Effectiveness and safety of the implantation of the trabecular micro-bypass device “iStent inject w” in comparison with “iStent inject” accompanied with phaco surgery.

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Purpose:

A comparative case series to evaluate the effectiveness and safety of the implantation of the trabecular micro-bypass device “iStent inject w” in comparison with “iStent inject” accompanied with phaco surgery.

Methods:

iStent inject w (group 1) with 4 eyes, and iStent inject (Group 2) with 4 eyes. Both groups have cataracts and POAG with at least one anti-glaucoma eyedrop. We evaluated the reduction in IOP and the reduction in the eye drops after 3 months from the surgery to evaluate the efficacy. BCVA, Ac Activity, Hyphema, and other complications were also controlled to evaluate the safety of the Procedure. Two Patients in this study had iStent inject in one eye and iStent inject W in the other eye.

Results:

Group 1: mean IOP before the surgery was 20.5 mmHg with a mean eyedrops of 1.75. Median IOP reduction was 6.5 mmHg after 3 months. Median BCVA improved from 0.425 to 0.95. Group 2: median IOP before the surgery was 20.25 mmHg with median eyedrops of 1.75. Median Mean reduction of the IOP was 5.25 mmHg, and BCVA improved from 0.45 to 0.875 after 3 months. The mean reduction of eyedrops was 1.25 eyedrops in both groups. No significant Complication was found in both groups. Mild residual blood in the AC (anterior chamber) over the iris was detected in the first group but no Hyphema. The Blood reflux after implantation of iStent inject w was significantly more but the Implantation is easier. No Patient from either group needed a second surgery.

Conclusions:

iStent inject and iStent inject w were both safe and effective in lowering IOP. The IOP reduction in iStent inject w group was slightly more, but the difference between the two groups was not statistically significant (P-value 0.3890). More studies with a larger number of patients are recommended.

Introduction

Glaucoma is the second most important reason for blindness that affects approximately 70 million people in the world [1]. Treatment options target the reduction of the intraocular pressure (IOP) to preserve the optic nerve and prevent the progression of defects in the visual field (VF) [2]. Eyedrops still the most popular option to treat glaucoma. Some studies suggest starting with selective laser trabeculoplasty (SLT) as an alternative to eye drops [3]. However, micro-invasive glaucoma surgery (MIGS) has in the past decade developed and played an important role in the therapy especially if the patient has a cataract simultaneously. iStent trabecular micro-bypass (iStent®, Glaukos Corporation, San Clemente, CA, USA) was the first US FDA-approved MIGS implant[4]. The stent creates a direct connection with Schlemm’s canal through the trabecular meshwork, which is known to be the most important site of the resistance to aqueous humor outflow [5]. Many studies and reviews showed the efficacy and safety of the iStent over 5 years with or without concomitant cataract surgery[6]. More recently, the new version of the second-generation iStent Inject ® W trabecular micro-bypass stent (Glaukos Corporation) has been developed. A few modifications in the diameter of the stent and the injector were made to facilitate the implantation of the stent and the outflow of the aqueous humor to

schlemm's canal. Just like iStent inject ®, iStent Inject ® W is made of heparin-coated titanium, and the injector is preloaded with two stents, but the diameter of the iStent inject W is 360 Micrometer instead of 230 Micrometer in iStent inject the central lumen in both of them is 80 micrometer. The stents are implanted ab interno through two different points (approximately 3 hours apart from each other) of the trabecular meshwork. The aqueous humor flows into the Schlemm's canal then into the collector channels en route out of the eye. The implantation of the two stents in two separate points increases the chance to reach more collector channels for aqueous humor outflow, which may lead to more reduction in the IOP.

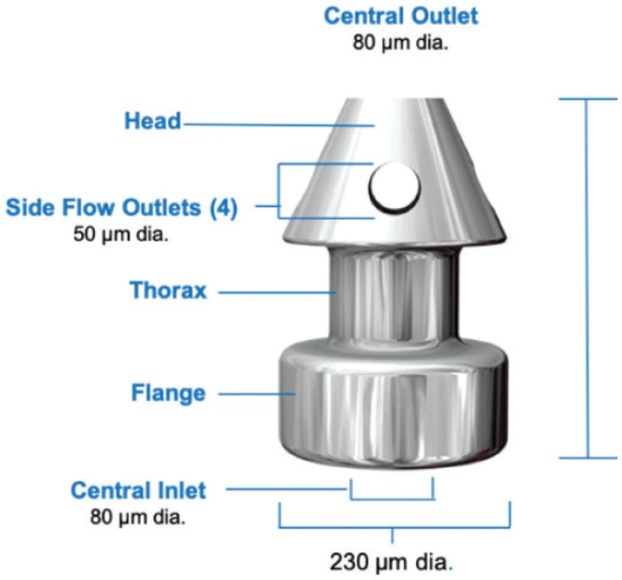

Figure 1 iStent inject

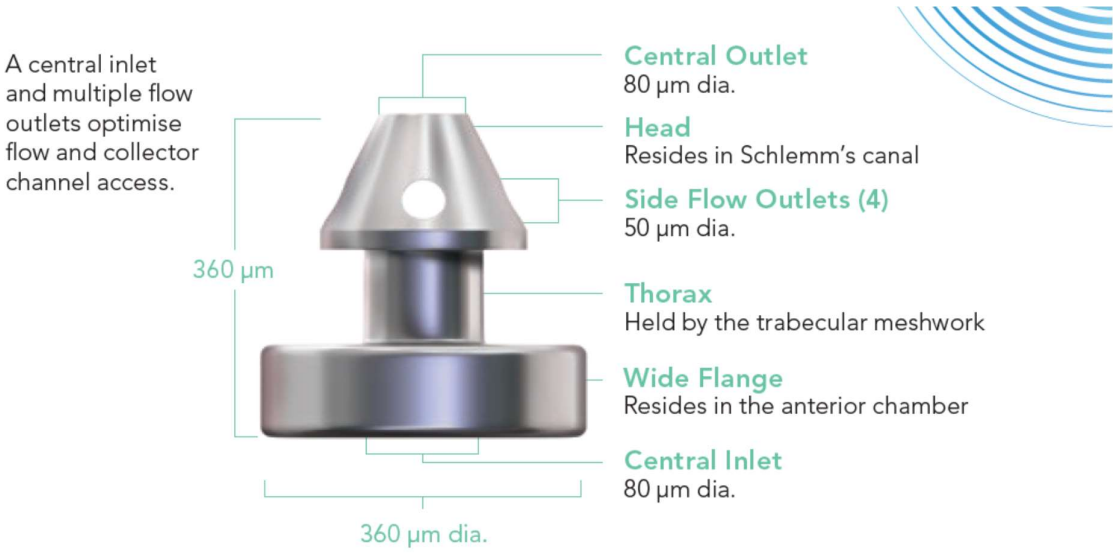

Figure 2 iStent inject W

Many studies reported the more reduction of IOP after iStent implantation if accompanied by cataract surgery [6-7]. In this study, we would compare the 3 months outcomes of Phaco with the new version of iStent inject W with the outcomes of Phaco with the old version of iStent inject.

Methods

Study Design

A non-randomized, comparative case series included eyes with the diagnosis of primary open-angle glaucoma (POAG) and cataract. 4 eyes had Phaco and iStent inject, and other 4 eyes had Phaco and iStent inject W. Two Patients have iStent inject in one eye and iStent inject W in the other eye. The IOP and reduction of the eyedrops (ED) were measured to evaluate the efficacy of the procedure, (IOP was 2 times measured by Goldmann applanation in each visit). The visual acuity was evaluated over 3 months in the department of ophthalmology in staedisches Klinikum Dresden hospital in Dresden in Germany. Intraoperative and postoperative adverse events (eg. corneal oedema, AC Activity, Hyphema) were evaluated to decide the safety of the surgery. All the surgeries were done by the same surgeon. After surgery, all patients received topical antibiotic ed 1 week (ciprofloxacin), and 5 weeks of topical steroid (dexamethasone). A paired *t*-test was used to compare the outcomes of IOP reduction in both groups over 3 months. No clinical trial registration was required for this case series. Patients have been followed through 3 months postoperatively, and follow-up is ongoing.

Inclusion criteria

1. Ability to provide written informed consent and comply with study assessments for the full duration of the study.

2. Diagnosis of mild to moderate POAG (Primary open-angle Glaucoma) which treated with at least one eye drops more than 2 years.

3. Diagnosis of cataract in the study eye.

4. Gonioscopy nasally is at least Schaffer grade 3.

Exclusion criteria:

1. Pregnancy (positive pregnancy test) or known to be pregnant, this will prevent treatment after surgery.

2. Participation in another ocular investigation or trial simultaneously.

3. Any condition that, in the opinion of the investigator, would preclude participation in the study.

4. Known history of a bleeding disorder or prolonged bleeding after surgery. (Patients treated with aspirin may be enrolled in the study).

5. history of previous glaucoma surgery

6. History of ocular trauma which may be clinically relevant to the result of this study. (eg, traumatic angle recession).

7. history of cataract surgery in the study eye.

8. history of intraocular surgery.

9. corneal diseases or surgery which may preclude the measurement of IOP after the surgery.

10. history of inflammation of the eye (eg, uveitis, endophthalmitis, blepharitis, herpetic ocular disease).

11. History of malignancy.

12. Steroid responsive patients.

Results

8 eyes with the diagnosis of nuclear cataract and mild to moderate POAG from 6 patients with 3 months follow-up are presented in this retrospective, non-randomized, comparative case series. The cataract in these patients was moderate and the mean VA before the surgery in Group 1 (with iStent inject w) was 0.425 and Group 2 (with the iStent inject) was 0.45. There was no significant difference in the hardness of the nucleus during the cataract surgery in all eyes, and all Phaco surgeries were done with the Constellation machine (Alcon). It is well known that phaco surgery has an effect on the IOP, and a reduction of 2.7±2.9 mmHg in the IOP is possible [8]. It has been suggested that the power from Phaco plays a role in the remodeling/ genetic programming of the Trabeculum as a mechanism of the IOP reduction [9]. The mean preoperative IOP in group 1 with iStent inject w 20.5 mmHg, and the mean IOP after the surgery was 14 mmHg. The mean reduction of the IOP after the surgery was 6.5 mmHg Chart 1.

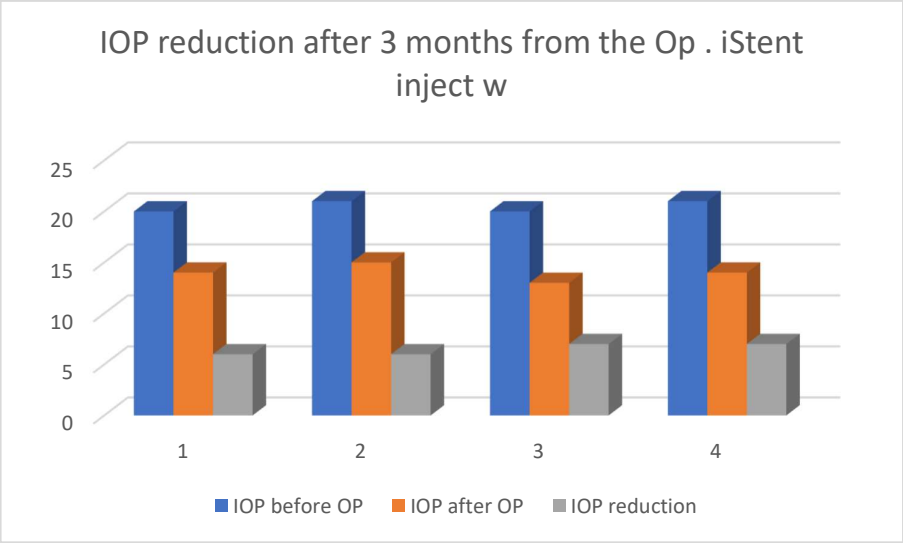

Chart 1 the IOP reduction in Group 1 (iStent inject w) after 3 months.

The Mean used eyedrops in Group 1 before the surgery was 1.75, and after 3 months from the surgery was 0.5, and the mean reduction of IOP was 1.25 mmHg Chart 2.

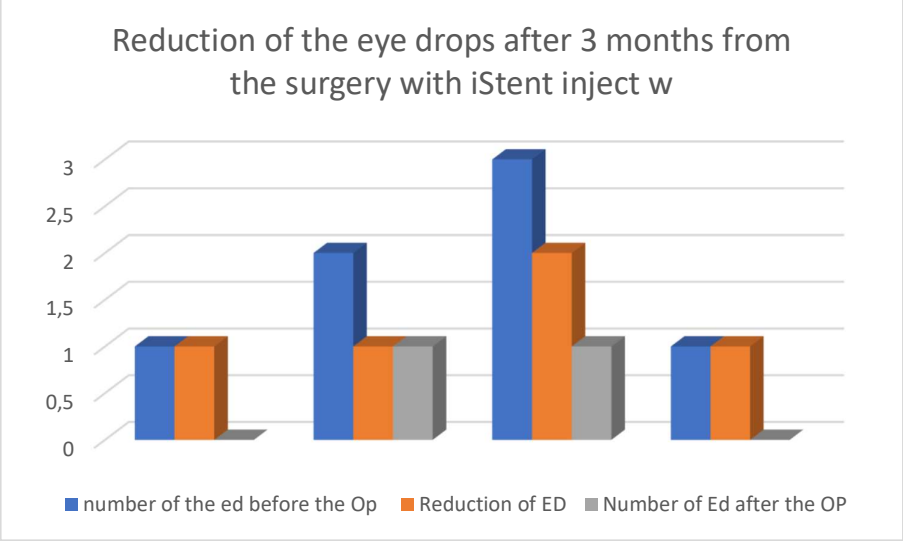

Chart 2: the reduction of the eye drops after 3 months in the group of iStent inject w.

The Improvement of VA in this group was 5.25 lines in Snellen charts. In Group 2 (with iStent inject) was the mean IOP before the surgery 20.25 mmHg and 15 mmHg after 3 months from the surgery with a mean IOP reduction of 5.25 mmHg chart 3.

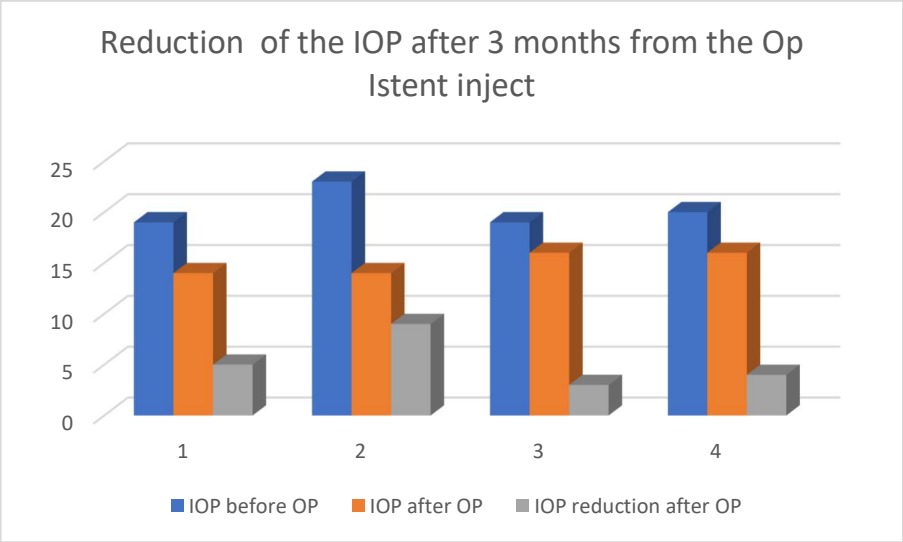

Chart 3: Reduction of IOP in Group of iStent inject after 3 months from the surgery.

Mean number of eyedrops in this group before the surgery was 1.75 then was 0.5 at the end of this follow-up, Chart 4.

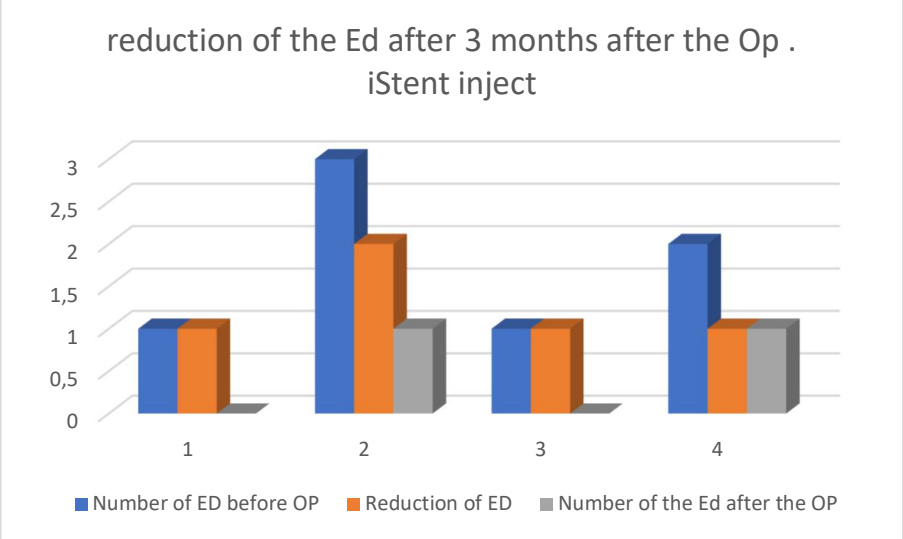

Chart 4: reduction of the eyedrops after 3 months from the surgery in Group 2 (of iStent inject).

We had no significant complications (corneal oedema, Hyphema and Ac Activity) in both groups. One patient in Group 1 had mild residual bleeding over Iris which disappeared after one day. In the first week after the Surgery was IOP within normal limits in G1 and G2, and no high readings were registered although we leave a little amount of the cohesive viscoelastic (avisc® Aivimed GmbH, Germany) in the AC to avoid Hyphema after the surgery. The implantation of iStent inject w was relatively easier, and the stent is more stable in the trabecula, but the Blood reflux was also relatively more. No second surgery in all eyes was indicated. The mean

IOP reduction in G1 was 6.5 mmHg and in G2 was 5.25 mmHg Chart 5, but after data analyses with *t*-test P-value was 0.3890, and there is no significant statically difference in IOP reduction between 2 groups. We have no information yet about the possible endothelial cell loss after iStent inject W and this needs a long follow up.

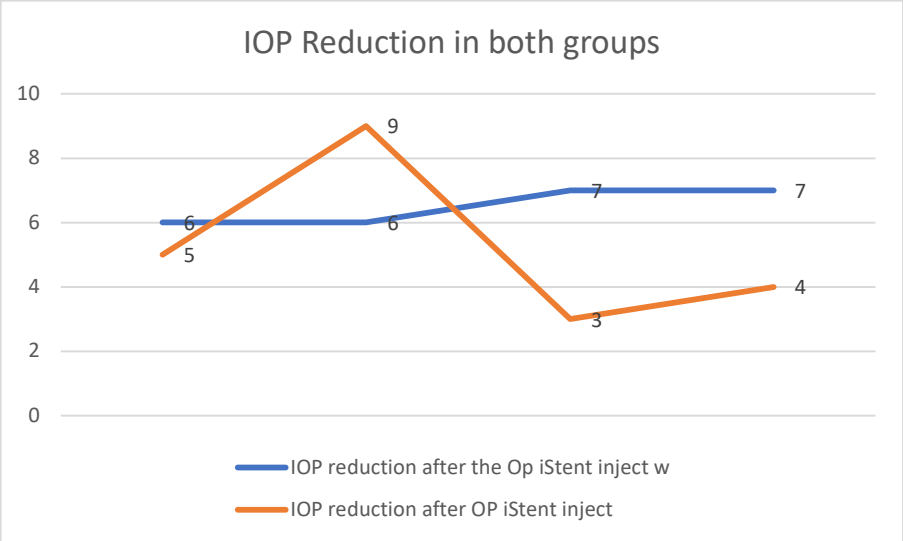

Chart 5: a comparison between IOP reduction after 3 months in both groups.

Conclusions:

iStent inject and iStent inject W were both safe and effective in lowering IOP. The IOP reduction in iStent inject W group was slightly more, but the difference between the two groups was not statistically significant (P-value 0.3890). More studies with a larger number of patients are recommended.

References

1. Quigley HA, Broman AT. The number of people with glaucoma worldwide in 2010 and 2020. Br J Ophthalmol. 2006;90(3):262–267
2. Leske MC, Heijl A, Hyman L, Bengtsson B, Komaroff E. Factors for progression and glaucoma treatment: The Early Manifest Glaucoma Trial. Curr Opin Ophthalmol. 2004;15:102–106. doi: 10.1097/00055735-200404000-00008
3. Gazzard G, et al. Selective laser trabeculoplasty versus drops for newly diagnosed ocular hypertension and glaucoma. Health Technol Assess. 2019 Jun;23(31):1-102. doi: 10.3310/hta23310.
4. Samuelson TW, Katz LJ, Wells JM, Duh YJ, Giamporcaro JE, Group USiS Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. Ophthalmology. 2011;118(3):459–467
5. Grant WM. Experimental aqueous perfusion in enucleated human eyes. Arch Ophthalmol. 1963;69:783–801
6. Marko Popovic, et al. Efficacy and Adverse Event Profile of the iStent and iStent Inject Trabecular Micro-bypass for Open-angle Glaucoma: A Meta-analysis. J Curr Glaucoma Pract. 2018 May-Aug; 12(2): 67–84.
7. Arriola-Villalobos Pedro, Martinez-de-la-Casa Jose Maria, Diaz-Valle David, Morales-Fernandez Laura, Fernandez-Perez Cristina, Garcia-Feijoo Julian. Glaukos iStent inject® Trabecular Micro-Bypass Implantation Associated with Cataract Surgery in Patients with Coexisting Cataract and Open-Angle Glaucoma or Ocular Hypertension: A Long-Term Study. Journal of Ophthalmology. 2016;2016:1–7.

8. Sengupta S, et al. Intraocular Pressure Reduction after Phacoemulsification versus Manual Small-Incision Cataract Surgery: A Randomized Controlled Trial.Ophthalmology. 2016 Aug;123(8):1695-1703. doi: 10.1016/j.ophtha.2016.04.014. Epub 2016 May 24.
9. Nan Wang, et al. Ultrasound Activates the TM ELAM-1/IL-1/NF-κB Response: A Potential Mechanism for Intraocular Pressure Reduction after Phacoemulsification. Invest Ophthalmol Vis Sci. 2003 May; 44(5): 1977–1981.