GLAUKOS®
TRANSFORMING VISION

Forward Vision: Delaying the silent theft of sight

Improving glaucoma outcomes and patients' quality of life

APRIL 2023 | POST-ROUNDTABLE REPORT

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EXECUTIVE SUMMARY

As the health system in the UK grapples with aiming to provide high standard and adequate care while managing significant patient backlogs, inequalities within the system arise. Access to medical devices, which are essential for improving patient outcomes, is often inconsistent for both patients and practitioners. This divergence between the treatments available from the NHS and at independent sector treatment centres (ISTCs) can lead to lost opportunities to achieve the best patient outcome.

With eye care accounting for nearly 10% of backlogs in the healthcare system, glaucoma has arisen as an area in urgent need of reform and improvement. The Glaucoma Parliamentary Roundtable was held in February 2023, which offered an opportunity for leading practitioners and industry professionals to examine the current standard of care for glaucoma and where it can be improved.

Currently, eye drops are the standard glaucoma-management option, but participants agreed that their effectiveness and the consistency of their use is too poor for many patients to manage their glaucoma successfully. Participants agreed that medical devices, like the iStent *inject®*, were safe and effective at mitigating the disease and that, with many patients suffering from glaucoma and cataracts at the same time, opportunities to tackle both diseases in one combined surgical intervention were frequently being missed in ISTCs.

It was decided that – whilst complying with strict measures to ensure patient safety and choice – a pilot should be set up to trial the use of such a device within ISTC ophthalmic settings, bringing their treatment options in line with in-house NHS provision. This trial would help demonstrate the value of combined procedures to the health service and to the patient.

WHAT IS GLAUCOMA?

Glaucoma is a chronic, progressive eye disease caused by damage to the optic nerve, which leads to visual field loss. Affecting around 480,000 people in England alone (NHS Digital, 2023), the condition develops as a result of fluid build up in the front part of the eye, increasing internal pressure leading to a loss of vision.

In its early stages, glaucoma is a symptomless disease and can damage sight and cause sight loss before it is detected. Those most at risk of developing Glaucoma are:

- People with high internal eye pressure, also known as intraocular pressure
- Aged over 55
- Those from Black, Asian or Hispanic heritage
- Those with certain medical conditions, such as diabetes, migraines, high blood pressure and sickle cell anaemia
- Those with corneas which are thin in the centre
- People with eye injury
- Those taking corticosteroid medicines (e.g. eye drops) for a long time

Relationship between glaucoma and cataracts

Whilst glaucoma and cataracts are not typically related, the risk factors for both eye conditions can worsen or develop with age. Cataract surgery is the most common elective procedure performed in the NHS (The Royal College of Ophthalmologists, 2022), and many cataract patients also suffer from glaucoma (Glaucoma Associates of Texas, 2023).

WHAT IS THE CURRENT PROBLEM?

Patient backlog

Ophthalmology services have long been overlooked and are in clear need of transformative support to prevent patients losing their sight, particularly with the Public Accounts Committee reporting that NHS England (NHSE) is expected to miss its Elective Recovery Targets (Public Accounts Committee, 2023).

During 2020, there was a 66% reduction in referrals for glaucoma into hospitals in England (Specsavers, 2022). This has resulted in a significant number of patients not being seen at the time and now – three years on – requiring further treatment within the NHS, with glaucoma waiting lists specifically cited as the longest they have ever been (Specsavers, 2022).

Now, ophthalmology accounts for 10% of the NHS backlog (Optometry Today, 2022) and is only expected to increase as someone is diagnosed with sight loss every six minutes (Fight for Sight, 2022). In a recent study, 72% of optometrists reported that they have seen a patient in the last six months who had experienced a delay to treatment of 12 months or more, while 43% had concerns about patients losing their sight unnecessarily (The Guardian, 2023).

Patient impact

Referred to as the 'silent thief of sight', the gradual and incremental progression of glaucoma, combined with prolonged waiting times for treatment, exacerbates patients' existing concerns over their health and future, often contributing to significant mental health concerns. Patients have spoken about their fear of losing their sight, job and ability to live their lives as normally as they had before being diagnosed with glaucoma. These fears are heightened by the risk of injury and other health issues resulting from their sight loss.

Alongside this emotional burden, there is a significant economic burden associated with poor eye health. It is currently estimated that the cost of blindness will be £33.5 billion by 2050 (Fight for Sight, 2020).

Slow adoption of technology

Despite the commitment from the NHS and Government in building a resilient healthcare system, there are significant barriers facing the adoption of innovative technologies. NHS England and NHS Improvement (NHSE&I) estimate that it takes 17 years on average (DHSC, 2020) for a new product or device to go from the clinical trial stage to mainstream adoption. Currently, companies typically have to engage and convince several layers of decision-makers within providers and each trust to get products adopted, resulting in some patients having access to innovative technologies in one area and others receiving a different quality of care.

Medical adherence

Currently, the main treatment for glaucoma is prescription eye drops, which lower the pressure in the eye and, thereby, prevent damage to the optic nerve (National Eye Institute, 2021). A lack of compliance with the prescription has been proven to accelerate the progression of the disease, while strict adherence has the opposite effect. However, the difficulty of self-administration, requiring a certain level of consistent timing and organisation, is something that patients often find too complicated. This results in critically low adherence levels, which in turn further disrupts a patient's lifestyle as their sight continually declines.

At times, the drops can have significant side effects – ocular surface irritation can occur as a result of the preservatives in the drops, causing patients significant discomfort, red eyes and blurred vision. Other side effects can include changes to eye colour, low blood pressure, reduced pulse rate, and fatigue. Long-term use of eye-drops can also cause corneal surface damage and promote ocular surface disease.

Systemic inequity

Currently, glaucoma treatment is predominantly taken care of by the NHS, while cataract surgery is often outsourced to ISTCs, which have the capacity to treat patients more quickly, with the aim of reducing backlogs in NHS care. However, while patients in three-quarters of NHS hospitals have access to revolutionary treatments such as the iStent *inject®*, patients at ISTCs do not. This means that the majority of the cataract patients in England are unable to benefit from life-changing technologies.

The Royal College of Ophthalmologists (Royal College of Ophthalmologists, 2021) has highlighted the need to improve patient safety and quality of service for patients being treated in the independent sector, allowing them to receive the same equity of care as provided within the NHS.

Objectives of the roundtable

There is a clear case for providing safe, effective, efficient and innovative treatment to transform glaucoma care across England and the health system, to help prevent avoidable sight loss. There is no longer a reason for glaucoma and cataract surgeries to be conducted as two separate procedures. Combined procedures can provide further efficiency to treat both cataract and glaucoma at the same time, for patients who have been diagnosed with both diseases, rather than four separate surgeries at different times.

We wanted to bring stakeholders across the entire patient pathway and health system to discuss how best to improve glaucoma outcomes, patient care and drive equity of care across the system, whilst also supporting the NHS in its ambitious elective recovery plan.

DISCUSSION POINTS

iStent *inject®*

The iStent *inject®* is the smallest implantable device in the human body (Glaukos, 2023 a, b). Studies have shown that it improves drainage and lowers eye pressure, which has been proven to reduce the risk of future sight loss and prevent the need for further invasive glaucoma treatment.

Over one million iStent technology implants have been delivered worldwide, with 25,000 in England specifically – with a decade of real-world evidence, the device can be seamlessly implemented into the ISTCs' treatment procedures, adding only a few minutes onto routine cataract surgery.

The ophthalmologists at the roundtable felt that the implantation of iStent *inject®* during cataract surgery was an obvious solution as it is the least complicated procedure, they said that it was time-efficient, led to a reduction of medication and better pressure control, and 60-70% of patients operated on needed further treatment.

System equity

ISTCs are currently performing about 50% of the cataract procedures in the UK (Royal College of Ophthalmologists, 2021) but they do not have access to iStent *inject®*. This causes a patient choice issue where patients can either go to an ISTC with a limited waiting list but no opportunity for combined cataract and glaucoma treatment, or an NHS treatment centre with combined procedures but a longer waiting list. If they choose to go to an ISTC for cataract procedure, they then remain on the NHS waiting list for later glaucoma treatment — creating patient inequality and lack of efficiency for elective recovery. There is also a need to ensure that those referring patients for treatment are aware of the new treatment options within the NHS and have the information available to have a fully-informed discussion with the patient, prior to referral.

Around 27,000 people are waiting 52 weeks for ophthalmology treatment at the time of writing (The Guardian, 2023). While the NHS is struggling to overcome the elective backlog, patients will be limited in their ability to have combined procedures.

Through ISTCs providing combined procedures, there is an opportunity for all providers to deliver the same standard of care and patients being seen in the same time frame to prevent further sight loss.

Clear need for alternative glaucoma treatment

The greatest issue with current treatment options is medical adherence with eye drops. Patients find them confusing and invasive. Those at the roundtable noted that the biggest point of use of a patient group helpline is calls around difficulty with eye drops. Patients' quality of life would be significantly increased if their reliance on eye drops was reduced or even removed.

The solution: ISTC Pilot

Once the discussion on the challenges concluded, it was recommended to commence a pilot of combined procedures at an ISTC. The aim of this pilot would be to highlight the value of iStent *inject®* for patient outcomes and demonstrate that this procedure can work within the ISTCs and improve the patient waiting list. All ISTCs present acknowledged the value that the pilot could bring to glaucoma services and that if combined procedures were not scaled up soon, there would continue to be systematic patient inequity for the foreseeable future.

To be able to effectively set the standard of care and change behaviour across the system, it was agreed that this pilot would need to be delivered to focus on patient outcomes, device safety and cost effectiveness. It was also agreed that it should be peer-reviewed and coupled with a patient impact assessment to understand the patient voice in the proposed new pathway.

"The iStent inject® is a remarkable device. It is the smallest device implantable into the human body, yet has a significant impact on improving patient's experience, and thus quality of care."
- Imran Masood

Patient selection

Throughout the pilot, it will be important to formulate clear and concise criteria for which patients will be eligible for combined procedures, ensuring patient voice and a choice of procedures when they are being referred for treatment. Whilst the vast majority of individuals will come in for cataract surgery, not every patient who has glaucoma will have cataracts and not every cataract patient will have glaucoma.

It is important to define a clear set of standards with optometrists and NHS trusts about when a patient should be offered the combined procedure as part of the trial.

Device selection

To remain impartial, the attendees discussed and considered the type of device that would be suitable to be scaled up within such a trial. There are several currently on the market with differing levels of evidence, efficacy and use. It was agreed that its safety profile was paramount to avoid patients returning back to the NHS.

After discussion, it was referenced that iStent *inject®* has the highest safety profile of any of the MIGS procedures and was rarely going to create a serious complication for the patient and deemed the most suitable device for the pilot.

Clinician experience and training

Patient safety was central to this discussion and to the delivery of care within the health system. It will be important to ensure that clinicians offering the dual procedure will have had proficient training for iStent *inject®*.

All those at the roundtable agreed that there should be a minimum number of years' experience required for those operating, to ensure the results of the pilot are as positive for the patient as possible.

System collaboration and next steps

As this pilot will include multiple referral points – such as community optometrists, NHS specialists and the ISTCs – it is vital that diagnosis, referral and follow-up routes are clarified from the beginning to ensure that no patient falls through the cracks.

Additionally, it is important that this is considered properly in relation to patient safety and optometrists' capacity, particularly when a patient is moving back into the NHS post-surgery. If timelines and routes are unclear, there is a risk of optometrists being overwhelmed with check-in appointments, or patients waiting too long to be seen.

It was positive to see a commitment for true partnership working between ISTCs and NHS to understand how this can be implemented and to deliver the best care for patients.

"I would say that anyone with real eye pressure problems should seriously consider having this [combined cataract / iStent inject® procedure] as they can have both of these issues attended to at the same time."

- Ollie Oliveria, iStent patient

RECOMMENDATIONS

An iStent *inject®* pilot with an ISTC

It was decided that a pilot scheme with iStent *inject®* would demonstrate the value of combined procedures for cataract and glaucoma treatment to the health services (through significant reductions in the need for further surgery by performing a combined procedure) and to patients (in their quality of life, sight-retention, and the opportunity to undergo a single operation which addresses both their cataracts and glaucoma).

The structure and location of the pilot will be decided during further detailed conversations.

Patient criteria

The pilot should only include patients on a strict medical-need basis, acknowledging that there is not a one-size-fits all solution. The criteria for patients should be decided with the optometrists and NHS specialists who are already engaging with these patients in the existing pathway.

Patient pathway

The pilot needs to consider the whole patient pathway and make the right choice for the patient. There needs to be joined-up discussions with optometrists, NHS trusts, ophthalmologists and ISTCs to ensure that the criteria and responsibility across the entire patient pathway is clear and well-communicated and documented.

Make dual procedures standard across the devolved nations

The participants acknowledged the four UK health systems, and recommended that inequality of care challenges should be tackled in all parts of the United Kingdom, not just England.

REFERENCES

1. NHS Digital, 2023
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3. Glaucoma Associates of Texas, 2023
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7. Fight for Sight, 2022
8. DHSC, 2020
9. National Eye Institute, 2021
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11. Fight for Sight, 2020
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13. Glaukos, 2023a
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INDICATION FOR USE: The iStent *inject*® , is intended to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma. The iStent *inject*® , can deliver two (2) stents on a single pass, through a single incision. The implant is designed to stent open a passage through the trabecular meshwork to allow for an increase in the facility of outflow and a subsequent reduction in intraocular pressure. The device is safe and effective when implanted in combination with cataract surgery in those subjects who require intraocular pressure reduction and/or would benefit from glaucoma medication reduction. The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and conventional glaucoma surgery. CONTRAINDICATIONS: The iStent *inject*® System is contraindicated under the following circumstances or conditions: • In eyes with primary angle closure glaucoma, or secondary angle-closure glaucoma, including neovascular glaucoma, because the device would not be expected to work in such situations. • In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. WARNINGS/PRECAUTIONS: • For prescription use only. • This device has not been studied in patients with uveitic glaucoma. • Do not use the device if the Tyvek® lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised. • Due to the sharpness of certain injector components (i.e. the insertion sleeve and trocar), care should be exercised to grasp the injector body. Dispose of device in a sharps container. • iStent *inject*® is MR-Conditional; see MRI Information below. • Physician training is required prior to use of the iStent *inject*® System. • Do not re-use the stent(s) or injector, as this may result in infection and/or intraocular inflammation, as well as occurrence of potential postoperative adverse events as shown below under "Potential Complications." • There are no known compatibility issues with the iStent *inject*® and other intraoperative devices. (e.g., viscoelastics) or glaucoma medications. • Unused product & packaging may be disposed of in accordance with facility procedures. Implanted medical devices and contaminated products must be disposed of as medical waste. • The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should consider an appropriate treatment regimen to reduce intraocular pressure. • Patients should be informed that placement of the stents, without concomitant cataract surgery in phakic patients, can enhance the formation or progression of cataract. ADVERSE EVENTS: Please refer to Directions For Use for additional adverse event information. CAUTION: Please reference the Directions For Use labelling for a complete list of contraindications, warnings and adverse events.