Viscocanalostomy and Canaloplasty

Description

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.

Background

Surgical procedures for glaucoma aim to reduce intraocular pressure (IOP) resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm’s canal. In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm’s canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of Schlemm’s canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir with a filtering “bleb” on the eye, which can effectively reduce IOP, but is associated with numerous and sometimes sight-threatening complications (e.g., leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation and deep sclerectomy, which removes the outer wall of Schlemm’s canal and excises deep sclera and peripheral cornea.

More recently the Trabectome™, an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm’s canal without external access or creation of a subconjunctival bleb. IOP with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Aqueous shunts may also be placed to facilitate drainage of aqueous humor (see policy 9.03.21). Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.
Alternative nonpenetrating methods that are being evaluated for glaucoma are viscocanalostomy and canaloplasty. Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates Schlemm’s canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution, such as sodium hyaluronate, is used to open the canal and create a passage from the canal to a scleral reservoir. It has been proposed that viscocanalostomy may lower IOP while avoiding bleb-related complications.

Canaloplasty was developed from viscocanalostomy and involves dilation and tension of Schlemm’s canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack™ illuminated microcatheter (iScience Interventional) to access and dilate the length of Schlemm’s canal and to pass the suture loop through the canal. An important difference between viscocanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of Schlemm’s canal, rather than one section of it.

Since aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system is critical for reaching the target IOP. Therefore, some procedures may not be able to reduce IOP below the pressure of the distal outflow system used, e.g., below 15 mm Hg, and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). Health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy if the procedure is unsuccessful, complications, and durability of the procedure.

Regulatory Status

The iTrack (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 iTrack 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

Related Policies

9.03.06  Glaucoma Testing
9.03.21  Aqueous Shunts for Glaucoma

Policy

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

Viscocanalostomy is considered not medically necessary.

**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 group. Although 19 patients (79%) in both groups achieved qualified success, fewer trabeculectomy patients required additional topical treatment (50% vs. 83%, respectively) to achieve qualified success. There were more early postoperative complications in the trabeculectomy group (e.g., hypotony, wound leak, choroidal detachment), but these did not affect the outcome. At 1 month, conjunctival blebs were observed in 19 (79%) of the trabeculectomy group and 16 (64%) of the viscocanalostomy group. At 12 months, blebs were observed in 19 (79%) of the trabeculectomy group and 14 (56%) of the viscocanalostomy group. The proportion of patients with conjunctival blebs at final follow-up and the statistical significance of these differences were not reported. It was reported that more bleb manipulations (7 vs. 1) and antimetabolites (5 vs. 1) were needed in the trabeculectomy group. The 3 patients who required cataract surgery were all in the viscocanalostomy group.
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).

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. (5) 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.(6) 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.

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.(7) 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(8) with 2- and 3-year
results reported in 2009 and 2011.(9,10) 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 synechiae, 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 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)(11) 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 viscoscanalostomy in the contralateral eye.(12) For the canaloplasty eye,
IOP decreased from 26.5 mm Hg on 2.1 medications to 14.5 on 0.3 medications. For the
viscoscanalostomy 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 viscoscanalostomy (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.

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. 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. 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. 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.

**Ongoing Clinical Trials**

A search of the online site: Clinicaltrials.gov in July 2014 found 2 randomized trials comparing canaloplasty to trabeculectomy. NCT01228799 is expected to enroll 60 subjects with completion in 2012. No publications have been submitted to date. NCT00854256 has an expected enrollment of 60 patients with completion in 2014. NCT01726543 will compare canaloplasty with non-penetrating deep sclerectomy. This study has an estimated enrollment of 80 patients with completion in 2014.
Practice Guidelines and Position Statements

The 2010 Preferred Practice Patterns on primary open-angle glaucoma from the American Academy of Ophthalmology (AAO) states that glaucoma surgical procedures currently under evaluation are canaloplasty with a tensioning suture (Prolene [Ethicon Inc., Somerville, NJ]), ab interno trabeculotomy using the Trabectome (NeoMedix, Tustin, CA), trabecular meshwork bypass stent, and the Ex-PRESS mini glaucoma shunt (Alcon Laboratories, Inc., Ft. Worth, TX). (16) The AAO considers laser trabeculoplasty as initial therapy in selected patients or as an alternative for patients who cannot or will not use medications reliably due to cost, memory problems, difficulty with instillation, or intolerance to the medication. The AAO considers nonpenetrating glaucoma surgery to be an alternative to trabeculectomy, although the precise role of nonpenetrating surgery in the surgical management of glaucoma remains to be determined. Nonpenetrating glaucoma surgery avoids a continuous passageway from the anterior chamber to the subconjunctival space, reducing the incidence of complications such as bleb-related problems and hypotony. The nonpenetrating procedures have a higher degree of surgical difficulty compared with trabeculectomy and require special instrumentation. The two main types of nonpenetrating glaucoma surgery are viscocanalostomy and nonpenetrating deep sclerectomy.

A 2011 Technology Assessment from the AAO included canaloplasty in its review of novel glaucoma procedures. (17) 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. (18)

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. (19) 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 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.
Summary

A number of small randomized trials have been conducted that compare viscocanalostomy with trabeculectomy. Meta-analysis of these trials indicates that trabeculectomy has a greater pressure-lowering effect than viscocanalostomy. Although trabeculectomy is associated with greater postoperative risk, most of the adverse events are mild and reversible. Reduction in IOP has also been shown to be greater with canaloplasty than viscocanalostomy in a small within-subject comparison. Overall, evidence is insufficient to evaluate health outcomes with this procedure in comparison with currently accepted alternatives. Therefore, viscocanalostomy is considered not medically necessary.

Positive 2- to 3-year outcomes have been reported for canaloplasty, along with a systematic review that found that Trabectome and canaloplasty provided modest IOP reduction with minimal intraoperative or postoperative complications. When combined with clinical input, evidence is sufficient for canaloplasty to be considered medically necessary in the subset of patients for whom medical therapy has failed to adequately control intraocular pressure and in whom other surgical procedures (e.g. trabeculectomy or a glaucoma drainage implant) are contraindicated. Further, canaloplasty is considered not medically necessary under all other conditions, including angle-closure glaucoma.

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.

References


This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 19, 2015 and is effective July 15, 2015.

Signature on File

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