Interventional Glaucoma – A Collaborative and Complimentary Approach

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Category: Glaucoma

Course Description:
The course will use a case-based format to illustrate challenges in providing glaucoma care. Topics include initiating treatment, medications versus laser, ocular surface disease, MIGS, incisional surgery and partnering with a consultant. [32 word count]

Learning Objectives:

1. Develop rational strategy for selecting a patient centric initial therapy plan.
2. Be able to present most recent data about laser as initial therapy, pros and cons.
3. Apply an algorithm for ocular surface disease management in patient on IOP lowering eye drops.
4. Develop an evidence-based understanding of various popular MIGS procedure to help guide patients in selection of surgeon and procedure.
5. Recognize common complications of glaucoma surgery and management options.
6. Create tools and strategies to get the best care and communication from glaucoma consultants.

Practice Gaps:

1. Adopt approach of rational stepped glaucoma therapy base on patient centric considerations.
2. Become familiar with them popular MIGS procedures and how to present expectations to patients.
3. Adopt tools and strategies to enhance communication and collaboration with your glaucoma consultant.
4.

Course Outline

Initiating Treatment

The are many options for initiating IOP lowering treatment. The first step is to decide that treatment is appropriate. There are two clinical situations in which treatment with IOP lowering modalities is indicated. The first is risk-based. If sufficient risk factors are present, most often elevated IOP, it is appropriate to reduce risk by lowering intraocular pressure. The presence of glaucomatous damage is usually but not always an indication for IOP lowering therapy. There are uncommon clinical situations in which damage may be present but IOP lowering treatment is not indicated. These typically fall in the category of documented past IOP elevation that has now resolved.

Once the determination has been made that treatment is warranted the clinician should consider and present to the patient various options. Medical therapy is a common first choice.

The loss of patent protection has created a market dominated by generic medications. Pharmacy benefit plans highly favor generic medications over branded medications. This is a question that has been debated by glaucoma specialists but economics have dictated the outcome. Even though generics are not identical to branded medication and do not need to demonstrate identical formulation or efficacy, they are assumed to be sufficiently alike that they become the de facto first choice.

Medication or laser trabeculoplasty

When laser trabeculoplasty (ALT) was introduced in the 1980s it was viewed as an alternative to trabeculectomy. Times have changed!

Selective laser trabeculoplasty is now considered as an option for initial therapy or as a first adjunctive treatment. Certain glaucomas are highly likely to respond well to laser trabeculoplasty. These include pseudoexfoliation and pigmentary glaucoma. A recent large clinical trial compared initial laser trabeculoplasty to initial treatment with prostaglandin.

Key Reference:

Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled trial. The Lancet. Volume 393Number 10180p1477-1568, e37. April 3, 2019
Interpretation:
Selective laser trabeculoplasty should be offered as a first-line treatment for open angle glaucoma and ocular hypertension, supporting a change in clinical practice.

The other challenge with eye drops is that getting a drop onto the eye is not a trivial task, particularly for an aging population who may have some arthritic or other changes. Wasted

Key Reference:
Realini T, Fechtner RD. 56,000 Ways to Treat Glaucoma. Ophthalmology. 2002; 109(11):1955-6.

An editorial in 2002 calculated all the permutations of eye drop therapy. It's not necessary to try 56,000 different approaches or even 56. A better approach is a limited and rational regimen.

Rational Medical Therapy

Maximal Medical Therapy for Glaucoma
Thom J. Zimmerman, MD, PhD; Robert D. Fechtner, MD
Arch Ophthalmol. 1997;115(12):1579-1580. doi:10.1001/archopht.1997.01100160749014

Adherence

Writing a prescription or even giving a sample should be considered "intent to treat". Unless the physician is administering the daily drops we have every reason to believe that adherence is, at best, inconsistent. One of the keys to a successful treatment plan is to keep it simple. Recruiting family or friends as support can help. Digital reminders have become widely available since many patients have a smart phone with alarm capability. Spending the office time to set this upset provide a better foundation for successful treatment.

Fragmented Care

Another challenge for particular geographic reasons is the quote snowbird End Quote effect. Retirees may choose to spend time in two different locations which fragments care. It's a New York based glaucoma specialist I find my patience spend six months plus one day in Florida for tax benefits. Until the day that electronic health records are universally shared we cannot know what our colleague in another location is doing. It becomes an important aspect of care to provide either the patient or the treating partner in another location with updated records on an annual basis. This is yet another burden that is shifted to the physician. Consider providing the patient with hard copy and let them be the messenger for their care.

How to partner with your glaucoma consultant

Communication, communication, communication. Just as you select a cataract surgeon as a partner, try to find someone with a special interest in glaucoma. This should be a two way partnership.

Key Recent Laser Studies

LiGHT Study (Initial treatment with laser versus eyedrops)

Lancet. 2019 Apr 13;393(10180):1505-1516. doi: 10.1016/S0140-6736(18)32213-X. Epub 2019 Mar 9.

Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled trial.

Gazzard G[1], Konstantakopoulou E[2], Garway-Heath D[2], Garg A[2], Vickerstaff V[3], Hunter R[4], Ambler G[5], Bunce C[6], Wormald R[7], Nathwani N[8], Barton K[2], Rubin G[9], Buszewicz M[4]; LiGHT Trial Study Group.
Collaborators (25)
Author information

Erratum in

- Department of Error. [Lancet. 2019]

Abstract

BACKGROUND:

Primary open angle glaucoma and ocular hypertension are habitually treated with eye drops that lower intraocular pressure. Selective laser trabeculoplasty is a safe alternative but is rarely used as first-line treatment. We compared the two.

METHODS:

In this observer-masked, randomised controlled trial treatment-naive patients with open angle glaucoma or ocular hypertension and no ocular comorbidities were recruited between 2012 and 2014 at six UK hospitals. They were randomly allocated (web-based randomisation) to initial selective laser trabeculoplasty or to eye drops. An objective target intraocular pressure was set according to glaucoma severity. The primary outcome was health-related quality of life (HRQoL) at 3 years (assessed by EQ-5D). Secondary outcomes were cost and cost-effectiveness, disease-specific HRQoL, clinical effectiveness, and safety. Analysis was by intention to treat. This study is registered at controlled-trials.com (ISRCTN32038223).

FINDINGS:

Of 718 patients enrolled, 356 were randomised to the selective laser trabeculoplasty and 362 to the eye drops group. 652 (91%) returned the primary outcome questionnaire at 36 months.

Average EQ-5D score was 0·89 (SD 0·18) in the selective laser trabeculoplasty group versus 0·90 (SD 0·16) in the eye drops group, with no significant difference (difference 0·01, 95% CI -0·01 to 0·03; p=0·23). At 36 months, 74·2% (95% CI 69·3-78·6) of patients in the selective laser trabeculoplasty group required no drops to maintain intraocular pressure at target. Eyes of patients in the selective laser trabeculoplasty group were within target intraocular pressure at more visits (93·0%) than in the eye drops group (91·3%), with glaucoma surgery to lower intraocular pressure required in none versus 11 patients. Over 36 months, from an ophthalmology cost perspective, there was a 97% probability of selective laser trabeculoplasty as first treatment being more cost-effective than eye drops first at a willingness to pay of £20 000 per quality-adjusted life-year gained.

INTERPRETATION:

Selective laser trabeculoplasty should be offered as a first-line treatment for open angle glaucoma and ocular hypertension, supporting a change in clinical practice.

FUNDING:

National Institute for Health Research, Health and Technology Assessment Programme.

Comment: Efficacy was not the primary outcome. Cost-efficacy was. At 36 months 74.2% of the SLT treated patients were still medication free.

SALT Trial (Steroids after SLT?)

Ophthalmology. 2019 Nov;126(11):1511-1516. doi: 10.1016/j.ophtha.2019.05.032. Epub 2019 Jun 6.

SALT Trial: Steroids after Laser Trabeculoplasty: Impact of Short-Term Anti-inflammatory Treatment on Selective Laser Trabeculoplasty Efficacy.

Groth SL[1], Albeiruti E[2], Nunez M[3], Fajardo R[4], Sharpsten L[4], Loewen N[2], Schuman JS[2], Goldberg JL[5].

Author information

Abstract

PURPOSE:

This study examined whether short-term use of topical nonsteroidal anti-inflammatory drug (NSAID) or steroid therapy affected the efficacy of selective laser trabeculoplasty (SLT).

DESIGN:

Double-masked, randomized, placebo-controlled, dual-center, multisurgeon trial.

PARTICIPANTS:

Patients older than 18 years with intraocular pressure (IOP) of more than 18 mmHg for whom the clinician decided SLT was the appropriately indicated therapy were randomized to 1 of 3 groups in a ratio of 1:1:1 as follows: ketorolac 0.5%, prednisolone 1%, or saline tears.

METHODS:

After SLT, patients randomized into each group were instructed to use an unmarked drop 4 times daily starting the day of SLT and continuing for 4 additional days. The Kruskal-Wallis test and Wilcoxon rank-sum test were used for continuous variables when comparing 2 or 3 treatment groups, respectively. The Fisher exact test was used for categorical variables.

MAIN OUTCOME MEASURES:

The primary outcome of this study was IOP at 12 weeks. Secondary outcome measures included IOP at 1 and 6 weeks, patient-reported pain, and detectable anterior chamber inflammation.

RESULTS:

Ninety-six eyes of 85 patients fit inclusion criteria and were enrolled between the 2 sites. The NSAID, steroid, and placebo groups were similar in baseline demographics and baseline IOP (mean, 23.3±3.9 mmHg; P = 0.57). There was no statistically significant difference in IOP decrease among groups at week 6. Both the NSAID and steroid groups showed a statistically significantly greater decrease in IOP at week 12 compared with the placebo group (mean, -6.2±3.1 mmHg, -5.2±2.7 mmHg, and -3±4.3 mmHg, respectively; P = 0.02 [analysis of variance] and P = 0.002 [t test] for NSAID vs. placebo groups; P = 0.02 for steroid vs. placebo groups).

CONCLUSIONS:

Significantly better IOP reduction at 12 weeks was measured in eyes treated with steroid or NSAID drops after SLT. Short-term postoperative use of NSAID or steroid drops may improve IOP reduction after SLT. Longer-term follow-up studies are indicated.

Published by Elsevier Inc.

PMID: 31444008
PMCID PMC6810843 [Available on 2020-11-01]
DOI: 10.1016/j.ophtha.2019.05.032

Comment: This study reports 12 week IOP reduction. Longer term study is needed to know whether this difference is maintained.

WIGLS STUDY

Am J Ophthalmol. 2017 Dec;184:28-33. doi: 10.1016/j.ajo.2017.09.022. Epub 2017 Sep 28.

West Indies Glaucoma Laser Study (WIGLS): 1. 12-Month Efficacy of Selective Laser Trabeculoplasty in Afro-Caribbeans With Glaucoma.

Realini T[1], Shillingford-Ricketts H[2], Burt D[3], Balasubramani GK[4].

Author information

Abstract

PURPOSE:

To characterize the 12-month intraocular pressure (IOP)-lowering efficacy of selective laser trabeculoplasty (SLT) as sole therapy for primary open-angle glaucoma (POAG) in an Afro-Caribbean population.

DESIGN:

Stepped-wedge trial.

METHODS:

Subjects in St. Lucia and Dominica with established POAG were randomized to prompt washout of IOP-lowering medications followed by SLT, 3-month delay followed by washout and SLT, or 6-month delay followed by washout and SLT. Baseline IOP was obtained on 2 different days after washout. Bilateral 360-degree SLT was performed in 1 session. Posttreatment assessments took place 1 hour, 1 week, and 3, 6, 9, and 12 months post-SLT. The main outcome measure was SLT success (defined as IOP ≤ target IOP in both eyes) at 12 months. Target IOP was a 20% or greater reduction in IOP from postwashout baseline.

RESULTS:

Overall, 72 patients underwent SLT treatment. Mean IOP at enrollment was 15.4 ± 3.6 mm Hg in right eyes and 15.4 ± 3.6 mm Hg in left eyes, which rose to 21.0 ± 3.3 mm Hg and 20.9 ± 3.0 mm Hg, respectively, after washout. Mean IOP at 3, 6, 9, and 12 months ranged from 12.5 mm Hg to 14.5 mm Hg (29.7% to 39.5%; $P < .0001$ in each eye at each time point). The 12-month success rate was 78%. Transient photophobia and discomfort were common.

CONCLUSIONS:

SLT monotherapy safely provides significant IOP reduction in Afro-Caribbean eyes with POAG. This treatment can play a significant role in preventing glaucoma vision loss and blindness in people of African descent living in resource-limited regions.

PMID: 28962966
PMCID: PMC5705413
DOI: 10.1016/j.ajo.2017.09.022

[Indexed for MEDLINE]
Free PMC Article

Comment: While there was no control group, SLT maintained IOP control in 78% of patients of African descent at 12 months. Retreatment was required in fewer patients than expected.

Key MIGS Studies

iStent

Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract.

Ophthalmology. 2011 Mar;118(3):459-67. doi: 10.1016/j.ophtha.2010.07.007. Epub 2010 Sep 15.

Samuelson TW[1], Katz LJ, Wells JM, Duh YJ, Giamporcaro JE; US iStent Study Group.

Abstract

OBJECTIVE:
To assess the safety and efficacy of the iStent trabecular micro-bypass stent (Glaukos Corporation, Laguna Hills, CA) in combination with cataract surgery in subjects with mild to moderate open-angle glaucoma.

DESIGN:
Prospective, randomized, open-label, controlled, multicenter clinical trial.

PARTICIPANTS:
A total of 240 eyes with mild to moderate open-angle glaucoma with intraocular pressure (IOP) ≤24 mmHg controlled on 1 to 3 medications were randomized to undergo cataract surgery with iStent implantation (treatment group) or cataract surgery only (control). Fifty additional subjects were enrolled to undergo cataract surgery with iStent implantation under protocol expansion. Data in this report are based on the first 240 eyes enrolled.

INTERVENTION:
Implantation of the iStent trabecular micro-bypass stent in conjunction with cataract surgery or cataract surgery only.

MAIN OUTCOME MEASURES:
The primary efficacy measure was unmedicated IOP ≤21 mmHg at 1 year. A secondary measure was unmedicated IOP reduction ≥20% at 1 year. Safety measures included best-corrected visual acuity (BCVA), slit-lamp observations, complications, and adverse events.

RESULTS:
The study met the primary outcome, with 72% of treatment eyes versus 50% of control eyes achieving the criterion (P<0.001). At 1 year, IOP in both treatment groups was statistically significantly lower from baseline values. Sixty-six percent of treatment eyes versus 48% of control eyes achieved ≥20% IOP reduction without medication (P = 0.003). The overall incidence of adverse events was similar between groups with no unanticipated adverse device effects.

CONCLUSIONS:
Pressure reduction on fewer medications was clinically and statistically significantly better 1 year after stent plus cataract surgery versus cataract surgery alone, with an overall safety profile similar to that of cataract surgery alone.

TRIAL REGISTRATION:
ClinicalTrials.gov NCT00323284.

Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: two-year follow-up.

J Cataract Refract Surg. 2012 Aug;38(8):1339-45. doi: 10.1016/j.jcrs.2012.03.025

Craven ER[1], Katz LJ, Wells JM, Giamporcaro JE; iStent Study Group

Abstract

PURPOSE:
To assess the long-term safety and efficacy of a single trabecular micro-bypass stent with concomitant cataract surgery versus cataract surgery alone for mild to moderate open-angle glaucoma.

SETTING:
Twenty-nine investigational sites, United States.

DESIGN:
Prospective randomized controlled multicenter clinical trial.

METHODS:
Eyes with mild to moderate glaucoma with an unmedicated intraocular pressure (IOP) of 22 mm Hg or higher and 36 mm Hg or lower were randomly assigned to have cataract surgery with iStent trabecular micro-bypass stent implantation (stent group) or cataract surgery alone (control group). Patients were followed for 24 months postoperatively.

RESULTS:
The incidence of adverse events was low in both groups through 24 months of follow-up. At 24 months, the proportion of patients with an IOP of 21 mm Hg or lower without ocular hypotensive medications was significantly higher in the stent group than in the control group (P=.036). Overall, the mean IOP was stable between 12 months and 24 months (17.0 mm Hg ± 2.8 [SD] and 17.1 ± 2.9 mm Hg, respectively) in the stent group but increased (17.0 ± 3.1 mm Hg to 17.8 ± 3.3 mm Hg, respectively) in the control group. Ocular hypotensive medication was statistically significantly lower in the stent group at 12 months; it was also lower at 24 months, although the difference was no longer statistically significant.

CONCLUSIONS:
Patients with combined single trabecular micro-bypass stent and cataract surgery had significantly better IOP control on no medication through 24 months than patients having cataract surgery alone. Both groups had a similar favorable long-term safety profile.

FINANCIAL DISCLOSURE:
Dr. Craven was an investigator in the clinical trial of the iStent. Dr. Katz is a consultant to Glaukos and was the medical monitor for the clinical trial of the iStent. Dr. Katz is a stockholder in Glaukos. Mr. Wells and Ms. Giamporcaro are employees of Glaukos.

Prospective, randomized study of one, two, or three trabecular bypass stents in open-angle glaucoma subjects on topical hypotensive medication.

Clin Ophthalmol. 2015 Dec 11;9:2313-20. doi: 10.2147/OPTH.S96695. eCollection 2015.

Katz LJ[1], Erb C[2], Carceller GA[3], Fea AM[4], Voskanyan L[5], Wells JM[6], Giamporcaro JE

Abstract

PURPOSE:

To assess the safety and efficacy of one, two, or three trabecular microbypass stents in eyes with primary open-angle glaucoma (OAG) not controlled on ocular hypotensive medication. A total of 119 subjects were followed for 18 months postoperatively.

MATERIALS AND METHODS:

Subjects with medicated intraocular pressure (IOP) 18-30 mmHg and postmedication-washout baseline IOP 22-38 mmHg were randomized to implantation of one, two, or three stents. Ocular hypotensive medication was to be used if postoperative IOP exceeded 18 mmHg.

RESULTS:

A total of 38 subjects were implanted with one stent, 41 subjects with two stents, and 40 subjects with three stents. Both month 12 IOP reduction ≥20% without ocular hypotensive medication vs baseline unmedicated IOP and month 12 unmedicated IOP ≤18 mmHg were achieved by 89.2%, 90.2%, and 92.1% of one-, two-, and three-stent eyes, respectively. Furthermore, 64.9%, 85.4%, and 92.1% of the three respective groups achieved unmedicated IOP ≤15 mmHg. Over the 18-month follow-up period, medication was required in seven one-stent subjects, four two-stent subjects, and three three-stent subjects. At 18 months, mean unmedicated IOP was 15.9±0.9 mmHg in one-stent subjects, 14.1±1.0 mmHg in two-stent subjects, and 12.2±1.1 mmHg in three-stent subjects. Month 18 IOP reduction was significantly greater ($P<0.001$) with implantation of each additional stent, with mean differences in reduction of 1.84 mmHg (95% confidence interval 0.96-2.73) for three-stent vs two-stent groups and 1.73 mmHg (95% confidence interval 0.83-2.64) for two-stent vs one-stent groups. Adverse events through 18 months were limited to cataract progression with best-corrected visual acuity loss and subsequent cataract surgery.

CONCLUSION:

In this series, implantation of each additional stent resulted in significantly greater IOP reduction with reduced medication use. Titratability of stents as a sole procedure was shown to be effective and safe, with sustained effect through 18 months postoperatively in OAG not controlled with medication.

iStent Inject

Prospective, Randomized, Controlled Pivotal Trial of an Ab Interno Implanted Trabecular Micro-Bypass in Primary Open-Angle Glaucoma and Cataract – Two-Year Results

Robert D. Fechtner, MD Course Handout

Ophthalmology 2019;126:811-821.

Thomas W. Samuelson, MD, Steven R. Sarkisian, Jr., MD, David M. Lubeck, MD, Michael C. Stiles, MD, Yi-Jing Duh, PhD, Eeke A. Romo, DSc, Jane Ellen Giamporcaro, MS, Dana M. Hornbeak, MD, MPH, L. Jay Katz, MD, for the iStent inject Study Group

Abstract

PURPOSE:

Evaluate the safety and effectiveness of an ab interno implanted (iStent inject) Trabecular Micro-Bypass System (Glaukos Corporation, San Clemente, CA) in combination with cataract surgery in subjects with mild to moderate primary open-angle glaucoma (POAG).

DESIGN:

Prospective, randomized, single-masked, concurrently controlled, multicenter clinical trial. Participants: Eyes with mild to moderate POAG and preoperative intraocular pressure (IOP) ≤ 24 mmHg on 1 to 3 medications, unmedicated diurnal IOP (DIOP) 21 to 36 mmHg, and cataract requiring surgery.

METHODS:

After uncomplicated cataract surgery, eyes were randomized 3:1 intraoperatively to ab interno implantation of iStent inject (Model G2-M-IS; treatment group, n . 387) or no stent implantation (control group, n = 118). Subjects were followed through 2 years postoperatively. Annual washout of ocular hypotensive medication was performed.

MAIN OUTCOME MEASURES:

Effectiveness end points were ≥ 20% reduction from baseline in month 24 unmedicated DIOP and change in unmedicated month 24 DIOP from baseline. Safety measures included best spectacle-corrected visual acuity (BSCVA), slit-lamp and fundus examinations, gonioscopy, pachymetry, specular microscopy, visual fields, complications, and adverse events.

RESULTS:

The groups were well balanced preoperatively, including medicated IOP (17.5 mmHg in both groups) and unmedicated DIOP (24.8±3.3 mmHg vs. 24.5±3.1 mmHg in the treatment and control groups, respectively, P = 0.33). At 24 months, 75.8% of treatment eyes versus 61.9% of control eyes experienced ≥20% reduction from baseline in unmedicated DIOP (P = 0.005), and mean reduction in unmedicated DIOP from baseline was greater in treatment eyes (7.0±4.0 mmHg) than in control eyes (5.4±3.7 mmHg; P < 0.001). Of the responders, 84% of treatment eyes and 67% of control eyes were not receiving ocular hypotensive medication at 23 months. Furthermore, 63.2% of treatment eyes versus 50.0% of control eyes had month 24 medication-free DIOP ≤18 mmHg (difference 13.2%; 95% confidence interval, 2.9–23.4). The overall safety profile of the treatment group was favorable and similar to that in the control group throughout the 2-year follow-up.

CONCLUSIONS:

Clinically and statistically greater reductions in IOP without medication were achieved after iStent inject implantation with cataract surgery versus cataract surgery alone, with excellent safety through 2 years. Ophthalmology 2019;126:811-821

Cypass

Initial Clinical Experience with the CyPass Micro-Stent: Safety and Surgical Outcomes of a Novel Supraciliary Microstent.

J Glaucoma. 2016 Jan;25(1):106-12. doi: 10.1097/IJG.0000000000000134.

Hoeh H, Vold SD, Ahmed IK, Anton A, Rau M, Singh K, Chang DF, Shingleton BJ, Ianchulev T

Abstract

PURPOSE:

To evaluate safety and clinical outcomes of a novel supraciliary device, the CyPass Micro-Stent, for surgical treatment of open-angle glaucoma when implanted in conjunction with cataract surgery.

PATIENTS AND METHODS:

Subjects (n=142) with open-angle glaucoma and cataract underwent combined phacoemulsification, with intraocular lens insertion, and microstent implantation into the supraciliary space of study eyes (n=167). Two analysis cohorts were prespecified based upon medicated baseline intraocular pressure (IOP): ≥21 mm Hg (cohort 1, n=65) or <21 mm Hg (cohort 2, n=102). Glaucoma medications were discontinued or tapered at surgery, and restarted at investigator discretion. The main postoperative outcome measures were adverse events, IOP changes, and number of IOP-lowering medications.

RESULTS:

Mean±SD follow-up was 294±121 days. No major intraoperative or postoperative complications occurred. Preoperative baseline mean IOP was 20.2±6.0 mm Hg and mean number of IOP-lowering medications was 2.0±1.1. Cohort 1 showed a 35% decrease in mean IOP and a 49% reduction in mean glaucoma medication usage; cohort 2 demonstrated a 75% reduction in mean medication usage while maintaining mean IOP<21 mm Hg. For all eyes, mean IOP at 12 months was 15.9±3.1 mm Hg (14% reduction from baseline). Early and late postoperative IOP elevation occurred in 1.2% and 1.8% of eyes, respectively. Two subjects developed mild transient hyphema, and none exhibited prolonged inflammation, persistent hypotony, or hypotony maculopathy.

CONCLUSIONS:

CyPass Micro-Stent implantation, combined with cataract surgery, resulted in minimal complications and reduced IOP and IOP-lowering medication use at 12 months postoperatively.

Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts.

Ophthalmology. 2016 Oct;123(10):2103-12. doi: 10.1016/j.ophtha.2016.06.032. Epub 2016 Aug 6.

Vold S[1], Ahmed II[2], Craven ER[3], Mattox C[4], Stamper R[5], Packer M[6], Brown RH[7], Ianchulev T[8]; CyPass Study Group

Abstract

PURPOSE:

We evaluated 2-year safety and efficacy of supraciliary microstenting (CyPass Micro-Stent; Transcend Medical, Inc., Menlo Park, CA) for treating mild-to-moderate primary open-angle glaucoma (POAG) in patients undergoing cataract surgery.

DESIGN:

Multicenter (24 US sites), interventional randomized clinical trial (RCT) (ClinicalTrials.gov identifier, NCT01085357).

PARTICIPANTS:

Subjects were enrolled beginning July 2011, with study completion in March 2015. Subjects had POAG with mean diurnal unmedicated intraocular pressure (IOP) 21-33 mmHg and were undergoing phacoemulsification cataract surgery.

METHODS:

After completing cataract surgery, subjects were intraoperatively randomized to phacoemulsification only (control) or supraciliary microstenting with phacoemulsification (microstent) groups (1:3 ratio). Microstent implantation via an ab interno approach to the supraciliary space allowed concomitant cataract and glaucoma surgery.

MAIN OUTCOME MEASURES:

Outcome measures included percentage of subjects achieving ≥20% unmedicated diurnal IOP lowering versus baseline, mean IOP change and glaucoma medication use, and ocular adverse event (AE) incidence through 24 months.

RESULTS:

Of 505 subjects, 131 were randomized to the control group and 374 were randomized to the microstent group. Baseline mean IOPs in the control and microstent groups were similar: 24.5±3.0 and 24.4±2.8 mmHg, respectively ($P > 0.05$); mean medications were 1.3±1.0 and 1.4±0.9, respectively ($P > 0.05$). There was early and sustained IOP reduction, with 60% of controls versus 77% of microstent subjects achieving ≥20% unmedicated IOP lowering versus baseline at 24 months ($P = 0.001$; per-protocol analysis). Mean IOP reduction was ↓7.4 mmHg for the microstent group versus ↓5.4 mmHg in controls ($P < 0.001$), with 85% of microstent subjects not requiring IOP medications at 24 months. Mean 24-month medication use was 67% lower in microstent subjects ($P < 0.001$); 59% of control versus 85% of microstent subjects were medication free. Mean medication use in controls decreased from 1.3±1.0 drugs at baseline to 0.7±0.9 and 0.6±0.8 drugs at 12 and 24 months, respectively, and in the microstent group from 1.4±0.9 to 0.2±0.6 drugs at both 12 and 24 months ($P < 0.001$ for reductions in both groups at both follow-ups vs. baseline). No vision-threatening microstent-related AEs occurred. Visual acuity was high in both groups through 24 months; >98% of all subjects achieved 20/40 best-corrected visual acuity or better.

CONCLUSIONS:

This RCT demonstrated safe and sustained 2-year reduction in IOP and glaucoma medication use after microinterventional surgical treatment for mild-to-moderate POAG.

Robert D. Fechtner, MD Course Handout

FDA Recall of Cypass

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=167047

Hydrus

A Randomized Trial of a Schlemm's Canal Microstent with Phacoemulsification for Reducing Intraocular Pressure in Open-Angle Glaucoma.

Ophthalmology. 2015 Jul;122(7):1283-93. doi: 10.1016/j.ophtha.2015.03.031. Epub 2015 May 9.

Pfeiffer N, Garcia-Feijoo J, Martinez-de-la-Casa JM, Larrosa JM, Fea A, Lemij H, Gandolfi S,Schwenn O, Lorenz K, Samuelson TW

Abstract

PURPOSE:
To assess the safety and effectiveness of the Hydrus Microstent (Ivantis, Inc, Irvine, CA) with concurrent cataract surgery (CS) for reducing intraocular pressure (IOP) in open-angle glaucoma (OAG).

DESIGN:
Prospective, multicenter, randomized, single-masked, controlled clinical trial.

PARTICIPANTS:
One hundred eyes from 100 patients 21 to 80 years of age with OAG and cataract with IOP of 24 mmHg or less with 4 or fewer hypotensive medications and a washed-out diurnal IOP (DIOP) of 21 to 36 mmHg.

METHODS:
On the day of surgery, patients were randomized 1:1 to undergo CS with the microstent or CS alone. Postoperative follow-up was at 1 day, 1 week, and 1, 3, 6, 12, 18, and 24 months. Washout of hypotensive medications was repeated at 12 and 24 months.

MAIN OUTCOME MEASURES:
Response to treatment was defined as a 20% or more decrease in washed out DIOP at 12 and 24 months of follow-up compared with baseline. Mean DIOP at 12 and 24 months, the proportion of subjects requiring medications at follow-up, and the mean number of medications were analyzed. Safety measures included change in visual acuity, slit-lamp observations, and adverse events.

RESULTS:
The proportion of patients with a 20% reduction in washed out DIOP was significantly higher in the Hydrus plus CS group at 24 months compared with the CS group (80% vs. 46%; P = 0.0008). Washed out mean DIOP in the Hydrus plus CS group was significantly lower at 24 months compared with the CS group (16.9±3.3 mmHg vs. 19.2±4.7 mmHg; P = 0.0093), and the

proportion of patients using no hypotensive medications was significantly higher at 24 months in the Hydrus plus CS group (73% vs. 38%; P = 0.0008). There were no differences in follow-up visual acuity between groups. The only notable device-related adverse event was focal peripheral anterior synechiae (1-2 mm in length). Otherwise, adverse event frequency was similar in the 2 groups.

CONCLUSIONS:
Intraocular pressure was clinically and statistically significantly lower at 2 years in the Hydrus plus CS group compared with the CS alone group, with no differences in safety.

A Schlemm Canal Microstent for Intraocular Pressure Reduction in Primary Open-Angle Glaucoma and Cataract: The HORIZON Study.

Ophthalmology. 2019 Jan;126(1):29-37. doi: 10.1016/j.ophtha.2018.05.012. Epub 2018 Jun 23. PMID:29945799

Samuelson TW, Chang DF, Marquis R, Flowers B, Lim KS, Ahmed IIK, Jampel HD, Aung T, Crandall AS, Singh K; HORIZON Investigators.

Abstract

OBJECTIVE:
To compare cataract surgery with implantation of a Schlemm canal microstent with cataract surgery alone for the reduction of intraocular pressure (IOP) and medication use after 24 months.

DESIGN:
Prospective, multicenter, single-masked, randomized controlled trial.

PARTICIPANTS:
Subjects with concomitant primary open-angle glaucoma (POAG), visually significant cataract, and washed-out modified diurnal IOP (MDIOP) between 22 and 34 mmHg.

METHODS:
Subjects were randomized 2:1 to receive a single Hydrus Microstent (Ivantis, Inc, Irvine, CA) in the Schlemm canal or no stent after uncomplicated phacoemulsification. Comprehensive eye examinations were conducted 1 day, 1 week, and 1, 3, 6, 12, 18, and 24 months postoperatively. Medication washout and MDIOP measurement were repeated at 12 and 24 months.

MAIN OUTCOME MEASURES:
The primary and secondary effectiveness end points were the proportion of subjects demonstrating a 20% or greater reduction in unmedicated MDIOP and change in mean MDIOP from baseline at 24 months, respectively. Hypotensive medication use was tracked throughout the course of follow-up. Safety measures included the frequency of surgical complications and adverse events.

RESULTS:
A total of 369 eyes were randomized after phacoemulsification to Hydrus Microstent (HMS) and 187 to no microstent (NMS). At 24 months, unmedicated MDIOP was reduced by ≥20% in 77.3% of HMS group eyes and in 57.8% of NMS group eyes (difference = 19.5%, 95% confidence interval [CI] 11.2%-27.8%, P < 0.001). The mean reduction in 24-month unmedicated MDIOP was -7.6±4.1 mmHg (mean ± standard deviation) in the HMS group and -5.3±3.9 mmHg in the NMS group (difference = -2.3 mmHg; 95% CI, -3.0 to -1.6; P < 0.001). The mean number of medications was reduced from 1.7±0.9 at baseline to 0.3±0.8 at 24 months in the HMS group and from 1.7±0.9 to 0.7±0.9 in the NMS group (difference = -0.4 medications; P < 0.001). There were no serious ocular adverse events related to the microstent, and no significant differences in safety parameters between the 2 groups.

CONCLUSIONS:
This 24-month multicenter randomized controlled trial demonstrated superior reduction in MDIOP and medication use among subjects with mild-to-moderate POAG who received a Schlemm canal microstent combined with phacoemulsification compared with phacoemulsification alone.

Xen

Phacoemulsification combined with a new ab interno gel stent to treat open-angle glaucoma: Pilot study.

J Cataract Refract Surg. 2015 Sep;41(9):1905-9. doi: 10.1016/j.jcrs.2015.01.019. Epub 2015 Oct 23.

Sheybani A, Lenzhofer M, Hohensinn M, Reitsamer H, Ahmed II

Abstract

PURPOSE:
To study the effect on intraocular pressure (IOP) of implanting a new gelatin stent at the time of cataract surgery in the treatment of open-angle glaucoma (OAG).

SETTING:
Multicenter university and private-practice settings.

DESIGN:
Nonrandomized prospective clinical trial.

METHODS:
The implantation of 2 models of a gelatin stent (Xen140 and Xen63) was performed at the time of cataract surgery without mitomycin-C. Complete success was defined as a postoperative IOP of less than 18 mm Hg and more than a 20% reduction in IOP at 12 months without glaucoma medication. Failure was defined as loss of light perception vision or worse, a need for additional glaucoma surgery, or less than a 20% reduction in the IOP from baseline.

RESULTS:
The study included 37 eyes of 37 patients. The mean preoperative IOP was 22.4 mm Hg ± 4.2 (SD) on 2.5 ± 1.4 medication classes. Twelve months postoperatively, the mean IOP was reduced to 15.4 ± 3.0 mm Hg on 0.9 ± 1.0 medication classes ($P < .0001$). This resulted in a qualified success of 85.3% and a complete success rate off medications of 47.1%. There were no failures.

CONCLUSION:
Cataract surgery combined with implantation of the gelatin stent resulted in a significant reduction in IOP in eyes with OAG.

Fluid Dynamics of a Novel Micro-Fistula Implant for the Surgical Treatment of Glaucoma.

Invest Ophthalmol Vis Sci. 2015 Jul;56(8):4789-95. doi: 10.1167/iovs.15-16625.

Sheybani A, Reitsamer H, Ahmed II

Abstract

PURPOSE:
The purpose of this study was to describe the fluidics of a novel non-valved glaucoma implant designed to prevent hypotony and compare the fluidics of this device with two commonly used non-valved glaucoma devices.

METHODS:
The XEN 45 micro-fistula implant was designed to limit hypotony by virtue of its length and width according to the Hagen-Poiseuille equation. Flow testing was performed using a syringe pump and pressure transducer at multiple flow rates. The pressure differentials across the XEN implant, the Ex-Press implant, and 10 mm of silicone tubing from a Baerveldt implant at a physiologic flow rate (2.5 µL/min) were extrapolated.

RESULTS:
The XEN 45 achieved a steady-state pressure calculated at 7.56 mm Hg at 2.5 µL/min. At the same flow rate, the Ex-Press device and Baerveldt tubing reached steady-state pressures of 0.09 and 0.01 mm Hg, respectively.

CONCLUSIONS:
Under flow testing, the XEN micro-fistula implant was able to maintain backpressure above numerical hypotony levels without the use of complex valve systems. This is due to the XEN implant's design, derived from the principles that dictate Newtonian fluids.

XEN voluntary recall

https://www.allergan.com › Product-Alerts › XEN45-Recall-Letter-103019

XEN returned to the market after a relatively brief recall

PresurFlo Microshunt (Formerly known as InnFocus Microshunt "FNAIM")

Clinical trial underway – Microshunt versus trabeculectomy

https://clinicaltrials.gov/ct2/show/NCT01881425?term=microshunt&cond=Glaucoma

Three-Year Follow-up of a Novel Aqueous Humor MicroShunt.

J Glaucoma. 2016 Feb;25(2):e58-65. doi: 10.1097/IJG.0000000000000368.

Batlle JF1, Fantes F, Riss I, Pinchuk L, Alburquerque R, Kato YP, Arrieta E, Peralta AC, Palmberg P, Parrish RK 2nd, Weber BA, Parel JM.

Abstract

AIMS:

An observational study to determine the safety and efficacy of filtering surgery employing a microlumen aqueous drainage device (InnFocus MicroShunt), used intraoperatively with Mitomycin C, implanted alone or in combination with phacoemulsification.

MATERIALS AND METHODS:

Single-site, prospective, nonrandomized study of 23 eyes that had failed maximum tolerated glaucoma medication, followed for 3 years. A MicroShunt was implanted ab externo through a needle tract under the limbus, draining aqueous from the anterior chamber to the scleral surface. Prespecified outcome measures include: intraocular pressure (IOP) control, with and without supplemental medication, success rate, medication use, and adverse events.

RESULTS:

Fourteen patients received the MicroShunt alone and 9 with cataract surgery. At 1 (n=23), 2 (n=22), and 3 (n=22) years of follow-up; the qualified success rate (IOP ≤ 14 mm Hg and IOP reduction ≥ 20%) was 100%, 91%, and 95%; mean medicated IOP was reduced from 23.8 ± 5.3 to 10.7 ± 2.8, 11.9 ± 3.7, and 10.7 ± 3.5 mm Hg, and the mean number of glaucoma medications/patient was reduced from 2.4 ± 0.9 to 0.3 ± 0.8, 0.4 ± 1.0, and 0.7 ± 1.1, respectively. The most common complications were transient hypotony (13%, 3/23) and transient choroidal effusion (8.7%, 2/23), all resolved spontaneously. There were no leaks, infections, migrations, erosions, persistent corneal edema, or serious long-term adverse events.

CONCLUSION:

Surgery with the InnFocus MicroShunt transscleral aqueous drainage tube with Mitomycin C achieved IOP control in the low teens in most subjects up to 3 years of follow-up with only transient adverse events occurring within the first 3 months after surgery.

<Referring Practice>
<Contact Information>
<Date of Referral>

Patient Name: _____

Date of Birth: _____

Insurance _____ <copy of insurance card>

Urgency: Urgent Semi-urgent Routine

Diagnosis _____

Visual Acuity R_____L_____

Maximum IOP R_____L_____ Date _____

Current IOP R_____L_____

Visual fields provided Yes No

Imaging test provided Yes No

Medications _____

_____

Med Failure/Intolerance _____

_____

Past Operations (dates) _____

_____