Outcome and safety of the Baerveldt glaucoma implant

PARAGRAPH OF IMPACT

Glaucoma is a degenerative optic neuropathy that is characterized by progressive visual field loss. When inadequately treated, the disease will lead to visual impairment and eventually blindness. Currently, glaucoma is the leading cause of irreversible blindness worldwide. It is estimated that by 2040 the number of affected glaucoma patients will increase to 112 million people [1]. Even in the Netherlands, a country with highly developed health care facilities, approximately 25% of people eventually go blind in one eye, 10% even become bilaterally blind at the end of their life, despite treatment [2].

Thus, there remains a large and unmet need for a proper treatment of glaucoma. Currently, the only proven treatment is by lowering intraocular pressure (IOP) to a target level where further visual field progression is halted. Treatment is usually started with (topical) medication and/or laser, however incisional surgery should be considered when target IOP is not reached or the disease keeps progressing. Surgical treatment should also be considered as an early option for patients who do not visit their ophthalmologist until in a late stage of the disease. Unfortunately, this still happens often as there are usually no symptoms until severe visual impairment sets in. It is estimated that for each diagnosed patient there is another patient out of care who is not aware of having glaucoma. Awareness, and early diagnosis and treatment should therefore be further promoted.

However, the unacceptable high proportion of patients that still severely progress despite diagnosis and treatment brings to light another problem: patients and ophthalmologists often shy away from surgical treatment, because they fear complications, vision loss and loss of quality of life after the procedure. As a result, medical treatment (often with multiple drugs) is continued, even when facing progression. This reasoning is understandable, as glaucoma surgery did not have a good reputation in the past.

Several decades ago, trabeculectomy became the gold standard procedure for the surgical treatment of glaucoma (see the introduction of this thesis for an historic overview of surgical techniques). However, trabeculectomy often failed, due to fibrosis and scarring of the filtering bleb. Almost 60% of filtering blebs failed within 15 years [3], and further treatment options were usually limited to high-risk cyclodestructive procedures. [4]

Early pioneers like Molteno and Baerveldt dramatically changed the landscape of glaucoma surgery from the second half of the twentieth surgery. The revolutionary concept of draining aqueous humour via a flexible silicone tube out of the anterior chamber of the eye to a subconjunctivally located endplate proved a successful answer to the widespread problem of failing filtering blebs.

During the years, glaucoma drainage devices (GDD) have become increasingly popular. The Baerveldt glaucoma implant (BGI) has become one of the most commonly used devices worldwide. Also, it has been the subject of many studies that investigated efficacy and safety when compared to other devices and trabeculectomy [5-8]. These studies have clearly demonstrated the value of the BGI for the current treatment of glaucoma.

However, the route to success of GDDs (and the BGI in particular) cannot be seen separately from the developments in other fields of ophthalmology, especially cataract and vitreoretinal surgery. Results of GDDs were further improved after the shift of cataract surgery from extracapsular (large incision) surgery to small incision clear cornea phacoemulsification, no longer needing to open the conjunctiva and thereby reducing the risk of conjunctival scarring. The same applies to retinal surgery, which has largely moved away from buckling procedures to small-incision vitreoretinal procedures, also sparing the conjunctiva. GDD placement can successfully be opted for before, after or directly combined with cataract or retinal surgery.

The research in the present thesis has offered important new insights for surgical glaucoma treatment with the BGI. A stable position of the tube in the anterior chamber, close to the iris or transiridial, will prevent the tube migrating towards the corneal endothelium (**chapter 3**). New imaging devices, such as Swept Source OCT, can accurately monitor tube position and distance to intraocular structures (especially cornea and iris) over time (chapter 2). The current thesis also clearly demonstrated for the first time that endothelial cell loss is a very important cause of failure of the BGI, leading to corneal decompensation in about 8% of cases (**chapters 4 and 5**). We strongly recommend to incorporate regular measurements of endothelial cell count (yearly) into routine clinical practice after placement of a GDD (BGI), especially if the tube has been inserted "free" into the anterior chamber, somewhere between cornea and iris. Doing this, severe endothelial cell loss can be detected timely and a surgical revision can be planned during which the tube is relocated to the ciliary sulcus or to the vitreous cavity (if applicable).

This thesis also demonstrated that the BGI can be safely used for many cases of secondary glaucoma. Most patients with uveitic glaucoma are better off after placement of a BGI (**chapter 7**) and a BGI can even be safely and successfully applied after treatment of intraocular tumors (**chapter 6**).

Finally, this thesis clearly showed that IOP results after BGI placement are stable and sustained in the low teens for many years, saving many patients from blindness (**chapter 5**).

Currently, evidence is emerging that early surgical intervention is indeed superior to the continuation of medical treatment. A recent study from the Netherlands demonstrated that the surgical event (often a BGI) has a small impact on visual function, however after approximately 1.5 years of follow up the surgical group performed better than the medication group, with less progression of visual loss. [9]

At the beginning of the third decade of the 21st century, trabeculectomy is still considered the gold standard procedure worldwide. [10] Through the years, the surgical technique has been greatly improved and with the additional application of antimetabolites (mitomycin C or 5 FU), success rates have been improved as well and severe complications have become less common. [11] It is also a low-cost procedure, making it available for many glaucoma surgeons worldwide. However, to obtain optimal results, good surgical skills and experience with the procedure are required.

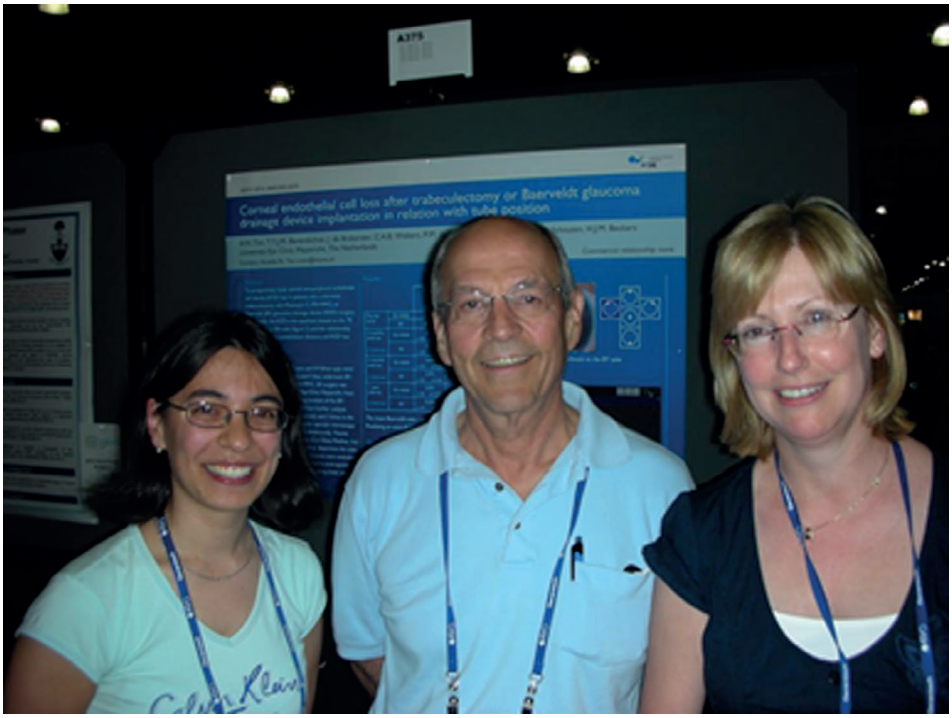
During the last three decades, trabeculectomy rates have been steadily declining while the number of GDD surgeries keeps growing, also for primary cases. In the Preferred Practice Pattern of the American Academy of Ophthalmology (2020) it is stated that currently there is insufficient information on superior results of GDDs versus trabeculectomy. [12] Selection of the desired procedure should be done in a process of "shared decision making" between the patient and the treating ophthalmologist. However, there is a growing consensus that trabeculectomy should probably be reserved for cases with primary open angle glaucoma, pseudophakic patients (after clear cornea incision phacoemulsification), cases in which very low IOP levels are needed, or cases in which there is objection to placement of a foreign body. [13] In all other cases, a GDD like the BGI may be considered, including primary surgeries.

However, factors like availability, experience with a surgical procedure and costs also play a role. Up till now, the higher costs of GDDs, including the BGI, has limited their usage in developing countries. New inventions like the Aurolab aqueous drainage implant, a cheap device that strongly resembles the BGI and was recently developed in India, may offer a reasonable alternative for these countries. [14]

In recent years, less invasive and minimally invasive, newer surgery procedures (MIGS) have come to the market. These new procedures claim to be safer than the traditional options, and are often used in combination with cataract surgery, earlier in the treatment algorithm. However, they are also very costly and mostly lead to IOP reductions in the mid/high teens. [15] Although strongly gaining popularity, the place of these newer devices and procedures within the treatment armamentarium of glaucoma has still to be established.

Although the BGI has amply proven its value, refinement of GDDs is also underway. Interpretation of results in literature, including the findings of this thesis, have paved the way for new designs, with smaller tube lumens and improved endplates. An example is the PAUL glaucoma implant, which has recently come to the market. [16] Also, new materials and combination with medications are being considered.

George Baerveldt must have been very satisfied with the impact his invention has had on the global community for the treatment of glaucoma and the prevention of blindness. He would also have been very interested in all new developments. However, unfortunately he is no longer among us and we cannot share the results of this thesis with him anymore.



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