penetrating techniques, such as viscocanalostomy and deep sclerectomy, have been reported in some studies with variable results. The authors concluded that further studies are needed to evaluate these newer surgical techniques, including the use of modern minimally invasive glaucoma surgeries, in this special and diverse group of young patients.

The current UpToDate review on “Open-angle glaucoma: Treatment” (Jacobs, 2016) still does not mention viscocanalostomy and phacoviscocanalostomy as therapeutic options.

Canaloplasty for the Treatment of Uveitic Glaucoma

Lommatzsch and colleagues (2016) noted that glaucoma is a common vision-threatening complication of uveitis. In a pilot study, these investigators examined the outcome of
canaloplasty in patients with chronic uveitis and uncontrolled secondary glaucoma. This was a retrospective study of 12 patients with medically uncontrolled secondary glaucoma who underwent canaloplasty (14 treated eyes), with follow-up of greater than or equal to 24 months. The primary outcome measure was complete and qualified (requirement for anti-glaucomatous medication) surgical success rates, as determined by a reduction in IOP and the need for anti-glaucomatous medication. Secondary outcome measures were uveitis activity, best-corrected visual acuity (BCVA), vision-threatening complications, and secondary glaucoma surgery. Canaloplasty resulted in a significant IOP reduction, from a mean pre-operative baseline level of 27.1 ± 12.3 mmHg to a mean of 14.5 ± 4.3 mmHg (p = 0.01) at 24 months. Complete success (limit of 15 mmHg) was achieved in 6 patients and qualified success in 1 patient. However, failure was noted in 5 patients, 2 of whom required additional glaucoma surgery. Topical anti-glaucomatous medications were reduced from 2.7 ± 1.2 (mean ± SD) at baseline to 0.6 ± 1.2 at 24 months (p = 0.007). Uveitis activity did not increase after surgery; BCVA was not reduced; cataract progressed in 2 patients. The authors concluded that at 2-year follow-up, overall success rate was 58% (IOP less than or equal to 15 with or without medication), and surgery failed in 5 eyes, 2 eyes requiring additional glaucoma surgery. No harmful complications or worsening of uveitis activity were noted. These preliminary findings from a small (n= 12 patients) pilot study need to be validated by well-designed studies.

Viscocanalostomy / Phacoviscocanalostomy for the Treatment of Glaucoma

In a retrospective study, Qian and colleagues (2017) evaluated the long-term outcome of viscocanalostomy combined with trabeculotomy (VCT) and mitomycin C in the treatment of PCG. A total of 42 eyes of 26 patients with PCG were enrolled; IOP, corneal diameter (mm) and cup/disc (C/D) were measured before and after the surgery respectively. Follow-up
period was 30 months. The mean pre-operative IOP was 30.6 ± 7.35 mm Hg. Of the 42 eyes, 2 eyes were required conversion to trabeculectomy for the absence of Schlemm's canal. Of remained 40 eyes, 38 eyes (95 %) achieved successful IOP control. The average post-operative IOP was 11.69 ± 4.18 mm Hg at 12 months. The mean reduction was 18.91 mm Hg (p < 0.0001); 18 (75 %) eyes presented a reduction in corneal diameter, and 25 (62.5 %) eyes presented a C/D ratio reversal after the surgery. There was no serious complication in any patients over the follow-up period. The authors concluded that the findings of this study demonstrated that VCT was safe and effective in controlling infantile glaucoma, and it could be an alternative choice for infantile glaucoma procedure in the future although controlled studies with large subject numbers and long follow-up period are needed.

Ho and associates (2017) evaluated the efficacy of viscocanalostomy/phacoviscocanalostomy (VC/PVC) in lowering IOP in patients with normal tension glaucoma (NTG). These investigators carried out a retrospective electronic database review of patients who underwent VC/PVC for NTG between December 2009 and November 2011 at Stanley eye unit in Abergele Hospital. Goldmann applanation tonometry (GAT) was used for all IOP measurements, which were taken at the time of listing for surgery and at 1 day, 1 week, 1 month, then 3-monthly up to 1 year, then half-yearly up to 3 years post-operatively. Statistical analysis was performed using unpaired t-test. A p value of < 0.05 was accepted as the level of significance. Operations were performed on 94 eyes from 67 patients over the study period. The mean age at the time of surgery was 76.4 years. Pre-operative IOP was 17.75 ± 2.19 mmHg (range of 12 to 21 mmHg); 3 year follow-up showed a mean IOP of 13.41 ± 2.22 mmHg (range of 8 to 18 mmHg). By year 3, a total of 17 patients needed laser goniopuncture and 25 patients needed anti-glaucoma drops; IOP was reduced by 24.4 % at 3 years post-surgery, which was statistically significant (p < 0.0001). The authors
concluded that from these findings, which showed a 24.5% reduction in IOP at 3 years with 12% complication rate, they proposed that a logical surgical management for NTG patients would be viscocanalostomy, thereby keeping trabeculectomy as an alternative.

The authors stated that this study had several drawbacks. First, it was a retrospective study. In addition the patients in this study were from a different population, without any control group compared to other studies. This might make interpretation of these findings with other study populations difficult. Post-operative evaluation including tonometry was not masked and therefore subject to observer bias. Second, this study did not consider analysis of phakic versus pseudophakic eyes, as study participants included only 6 phakic eyes within the VC subgroup, compared to 88 pseudophakic eyes either from previous cataract operations or as a result of combined PVC surgeries. These researchers considered the number of phakic eyes to be too low to draw any statistical conclusions with sufficient power. Third, VA was not analyzed in this study. Lastly, visual field analysis in previous papers was performed using various methods, making it difficult to directly compare the visual field analysis from this study.

Corticosteroid-Induced Glaucoma

Brusini and colleagues (2018) presented the mid-term results of canaloplasty in a small cohort of patients with corticosteroid-induced glaucoma (CIG). A total of 9 eyes from 7 patients with various types of CIG in maximum medical therapy underwent canaloplasty. Patients underwent complete ophthalmic examination every 6 months. Success was defined as: post-operative IOP of less than or equal to 21 mmHg and less than or equal to 16 mmHg without ("complete success"), and with/without medical treatment ("qualified success"). The IOP reduction had to be greater than or equal to 20. The number of medications before and after surgery was considered. The
follow-up mean period was 32.7 ± 20.8 months (range of 14 to 72 months). The pre-operative mean IOP was 30.7 ± 7.2 mmHg (range of 24 to 45). The mean IOP at 6 and 12-month follow-up was 13.1 ± 2.6 mmHg, and 13.7 ± 1.9 mmHg, respectively. Qualified and complete success at 6 and 12 months was 100% for both of the 2 definitions. The number of medications used pre-operatively and at the 12-month follow-up was 4.3 ± 0.7, and 0.2 ± 1.0, respectively. No serious complication was observed. The authors concluded that the mid-term results of canaloplasty in patients with CIG appeared to be very promising. They stated that canaloplasty should be considered as a possible alternative to filtering surgery in this form of glaucoma, when medical therapy is not sufficient to maintain the IOP within reasonable limits.

Moreover, they stated that the study is currently still underway. New patients with CIG that fit the inclusion criteria are being added and follow-up data of existing patients are being constantly updated to provide long-term results and a larger cohort for the future study. Regarding these patients, multi-centric randomized studies with a larger population, where canaloplasty is compared to gold standard surgery (trabeculectomy), are needed to draw more definite and robust conclusions.

The authors stated that even the results obtained were very promising, it should be remembered that this was a non-randomized study with a small sample of patients (n = 9 eyes) without a control group. Another drawback of this study was that both eyes of 2 patients had been considered. Even if this could be incorrect from a statistical point of view, considering the small number of patients treated, these researchers decided to describe all cases they treated with this surgical procedure.

Stegmann Canal Expander for Canaloplasty
In a non-comparative, prospective study, Grieshaber and colleagues (2017) examined longer-term post-surgical safety and efficacy of a new expander for Schlemm's canal (SC). A total of 42 White patients with medically uncontrolled POAG underwent primary canaloplasty with greater than 2-year follow-up. The bleb-independent procedure comprised catheter-assisted canaloplasty and implantation of 2 Stegmann Canal Expanders to maintain trabecular distension and canal patency over 180°; IOP, glaucoma medication use and complications were assessed. Mean IOP was 26.8 ± 5.6 mmHg pre-surgery, 12.8 ± 1.5 mmHg at 6 months, 13.2 ± 1.2 mmHg at 12 months and 13.3 ± 2.5 mmHg at 24 months (p < 0.001). Rate of complete success, defined as IOP less than or equal to 21, less than or equal to 18, and less than or equal to 16 mmHg and a ≥ 30 % IOP reduction, was 85 % (95 % CI: 0.76 to 0.95), 85 % (0.76 to 0.95) and 82 % (0.70 to 0.96) at 12 months and 83 % (0.73 to 0.94), 80 % (0.70 to 0.92) and 80 % (0.70 to 0.92) at 24 months. Pre-operative factors were not significant predictors of less than or equal to 16 mmHg IOP reduction: IOP (hazard ratio [HR]: 0.68; 95 % CI: 0.44 to 1.04; p = 0.08), mean visual defect (1.06; 0.90 to 1.20; p = 0.47), number of medications (0.59; 0.17 to 2.14; p = 0.42) and age (0.96; 0.87 to 1.13; p = 0.41). Number of medications dropped from 2.8 ± 0.4 pre-surgery to 0.2 ± 0.5 post-surgery (p < 0.001). Mean pre-operative BCVA was 0.19 ± SD 0.21 (range of 0 to 1.6), and logMAR was similar to 0.23 ± 0.16 (range of 0 to 1.6; p = 0.42) after a mean follow-up of 27.4 months.

Complications included peripheral Descemet's membrane detachment (7.2 %) and trimming of the expander (4.7 %) during surgery, and transient microhyphema (23.8 %) and IOP elevation (7.2 %) post-surgery. The authors concluded that canaloplasty with the Stegmann Canal Expander was a safe and effective procedure to reduce IOP in White patients with moderate-to-advanced POAG; however, comparative, randomized trials are needed to draw final conclusions.
The authors stated that in spite of the promising findings, the results of this study need to be interpreted with caution due to study limitations. First, the study design was un-masked and non-comparative; thus, it lacked a control group, namely standard canaloplasty. Second, the Stegmann Canal Expander has only been evaluated in White patients with POAG undergoing primary surgery, thus, the results could not be extrapolated to patients of other ethnicity, to eyes with other types of glaucoma, or to eyes with previous surgery, which could have impeded cannulation of SC and implantation of the device. Furthermore, it should be noted that the surgeons in this study had many years of experience with non-penetrating glaucoma surgery, and thus, the results did not include the long learning curve related to the dissection of the scleral flaps and preparation of the Descemet's membrane window.

Grieshaber (2018) stated that the concept of canaloplasty is to increase aqueous egress through all structures that control the aqueous outflow, such as the trabecular meshwork, SC, and collector channels, by visco-modulation and by placing of a suture stent into the canal. Clinical studies showed canaloplasty to be safe and efficient in lowering the IOP; however, proper knotting of the tensioning suture is technically challenging and even impossible if circumferential cannulation cannot be achieved. Furthermore, protrusion of the suture stent is a potential lifelong risk. The specific design of the Stegmann Canal Expander allows a permanent expansion of the canal and distension of the trabecular meshwork; 2 expanders are implanted on either side of the surgically created ostium of SC to treat half of the circumferential outflow system. The author described the technique step-by-step, provided the clinician with surgical pearls, and highlighted the management of adverse events (AEs). This investigator noted that technically, implantation of the Stegmann Canal Expander was simple and did not require a long learning curve, compared to placing and knotting a tensioning suture. Most issues were related to the 2-flap dissection technique (deep sclerectomy technique) and not to implantation of the
Stegmann Canal Expander; and IOP reduction without medications to the low teens could be achieved. The authors concluded that Stegmann Canal Expander is a novel micro-device that has the potential to make canaloplasty a simplified, more controlled, and reproducible surgical procedure.

Furthermore, an UpToDate review on “Open-angle glaucoma: Treatment” (Jacobs, 2019) does not mention canal expander as a management tool.

Combined Phacoemulsification and Viscocanalostomy with Ologen Implant

In a prospective, interventional, randomized clinical study, Gad and colleagues (2019) examined the efficacy of the biodegradable collagen implant Ologen as an adjuvant in phaco-viscocanalostomy in patients with co-existing cataract and POAG. This trial entailed patients with co-existing cataract and glaucoma who were randomized to receive either phaco-viscocanalostomy (Phacovisco group) (39 eyes) or phaco-viscocanalostomy with Ologen implant (OloPhacovisco group) (40 eyes). Follow-up period was 2 years; Nd:YAG laser gonio-puncture was performed in cases where the IOP was elevated above 21 mmHg after discontinuation of corticosteroid eye drops at any follow-up visit. No significant operative or post-operative complications (other than failure) were encountered in either group. At 2 years follow-up, the mean IOP level was statistically significantly decreased in the OloPhacovisco group (p = 0.02) and complete success occurred in 23 eyes (59.0 %) in the Phacovisco group and in 32 eyes (80.0 %) in the OloPhacovisco group. There was a statistically significant higher success rate regarding complete success in patients that received Ologen implant (p = 0.04). The authors concluded that Ologen implant improved the success rate of phaco-viscocanalostomy. Moreover, these researchers stated that larger studies with longer follow-up periods are needed to confirm the safety and efficacy of this device in viscocanalostomy. The main drawbacks of this study
were the relatively small sample size (40 eyes in the OloPhacovisco group) and short follow-up period (2 years).

**CPT Codes / HCPCS Codes / ICD-10 Codes**

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td><strong>CPT codes covered if selection criteria are met:</strong></td>
<td></td>
</tr>
<tr>
<td>66174</td>
<td>Transluminal dilation of aqueous outflow canal; without retention of device or stent [not covered with glaucoma gene therapy]</td>
</tr>
<tr>
<td>66175</td>
<td>with retention of device or stent [not covered with glaucoma gene therapy]</td>
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<tr>
<td><strong>CPT codes not covered for indications listed in the CPB:</strong></td>
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</tr>
<tr>
<td>66170</td>
<td>Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery [not covered if reported for viscocanalostomy or phacoviscocanalostomy]</td>
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<td><strong>ICD-10 codes covered if selection criteria are met:</strong></td>
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<tr>
<td>H40.1110 - H40.1194</td>
<td>Primary open angle glaucoma</td>
</tr>
<tr>
<td><strong>ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):</strong></td>
<td></td>
</tr>
<tr>
<td>H40.001 - H40.10x+, H40.121+ - H42</td>
<td>Glaucoma</td>
</tr>
<tr>
<td>H44.511 - H44.519</td>
<td>Absolute glaucoma</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>----------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Q15.0</td>
<td>Congenital glaucoma</td>
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<tr>
<td>T38.0X1A</td>
<td>Poisoning by, adverse effect of and underdosing of glucocorticoids and synthetic analogues [corticosteroid-induced glaucoma]</td>
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**Combined phacoemulsification and viscocanalostomy with Ologen implant:**

**CPT codes not covered for indications listed in the CPB:**

**Viscocanalostomy with Ologen implant - no specific code:**

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<tr>
<td>66982</td>
<td>Exacapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage [phacoemulsification and viscocanalostomy with Ologen implant]</td>
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</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E08.36</td>
<td>Diabetes mellitus due to underlying condition with diabetic cataract</td>
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<tr>
<td>E09.36</td>
<td>Drug or chemical induced diabetes mellitus with diabetic cataract</td>
</tr>
<tr>
<td>E10.36</td>
<td>Type 1 diabetes mellitus with diabetic cataract</td>
</tr>
<tr>
<td>E11.36</td>
<td>Type 2 diabetes mellitus with diabetic cataract</td>
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<td>E13.36</td>
<td>Other specified diabetes mellitus with diabetic cataract</td>
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<tr>
<td>H25.011 - H25.9</td>
<td>Age-related cataract</td>
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<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>H26.001  - H26.9</td>
<td>Other cataract</td>
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<tr>
<td>H28</td>
<td>Cataract in diseases classified elsewhere</td>
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<td>H40.1110 - H40.1194</td>
<td>Primary open angle glaucoma</td>
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<tr>
<td>Q12.0</td>
<td>Congenital cataract</td>
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<tr>
<td>Z98.4    - Z98.49</td>
<td>Cataract extraction status</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


14. O'Brart DP, Shiew M, Edmunds B. A randomised, prospective study comparing trabeculectomy with viscocanalostomy with adjunctive antimetabolite usage for the management of open angle glaucoma.


43. Ayyala RS, Chaudhry AL, Okogbaa CB, Zurakowski D. Comparison of surgical outcomes between

44. Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma. 2012;21(2):129-134.


46. Jacob DS. Open-angle glaucoma: Treatment. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2014.


59. Jacob DS. Open-angle glaucoma: Treatment. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2016.


70. Jacobs DS. Open-angle glaucoma: Treatment. UpToDate [online serial], Waltham, MA: UpToDate; reviewed February 2019.

There are no amendments for Medicaid.