TOROIDAL GLAUCOMA DRAINAGE DEVICE (Tel Hashomer)
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TOROIDAL GLAUCOMA DRAINAGE DEVICE

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Abstract

Ocular hypertension has been associated with a number of eye conditions, including Glaucoma, eye trauma, pseudoexfoliation syndrome, pigment dispersion syndrome and corneal arcus. In the majority of cases, vision loss usually occurs when the eye pressure is too high for the specific individual and damages the optic nerve. Any resultant damage cannot be reversed. In eyes with glaucoma, peripheral (side) vision is affected first. The changes in vision may be so gradual that they are not noticed until a lot of vision loss has already occurred. Ocular hypertension must be monitored and treated to save vision lost.

The modern goals of glaucoma management are to avoid glaucomatous damage and nerve damage, and preserve visual field and total quality of life for patients, with minimal side effects. Although intraocular pressure is only one of the major risk factors for glaucoma, lowering it via various pharmaceuticals and/or surgical techniques is currently the mainstay of glaucoma treatment.

Vascular flow and neurodegenerative theories of glaucomatous optic neuropathy have prompted studies on various neuroprotective therapeutic strategies, including nutritional compounds, some of which may be regarded by clinicians as safe for use now, while others are on trial.

Currently approved treatments for glaucoma include a number of pharmaceutical drugs, laser therapies and surgical procedures. Each of these approaches to treating this disease has both side-effects and risks: Pharmaceuticals (usually formulated as eye-drops), Laser Surgery - "Laser Trabeculoplasty" , Filtering Surgery and Drainage Implants.

The Need

Glaucoma includes a number of eye diseases that damage the optic nerve, resulting in gradual loss of vision. Glaucoma is the second most common cause of blindness worldwide. Recent medical studies estimate that nearly 70 million people worldwide are affected by glaucoma and this is expected to increase to over 80 million by 2020. Almost 50% of patients with glaucoma are undiagnosed until damage to the eye has already occurred, with blurred vision, eye pain, headaches or haloes round lights often being the first symptoms. Left untreated, glaucoma can lead to blindness.

The main modifiable risk factor of glaucoma is high intraocular pressure (IOP), thus all the treatment options try to control it. Eye drops or oral medications are employed to lower the eye pressure, but they often do not succeed in controlling eye pressure or they result in hardly tolerable side effects, necessitating surgery. The surgical procedures usually include trabeculectomy aiming at opening the

full thickness of the drainage area, or laser trabeculoplasty that partially opens the drainage area.

The Technology and Product

Our invention is a novel, minimally invasive device, improving outflow of eye fluid and has the potential to advance the surgical treatment of glaucoma. The device and methods of use thereof enable fine regulation of the eye fluid outflow.

Applications

Glaucoma drainage device implantation is usually reserved for cases with refractory glaucoma, or those unlikely to respond successfully to a conventional filtration surgery. The indications for GDD implantation include the following:

Neovascular glaucoma

Penetrating keratoplasty with glaucoma

Retinal detachment surgery with glaucoma

Iridocorneal endothelial syndrome

Traumatic glaucoma

Uveitic glaucoma

Open angle glaucoma with failed trabeculectomy

Epithelial down growth

Refractory infantile glaucoma

Contact lens wearers who need glaucoma filtration surgery

Sturge-Weber's syndrome.

Contraindications:

Eyes with severe scleral or sclera-limbal thinning

Extensive fibrosis of conjunctiva

Ciliary block glaucoma.

Relative Contraindications:

Vitreous in AC

Intra-ocular silicone oil-Implant if required is placed in inferio-temporal quadrant

Advantages

In a study published in 2012 (Gedde SJ*et al*. in the Am J Ophthalmol 2012;153:789-803) , they have

demonstrated that tube shunt surgery had a higher success rate compared to trabeculectomy with MMC during 5 years of follow-up in the TVT Study. Both procedures were associated with similar IOP reduction and use of supplemental medical therapy at 5 years. A total of 212 eyes of 212 patients were enrolled, including 107 in the tube group and 105 in the trabeculectomy group. At 5 years, IOP (mean SD) was 14.4 6.9 mmHg in the tube group and 12.6 5.9 mmHg in the trabeculectomy group (P = 0.12). The number of glaucoma medications (mean SD) was 1.4 1.3 in the tube group and 1.2 1.5 in the trabeculectomy group (P = 0.23). The cumulative probability of failure during 5 years of follow-up was 29.8% in the tube group and 46.9% in the trabeculectomy group (P = 0.002; hazard ratio = 2.15; 95% confidence interval = 1.30-3.56). The rate of reoperation for glaucoma was 9% in the tube group and 29% in the trabeculectomy group (P = 0.025).

GDD have been successful in controlling IOP in eyes with previously failed trabeculotomy and for cases with refractory glaucoma. Since their introduction, numerous modifications in design and improvements in surgical technique have enhanced clinical outcomes and minimized complications.

The Market

Blindness from open-angle glaucoma forecast to reach 5.9 million people globally by 2020 .

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