Bleb-less Surgery and Phaco – the iStent Saga

J Garcia Feijoo

Professor and Chairman, Department of Ophthalmology, Hospital Clínico San Carlos, Universidad Complutense de Madrid, Madrid, Spain; 2. Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC), Madrid, Spain; 3. Cooperative Research Network on Age-Related Ocular Pathology, Visual and Life Quality, Instituto de Salud Carlos III, Madrid, Spain

Abstract

In the past years there is been a rapid evolution of cataract surgery; however, in glaucoma filtration surgery is still the 'gold standard'. New techniques and devices have been developed and may change the surgical algorithm. Minimally invasive glaucoma surgery (MIGS) is safe, can be performed *ab interno* through sub-1.8 mm corneal incisions and a postop intraocular pressure in mid-teens can be obtained.

Keywords

MIGS, glaucoma, outflow, suprachoroidal, trabecular meshwork

Disclosure: J Garcia Feijoo is on the advisory board/consultor surgery for ALCON, Ivantis, Glaukos and Transcend and has been involved in trials supported by Glaukos, Transcend, Ivantis and InnFocus. No funding was received in the publication of this article.

Received: 20 November 2014 **Accepted**: 2 December 2014 **Citation**: *European Ophthalmic Review* 2014;8(2):104–5 *DOI: 10.17925/EOR.2014.08.02.104*

Correspondence: J Garcia Feijoo, Paseo de San Francisco de Sales 23. C-2. 10ºB. Madrid 28003, Spain. E: jgarciafeijoo@hotmail.com

Glaucoma affects over 60 million people worldwide and after cataract is the second leading cause of irreversible blindness; its prevalence is increasing due to the ageing of the population.[1] If we consider the direct and indirect costs of glaucoma there is an increase in the global cost and the economic burden as glaucoma worsens.[2,3] Also the impact of the disease on quality of life (QoL) of patients is important, especially in those with advanced disease and bilateral visual field damage.[4]

The only uncontroversial treatment modality that reduces the risk of disease progression is intraocular pressure (IOP) reduction.[5] So the main objective of glaucoma management is to preserve visual function by achieving a stable and continuous IOP decrease through treatments with a good safety profile and no repercussions on QoL. However, today no therapeutic option has all these characteristics.

In the past 15 years we have witnessed the rapid evolution of cataract surgery. Corneal incisions of 1.8–2.2 mm can be considered standard and microincision cataract surgery (MICS) through sub-1.8 mm is more and more common. This process has had a favourable impact on the patient's QoL. But in glaucoma surgery this evolution is still pending.

Filtration surgery (trabeculectomy and non-penetrating surgeries) is the most effective way of reducing IOP and preventing the progression of the disease, and though there is a variation on the surgical technique among surgeons, it can be considered the 'gold standard' for the majority of the patients that require surgery. But filtration surgery with or without the adjunctive use of antimetabolites has been linked to complications such as vision loss, bleb leak, inflammation, hypotony and endophthalmitis.[6,7]

So, and probably partially related to the fear of complications, glaucoma surgery is usually performed when topical antiglaucoma drugs and laser treatments fail to sufficiently reduce IOP or when progression in detected. This trend has probably led to a delay in the indication of surgery.

In the past years new surgeries have been developed and eventually could be the driving force for a change in the paradigm of glaucoma surgery.[8] The questions would be: do we really need aggressive surgeries for all our patients, and if surgeries are undertaken, which are less effective in terms of IOP-lowering effect, but with a very good safety profile, they could help to increase the surgical indications for the benefit of patients with early glaucoma and/or those not requiring a very low IOP.

The new surgical approaches could be classified into two groups. The first being those aimed at improving the safety consequences on QoL and the reproducibility of the 'conjunctival bleb dependent surgeries'. These could be considered as 'minimally penetrating', but their mechanism of action is still the conjunctival bleb. For this reason the indications are similar to conventional filtration surgery. If these surgeries demonstrated a better safety profile and similar outcomes they could match conventional filtration surgery and eventually play an important role in the 'conventional treatment algorithm', when IOP in the low teens is required. Subconjunctival implants such us XEN (AqueSys Inc., Aliso Viejo, US) or the InnFocus MicroShunt (InnFocus, Inc., Miami, US) are examples of this approach.

The second approach is to increase the outflow, thus enhancing the physiological drainage pathways. These techniques offer an IOP reduction totally independent from the formation of a subconjunctival bleb and there is no need for antimetabolites. Using an *ab interno* approach and increasing the trabecular outflow or the suprachoidal drainage, these could be truly considered minimally invasive glaucoma surgery (MIGS).

Also, if needed, they can be combined with the microincision cataract surgery (MICS) procedure.

For trabecular surgeries, the first device on the market was the G1 iStent Trabecular Micro Bypass (Glaukos Corp., Laguna Hills, US). The published studies have shown an excellent safety profile, similar to MICS surgery, and a moderate IOP reduction (around 20–30 % at 1 year) with a decrease in the number of medications (0.5–2 at 1 year).[9–11] Two other devices are under investigation: the IStent inject (Glaukos Corp), designed to facilitate the implantation keeping efficacy[12] and the nitinol Hydrus Schlemm canal scaffold (Ivantis Inc., Irvine, US), an 8 mm device that also expands the canal. An IOP in the mid-teens with a significant decrease in the number of medications can be expected. Both devices have shown to increase the outflow facility.[13,14]

The second approach is to create a controlled flow to the suprachoroidal space. This approach could be theoretically more effective, but little is known of the scarring process in this space and how it can be better controlled. Transcend Medical developed the CyPass, which is a 6.35 mm polyamide tube designed to be inserted into the suprachoidal space.[15] Again the safety profile is good and the post-operative IOP is in the mid-teens with a significant decrease in the number of medications. Glaukos has also designed a suprachoidal device: the iStent Supra.

It is fair to say that there are some questions that should be answered, such as the long-term efficacy and safety, but MIGS as a group offers an excellent safety profile and can be used in combination with MICS. So these techniques are a good option for patients with early disease and co-existing cataract. Even if the IOP-lowering effect is around 20–35 % there are other potential benefits that should be considered, such as the decrease in the number of medications and the QoL effects.

But how could the results be improved? Adequate surgeon training is imperative. Correct patient selection is also important as the surgery success rate depends on the functionality of the outflow system distal components and, in the case of the suprachoroidal approach, a better understanding of the suprachoroidal wound healing. The technical evolution of the goniolens, devices and inserters will probably ease the implantation. This, for instance, is the case of the Glaukos iStent trabecular bypass evolution. The Generation 2 iStent can be easily injected into the Schlemm's canal using a multiload inserter.

It is clear that a better anatomical knowledge is required and could make the difference in the case of trabecular surgery. If we could consistently and pre-operatively assessed the collector channels and identified those with more outflow/better connection with the episcleral veins we could select the best location to insert the device and possibly improve the outcome.

Although more evidence is required, the interest in MIGS is growing and I think these procedures will have an increasing role in the management of glaucoma as an early glaucoma surgery. ■

1. Quigley HA, Broman AT, The number of people with glaucoma worldwide in 2010 and 2020, *Br J Ophthalmol*, 2006;90:262–7.
2. Varma R, Lee PP, Goldberg I, Kotak S, An assessment of the health and economic burdens of glaucoma, *Am J Ophthalmol*, 2011;152:515–22.
3. Traverso CE, Walt JG, Kelly SP, et al., Direct costs of glaucoma and severity of the disease: a multinational long term study of resource utilisation in Europe, *Br J Ophthalmol*, 2005;89:1245–49.
4. Nelson P, Aspinall P, Papasouliotis O, et al., Quality of life in glaucoma and its relationship with visual function, *J Glaucoma*, 2003;12:139–50.
5. Leske MC, Heijl A, Hyman L, et al., Factors for progression and glaucoma treatment: the Early Manifest Glaucoma Trial, *Curr Opin Ophthalmol*, 2004;15:102–6.
6. Jampel HD, Musch DC, Gillespie BW, et al., Perioperative complications of trabeculectomy in the collaborative initial glaucoma treatment study (CIGTS), *Am J Ophthalmol*, 2005;140:16–22.
7. Ang GS, Varga Z, Shaarawy T, Postoperative infection in penetrating versus non-penetrating glaucoma surgery, *Br J Ophthalmol*, 2010;94:1571–6.
8. Saheb H, Ahmed IK, Micro-invasive glaucoma surgery: current perspectives and future directions, *Curr Opin Ophthalmol*, 2012:23:96–104.
9. Brandão LM, Grieshaber MC, Update on Minimally Invasive Glaucoma Surgery (MIGS) and new implants, *J Ophthalmol*, 2013;2013:705915.
10. Arriola-Villalobos P, Martínez-de-la-Casa JM, Díaz-Valle D, et al., Combined iStent trabecular micro-bypass stent implantation and phacoemulsification for coexistent open-angle glaucoma and cataract: a long-term study, *Br J Ophthalmol*, 2012;96:645–9.
11. Samuelson TW, Katz LJ, Wells JM, et al., Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract, *Ophthalmology*, 2011;118:459–67.
12 Arriola-Villalobos P, Martínez-de-la-Casa JM, Díaz-Valle D, et al., Mid-term evaluation of the new Glaukos iStent with phacoemulsification in coexistent open-angle glaucoma or ocular hypertension and cataract, *Br J Ophthalmol*, 2013;97:1250–5.
13. Fernández-Barrientos Y, García-Feijoó J, Martínez-de-la-Casa JM, et al., Fluorophotometric study of the effect of the Glaukos trabecular microbypass stent on aqueous humor dynamics, *Invest Ophthalmol Vis Sci*, 2010;51:3327–32.
14. Gulati V, Fan S, Hays CL, et al., A novel 8-mm Schlemm's canal scaffold reduces outflow resistance in a human anterior segment perfusion model, *Invest Ophthalmol Vis Sci*, 2013;54:1698–1704.
15. Hoeh H, Ahmed I, Grisanti S, et al., Early postoperative safety and surgical outcomes after implantation of a suprachoroidal micro-stent for the treatment of open-angle glaucoma concomitant with cataract surgery, *J Cataract Refract Surg*, 2013; 39: 431–7.