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Subject **Viscocanalostomy and Canaloplasty**

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Corneal Pachymetry
Retinal Imaging for Diabetic Retinopathy

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Coverage Policy

CIGNA does not cover viscocanalostomy (including phacoviscocanalostomy) or canaloplasty for the treatment of glaucoma because they are considered experimental, investigational or unproven.

General Background

Glaucoma refers to a group of optic neuropathies typically characterized by visual field loss and structural damage to the optic nerve fiber. The primary glaucomas, those which are not due to other systemic or eye disease, are classified as open-angle glaucoma (i.e., chronic) and angle closure glaucoma (i.e., acute glaucoma, narrow-angle glaucoma, or closed-angle glaucoma). Open-angle glaucoma (OAG) is the most common form of glaucoma, occurs gradually over time, and is asymptomatic. It is caused by poor drainage of the aqueous humor, resulting in increased pressure. Angle closure glaucoma, affecting nearly half a million people, may be the result of a congenital malformation with a narrow angle between the iris and cornea. Examination for glaucoma may include: measurement of intraocular pressure (IOP), inspection of the drainage angle of the eye, evaluation for optic nerve damage, and visual field testing. Symptoms of glaucoma include blurred vision, rainbow-colored halos around lights, eye pain, headaches, nausea, and vomiting. For most patients, glaucoma is characterized by elevated IOP. However, some types of the disease show evidence of optic nerve damage without elevated IOP. A particular danger posed by glaucoma is that many people do not experience obvious symptoms until significant damage has occurred to the optic nerve head and retinal nerve fiber layer. Consequently, treatment is often not initiated early enough to reduce or prevent vision loss.

Currently, IOP is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of visual field loss. IOP of 14–17 millimeters of mercury (mmHg) is considered normal, but up to 20 mmHg may be within the normal range. IOP over 22 mmHg warrants attention.

Glaucoma cannot be cured, but treatment can slow its progression. In most cases, medication, taken orally or applied topically, is the first treatment of choice. A variety of medications, including beta-adrenergic receptor antagonists, carbonic anhydrase inhibitors, and prostaglandin analogs can be used to treat glaucoma. These pharmacological agents reduce IOP either by decreasing intraocular fluid production or by increasing ocular fluid efflux. Most patients experience mild or no side effects. These medications must be used continuously for as long as control of IOP is required. For patients who are unwilling or unable to rely on available medications, surgical treatment, such as laser trabeculoplasty, is an option. This procedure uses pulses of laser light to increase the porosity of the trabecular network, a primary pathway for the drainage of intraocular fluid. Although laser trabeculoplasty reduces IOP initially, its effects diminish over the course of a few years, and repetition of the procedure may not be beneficial.

An ocular surgery that provides more durable relief of excessive IOP is trabeculectomy. This guarded filtration procedure involves creating a new channel through the sclera that allows fluid drainage via a filtering bleb into the subconjunctival space, resulting in subsequent IOP reduction. To prevent closure of the new channel after a trabeculectomy, patients often undergo treatment with 5-fluorouracil or mitomycin-C, which inhibits fibroblast proliferation. Although trabeculectomy has become the current gold standard among the nonpenetrating, filtering surgical techniques for reduction of IOP, it can result in extremely low IOP, causing serious ocular damage. Reported complications of trabeculectomy include hyphema, fibrinous uveitis, hypotony, bleb-related complications (e.g., delayed leads), and cataract formation.

Other nonpenetrating surgical procedures, such as viscocanalostomy and canaloplasty, have been developed in an attempt to provide the benefits of trabeculectomy with fewer risks. The goal of viscocanalostomy is to provide durable normalization of IOP, preventing the progression of glaucoma without exposing patients to the dangers of subnormal IOP. Viscocanalostomy involves deep scleral dissection, exposing of the Schlemm's canal, excising the scleral flap, and creating a scleral reservoir. An injection of a viscoelastic, biocompatible polymer, such as high-molecular-weight sodium hyaluronate opens the ostia of the canal, allowing passage of fluid from the anterior chamber into the canal. According to proponents of this technique, proper placement of the viscoelastic polymer dilates a section of Schlemm's canal. After the polymer injection, suturing closes the scleral incisions. The procedure avoids full-thickness penetration into the anterior chamber of the eye.

Viscocanalostomy is also being proposed for use in conjunction with phacoemulsification (i.e., the removal of the inner nucleus of the lens capsule by breaking up the nucleus into tiny pieces for abstraction) during cataract surgery. The combination of cataract surgery and viscocanalostomy is called phacoviscocanalostomy and is being proposed for use in the place of phacotrabeculectomy. The combined surgery is used for patients who require surgical intervention for the treatment of cataract and glaucoma. Compared to cataract surgery alone, phacoviscocanalostomy is proposed to provide better long-term control of IOP, protection from postoperative IOP spikes and prevention of late-failure trabeculectomy (Kobayashi and Kobayashi, 2007; Shoji, et al., 2007; Park, et al., 2006; Wishart, et al., 2006).

Canaloplasty is a nonpenetrating procedure, similar to viscocanalostomy, which aims to lower the IOP by permanently stretching the trabecular meshwork and restoring the natural drainage of fluid out of the eye. Compared to viscocanalostomy, canaloplasty adds a step that keeps the ostia open and stretches the trabecular network permanently. The surgery may be performed under local or general anesthesia, and ultrasound is used to identify and visualize the canal during the procedure. Canaloplasty involves making a flap into the sclera, exposing Schlemm's canal, advancing a microcatheter or microcannula through the entire length of the canal, and injecting viscoelastic to dilate the canal. A suture is tied at the distal end of the canal, and as the microcatheter is withdrawn, the suture is guided out of the canal and tied in a loop encircling the inner wall of the canal. Tightening of the suture distends the trabecular meshwork inward and keeps the canal open to allow drainage (Goldberg, 2006; Koerber, 2007; National Institute for Health and Clinical Excellence [NICE], 2008b).

Literature Review - Viscocanalostomy

Early published reports from five randomized controlled trials (RCTs) compared viscocanalostomy to trabeculectomy, the gold standard surgical treatment (Jonescu-Cuypers, et al., 2001; Lüke, et al., 2002; O'Brart, et al., 2002; Carassa, et al., 2003; Kobayashi, et al., 2003). The medical evidence is conflicting, and only one of

these studies (Carassa, et al., 2003) found viscocanalostomy to be as effective as trabeculectomy for control of IOP. In the other four studies, although viscocanalostomy provided IOP control for up to 64% of eyes, trabeculectomy provided statistically significant decreases in IOP and increases in IOP control compared to viscocanalostomy. Two studies reported that trabeculectomy was associated with a statistically significant increase in hypotony, hyphema and formation of a flat or shallow anterior chamber (i.e., a complication of choroidal detachment), while the data regarding bleb formation were conflicting (Lüke, et al., 2002; O'Brart, et al., 2002). Another study found that trabeculectomy was associated with a higher incidence of early or transient complications, including hyphema, transient anterior chamber shallowing, and a significantly higher incidence of cataracts after trabeculectomy than after viscocanalostomy (Kobayashi, et al., 2003). However, none of the other reviewed studies confirmed this observation.

A prospective controlled study (O'Brart, et al., 2004) randomized 45 patients/50 eyes with uncontrolled OAG to receive either a trabeculectomy or a viscocanalostomy procedure. All groups had significantly reduced IOP immediately postoperatively. The results of viscocanalostomy were encouraging at six months. However, at a later follow-up (i.e., mean 20 months) the complete success rate (IOP < 21 mmHg without medication) for trabeculectomy (68%) was superior to that for viscocanalostomy (34%). Additionally, significantly fewer medications were required postoperatively with trabeculectomy to maintain an IOP < 21 mmHg. Early postoperative complications were more common with trabeculectomy but were transient. Late postoperative cataract formation was similar between the two groups.

In a three-year prospective, randomized clinical trial (Yalvac, et al., 2004), 50 patients/50 eyes with uncontrolled primary OAG were randomly assigned to receive either a trabeculectomy or a viscocanalostomy procedure. The complete success rate (IOP 6–21 mmHg without medication) at three years was reported to be 55.1% in the trabeculectomy group and 35.0% in the viscocanalostomy group ($p>0.5$). The mean number of medications was also lower in the trabeculectomy group at three years. Early complications were more common in the trabeculectomy group but were transient. There was a lower incidence of cataract formation in the viscocanalostomy group.

A prospective, randomized study by Yarangümeli, et al. (2004) compared the results of trabeculectomy with the results of viscocanalostomy in patients with medically uncontrolled bilateral, symmetrical, high-tension glaucoma. The study population was comprised of 44 eyes/22 patients (i.e., seven primary open-angle glaucoma; 11 pseudoexfoliative glaucoma; and four primary chronic, angle closure glaucoma). One eye was randomly selected for trabeculectomy or viscocanalostomy, and two weeks later the other eye was treated with the remaining surgical procedure. Outcomes were measured in terms of pre- and postoperative IOP levels, complications, pre- and postoperative medication, conjunctival blebs, and surgical success rates (i.e., complete surgical success, IOP \leq 18 mmHg without medications). Reported outcomes included: 1) significantly lower IOP with trabeculectomy; 2) no significant difference in complications between the two groups; 3) no significant difference in pre- and postoperative medications between the groups; and 4) various types of postoperative blebs observed in all eyes. After 18 months, complete success rates were 64% and 59% for trabeculectomy and viscocanalostomy, respectively ($p=0.750$).

Cheng et al. (2004) conducted a meta-analysis, which included 37 articles, and compiled data to determine the overall success rate of nonpenetrating trabecular surgeries (i.e., deep sclerectomy alone [n=14], deep sclerectomy with collagen implant [n=10], deep sclerectomy with reticulated hyaluronic acid implant [n=9] and viscocanalostomy [n=8]). Studies were included in which patients with medically uncontrolled open-angle glaucoma had been treated with nonpenetrating surgery. The complete success rate (i.e., IOP < 21 mmHG without the use of medication) calculated for viscocanalostomy from the eight articles (i.e., case series) (n=447 eyes) was 72.0%.

A small, prospective, interventional, noncomparative case series by Stangos et al. (2005) assessed the safety and efficacy of viscocanalostomy in medically uncontrolled juvenile, open-angle glaucoma. Viscocanalostomy was performed on 20 consecutive eyes. Outcomes were based upon visual field deterioration, optic neuropathy progression, and pre- and postoperative IOP with and without the use of medication. Thirty-six months postoperatively, 16 cases were considered an overall success, and four cases failed. The authors, recognizing this is a small study, suggested viscocanalostomy could be considered safe and effective in this population, but further randomized, comparative studies were indicated.

A 2006 study (Noureddin, et al.) included eight consecutive patients with newly diagnosed bilateral primary congenital glaucoma who were treated with either trabeculotomy or viscocanalostomy. The more severely affected eye was randomly assigned to either trabeculotomy or viscocanalostomy. The second eye underwent the alternate surgery. Mean IOP values in the trabeculotomy group included a baseline value of 34.0 ± 2.6 mmHg and a 16-month postoperative value of 14.8 ± 2.9 mmHg ($p < 0.001$) compared to 32.3 ± 4.1 mmHg at baseline and 12.9 ± 3.9 mmHg 12-months postoperatively ($p < 0.001$) in the viscocanalostomy group. The differences in the mean baseline IOP and the one-week, and six-month values were also statistically significant for both groups ($p < 0.001$ at each visit). There was also a significant decrease in the vertical and horizontal corneal diameters postoperatively in the trabeculotomy eyes ($p = 0.064$; $p = 0.009$, respectively), as well as with the viscocanalostomy eyes ($p = 0.08$; $p = 0.019$, respectively). There were no statistical differences between the IOP levels between the groups at each visit ($p > 0.1$). Complication in the trabeculotomy group included hyphema, vitreous loss and choroidal detachment. Hyphema, button hole, and Descemet's detachment were reported in the viscocanalostomy group. Limitations of the study include the small patient population and short-term follow-up.

Gilmour et al. (2007) conducted an RCT to compare the safety and effectiveness of viscocanalostomy compared to trabeculectomy. The study included 43 patients, age greater than 50 years, with a diagnosis of primary OAG (one patient had pseudoexfoliation glaucoma) with indications for surgery due to intolerance to, or inadequate response to, or non-compliance to medical therapies. Patients were randomly assigned to either viscocanalostomy ($n = 22$ eyes) or trabeculectomy ($n = 21$). Follow-up visits occurred at day one, weeks one and two, months one and three, and every six months thereafter; mean follow-up was 40 months (range six to 60 months). The trabeculectomy group experienced a greater decrease in IOP than the viscocanalostomy group, and the difference was maintained throughout the study. At the last follow-up, ten trabeculectomy patients (42%) experienced a successful outcome (i.e., an IOP less than 18 mmHg) without postoperative treatment compared to five viscocanalostomy patients (21%). The trabeculectomy group had a statistically significant greater decrease in IOP compared to viscocanalostomy at months 12 ($p < 0.001$), 24 ($p < 0.001$), 30 ($p = 0.030$), 36 ($p = 0.001$) and 48 ($p = 0.018$). Postoperatively, the mean number of treatments in the trabeculectomy group dropped from 1.38 to 0.67 compared to 1.43 to 1.25 in the viscocanalostomy group ($p = 0.111$). There were no significant differences between the two groups in best corrected visual acuity. Both groups experienced wound leakage, and anterior chamber fibrinous membranous formation. The trabeculectomy group also experienced early postoperative complications including hypotony ($n = 5$), choroidal detachment ($n = 2$) and one occurrence of hyphema, hypotonous, and maculopathy which did not have a significant influence on outcomes. Neither group experienced late complications. More bleb manipulations and antimetabolites were needed in the trabeculectomy group postoperatively. A limitation of the study is the small patient population and the number of patients lost to follow-up.

Hondur et al. (2008) performed a meta-analysis of the available evidence for nonpenetrating glaucoma surgery, including deep sclerectomy ($n = 22$) and viscocanalostomy ($n = 14$). The literature was examined for treatment efficacy according to the severity of glaucoma. The number of cases, preoperative and postoperative mean IOP, visual field parameters, cup/disk (C/D) ratio, and percentage of cases achieving target IOP were noted. Most of the reviewed studies accepted 21 mm Hg as the target IOP. Data related to postoperative goniopuncture and needling with antimetabolite application were also noted. In general, the mean follow-up of the studies was in the range of three years. The percentage of cases achieving ≤ 21 mm Hg ranged from 36.8–51.1% after viscocanalostomy. With lower set IOP targets, the rates of success varied between 10% and 67% for viscocanalostomy. Several factors were identified that may account for the wide variation in the success rates of nonpenetrating glaucoma surgery including the diversity of the variations in surgical techniques, variation in success criteria and target IOPs, and differences in follow-up lengths. In the opinion of the authors, the analysis suggested that nonpenetrating glaucoma surgery can achieve IOP reduction, however longer-term studies with data related to glaucoma severity and proper target IOPs are needed (Hondur, et al., 2008).

Literature Review – Phacoviscocanalostomy

Park et al. (2006) compared the outcomes of phacoviscocanalostomy (VCS) ($n = 110$) to phacotrabeculectomy (LOT) ($n = 110$) in patients with OAG. Mean preoperative IOP in the VCS group was 20.2 ± 3.5 mmHg compared to 20.9 ± 3.5 mmHg in the LOT group ($p = 0.3377$). The mean VCS IOP at 12 months postoperatively was 15.0 ± 3.0 ($n = 100$) compared to 16.3 ± 2.9 mmHg ($p = 0.0088$) in the LOT group ($n = 95$). However, the statistical difference was not persistent at the two- and three-year follow-ups ($p = 0.5203$ and $p = 0.4993$, respectively). Both groups required less medication postoperatively ($p < 0.001$), with the VCS group using less antiglaucoma medications than the LOT group ($p < 0.0001$ at one month; $p = 0.13$ at 36 months). Two VCS eyes and three LOT

eyes required trabeculectomy during the three year follow-up period. Hyphema and IOP spike occurred in more LOT patients ($p < 0.001$ each) than in VCS patients. Microperforation of the Descemet's membrane ($n=19$) and iris incarceration ($n=6$) occurred in the VCS group, but not the LOT group. There were no significant differences in visual acuities between the two groups. Limitations of the study include the retrospective study design and the number of patients lost to follow-up.

Wishart et al. (2006) evaluated the outcomes of 165 consecutive eyes treated with phacoviscocanalostomy in patients with cataract and medically uncontrolled glaucoma. Follow-up ranged from 12–90 months, with a mean 38.7 ± 19.3 months and a minimum of 12 months. One day postoperatively, the mean IOP dropped from 24.1 ± 5.1 mmHg to 13.8 ± 8.1 mmHg ($p < 0.001$) which was persistent to the final follow-up. At the final follow-up, 48.5% of the eyes had achieved complete success (i.e., IOP reduction of 30% or more). At five years, 80.6% of eyes had an IOP of 21 mmHg or less without the use of medication. Mean IOP was 16.6 ± 4.4 mmHg at the 72-month follow-up ($n=17$) compared to 13.8 ± 8.1 mmHg at one day postoperative. The mean IOP reduction was 7.9 mmHg at the last follow-up. Medication usage dropped from a mean per eye of 2.5 ± 0.9 mmHg preoperatively to 0.1 ± 0.5 at last follow-up ($p < 0.001$). An IOP reduction of more than 30% without medication (i.e., complete success) was achieved in 48.5% of eyes. Complications included zonular dehiscence with no vitreous loss, posterior capsule tear with vitreous loss, peripheral choroidal detachment not affecting the macula, a tear of the trabecular meshwork-Descemet's membrane (TDW) requiring peripheral iridotomy, and microperforation of the TDW with no iris prolapse. Loss of visual acuity in five patients was attributed to progressive glaucoma and preexisting age-related macular degeneration. No long-term bleb-related complications occurred. Limitations of the study include the lack of randomization and a control group, and the number of patients lost to follow-up.

Kobayashi and Kobayashi (2007) conducted a trial including 40 patients who had primary OAG. One eye was randomized to undergo either phacotrabeculectomy ($n=20$) or phacoviscocanalostomy ($n=20$). When both eyes were eligible, the right eye became the study eye. Following surgery, goniotomy was performed in the phacoviscocanalostomy group if the IOP was not low enough and laser suture lysis was performed in the phacotrabeculectomy group if the bleb was flat or the IOP was not low enough. Mitomycin C was used in the trabeculectomy group postoperatively. Mean baseline IOP in the phacoviscocanalostomy group was 24.0 ± 2.0 mmHg compared to a 12-month postoperative value of 14.9 ± 3.0 mmHg. In the phacotrabeculectomy group, mean baseline IOP was 23.7 ± 2.6 mmHg compared to 14.1 ± 4.4 mmHg, 12 months postoperatively. There were no significant differences in the IOP between the two groups at anytime during the one year follow-up, but the values were consistently lower in the phacotrabeculectomy group. At 12 months, an IOP of 20 mmHg or less was achieved by 17 viscocanalostomy patients and 16 trabeculectomy patients. Complications included intraoperative microperforation of Descemet's membrane in the viscocanalostomy group and flat/shallow anterior chamber and hypotony in the trabeculectomy group. Although better in the phacoviscocanalostomy group, the difference in the mean best corrected visual acuity between the two groups was not statistically significant. The authors noted that the small patient population was a limitation of the study that precluded assessment of safety and that a "masked study design might have reduced observer bias." The short-term follow-up is also a limitation of the study.

Shoji et al. (2007) compared the outcomes of phacoviscocanalostomy (PV) ($n=31$) to cataract surgery only (CSO) ($n=35$) in consecutive patients, age range 54–87 years, with normal-tension glaucoma (NTG) with an IOP not exceeding 21 mmHg. Follow-up ranged from 7–78 months; mean 34.9 ± 19.8 months. Mean baseline IOP was 17.2 ± 1.6 mmHg in the PV group and 16.7 ± 1.4 mmHg in the CSO group. The PV group experienced a significant reduction in mean IOP one month postoperatively (12.3 ± 2.7 mmHg; $p < 0.001$) which was persistent to the 36-month follow-up (14.1 ± 1.6 mmHg; $p < 0.001$; $n=16$). The CSO group experienced a significant reduction at the one-month and two-month follow-up visits (15.0 ± 2.4 mmHg; $p < 0.001$ and 15.2 ± 2.4 mmHg; $p < 0.001$, respectively); thereafter the difference was not significant. At 36 months, the CSO mean IOP was 15.6 ± 3.4 mmHg ($p=0.564$) ($n=20$). The differences in the decreased IOP between the two groups were significant at all times ($p < 0.05$). Postoperatively, the PV group medication requirement dropped from a mean 1.0 at baseline to 0.4 at the 36-month follow-up compared to a mean 0.8 baseline for the CSO group and 0.8 at the 36-month follow-up. Complications in the PV group included intraoperative microperforation of Descemet's membrane, and postoperative fibrin reaction, bleb formation and prolonged hyphema. In the CSO group, there was one occurrence each of fibrin reaction and IOP spike. The CSO group experienced significantly more adverse visual outcomes ($p=0.24$). Author-noted limitations included: the use of different visual field assessment tools, the long latency associated with NTG development and the four-year duration of the trial may have had an affect on the

visual fields, exclusion of eyes with severe damage, and the retrospective study design. Other limitations of the study include the small patient population, short-term follow-up, and the loss of patients to follow-up.

Literature Review – Canaloplasty

Lewis et al. (2007) reported on an ongoing 14-center, open-label study conducted in the United States and Germany to demonstrate the safety and efficacy of canaloplasty. All patients were candidates for glaucoma or cataract and glaucoma surgery. IOP-lowering medications were not discontinued prior to enrollment. Diagnoses included primary OAG, pigmentary dispersion glaucoma, exfoliation glaucoma or primary OAG mixed with another type of glaucoma. IOPs were 16 mmHg or higher within 60 days of surgery (i.e., baseline) and patients had a maximum historical IOP of 21 mmHg or greater. Only one eye per patient was included. Data was analyzed in different subgroups of patients and treatment options. Efficacy analysis of canaloplasty was based on two subgroups. Group 1 (n=94) included all patients and group 2 (n=74) included only patients with successful suture implantation. Other subgroups were analyzed evaluating canaloplasty alone vs. canaloplasty performed with cataract procedures and the relationship of trabecular meshwork distension to IOP. The mean baseline IOP, three-month IOP, six-month IOP and 12-month IOP for group 1 were 24.7 ± 4.8 mmHg, 16.5 ± 4.9 mmHg, 15.7 ± 4.2 mmHg, and 15.3 ± 3.9 mmHg, respectively compared to 23.9 ± 4.3 mmHg, 16.1 ± 4.7 mmHg, 15.6 ± 4.0 mmHg, and 15.3 ± 3.8 mmHg, respectively for group 2. The number of subjects at each postoperative follow-up decreased for each group with 59 vs. 48 subjects remaining in group 1 and group 2, respectively at 12 months. There was a statistically significant difference in baseline and follow-up visits ($p < 0.0001$) in groups 1 and 2. Of the 27 patients who had combined surgery, 20 experienced successful suture placement. The mean IOP of the combined group dropped by 46% from baseline compared to 33% in the canaloplasty-only group. The differences in the IOP measurements of the combined group and the canaloplasty group were significant at the six-month and 12-month follow-up visits ($p = 0.0002$, $p = 0.005$, respectively). For all patients, medication usage dropped from 1.9 ± 1.0 at baseline to 0.6 ± 0.9 at twelve months (n=59). The difference in medication usage between groups 1 and 2 was statistically significant ($p < 0.001$). Vision loss occurred in 19 patients at one week. Most loss of acuity had returned to normal by the third postoperative month. Three patients experienced hyphema and elevated IOP, while one patient each suffered Descemet's membrane detachment, hypotony, choroidal effusion and exposed closure suture. Four patients were converted to trabeculectomy due to poor IOP control following canaloplasty. Author-noted limitations included the lack of randomization and a control group, and the learning curve associated with performance of the procedure. Other limitations include the small, heterogeneous patient population, short-term follow-up, and the number of patients lost to follow-up.

Shingleton et al. (2008) evaluated the safety and efficacy of canaloplasty combined with clear corneal phacoemulsification and posterior chamber intraocular lens (IOL) implantation for the treatment of OAG. Adult patients with qualifying treated preoperative IOP of at least 21 mm Hg or higher and open angles were eligible. Data from 54 eyes that had combined glaucoma and cataract surgery performed by 11 surgeons at nine study sites were presented in this interim analysis. The primary endpoints included mean IOP and mean number of glaucoma medications at the three, six, and 12 months of follow-up. Secondary endpoints included the use of glaucoma medications and visual acuity. Two patients (4%) were lost to follow-up during the postoperative period. At the three-, six-, and 12-month follow-up, 85%, 89%, and 74% of eyes were examined respectively. 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 postoperative 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 ($p < 0.0001$). Medication use dropped to a mean of 0.2 ± 0.4 per patient at 12 months ($p < 0.0001$). Surgical complications 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 four eyes (7.3%) one day postoperatively. Study limitations include a lack of randomization and a control group. It was also acknowledged that the learning curve inherent to this and many new surgical procedures also played a key role in outcomes, as sites with larger numbers of enrolled patients had greater success with the procedure.

Technology Assessment

An interventional procedure guidance by the National Institute for Health and Clinical Excellence (NICE), a United Kingdom government-funded organization, states that canaloplasty for the treatment of primary open-angle glaucoma should be used only in the "context of research or formal prospective data collection." They state that the current evidence on the safety and efficacy of canaloplasty is inadequate in quality and quantity (NICE, 2008c).

Professional Society Statements

The American Academy of Ophthalmology (AAO) has published practice guidelines on the management of primary open-angle and angle closure glaucoma (AAO, 2005). In their discussion of the treatment for primary open-angle glaucoma, AAO recognizes viscocanalostomy as being a nonpenetrating surgery used by some physicians as an alternative to trabeculectomy, but they state that the precise role of nonpenetrating surgeries (i.e., viscocanalostomy and nonpenetrating deep sclerectomy) is yet to be determined.

The published guidelines by The Royal College of Ophthalmologists (2004) for the "Management of Open-Angle Glaucoma and Ocular Hypertension" states there is insufficient evidence to support the routine use of viscocanalostomy. There are no studies showing that viscocanalostomy has few complications while maintaining good IOP.

Summary

Viscocanalostomy and canaloplasty are nonpenetrating surgical procedures proposed for the treatment of glaucoma in an attempt to preclude some of the complications associated with trabeculectomy, the gold standard surgery. Intraocular pressure (IOP) is the most crucial factor in controlling glaucoma and preventing irreversible nerve damage and resulting blindness, and is, therefore, a consistent outcome measurement in clinical trials. Most studies have found that trabeculectomy lowers IOP more significantly than viscocanalostomy, demonstrating better or superior IOP control. The medical evidence indicates that viscocanalostomy is not as effective as trabeculectomy in reducing IOP in patients with glaucoma. Some studies reported that viscocanalostomy was associated with a statistically significant decrease in the incidence of certain complications relative to trabeculectomy, but most of the complications of trabeculectomy were transient and/or minor. The evidence in the available peer-reviewed scientific literature does not support the efficacy of viscocanalostomy.

Evidence in the published, peer-reviewed scientific literature is limited and does not support the safety and efficacy of the use of canaloplasty for the treatment of glaucoma. The available study involves a small heterogeneous patient population with short-term follow-up and lack of a comparison to accepted methods of treatment.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
0176T	Transluminal dilation of aqueous outflow canal; without retention of device or stent
0177T	Transluminal dilation of aqueous outflow canal; with retention of device or stent

ICD-9-CM Diagnosis Codes	Description
365.00-365.9	Glaucoma

*Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	3/15/2008	0035	Viscocalostomy and Canaloplasty

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