DRAINAGE IMPLANTS

New devices are under development

by Roibeard O’hEineachain in Vienna

While the various designs of glaucoma drainage devices currently under development all offer potential advantages, they all also have their drawbacks, said K Sheng Lim MD, FRCOphth, St Thomas’ Hospital, London, UK, at the XXIX Congress of the ESCRS.

Dr Lim noted that the ideal glaucoma implant would incorporate into its design the best drainage site, the best design for regulating flow and the most biocompatible material. The available implants all have at least one of those factors in their favour, though in practice the lack of one or more essential quality limits their utility, he said.

Regarding the different potential destinations for the drained aqueous humour, the four main options are: the outside of the eye, Schlemm’s canal, the subconjunctival space, and the suprachoroidal space, he noted.

External drainage has both the obvious advantage of unlimited drainage capacity and the obvious disadvantage of infection risk, he said. One external drainage design that has been proposed has a tube going from the anterior chamber into the subconjunctival space and a plate that sits on top of the superior conjunctiva. At present there is no published data on any external drainage device, he said.

“The theoretical disadvantages inherent in such a design are the risks of infection and also extrusion given the constant rubbing of the plate by the eyelid over time,” Dr Lim said.

Schlemm’s canal As regards to drainage into Schlemm’s canal, one device that is currently generating a lot of interest is the iStent. This titanium device bypasses the trabecular meshwork, which is the main area of resistance to outflow in glaucomatous eyes. Another of its advantages is that if one of the stents does not adequately reduce IOP, more can be implanted. However, although the material is inert, its hardness may increase the risk of scarring and extrusion over the long term.

However, it is one of the few drainage devices that have been tested in a proper randomised controlled trial (Samuelson et al, Ophthalmology. 2011; 118:459-67). Dr Lim pointed out. The study involved 240 cataract patients with open angle glaucoma who were randomised to receive either cataract surgery alone or with an iStent implant.

At one year’s follow-up, IOP was 21.0 mmHg or lower without medication in 70 per cent of eyes with the implant, compared to only 50 per cent of control eyes (P<0.001). Moreover, 66 per cent of eyes with the implant achieved a 20 per cent or greater reduction of IOP compared to only 40 per cent of controls (p =0.003).

On the other hand, the overall amount of the IOP reduction with or without medication was similar in the two groups, 8.4 mmHg in the iStent group and 8.5 mmHg in the control group, Dr Lim said.

Dr Lim noted that the subconjunctival approach has a long history but has never worked unless there is a plate to maintain a minimum size bleb. Current designs include the ExPress Implant (Optonol) and the SIBS implant (Innovia). The theoretical advantages of both implants are their flow restrictors, but they also share an important disadvantage in lacking a plate. The SIBS implant may have an advantage over the ExPress implant in that its material may be more biocompatible, Dr Lim said.

Suprachoroidal drainage The suprachoroidal area may be the ideal place to direct aqueous out of the anterior chamber, since it has an almost unlimited capacity for drainage. Nevertheless, attempts at this type of drainage have proved problematic.

One approach to suprachoroidal drainage is to create a scleral flap, as in trabeculectomy, and placing silicone tubes on either side into the suprachoroidal space and performing a trabeculectomy and peripheral iridectomy, so that the aqueous could drain into the suprachoroidal space.

In a pilot study involving 23 patients who underwent the procedure for open angle glaucoma, the postoperative IOP after a mean follow-up of 324 days was 13.8 mmHg compared with a preoperative value of 25.4 mmHg. The mean number of postoperative medications was only 1.1 compared with a preoperative value of 3.0 (Jablonski et al, J Glaucoma. 2005;14(2):91-7). However, many patients developed hypotony and hyphaema.

Another implant designed for suprachoroidal drainage is the commercially available Gold Shunt (Solx). It has the advantage of a flow control mechanism, but like the Express implant it is composed of material that is inert but not necessarily biocompatible with ocular tissues. The shunt consists of a gold plate with channels that direct a titratable amount of aqueous directly from the anterior chamber into the suprachoroidal space with a lower risk of hypotony.

In a recently published study involving a case of 55 eyes with refractory glaucoma the rate of complete success with the shunt at one year was less than 20 per cent, although 80 per cent achieved partial or complete success. Fibrosis around the implant appears to have been a factor in the low rate of complete success and suprachoroidal drainage may require the use of more biocompatible material (Figuers et al,Br J Ophthalmol, published online August 2011).

“...This is an exciting time for glaucoma surgeons, with many implants currently in development. Suprachoroidal drainage has the best potential. Scarring is still the main Achilles’ heel for this type of design, but in the future there will probably be a marriage of material and suprachoroidal drainage that will work,” he concluded.

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