AADI glaucoma shunt – a quality control study

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Purpose:

To investigate the effect and safety of implantation of AADI (Aurolab's Aqueous Drainage Implant) drain on eyes with medical intracable glaucoma.

Background:

Chief physician Peter Ruhlmann (PR), who is responsible for glaucoma tube shunt implantation on Department of Ophtahlamlogy, Odense University Hosital (OUH), has over the past 7 years acquired highly specialized knowledge from national and international eye departments, and has started the treatment methods at OUH in 2011-2012. During this period, the number of annual treatments with glaucoma drainage devices has gradually increased, both in Denmark and abroad. There are several different types of glaucoma shunts, but in Denmark, two types of devices have been used: Ahmed drainage (with built-in flow restrictor in the drain pipe) and Baerveldt drain (without built-in flow restrictor). The Bearveldt drain is believed to have a better pressure lowering effect in the longer term than the Ahmed drain, but at the expense of a higher complication rate. Chief surgeon PR, is one of two glaucoma surgeons in Denmark with the greatest experience in the field of implantation of Baerveldt drainage devices.

Tube shunt implantation is a relatively expensive treatment method,but may be a good treatment option for refractory glaucoma patients where traditional surgery is futile or attempted. In recent years, many new forms of drainage have been added, including the AADI drain (Figure 1). This drain is a copy of the original Baerveldt drain (with permission from the inventor of the drain, Prof. George Baerveldt) but at a fraction of the price. The AADI drain has been commercially available since 2013, initially primarily in India, but has now also gained ground on the world's leading eye hospitals, including the Bascom Palmer Eye Institute in Miami, the United States, and many European hospitals. The product is approved for Danish conditions, CE (Conformité Européene) labeled, and its effects and side effect profile is documented to be at a level compared to the Ahmed drain, and can be expected to be equated with the Bearveldt drain.

With this prospective quality control study, we want to investigate the effect and safety after drainage implantation with AADI in the period 2019-2020. The project starts from the OUH Eye Department at the request of the country's leading glaucoma surgeons.

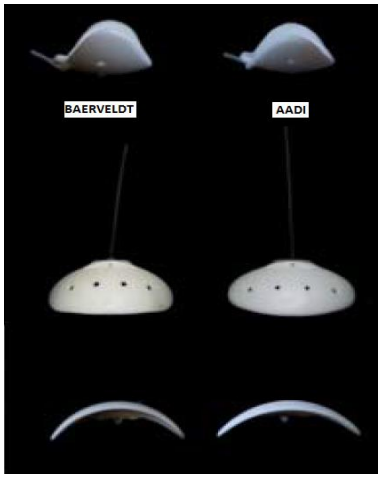

Figure 1: Baerveldt and AADI shunts

Methods:

A prospective quality assessment of all glaucoma patients with an AADI drain in the period 2019-2020 at Eye section E, OUH. Patients who would normally be offered Baerveld drainage implantation are instead offered the AADI. Pre- and postoperative controls will take place as usual, ie. the patients will have the same examinations and controls as for the implantation of Baerveldt and Ahmed drainage devices. Data is then transferred to the Oculus glaucoma database, which is a region-based web database with all necessary permissions and a high safety profile. The data can then be extracted anonymously or pseudonymised (with ID no.) for further analysis and statistics. Patients are followed as usual, up to 1 year postoperatively, and possibly up to 2 years after surgery.

The following parameters will be noted:

- age
- sex
- number and type of intraocular pressure lowering eye drops pre- and postoperatively
- previous laser tools (SLT) or surgery (eg, cataract surgery and trabeculectomy)
- endothelial cell count pre- and postoperatively
- Visual Field Index and Mean Defect pre- and postoperatively
- intraocular pressure pre- and postoperatively
- pre- and postoperative vision
- retinal photos pre- and postoperatively including oximetry maps
- per- and postoperative complications eg. bleeding, hypotension, infection, need for further surgery, progression of glaucoma.

Time schedule:

The project is expected to start at the end of February. 2019. Data processing is expected to be completed by the end of 2022. The results will be presented at national and international glaucoma congresses.

Ethics:

The project has been approved by the Data Inspectorate ("Datatilsynet") at Odense University Hospital and the Region of Southern Denmark, as a prospective quality assurance and quality development project with ID no. 19/7009 . Data will be processed according to the safety requirements for the processing of personally identifiable information.

A written informed consent is sought from the patients prior to the treatment. If patients do not want treatment with AADI, as usual, treatment with Bearveldt drainage can be done.

Ref.:

Oftalmolog dec. 2011, Glaukomdræn.

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Br J Ophtalmol, 2017 Dec;101(12):1623-1627, Safety and efficacy of low-cost glaucoma drainage device for refractory childhood glaucom