Canaloplasty—A New Approach to Nonpenetrating Glaucoma Surgery

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ABSTRACT

Canaloplasty is a new nonpenetrating glaucoma operation, which utilizes the experience with viscocanalostomy and adds a further surgical step to keep the ostia open and to stretch the trabecular meshwork permanently.

During the operation, a deep sclerectomy and viscocanalostomy are performed as described by Stegmann et al. After this, a 200-μm microcatheter (iTrack; iScience Surgical Corp, Menlo Park, Calif) is used to dilate the Schlemm canal circumferentially, injecting microvolumes of viscoelastic during catheterization. Retracting the catheter subsequent to the dilatation, the surgeon places a 10-0 Prolene tensioning suture loop in the canal and ties it to apply tension to the trabecular meshwork.

Trabeculectomy is a widely used surgical procedure used to lower intraocular pressure (IOP) in the treatment of glaucoma. Although trabeculectomy with or without antimetabolites may be successful in controlling IOP, numerous intraoperative and postoperative complications often involving surgical trauma and conjunctival bleb are associated with the treatment.

Direct surgical treatment of the aqueous outflow system including the Schlemm canal to restore normal function and IOP control has long been of interest in the study of open-angle glaucoma. Nonpenetrating surgical methods to access the Schlemm canal and increase aqueous outflow have been developed and presented by numerous clinical researchers. Stegmann et al. reported on a nonpenetrating procedure called viscocanalostomy in 1999, with the intention of creating a blebless procedure to restore the trabeculocanalicular drainage pathway. The procedure involves incising superficial and deep scleral flaps, unroofing the Schlemm canal, creating a Descemet window, and then excising the deep scleral flap to create a scleral reservoir. High-viscosity sodium hyaluronate viscoelastic is used to open the ostia of the canal to allow passage of aqueous from the anterior chamber into the canal; the superficial scleral flap is then sutured watertight to prevent the formation of a bleb. While viscocanalostomy has demonstrated effective IOP lowering, comparative clinical research indicates that IOP is more significantly decreased with trabeculectomy, but viscocanalostomy is associated with fewer postoperative complications.

Another nonpenetrating procedure, deep sclerectomy, uses similar cut-down techniques and access to the canal, but is designed to yield a filtering bleb as in trabeculectomy. Deep sclerectomy also provides a reduction in IOP with fewer postoperative complications as compared with penetrating procedures such as trabeculectomy.

Recent advances in technologies have allowed surgeons to use a flexible microcannula or microcatheter to access the entire length of the Schlemm canal (Fig. 1).

Beginning with the traditional viscocanalostomy, as described by Stegmann et al, after limbal peritomy to avoid cautery, a small sponge soaked in an adrenaline solution (1:10,000) is pressed on the sclera for 1 minute. A superficial parabolic flap of approximately 250- to 300-μm thickness, 4.5 × 4.5 mm, is made (Fig. 2).

A deep flap is created within 0.5 mm of the margins of the superficial flap. The deep flap is dissected down to a depth very close to the choroid and then carefully...
progressed anteriorly until the Schlemm canal is revealed and deroofed (Fig. 3).

The ostia of the canal are carefully dissected to allow for easy access by the microcatheter and to prevent scarring by rugged edges. The inner flap is advanced into the cornea by gentle blunt separation of the Descemet membrane from the corneal stroma. This flap is removed by careful dissection, exposing the trabecular meshwork and an intact Descemet window (Fig. 4).

Blunt forceps is used to manipulate the microcatheter and place the tip in alignment with the canal. The microcatheter is gently advanced 12 clock-hours within the canal while the surgeon observes the location of the beacon tip through the sclera and injects viscoelastic (Healon GV; Advanced Medical Optics, Irvine, Calif) as the tip is advanced (Fig. 5). The tip is visible through the sclera by the light emitted from the laser fiber inside the catheter (iLumin; iScience Surgical Corp, Menlo Park, Calif).

The general protocol for injection is approximately 4 to 6 mg of viscoelastic injected every 2 clock-hours of advancement with the use of a thumbwheel, which is part of the iTrack device (Fig. 6).

After completing the catheterization of the entire canal length with the microcatheter, and with the distal tip exposed at the surgical cut-down, a 10-0 Prolene suture is tied to the distal tip and the microcatheter withdrawn, pulling the suture into the canal (Fig. 7).

Further viscoelastic dilation can be performed during the withdrawal. The suture is cut from the microcatheter and then tied in a loop encircling the inner wall of the canal using a slipknot preferred by most surgeons. In our center, we prefer to lower the IOP down to about 5 mm Hg by paracentesis and then to apply a tight surgical knot distending the trabecular meshwork visibly inward. The suture loop is tightened to distend the trabecular meshwork inward, placing the tissues in tension, and then locking knots are added (Fig. 8).

The outer flap is sutured with watertight 10-0 Vicryl sutures. It is important not to perforate the flap to prevent the creation of fistulation through the suture tracks. The needle is guided tangentially through the rim of the flap and then enters the sclera at the inner edge of the step existing at the rim of the first flap, touching the rim of the inner flap (Fig. 9).
Before closing the conjunctiva with another one or two 10-0 Vicryl suture, the watertight closure of the scleral flap is tested by gentle injection of viscoelastic under the flap into the scleral lake. Care has to be taken to avoid rupturing of the Descemet-trabecular tissue by excessive injection.

**COMPLICATIONS AND MANAGEMENT**

One of the major advantages of canaloplasty is the absence of vision-threatening complications such as choroidal detachments, shallow or collapsed anterior chambers, and prolonged hypotensive periods.

In a small number of cases, we observed a postoperative hyphema, usually 0.5 to 1 mm, which resolved spontaneously. A Descemet tear when the Descemet window is created occurs also in a small number of cases. If the tear is microscopical (microperforation), this is of no consequence, and the operation can be finished as planned without a negative impact on the result.

In case of a big tear (rupture), a basal iridectomy should be performed to prevent adhesion of the iris base. A 360-degree cannulation and dilatation can still be performed, but introducing a suture may be impossible. In 1 case of failed trabeculectomy with postoperative use of 5-fluorouracil, we were able to cannulate the trabeculectomy site and to place a tensioning suture. This eye still is at a pressure of 16 mm Hg post-operatively without therapy, with a preoperative pressure in the end-30s with triple local therapy. So the application of a suture makes sense also in eyes with a defective Descemet window—if it can be achieved. The outer flap can be sutured watertight as in the standard operation protocol.

Elevated postoperative pressures occur in a low percentage of cases due to steroid response and to possible inflammatory changes in the canalicular structures.

In 1 case, we observed a detachment of the Descemet membrane at Schwalbe line because of excessive injection of viscoelastic while advancing the iTrack. This led to Descemet membrane detachment, which resolved spontaneously after 10 weeks.

**ULTRASOUND IMAGE (HIGH-RESOLUTION ULTRASOUND), FIRST DAY POSTOPERATIVELY**

As mentioned already, the severe complications of trabeculectomy with or without antimetabolites have not occurred, so this operation leaves us with good feeling already during and after surgery.

**POSTOPERATIVE TREATMENT**

Postoperative treatment to prevent early scarring by inflammatory processes in the outflow chamber and in the canalicular tissues is performed for 4 weeks.

### TABLE 1. Trabecular Meshwork (TM) Tensioning Multicenter Clinical Study, 3 German Sites

<table>
<thead>
<tr>
<th>TM Distention</th>
<th>1 mo Postop</th>
<th>3 mo Postop</th>
<th>6 mo Postop</th>
<th>9 mo Postop</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;0.5</td>
<td>≥0.5</td>
<td>&lt;0.5</td>
<td>≥0.5</td>
</tr>
<tr>
<td>n</td>
<td>15</td>
<td>35</td>
<td>15</td>
<td>34</td>
</tr>
<tr>
<td>Average IOP (mm Hg)</td>
<td>19.0</td>
<td>15.3</td>
<td>17.8</td>
<td>14.8</td>
</tr>
<tr>
<td>SD IOP (mm Hg)</td>
<td>5.5</td>
<td>4.3</td>
<td>8.4</td>
<td>4.2</td>
</tr>
<tr>
<td>Average, no. medications</td>
<td>0.2</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
</tr>
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**FIGURE 6.** Catheter after 360-degree dilatation.

**FIGURE 7.** Fixation of the suture to the catheter.
For 1 week, a local antibiotic treatment is advisable. The anti-inflammatory treatment begins 1 week preoperatively with a nonsteroidal topical treatment QID, which is continued for 4 weeks postoperatively QID.

A local steroid is applied QID and tapered by 1 drop per week, ending after week 4 (prednisone forte).

## RESULTS

We present the preliminary data of the Cologne study eyes, as far as 1-year results are available.

The preoperative pressure values are to be discussed, as according to the strict study protocol, only the last preoperative pressure under maximum therapy could be used for the statistical analysis. If we would calculate the preoperative values with the maximum IOP under therapy during the preoperative weeks, the preoperative mean pressure is 28.7 mm Hg with a mean of 2.8 drugs applied.

Postoperatively, the number of medications is 0.3 after 6 months and 0.1 after 12 months in the cases shown in the diagram (Fig. 10). All these eyes had a tensioning suture applied with a good tension, as could be proved by postoperative evaluation using high-resolution ultrasound system (Fig. 11).

The relation between IOP reduction and suture tension was presented at the European Society of Cataract and Refractive Surgeons Congress in London in 2006.

These data from the study centers in Berlin, Cologne, and Gross-Pankow show us that the reduction in IOP is strongly influenced by the suture tension Table 1. Gradating the suture tension from 0.5 to 2 in an analysis of the trabecular distension on the ultrasound images, after 1 year—we stress these long-time data—the IOP in the eyes with a suture tension of more than 0.5 in average is 12.6 mm Hg. This is very close to the Cologne results after 1 year with a mean pressure of 12.3 mm Hg.

The cases with lower suture tension (>0.5) after 1 year show an IOP of 19.5, which is a relative success, as also can be concluded from the number of medications: 0.5 in the low-suture-tension cases versus 0.1 in the good-tension eyes.

## DISCUSSION

The canaloplasty procedure is an operation which aims to lower the IOP by permanently stretching the trabecular meshwork. It bypasses all the negative aspects of fistulating bleb-dependent surgery and avoids the early
and late complications of these operations. The success rate is high, and the complication rate is summing up to about 10% in total, without any sight-threatening events.

The author is strongly convinced that this operation is a major step forward in the treatment of glaucoma. Nevertheless, it is a difficult procedure, which needs an experienced deep sclerectomy or viscocanalostomy surgeon. The surgeons from the 3 German study sites have been performing viscocanalostomies for 10 years, so the introduction of canaloplasty in the centers was a further step in surgery and not a completely new beginning.

Surgeons without experience in this kind of surgery will experience a significant learning curve with initial frustrations, which cannot be related to the method of operation.

We can state that canaloplasty is a safe and very effective method for the operative treatment of glaucoma.

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■ REFERENCES