Learnings and trends in the management of open-angle and angle-closure glaucoma

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To be truly disruptive, newer technologies need to offer a quality of life benefit over medication to a broad population of glaucoma sufferers. Evidence and converging trends in medical and surgical management of glaucoma were explored in counterpoint discussions and presentations at the 9th Moorfields International Glaucoma Symposium 2017. Shared learnings for service redesign illustrate the potential of extended roles for non-ophthalmologists in strengthening service capacity to meet increasing demand. Newer competing surgical technologies and novel investigational treatments also promise a new era of multiple pressure-lowering options to overcome barriers to treatment compliance. The authors provide an overview of practice considerations.

The evidence for treatment of angle closure

Laser peripheral iridotomy (LPI) is commonly performed in asymptomatic primary angle closure suspects (PACS), but currently there is no clear consensus on indications for prophylactic LPI in primary angle closure. Hon-Tym Wong, National Healthcare Group Eye Institute, Singapore, outlined results from Singapore's Asymptomatic Narrow Angles-Laser Iridotomy (ANA-LIS) Trial, designed to establish the efficacy of LPI in preventing progression to subsequent stages and to establish risk factors for progression. Without intervention 10.1% of PACS progressed to angle closure disease versus 5.3% after LPI. Older age, male gender, diabetes and higher baseline intraocular pressure (IOP) may be associated with progression. Based on these results, LPI would still be offered to patients with narrow angles, with a clearer number needed to treat to support an informed discussion of treatment benefit (prophylactic LPI in 21 patients will prevent progression in one patient over five years).

Professor Augusto Azuara-Blanco, Queen's University Belfast, outlined implications for clinicians and patients from the EAGLE trial, which demonstrated clear-lens extraction was more effective than LPI for the treatment of primary angle-closure glaucoma (PACG) [1]. Clear-lens extraction can be used as an initial intervention for patients with primary angle closure with IOP >30 mmHg or PACG (mild / moderate disease), although there is a small risk of posterior capsule rupture, requiring an individualised decision. Results from EAGLE may not be generalisable to people with PACG with severe glaucoma and primary angle closure with IOP <30mmHg.

Severe visual morbidity is rare and blindness is now uncommon with appropriate management of angle closure, due in part to rising rates of cataract surgery [2,3]. Nonetheless, there are still sizeable numbers of individuals with PACG in Europe and the United States (US) [4]. It is important therefore to establish protocols and treatment practice patterns for securing the best outcomes, commented Paul Foster. General principles include: control of IOP if 'acutely' raised; control symptoms such as pain, nausea and vomiting; exclude secondary causes of angle closure; perform iridotomy (-ectomy) as soon as possible, unless cases involve end-stage glaucomatous optic neuropathy; assess the impact of PI, document disc and field, biometry and remove the lens wherever justifiable on visual acuity (VA) grounds (consider if the angle remains closed).

A large proportion of eyes with PACG develop a clinically significant rise in IOP on follow-up after primary treatment with LPI, necessitating further intervention. A randomised trial (n=106) found that after one year, argon laser peripheral iridoplasty (ALPI) was associated with higher failure rates and lower IOP reduction compared with prostaglandin analogue therapy (failure rate of 30% vs. 7.5% and mean percentage IOP change from baseline of 19.3% vs. 25.5%, respectively) in eyes with persistent appositional angle closure and raised IOP after undergoing laser iridotomy [5]. Associate Professor Tina Wong, Singapore National Eye Centre, Singapore, said that the favoured approach is always first to try to control the condition medically.

'Big bang' debates: the future of the universe in glaucoma care

Optometrist-led management of routine glaucoma:

Co-management of glaucoma patients by

Virtual Clinics: OHT / suspect only - two reviewing sessions / wk	• Nurses and technicians data collection • Optometrist virtual review on another occasion
Suspect / OHT / low risk glaucoma clinic - two clinic sessions / wk	• Optometrist only; 9pxs/clinic • Glaucoma suspects / OHTs (with and without treatment) • COAG pxs at lowest risk of visul loss (aged >75yrs & VF loss not threatening fixation or MD worse than -15dB in both eyes)
Stable glaucoma - 34 clinic sessions / wk (including peripheral sites)	• Optometrist clinics running in parallel with ophthalmologist clinics; 9pxs / clinic • Early OAG • (Apparently stable) moderate / advanced COAG
Complex / medical glaucoma - four clinic sessions/wk	• Optometrist working in clinic with supervising ophthalmologist; 8pxs / clinic • Patients at high risk of significant visual loss • Patients having recently undergone glaucoma surgery • Complex secondary, uncommon and paediatric glaucomas

Abbreviations: Ocular hypertension (OHT); Week (wk); Patients (PXS); Chronic open-angle glaucoma (COAG); Visual function (VF); Mean deviation (MD) and Decibel (dB).

Figure 1: Bristol Eye Hospital Glaucoma Service follow-up clinic models.

nurses and optometrists is now a key part of glaucoma services in many hospital eye service units. Leon Au from Manchester Royal Eye Hospital argued that optometrist-led management of routine glaucoma needs to be done, can be done, and should be done, helping free capacity and maximise use of consultant expertise. Good agreement has been shown between specially trained optometrists and glaucoma-specialist consultant ophthalmologists in their respective decisions regarding the stability and management of glaucoma patients [6]. Skilled optometrists are consistent, thorough and good at detecting co-pathology. The Optometric-Led Glaucoma Assessment (OLGA) clinic at Manchester Royal Eye Hospital has released 11,550 additional patient slots each year. Well managed cases of glaucoma progress very slowly, but there is a need to find ways of detecting those presenting with advanced loss earlier, either with more sensitive tests or the application of current tests to more people.

It is the role of the ophthalmologist to secure the complete diagnostic picture, the most appropriate treatment plan and determine the possible benefit of surgical intervention, countered Professor Joseph Caprioli, University of California, Los Angeles, US. Every patient is different and glaucoma is many diseases with varied phenotypes and associated, often complex, medical syndromes. Treatment decisions require understanding of the safety profile of different medications (e.g. cardiopulmonary side-effects and acute bronchospasm with topical beta-blocker therapy), contraindications and interactions. A decision supporting filtration surgery is often key.

Paul Spry described the contribution of a shared care optometrist-led glaucoma service at Bristol Eye Hospital. Follow-up consultations with an optometrist as a percentage of glaucoma service follow-up capacity have grown from 50% in 2000 to 85% in 2014 (Figure 1). The glaucoma optometrist training programme entails a semi-informal apprenticeship, designed to take 'general optical council (GOC) core competence' optometrists to 'glaucoma specialist optometrist' level working at full clinic capacity.

Preservative free or preserved topical glaucoma medications:

Ocular hypotensive drugs are highly effective, easy to use and readily discontinued in the event of adverse reactions, argued Gus Gazzard. That said, ocular surface disease (OSD) is common, especially in glaucoma patients, and preservatives in glaucoma eye drops can cause harm. Preservatives such as benzalkonium chloride (BAK), a cell-membrane damaging detergent, wreak havoc on the ocular surface, ruin compliance, compromise the success of filtration surgery, damage the trabecular meshwork and diminish health-related quality of life. As a subspecialty, glaucoma practitioners underestimate the toxicity impact of preserved medications on trabeculectomy failure as well as long-term trabecular degeneration and enhanced outflow resistance caused by BAK, observed Mr Gazzard [7].

It is often argued that a major cause of patient non-compliance is due to OSD caused by preserved medications. Adherence and persistence rates differ by class of antiglaucoma drug, with higher persistence rates associated with use of prostaglandin medications [8]. Preservatives in glaucoma medications permit long-term storage at room temperature and act as drug penetration enhancer. Prof Wong said that as glaucoma disproportionately affects people in Asia and Africa [9], preservative free glaucoma medications are an unaffordable luxury for the majority of worldwide glaucoma sufferers. However, it was conceded they have a beneficial role in providing a treatment option for glaucoma patients.

No bleb, no pressure control?

Bleb forming surgery is the standard of care for moderate to severe glaucoma, in patients with very high IOPs and for severe normal tension glaucoma (NTG), commented Deborah Kamal. Convincing evidence supports the efficacy and safety of current trabeculectomy surgery, although intensive proactive postoperative care is needed [10]. A retrospective, consecutive case series evaluation (n=131 eyes) demonstrated successful long-term outcomes of trabeculectomy for NTG with contemporary surgical techniques, virtually eliminating long-term progression risk [11]. Bleb forming filtration surgery consistently lowers the IOP below 16mmHg and trabeculectomy is increasingly safe with modern surgical techniques.

Malik Kahook, Professor of Ophthalmology, University of Colorado School of Medicine, Colorado, US, emphasised the era of tailored therapy to arrive at the best option for each specific patient based on disease status, change over time, age, IOP (current and goal) and previous ocular surgery. A survey of glaucoma surgical preferences and postoperative care in the UK amongst glaucoma subspecialists found trabeculectomy with mitomycin C (MMC) is the primary choice for advanced glaucoma in 79% [12]. Around 20% of respondents sometimes used minimally invasive glaucoma surgery (MIGS) as the first option in advanced glaucoma. Prof Kahook argued that ab interno approaches can be used successfully for mild to moderate glaucoma disease, with trabeculectomy / tube implant procedures reserved as potential future options.

What your glaucoma service can learn from me

Practical tips for maintaining quality while improving efficiency:

Population ageing, doctor shortages, rising costs and performance audit mean increasingly that physicians need to provide value and prove it. Prof Caprioli recounted insights from an efficiency improvement programme undertaken at an academic department of ophthalmology. Tips on quality of process and physician-patient relationship include:

- Use ancillary persons to the limits of their abilities, not beyond.
- Empower people and hold them responsible, train and retrain to keep the bar high, and make it clear to patients that only you make the decisions.
- Keep patients informed of the process and waiting status, and let them know what tests will be done before they see you.
- At consultation, engage the patient immediately, make the patient feel that they have your full undivided attention, show empathy and explain findings simply and clearly.
- Always ask the patient whether they have any other questions or need prescriptions refilled, then close and touch or shake hands again.

Redesigning care in the cataract operating theatre:

Hon-Tym Wong outlined experiences having implemented a redesign of a cataract care pathway to improve productivity ahead of an expected increased workload. Solutions aimed to reduce variation in technical complexity in operating lists via stringent patient selection according to straightforward or complex, and standardisation of surgical style and instrumentation through consensus practice. Outcome evaluations demonstrated visual outcomes and complication rates that were equivalent to original workflow practice, with surgeons receiving monthly performance reports. Average patient flow timings in the new facility were significantly improved, with a 16% cost reduction for cataract surgery per one patient activity. Elimination of first postoperative day visit saved more than

1000 clinic visit slots in 2013.

Sharing best practice in medical retina service – extending the role of nurse practitioners:
Trained nurse practitioners can contribute to enhanced clinical outcomes and quality improvement of service delivery in ophthalmic care, said Nurse Consultant Adam Mapani. Technological advances in ophthalmic imaging have opened the way for virtual pathway clinics, designed as high patient throughput, maximum capacity with minimal clinician contact. The medical retina service at Moorfields Eye Hospital has introduced several nurse-led virtual and face-to-face care pathways, including a nurse-led virtual stable 'wet' age-related macular degeneration (AMD) service, reviewing 40 patients per session, and a virtual new 'wet' AMD referral process, with technician-led vision assessment and onward referral for diagnosis.

More than 90% of all intravitreal anti-vascular endothelial growth factor (anti-VEGF) injections at Moorfields Eye Hospital are delivered by trained nurse practitioners. There were three cases of endophthalmitis reported from a total of 24,112 nurse-delivered intravitreal anti-VEGF injections performed during a one-year period 2014-2015 (0.0124% or 1 in 8000) [13]. Lyall et al. estimated an incidence rate of presumed infective endophthalmitis following intravitreal anti-VEGF therapy in the UK of 0.025% (1 in 4000) [14].

Learning from difficult cases

Tube-related endophthalmitis, truncate or explant?
Erosion overlying the tube is the commonest cause of tube-related endophthalmitis. Medina et al. reported exposure in eight of 13 eyes with endophthalmitis associated with glaucoma drainage implants [15]. Although explantation was performed in many patients, successful treatment was accomplished in some patients without removal. Visual outcomes were generally poor. Among 702 primary drainage device implant cases evaluated by Levinson et al., there were 41 cases of exposure (5.8%), with the highest rate of exposure for primary implants in the inferior-nasal quadrant (17.2%, 5 of 29) [16]. Exposures over inferior implants were more likely to be associated with infection than exposures over superior implants (41.7% vs. 8.1%; P=.0151). Alessandra Martins explained that moxifloxacin is now given for all cases of device exposure.

Combined phaco-trabeculectomy:
Failure of filtering surgery in combined cataract and glaucoma filtration surgery is a fundamental challenge, noted Prin Rojanapongpun, Chulalongkorn University and King Chulalongkorn Memorial Hospital, Bangkok, Thailand. Combined phaco-trabeculectomy is not a uniform surgery, and without changing the procedure, the IOP outcome will still be poorer than that after trabeculectomy alone, as the visual outcome may be compromised with more complications. Enhanced surgical technology, use of devices, advanced pharmacological intervention, surgical technique modification, wound healing modulation and better conjunctiva health are needed for a better outcome in combined phaco-trabeculectomy. A drug-free / BAK-free period is necessary to ensure a good conjunctiva to begin with.

What's around the corner in microshunts, drugs and sustained delivery systems?

MIGS implants:
There are many competing newer surgical glaucoma technologies emerging, which are generally safe and predictable but limited by an efficacy ceiling. In the pivotal iStent trabecular micro-bypass stent (Glaukos) study, 66% of eyes in the phaco / iStent group achieved ≥20% IOP reduction without medication at one year vs. 48% of cataract surgery only eyes [17]. The supraciliary CyPass Micro-Stent (Alcon) generated sustained reduction in IOP and glaucoma medication use through two years in patients with mild-to-moderate primary open-angle glaucoma (POAG) undergoing cataract surgery in a randomised clinical trial (n=505, 24 US centres) [18]. At 24 months, mean IOP reduction was 7.4mmHg for the Cypass group versus 5.4mmHg for controls (P<0.001), with 85% of microstent subjects not requiring IOP medications.

An interim analysis of primary outcomes (total population 215) using the XEN Gel Stent (Allergan) (ab interno external drainage) from an ongoing phase IV Apex study showed a mean IOP of 13.1mmHg at 18 months postoperatively, representing a 36.5% reduction from preoperative mean IOP (n=51). Table 1 shows approved indications of several MIGS devices.

Is there anything better around the corner? Three-year follow-up results evaluating the InnFocus microshunt (Santen), a microlumen aqueous drainage device, implanted alone or in combination with phacoemulsification in patients who had failed maximum tolerated glaucoma medication show control of IOP in the low teens for most subjects [19]. Average IOP reduction from preoperative mean IOP ranged between 50-55%. A phase 2/3 randomised clinical trial underway in the US will evaluate the InnFocus microshunt vs. standard trabeculectomy in subjects with POAG.

One year results from the Primary Tube Versus Trabeculectomy (PTVT) Study:
Trabeculectomy with MMC had a higher success rate than tube shunt implantation after one year in glaucoma patients without previous ocular surgery in the PTVT Study, explained K Sheng Lim, St Thomas' Hospital, London. Greater IOP reduction with use of fewer glaucoma medications was observed following trabeculectomy with MMC compared with tube shunt placement. In contrast, there was a higher success rate with tube shunt surgery compared with trabeculectomy with MMC during five years of follow-up in the Tube Versus Trabeculectomy (TVT) study [20]. Surgical techniques and different patient population features such as ethnicity, prior ocular surgery and lens status may have influenced the outcome in the PTVT study. To address these issues, a randomised single-centre feasibility trial named PEACE will evaluate trabeculectomy with MMC versus Baerveldt tube with or without MMC in African-Caribbean POAG patients.

New glaucoma therapies and drug delivery systems:
Medical IOP-lowering therapy remains the first-line treatment for most glaucoma patients. Investigational novel ocular hypotensive medications and sustained-release drug delivery systems, as well as subconjunctival injectables, hold promise of a new era of multiple different glaucoma treatments designed to address some of the barriers to treatment adherence, explained Professor Sanjay Asrani, Duke University, Durham, US (Table 2).

Peregrine Ophthalmic is developing a sustained drug delivery solution using nano-liposomes combined with latanoprost, administered by subconjunctival injection and designed to achieve IOP lowering for up to six months. Preliminary data

"Technological advances in ophthalmic imaging have opened the way for virtual pathway clinics."

Table 1: Indications of MIGS devices in the UK and US.

	iStent® Manufacturer: Glaukos Indication	XEN Gel® Manufacturer: Allergan Indication	CyPass® Manufacturer: Alcon Indication
UK	CE Marked: Standalone procedure or in conjunction with cataract surgery	CE Marked: Standalone procedure or in conjunction with cataract surgery	CE Marked: Standalone procedure or in conjunction with cataract surgery
US	PMA*: In conjunction with cataract surgery	510(k) clearance: Standalone procedure or in conjunction with cataract surgery	PMA*: In conjunction with cataract surgery

* PMA: Premarket approval (PMA) is the Food and Drug Administration (FDA) process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Medical devices that do not require FDA review before the devices are marketed are considered "510(k) exempt".

Table 2: Examples of topical medications for glaucoma currently in development and US market status*.

Medication	Sponsor	Mechanism of action	Current US market status
Netarsudil (AR-13324)	Aerie Pharmaceuticals	Rho Kinase inhibitor + norepinephrine transporter inhibitor	Phase III trials completed
Netarsudil / latanoprost fixed-dose combination	Aerie Pharmaceuticals	Rho Kinase inhibitor + norepinephrine transporter inhibitor + prostaglandin analogue	Phase III trials completed
Latanoprostene bunod	Bausch + Lomb	Nitric oxide donor + prostaglandin analogue	New Drug Application pending with FDA
Trabodenoson (INO-8875)	Inotek Pharmaceuticals Corporation	Adenosine receptor agonist	Phase III trials ongoing
DE-117	Santen Pharmaceuticals	Prostanoid receptor agonist	Phase II and III trials ongoing
ONO-9054	Ono Pharmaceuticals	Prostanoid receptor agonist	Phase II trials completed
Bamosiran (SYL040012)	Sylentis	Small interfering RNA (siRNA)	Phase II trials completed

* Source: Schehlein EM, et al. *Curr Opin Ophthalmol* 2017;**28(2)**:161-8.

demonstrate good tolerability and ability to successfully deliver medications over a six-month period with a double lobed transparent polymer contact lens insert (Amorphex Therapeutics). Durasert by pSivida is a bioerodable insert injected in the subconjunctival space delivering latanoprost for six to 12 months' duration. A single treatment with bimatoprost sustained release intracameral implant (BIM SR) controlled IOP up to 16 weeks in 91% of treated patients and for six months in 71% [21]. In an interim analysis of a phase II trial, nine-months' IOP-lowering duration was demonstrated using an intracameral extended-release biodegradable travoprost microchip formulation (ENV515, Envisia Therapeutics), with IOP lowering comparable to pre-washout levels on standard of care prostaglandin treatment and comparable to timolol 0.5% twice daily in non-study eyes.

Gene therapy for the treatment of glaucoma

Results from recent gene therapy trials have shown only modest and transient benefit, and there are significant obstacles ahead in the quest to develop gene therapy as a feasible option for practical treatment of glaucoma (i.e., something that either protects or improves vision rather than surrogate markers in small carefully selected populations), commented Ananth Viswanathan.

Professor Keith Martin, University of Cambridge, said there remains a huge burden of blindness due to glaucoma, underscoring the need to better identify who is at higher lifetime risk [22]. The risk of significant visual loss is much higher in those with initial damage [23]. Neuroprotective gene therapy strategies for glaucoma are evolving with effective vectors available. Gene therapy may be an option for those who are continuing to lose vision due to glaucoma and who are currently failing all conventional treatments available, although the future role of gene therapy for glaucoma depends ultimately on outcomes of ongoing clinical trials.

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