9.03.26 Viscocanalostomy and Canaloplasty

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**Viscocanalostomy and Canaloplasty**

**Summary**

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, alternative surgical treatments such as transluminal dilation by viscocanalostomy and canaloplasty are being evaluated for patients with glaucoma.

The evidence for viscocanalostomy in individuals who have open-angle glaucoma and have failed medical therapy includes small randomized controlled trials (RCTs) that compare viscocanalostomy with trabeculectomy. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. Meta-analysis of these trials has indicated that trabeculectomy has a greater IOP-lowering effect than viscocanalostomy. Reduction in IOP was greater with canaloplasty than viscocanalostomy in a small within-subject comparison. Viscocanalostomy has not been shown to be as good as or better than established alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for canaloplasty in individuals who have open-angle glaucoma and have failed medical therapy includes an RCT and case series. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. The RCT found a significantly higher complete success rate with trabeculectomy than with canaloplasty, but a higher complication rate as well. The qualified success rate (with medication) was similar between the 2 groups. A systematic review found that canaloplasty provided modest IOP reduction (to \(\approx 16\) mm Hg) with minor intraoperative or postoperative complications. Further RCT evidence is required to corroborate results of this single trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

**FDA REGULATORY STATUS**

The iT Track (iScience Interventional) received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2004 as a surgical ophthalmic microcannula that is indicated for the general purpose of “fluid infusion and aspiration, as well as illumination, during surgery.” In 2008, the iT Track received FDA-clearance for the indication of “catheterization and viscodilation of Schlemm’s canal to reduce intraocular pressure in adult patients with open angle glaucoma.” FDA product code: MPA
**POLICY STATEMENT**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Canaloplasty may be considered medically necessary as a method to reduce intraocular pressure in patients with chronic primary open-angle glaucoma under the following conditions:

- Medical therapy has failed to adequately control intraocular pressure, AND
- The patient is not a candidate for any other intraocular pressure lowering procedure (e.g. trabeculectomy or glaucoma drainage implant) due to a high risk for complications.

Canaloplasty is considered not medically necessary under all other conditions, including angle-closure glaucoma. Viscocanalostomy is considered not medically necessary.

**POLICY GUIDELINES**

Tensioning devices are only able to reduce intraocular pressure (IOP) to the mid-teens and may be inadequate when very low IOP is needed to reduce glaucoma damage.

**BENEFIT APPLICATION**

The BCBS FEP contract stipulates that FDA-approved biologics, drugs and certain devices may not be considered investigational when used for their intended purpose and thus these products may only be assessed based on medical necessity.

**RATIONALE**

**Viscocanalostomy**

A 2010 meta-analysis by Chai and Loon compared the safety and efficacy of viscocanalostomy with the gold standard of trabeculectomy. (1) Ten randomized controlled trials with a total of 458 eyes (397 patients) with medically uncontrolled glaucoma were included in the analysis. The number of eyes in each study ranged from 20 to 60, with follow-up ranging from 6 months to 4 years. The majority of eyes (81%) had primary open angle glaucoma, while 16.4% had secondary open angle glaucoma, and 1.7% had primary angle closure glaucoma. Meta-analysis found that trabeculectomy had a significantly better pressure-lowering outcome. The difference in intraocular pressure between the treatments was 2.25 mm Hg at 6 months, 3.64 mm Hg at 12 months, and 3.42 mm Hg at 24 months. Viscocanalostomy had a significantly higher relative risk (RR) of perforation of Descemet's membrane (RR: 7.72). In contrast, viscocanalostomy had significantly fewer postoperative events compared with trabeculectomy (hypotony RR: 0.29, hyphema RR: 0.50, shallow anterior chamber RR: 0.19, and cataract formation RR: 0.31). Trabeculectomy had a greater pressure-lowering effect. Although viscocanalostomy had a better risk profile, most of the adverse events associated with trabeculectomy were considered to be mild and reversible. Edaly et al that included two small-randomized trials (50 eyes) obtained similar results in a 2014 Cochrane review and meta-analysis. (2)

One of the studies included in the systematic review was a randomized trial with 4-year follow-up by Gilmour et al. from 2009. (3) Patients (n=43) with open angle glaucoma were randomized to viscocanalostomy (25 eyes) or trabeculectomy (25 eyes) and prospectively followed at regular intervals for up to 60 months. A successful outcome was defined as intraocular pressure (IOP) less than 18 mm Hg with no medications; a qualified success was defined as IOP less than 18 mm Hg with or without topical treatment. One patient in each group was lost to follow-up. At baseline, patients had a mean IOP of 25 mm Hg and were using an average of 1.4 medications. At mean follow-up of 40 months (range, 6 to 60 months), 10 patients (42%) in the trabeculectomy group had achieved success compared to 5 patients (21%) in the viscocanalostomy.
9.03.26 Viscocanalostomy and Canaloplasty

In 2003, Kobayashi et al. reported a within-subject safety and efficacy comparison of trabeculectomy (with mitomycin C) and viscocanalostomy in 25 patients with bilateral primary open-angle glaucoma who had IOP greater than 22 mm Hg under medical therapy. (4) Patients were randomly assigned to receive trabeculectomy in one eye and viscocanalostomy (with removal of the internal wall of Schlemm’s canal) in the other eye. Follow-up was performed at 1 and 3 days, 1 and 2 weeks, and 1, 2, 3, 4, 5, 6, 9, and 12 months after surgery. Throughout follow-up, the mean IOP decreased significantly more in trabeculectomy-treated eyes (e.g., from 24.8 to 12.6 mm Hg at 12 months) than in viscocanalostomy-treated eyes (from 25.0 to 17.1 mm Hg). At 12 months, significantly more trabeculectomy-treated eyes achieved an intraocular pressure less than 20 mm Hg without medication (88% vs. 64%, respectively). The mean IOP reduction was 48.9% in trabeculectomy-treated eyes and 30.5% in viscocanalostomy-treated eyes. Overall success, defined as IOP less than 20 mm Hg and IOP reduction greater than 30% with or without glaucoma medication, was not significantly different between the 2 groups (96% for trabeculectomy and 92% for viscocanalostomy). Although trabeculectomy had a greater IOP-lowering effect, there were fewer complications with viscocanalostomy (1 micro perforation of Descemet’s membrane compared with 4 cases of shallow anterior chamber and 5 cases of hypotony with IOP < 4 mm Hg).

Grieshaber et al reported long-term results of viscocanalostomy in a series of 726 patients. (5) Mean IOP before surgery was 42.6 mm Hg. Mean IOP was 15.4 mm Hg at 5 years, 15.5 mm Hg at 10 years, and 16.8 mm Hg at 15 years. Qualified success (with or without medications) at 10 years (of 18 mm Hg) was 40% in the European population and 59% in the African population. Laser goniopuncture was performed postoperatively on 127 (17.7%) eyes. Fifty-three (7.3%) eyes were considered failures and required reoperation. There were no significant complications.

Stangos et al. reported the effect of the learning curve on the surgical outcome of viscocanalostomy from a retrospective series of 180 consecutive cases performed by 2 surgeons at a single center in Europe. (6) Overall success, defined as no visual field deterioration with an IOP of 20 mm Hg or less and IOP reduction of 30% or greater compared to baseline values, improved from 64% to 91% when comparing the first 45 to the last 45 cases of the series. Complete success, defined as no medications required, improved from 38% to 73%. Surgical complications were not significantly different between the first and last 45 cases (16 vs. 10, respectively).

Canaloplasty
A comparative effectiveness review of newer (Trabectome and canaloplasty) and older (trabeculectomy and Baerveldt shunt) surgeries for glaucoma was published in 2009. (7) Twelve-month outcomes (intracocular pressure adjunctive medications and complications) were compared after glaucoma-only and combined glaucoma-phacoemulsification surgeries. The review found that Trabectome and canaloplasty provided modest IOP reduction (to about 16 mm Hg) with minimal intraoperative or postoperative complications. Results of Baerveldt glaucoma implant IOP reduction were comparable with trabeculectomy (about 12 mm Hg), but typically, this shunt required more postoperative IOP-lowering medication (average of 1.3 vs 0.5 medications, respectively) to achieve a success rate comparable with trabeculectomy. Patients treated with Trabectome required more medications (average of 1.5) to control IOP than patients treated with canaloplasty (average of 0.6). The study concluded that Trabectome and canaloplasty are reasonable surgical therapy choices for patients in which IOPs in the mid-teens seem adequate; although
trabeculectomy remains the most effective IOP-lowering procedure, it also has the highest serious complication rates.

In 2015, Matlach et al reported on an RCT with 62 patients that compared canaloplasty (n=31) with trabeculectomy (n=31) for the treatment of open-angle glaucoma. (8) Patients included had medically uncontrolled or not sufficiently lowered IOP and progression of visual field defects or structural changes to the optic disc over time. The primary end point was an IOP of 18 mm Hg or less or an IOP reduction of at least 20% and less than 21 mm Hg without medication. Complete success at 2 years was achieved in 74.2% of patients after trabeculectomy and 39.1% of patients after canaloplasty (p=0.01). The qualified success rate (with medication) did not differ significantly between the 2 groups, although more patients in the canaloplasty group needed IOP-lowering medication (52.2% vs 25.8%, respectively). Mean absolute IOP reduction was similar for both interventions. There was a trend (p=0.08) for visual acuity to be lower in the canaloplasty group during follow-up. Trabeculectomy was associated with more frequent postoperative complications, including hypotony (37.5%), choroidal detachment (12.5%), and corneal erosion (43.8%). Scarring of the filtering bleb was a late complication in 25% of trabeculectomy patients. One study flaw was the unequal rate of dropouts (23.3% [7/30] for canaloplasty vs 3.1% [1/32] for trabeculectomy) over the 2 years of study. Another study by this group found higher quality of life (QOL) at 24 months following canaloplasty than trabeculectomy in a questionnaire survey of 327 patients. (9) Canaloplasty patients had a higher positive postoperative mood, higher satisfaction with results of surgery, and lower rates of visual and nonvisual symptoms and stress caused by surgery or postsurgical treatment. Difficulties with activities of daily living (eg, reading) and complaints (eg, eye burning) were significantly lower in the canaloplasty group. Some questions used were not from validated QOL questionnaires.

The primary literature on canaloplasty consists mainly of case series that compare post-treatment IOP with pretreatment IOP. One retrospective comparative study evaluated outcomes from 33 eyes (33 patients) that underwent canaloplasty and 46 eyes (46 patients) that underwent trabeculectomy during a 2-year period and had a minimum of 12 month of follow-up. (10) This study group was drawn from a larger group of 243 patients who underwent surgery during the same 2-year period (87 canaloplasty procedures and 156 trabeculectomy procedures). The specific procedure was determined by the ability to obtain insurance coverage for canaloplasty, and the groups were comparable in demographics, previous surgery, and visual acuity at baseline. At 12 months after surgery, the mean reduction in IOP from preoperative values was 32% for canaloplasty and 43% for trabeculectomy (p=0.072). IOP was slightly lower in the trabeculectomy group (11.6 vs 13.8 mm Hg; p=0.03), and fewer patients needed postoperative glaucoma medications. There was no significant difference in surgical reoperation rates between the 2 procedures (15% canaloplasty and 11% trabeculectomy). This study is limited by the potential for bias in the selection of patients for the study. Only a minority of all surgical patients had 12- month follow-up data and was included in the study, and selection into treatment groups was dependent on insurance status.

In 2007, Lewis et al reported interim data analysis from a company-sponsored multicenter (15 centers) safety/efficacy study on canaloplasty using the iTrack microcatheter (11) with 2- and 3-year results reported in 2009 and 2011. (12, 13) The study included 157 patients with a diagnosis of primary open-angle glaucoma, pigmentary glaucoma, exfoliative glaucoma, and a baseline IOP of 16 mm Hg or higher before surgery, with a historical IOP of 21 mm Hg or higher. Exclusion criteria were neovascular disease, uveitis, peripheral anterior synchiae, angle recession, and developmental or secondary glaucoma (except for pigmentary and exfoliative glaucoma). At baseline, the mean IOP was 23.8, and patients were on an average 1.8 medications. Canaloplasty was successful in 133 eyes (85%). Eyes that did not have placement of a tensioning suture were viscodilated to the extent possible by catheterizing the canal from both ostia. Early surgical/postoperative complications included microhyphema (12%), hyphema (10%), elevated IOP (6%), Descemet membrane detachment (3%), suture extrusion (1%), and hypotony (1%). Late postoperative complications included cataract (12.7%), transient IOP elevation (6.4%), and partial suture extrusion through the trabecular meshwork (0.6%). At 3 years postoperatively, 134 study eyes (85% follow-up) had a mean IOP of 15.2 mm Hg and mean glaucoma medication use of 0.8 medications; 66 eyes (49.3%) were on no medications. Another 7 patients (4.4%) had additional glaucoma surgery. With qualified success defined as achieving IOP of 18 mm Hg or lower (with 0 to 2 medications), success was
9.03.26 Viscocanalostomy and Canaloplasty

achieved in 69 of the 89 eyes (77.5%) that had successful suture implantation alone and 24 of the 27 eyes (89%) with successful suture placement combined with phacoemulsification.

Additional reports from this group of investigators included interim 1-year results for 40 patients who had combined canaloplasty and cataract surgery (potential overlap in patients from the study described earlier) (14) and a within subject comparison in 15 of the patients who participated in the trial described earlier who had bilateral primary open-angle glaucoma (POAG) and received canaloplasty in 1 eye and viscocanalostomy in the contralateral eye. (15) For the canaloplasty eye, IOP decreased from 26.5 mm Hg on 2.1 medications to 14.5 on 0.3 medications. For the viscocanalostomy eye, IOP decreased from 24.3 mm Hg on 1.9 medications to 16.1 on 0.4 medications. The reduction in IOP from baseline was significantly greater with canaloplasty than with viscocanalostomy (12.0 vs 8.2 mm Hg, p=0.02). There was no loss in visual acuity and no adverse events from either procedure. The authors noted that this study evaluates the effects of 2 additional maneuvers associated with canaloplasty: first, 360 degrees viscodilation of Schlemm canal, as opposed to partial dilation achieved with viscocanalostomy, and second, prolonged opening and tensioning of Schlemm canal with suture placement. (15)

The same investigators reported an industry-sponsored 3-year prospective, multicenter study of 109 open-angle glaucoma patients (109 eyes) who underwent canaloplasty or combined cataract-canaloplasty surgery. (16) All patients had documented visual field loss and met criteria for the diagnosis of glaucoma and failure of prior medical or laser therapy. A tensioning suture was successfully placed in 98 eyes (89.9%) and 96 eyes (88.1%) completed the 3-year follow-up. Of the 13 patients who did not complete follow-up, 4 (3.7%) had undergone additional glaucoma surgery; these patients were not included in the analysis. In eyes treated with canaloplasty with a successful tensioning suture, IOP decreased from 23 mm Hg on 1.9 medications to 15.1 mm Hg on 0.9 medications. In eyes treated with combined cataract-canaloplasty surgery with a successful tensioning suture, IOP decreased from 24.3 mm Hg on 1.5 medications to 13.8 mm Hg on 0.5 medications. For the 11 eyes that had canaloplasty without suture placement, IOP decreased from 24.4 on 1.9 medications to 15.6 on 1.2 medications. Late postoperative complications included cataracts (19.1%) and transient IOP elevation (1.8%).

A prospective series with 60 consecutive South African patients with POAG who underwent canaloplasty was reported by Grieshaber et al in 2010. (17) The mean preoperative IOP was 45 mm Hg. At 12-month follow-up, the IOP was 15 mm Hg (n=54), and at 36 months, the IOP was 13.3 mm Hg (n=49). Eleven patients (18%) were lost to follow-up at 3 years. With qualified success defined as achieving IOP of 21 mm Hg or lower (with or without medications), success was achieved in 40 of 49 patients (82%). When defined as an IOP of 16 mm Hg or less without medications, 47% of eyes met criteria for complete success. There were no severe complications in this series.

Three-year follow-up from an independent series of 214 patients treated with canaloplasty in Europe was reported by Brusini in 2014. (18) Mean IOP was reduced from 29.4 mm Hg at baseline to 17.0 mm Hg, after excluding 17 patients (7.9%) who later underwent trabeculectomy. IOP was 21 mm Hg or lower in 86.2% of patients, 18 mm Hg or lower in 58.6%, and 16 mm Hg or lower in 37.9%. There was a decrease in mean medication use, from 3.3 at baseline to 1.3 at follow-up. Complications, which included hyphema, Descemet membrane detachment, IOP spikes, and hypotony, were fewer than is typically seen with trabeculectomy. Several disadvantages of the procedure were noted, including the inability to complete the procedure in 16.4% of eyes.

In 2015, Voykov et al reported 5-year follow-up on patients (20 eyes) with open-angle glaucoma who underwent canaloplasty at a single center in Germany. (19) Mean IOP decreased from 25.7 mm Hg at baseline (n=33) to 15.5 mm Hg (n=19) at 1 year, 15.1 mm Hg (n=18) at 3 years, and 14.2 mm Hg (n=18) at 5 years. At each time point, reductions in mean IOP were statistically significant versus baseline (p<0.001). Mean number of medications used was 3.4 at baseline, 1.5 at 1 year, 1.6 at 3 years, and 1.7 at 5 years. At each time point, medication use was significantly lower than baseline (p<0.001). Thirteen (65%) of 20 eyes underwent another surgical procedure due to inadequate IOP control. Median length of time before
Section: Other
Subsection: Vision

9.03.26 Viscocanalostomy and Canaloplasty

Additional surgery was 24 months (95% confidence interval, 1 to 51 months). The complication rate was low, the most common being hyphema (7/20 [35%] eyes). No sight-threatening complications were reported.

Summary of Evidence

The evidence for viscocanalostomy in individuals who have open-angle glaucoma and have failed medical therapy includes small randomized controlled trials (RCTs) that compare viscocanalostomy with trabeculectomy. Relevant outcomes are symptoms, morbid events, quality of life, and medication use. Meta-analysis of these trials has indicated that trabeculectomy has a greater intraocular pressure (IOP)—lowering effect than viscocanalostomy. Reduction in IOP was greater with canaloplasty than viscocanalostomy in a small within-subject comparison. Viscocanalostomy has not been shown to be as good as or better than established alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Ongoing Clinical Trials

A search of ClinicalTrials.gov in February 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

A 2011 Technology Assessment from the AAO included canaloplasty in its review of novel glaucoma procedures. (20) The AAO concluded that all of the techniques and devices reviewed were still in the initial stage (≤5 years) of clinical experience and lacking widespread use, with only level III evidence (cohort studies) in support of the procedures. In addition to describing potential advantages and disadvantages of the procedure, it was noted that the long-term effects of a foreign body in Schlemm’s canal are not known.

The 2008 guidance from the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) stated that the current evidence on the safety and efficacy of canaloplasty for primary open-angle glaucoma is inadequate in both quality and quantity and that this procedure should only be used in the context of research or formal prospective data collection. (21)

NICE and the National Collaborating Centre for Acute Care published guidance on the diagnosis and management of chronic open angle glaucoma and ocular hypertension in 2009. (22) When comparing penetrating surgery (trabeculectomy) with non-penetrating surgery (deep sclerectomy and viscocanalostomy), the evidence review found moderate quality evidence that trabeculectomy is more effective than non-penetrating surgery in reducing the number of eyes with an unacceptable IOP but was more likely to cause cataract formation and persistent hypotony at 12 to 36 months’ follow-up. There was very low quality evidence that trabeculectomy is more effective than non-penetrating surgery in reducing IOP from baseline at 6 and 12 months’ follow-up, but the effect size may be too small to be clinically significant. The guidance recommended offering information on the risks and benefits associated with
9.03.26 Viscocanalostomy and Canaloplasty

surgery and offering surgery (type not specified) with pharmacological augmentation to people with chronic open angle glaucoma who are at risk of progressing to sight loss despite treatment.

**U.S. Preventive Services Task Force Recommendations**

Viscocanalostomy and canaloplasty are not preventive services.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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9.03.26 Viscocanalostomy and Canaloplasty


15. Koerber NJ. Canaloplasty in one eye compared with viscocanalostomy in the contralateral eye in patients with bilateral open-angle glaucoma. J Glaucoma. Feb 2012;21(2):129-134. PMID 21278587


POLICY HISTORY

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<th>Action</th>
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<td>New Policy</td>
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<td>December 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 4, 10, and 14 added; policy statement unchanged.</td>
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<td>Policy updated with literature review, references 5, 8, 9 and 19 added. Policy statements unchanged.</td>
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