Are There Problems with Non-penetrating Glaucoma Surgery?

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Abstract

Non-penetrating glaucoma surgery (NPGS) has been around in various guises for 50 years, yet its acceptability among the ophthalmological community is variable. This article aims to debunk some of the myths associated with NPGS and to explain the differences in NPGS techniques. Once these differences have been explained, we scrutinize and meaningfully compare the good-quality research that has been published on the subject. In doing so, we aim to help readers determine which techniques work best and why. Finally, we hope to show the readers where NPGS has a place in the glaucomatologist's armamentarium.

Keywords

Deep sclerectomy, viscocanalostomy, canaloplasty, collagen implant, non-penetrating glaucoma surgery, *ab externo* canal surgery, combined glaucoma surgery

In the 1960s, Krasnov[1] began to develop what became known as 'non-penetrating glaucoma surgery' (NPGS). The 'sinusotomy' he described consisted of de-roofing Schlemm's canal from 10–2 o'clock via an external approach and then covering the canal with conjunctiva. With little post-operative detail in the report, plus the need for an operating microscope, the procedure was never accepted.

In 1989, Koslov et al.[2] described 'deep sclerectomy' (DS): an 'en-bloc' resection of the external wall of Schlemm's canal, along with corneal stroma adjacent to the anterior trabeculum and, more anteriorly, exposure of Descemet's membrane over 4–5 mm. These structures were removed with a slice of sclera beneath a superficial scleral flap: hence the term deep sclerectomy. In 1998, Vaudaux et al.[3] demonstrated increased aqueous humor outflow, while protecting the eye from hypotony-related complications. At that time, Watson et al.'s trabeculectomy complications[4] included 28 % with iridocorneal touch, a further 1 % with lenticulo-corneal touch, and early intraocular pressures (IOPs) of ≤5 mmHg in 25 % of eyes; Popovic's series[5] had IOPs ≤5 mmHg in one in three patients at one week post-operatively; Migdal and Hitchings[6] reported that 29 % of patients had IOPs ≤8 mmHg for over two weeks post-operatively; Stewart et al.'s results[7] showed 76 % with IOP <5 mmHg and 47 % with iridocorneal touch, both at two days post-operatively. Despite these rates of complications occurring early in the post-operative period, trabeculectomy became established as the technique of choice for glaucoma. It was considerably safer than its predecessors, namely anterior and posterior lip sclerectomy, iridencleisis, and posterior lip sclerectomy with or without cautery.

Today, post-trabeculectomy complication rates are far less high than these owing to improvements in surgical technique. At the time, however, they were the benchmark, driving the search for an alternative. Koslov's deep sclerectomy was appealing.

Ideal surgery would create consistently an immediate, controlled IOP reduction with stable visual acuity and a minimal surgical learning curve. A realistic goal would be an operation that did not give rise to problems associated with early hypotony, late leaks, cataract formation or endophthalmitis, one that necessitated infrequent follow-up and was not bleb-dependent for success. DS and viscocanalostomy (VC) represent attempts to achieve this goal. In particular, VC aims to be bleb-free. Both operations may provoke less post-operative inflammation than trabeculectomy surgery,[8] with smaller amounts of post-operative steroids required. These advantages translate into less intensive follow-up than following trabeculectomy.[9]

Where are the Problems with Non-penetrating Glaucoma Surgery?

NPGS may be less effective to control IOP than trabeculectomy. Another challenge is the relative complexity of these procedures compared with trabeculectomy. A high level of skills is required to dissect a longer scleral flap of uniform thickness and to create a trabeculo-Descemet window (TDW) without entering the anterior chamber. Another problem is the very general appellation 'NPGS': there are many surgical variations all grouped under the same umbrella term. To many ophthalmologists, this acronym suggests one type of operation, perhaps with a few

Table 1: Summary of the Studies Presented

Study	Technique	Patients Achieving Success (%)	Number of Patients	Definition of Success (IOP mmHg)	Follow-up (Years)	GP (%)	Post-operative 5-FU/MMC (%)
Khairy et al., 2009[14]	DS	37	43	<22	2	4.6	
Chiselita, 2001[15]	DS	45	17	<21	1.5		
Bissig et al., 2008[16]	DSI	48	52	≤21	10	60	25 (5-FU)
Kozobolis et al., 2002[17]	DSMMC	50	40	<22	3	0	29 (5-FU)
Guedes et al., 2010[18]	DSMMC	58	285	<21	3	13	
Anand et al., 2011[20]	DSIMMC	78	146	<19	3	63	
Sunaric-Mégévand and Leuenberger, 2001[25]	VC	59	17	≤20	3	9	
Carassa et al., 2003[9]	VC	76	19	≤21	2	4.5	
Lüke et al., 2002[26]	VC	30	30	<22	1		
O'Brart et al., 2004[27]	VCMMC	60	25	<21	1	12	23 §
Tanito et al., 2002[29]	PhacoVC	95	18	<21	1		
Park et al., 2005[30]	PhacoVC	61	84	<21	2		
Wishart and Dagres, 2006[28]	PhacoVC	89	80	≤21	3		
Anand and Anand, 2008[32]	PhacoDS	60	48	<22	2	71	21 § (5-FU/MMC)
Anand and Anand, 2008[32]	PhacoDSMMC	76	48	<19	2	62	18 § (5-FU/MMC)
Guedes et al., 2010[18]	PhacoDSMMC	56	41	<21	3	12	
Grieshaber et al., 2011[37]	VCc	94	25	≤21	1	24	
Lewis et al., 2011[38]	VCc	40	89	≤21	3		
Lewis et al., 2011[38]	PhacoVCc	78	27	≤21	3		

5-FU = 5-fluorouracil; DS = deep sclerectomy; DSI = DS + implant; DSMMC = DS + mitomycin C; GP = goniopuncture; IOP = intraocular pressure; MMC = mitomycin C; Phaco = phacoemulsification; VC = viscocanalostomy; VCc = VC + canaloplasty; VCMMC = VC + mitomycin C; § = plus needling procedure.

ndividual nuances. Originally, the only version of NPGS was DS. As surgical techniques have evolved, there are now several variations of the original DS. In 1980, George Spaeth[10] commented on comparing results between different surgical techniques: "This is not really surprising when one considers the vast variety of techniques entitled… trabeculectomy." The historical term NPGS has stuck, but is no longer relevant and its use should be discouraged to avoid confusion between the different techniques. The many variations of NPGS make it difficult to compare meaningfully results of trabeculectomy surgery and between surgeons. The multiple variations in surgical technique lead to confusion, even among glaucomatologists. For example, Fyodorov is often credited as one of the fathers of NPGS, yet the operation he described, DS,[11] involves a basal iridectomy. The grouping of all the 'non-penetrating' procedures under one term (NPGS) for reasons of simplification or comparison is as useful as grouping trabeculectomy and tube surgery under the label 'penetrating glaucoma surgery'; it is as inappropriate as it is unhelpful. The natural evolution of NPGS has rendered the term inaccurate and obsolete.

Review of Literature on *Ab Externo* Canal Surgery in the Context of Open-angle Glaucoma

We have identified several significant permutations in surgical techniques that may lead to a difference in outcome and have analyzed them separately. There are two broad categories: the deep sclerectomies and the viscocanalostomies. As explained by Mendrinos et al.,[12] in DS, the aqueous is designed to drain subconjunctivally – as in trabeculectomy surgery. The main advantages are reduced hypotony in the immediate post-operative period, lower risk of endophthalmitis, and less inflammation (from not entering the anterior chamber and not performing a peripheral iridectomy). VC aims for aqueous flow along

Schlemm's canal, with no subconjunctival drainage. A viscoelastic is injected into the cut ends of Schlemm's canal and the sclera is sutured down tightly, to prevent aqueous egress – unlike in DS where the superficial scleral flap is sutured loosely or not at all.

In DS, some surgeons use collagen and/or hyaluronic acid implants to prolong success rates and/or antimetabolites to achieve lower post-operative IOPs. These groups are all examined separately. In VC, we have differentiated between tight scleral closure, as per Stegmann's original paper,[13] and loose closure aiming for subconjunctival drainage. Both DS and VC have been combined with cataract extraction, with further separation in this article for analytical purposes. More recently, VC has been combined with canaloplasty, which again is discussed separately.

Nd:YAG laser goniopuncture (GP) rates and post-operative use of antimetabolites are included where published.

In an attempt to reduce inter-publication heterogeneity, we have stuck to 'complete success rates' as a definition of success, i.e., tonometric success achieved without topical hypotensive medications. As several tonometric definitions of success have been used, for homogeneity, we have used the following: <19 mmHg; <20 mmHg; ≤21 mmHg; <22 mmHg. To obtain an idea of surgical durability, only studies with more than 12 months follow-up have been included. Study endpoints have only been included where the numbers of participants reaching that particular endpoint have been published. The only implants examined are the more commonly used SKGel™ (Corneal, France) and AquaFlow™ (STAAR, Switzerland). A summary of all the studies in this paper is presented in *Table 1*.

Deep Sclerectomy
Deep Sclerectomy Alone

Khairy et al.[14] published success rates of 37 % at 24 months (n=43, success <22 mmHg); two patients required 5-fluorouracil (5-FU) injections and two required GP. Chiselita[15] published success rates of 45 % at 18 months (n=17, success <21 mmHg). Short-term success rates are low, possibly from bleb fibrosis.

Deep Sclerectomy + Implant (DSI)

Koslov[2] first used seton-like scleral bed implants to help the aqueous reach the subconjunctival space. Bissig et al.[16] published impressive 10-year success rates of 48 % (n=52, success ≤21 mmHg). Sixty percent of eyes required GP, while 25 % required 5-FU post-operatively. The use of an implant may improve the long-term success of DS.

Deep Sclerectomy + Mitomycin C (DSMMC)

Kozobolis et al.[17] presented three-year data comparing DS + mitomycin C (DSMMC) with 'unaugmented' DS, showing a 50 % chance of complete success with DSMMC (n=40, success <22 mmHg), as compared with 42 % in the DS group (n=40, success <22 mmHg). This difference was not statistically significant. Thirty-eight percent of eyes in the DS group required post-operative 5-FU, as compared with 29 % in the DSMMC group. No patient required GP and none developed thin-walled avascular blebs. Guedes et al.[18] published three-year success rates of 58 % with DSMMC (n=285, success <21 mmHg); 13 % required GP.

In a retrospective case note analysis of their DSMMC patients, Anand and Atherley[19] noticed avascular areas of conjunctiva within blebs in 70 % of patients and transconjunctival oozing of aqueous in 48 % of patients (0.2 mg/ml mitomycin C [MMC] for two minutes).

The use of concomitant MMC may improve the medium-term success rates of DS. In the context of DS, the use of concomitant MMC may lead to similar post-operative complications to trabeculectomy.

Deep Sclerectomy + Implant + Mitomycin C (DSIMMC)

Anand et al.[20] published three-year success rates of 78 % (n=146, success <19 mmHg). Sixty-three percent of eyes required GP. The combined use of an implant and MMC may improve the medium-term success rates of DS, compared with DSMMC or DS + implant (DSI).

Deep Sclerectomy and Post-operative Infection

There have been two reports of blebitis after DS.[20,21] There has been one report of endophthalmitis following DSMMC, where intra-operative perforation of the TDW had occurred.[20] There have been no reports of endophthalmitis following DS.[22] This is in contrast to augmented trabeculectomy, where post-operative infection, although rare, remains a risk.

Viscocanalostomy
Viscocanalostomy Alone

Cannulation of Schlemm's canal and injection of an ophtalmic viscoelastic device (OVD) dilate both Schlemm's canal and collector channels and also disrupt the Schlemm's canal wall.[23] Given that the luminal diameter of Schlemm's canal is large, it does not provide resistance to aqueous outflow;[24] hence its dilatation is unlikely to improve flow of aqueous. The disruption of the canalicular wall may allow aqueous to percolate through from the anterior chamber, in the manner of a trabeculotomy. The anti-inflammatory effect of the OVD may help prevent the cut ends of Schlemm's canal and the subscleral space from fibrosing post-operatively.

Sunaric-Mégévand and Leuenberger[25] published three-year success rates of 59 % with VC (n=17, success ≤20 mmHg). Nine percent required GP. Carassa et al.[9] published two-year success rates of 76 % in their VC group (n=19, success ≤21 mmHg), compared with 80 % in their unaugmented trabeculectomy group (n=20, success ≤21 mmHg). The inter-group difference was not statistically significant. One patient required GP. Lüke et al.[26] published 12-month success rates of 30 % in their VC group (n=30, success <22 mmHg), compared with 57 % in their control trabeculectomy group (n=30, success <22 mmHg).

Viscocanalostomy + Mitomycin C (VCMMC)

O'Brart et al.[27] published a randomized, prospective study comparing VC plus 5-FU and/or MMC with trabeculectomy plus 5-FU and/or MMC, with 12-month success rates of 60 % (n=25, success <21 mmHg), but in the augmented trabeculectomy group the 12-month success rate was 91 % (n=25, success <21 mmHg). Three eyes in the VC group required GP. Needling procedures were required in 23 % of the augmented VC group and in 64 % of the augmented trabeculectomy group.

Viscocanalostomy and Blebs

Some surgeons who carry out VC observe post-operative drainage blebs, whereas others do not. Stegmann's[13] original technique described tight closure of the scleral flap with five sutures and no post-operative blebs were observed.

O'Brart et al.'s and Lüke et al.'s techniques involved two or three sutures to close the scleral flap. O'Brart et al.[27] observed drainage blebs in 100 % of eyes with success and Lüke et al.[26] in 57 %.

While Carassa et al.[9] sutured the scleral flap until they observed no egress of aqueous, Sunaric-Mégévand and Leuenberger[25] used four to five sutures to achieve this. Wishart and Dagres[28] used five to seven sutures for the scleral flap. Carassa et al. found post-operative blebs in only 16 % of their patients. Sunaric-Mégévand and Leuenberger reported blebs in 9 % of patients. Wishart and Dagres found no blebs.

From these reports, it can be deduced that the more sutures are applied to the scleral flap, the less there is a chance of a subconjunctival drainage bleb. This is important, both to establish the mechanism through which VC may work and to disseminate results accurately according to technique. O'Brart et al. quote Stegmann's technique, but then deviate from it both in the suture method and in antimetabolite application (they use VCMMC).

How Do Viscocanalostomy and Deep Sclerectomy Compare?

If VC results in a bleb, is it functioning similarly to DS? Both techniques involve an OVD under a scleral flap; the only differences are the scleral flap suturing and the 'viscocanalostomy' maneuver. Are VC results comparable with DS outcomes? Twelve-month success rates from the

DS group include rates of 61 %[14] and 52 %,[15] which are better than those of Lüke et al.'s VC group (following which they observed a bleb), who had 12-month success rates of 30 %. In trabeculectomy, establishing subconjunctival flow of aqueous is essential to bleb survival. Speculatively, by creating two routes for the aqueous to drain, (i.e., through Schlemm's canal and subconjunctivally in the case of those who perform VC with loose scleral flap suturing), both routes may work suboptimally: if flow through Schlemm's canal diverts flow away from the subconjunctival bleb, this may affect bleb survival, with a reciprocal effect on Schlemm's canal.

By applying a similar logic to VCMMC and DSMMC, the expectation is that the VCMMC group would fare less well than the DSMMC group. Twelve-month success results from the DSMMC group include 78 %[17] and 67 %.[18] These are slightly better than O'Brart et al.'s VCMMC group (following which they observed a bleb) 12-month results of 60 %.[27]

VC with tight suturing of the sclera appears effective at lowering IOP in the medium term. Loose suturing of the scleral flap may be detrimental to the success rates of VC surgery.

Combined Cataract Extraction and Viscocanalostomy
Tanito et al.[29] published 12-month data with success rates of 95 % (n=18, success <21 mmHg, separate-site cataract surgery) with combined cataract extraction and VC (phacoemulsification + VC [PhacoVC]). Park et al.[30] published 24-month success rates of 61 % (n=84, success <21 mmHg, separate site cataract surgery). Wishart and Dagres[28] published three-year success rates of 89 % (n=80, success ≤21 mmHg, same-site cataract surgery). Wishart and Dagres's results are better than those of the VC group, which featured multiple scleral flap sutures,[9,25] where three-year results were 59 % and 76 %, respectively. Wishart and Dagres[28] commented on lower GP rates in PhacoVC. As Wishart's cataract surgery is achieved through the same site as VC, could the cataract wound contribute to IOP control post-operatively, at least for a short time? This might explain the lower rates of post-operative GP in this group. If the same-site keratotomy wound (used for phacoemulsification) does remain patent post-operatively, thereby acting as an *ab interno* goniotrabeculotomy, then separate-site PhacoVC might be expected to have poorer success rates than same-site PhacoVC. Indeed, Park et al.'s results[30] are not as good as Wishart and Dagres's[28] at equivalent time-points: Wishart and Dagres's 24-month success rate was 92 % (n=131, success ≤21 mmHg). Park et al.'s patients were Japanese and Wishart and Dagres's were Caucasian.

Concomitant cataract surgery through same-site incision may improve short-to-medium-term success rates of VC surgery.

Combined Cataract Extraction and Deep Sclerectomy
Unlike PhacoVC, combined cataract extraction and DS (PhacoDS) through the same site would likely increase the risks of hypotony and flat anterior chambers, as there would no longer be a 'guarding' effect from an intact TDW. Hence, surgical techniques in the literature describe separate-site surgery for this technique. As cataract surgery alone has been shown to reduce IOP in open-angle glaucoma,[31] one

would expect PhacoDS results to be better than the DS group. Anand and Anand[32] published two-year success rates of 60 % (n=48, success <19 mmHg) with PhacoDS. Seventy-one percent required GP; 21 % required needle revisions with either 5-FU or MMC. This compares favorably with the success rates of Khairy et al.[14] of 37 % at 24 months (n=43, success <22 mmHg) with DS. This contrasts with phacotrabeculectomy, where IOP reduction rate and progressive follow-up results seem better when trabeculectomy is performed alone.[33–36] Perhaps excessive inflammation generated during phacotrabeculectomy leads to increased probability of surgical failure.

Concomitant cataract extraction with DS may improve short-term success rates of DS surgery.

Cataract Extraction + Deep Sclerectomy + Mitomycin C (PhacoDSMMC)
Anand and Anand[32] published two-year success rates of 76 % with PhacoDS + MMC (PhacoDSMMC), comparing favorably with 60 % in the PhacoDS group (n=48, success <19 mmHg). In the PhacoDS group, 71 % required GP and 21 % required needle revisions with either 5-FU or MMC. In the PhacoDSMMC group, 62 % required GP and 18 % required needle revisions with either 5-FU or MMC. Guedes et al.[18] published three-year success rates of 56 % in PhacoDSMMC (n=41, success <21 mmHg); 12 % required GP.

Concomitant use of MMC may improve the short-to-medium-term success rates of DS.
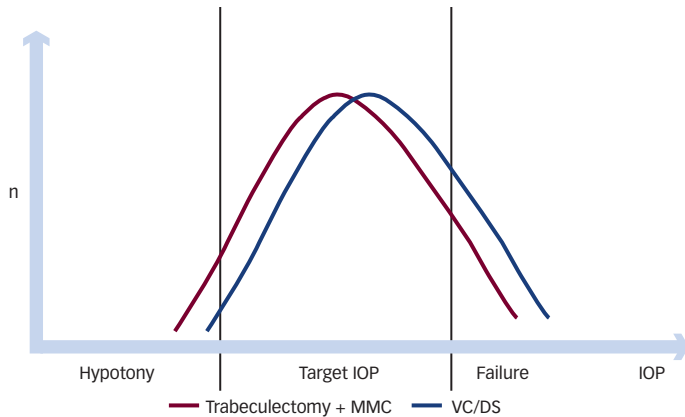
Viscocanalostomy + Canaloplasty (VCc)
In VC + canaloplasty (VCc), once Schlemm's canal has been de-roofed, it is viscodissected and circumferentially cannulated with a microcatheter. Once Schlemm's canal has been cannulated, the microcatheter is withdrawn with a 10/0 polypropylene suture attached to the distal end. Having been pulled back through the entire length of the Schlemm's canal with the withdrawal of the microcatheter, this suture is then locked under tension on a hypotonous eye. The rest of the procedure is as per VC. Grieshaber et al.[37] published 12-month success rates of 94 % (n=25, success ≤21 mmHg); GP was required in six eyes. Lewis et al.[38] published three-year success rates of 40 % (n=89, success ≤21 mmHg), while their 12-month success rate was 57 % (n=91, success ≤21 mmHg). They also published a three-year success rate of 78 % (n=27, success ≤21 mmHg) when combined with cataract surgery.

VCc can achieve excellent success rates in the short term. Excellent medium-term success rates can be obtained with concomitant cataract extraction. Whether these results are better than VC and PhacoVC remains to be determined.

Who Should Undergo Deep Sclerectomy or Viscocanalostomy?
What is a surgeon's motivation not to perform a trabeculectomy? Is it early hypotony or flat anterior chambers? Is it late bleb leaks or late endophthalmitis and a wish to avoid using MMC? (And if so, can the patient afford collagen/hyaluronic acid implants?) Is it to minimize post-operative care? The answers to these questions will determine which alternative to trabeculectomy may be optimal.

Figure 1: Qualitative Comparison of Tonometric Success Rates Between Trabeculectomy and NPGS

DC = deep sclerectomy; IOP = intraocular pressure; MMC = mitomycin C; NPGS = non-penetrating glaucoma surgery; VC = viscocanalostomy.

What Does the Lead Author Do?

With limited although similar experience in both VC/PhacoVC and trabeculectomy surgery, the lead author's preferred surgical techniques are indicated as follows.

Trabeculectomy and MMC for:
- uncontrolled open-angle glaucoma with severe damage;
- open-angle glaucoma with damage occurring at modest IOP levels;
- neovascular glaucoma that is quiescent;
- severe chronic angle-closure glaucoma with separate-site phacoemulsification; and
- abnormal-angle anatomy.

PhacoVC/VC for:
- uncontrolled open-angle glaucoma with moderate damage;
- uveitic glaucoma (to reduce post-operative hypotony and inflammation);
- chronic angle-closure glaucoma with moderate damage;
- patient who would otherwise undergo phacotrabeculectomy;
- only eye;
- split fixation;
- uncontrolled ocular hypertension;

- controlled glaucoma in a patient undergoing cataract surgery who wishes to avoid medication; and
- patient unhappy on topical hypotensives.

When very low IOP is the target, augmented trabeculectomy surgery offers the best chance of success. The question is not whether trabeculectomy can achieve lower IOPs; the question is, lower IOP at what cost in terms of risk of complications? By offering surgery earlier in the course of the disease (when possible) when the target IOP might be higher, it is possible to choose a safer alternative to trabeculectomy. If the target IOP is higher, then the success rate of any surgery is higher. *Figure 1* summarizes these points. By adopting this paradigm, more patients would undergo glaucoma surgery earlier in their disease process. Whereas, a lot of the time, trabeculectomy is a necessity, VC or DS may be an option.

PhacoVC/VC could be offered earlier in the course of the disease, even when glaucoma is not progressive; if a stable glaucoma patient requires cataract extraction, the patient could be offered PhacoVC in an attempt to discontinue topical hypotensives. If the patient does not like using topical hypotensives, PhacoVC/VC can be considered.

While a low target IOP and/or inability to consider ongoing hypotensives argues for augmented trabeculectomy, post-operative complications that might be visually dangerous support VC and DS as options.

Conclusions in 2012

As the level of evidence is mainly moderate to weak, it would be dangerous to conclude too much. Regarding DS, the addition of an implant improves the longevity of success rates; the concomitant use of MMC may further improve success rates, but with the risk of late bleb leaks; concomitant phacoemulsification may also improve success rates. With VC, tight suturing of the scleral flap may be beneficial to success rates, along with same-site phacoemulsification. The best mid-term success rates were obtained by Wishart and Dagres[28] with PhacoVC (three-year success rate of 89 %). The best long-term results were obtained from Bissig et al.[16] with DSI (10-year success rate of 48 %). VCc offers an alternative to VC and DS, but with it comes a significant equipment cost. Attention to surgical technique appears crucial to determine whether or not the procedure works 'in your hands' and when comparing results between studies. ■

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