



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. This report was prepared by Health Technology Wales on behalf of the Bevan Commission. It summarises the existing evidence on the technology of interest to support a Bevan health technology exemplar application.

Topic:	iStent® technologies for trabecular microbypass stent for chronic open angle glaucoma
Topic exploration report number:	TER020
Referrer:	Luke Anderson
Topic exploration undertaken by:	Health Technology Wales

Aim of Search

Health Technology Wales researchers searched for evidence on the use of iStent® technologies for trabecular microbypass stent for chronic open angle glaucoma.

Summary of Findings

A systematic review in 2015 reported low quality evidence that combined cataract and glaucoma surgery may result in better intraocular pressure (IOP) control at one year compared with cataract surgery alone. A subsequent systematic review in 2018 concluded that larger randomised trials and real-world observational studies are needed for Micro-Invasive Glaucoma Surgery (MIGS) devices to better assess clinical and economic effectiveness. It was reported that, given the shortage of published data and increasing use of such procedures, living systematic reviews may help to provide ongoing and timely evidence-based direction for clinicians and decision makers. The review highlighted the current unmet need for treatments that are easy to implement and reduce long-term IOP levels without increasing postoperative aftercare and cost. Since data cut off for the 2018 systematic review, there have been a number of papers, including Chansangpetch S, Lau K, Perez CI, et al 2018 which concluded combined cataract surgery with iStent® implantation significantly increased the success rate and reduced the number of medications in angle closure patients who showed deepening of the angle after laser peripheral iridotomy.

Key sources of evidence

- Agrawal P and Bradshaw SE (2018). Systematic Literature Review of Clinical and Economic Outcomes of Micro-Invasive Glaucoma Surgery (MIGS) in Primary Open-Angle Glaucoma. *Ophthalmol Ther.* 7(1): 49-73: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5997597/>
- Chansangpetch S, Lau K, Perez CI, et al (2018) Efficacy of cataract surgery with trabecular micro-bypass stent implantation in combined-mechanism angle closure glaucoma patients. *Am J Ophthalmol.* Aug 8. pii: S0002-9394(18) 30443-4: <https://www.ncbi.nlm.nih.gov/pubmed/30098352>
- Interventional procedures guidance [IPG575] (2017) Trabecular stent bypass microsurgery for open-angle glaucoma: <https://www.nice.org.uk/guidance/ipg575>.

Areas of Uncertainty

There was a lack of published data included in the systematic review that was published in 2018. The review highlighted the current unmet need for treatments that are easy to implement and reduce long-term IOP levels without increasing postoperative aftercare and cost. Since the data cut off of Dec 2016 in the 2018 systematic review, there have been publications indicating that there may be advantages to using iStent® technologies for trabecular microbypass stent for chronic open angle glaucoma, but no systematic reviews to confirm this.

Brief literature search results

Resource	Results
<p>Guidelines and guidance</p> <p>NICE</p> <p><i>We searched for guidelines, technology appraisals, diagnostics, interventional procedures, and medical technologies guidance.</i></p>	<ul style="list-style-type: none"> • Quality standard [QS7] Glaucoma in adults: https://www.nice.org.uk/guidance/qs7 • NICE guideline [NG81] Glaucoma: diagnosis and management: https://www.nice.org.uk/guidance/ng81 • Interventional procedures guidance [IPG605] Ab interno supraciliary microstent insertion with phacoemulsification for primary open-angle glaucoma: https://www.nice.org.uk/guidance/ipg605 • Interventional procedures guidance [IPG612] Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma: https://www.nice.org.uk/guidance/ipg612 • NICE pathways: Glaucoma: https://pathways.nice.org.uk/pathways/glaucoma • Interventional procedures guidance [IPG397] Trabeculotomy ab interno for open angle glaucoma: https://www.nice.org.uk/guidance/ipg397 • Interventional procedures guidance [IPG575] Trabecular stent bypass microsurgery for open-angle glaucoma: https://www.nice.org.uk/guidance/ipg575
<p>Healthcare Improvement Scotland:</p> <p><i>We searched the HIS website for any relevant advice and hand-searched Scottish Health Technologies Group and Scottish Intercollegiate Guidelines Network publications.</i></p>	<ul style="list-style-type: none"> • SIGN144 Glaucoma referral and safe discharge: https://www.sign.ac.uk/sign-144-glaucoma-referral-and-safe-discharge.html
<p>Guidelines International Network</p>	<ul style="list-style-type: none"> • Management of Primary Open Angle Glaucoma (HTA DoH Malaysia) • Guidelines for the Screening, Prognosis, Diagnosis, Management and Prevention of Glaucoma (CP 113, CP113b) (National Health and Medical Research Council Australia) • NICE guideline 81 [NG81]: see NICE search above • SIGN 144: See Healthcare Improvement Scotland search above • Guideline clearing reports plus guidelines in foreign language also available: https://www.g-i-n.net/library/international-guidelines-library/@@guideline_search_results?type=basic&basic-searchable-text=glaucoma

Secondary literature and economic evaluations	
<p>ECRI</p>	<p>Custom product briefs:</p> <ul style="list-style-type: none"> • iStent Trabecular Microbypass Stent (Glaukos Corp.) for Treating Open-angle Glaucoma during Cataract Surgery • XEN Glaucoma Treatment System (Allergan plc) for Treating Open-angle Glaucoma • CyPass Micro-Stent (Alcon Laboratories, Inc.) for Treating Open-angle Glaucoma during Cataract Surgery • Overview of Three Eye Stents for Treating Glaucoma <p>FDA approval/technology news:</p> <ul style="list-style-type: none"> • Premarket approval of iStent inject: FDA Approves Next-generation iStent with Autoinject Device for Treating Glaucoma
<p>Cochrane library</p> <p><i>We searched for relevant Cochrane Reviews.</i></p>	<ul style="list-style-type: none"> • Combined surgery versus cataract surgery alone for eyes with cataract and glaucoma (Review) (2015): https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008671.pub3/epdf/full • Aqueous shunts for glaucoma (2017): https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004918.pub3/epdf/full • Ab interno trabecular bypass surgery with Trabectome for open angle glaucoma (2016): https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011693.pub2/epdf/full
<p>Medline</p> <p><i>We searched the Medline database for systematic reviews, meta-analyses, economic evaluations only.</i></p>	<ul style="list-style-type: none"> • Agrawal P and Bradshaw SE (2018). Systematic Literature Review of Clinical and Economic Outcomes of Micro-Invasive Glaucoma Surgery (MIGS) in Primary Open-Angle Glaucoma. <i>Ophthalmol Ther.</i> 7(1): 49-73: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5997597/ • Lavia C, Dallorto L, Maule M et al. (2017) Minimally-invasive glaucoma surgeries (MIGS) for open angle glaucoma: A systematic review and meta-analysis. <i>PLoS One.</i> 12(8): e0183142: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5574616/ • Zhang ML, Hirunyachote P and Jampel H. (2015) Combined surgery versus cataract surgery alone for eyes with cataract and glaucoma <i>Cochrane Database Syst Rev.</i> (7): https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008671.pub3/epdf/full • Francis BA, Singh K, Lin SC, et al (2011) Novel glaucoma procedures: a report by the American Academy of Ophthalmology. <i>Ophthalmology.</i> 118(7): 1466-80: https://ac.els-cdn.com/S0161642011002910/1-s2.0-S0161642011002910-main.pdf?_tid=f4a94bcd-6562-4ece-8050-27b198303cae&acdnat=1536137793_e6a312956870acb63d2b07b914eab479 • Minckler DS and Hill RA. (2009) Use of novel devices for control of intraocular pressure. <i>Exp Eye Res.</i> 88(4): 792-8: https://www.sciencedirect.com/science/article/pii/S0014483508003904?via%3Dihub
Primary studies	
<p>Medline</p> <p><i>We searched the Medline database for studies of any design.</i></p>	<ul style="list-style-type: none"> • Ngan K, Fraser E, Buller S et al (2018) A cost minimisation analysis comparing iStent accompanying cataract surgery and selective laser trabeculoplasty versus topical glaucoma medications in a public healthcare setting in New Zealand. <i>Graefes Arch Clin Exp Ophthalmol</i> Aug 21: https://link.springer.com/article/10.1007%2F00417-018-4104-8 • Chansangpetch S, Lau K, Perez CI et al (2018) Efficacy of cataract surgery with trabecular micro-bypass stent implantation in combined-mechanism angle closure glaucoma patients. <i>Am J Ophthalmol.</i> Aug 8. pii: S0002-9394(18) 30443-4: https://www.clinicalkey.com/#!/content/playContent/1-s2.0-S0002939418304434?returnurl=https:%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0002939418304434%3Fshowall%3Dtrue&referrer=https:%2F%2Fwww.ncbi.nlm.nih.gov%2Fpubmed%2F30098352

	<ul style="list-style-type: none"> • Alnawaiseh M, Müller V, Lahme L et al (2018) Changes in Flow Density Measured Using Optical Coherence Tomography Angiography after iStent Insertion in Combination with Phacoemulsification in Patients with Open-Angle Glaucoma. J Ophthalmol. Jan 31: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5831894/ • Myers JS, Masood I, Hornbeak DM et al (2018) Prospective Evaluation of Two iStent® Trabecular Stents, One iStent Supra® Suprachoroidal Stent, and Postoperative Prostaglandin in Refractory Glaucoma: 4-year Outcomes. Adv Ther. 35(3): 395-407: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5859115/ • Vinod K (2018) Suprachoroidal shunts. Curr Opin Ophthalmol. 29(2): 155-161: https://www.ncbi.nlm.nih.gov/pubmed/29206652 • Gonnermann J, Bertelmann E, Pahlitzsch M, et al (2017) Contralateral eye comparison study in MICS & MIGS: Trabectome® vs. iStent inject®. Graefes Arch Clin Exp Ophthalmol. 255(2): 359-365: https://link.springer.com/article/10.1007%2Fs00417-016-3514-8 • Arriola-Villalobos P, Martinez-de-la-Casa JM, Diaz-Valle D, et al (2016) Glaukos iStent inject® Trabecular Micro-Bypass Implantation Associated with Cataract Surgery in Patients with Coexisting Cataract and Open-Angle Glaucoma or Ocular Hypertension: A Long-Term Study. J Ophthalmol. 2016: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5108856/pdf/JOPH2016-1056573.pdf
<p>Cochrane library</p> <p><i>We searched the Cochrane Trials database for studies of any design.</i></p>	<ul style="list-style-type: none"> • Katz LJ, Erb C, Carceller Guillamet A, et al. (2018) Long-term titrated IOP control with one, two, or three trabecular micro-bypass stents in open-angle glaucoma subjects on topical hypotensive medication: 42-month outcomes. Clinical ophthalmology (auckland, NZ). 12:255-62: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01459943/full • Vinod K, Gedde SJ. (2017) Clinical investigation of new glaucoma procedures. Current opinion in ophthalmology. 28(2): 187-93: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01337712/full • NCT03274323. (2017) Trabeculectomy Versus 2-iStent and Prostaglandin Study: https://clinicaltrials.gov/show/nct03274323 • NCT03106181. (2017) A Comparison of Cataract Surgery Alone and Cataract Surgery With iStent: https://clinicaltrials.gov/show/nct03106181 • Kerr NM, Wang J, Barton K. (2016) Minimally invasive glaucoma surgery as primary stand-alone surgery for glaucoma. Clinical & experimental ophthalmology. (no pagination): https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01333424/full
Ongoing research	
<p>Clinicaltrials.gov</p>	<ul style="list-style-type: none"> • NCT03624699: Investigation of the iStent Inject® Devices in Open-Angle Glaucoma: https://clinicaltrials.gov/ct2/show/NCT03624699 • NCT03478293: iStent Inject in OAG Subjects on 2 Pre-op Topical Ocular Hypotensive Medications: https://clinicaltrials.gov/ct2/show/NCT03478293 • NCT03106181: A Comparison of Cataract Surgery Alone and Cataract Surgery With iStent: https://clinicaltrials.gov/ct2/show/NCT03106181 • NCT01841450: Multicenter Post-Approval Study Of The Glaukos® iStent® Trabecular Micro-Bypass Stent System In Conjunction With Cataract Surgery: https://clinicaltrials.gov/ct2/show/NCT01841450 • NCT01444040: Subjects With Open-angle Glaucoma, Pseudoexfoliative Glaucoma, or Ocular Hypertension Naïve to Medical and Surgical Therapy, Treated With Two Trabecular Micro-bypass Stents (iStent Inject) or Travoprost: https://clinicaltrials.gov/ct2/show/NCT01444040

Date of search:	September 2018
Concepts used:	istent, istent inject, trabecular microbypass, chronic open angle glaucoma, glaucoma, cataract, ocular hypertension