Feasibility of Drainage to the External Ocular Surface as a New Glaucoma Therapy

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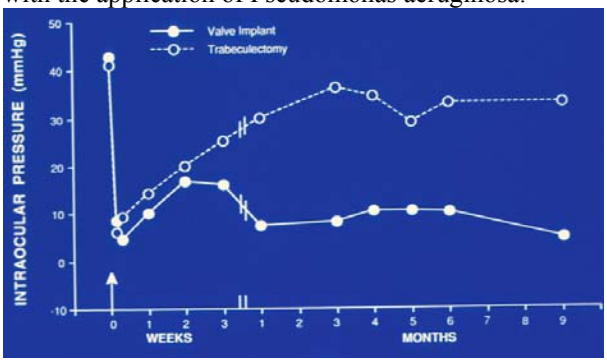
Statement of Purpose: Glaucoma is the second leading cause of irreversible blindness in the United States, the leading cause of irreversible blindness in African-Americans, and affects approximately 67 million people world-wide.[1] The major risk factor for the development of glaucoma is excessive intraocular pressure (IOP) in the eye due to increased outflow resistance in aqueous humor pathway.[2] The surgical procedures used to treat these excessive IOPs drain aqueous humor from the anterior chamber of the eye into the subconjunctival space, where the drainage of aqueous humor is dependent on the pressure gradient and resistance across these two regions of the eye.[3] Unfortunately, these procedures are suboptimal in terms of success rate, complications, safety, and predictability. Surgical outcomes are primarily determined by the process of wound healing, which is a very complicated and unpredictable biological process, in the subconjunctival space. [4] Therefore, we describe a novel glaucoma drainage device (GDD) that drains aqueous humor to the external ocular surface to improve the efficacy, safety, and predictability. External drainage circumvents many of the problems related to wound healing, since the pressure gradient is controlled by the communication of the anterior chamber with atmospheric pressure rather than the healing process in the subconjunctival space. Additionally, the resistance to aqueous humor outflow is controlled by a valve/filter mechanism within the device. Therefore success is not influenced by biological principles, but instead is determined by the mechanical and material properties of the device.

Methods: A very early prototype consisted of a silastic tube with an inside diameter of 0.3 mm and an outside diameter of 0.65. To prevent bacterial migration and set the resistance to flow, an internal filter having a pore-size of 0.4 μm was incorporated in the lumen of the tube. The valve was set to open at an IOP of 10 mmHg. The distal end of the tube is sealed with perpendicular slits which function as a unidirectional, pressure sensitive valve. Three cynomolgus monkeys underwent a glaucoma inducing bilateral argon-laser treatment, which scars the trabecular meshwork over causing increased IOP. Once the IOP readings were above 25mmHg, the prototype was inserted in an eye of each monkey. The proximal end was inserted at the limbus 3 mm into the anterior chamber, parallel to the iris, under a fornix based conjunctival flap. The device was secured to the episcleral tissue near the limbus using nylon sutures. The anterior 5 mm of the tube was covered with a donor scleral patch graft. The posterior aspect of the tube lies underneath the conjunctiva and exits 8 mm from the limbus in the cul-de-sac region. The contralateral control eyes underwent standard trabeculectomies. The postoperative IOPs were followed-up for a minimum of 8 months. Pseudomonas aeruginosa was repeatedly applied to the external aspect of the device to determine whether intraocular infection could be produced.

Results: The postoperative IOPs were maintained lower than 15 mmHg in all 3 eyes with the novel GDD, but rose to > 20 mmHg within 1 to 4 weeks in the 3 control eyes for the 8 month follow-up period. No infection occurred with the application of Pseudomonas aeruginosa.



Conclusions: External drainage when coupled with a micro-pore filter and a valve mechanism has a potential means of stabilizing and reducing IOP without risking pseudomonas endophthalmitis.

References:

1. Quigley HA. Number of people with glaucoma worldwide. Br J Ophthalmol. 1996 May;80(5):389-93.
2. Kass MA, Heuer DK, Higginbotham EJ, et al. The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. Arch Ophthalmol. 2002 Jun;120(6):701-13; discussion 829-30.
3. Lim KS, Allan BD, Lloyd AW, Muir A, Khaw PT. Glaucoma drainage devices; past, present, and future. Br J Ophthalmol. 1998 Sep;82(9):1083-9.
4. Hong CH, Arosemena A, Zurakowski D, Ayyala RS. Glaucoma drainage devices: a systematic literature review and current controversies. Surv Ophthalmol. 2005 Jan-Feb;50(1):48-60.