



TITLE: Minimally Invasive Glaucoma Surgery: Clinical and Cost-Effectiveness and Guidelines

DATE: 27 April 2016

RESEARCH QUESTIONS

1. What is the clinical effectiveness of minimally invasive glaucoma surgery in adult patients with glaucoma?
2. What is the cost-effectiveness of minimally invasive glaucoma surgery in adult patients with glaucoma?
3. What are the evidence-based guidelines associated with surgical treatments for glaucoma?

KEY FINDINGS

One health technology assessment, four systematic reviews, three randomized controlled trials, one non-randomized study, one economic evaluation, and one evidence-based guideline were identified regarding minimally invasive glaucoma surgery.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to the main search to limit the retrieval by study type. Methodological filters were applied for research question 3 to limit retrieval to guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2011 and April 21, 2016. Internet links were provided, where available.

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SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

| | |
|----------------------|--|
| Population | Adult patients (≥ 18 years of age) with glaucoma |
| Intervention | The following minimally invasive glaucoma surgery (MIGS) procedures performed alone or in combination with cataract surgeries: <ul style="list-style-type: none"> • Trabectome • iStent • Gonioscopy-assisted transluminal trabeculectomy (GATT) • Excimer laser trabeculotomy • Endocyclophotocoagulation (also termed photocoagulation) |
| Comparator | Other surgical options for glaucoma (e.g., trabeculectomy [gold standard], tube shunt surgeries, laser trabeculoplasty, canaloplasty) |
| Outcomes | Clinical effectiveness (e.g., quality of life, etc., and safety e.g., procedure related complications, etc.) Cost-effectiveness Guidelines |
| Study Designs | Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines |

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.

One health technology assessment, four systematic reviews, three randomized controlled trials, one non-randomized study, one economic evaluation, and one evidence-based guideline were identified regarding minimally invasive glaucoma surgery.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

1. Boland MV, Ervin AM, Friedman D, Jampel H, Hawkins B, Volenweider D, et al. Treatment for glaucoma: comparative effectiveness [Internet]. Comparative effectiveness review no. 60. (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. HHSA 290-2007-10061-I.) AHRQ publication no. 12-EHC038-EF. Rockville (MD): Agency for Healthcare Research and Quality. 2012 Apr [cited 2016 Apr 27]. Available from: https://www.effectivehealthcare.ahrq.gov/ehc/products/183/1024/CER60_Glaucoma-Treatment_20120524.pdf

Note: Term “minimally invasive” not used within report

Systematic Reviews and Meta-Analyses

2. Kaplowitz K, Bussel II, Honkanen R, Schuman JS, Loewen NA. Review and meta-analysis of ab-interno trabeculectomy outcomes. *Br J Ophthalmol*. 2016 May;100(5):594-600.
[PubMed: PM26733487](#)
3. Malvankar-Mehta MS, Chen YN, Iordanous Y, Wang WW, Costella J, Hutnik CM. iStent as a solo procedure for glaucoma patients: a systematic review and meta-analysis. *PLoS ONE* [Internet]. 2015 [cited 2016 Apr 27];10(5):e0128146. Available from:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4446040>
[PubMed: PM26018579](#)
4. Malvankar-Mehta MS, Iordanous Y, Chen YN, Wang WW, Patel SS, Costella J, et al. iStent with phacoemulsification versus phacoemulsification alone for patients with glaucoma and cataract: a meta-analysis. *PLoS ONE* [Internet]. 2015 [cited 2016 Apr 27];10(7):e0131770. Available from:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4492499>
[PubMed: PM26147908](#)
5. Zhang ML, Hirunyachote P, Jampel H. Combined surgery versus cataract surgery alone for eyes with cataract and glaucoma. *Cochrane Database Syst Rev*. 2015;7:CD008671.
[PubMed: PM26171900](#)

Randomized Controlled Trials

6. Fea AM, Consolandi G, Zola M, Pignata G, Cannizzo P, Lavia C, et al. Micro-bypass implantation for primary open-angle glaucoma combined with phacoemulsification: 4-year follow-up. *J Ophthalmol* [Internet]. 2015 [cited 2016 Apr 27];2015:795357. Available from:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4637500>
[PubMed: PM26587282](#)
7. Craven ER, Katz LJ, Wells JM, Giamporcaro JE, iStent Study Group. 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.
[PubMed: PM22814041](#)
8. Samuelson TW, Katz LJ, Wells JM, Duh YJ, Giamporcaro JE, US iStent Study Group. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. *Ophthalmology*. 2011 Mar;118(3):459-67.
[PubMed: PM20828829](#)

Non-Randomized Studies

9. El Wardani M, Bergin C, Achache F, Sharkawi E. Evaluating the trabecular micro-bypass stent combined with phacoemulsification compared to phacoemulsification alone. *Klin Monbl Augenheilkd*. 2015 Apr;232(4):442-5.
[PubMed: PM25902094](#)

Economic Evaluations

10. Iordanous Y, Kent JS, Hutnik CM, Malvankar-Mehta MS. Projected cost comparison of Trabectome, iStent, and endoscopic cyclophotocoagulation versus glaucoma medication in the Ontario Health Insurance Plan. J Glaucoma. 2014 Feb;23(2):e112-e118.
[PubMed: PM23807348](#)

Guidelines and Recommendations

11. Trabecular stent bypass microsurgery for open angle glaucoma [Internet]. NICE interventional procedure guidance [IPG396]. London (UK): NICE; 2011 May [cited 2016 Apr 27]. Available from: <https://www.nice.org.uk/guidance/ipg396/resources/trabecular-stent-bypass-microsurgery-for-open-angle-glaucoma-1899867878918341>
Overview: <https://www.nice.org.uk/guidance/ipg396/evidence/overview-495909181>

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APPENDIX – FURTHER INFORMATION:**Randomized Controlled Trials – Alternate Comparator**

12. Fea AM, Belda JI, Rekas M, Junemann A, Chang L, Pablo L, et al. Prospective unmasked randomized evaluation of the iStent inject® versus two ocular hypotensive agents in patients with primary open-angle glaucoma. *Clin Ophthalmol* [Internet]. 2014 [cited 2016 Apr 27];8:875-82. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4019628>
[PubMed: PM24855336](#)

Non-Randomized Studies – No Comparator Group

13. Hoeh H, Vold SD, Ahmed IK, Anton A, Rau M, Singh K, et al. 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.
[PubMed: PM25304276](#)
14. Perez-Torregrosa VT, Olate-Perez A, Cerda-Ibanez M, Gargallo-Benedicto A, Osorio-Alayo V, Barreiro-Rego A, et al. Combined phacoemulsification and XEN45 surgery from a temporal approach and 2 incisions. *Arch Soc Esp Oftalmol*. 2016 Mar 16. [Epub ahead of print]
[PubMed: PM26995503](#)
15. Yildirim Y, Kar T, Duzgun E, Sagdic SK, Ayata A, Unal MH. Evaluation of the long-term results of Trabectome surgery. *Int Ophthalmol*. 2016 Feb 9. [Epub ahead of print]
[PubMed: PM26857725](#)
16. Seuthe AM, Januschowski K, Szurman P. Micro-invasive 360-degree suture trabeculotomy after successful canaloplasty - one year results. *Graefes Arch Clin Exp Ophthalmol*. 2016 Jan;254(1):155-9.
[PubMed: PM26467723](#)
17. Anton A, Heinzelmann S, Ness T, Lubke J, Neuburger M, Jordan JF, et al. Trabeculectomy ab interno with the Trabectome® as a therapeutic option for uveitic secondary glaucoma. *Graefes Arch Clin Exp Ophthalmol*. 2015 Nov;253(11):1973-8.
[PubMed: PM26205735](#)
18. Garcia-Feijoo J, Rau M, Grisanti S, Grisanti S, Hoh H, Erb C, et al. Supraciliary micro-stent implantation for open-angle glaucoma failing topical therapy: 1-year results of a multicenter study. *Am J Ophthalmol*. 2015 Jun;159(6):1075-81.
[PubMed: PM25747677](#)
19. Neuhann TH. Trabecular micro-bypass stent implantation during small-incision cataract surgery for open-angle glaucoma or ocular hypertension: long-term results. *J Cataract Refract Surg*. 2015 Dec;41(12):2664-71.
[PubMed: PM26796447](#)
20. Ahmed II, Katz LJ, Chang DF, Donnerfeld ED, Solomon KD, Voskanyan L, et al. Prospective evaluation of microinvasive glaucoma surgery with trabecular microbypass stents and prostaglandin in open-angle glaucoma. *J Cataract Refract Surg*. 2014

Aug;40(8):1295-300.

[PubMed: PM25088627](#)

21. Grover DS, Godfrey DG, Smith O, Feuer WJ, Montes de Oca I, Fellman RL. Gonioscopy-assisted transluminal trabeculotomy, ab interno trabeculotomy: technique report and preliminary results. *Ophthalmology*. 2014 Apr;121(4):855-61.
[PubMed: PM24412282](#)
22. Hoh H, Grisanti S, Grisanti S, Rau M, Ianchulev S. Two-year clinical experience with the CyPass Micro-Stent: safety and surgical outcomes of a novel supraciliary micro-stent. *Klin Monbl Augenheilkd*. 2014 Apr;231(4):377-81.
[PubMed: PM24771171](#)
23. Voskanyan L, Garcia-Feijoo J, Belda JI, Fea A, Junemann A, Baudouin C, et al. Prospective, unmasked evaluation of the iStent® inject system for open-angle glaucoma: synergy trial. *Adv Ther [Internet]*. 2014 Feb [cited 2016 Apr 27];31(2):189-201. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3930835>
[PubMed: PM24452726](#)
24. Hoeh H, Ahmed II, Grisanti S, Grisanti S, Grabner G, Nguyen QH, et al. Early postoperative safety and surgical outcomes after implantation of a suprachoroidal micro-stent for the treatment of open-angle glaucoma concomitant with cataract surgery. *J Cataract Refract Surg*. 2013 Mar;39(3):431-7.
[PubMed: PM23506920](#)
25. Arriola-Villalobos P, Martinez-de-la-Casa JM, Diaz-Valle D, Fernandez-Perez C, Garcia-Sanchez J, Garcia-Feijoo J. Combined iStent trabecular micro-bypass stent implantation and phacoemulsification for coexistent open-angle glaucoma and cataract: a long-term study. *Br J Ophthalmol*. 2012 May;96(5):645-9.
[PubMed: PM22275344](#)
26. Buchacra O, Duch S, Milla E, Stirbu O. One-year analysis of the iStent trabecular microbypass in secondary glaucoma. *Clin Ophthalmol [Internet]*. 2011 [cited 2016 Apr 27];5:321-6. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3065574>
[PubMed: PM21468340](#)

Clinical Practice Guidelines – Methodology Not Specified

27. Terminology and guidelines for glaucoma [Internet]. 4th ed. Savona (Italy): European Glaucoma Society; 2014 Jun [cited 2016 Apr 27]. Available from: http://www.icoph.org/dynamic/attachments/resources/egs_guidelines_4_english.pdf
See: 3.6.3.2 Alternative Methods of Preventing Filtering Bleb Scarring, page 174

Horizon Scan

28. Horizon Scanning Research & Intelligence Centre. XEN Gel Stent for glaucoma treatment [Internet]. Birmingham (UK): NIHR Horizon Scanning Centre, University of Birmingham; 2015 Feb [cited 2016 Apr 27]. Available from: <http://www.hsric.nihr.ac.uk/topics/xen-gel-stent-for-glaucoma-treatment/>

Review Articles

29. Pinchuk L, Riss I, Battle JF, Kato YP, Martin JB, Arrieta E, et al. The use of poly(styrene-block-isobutylene-block-styrene) as a microshunt to treat glaucoma. *Regen Biomater* [Internet]. 2016 Jun [cited 2016 Apr 27];3(2):137-42. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4817329>
[PubMed: PM27047682](#)
30. Richter GM, Coleman AL. Minimally invasive glaucoma surgery: current status and future prospects. *Clin Ophthalmol* [Internet]. 2016 [cited 2016 Apr 27];10:189-206. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4734795>
[PubMed: PM26869753](#)
31. Tsang S, Cheng J, Lee JW. Developments in laser trabeculoplasty. *Br J Ophthalmol*. 2016 Jan;100(1):94-7.
[PubMed: PM26377417](#)
32. Khaimi MA. Canaloplasty: a minimally invasive and maximally effective glaucoma treatment. *J Ophthalmol* [Internet]. 2015 [cited 2016 Apr 27];2015:485065. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4606093>
[PubMed: PM26495135](#)
33. Pinchuk L, Riss I, Battle JF, Kato YP, Martin JB, Arrieta E, et al. The development of a micro-shunt made from poly(styrene-block-isobutylene-block-styrene) to treat glaucoma. *J Biomed Mater Res B Appl Biomater*. 2015 Sep 18. [Epub ahead of print]
[PubMed: PM26380916](#)
34. Wellik SR, Dale EA. A review of the iStent® trabecular micro-bypass stent: safety and efficacy. *Clin Ophthalmol* [Internet]. 2015 [cited 2016 Apr 27];9:677-84. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4404878>
[PubMed: PM25931808](#)
35. Kaplowitz K, Schuman JS, Loewen NA. Techniques and outcomes of minimally invasive trabecular ablation and bypass surgery. *Br J Ophthalmol* [Internet]. 2014 May [cited 2016 Apr 27];98(5):579-85. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4108346>
[PubMed: PM24338085](#)
36. Le K, Saheb H. iStent trabecular micro-bypass stent for open-angle glaucoma. *Clin Ophthalmol* [Internet]. 2014 [cited 2016 Apr 27];8:1937-45. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4181749>
[PubMed: PM25284980](#)
37. Lewis RA. Ab interno approach to the subconjunctival space using a collagen glaucoma stent. *J Cataract Refract Surg*. 2014 Aug;40(8):1301-6.
[PubMed: PM24943904](#)
38. SooHoo JR, Seibold LK, Radcliffe NM, Kahook MY. Minimally invasive glaucoma surgery: current implants and future innovations. *Can J Ophthalmol*. 2014 Dec;49(6):528-33.

[PubMed: PM25433743](#)

39. Brandao LM, Grieshaber MC. Update on minimally invasive glaucoma surgery (MIGS) and new implants. J Ophthalmol [Internet]. 2013 [cited 2016 Apr 27];2013:705915. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863473>
[PubMed: PM24369494](#)
40. Augustinus CJ, Zeyen T. The effect of phacoemulsification and combined phaco/glaucoma procedures on the intraocular pressure in open-angle glaucoma. A review of the literature. Bull Soc Belge Ophtalmol. 2012;(320):51-66.
[PubMed: PM22978183](#)
41. Saheb H, Ahmed II. Micro-invasive glaucoma surgery: current perspectives and future directions. Curr Opin Ophthalmol. 2012 Mar;23(2):96-104.
[PubMed: PM22249233](#)

Additional References

42. Hoffman RS, Crandall AS, Crandall DA, Fine IH, Packer M, Sims AC. Minimally invasive external mini-glaucoma shunt implantation without conjunctival dissection. J Glaucoma. 2014 Apr;23(4):254-7.
[PubMed: PM22922664](#)