South African Glaucoma Society - Policy Statement on Glaucoma Surgery -

- July 2019 -

Contents

Introduction

This document was prepared on behalf of the South African Glaucoma Surgery Interest Group, under the auspices of SAGS, in order to define and classify the surgical treatment of glaucoma in patients for whom medical management is either inappropriate or ineffective, in order to maximise intraocular pressure reduction and limit the impact of glaucoma damage.
The purpose of the guidelines is to provide guidance to general practitioners, ophthalmologists and funders on the appropriate indications for surgical intervention in glaucoma and to provide information to glaucoma surgeons and funders on the various surgical options available for the surgical management of glaucoma.

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Declarations

The meeting where this guideline was formulated was held in November 2017 at the OR Tambo International Airport. The meeting was sponsored by Allergan through a grant towards the venue and accommodation for delegates as well as flights for delegates not from Gauteng. All other declarations added as Appendix 1. The document was reviewed on 11 July 2019 and all authors confirmed that it was still relevant and current.

Objectives

The purpose of this document is to:

1. Define and classify the surgical treatment of glaucoma in patients for whom medical management is either inappropriate or ineffective, in order to maximise intraocular pressure reduction and limit the impact of glaucoma damage.
2. Present current treatment options in South Africa, for the management of glaucoma according to best available evidence and local best practice, focusing specifically on surgical interventions.

This guidance was updated in November 2017 and was disseminated to relevant roleplayers for external review and endorsement via the SAGS Website, SAOJ and written invitation, and all input and comment was collated and included prior to final publication. Due to the dynamic nature of the surgical environment in ophthalmology, in terms of technological and clinical advances as well as the funding environment, these guidelines will be reviewed and updated to incorporate any advances that may influence the decision-making process in the surgical management of glaucoma in the South African setting, as regularly as required.

Information Gathering

Literature Review

The medical literature was searched to identify studies and reviews relevant to the surgical management of glaucoma. The following databases were searched, covering the period from their start to 17th November 2017 in order to gather evidence for these guidelines:

Pubmed (MEDLINE, & EMBASE), Cochrane Library, as well as the Internet were searched. No language restriction was applied to the searches

Databases	**Date searched**
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	10/11/2017
PubMed	10/11/2017

Websites searched on 11/11/2017

- National Institute for Health and Care Excellence (NICE)
- SAGS
- Helio
- Brightfocus
- Medscape
- NICE
- General internet search

Each topic and device was searched independently within the above sources and evidence was evaluated by the group for relevance.

Company engagement

Information on the included devices was gathered from the relevant company websites and input to the guidelines was provided by the Medical Advisors of two of aligned pharmaceutical companies:

Dr Juliet Paxton
Medical Advisor, Allergan

Dr Rochester Shen
Medical Advisor, Alcon

Patient commentators' opinions

Patient opinion on glaucoma surgery was evaluated through literature surveys and questionnaires in the public domain.

The Consensus of the Working Group/Executive Summary

Glaucoma is a group of diseases, with marked complexity and variability. Current treatment is aimed at lowering intraocular pressure (IOP), thereby attempting to reduce glaucoma progression such as structural and functional loss of the optic nerve. [1]

Glaucoma is difficult to treat due to differing individual responses and must be tailored to maximise the pressure reduction. Management must include early detection, continuous monitoring and earlier intervention with surgery, to limit the impact of glaucoma damage.

Surgery has the potential to fulfil many features of an ideal approach to reducing IOP over drugs. It can lower the IOP to low teens, achieve long-term IOP reduction, minimise IOP fluctuations, lower the cost, and minimise local and systemic side effects. The major drawback, of traditional surgical options such as trabeculectomy and glaucoma drainage devices though, is the potentially devastating, but rare, ocular side effects. [2] [3]This has resulted in the ongoing development of alternative surgical procedures and several alternatives have emerged as effective options.

The ideal procedure is one that is easy to perform, reproducible, with a low incidence of early postoperative complications and long term, adequate IOP control. Glaucoma surgery has progressed, and recent advances have addressed the flaws in original surgical options. There is, however no "one size fits all" solution and one needs to be selective in choosing surgical procedures. [3]

In general, surgical options requiring smaller incisions (microsurgery) are a significant advance on traditional therapies, reducing IOP with minimal tissue destruction and anatomic structure preservation, short surgical time, simple instrumentation and fast postoperative recovery. The newer advances, with drainage devices of varying materials, targeting varying outflow pathways, offer a selection of IOP lowering opportunities reduced associated risks, time consumption and surgical complexity of older traditional options.

The **SOUTH AFRICAN GLAUCOMA SOCIETY (SAGS)** endorses that all glaucoma surgical devices must be FDA and /or Conformité Européene (CE) approved and/or conform to the South African Regulator (SAHPRA) requirements, before being allowed to be used in South Africa. All the devices discussed in this document have either FDA or CE approval or both. They have all already undergone multiple trials before release for surgeons to use. They are all approved devices and patient safety has been tested and confirmed.

When considering surgery, the surgeon must take an individualised patient approach. Surgery should not be reserved as a last resort, as evidence has shown that earlier surgical intervention can confer benefit. Considerations include the target pressure, the patient's previous history and risk profile, the drainage route: trabecular, suprachoroidal or subconjunctival and whether or not the procedure is being performed in association with cataract surgery or as a solo procedure.

Glaucoma

Definition and Classification

Glaucoma is the only eye disease classified as a chronic disease, amongst the legislated 25 chronic disease conditions in South Africa [4].
Glaucoma is one of the leading causes of blindness in South Africa [5] and as such, deserves adequate, up to date management guidelines. The prevalence of glaucoma in Africa is the highest in the world, 4.16% [6] and is higher amongst the black population than the Caucasian population. [7] (Around 5 to 7% in the black population and 3% to 5% in the white population of South Africa). It thus has a major impact on the visual health of our nation. With proper treatment, the quality of vision and of life can be maintained, but inadequate treatment can lead to blindness and the resultant socioeconomic burden to the State. [6] [8] [9]

Glaucoma is a generic name for a complex group of diseases which can present in many ways making no one method of treatment universal for all cases. [10]

Treatment of Glaucoma

(Refer to Glaucoma Algorithm and Guidelines for Glaucoma - South African Glaucoma Society) [11]

The goal of glaucoma treatment is to maintain the patient's visual function and related quality of life, at a sustainable cost. The cost of treatment in terms of inconvenience and side effects, as well as financial implications for the individual and society, requires careful evaluation. Quality of life is closely linked with visual function. Patients with early to moderate glaucoma damage have good visual function and a modest reduction in quality of life, while quality of life is considered reduced if both eyes have advanced visual function loss.

In a study performed to determine which factors were important to patients with glaucoma it was clear that the loss of vision is perceived as the greatest threat by patients. It was concluded that patients are concerned with their visual outcome and not their method of treatment. The low patient preference to treatment modality means that physician preference plays a larger role in its selection. [12]

Due to the complexity glaucoma, as well as the significant interpatient variability and surgical proficiency required, ophthalmologists, and in particular glaucoma surgeons, should be consulted on and included in the procedures and decisions being employed to manage these patients.

The SAGS Treatment Guidelines are intended to support the general ophthalmologist in managing patients affected or suspected of having glaucoma. The clinical guidelines are to be considered as recommendations. Clinical care must be individualized to each patient, the treating ophthalmologist and the socioeconomic milieu. The availability of randomized controlled trials makes it possible to apply scientific evidence to clinical recommendations.

Surgical Management of Glaucoma *(10) (13) (14) (15)*

The following situations glaucoma patients indicate that surgical intervention is required:

Acute Surgery

Primary Glaucomas

- Congenital Glaucoma
- Acute Angle Closure Glaucoma

Secondary Glaucomas

- Acute Obstructive
  - Acute Rubeotic Glaucoma
  - Acute Uveitic Glaucoma
  - Posner Schlossman Syndrome
  - Acute Post-Surgical Glaucoma
  - Malignant Glaucoma
  - Non-Responsive Traumatic Glaucoma
  - Acute Hyphaema
  - Lens-Induced Glaucoma
- Drug-Induced Glaucoma

Surgery for Chronic Glaucomas

The majority of Glaucoma disorders are chronic, slowly progressive diseases. These conditions are usually started on medical therapy.

A percentage of these cases, [16] [13] despite following recognized algorithms of medical treatment, continue to progress and are labeled "failed" on maximum tolerated medical treatment and still present documented structural and functional progression.

Primary Glaucomas

- Open Angle Glaucoma
- Normal Tension Glaucoma

Secondary Open Angle Glaucomas

- Pseudoexfoliation Glaucoma
- Pigmentary Glaucoma
- Chronic Uveitic Glaucoma
- Angle Recession Glaucoma
- Fuchs Iridocyclitis
- Chronic Angle Closure Glaucoma
- Congenital Secondary Glaucoma
- Post-Surgery Glaucoma
- Drug Induced Glaucoma
- Aphakic Glaucoma
- Neovascular Glaucoma
- Acquired Angle Abnormalities/Carcinoid Syndromes

Indications for Surgery of Chronic Glaucoma [13]

The consensus group states that the following are the criteria for surgery:
In the chronic glaucomas documented above, surgery is indicated in the following situations

1. IOP above **target IOP** (see explanatory notes on determination of target IOP) on **maximum tolerated medical therapy** (see explanatory notes on maximum tolerated medical therapy)

2. **Progression** of glaucoma (see explanatory notes on determination of progression) on **maximum tolerated medical therapy** (see explanatory notes on maximum tolerated medical therapy)

3. **Contraindications** to medical therapy

4. **Side-effects** of medical therapy
   - Local side-effects
     - Allergy
     - Allergy to preservatives
     - Orbitopathy
   - Systemic side-effects

5. Inability to administer pharmacotherapy (E.g. Rheumatoid Arthritis)

6. Other clinically appropriate situations where primary or early surgery/non-pharmacotherapy intervention may be indicated.

Explanatory notes:

1. **Target IOP (EGS guidelines)** [13]
   Target IOP is the upper limit of the IOP estimated to be compatible with a rate of progression sufficiently slow to maintain vision-related quality of life in the expected lifetime of the patient. It should be re-evaluated regularly and, additionally, when progression of disease is identified or when ocular or systemic comorbidities develop.
   There is no single Target IOP level that is appropriate for every patient, so the Target IOP needs to be estimated separately for each eye of every patient.

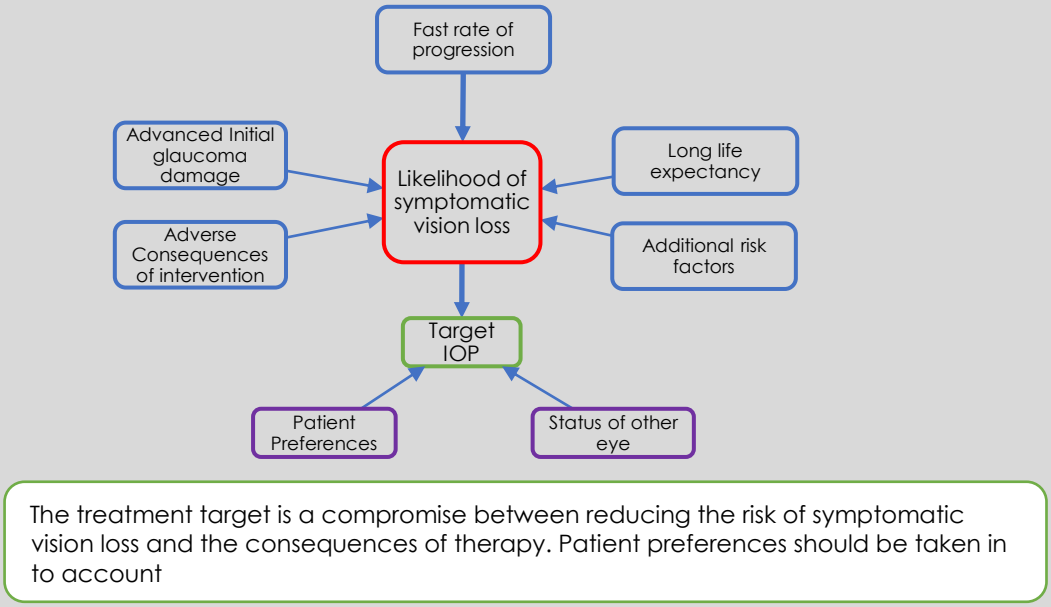


Figure 1

Factors to consider when setting the Target IOP include:

- Stage of Glaucoma
  - The greater the pre-existing glaucoma damage, the lower the Target IOP should be
- IOP level before treatment
  - The lower the untreated IOP levels, the lower the Target IOP should be
- Age and life expectancy
  - Whilst younger age implies greater life expectancy and, therefore, a lower Target IOP, older age is a risk factor for more rapid progression
- Rate of progression during follow up
  - The faster the rate of progression, the lower the Target IOP should be
- The presence of other risk factors, e.g., exfoliation syndrome
- The side effects and risks of treatment
- Patient preference

2. **Maximum medical therapy** [13] [17] [18]

Maximum glaucoma therapy in glaucoma may be defined as the maximisation of the benefits of medical therapy, while maintaining the quality of life of a glaucoma patient. It is not related to maximal tolerable therapy, nor to maximal IOP lowering, but to optimal benefit. In other words, maximum medical therapy is the art of achieving the best possible therapeutic result with medications while avoiding toxicity and inconvenience as much as possible; where the practitioner uses the least amount of medicine, to achieve the desired goal, with the least adverse effects. To achieve this, the practitioner is required to monitor the interaction between the medication, the patient, and the disease, as patients' responses are highly individual and often unpredictable. In addition, the instability of the disease itself requires frequent assessments as part of the overall strategy to preserve a patient's visual function

Throughout the treatment process the practitioner must ensure that the patient can adhere to therapy and consider that patients seldom experience any benefit from medications but

usually notice the immediate side effects such as ocular discomfort and hyperaemia. The possibility of side effects and a reduction in adherence increases with the number and dose of glaucoma medications

For the patient with insufficient IOP control on medical therapy, the question remains, when does one stop adding medications and consider surgical options? Despite there being extensive possibilities, trying every combination of medications available is not a practical option. In addition to the potential failure of maximal medical therapy, there is a cost associated with trying all available combinations of medications. While one is waiting to find a combination that may work, time is passing where the IOP is above the theoretical target and the patient may be losing ground and the disease may be progressing.

After the second, and certainly after the third medication is added, it is difficult to make a good case for continuing to add additional agents. A point of diminishing returns is reached due to compliance issues and surgical intervention should be considered.

Criteria for progression (19) (20) (21). (22), (23) (24) (25). (26)

Detection of progression and estimation of rates of disease deterioration are essential to evaluate risk of functional impairment and establish treatment strategies.
Due to the lack of correlation between structural and functional loss at different stages of glaucoma, it is important to assess both data to detect progression and estimate rates of change in the disease.
The identification of structural and/or functional changes which are found to be outside of the age-related norms, indicate loss which can be attributed to disease progression. Occurrence of future visual impairment (depicted as a certain amount of visual field loss) can be predicted from the current visual field loss of a patient compared to previous visual field tests.

a. Visual Field Progression
   - Functional Rate of Progression is measured in decibels (MD) or percentage (VFI) per year
   - In general terms, VFI relates to MD:
     1%/year = 0.3 dB/year
   - RoP ≥ 3 %/year (≤ -1 dB/year) may lead to significant loss of QoL almost at any age

b. Retinal Nerve Fibre Layer Damage (RNFL) on OCT
   - Normal rate of age-related change is estimated to be between 0.2 and 0.5 µm/year (2–5 µm/10 years)

c. Optic Nerve Head (ONH) Structural Progression
   - In healthy adults, mean cup-to-disc (CD) ratio increases by approximately 0.1 in four decades
   - In adults, significant changes in all HRT parameters in 11 years
     - MRA classification: 9 out of 31 eyes (29%) changed for the worse in the global or any of the sector classifications

d. Retinal Ganglion Cell (RGC) Loss
   - By the time visual field loss is identified, up to 50% of retinal ganglion cells may be lost.

Table 3. Change in OCT Average RNFL Thickness Measurements Corresponding to Different Amounts of Change in Estimated RGC Counts at Different Stages of the Disease

Stage of Disease		Change in Average RNFL Thickness, µm, for a Change of:		
MD, dB	Estimated RGC Count	10,000 RGCs	35,000 RGCs	100,000 RGCs
0.4*	1,020,000	0.5	1.9	5.4
−2	710,000	0.5	1.7	5.0
−5	560,000	0.5	1.5	4.5
−10	403,000	0.4	1.0	2.6
−15	281,000	0.3	0.6	1.5
−20	193,000	0.05	0.1	0.4
−25	121,000	0.03	0.1	0.3

* Average MD of the healthy eyes included in the study.

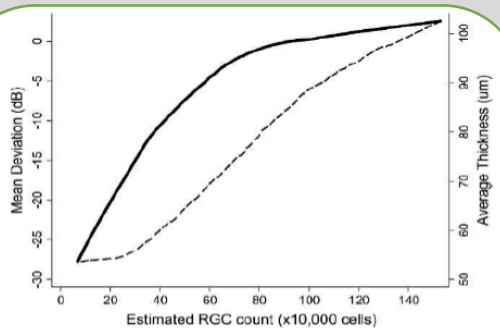


Figure 4. Relationship between MD, average RNFL thickness measurements, and estimated RGC counts. At early stages of damage (high RGC counts), changes in estimated RGC counts correspond to relatively smaller changes in MD (*continuous line*) and relatively larger changes in average RNFL thickness (*dashed line*). At advanced stages of damage (low RGC counts), changes in estimated RGC counts correspond to relatively large changes in MD, but only small changes in average RNFL thickness.

Glaucoma Surgical Procedures

The purpose of glaucoma surgery is to reduce intra-ocular pressure (IOP). [13] [27] [3]

IOP is determined by the equilibrium between aqueous humour production within the eye and drainage from the eye. [28]

Aqueous humour is produced by the ciliary body and drains out of the eye via the trabecular meshwork into the canal of Schlemm and from there into the collector channels and episcleral venous circulation. There is also uveoscleral drainage of aqueous humour. [29]

The surgical reduction of IOP can therefore be achieved by: [29]

1. Reducing aqueous humour production
   a) Cyclodestructive procedures (procedures that target the ciliary body)
2. Increasing outflow of aqueous from the eye
   a) Subconjunctival filtration (these procedures bypass the trabecular meshwork/canal of Schlemm and produce drainage 'blebs' under the conjunctiva. Aqueous exits the eye via the conjunctival vessels into the episcleral venous circulation)
   b) Enhanced filtration into the canal of Schlemm (these procedures bypass the trabecular meshwork and drain directly into the canal of Schlemm)
   c) Suprachoroidal filtration (these procedures create a direct pathway from the anterior chamber into the suprachoroidal space into the episcleral venous circulation)

For each of these groups the surgical approach may be subdivided into either *ab interno* (this implies a surgical approach from within the anterior chamber of the eye – a less invasive and more direct approach) or *ab externo* (this implies a surgical approach from the exterior of the eye – this usually implies a conjunctival recession and incision through the sclera – removing or modifying tissue). [27]

General Principles [13] [27]

The different techniques of incisional surgery have different indications depending on the type of glaucoma. There adoption depends on:

- The target IOP chosen for the individual eye
- The previous history (surgery, medications, degree of visual field loss)
- The risk profile (i.e. single eye, occupation, refractive status)
- Preferences and experience of the surgeon
- The patient opinion, expectation and postoperative compliance

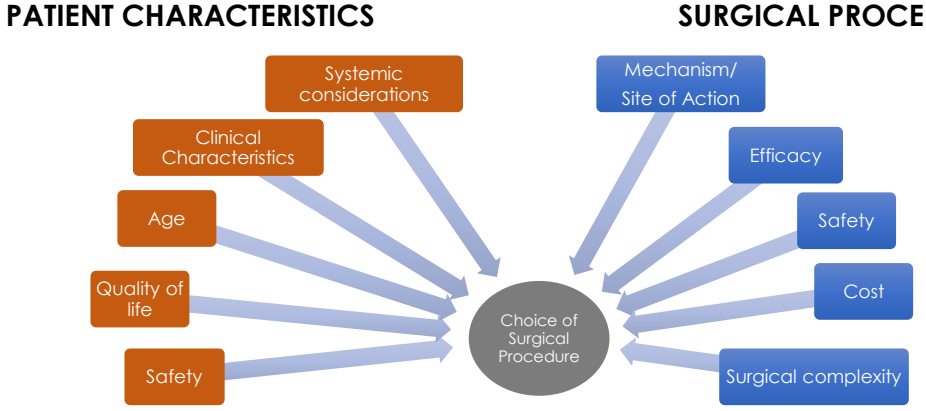
The decision to recommend glaucoma surgery should be made in light of published clinical trials. In the individual patient, a multitude of factors must be taken into account when deciding treatment, including compliance, stage of glaucoma, etc. Nevertheless, surgery should be considered whenever medical or laser treatment are unlikely to maintain sight in the glaucomatous eye. It should not be left as a last resort. Angle-closure glaucoma is usually initially approached by laser iridotomy or peripheral iridectomy. Primary congenital glaucoma is treated with goniometry or trabeculotomy, or seton surgery with antifibrotic agents.
For repeated surgery, cysclodestructive procedures and tube implants are more commonly used.

Surgical Procedures (30)

Surgical Procedure	*Ab Interno*	*Ab Externo*
Cyclodestructive	Endocyclophotocoagulation	Micropulse Cyclodiode Cyclodiode
Subconjunctival filtration	Xen Implant	Trabeculectomy Trabeculotomy Express Deep Sclerectomy CO2 laser assisted sclerectomy Ahmed Valve Molteno Implant Baerveldt Implant Innfocus Microshunt
Enhanced filtration into the canal of Schlemm	Canaloplasty ab interno SLT, ALT iStent Hydrus Excimer laser trabeculoplasty Trabectome	Viscocanaloplasty Viscocanalostomy
Suprachoroidal filtration	CyPass iStent Supra	

There are therefore numerous surgical options. Each has its own advantages and disadvantages. Some are more effective at pressure lowering but at the expense of numerous potential complications. Some procedures are much safer and still others are faster and easier to perform. Some patients may not be anatomically suited to certain surgical approaches. There may be specific contra-indications to certain approaches. Some approaches require more extensive post-operative care including a return to theatre. Some procedures require augmentation.

Each patient needs an individual assessment to determine the best procedure for that situation. (9) Factors that need to be considered when deciding on the best procedure for a given clinical situation are illustrated below



Drainage Devices *(31) (3) (32)*

History

South Africa has a long history of Glaucoma drainage devices. A South African Ophthalmologist, Dr Anthony Molteno (BJO 1969) was one of the earliest pioneers in the use of glaucoma drainage devices. Other South Africans such as Dr George Baerveldt have also developed devices. This was in response to the difficult types of glaucoma being managed and because the treatment methods available were not completely successful. Much of the early experience of glaucoma devices was developed in South Africa. (33)

New Approaches

New engineering and new concepts are producing multiple new approaches. Better understanding of the pathophysiology of glaucoma as well as many more doctors working on the concepts and treatment of glaucoma has produced many new approaches and new methodologies to treat glaucoma. The new advanced engineering capabilities have also produced the ability to produce smaller and better engineered devices to standards not possible in the past. The surgical routes are now directed at multiple sites: directly into the Schlemm canal (SC) or bypassing the trabecular meshwork into the SC, directly into the suprachoroidal space, ab interno into the sub conjunctival space, ab externo into the trabecular meshwork and several other routes. The newer drainage devices are aimed at being minimally invasive and to have a higher safety profile. Glaucoma surgery has a significant complication rate which can impact on vision as well as a variable long-term success rate. The newer devices are significantly less invasive and have less potential of vision impairment from the earlier procedures

SAGs Standpoint

The **SOUTH AFRICAN GLAUCOMA SOCIETY (SAGS)** endorses that all devices must be FDA, CE and /or SAHPRA approved before being allowed to be used in South Africa and covered by funders. All the devices listed below have either FDA and/or CE and SAHPRA approval. They have all already undergone multiple trials before release for surgeons to use. They are all approved devices and patient safety has been tested and confirmed.

Devices Currently Available in South Africa

Ab Interno Canaloplasty

How it Works (34) (35) (36)
AB- interno Canaloplasty (ABiC) evolving directly from Canaloplasty, is a new Minimally Invasive Glaucoma Surgery (MIGS) procedure that may achieve similar IOP-lowering effects to traditional (ab-externo) Canaloplasty in patients with mild to moderate POAG.
As with traditional Canaloplasty, ABiC is designed to access, catheterize, and viscodilate all aspects of outflow resistance – the trabecular meshwork, Schlemm's canal, and the distal outflow system beginning with the collector channels. The key difference, however is that no tensioning suture is required to maintain the IOP reduction with the ab-interno approach and the procedure spares conjunctival manipulation for future procedures if required.
Like traditional Canaloplasty, ABiC addresses all the key structures that control ocular outflow – the trabecular meshwork, Schlemm's canal and collector channels. It is also follows the same dilatation principles as traditional Canaloplasty where gentle application of viscoelastic during insertion allows the compressed tissue planes of trabecular meshwork and sclera to separate and any herniated trabecular meshwork tissue to withdraw from collector channels. Again, similar to traditional canaloplasty, after circumferential passage of the iTrack 250A canaloplasty microcatheter, viscoelastic is emitted upon single clicks of the viscoinjector knob (35) (34) (36).

Advantages/Disadvantages (35) (34) (36)
It eliminates the need of conjunctival and scleral incisions. The eye looks normal after the procedure. It preserves outflow channels and minimises surgical trauma to the eye. However, the learning curve is very long and steep.

Indications (35) (34) (36)
Mild-to-moderate Primary Open-Angle Glaucoma. It can be performed in conjunction with cataract surgery.

Complications (35) (34) (36)
The procedure has minimal complications.
However, a poor surgical technique may result in injury to anterior segment structures like peripheral cornea, iris and lens.

Canaloplasty

How it Works (37) (38) (34) (39) (40)
Canaloplasty is a modification of viscocanalostomy, a form of non-penetrating glaucoma surgery. In this older technique, an ophthalmic viscoelastic device is injected into Schlemm's canal on either side of the external scleral dissection side with a metal cannula. The cannula is not flexible, can only be extended into Schlemm's canal for a limited distance and thus only dilates a limited portion of the canal on either side of the dissection site.

Indications (37) (38) (34) (39) (40)

1. Canaloplasty can be proposed in patients with moderate to advanced glaucoma when Schlemm's canal is not completely fibrosed.
2. Open angle glaucoma.
3. PXS glaucoma
4. Juvenile/congenital glaucoma
5. Pigmentary glaucoma
6. Some cases of traumatic glaucoma
7. Failed trabeculectomy in which SC has been left undamaged.

Contraindications (37) (38) (34) (39) (40)

1. Non-reversible collapse of collector channels and outflow pathways that cannot be enlarged due to anatomical factors.
2. Angle-closure glaucoma.
3. Narrow-angle glaucoma
4. Neovascular glaucoma.
5. Inflammatory glaucoma
6. Post traumatic glaucoma
7. Interruption /damage to SC due to previous ocular surgery or extensive laser trabeculoplasty with peripheral anterior synechiae.
8. Ocular hypertension due to increased episcleral venous pressure
9. Other forms of secondary glaucoma.

Surgical Techniques (37) (38) (34) (39) (40)
Canaloplasty creates a conjunctival flap in the supranasal quadrant. A superficial scleral flap is dissected forward into clear cornea and Schlemm's canal is opened. The deep scleral flap is removed and the two ostia of the canal are dilated with viscoelastic. The iTrack 250-micron microcatheter is then inserted and guided within Schlemm's canal for the entire 360 degrees until it emerges at the other end of the canal opening. A stent suture is then tied to the catheter's distal tip and the microcatheter is reversed back through Schlemm's canal in the opposite direction. Inward distension of the trabecular meshwork is achieved by knotting the suture under tension. The superficial scleral flap is repositioned and sutured to its position in a watertight fashion.
Viscodilation is a fundamental component of the procedure circumferential (360^0) catheterization of Schlemm's canal with the iTrack 250A, combined with gentle vasodilatation, breaks adhesions within Schlemm's canal stretches the trabecular plates creating micro perforations within the inner wall of the trabecular meshwork

thus allowing flow into the Schlemm's canal, and separates herniations of the inner wall of the trabecular meshwork into the outer wall collector channels.
One of the more compelling reasons for using Canaloplasty is that it takes due account of the eye's natural outflow system and restores the physiological outflow pathways. This is in contrast to most other glaucoma treatments which not only fail to address the eye's natural drainage system but may also, in some cases, even impede this outflow function.

Advantages/Disadvantages (37) (38) (34) (39) (40)

Advantages

1. It is a blebless procedure that restores physiological aqueous humour outflow.
2. No subconjunctival bleb.
3. No antimetabolites.
4. Few post-operative complications
5. The vast majority of patients tend to have a normal looking eye after a few weeks, without ocular discomfort.
6. Faster visual rehabilitation after surgery.
7. Post-operative results and IOP levels tend to be stable overtime.
8. May be considered in eyes with chronic conjunctivitis arising from long-term anti-glaucoma medical treatment or suffering from severe conjunctival scarring from filtering techniques

Disadvantages

1. A long and rather steep learning curve.
2. Requires specifically designed, expensive instruments.
3. Average post-operative IOP levels tend not to be very low.
4. Limited indications.
5. Impossible to cannulate SC in about 10 to 15% of cases and might need convert to viscocanalostomy.
6. Might need trabeculectomy if there is poor IOP control.

Complications (37) (38) (34) (39) (40)

1. Transient decrease in visual acuity in the first two weeks, due to induced with-the-rule astigmatism which is suture-related.
2. Schlemm's canal rupture and descemet's membrane detachment.
3. Intracorneal haematoma may result from descemet's detachment.
4. Microhyphaema due to open and functioning outflow channels. This is usually a good prognostic sign.
5. Transient intra-ocular pressure (IOP) rise. If pressure rise persists beyond two weeks non-invasive intervention may be considered.

Administrative Information

Sterigenics International LLC

FDA Approved
Product class: HMX
Device class: 1
Reg. No: 886.4350
Reg Estab No: 2953359
Owner no:10029425

Key Points

Outcomes of Canaloplasty appear to be superior to other well-established surgical techniques such as viscocanalostomy but statistically inferior to trabeculectomy with antimetabolites in which post-operative IOP tends to be in the lower teens

Ocular Cryotherapy (Cyclocryotherapy)

How it Works
Generally used as a surface technique [41], with the probe applied to the eye without any incision into the tissue. It is a less invasive type of procedure.

Indications
1. Severe intractable glaucoma that is not amenable to conventional glaucoma medication or surgery [41] [42] [43]
2. Neovascular glaucoma
3. Progressive functional visual loss despite a maximum tolerated medical therapy
4. Blind painful eye- Cyclocryotherapy achieves pain relief even if good pressure control is not achieved

Contraindications
Active infection i.e. bacterial, viral, fungal or blepharitis.

Surgical Techniques
Cryotherapy is based on the tissue changes induced by subfreezing temperatures. Living tissue responds to extremely cold temperatures through ice formation, both within the cells and also in the extra cellular fluid surrounding the cells.

In addition, subfreezing temperatures cause ice formation with small blood vessels interrupting blood supply to adjacent cells. A combination of these factors destroys living tissue through ischaemia and necrosis and induces inflammation as a response to cell death.

Parameters such as temperature, duration, probe diameter, pressure on the sclera extent of ciliary body freezing and any need for additional Cyclocryotherapy determine the amount and rate of tissue destruction [43].

Cyclocryotherapy can be applied in the lower 180^0 or 360^0 of the globe, posterior to the limbus with a 2,5 mm diameter cryoprobe.

Advantages/Disadvantages
It is a simple and non-invasive [42] short ablative surgical procedure that has been effectively used to treat advanced uncontrolled glaucoma.
However, it may have to be repeated.

Complications
1. Deterioration in visual acuity [42] [44]
2. Phthisis bulbi [42] [44] [45].
3. Conjunctival congestion [45].
4. Iridocyclitis [45] [44]

Deep Sclerectomy (46) (47) (48) (49) (50)

How it Works
Non-penetrating surgical technique that takes advantage of the eye's natural drainage network to reduce IOP in patients with POAG

Indications
1. POAG
2. Pediatric Glaucoma
3. Uveitic glaucoma

Contraindications
1. Neovascular glaucoma
2. Angle dysgenesis
3. Plateau Iris
4. Corneal oedema or opacities
5. Elevated episcleral venous pressure
6. Angle Closure Glaucoma

Surgical Techniques
Steep learning curve

Advantages/Disadvantages
1. Neovascular glaucoma
2. Angle dysgenesis
3. Plateau Iris
4. Corneal oedema or opacities
5. Elevated episcleral venous pressure
6. Angle Closure Glaucoma

Endo-Cyclo Photocoagulation

How it works

Selective destruction of the ciliary body to treat glaucoma
ECP, a miniature endoscopic camera is placed inside the eye to view the ciliary processes that produces the fluid inside the eye. This area is then directly treated with a laser which decreases the production of fluid in the eye, and leads to decreased eye pressure

Indications

Refractory Glaucoma

Advantages/Disadvantages

Good safety profile
Minimally invasive
ECP can be combined with cataract surgery.

Complications

Fibrin exudates
Hyphemia
Cystoids edema
Vision loss of 2 lines or more.

Contra-indications

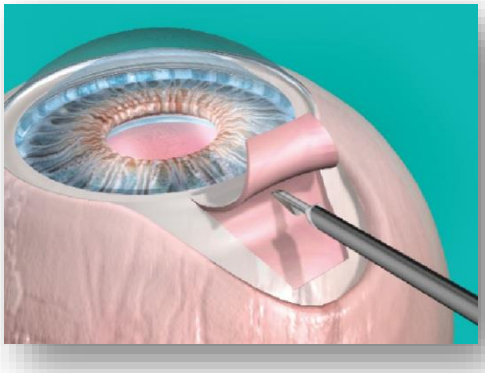
Infections
Uveitic Glaucoma

Express Implant [51] [52]

A stainless-steel non-valved filtration device, current model: 2.64 mm length, internal lumen of 50/200µm, designed to simplify device implantation with its 6-point engineering specifications: stainless steel, length, fixed diameter, dual inlet, restrictor bar, surface footplate with vertical channel)

How it Works

The device is inserted under a scleral flap into the anterior chamber.
It shunts aqueous from the anterior chamber to a subconjunctival filtration bleb
Aqueous flow is limited by the device's internal diameter



Indications

1. Patients with POAG, uncontrolled on medications or laser therapy
2. Patients with controlled uveitis
3. Patients with a higher risk of bleeding

Contra-Indications

Acute angle-closure glaucoma/patients with narrow angles

Advantages/Disadvantages

Advantages

1. Can be combined with cataract surgery
2. Average learning curve

Disadvantages

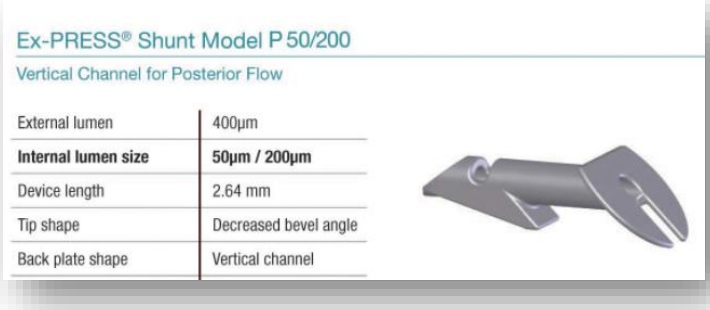
1. Tube migration/extrusion
2. Risk of lumen obstruction
3. MRI safety (risk during initial 2-week post-operative period)

Complications

1. Early post op hypotony
2. Flat anterior chamber
3. Hyphaemia
4. Cataract

Administrative Information

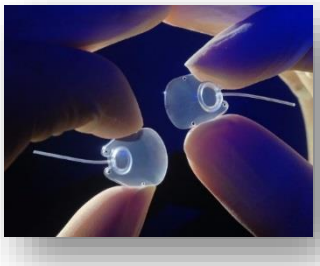
ALCON Research LTD
FDA Approved
K012852
Product code: KYF
Device Code:2
Reg no: 886.3920
Reg Establ No: 2523835
Owner No:1610287



Glaucoma Setons (53) (32)

Examples

- Molteno Valve
  - First
  - Second
  - Third Generation: biological Ahmed Valve
- Baerveldt Valve

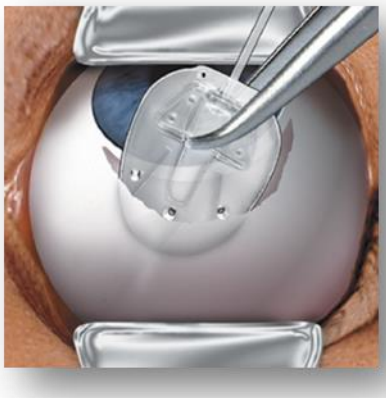


How they Work

A glaucoma seton is a medical shunt bypassing the drainage angle to reduce intraocular pressure (IOP).

Indications

1. These are indicated for glaucoma patients not responding to maximal medical therapy, with previous failed guarded filtering surgery.
2. Refractory glaucoma
3. Neovascular glaucoma
4. Uveitic glaucoma
5. Juvenile glaucoma
6. Silicone glaucoma



Contraindications

1. Infections
2. Conjunctival scarring

Surgical Techniques

Steep learning curve

Advantages/Disadvantages

1. Good Pressure reduction
2. Can be used with refractory Glaucomas
3. Neovascular glaucoma

Complications

1. Hypotony and IOP rise
2. Choroidal detachment
3. Diplopia
4. Corneal oedema/ injury
5. Iridocyclitis
6. Vision loss
7. Tube erosions
8. Tube occlusions
9. Encapsulated bleb

Administrative Information

FDA approvals:

- Molteno glaucoma implant
  - K062252
  - K902489
  - K890598
  - K152996
- Ahmed glaucoma implant
  - K925636
  - K980657
- Baerveldt Glaucoma implant
  - K905129
  - K955455

iStent/iStent Inject (54) (55)

1. THE I-STENT

1ST generation trabecular micro-bypass product
Approved by FDA
Composed of titanium, heparin-coated
Connects the Schlemm's canal directly to the anterior chamber and allows aqueous to flow freely between the two spaces
Dimensions: 1mm long and 0.3 mm in height
How it works:

The longer pointed end facilitates entry into Schlemm's canal.
The 3 retention arches secure it position.
The half cylinder profile with an open posterior wall prevents blockage or fibrosis over the tip.
The inserter consists of 26-gauge tubing and 4 finger extensions. the latter allows re-grasping of the device if further manipulation or repositioning is necessary.
Implanted via a clear corneal incision and an ab interno approach under gonioscopy

2. (I-STENT INJECT) 2ND GENERATION MODEL

Certified in Europe
Composed of Titanium
360 microns long, 230 microns wide apical head with 4 inlets to allow passage of aqueous. the narrow body contains the lumen and sits within the trabecular meshwork. A flange secures the device on the inner wall of the meshwork.
The injector is covered by a 23-gauge stainless steel insertion sleeve. it comes pre-loaded with 2 stents.
Advantages:

Easier surgical technique. no sideways sliding of the stent required for positioning. 2 devices can be inserted with one inserter without exiting or re-entering the eye.
The procedure can be performed with phacoemulsification

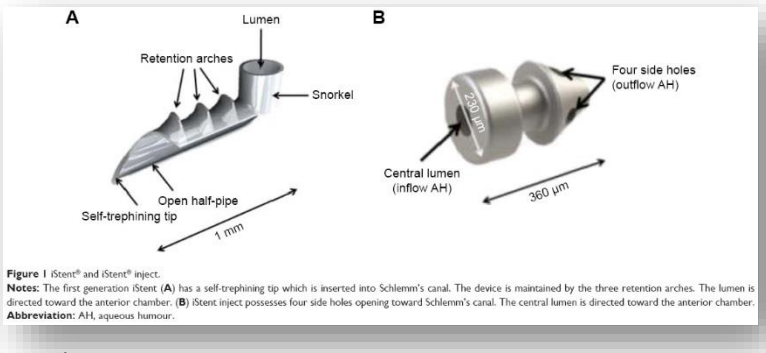


Figure 1 iStent® and iStent® inject.
Notes: The first generation iStent (**A**) has a self-trephining tip which is inserted into Schlemm's canal. The device is maintained by the three retention arches. The lumen is directed toward the anterior chamber. (**B**) iStent inject possesses four side holes opening toward Schlemm's canal. The central lumen is directed toward the anterior chamber.
Abbreviation: AH, aqueous humour.

Mechanism of Action

Creates and maintains a channel between aqueous in the A/C and Schlemm's canal
One I-Stent reduced total out flow resistance by 30% and IOP by 6 mmHg. Two I-Stents decreased resistance by 44% and IOP by 8.9 mmHg.
One I-Stent inject increased outflow facility from 0.16 to 0.38 µL/min/mmHg. Two I-Stent inject increased outflow facility from 0.16 to 0.78 µL/min/mmHg.

Efficacy

RCT and Case Series have documented IOP reductions that ranged from16%-33% and medication reduction ranging from 0.5-2.0 agents.

Safety
The 1st generation studies reported consistent safety data with few adverse events <2% requiring a trabeculectomy. Case series also reported good visual outcomes with no hypotony, choroidal effusions or flat anterior chamber.
Most complications related to Stent malpositioning or occlusion in the early pre-op period. (4%-18%)
Complication rate decreased with Surgeon experience

Indications
1. Primary Open Angle Glaucoma
2. Pseudo exfoliation Glaucoma
3. Traumatic Glaucoma
4. Steroid-Induced glaucoma
5. OHT

Contra-Indications
All forms of angle closure glaucoma and post trabecular causes of open angle glaucoma

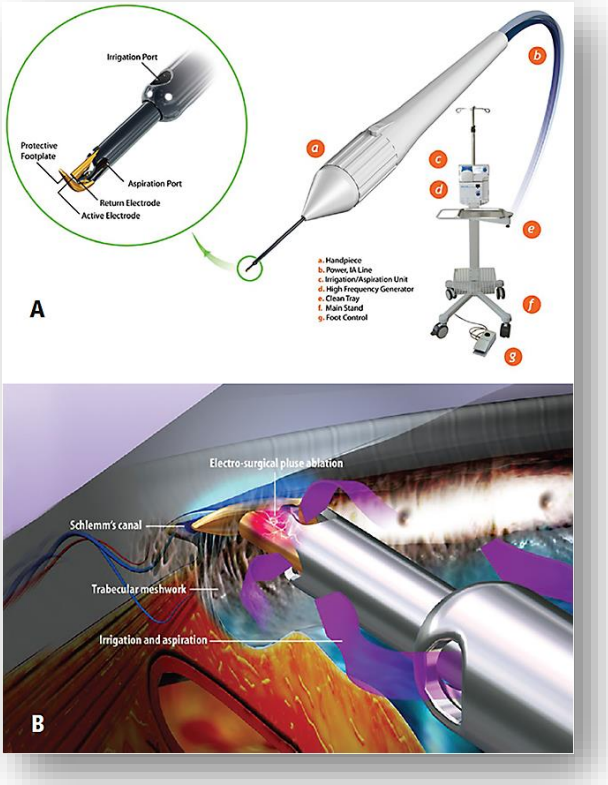
Cost
Study was done in Canada comparing the cost of 2 I-Stents versus medical therapy
The price of 2 I-Stents plus disposable intraoperative materials excluding the surgeon's fee was 1,044 Can Dollars. Over 6 years cost savings of 20.77Can Dollars, 1,272.55 Can Dollars and 2,124.71 Can Dollars per patient were found when comparing 2 I-Stents vs Monodrug, Bi-Drug and Tri-Drug Therapy

Quality of Life (QOL)
Studies not done but improvement in QoL is expected due to reduction or elimination of glaucoma medication.

Trabectome (56) (57) (58)

How it Works
Electro-cautering of the Trabecular Meshwork(TM) is done for aqueous drainage to the collector channels, lowering the IOP to normal episcleral venous pressure

Indications
- Primary and secondary open angle glaucomas
- Paediatric glaucoma
- Pigment dispersion syndrome
- Pseudo exfoliation syndrome
- Uveitic glaucoma



Contraindications
- Neovascular glaucoma
- Angle dysgenesis
- Plateau Iris
- Corneal oedema or opacities
- Elevated episcleral venous pressure
- Angle Closure Glaucoma

Surgical Techniques
Steep learning curve

Advantages/Disadvantages
- Minimal invasive
- Can be used in conjunction with cataract surgery
- Conjunctiva is spared
- Excellent safety profile
- Rapid recovery
- Directly improves physiological outflow
- Positive patient outcome

Complications
- Mild hyphema - 1 week
- Fluctuating IOP for 1 month - keep on meds
- Peripheral anterior synechiae need Isopto-carpine 2%

Administrative Information
Neomedix corporation
FDA Approved 2004
21 CFR 878.4400
K061258
CE Approval 2003
Machine: M4558
Hand piece: DM1207844

Trabeculectomy [59] [60] [61] [62] [63] [64] [65]

Cairns was the first to report success with this procedure in 1968 and it has been the standard glaucoma procedure since then.

How it works

Trabeculectomy creates a fistula between the anterior chamber and the sub conjunctival space. This provides an alternative method of aqueous filtration when the natural trabecular network is blocked.

The goal is to create the correct amount of flow without causing over filtration. Its success relies on the continued patency of the fistula and the continued ability of the filtering bleb created to absorb aqueous.

The success of the procedure, depends on the surgical technique, the intra-operative and post-operative procedures to modulate wound healing.

The use of anti-metabolites like Mitomycin C tries to prevent tenons and conjunctival scarring.

Indications:

1. Primary open angle glaucoma not responding to conventional treatment
2. Primary angle closure glaucoma not responding to standard treatment
3. Secondary open angle glaucoma
4. Secondary angle closure glaucoma
5. Childhood glaucoma

Trabeculectomy is performed for all types of glaucoma patients who develop glaucoma progression on maximum tolerated medication.

Contraindications:

1. Hypotony
2. Hyphema
3. Tenons conjunctival scarring

Surgical technique:

1. A surgical incision is made through the conjunctiva to create a conjunctival flap and a partial thickness scleral flap.
2. A full thickness surgical fistula is created at the base of the scleral flap to connect the anterior chamber with the sub conjunctival space
3. Peripheral iridectomy is performed, followed by suturing of scleral and conjunctival flaps.

Particular care must be taken to make sure that the conjunctival flap is water tight to prevent postoperative wound leaks.
Intra operative Mitomycin C is used to prevent fibrosis and increase the success rate. Mitomycin C can cause complications like wound leakage.

Complications:
Intraoperative complications:

- Conjunctival buttonhole or tear
- Scleral flap buttonhole
- Premature entry into the anterior chamber
- Crystalline lens injury
- Hyphema
- Vitreous loss
- Intraoperative suprachoroidal haemorrhage
- Intraoperative aqueous misdirection syndrome

Early postoperative complications:

- Anterior chamber haemorrhage
- Wound leak or dehiscence
- Hypotony
- Choroidal effusion
- Shallow or flat anterior chamber
- Pupillary block
- Corneal or ciliary body toxicity secondary to antimetabolites

Late postoperative complications:

- Blebitis and bleb related endophthalmitis
- Encapsulated bleb
- Late bleb failure
- Late bleb leak
- Hypotony
- Cataract formation or progression
- Cystic bleb
- Bleb dysesthesia
- Overhanging bleb

Key Points

While officially trabeculectomy is still the gold standard filtration surgery, in recent years, due to innovation of the new glaucoma devices, there has been a significant move to safer, less invasive procedures, most of which allow a trabeculectomy to be performed at a later stage if required.

Trans Scleral Photocoagulation

How it Works

Laser photocoagulation of the ciliary body, through the sclera, decreases the production of aqueous humour in the eye, leading to decreased intra-ocular pressure

1. **Traditional TSCPC:**
   Traditional TSCPC uses continuous wave diode laser in a destructive way and the non-fractionation causes a significant build-up of heat in target tissues causing both the destruction of tissues producing aqueous and a significant amount of inflammation. [66]
2. **Micropulse diode TSCPC**:
   Micropulse TSCPC employs a fractionated continuous wave diode laser which targets melanin in a non-destructive way in ciliary body tissues, the tissue responsible for production of aqueous humour. Chopping the continuous wave of laser energy into micropulses allows a significant and clinically efficacious amount of heat to be applied to target tissues while allowing the heat to dissipate between pulses, preserving the efficacy while preventing unwanted inflammation, scarring, and hypotony. The time between the pulses is called the thermal relaxation time. Pulsing or fractionating laser has also been used for retinal treatments of CSCR, AMD and macular oedema by and in CO_2 lasers used for cosmetic surgery. ([66]

Indications

1. **Traditional TSCPC**
   - Intractable / uncontrolled glaucoma
   - Elevated intra-ocular pressure with poor visual potential
   - Pain relief in a blind eye
   - Medically not suited for surgery

2. **Micropulse TSCPC**
   - Primary treatment of all kinds of glaucoma
     - TSCPC has been shown to be safe and effective alternative for glaucoma therapy for patients with Open Angle Glaucoma [66].
     - It works well in exfoliation and angle closure glaucoma [67].
   - Patients who cannot take medications [67]
     - Unwilling or unable to instil drops [66]
     - Those with dry eye disease worsened by topical medications or preservatives [66]
   - Patient who prefers laser over incisional surgery [68], but in whom previous laser therapy (ALT / SLT [66]) has lost effect over time and those whose response to previous laser therapy has been inadequate (69).
   - Primary surgery for elderly patients [68] or other patients not fit for surgery
   - Preferred over traditional filtration surgery
     - When a patient's response to the surgery was poor in the fellow eye[69]
     - When the risk of the traditional filtration surgery's failing is high [69]
     - When there is an increased risk of complications from traditional filtration or incisional surgery [67], [69]

    - If the patient has a very high IOP or a history of vitrectomy or retinal surgery, and is more likely to experience hypotony maculopathy or choroidal effusions [69]
- Patients with previous choroidal haemorrhage in fellow eye [68]
- Failed tube or IOP after previous tube not low enough [68] – compliments prior tube shunt devices [67]
- Patient with severe blepharitis [68]– not fit for surgery due to increased risk of infection [67]
- Patient in whom a bleb is undesirable [69]
- Ocular cancer [68]
- When there is no one to take the patient home after the procedure [68] or they have problems with transportation back to the office for postoperative care

Advantages

1. Non-invasive - negating all the risks of invasive surgery. Its excellent safety profile allows us to fill the gap between medications and riskier surgeries. [68]
2. Ability to titrate energy settings, which allows surgeons to customize treatment to the individual patient [66]
3. Postoperative restrictions are non-existent [66]
4. Allows the patient to maintain his / her quality of life, without having to undergo incisional glaucoma surgery [67]
5. The burden of postoperative visits tends to be less than with traditional glaucoma surgical approaches. [66]
6. With lower energy settings, it is less likely that CPC will lead to conjunctival scarring, leaving the vast majority of patients candidates for further surgical intervention involving the conjunctiva, should it be needed. [66]
7. The procedure can be performed in the office or an OR setting. [66]
8. No major recovery time (67), great for patients who are working, travelling or have difficulty making postoperative visits [68] .

Disadvantages

1. Painful procedure – needs retrobulbar anaesthetic [67]
2. May have mild post-procedure pain

Complications

1. **<u>Traditional TS-CPC</u>**
    - Conjunctival scarring [66]
    - Hypotony [66]
    - Vision loss - can result from cataract formation, cystoid macular oedema, ocular surface issues related to neurotrophic corneal effects, hypotony, or chronic inflammatory effects such as choroidal effusions. [66]
    - Iritis [66]
    - Risk of chronic pain, and /or an atonic pupil

2. **Micropulse TS-CPC**
   - Mild post-procedure pain [66]
   - Very low risk of
     - Chronic uveitis
     - Loss of vision [66]
     - Cataract formation [66]
     - Conjunctival scarring

Contra-Indications

1. **Traditional TS-CPC**
   - Good vision

2. **Micropulse TS-CPC**
   - Good vision?
   - Previous uveitis?

Administrative

1. **Traditional TS-CPC**
   Cyclodiode laser

2. **Micropulse TS-CPC**
   The CYCLO G6 (IRIDEX), a new glaucoma-dedicated laser system; an 810-nanometer laser that delivers therapy through the MicroPulse P3 (MP3) glaucoma probe. [66]

   IRIDEX available from MedeQuip, Edenvale
   www.medequip.co.za
   011-454-2610

Conclusion

The American Academy of Ophthalmology's guidelines state that "cyclophotocoagulation is indicated for patients with refractory glaucoma who have failed trabeculectomy or tube shunt procedures, patients with minimal useful vision and elevated IOP, patients who have no visual potential and need pain relief, and patients with complicated glaucoma and conjunctival scarring from previous surgery. It may be useful for patients whose general medical condition precludes invasive surgery or who refuse more aggressive surgery." [66] Further research will likely influence the future role of CPC in glaucoma management. Long-term studies of MicroPulse CPC are needed. A review of current CPC studies shows wide variation in the laser power and duration used. Further investigations that compare varying energy/duration with the use of the G-probe would also help surgeons determine the best balance between safety and efficacy. Varying energy/duty cycles with the use of the MP3 probe may also be worth evaluating.

CPC may never achieve the refined sophistication that phacoemulsification has today, but it is worth remembering that the latter procedure was barbaric in its original form compared to its current iteration. The evolution of glaucoma surgery is leading to earlier intervention in the disease process with the development of micro-invasive techniques and devices. As a repeatable non-invasive glaucoma intervention, CPC deserves another look by surgeons who have categorized it as a treatment option for refractory glaucoma in poorly sighted eyes only. Varying technique and the use of different laser delivery platforms have been shown to have a safety profile that is distinct from the highly destructive CPC treatments of the past. Sufficient evidence exists to consider using CPC in a wider range of patients. [66]

Viscocanalostomy

How it Works [70]
The procedure reroutes aqueous flow through a newly created window in Descemet's membrane (DM), thus by-passing the trabecular meshwork.

Indications
All glaucomas including difficult cases like traumatic glaucomas, congenital glaucomas and secondary glaucomas.

Contraindications
Neovascular glaucoma due to a very poor success rate with the procedure.

Advantages
1. It is a safer technique with significantly lower complication rate compared with trabeculectomy [71].
2. Almost no effect on visual acuity [72]
3. No blebs and related bleb complications
4. No hypotony and flat chambers [71]
5. No choroidal effusions
6. No retinopathies
7. No late endophthalmitis
8. No hyphaema
9. No uveitis
10. No peripheral anterior synechiae
11. Less post-operative care and fewer post-operative visits
12. The absence of anterior chamber opening and iridectomy limits the risk of cataract and infection [71].

Disadvantages
1. Steep learning curve
2. Procedure takes longer than trabeculectomy– 45 to 60 minutes as compared 10 to 15 minutes [70].
3. Higher final IOP's than trabeculectomy [71]. [73].

Technique
The conjunctiva is incised. A 5 X 5mm outer parabolic flap approximately 200µm thick is dissected, followed by inner concentrically 4 X 4mm scleral flap beneath the previous one. The dissection is advanced until Schlemm's canal (SC) is entered. It is crucial to be in the correct plane, to avoid missing SC. The two ostia of SC are then cannulated with a special cannula and SC is dilated by slow and repeated injections of high molecular weight sodium hyaluronate about thrice in each ostium [71].
Pulling the inner scleral flap upwards and depressing the floor of the DM with the tip of a microsponge, the membrane itself is cleaved from the cornea and the cleavage is advanced into clear cornea for 1mm creating a descemet window. The inner scleral flap is excised. Tight sutures close the outer flap with seven 10-0 or 11-0 nylon. High molecular weight sodium hyaluronate is injected to fill the intrascleral space preventing it from collapsing and scarring in the early post-operative period. Finally, the conjunctiva is sutured in place [71].

As a result of this procedure, the flow of aqueous is redirected from the anterior chamber though the trabecular meshwork and descemet's window under the scleral flap, the ostia into the SC and finally into the collector channels and systemic circulation.

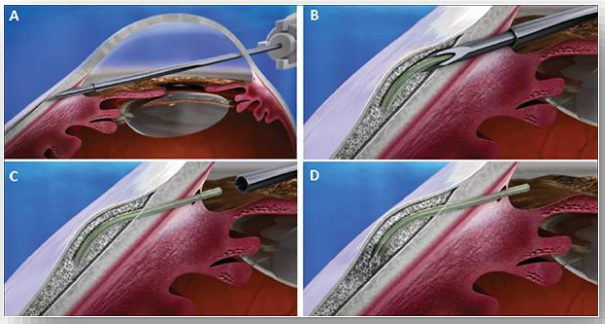
Complications

1. Microhyphema clearing rapidly
2. Failure of the procedure

XEN45® Glaucoma Treatment

How it Works (74) (75)

The XEN Glaucoma Gel Implant is intended to create a new channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space to reduce intraocular pressure (IOP), using the same principle as trabeculectomy. The XEN Gel Implant is inserted using the XEN Injector via an *ab interno* approach, through a small corneal incision



Indications (74)

The XEN Gel Implant is intended to reduce intraocular pressure in patients with primary open angle glaucoma where previous medical treatments have failed.

Contraindications (74)

The XEN Gel Implant is contraindicated under the following circumstances or conditions:

- Angle closure glaucoma, previous glaucoma shunt/valve in the target quadrant,
- Presence of conjunctival scarring,
- Prior conjunctival surgery or other conjunctival pathologies (e.g. pterygium) in the target quadrant,
- Active inflammation (e.g., blepharitis, conjunctivitis, keratitis, uveitis)
- Active iris neovascularization or neovascularization of the iris within six months of the surgical date,
- Anterior chamber intraocular lens
- Presence of intraocular silicone oil,
- Vitreous present in the anterior chamber,
- Impaired episcleral venous drainage (e.g., Sturge-Weber or nanophthalmos or other evidence of elevated venous pressure),
- Known or suspected allergy or sensitivity to drugs required for the surgical procedure or any of the device components (e.g., porcine products or glutaraldehyde),
- History of dermatologic keloid formation.

Surgical Techniques (74)

- The needle of the XEN Injector preloaded with the XEN Gel Implant is advanced through the peripheral cornea and across the anterior chamber (i.e., ab interno) toward the targeted quadrant. Corneal entry should be at least 1 to 2 mm anterior to the limbus (i.e., not at the limbus or behind it) to ensure there is a proper angulation on the Gel Implant up and away from the iris. The Gel Implant should be placed through the centre of the angle.
- Once the needle is aligned with the desired entry point in the anterior chamber angle, the surgeon advances the needle in the anterior chamber angle and sclera until the surgeon can visualize the needle bevel as it exits the sclera into the subconjunctival space.

The surgeon initiates release of the XEN Gel Implant by moving the slider of the XEN Injector. To deploy the Gel Implant, a forward movement of the blue slider at the centre of the Injector delivers the Gel Implant and retracts the needle. The slider will stop at the end of its travel indicating that the procedure is complete.

Advantages/Disadvantages

- Works immediately to achieve and maintain low-teen intraocular pressure (42% reduction from baseline) [76] [77]
- Comparable efficacy to trabeculectomy [78]
- Designed to control hypotony [75] [79]
- Avoids major tissue trauma and leaves the conjunctiva intact [79]
- Potential for future surgeries [75] [79]
- Used in a broad range of glaucoma patients [74] [75]
- 95% reduction in medications from baseline [80] [76]
- Is a soft, tissue-conforming biological implant [74] [75] [79]
- Three XEN procedures can be done in the time of one trabeculectomy [81]
- Ease of procedure
- Low-lying bleb, resembles healthy conjunctiva [37] [82]
- Can be combined with cataract surgery or done as a standalone procedure [76]
- Post-operative needling of device is possible [83]

Complications

- Hyphaema (2.6%) [84]
- Transient hypotony (2.4%) [77]
- Anterior chamber reformation indicated (0.8%) [85]
- Implant obstruction (2.4%) [77]
- Device migration (2.4%) [77]
- Subconjunctival haemorrhage (36.5%) [80]
- Transient intraoperative anterior chamber bleeding (24.3%)
- Transient choroidal detachment (2.4%) [77]

Administrative Information

ALLERGAN
CE Mark approved
CE 597638
FDA Procedure
Product Code: KYF
Device class: 2
Reg No: 886.3920
Reg Establ No: 3007851988
Owner No: 10039662

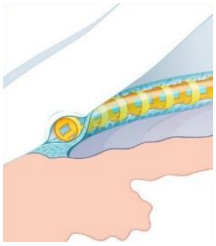
Key Points

Xen microstent connects the anterior chamber with the subconjunctival space. It is inserted into the anterior chamber through the peripheral cornea. In the case of late failure due to fibrosis, slit lamp procedures like needling, performed in the consulting rooms, restore drainage.

Devices that May Become Available in South Africa in the Future

1. Canal expanders

How it works



The Stegmann Canal expander® is the latest development in Canaloplasty, and the first implantable device into Schlemm's canal. The Canal expander is a biocompatible, non-metal, non-gelatin micro-implant and was approved for the European market (CE mark 0124) in 2012. It is twice the size of a human hair.

Indications [86] [87] [88] [89] [90]

Moderate to advanced glaucoma

Advantages/Disadvantages

Reduced risk of complications, the independence of bleb formation and no need for metabolites [86].

The surgery is technically difficult, requires a steep learning curve and highly specialised instruments including the Canal expander.

Less than 5% of patients may not be fully catheterized. The IOP is not lowered as much as when Schlemm's canal is fully dilated [87].

Complications

1. Hyphaema, confirming that Schlemm's canal has been reopened.
2. Transient elevation of the intraocular pressure.
3. Hypotony.
4. Descemet's detachment.

Contra-indications

In cases where there is limited or no access to the Schlemm's canal the procedure cannot be performed. This will include inflammatory glaucoma and angle-closure glaucoma.

Technique

Schlemm's canal is unroofed ab externo, and dilated with viscoelastic material and a microcatheter is inserted. The Stegmann Canal Expander is a flexible, fenestrated hollow implant of 9mm in length. One expander is implanted into either side of the created ostium to keep the Schlemm's canal permanently open over 180°. The superficial scleral flap is closed watertight [89] [90].

Administrative

CE Mark approval in 2012
(CE 0124)
Material is FDA approved

2. HYDRUS Aqueous Implant

How it works

Micro stent - semi-circular tube with perforated walls, 8mm long
Titanium alloy
Inserted into Schlemm's canal
Preventing the collapse of SC
Enhanced outflow and access to the collector channels

Indications

Mild to moderate open angle glaucoma with co-existing cataract
PXE, PDS, adjunctive procedure in poly pharmacy
Poor compliance

Advantages/Disadvantages

Reduce medication burden
No scarring of ocular tissues
Fast recovery
Transient hyphaemia
No major complications
Steep learning curve

Complications

Potential displacement
Potential damage to structures
Intra-ocular inflammation

Contra-indications

Angle closure glaucoma
Previous glaucoma surgery
Advanced glaucomas

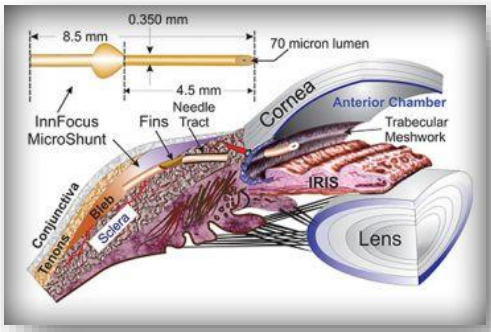
Administrative

IVANTIS, INC
FDA Approved
Product code: OGO

3. InnFocus Microshunt (formerly MIDI Arrow)

How it works

The drainage implant consists of a small micro-tube (about twice the size of an eyelash) leading aqueous from the anterior chamber under a sub-conjunctival/sub-Tenon flap. The shunt conforms to the curvature of the eye.



Indications

POAG

Advantages/Disadvantages

The implantation time is short

Easy to perform

Complications

Bleb related complications

Contra-indications

Risk for infections and bleeding

Administrative

InnFocus Inc

FDA Approved

Product code: KYF

Device Class: 2

Reg No: 886.3920

Reg Establ no: 3011035920

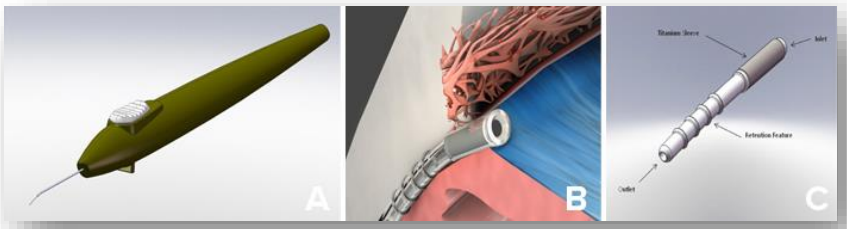
Owner no: 10047248

InnFocus developed the Microshunt™ (formerly known as MIDI Arrow)

4. iStent Supra

How it works

Micro stent is placed in the supra-ciliary space directing aqueous into the uveoscleral space



Indications

Open angle glaucomas

POAG, PXG, PDS, Steroid induced glaucoma

Complications

Temporary stent obstruction

Malpositioning

Failure of procedure

Contra-indications

Angle closure glaucoma

Administrative

GLAUCOS CORP FDA Approval

Product code: OGO

Device Class: 3

2032546

Coding

ICD10 Codes

H40	Glaucoma
H40.0	Glaucoma suspect
H40.1	Primary open-angle glaucoma
H40.2	Primary angle-closure glaucoma
H40.3	Glaucoma secondary to eye trauma
H40.4	Glaucoma secondary to eye inflammation
H40.5	Glaucoma secondary to other eye disorders
H40.6	Glaucoma secondary to drugs
H40.8	Other Glaucoma
H40.9	Glaucoma, unspecified
H42	Glaucoma diseases classified elsewhere
H42.0	Glaucoma in endocrine nutritional and metabolic diseases
H42.8	Glaucoma in other diseases classified elsewhere
Q15.0	Congenital glaucoma

Procedure Codes

Procedures	Clinical Application	Procedure codes	RVU Units	Procedure Description	Expanded Description
1	Drainage procedure	3061	247	Drainage procedure	
	Implant of Aqueous Shunt device	3062	60	Implant of Aqueous Shunt device	
2	Cyclocryotherapy or Cyclolaser	3063	105	Cyclocryotherapy or Cyclolaser	
		3201		Laser hire fee	
3	Laser trabeculoplasty	3064	105	Laser trabeculoplasty	
		3201		Laser hire fee	
		0004		Procedures performed in own procedure rooms	
4	Anterior chamber washout	3065	105	Removal of blood from anterior chamber	Anterior Chamber wash out
5	Goniotomy	3067	210	Goniotomy	
6	Iridotomy or iridectomy surgical	3149	132	Iridotomy or iridectomy surgical	
7	Laser Iridectomy/Iridotomy	3153	105	Laser Iridectomy/Iridotomy	
		3201		Laser hire fee	
8	Reformation of anterior chamber	3158	142.4	Repair of iris dialysis and anterior chamber reconstruction	hypotony/flat anterior chamber
9	Aqueous Leakage	3199	132	Repair of conjunctiva by grafting	
10	exposure of drainage device	3121	289	Corneal Graft (rule C)	Scleral Graft or other patch graft used - use Rule C with 3131
		3199	132	Repair of conjunctiva by grafting	

Procedure Codes (Cont.)

Procedures	Clinical Application	Procedure codes	RVU Units	Procedure Description	Expanded Description
11	revision of drainage devices	3062	60(75%)	Implant of Aqueous Drainage device	
		3157	132	Division anterior synechiae (Rule C)	
12	encapsulated Seton	3199	132	Repair of conjunctiva by grafting	
		3089	10	Subconjunctival injection	
13	needling (theatre)	3157	132	Division anterior synechiae (Rule C)	use Rule C with 3157
		3089	10	Subconjunctival injection	
14	needling (rooms)	3131	53	Paracentesis (see explanation for Rule C)	use Rule C with 3131
		3089	10	Subconjunctival injection	
		0201		Material used during consultation (MMC)	
		0202		Setting of Sterile Tray	
		0004		Procedures performed in own procedure rooms	
		3060	4	Use of own microscope in rooms	
15	Aqueous Misdirection	3095	105	Biopsy of vitreous body and anterior chamber contents	
		3097	280	Anterior vitrectomy	
		3052	105	Laser Capsulotomy	
		3201		Laser hire fee	
16	Intravitreal injection	3090	47.6	Intravitreal injection	anti VEGF/Steroid/ Antibiotics
		0202		Setting of Sterile Tray	
		0201		Material used during consultation (NAPPI)	
17	Use of own diamond knife	3196		Use of own diamond knife	

Surgical Management of Glaucoma – Summary of Evidence

Surgical management options for Glaucoma include procedures either with or without the inclusion of a drainage device.
The following international guidelines were reviewed, their evidence evaluated, and where appropriate, their recommendations were adopted:

- American Academy of Ophthalmology
- EGS Guidelines

Appendix 1

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