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

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

Norbert Pfeiffer[1], Katrin Lorenz[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 device to lower IOP in patients with mild to moderate open angle glaucoma who were concurrently undergoing cataract surgery.

A total of 29 patients were recruited from 6 centers. Key inclusion criteria were a diagnosis of POAG or PXG confirmed by Visual Field defect or RNFL, an age related cataract, BCVA worse than 20/40, and a screening IOP of 24 mmHg or less on no more than 4 medications. Secondary glaucoma, significant ocular pathology other than cataract and glaucoma, and prior glaucoma surgery were excluded.

Qualified subjects were washed out of all glaucoma medications prior to surgery. 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.

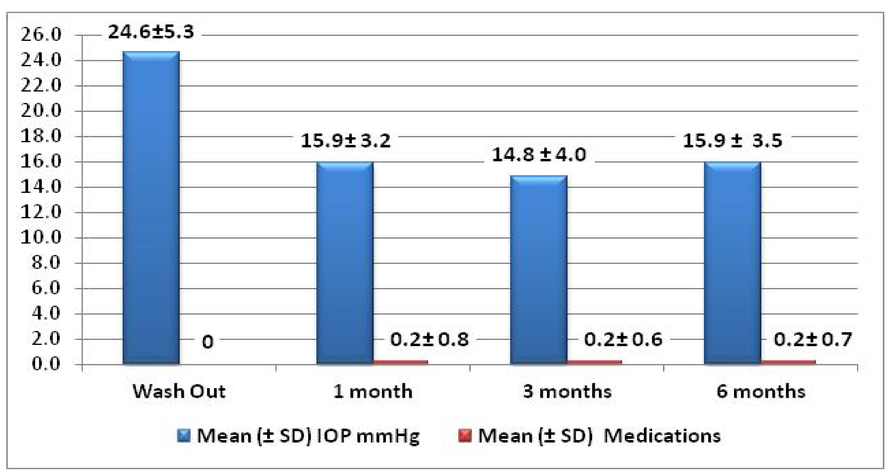
RESULTS

Subjects in the study had a mean age of 70.9 ± 6.5 years and were 55% female. 76% of subjects were Caucasian and 21% were Hispanic. POAG was diagnosed in 79% of subjects, with average mean deviation of -4.49 ± 4.62 and PSD of 4.92 ± 3.31. At screening, IOP was 21.1 ± 5.6 mmHg treated with an average of 2.2 ± 1.4 glaucoma medications.

All surgeries resulted in successful Hydrus implantation. There was one case of mild iris damage; there were no other surgical complications. 100% of study subjects completed all the scheduled follow up visits through 6 months.

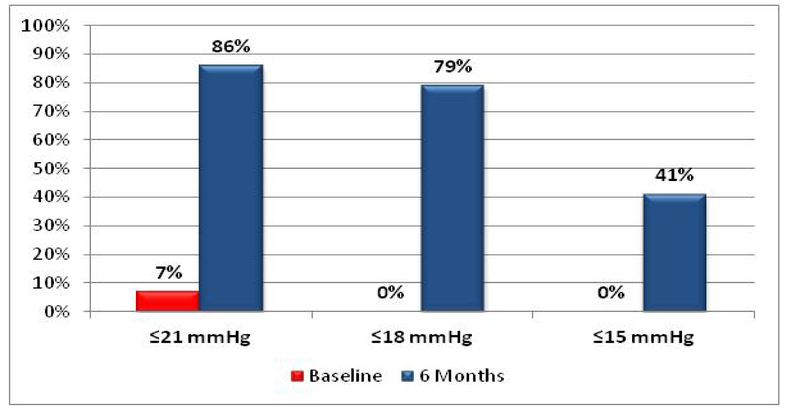
The mean (± SD) IOP and medication use through 6 months follow up are presented in the table below. From the wash out period to 6 months, mean IOP decreased by 8.7 points while medication use only increased to an average of 0.2 meds/patient. Through 6 months, 26/29 of patients were entirely medication free.

FOLLOW UP IOP & MEDICATIONS



A positive response to the implant was defined as a medication free IOP of 21 mmHg or less. Through 6 months, the response rate in this study was 86%. In addition, 79% of patients obtained a medication free IOP of 18 mmHg or less. The median IOP was 15.5 mmHg, absent all medications.

MEDICATION FREE IOP



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 with mean IOP of 15.9 mmHg. There were no reports of hypotony, endophthalmitis, or shallow AC. There was one patient with a small area of PAS at the inlet area of the device, and one patient with PCO.

CONCLUSION

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

1. University Med. 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, Mnpls., MN