6 Month Results from a Prospective, Multicenter Study of a Nickel-titanium Schlemm's Canal Scaffold for IOP Reduction in Open Angle Glaucoma

Augenklinik und Poliklinik
Direktor: Professor Dr. med. N. Pfeiffer

Katrin Lorenz[1], Norbert Pfeiffer [1], Marina Ramirez[2], Gabor Scharioth[3], Manfred Tetz[4], Clemens Vass[5], Swaantje Grisanti[6], Thomas Samuelson[7]

INTRODUCTION

A novel intracanalicular scaffold (Hydrus™ Aqueous Implant, Ivantis, Inc., Irvine, CA) increases outflow facility by bypassing the TM and dilating SC to increase circumferential flow. The implant is comprised of Nitinol (nickel-titanium alloy) and has a non-luminal open design to improve flow of aqueous humor into SC and gain better access to collector channels within the canal.

PURPOSE & METHODS

The objective of the study was to evaluate the ability of the Hydrus device alone to lower IOP in patients with mild to moderate open angle glaucoma. Endpoints include IOP, medication use, frequency of adverse events and ocular safety findings at 12 months.

The study was performed under Medical Ethics Committee approvals. Subjects were recruited from 6 international centers. Key inclusion criteria were a diagnosis of POAG or PXG confirmed by Visual Field defect or RNFL, BCVA worse than 20/40, age > 18 years, and a screening IOP of 24 mmHg or less on no more than 4 hypotensive medications. Patients naïve to medication were allowed. Secondary glaucoma, significant ocular pathology other than glaucoma, and prior glaucoma surgery were excluded.

Post operatively, subjects were followed up at 1, 7, 30, 90 , and 180 days. Follow up will continue through 2 years, with wash out at the 1 and 2 year follow up periods.

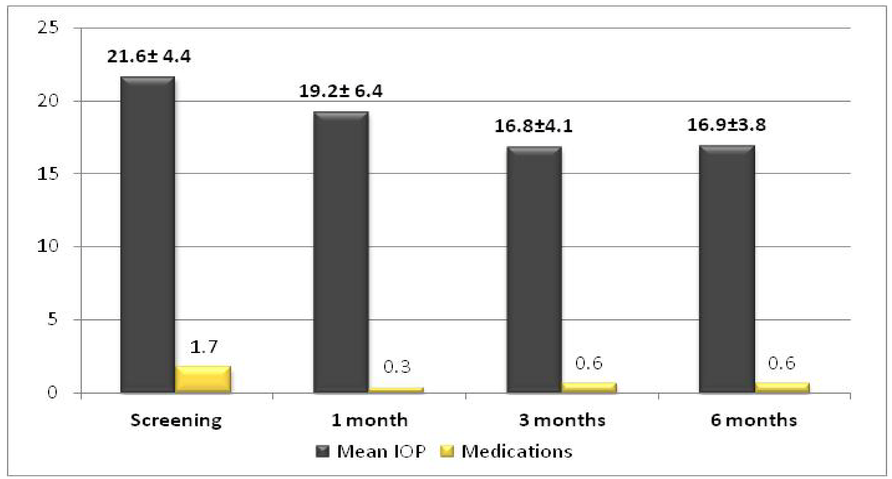
RESULTS

Subjects in the study had a mean age of 65.4 ± 10.9 years and were 69% female. 42% of subjects were Caucasian and 56% were Hispanic. Mild to Moderate POAG was diagnosed in 93% of subjects, with average MD of -4.82 ± 4.06 and PSD of 4.39 ± 2.72. At screening, IOP was 21.6 ± 4.4 mmHg treated with an average of 1.7 ± 1.4 glaucoma medications.

40 subjects were successfully treated with the Hydrus device. Intraoperative complications included 2 cases of iris damage and 3 cases of mild hyphema that resolved within 1 week. 100% of study subjects completed all the scheduled follow up visits through 3 months and 37/40 patients completed the 6 month follow up.

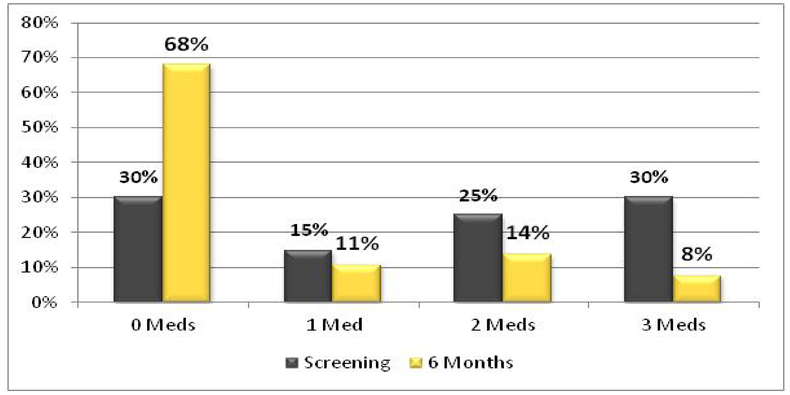
The mean (± SD) IOP and medication use through 6 months follow up are presented in the table below. At 6 months, mean IOP decreased to 16.9 mmHg with an average of 0.6 meds/patient.

FOLLOW UP IOP & MEDICATIONS



The change in medication count from baseline to 6 months is presented in the chart below. Medication use was consistently reduced at all levels. Overall 68% of study subjects were medication free at 6 months follow up.

CHANGE IN MEDICATION USE



DISCUSSION

The use of the implant resulted in significant drops in IOP and medication use from baseline values. Through 6 months the majority of patients were medication free in the study eye, and 58%patients reduced their medication usage by more than 1 medication. There were no reports of hypotony, endophthalmitis, or shallow AC. Safety findings included 4 patients with small PAS observed near the device inlet, and one patient with PCO.

CONCLUSION

A permanent implant that provides continuous, durable IOP control may offer a viable alternative to medical therapy.

1. University Medical Center, Mainz, Germany; 2. CODET Vision Institute, Tijuana, Mexico; 3. Recklinghausen, Germany; 4. Berlin, Germany; 5. Vienna, Austria; 6. Lübeck, Germany; 6. Minn. Eye Consultants, Minneapolis, MN