

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of ab interno canaloplasty for open-angle glaucoma

Open-angle glaucoma is a progressive condition that causes increased pressure in the eye. This damages the nerve that connects the eye to the brain and may lead to permanent sight loss. This procedure involves making a small cut in the eye (ab interno) and inserting a tiny tube into the channel that drains fluid from the eye. The tube widens the drainage channel (canaloplasty), then gel is injected into it and the tube is removed. The gel keeps the channel wider for a few days then dissolves, leaving the channel permanently wider, allowing excess fluid to drain away. The aim is to reduce pressure in the eye.

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Abbreviations

| Word or phrase | Abbreviation |
|----------------------|--------------|
| Intraocular pressure | IOP |
| Standard deviation | SD |

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2022.

Procedure name

- Ab interno canaloplasty for open-angle glaucoma

Professional societies

- Royal College of Ophthalmologists
- UK and Éire Glaucoma Society.

Description of the procedure

Indications and current treatment

Glaucoma is usually a chronic condition that is typically associated with raised intraocular pressure (IOP). The most common type of glaucoma in the UK is primary open-angle glaucoma. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic. But, as the condition progresses, it causes visual impairment and, if untreated, blindness.

In the healthy eye, aqueous humor drains through the trabecular meshwork (into Schlemm's canal) and through the uveoscleral outflow pathway. In glaucoma,

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this drainage becomes impaired either via resistance in the trabecular meshwork pathway (primary open-angle glaucoma) or via obstruction by the iris (primary closed-angle glaucoma).

Treatment usually involves eye drops containing medicines that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, deep sclerectomy, trabeculotomy, stenting, canaloplasty, or laser trabeculoplasty may be used.

What the procedure involves

Ab interno canaloplasty aims to reduce IOP by improving the drainage of aqueous fluid from the eye in people with open-angle glaucoma. It is done under local or general anaesthetic. Unlike traditional (ab externo) canaloplasty, which is done by cutting through the conjunctiva and sclera, ab interno canaloplasty uses an internal approach via a clear corneal or limbal incision. A microcatheter is introduced into the canal through a small opening in the trabecular meshwork and advanced around its entire circumference. As the catheter tip is withdrawn, viscoelastic fluid is injected into the canal to dilate it. The microcatheter is then removed. The viscoelastic fluid disperses down the collector channels of the eye within 2 to 3 days. The aim is to permanently dilate the canal to allow increased drainage of aqueous humor from the eye and thereby lower IOP. Some devices allow canaloplasty to be done simultaneously with trabeculotomy. Canaloplasty is often done concurrently with phacoemulsification (cataract surgery).

Efficacy summary

IOP reduction

In a before-and-after study of 60 eyes in 53 people, there was a statistically significant decrease in IOP from 20.7 mmHg before surgery to 13.6 mmHg at 12 months and 13.5 mmHg at 24 months after surgery (both $p < 0.001$ compared to baseline). There was no statistically significant difference in the mean change in IOP between people who had canaloplasty alone and people who had canaloplasty and phacoemulsification (Gallardo, 2021).

In a before-and-after study of 180 eyes in 130 people, results were presented as stratified by baseline IOP. In people with baseline IOP of ≥ 18 mmHg ($n=111$ eyes at baseline), there was a statistically significant decrease in IOP from 22.0 mmHg before surgery to 15.7 mmHg at 6 months and 17.2 mmHg at 12 months after surgery (both $p < 0.0001$ compared to baseline). In people with baseline IOP of < 18 mmHg ($n=69$ eyes at baseline), there was little change in IOP from before to after surgery (statistical significance not reported) (Tracer, 2020).

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In a before-and-after study of 89 eyes in 64 people, there was a statistically significant decrease in IOP from 24.5 mmHg before surgery to 16.5 mmHg at 12 months ($p < 0.0005$) and 15.8 mmHg at 18 months ($p < 0.0005$). There was no statistically significant difference in the mean change in IOP between people who had canaloplasty alone and people who had canaloplasty and phacoemulsification (Hughes, 2020).

In a before-and-after study of 106 eyes in 71 people, eyes were stratified by baseline IOP. In people with baseline IOP of ≥ 18 mmHg ($n = 72$ eyes at baseline), there was a statistically significant decrease in mean IOP from 24.6 mmHg before surgery to 14.6 mmHg at 12 months after surgery ($p < 0.001$). In people with baseline IOP of < 18 mmHg ($n = 34$ eyes at baseline), there was no statistically significant change in mean IOP from before surgery to 12 months after surgery (Ondrejka, 2019).

In a before-and-after study of 80 eyes in 73 people, there was a statistically significant decrease in mean IOP from 22.5 mmHg before surgery to 15.0 mmHg at 12 months after surgery ($p < 0.001$). There was no statistically significant difference in the mean change in IOP between people who had canaloplasty alone and people who had canaloplasty and phacoemulsification (Toneatto, 2022).

In a before-and-after study 71 eyes (total people not reported), there was a statistically significant decrease in mean IOP from 23.6 mmHg before surgery to 14.2 mmHg at 12 months after surgery ($p < 0.001$) (Gillman, 2021).

Glaucoma medicine reduction

In the before-and-after study of 60 eyes in 53 people, there was a statistically significant decrease in the number of glaucoma medicines used per person from a mean of 2.8 before surgery to 1.1 at 12 months and 1.7 at 24 months after surgery (both $p < 0.001$ compared to baseline). There was no statistically significant difference in the reduction in glaucoma medicine use between people who had canaloplasty alone and people who had canaloplasty and phacoemulsification (Gallardo, 2021).

In the before-and-after study of 180 eyes in 130 people, results were presented as stratified by baseline IOP. In people with baseline IOP of ≥ 18 mmHg ($n = 111$ eyes at baseline), there was no change in glaucoma medicine use per person from a mean of 0.9 before surgery to 1.0 at 12 months after surgery ($p = 0.7$). In people with baseline IOP of < 18 mmHg ($n = 69$ eyes at baseline), there was a statistically significant decrease in the mean glaucoma medicine use per person from 1.1 at baseline to 0.6 at 12 months follow up ($p < 0.05$) (Tracer, 2020).

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In the before-and-after study of 89 eyes in 64 people, there was a statistically significant decrease in the number of glaucoma medicines used from a mean of 2.5 before surgery to 1.8 at 12 months ($p < 0.0005$) and 1.7 at 18 months ($p < 0.05$). There was no statistically significant difference in the reduction in glaucoma medicine use between people who had canaloplasty alone and people who had canaloplasty and phacoemulsification (Hughes, 2020).

In the before-and-after study of 106 eyes in 71 people, eyes were stratified by baseline IOP. In people with baseline IOP of ≥ 18 mmHg ($n = 72$ eyes at baseline), there was a statistically significant decrease in mean glaucoma medicine use from 2.1 before surgery to 0.2 at 12 months ($p < 0.001$). In people with baseline IOP of < 18 mmHg ($n = 34$ eyes at baseline), there was a statistically significant decrease in mean glaucoma medicine use from 1.8 before surgery to 0.2 at 12 months after surgery ($p < 0.001$) (Ondrejka, 2019).

In the before-and-after study of 80 eyes in 73 people, there was a statistically significant decrease in mean glaucoma medicine use from 3.2 before surgery to 1.9 at 12 months after surgery ($p < 0.001$). There was no statistically significant difference in the reduction in glaucoma medicine use between people who had canaloplasty alone and people who had canaloplasty and phacoemulsification (Toneatto, 2022).

In the before-and-after study 71 eyes (total people not reported), there was a statistically significant decrease in mean glaucoma medicine use from 2.9 before surgery to 0.6 at 12 months after surgery ($p < 0.001$) (Gillman, 2021).

Surgical success

In the before-and-after study of 80 eyes in 73 people, eyes that reached a target IOP on no medicines were considered 'complete successes' and eyes that reached a target IOP on no more medicines than baseline were considered 'qualified successes'. At a target IOP of 16 mmHg or less and a 25% or more reduction in IOP, 10.3% of eyes were complete successes and a further 43.6% of eyes were qualified successes at 12 months. At a target IOP of 18 mmHg or less and a 25% or more reduction in IOP, 11.5% of eyes were complete successes and a further 50.0% of eyes were qualified successes at 12 months (Toneatto, 2022).

In the before-and-after study 71 eyes (total people not reported), eyes that had a 20% or more reduction in IOP with no medicine were considered 'complete successes'. 'Qualified successes' were those who had a 20% or more reduction in IOP with no more medicine use than baseline. Failures were those that did not meet the criteria for success, or those that required additional glaucoma surgery or had loss of light perception. Complete success was achieved in 46% of eyes, with a further 19% achieving qualified success. Failure was seen in 35% of eyes,

all due to uncontrolled IOP, 36.8% (7 eyes) of which required further filtering surgery (Gillman, 2021).

Safety summary

Need for further surgery

The before-and-after study of 89 eyes in 64 people reported that 6 people required filtering surgery for glaucoma after canaloplasty. These people had higher baseline IOP and medicine use than the cohort mean (Hughes, 2020).

The before-and-after study of 80 eyes in 73 people reported that 12 eyes required further surgery after canaloplasty. This included 9 trabeculectomies and 3 deep sclerectomies (Toneatto, 2022).

The before-and-after study of 71 eyes reported that 7 eyes required further filtering glaucoma surgery after canaloplasty (Gillman, 2021).

Loss of visual acuity

In the before-and-after study of 60 eyes in 53 people, visual acuity was improved at 24-month follow up in all eyes, with 19 people (42.2%) gaining 2 or more lines of Snellen corrected distance visual acuity. Statistically significant improvements in visual acuity were only observed in the people who had both canaloplasty and phacoemulsification (Gallardo, 2021).

In the before-and-after study of 80 eyes in 73 people, there was no statistically significant change in visual acuity observed in people who had canaloplasty alone ($p=0.31$). In people who had canaloplasty and phacoemulsification, there was a statistically significant change in visual acuity in from 6.8/10 (SD 2.1) before surgery to 9.1/10 (SD 2.6) at 12 months after surgery ($p<0.001$).

Raised IOP

The before-and-after study of 180 eyes in 130 people reported 2 cases of IOP spikes of 10 mmHg or more above baseline (Tracer, 2020).

The before-and-after study of 80 eyes in 73 people reported 1 case of an IOP spike of more than 10 mmHg above baseline (Toneatto, 2022).

The before-and-after study of 71 eyes reported 12 cases of IOP spikes over 30 mmHg (Gillman, 2021).

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Hypotony

The before-and-after study of 80 eyes in 73 people reported 4 cases of mild hypotony (Toneatto, 2022).

Bleeding and hyphaema

Note, Hughes (2020), Toneatto (2022), and Gillman (2021) did not consider mild or microhyphema to be an adverse event of this procedure.

The before-and-after study of 60 eyes in 53 people reported an unspecified number of cases of microhyphema and an unspecified number of cases of intraoperative bleeding at the goniotomy site (Gallardo, 2021).

The before-and-after study of 180 eyes in 130 people reported 3 cases of hyphaema (Tracer, 2020).

The before-and-after study of 106 eyes in 71 people reported 14 cases of hyphaema (Ondrejka, 2019).

The before-and-after study of 80 eyes in 73 people reported 2 cases of moderate or severe hyphaema (Toneatto, 2022).

The before-and-after study of 71 eyes reported 1 case of a self-resolving corneal endothelial blood stain (Gillman, 2021).

Device malfunction

The before-and-after study of 106 eyes in 71 people reported 1 case of the VISCO360 device malfunctioning. The catheter detached from the handle and cannula and had to be retrieved with vitrectomy forceps. The person had no adverse sequelae (Ondrejka, 2019).

Fibrin complications

The before-and-after study of 106 eyes in 71 people reported 1 case of fibrin in pupillary plane (Ondrejka, 2019).

The before-and-after study of 71 eyes reported 1 case of a fibrin plug (Gillman, 2021).

Other complications

Single cases of the following complications were reported:

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- The before-and-after study of 180 eyes in 130 people (Tracer, 2020):
 - Mild anterior chamber inflammation.
- The before-and-after study of 71 eyes (Gillman, 2021):
 - Intraocular lens subluxation.
 - Iris atrophy.
 - Pupillary block.

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events that they have heard about) and about theoretical adverse events (events that they think might possibly occur, even if they have never happened).

For this procedure, professional experts listed the following anecdotal adverse events: cyclodialysis, retinal detachment, Descemet's detachment, formation of peripheral anterior synechiae, and transient refractive change. They considered that the following were theoretical adverse events: catheter entering a collector channel, subretinal space, or macular area.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to ab interno canaloplasty for open-angle glaucoma. The following databases were searched, covering the period from their start to 29 November 2022: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched. No language restriction was applied to the searches (see the [literature search strategy](#)). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The [inclusion criteria](#) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

| Characteristic | Criteria |
|-------------------|---|
| Publication type | <p>Clinical studies were included. Emphasis was placed on identifying good quality studies.</p> <p>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.</p> <p>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.</p> |
| Patient | People with open-angle glaucoma. |
| Intervention/test | Ab interno canaloplasty. |
| Outcome | Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy. |
| Language | Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base. |

List of studies included in the IP overview

This IP overview is based on 586 eyes from approximately 430 people from 6 before-and-after studies.

Other studies that were considered to be relevant to the procedure but were not included in the main [summary of the key evidence](#) are listed in the [appendix](#).

Summary of key evidence on ab interno canaloplasty for open-angle glaucoma

Study 1 Gallardo MJ (2021)

Study details

| | |
|---|--|
| Study type | Single centre, retrospective, before-and-after study |
| Country | US |
| Recruitment period | 2014 to 2016 |
| Study population and number | n=53 people, 60 eyes Adults with primary open-angle glaucoma. |
| Age and sex | Mean 73.6 years; 60% female |
| Patient selection criteria | Inclusion criteria: adults (18 or older) with a diagnosis of mild-moderate, or severe primary open-angle glaucoma. Exclusion criteria: any sign of angle disease; had undergone laser trabeculoplasty within 6 months of surgery or other angle-based micro-invasive procedure; had neovascular disease, uveitis, peripheral anterior synechiae, or developmental or other forms of secondary glaucoma, such as steroid-induced glaucoma. |
| Technique | Ab interno canaloplasty using the iTrack device. In 29 eyes, canaloplasty was concurrently with phacoemulsification. The microcatheter was inserted via a clear corneal incision and goniotomy into Schlemm's canal. The microcatheter was advanced 360 degrees, then withdrawn whilst depositing high-molecular-weight hyaluronic acid-based ophthalmic viscoelastic. Glaucoma treatments were stopped 1 day after surgery and only restarted if pressure rose above target. |
| Follow up | 24 months |
| Conflict of interest/source of funding | Conflict of interest: The author is an investigator, consultant, and speaker for Nova Eye Medical, the manufacturer of iTrack, and for Sight Sciences, the manufacturer of the OMNI and VISCO360 devices. Source of funding: Not reported. |

Analysis

Follow up issues: Although not explicitly described in the publication, this study captures a highly similar population as a 2018 study by the same author (as summarised in the appendix). In the 2018 study, the 12-month outcomes of 75 eyes in 68 people are described. This study describes the 24-month outcomes of 60 eyes in 53 people, implying 15 eyes were lost to follow up and were not included here.

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Study design issues: This single centre, before-and-after study reported the 24-month outcomes of people who had ab interno canaloplasty for primary open-angle glaucoma. Cases were identified retrospectively from an analysis of patient records. Primary outcomes included mean IOP and mean number of glaucoma medicines at 12 and 24 months. Safety outcomes included complications and loss of visual acuity.

A repeated-measures ANOVA test was used to compare mean IOP and number of medicines between groups over time followed by a post hoc Tukey's test for multiple comparisons across the visits. $p < 0.05$ was considered statistically significant. A t-test was performed to compare the percentage reduction in IOP and number of medicines between groups.

Study population issues: The study cohort consisted of people from Hispanic (74%), black (6%), or white (21%) ethnicity, and the glaucoma stages of mild (38%), moderate (17%) and severe (38%).

Key efficacy findings

IOP reduction

Number of people analysed: 53 people, 60 eyes

Follow up at time of assessment: 24 months

- There was a statistically significant decrease in IOP from 20.7 mmHg (SD 4.9 mmHg) before surgery to 13.6 mmHg (SD 1.9 mmHg) at 12 months and 13.5 mmHg (SD 2.6 mmHg) at 24 months after surgery (both $p < 0.001$ compared to baseline).
 - In 29 eyes that had canaloplasty plus phacoemulsification, there was a statistically significant decrease in IOP from 19.8 mmHg (SD 3.9 mmHg) before surgery to 13.0 mmHg (SD not reported) at 12 months and 13.2 mmHg (SD 2.1 mmHg) at 24 months after surgery (both $p < 0.001$ compared to baseline).
 - In 31 eyes that had canaloplasty alone, there was a statistically significant decrease in IOP from 21.6 mmHg (SD 5.7 mmHg) before surgery to 14.1 mmHg (SD not reported) at 12 months and 13.8 mmHg (SD 3.1 mmHg) at 24 months after surgery (both $p < 0.001$ compared to baseline).
 - There was no statistically significant difference in the IOP reduction between people who had canaloplasty alone and those who had canaloplasty and phacoemulsification.
 - There were similar decreases in IOP for people with mild/moderate glaucoma and for people with severe glaucoma.

Glaucoma medicine reduction

Number of people analysed: 53 people, 60 eyes

Follow up at time of assessment: 24 months

- There was a statistically significant decrease in the mean number of glaucoma medicines used per person from 2.8 (SD 0.9) before surgery to 1.1 (SD 1.1) at 12 months and 1.7 (SD 1.3) at 24 months after surgery (both $p < 0.001$ compared to baseline).
 - In 29 eyes that had canaloplasty plus phacoemulsification, there was a statistically significant decrease in the mean number of glaucoma medicines used per person from 2.5 (SD 1.1) before

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surgery to 0.8 (SD 0.9) at 12 months and 1.3 (SD 1.2) at 24 months after surgery (both $p < 0.001$ compared to baseline).

- In 31 eyes that had canaloplasty alone, there was a statistically significant decrease in the mean number of glaucoma medicines used per person from 3.0 (SD 0.7) before surgery to 1.4 (SD 1.2) at 12 months and 2.1 (SD 1.3) at 24 months after surgery (both $p < 0.001$ compared to baseline).
- There was no statistically significant difference in the reduction in glaucoma medicine use between people who had canaloplasty alone and those who had canaloplasty and phacoemulsification.
- There were similar decreases in medicine use for people with mild/moderate glaucoma and for people with severe glaucoma.

Key safety findings

Complications

Number of people analysed: 53 people, 60 eyes

Follow up at time of assessment: 24 months

- Intraoperative bleeding at the goniotomy site, number not specified
- Microhyphaema, number not specified
 - Both resolved within 1 week without sequelae.

Visual acuity

Number of people analysed: 53 people, 60 eyes

Follow up at time of assessment: 24 months

- Visual acuity was improved at 24-month follow up in all eyes, with 19 people (42.2%) gaining 2 or more lines of Snellen corrected distance visual acuity.
- In 29 eyes that had canaloplasty plus phacoemulsification, there was a statistically significant improvement in the proportion of people with 20/40 vision from 34.5% before surgery to 80.8% at 24 months after surgery ($p = 0.0042$).
- In 31 eyes that had canaloplasty alone, there was no statistically significant change in the proportion of people with 20/40 vision from 64.5% before surgery to 70.0% at 24 months after surgery ($p = 0.4716$).

Study 2 Tracer N (2020)

Study details

| | |
|---|--|
| Study type | Single centre, before-and-after study |
| Country | US |
| Recruitment period | 2015 to 2017 |
| Study population and number | n=130 people, 180 eyes Adults with mild to moderate open-angle glaucoma. |
| Age and sex | Mean 70 years; 52% female |
| Patient selection criteria | Inclusion criteria: diagnosis of mild to moderate open-angle glaucoma (most were primary open-angle glaucoma). Exclusion criteria: advanced glaucoma, prior penetrating glaucoma surgery. |
| Technique | Ab interno canaloplasty using the VISCO360 device. In all eyes, canaloplasty was concurrently with phacoemulsification. The microcatheter was inserted via a clear corneal incision and goniotomy into Schlemm's canal. The microcatheter was advanced 180 degrees, then withdrawn whilst depositing viscoelastic. This was repeated for the second 180 degrees. Glaucoma medicines were continued until the day of surgery and tapered postoperatively as warranted by IOP. |
| Follow up | 12 months |
| Conflict of interest/source of funding | Conflict of interest: 1 author is an employee of Sight Sciences, the manufacturer of the VISCO360 and OMNI devices. One author reports personal fees from Sight Sciences. Source of funding: Not reported. |

Analysis

Follow up issues: Of the 180 eyes that were treated, 122 had data available at 6 months, and 95 had data available at 12 months.

Study design issues: This single centre, before-and-after study reported the 12-month outcomes of ab interno canaloplasty for people with open-angle glaucoma. Cases were identified retrospectively from an analysis of patient records. As per the study design, patients were stratified by baseline IOP. In those with baseline IOP ≥ 18 mmHg, the primary endpoint was reduction in pressure. In those with baseline IOP < 18 mmHg, the primary endpoint was medicine reduction (with maintenance of IOP).

Paired t-tests were used to evaluate differences between baseline and 12-month outcomes. $p < 0.05$ was considered statistically significant. There was no adjustment for multiple comparisons.

Study population issues: Six eyes were from people who self-reported that they were Caucasian, 45 from people who were Black, 120 from people who were Hispanic, and 9 listed as 'other'.

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Key efficacy findings

IOP reduction

Number of people analysed: 180 eyes at baseline; 122 eyes at 6 months; 95 eyes at 12 months
Follow up at time of assessment: 12 months

- In people with baseline IOP of ≥ 18 mmHg (n=111 eyes at baseline; number at follow up not reported), there was a statistically significant decrease in IOP from 22.0 mmHg (SD 5.5 mmHg) before surgery to 15.7 mmHg (SD 4.3 mmHg) at 6 months and 17.2 mmHg (SD 5.1 mmHg) at 12 months after surgery (both $p < 0.0001$ compared to baseline). The increase in IOP between 6 months and 12 months was not quite statistically significant ($p = 0.058$).
- In people with baseline IOP of < 18 mmHg (n=69 eyes at baseline; number at follow up not reported), there was little change in IOP from 14.3 mmHg (SD 2.3 mmHg) at baseline to 15.0 mmHg (SD 3.3 mmHg) at 6 months and 15.4 mmHg (SD 4.1 mmHg) at 12 months follow up (statistical significance not reported).

Glaucoma medicine reduction

Number of people analysed: 180 eyes at baseline; 122 eyes at 6 months; 95 eyes at 12 months
Follow up at time of assessment: 12 months

- In people with baseline IOP of ≥ 18 mmHg (n=111 eyes at baseline; number at follow up not reported), there was no change in the mean glaucoma medicine use per person from 0.9 (SD 0.9) before surgery to 1.0 (SD 0.9) at 12 months after surgery ($p = 0.7$).
- In people with baseline IOP of < 18 mmHg (n=69 eyes at baseline; number at follow up not reported), there was a statistically significant decrease in the mean glaucoma medicine use per person from 1.1 (SD 0.9) at baseline to 0.6 (SD 0.6) at 12 months follow up ($p < 0.05$).

Key safety findings

Number of people analysed: 180 eyes at baseline; 122 eyes at 6 months; 95 eyes at 12 months
Follow up at time of assessment: 12 months

- Hyphaema. n=3 eyes
- IOP spikes ≥ 10 mmHg above baseline IOP, n=2 eyes
- Mild anterior chamber inflammation, n=1 eye.

Study 3 Hughes T (2020)

Study details

| | |
|---|---|
| Study type | Single centre, before-and-after study |
| Country | US |
| Recruitment period | 2018 to 2019 |
| Study population and number | n=64 people, 89 eyes Adults with mild to moderate open-angle glaucoma. |
| Age and sex | Mean 72.1 years; 64% male |
| Patient selection criteria | Inclusion criteria: Adults with mild to moderate open-angle glaucoma. Exclusion criteria: pseudoexfoliative glaucoma, pigmentary glaucoma, glaucoma associated with ocular trauma, glaucoma associated with ocular inflammation, previous incisional glaucoma surgery, and eyes with less than 90 degrees of viscodilation. |
| Technique | Ab interno canaloplasty using the OMNI or VISCO360 device. In 72 eyes, canaloplasty was concurrently with phacoemulsification. The microcatheter was inserted via a clear corneal incision and goniotomy into Schlemm's canal. The microcatheter was advanced 180 degrees, then withdrawn whilst depositing viscoelastic. This was repeated for the second 180 degrees. The anterior chamber was irrigated, pressurised to physiological pressure, and injected with an antibiotic/corticosteroid. Glaucoma medicines were continued after surgery and tapered postoperatively as warranted by IOP. |
| Follow up | 18 months |
| Conflict of interest/source of funding | Conflict of interest: Both authors report research grants from Sight Sciences, the manufacturer of the OMNI and VISCO360 devices, for this research. Source of funding: See above. |

Analysis

Follow up issues: Of the 89 eyes assessed preoperatively, 61 had 6 month follow up data, 42 had 12 month, and 22 had 18 month.

Study design issues: This single centre, before-and-after study assessed the 18-month outcomes of ab interno canaloplasty for open-angle glaucoma. Cases were identified retrospectively from an analysis of patient records. Eyes with less than 90 degrees of viscodilation were excluded, potentially excluding people in whom the procedure was attempted but not completed. The efficacy and safety outcomes of these eyes were not reported. The primary outcomes were the difference in IOP and glaucoma medicine use from before to after surgery.

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Paired t-tests were used to evaluate the differences between baseline and each postoperative timepoint for IOP and medicine use. $p < 0.05$ was considered statistically significant. There was no adjustment for multiple comparisons.

Key efficacy findings

IOP reduction

Number of people analysed: 89 eyes at baseline, 42 at 12 months, 22 at 18 months

Follow up at time of assessment: 18 months

- There was a statistically significant decrease in IOP from 24.5 mmHg (SD 8.3 mmHg) before surgery to 16.5 mmHg (SD 3.4 mmHg) at 12 months ($p < 0.0005$) and 15.8 mmHg (SD 2.5 mmHg) at 18 months ($p < 0.0005$).
 - There was no statistically significant difference in the mean change in IOP between people who had ab interno canaloplasty combined with phacoemulsification and for those people who had ab interno canaloplasty only.

Glaucoma medicine reduction

Number of people analysed: 89 eyes at baseline, 42 at 12 months, 18 at 18 months

Follow up at time of assessment: 18 months

- There was a statistically significant decrease in the mean number of glaucoma medicines used from 2.5 (SD 1.3) before surgery to 1.8 (SD 1.4) at 12 months ($p < 0.0005$) and 1.7 (SD 1.5) at 18 months ($p < 0.05$).
 - There was no statistically significant difference in the change in glaucoma medicine use between people who had ab interno canaloplasty combined with phacoemulsification and for those people who had ab interno canaloplasty only.

Key safety findings

Number of people analysed: 89 eyes at baseline, 42 at 12 months, 22 at 18 months

Follow up at time of assessment: 18 months

Mild intraoperative bleeding at the surgery site with subsequent microhyphaema not considered an adverse event for this surgery. There were no clinically significant hyphaemas.

- Need for future glaucoma filtering surgery, $n=6$
 - These people had higher baseline IOP and medicine use than the cohort mean.

Study 4 Ondrejka S (2019)

Study details

| | |
|---|---|
| Study type | Single centre, before-and-after study |
| Country | Germany |
| Recruitment period | 2015 to 2018 |
| Study population and number | n=71 people, 106 eyes Adults with mild to moderate open-angle glaucoma. |
| Age and sex | Mean 75.0 years; 63% female |
| Patient selection criteria | Inclusion criteria: people who had insufficiently controlled IOP on current medicine (Group 1; baseline IOP \geq 18 mmHg) or, if adequately controlled, in need of reduced medicine burden (Group 2; baseline IOP <18 mmHg). Exclusion criteria: glaucoma other than primary open-angle glaucoma, prior glaucoma surgery, terminal stage of open-angle glaucoma, or central retinal vein occlusion. |
| Technique | Ab interno canaloplasty using the VISCO360 device. In 94 eyes, canaloplasty was concurrently with phacoemulsification. The microcatheter was inserted via a clear corneal incision and goniotomy into Schlemm's canal. The microcatheter was advanced 180 degrees, then withdrawn whilst depositing viscoelastic. This was repeated for the second 180 degrees. The anterior chamber was then irrigated and aspirated. Glaucoma medicines were continued until the day of surgery and were then discontinued. |
| Follow up | 12 months |
| Conflict of interest/source of funding | Conflict of interest: The authors declared no conflict of interest. Source of funding: Sight Sciences, the manufacturer of the VISCO360 device, provided financial assistance to support writing, editorial, and statistical analysis. |

Analysis

Follow up issues: 105 eyes had data available for analysis at 12 months (SD 3 months) follow up.

Study design issues: This single centre, before-and-after study assessed the outcomes of ab interno canaloplasty in people with open-angle glaucoma. Cases were identified retrospectively from an analysis of patient records. As per the study design, patients were stratified by baseline IOP into Group 1 (baseline IOP \geq 18 mmHg) and Group 2 (baseline IOP <18 mmHg). The primary outcome measure for Group 1 was change in mean IOP and mean number of glaucoma medicines at 12 months. The primary outcome for Group 2 was change in the mean number of glaucoma medicines at 12 months.

Paired t-tests with post hoc Tukey adjustment to account for multiple comparisons was done to compare IOP and the number of glaucoma medicines with baseline. $p < 0.05$ was considered statistically significant.

IP overview: Ab interno canaloplasty for open-angle glaucoma

Key efficacy findings

IOP reduction

Number of people analysed: 72 eyes (Group 1: baseline IOP \geq 18 mmHg), 34 eyes (Group 2: baseline IOP $<$ 18 mmHg)

Follow up at time of assessment: 12 months (plus or minus 3 months)

- Group 1: There was a statistically significant decrease in mean IOP from 24.6 mmHg (SD 7.1 mmHg) before surgery to 14.6 mmHg (SD 2.8 mmHg) at 12 months after surgery ($p < 0.001$).
- Group 2: There was no statistically significant change in mean IOP from before surgery to 12 months after surgery.

Glaucoma medicine reduction

Number of people analysed: 72 eyes (Group 1: baseline IOP \geq 18 mmHg), 34 eyes (Group 2: baseline IOP $<$ 18 mmHg)

Follow up at time of assessment: 12 months (plus or minus 3 months)

- Group 1: There was a statistically significant decrease in mean glaucoma medicine use from 2.1 (SD 1.0) before surgery to 0.2 (SD 0.6) at 12 months after surgery ($p < 0.001$).
- Group 2: There was a statistically significant decrease in mean glaucoma medicine use from 1.8 (SD 0.9) before surgery to 0.2 (SD 0.6) at 12 months after surgery ($p < 0.001$).

Key safety findings

Number of people analysed: 106 eyes (105 at 12 months)

Follow up at time of assessment: 12 months

- VISCO360 device deficiency, n=1
 - Catheter detached from the handle and cannula and had to be retrieved with vitrectomy forceps.
 - The patient had no adverse sequelae.
- Hyphaema, n=14
 - All resolved within 7 days without the need for further intervention.
- Fibrin in pupillary plane, n=1

Study 5 Toneatto G (2022)

Study details

| | |
|---|---|
| Study type | Double-centre, before-and-after study |
| Country | Italy |
| Recruitment period | 2017 to 2020 |
| Study population and number | n=73 people, 80 eyes Adults with mild to moderate open-angle glaucoma. |
| Age and sex | Mean 74.5 years; 59% female |
| Patient selection criteria | Inclusion criteria: people who had primary open angle glaucoma, pigmentary glaucoma, and pseudoexfoliative glaucoma. Exclusion criteria: not reported. |
| Technique | Ab interno canaloplasty using the OMNI device. In 30 eyes, canaloplasty was concurrently with phacoemulsification. The microcatheter was inserted via a clear corneal incision and goniotomy into Schlemm's canal. The microcatheter was advanced 180 degrees, then withdrawn whilst depositing viscoelastic. This was repeated for the second 180 degrees. The anterior chamber was then irrigated and aspirated. |
| Follow up | 12 months |
| Conflict of interest/source of funding | Conflict of interest: The authors declared that they had no conflict of interest. Source of funding: The authors declared that external funding was not received. |

Analysis

Follow up issues: Of the 80 eyes at baseline, 66 completed the 12 months follow up.

Study design issues: This double-centre, before-and-after study assessed the outcomes of ab interno canaloplasty in people with open-angle glaucoma. Cases were identified retrospectively from an analysis of patient records. This study allowed people with pseudoexfoliative glaucoma or pigmentary dispersion glaucoma, and those who had previous glaucoma surgery. The primary outcome measures were IOP reduction and reduction in the mean number of glaucoma medicines at 12 months. Surgical success rates were also calculated. Complete successes were those who reached an IOP target no glaucoma medicine. Qualified successes were those reached an IOP target with no more glaucoma medicine use than baseline.

The mean levels of IOP at different follow up times were compared to baseline by a paired sample t-test. The decrease of glaucoma medicine use in each group was analysed by a non-parametric Wilcoxon matched-pairs signed rank test. There was no adjustment for multiple comparisons.

Study population issues: Diagnoses included primary open-angle glaucoma (63.8%), pseudoexfoliative glaucoma (33.7%), and pigmentary dispersion glaucoma (2.5%). Previous glaucoma surgeries included laser trabeculoplasty (18.8%), deep sclerectomy (12.5%), and trabeculectomy (3.8%).

IP overview: Ab interno canaloplasty for open-angle glaucoma

Key efficacy findings

IOP reduction

Number of people analysed: 73 people, 80 eyes at baseline, 66 eyes at 12 months
Follow up at time of assessment: 12 months

- There was a statistically significant decrease in mean IOP from 22.5 mmHg (SD 5.3 mmHg) before surgery to 15.0 mmHg (SD 3.6 mmHg) at 12 months after surgery ($p < 0.001$).
 - In people who had canaloplasty alone, there was a statistically significant reduction in mean IOP from 23.0 mmHg (SD 5.7 mmHg) before surgery to 15.6 mmHg (SD 3.6 mmHg) at 12 months after surgery ($p < 0.001$).
 - In people who had canaloplasty and cataract surgery, there was a statistically significant reduction in mean IOP from 21.5 mmHg (SD 4.7 mmHg) before surgery to 14.1 mmHg (SD 3.3 mmHg) at 12 months after surgery ($p < 0.001$).
 - The difference in mean IOP decrease between groups was not statistically significant.

Glaucoma medicine reduction

Number of people analysed: 73 people, 80 eyes at baseline, 66 eyes at 12 months
Follow up at time of assessment: 12 months

- There was a statistically significant decrease in mean glaucoma medicine use from 3.2 (SD 1.0) before surgery to 1.9 (SD 1.4) at 12 months after surgery ($p < 0.001$).
 - In people who had canaloplasty alone, there was a statistically significant reduction in mean glaucoma medicine use from 3.0 (SD 1.1) before surgery to 2.0 (SD 1.4) at 12 months after surgery ($p < 0.001$).
 - In people who had canaloplasty and cataract surgery, there was a statistically significant reduction in mean glaucoma medicine use from 3.4 (SD 0.8) before surgery to 1.9 (SD 1.4) at 12 months after surgery ($p < 0.001$).
 - The difference in mean glaucoma medicine use decrease between groups was not statistically significant.

Surgical success

Number of people analysed: 73 people, 80 eyes at baseline, 66 eyes at 12 months
Follow up at time of assessment: 12 months

- Target IOP 16 mmHg or less and 25% or more reduction in IOP:
 - At 12 months, 10.3% of eyes were complete successes.
 - A further 43.6% of eyes were qualified successes.
- Target IOP 18 mmHg or less and 25% or more reduction in IOP:
 - At 12 months, 11.5% of eyes were complete successes.
 - A further 50.0% of eyes were qualified successes.

IP overview: Ab interno canaloplasty for open-angle glaucoma

Key safety findings

Complications

Number of people analysed: 73 people, 80 eyes at baseline, 66 eyes at 12 months
Follow up at time of assessment: 12 months

Mild or microhyphaema were not considered adverse events for this surgery.

- Moderate or severe hyphema, n=2
 - Both cases required a wash of the anterior chamber. Both recovered within 10 days.
- Mild hypotony, n=4
- IOP spike of 10 mmHg or more above baseline, n=1
- Further surgery, n=12
 - Trabeculectomy, n=9
 - Deep sclerectomy, n=3

Visual acuity

Number of people analysed: 73 people, 80 eyes at baseline, 66 eyes at 12 months
Follow up at time of assessment: 12 months

- No statistically significant change in visual acuity was observed in people who had canaloplasty alone ($p=0.31$)
- There was a statistically significant change in visual acuity in people who had canaloplasty and phacoemulsification from 6.8/10 (SD 2.1) before surgery to 9.1/10 (SD 2.6) at 12 months after surgery ($p<0.001$).

Study 6 Gillman K (2021)

Study details

| | |
|---|--|
| Study type | Single centre, before-and-after study |
| Country | Switzerland |
| Recruitment period | 2015 to 2019 |
| Study population and number | n=71 eyes, total people not reported Adults with mild to moderate open-angle glaucoma. |
| Age and sex | Mean 73.1 years; 52% female |
| Patient selection criteria | Inclusion criteria: uncontrolled mild-to-moderate open-angle glaucoma with concomitant clinically significant cataract. Exclusion criteria: not reported. |
| Technique | Ab interno canaloplasty using the iTrack device. In all eyes, canaloplasty was concurrently with phacoemulsification. The microcatheter was inserted via a clear corneal incision and goniotomy into Schlemm's canal. The microcatheter was advanced 360 degrees, then withdrawn whilst depositing viscoelastic. Postoperatively, glaucoma medicine was initially withheld, then reinstated as needed to maintain IOP below 15 mmHg. |
| Follow up | 12 months |
| Conflict of interest/source of funding | Conflict of interest: The authors declared that they had no conflict of interest. Source of funding: The authors declared that external funding was not received. |

Analysis

Follow up issues: Of the 71 eyes identified that had ab interno canaloplasty during the study period, 54 eyes in 41 people had 12 month follow up data.

Study design issues: This single centre, before-and-after study assessed the outcomes of ab interno canaloplasty for open-angle glaucoma in combination with phacoemulsification. Cases were identified retrospectively from an analysis of patient records. Cases without 12 month follow up were excluded unless they were considered failures due to reoperation or severe complications. The primary outcome measure was IOP reduction. Surgical success rates were also calculated. Complete successes were those who had a 20% or more reduction in IOP with no medicine. Qualified successes were those who had a 20% or more reduction

IP overview: Ab interno canaloplasty for open-angle glaucoma

in IOP with no more medicine use than baseline. Failures were those who did not meet the criteria for success, or those who had additional glaucoma surgery or loss of light perception.

The cumulative probability of success was assessed using Kaplan-Meier survival curves. The tests were 2-tailed. $p < 0.05$ was considered statistically significant. There was no adjustment for multiple comparisons.

Study population issues: All included people were Caucasian. Diagnoses included primary open-angle glaucoma (66.7%), pseudoexfoliative glaucoma (18.5%), and pigmentary glaucoma (14.8%). A total of 4 eyes had previous glaucoma surgery.

Key efficacy findings

IOP reduction

Number of people analysed: 41 people, 54 eyes

Follow up at time of assessment: 12 months

- There was a statistically significant decrease in mean IOP from 23.6 mmHg (SD 7.4 mmHg) before surgery to 14.2 mmHg (SD 2.9 mmHg) at 12 months after surgery ($p < 0.001$).

Glaucoma medicine reduction

Number of people analysed: 41 people, 54 eyes

Follow up at time of assessment: 12 months

- There was a statistically significant decrease in mean glaucoma medicine use from 2.9 (SD 1.0) before surgery to 0.6 (SD 1.1) at 12 months after surgery ($p < 0.001$).

Surgical success

Number of people analysed: 41 people, 54 eyes

Follow up at time of assessment: 12 months

- Complete success was achieved in 46% of eyes, with a further 19% achieving qualified success.
- Failure was seen in 35% of eyes, all due to uncontrolled IOP, 36.8% of which required further filtering surgery.

Key safety findings

Number of people analysed: 41 people, 54 eyes

Follow up at time of assessment: 12 months

Self-resolving hyphaema was not considered an adverse event.

- Complications up to 30 days after surgery:
 - IOP spikes over 30 mmHg, n=12
 - Self-resolving endothelial blood stain, n=1

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- Iris atrophy, n=1
- Pupillary block, n=1
- Fibrin plug, n=1
- Complications from 1 month after surgery onwards:
 - IOL subluxation, n=1
 - Additional glaucoma surgery, n=7

Validity and generalisability of the studies

- The studies were similar regarding patient characteristics. However, there were differences in the types of glaucoma permitted – some studies permitted pigmentary or pseudoexfoliative glaucoma as well as primary open-angle glaucoma.
- The surgical technique was highly consistent across studies. Minor differences were seen in the degrees of cannulation (180 degrees twice, or 360 degrees) and in the postoperative care.
- All of the studies included at least some people who had canaloplasty combined with phacoemulsification. Phacoemulsification can often lower IOP by a small amount. Each of the studies that included people who had canaloplasty alone and people who had canaloplasty plus phacoemulsification reported that there were no statistically significant differences in the amount of IOP reduction between the 2 groups.
- CE marked devices were used in all studies.
- Cases were identified retrospectively from patient records. This can lead to selection bias. Furthermore, outcome data was collected as part of normal follow up – this may have been a reason for the high attrition reported by several studies.
- Most studies did not report adjustment for multiple comparisons. Testing many hypotheses without adjustment for multiple comparisons increases the likelihood of finding a statistically significant difference between data that are only different due to chance.
- All studies had a before-and-after design. There were no randomised studies identified.
- Studies were conducted in the US, Germany, Italy, and Switzerland. There may exist differences in clinical practice between the UK and these countries that prevent generalisation of the findings to a UK context.
- The longest follow-up assessment was 2 years, and some studies showed an attenuation of treatment effect over time.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

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Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- [High-intensity focused ultrasound for glaucoma](#) (2019) NICE interventional procedures guidance 661.
- [Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma](#) (2018) NICE interventional procedure guidance 612.
- [Ab externo canaloplasty for primary open-angle glaucoma](#) (2017) NICE interventional procedure 591.
- [Trabecular stent bypass microsurgery for open-angle glaucoma](#) (2017) NICE interventional procedures guidance 575.
- [Trabeculotomy ab interno for open angle glaucoma](#) (2011) NICE interventional procedure guidance 397.

NICE guidelines

- [Glaucoma: diagnosis and management](#) (2017) NICE guideline NG81

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Four professional expert questionnaires for ab interno canaloplasty for open-angle glaucoma were submitted and can be found on the [NICE website](#).

Patient commentators' opinions

NICE's Public Involvement Programme sent questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). NICE received 3 completed questionnaires.

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Company engagement

A structured information request was sent to 2 companies who manufacture a potentially relevant device for use in this procedure. NICE received 2 completed submissions. These were considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Most studies using the OMNI device were included in Appendix A. This is because the OMNI device is capable of ab interno canaloplasty and trabeculotomy and these studies used both techniques. This overview is focused on ab interno canaloplasty alone.
- A randomised controlled trial of OMNI vs. iTrack for open-angle glaucoma is upcoming ([NCT04769453](#)). This is sponsored by Nova Eye, the manufacturer of the iTrack device.

References

1. Gallardo MJ. (2021) 24-month efficacy of viscodilation of schlemm's canal and the distal outflow system with iTrack ab-interno canaloplasty for the treatment of primary open-angle glaucoma. *Clinical Ophthalmology* 15:1591-9.
2. Tracer N, Dickerson JE, and Radcliffe NM. (2020) Circumferential viscodilation ab interno combined with phacoemulsification for treatment of open-angle glaucoma: 12-month outcomes. *Clinical Ophthalmology* 14:1357-64.
3. Hughes T and Traynor M. (2020) Clinical results of ab interno canaloplasty in patients with open-angle glaucoma. *Clinical Ophthalmology* 14:3641-50.
4. Ondrejka S and Korber N. (2019) 360-degree ab-interno schlemm's canal viscodilation in primary open-angle glaucoma. *Clinical Ophthalmology* 13:1235-46.
5. Toneatto G, Zeppieri M, Papa V, et al. (2022) 360° Ab-interno schlemm's canal viscodilation with OMNI viscosurgical systems for open-angle glaucoma-midterm results. *Journal of Clinical Medicine* 11(1).
6. Gillmann K, Aref A, Niegowski LJ, and Baumgartner JM. (2021) Combined ab interno viscocanaloplasty (ABiC) in open-angle glaucoma: 12-month outcomes. *International Ophthalmology* 41(10):3295-301.

Literature search strategy

| Databases | Date searched | Version/files |
|---|---------------|-------------------------------|
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library) | 29/11/2021 | Issue 11 of 12, November 2021 |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 29/11/2021 | Issue 11 of 12, November 2021 |
| International HTA database | 29/11/2021 | - |
| MEDLINE (Ovid) | 29/11/2021 | 1946 to November 24, 2021 |
| MEDLINE In-Process (Ovid) & MEDLINE ePubs ahead of print (Ovid) | 29/11/2021 | 1946 to November 24, 2021 |
| EMBASE (Ovid) | 29/11/2021 | 1974 to 2021 November 24 |
| Embase Conference (Ovid) | 29/11/2021 | 1974 to 2021 November 24 |

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

MEDLINE search strategy

The MEDLINE search strategy was translated for use in the other sources.

- 1 Glaucoma, Open-Angle/
- 2 ((Primary or second* or refract* or compensat*) adj4 open angle glaucoma*).tw.
- 3 (POAG or COAG).tw.
- 4 Ocular Hypertension/
- 5 Intraocular Pressure/

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6 IOP.tw.
7 ((Ocular* or intraocul* or eye) adj4 (hypertens* or pressure*)).tw.
8 (open adj4 angle* adj4 glaucoma*).tw.
9 Pseudo-exfoliative glaucoma.tw.
10 Pigment* glaucoma*.tw.
11 (simpl* adj4 glaucoma).tw.
12 or/1-11
13 ab interno.tw.
14 canaloplast*.tw.
15 ABiC.tw.
16 (circumferent* adj4 viscodilat*).tw.
17 or/13-16
18 12 and 17
19 iTrack.tw.
20 18 or 19
21 Animals/ not Humans/
22 20 not 21

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the [summary of the key evidence](#). It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

| Article | Number of patients/ follow up | Direction of conclusions | Reasons for non-inclusion in summary of key evidence section |
|--|---|---|--|
| Brown RH, Tsegaw S, Dhamdhare K, and Lynch MG. (2020) Viscodilation of Schlemm canal and trabeculotomy combined with cataract surgery for reducing intraocular pressure in open-angle glaucoma. Journal of cataract and refractive surgery 46(4) | n=24 people, 41 eyes FU=4.1 months | This study found that OMNI combined with phacoemulsification reduced intraocular pressure. The magnitude of pressure lowering with OMNI was highly correlated with the preoperative intraocular pressure. | Combined use of canaloplasty and trabeculotomy. |
| Davids AM, Pahlitzsch M, Boeker A, et al. (2019) Ab interno canaloplasty (ABIC)-12-month results of a new minimally invasive glaucoma surgery (MIGS). Graefe's archive for clinical and experimental ophthalmology 257(9):1947-53 | n=28 people, 36 eyes FU=12 months | Ab interno canaloplasty effectively lowered the IOP in primary open-angle glaucoma in the short-term follow up of 12 months. A reduction of glaucoma therapy was not achieved. | Studies with more people or longer follow up were included. |
| Docherty G, Waldner D, Schlenker M, et al. (2020) Ab Interno Canaloplasty in Open-angle Glaucoma Patients Combined With In Vivo Trypan | n=5 people FU=up to 18 months | The primary purpose of this paper is to describe canalogram patterns observed during ab interno canaloplasty with trypan blue. There were drops in intraocular | Studies with more people or longer follow up were included. |

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| Article | Number of patients/ follow up | Direction of conclusions | Reasons for non-inclusion in summary of key evidence section |
|---|--|--|--|
| Blue Aqueous Venography. Journal of glaucoma 29(12):e130-e134 | | pressure and medicine use in all patients treated. There were no complications. | |
| Gallardo MJ, Supnet RA, Ahmed IIK. (2018) Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. Clinical Ophthalmology 12:2149-55 | n=68 people, 75 eyes FU=12 months | Ab interno canaloplasty was effective at reducing IOP and medicine use in eyes with uncontrolled primary open-angle glaucoma with or without cataract surgery. | Overlap with Gallardo (2021), with shorter follow up. |
| Gallardo MJ, Supnet RA, and Ahmed IIK. (2018) Circumferential viscodilation of Schlemm's canal for open-angle glaucoma: Ab-interno vs ab-externo canaloplasty with tensioning suture. Clinical Ophthalmology 12:2493-2498 | n=12, 12 eyes FU=12 months | This paired eye study found ab interno canaloplasty to have comparable IOP lowering and glaucoma medicine reduction to ab externo canaloplasty in open-angle glaucoma. This suggests ab interno canaloplasty may be a suitable method for improving aqueous outflow via the trabecular pathway. Further large-scale investigation is needed. | Studies with more people or longer follow up included. |
| Gallardo MJ, Sarkisian SR, Vold SD, et al. (2021) Canaloplasty and trabeculotomy combined with phacoemulsification in open-angle glaucoma: Interim results from the GEMINI study. Clinical Ophthalmology 15:481-489 | n=137 people FU=6 months | Canaloplasty followed with trabeculotomy (performed by the OMNI system) and performed concomitantly with phacoemulsification has favourable intra and perioperative safety, significantly reduces intraocular pressure and glaucoma medicines through 6 months in eyes with mild-moderate open-angle glaucoma. | Combined use of canaloplasty and trabeculotomy. |

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| Article | Number of patients/ follow up | Direction of conclusions | Reasons for non-inclusion in summary of key evidence section |
|---|--|--|---|
| Gillmann K and Mansouri K. (2020) Minimally Invasive Glaucoma Surgery: Where Is the Evidence? Asia-Pacific journal of ophthalmology 9(3):203-14 | n=4 studies | Systematic review and meta-analysis. Based on meta-analysis of 4 studies, ab interno canaloplasty reduced intraocular pressure by 36.2% and reduced glaucoma medicine use by 62.1%. | One of the studies included in the meta-analysis used ab externo canaloplasty. The other 3 studies are either described in the key evidence or appendix of this overview. |
| Grabska-Liberek I, Duda P, Rogowska M, et al. (2021) 12-month interim results of a prospective study of patients with mild to moderate open-angle glaucoma undergoing combined viscodilation of Schlemm's canal and collector channels and 360degree trabeculotomy as a standalone procedure or combined with cataract surgery. European Journal of Ophthalmology | n=15 people, 17 eyes FU=12 months | Viscodilation of Schlemm's canal and collector channels paired with ab interno trabeculotomy performed with a single integrated instrument (OMNI), whether as standalone or combined with phacoemulsification, effectively lowers both IOP and the need for glaucoma medicines through 12 months of follow up. | Combined use of canaloplasty and trabeculotomy. |
| Habash AA, Aljindan M, Alrushoud M, et al. (2020) Combined gonioscopy-assisted transluminal trabeculotomy (GATT) with ab interno canaloplasty (ABiC) in conjunction with phacoemulsification: 12-month outcomes. Clinical Ophthalmology 14: 2491-96 | n=19 people, 20 eyes FU=12 months | The 12-month results of this study suggest that combined GATT with ab interno canaloplasty in conjunction with phacoemulsification is a safe and effective alternative in decreasing the IOP and number of glaucoma medicines in people with primary open-angle glaucoma. | Combined use of canaloplasty and trabeculotomy. |

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| Article | Number of patients/ follow up | Direction of conclusions | Reasons for non-inclusion in summary of key evidence section |
|---|--|---|--|
| Heersink M and Dovich JA. (2019) Ab interno canaloplasty combined with trabecular bypass stenting in eyes with primary open-angle glaucoma. <i>Clinical Ophthalmology</i> 13:1533-42 | n=86 eyes FU=6 months | At 6 months, a greater proportion of people who had cataract extraction, trabecular meshwork bypass, and canaloplasty achieved an IOP reduction of 20% or more and an IOP of less than 18 mmHg on the same or fewer medicines than for people who had trabecular meshwork bypass and cataract extraction. | Combined use of canaloplasty and stenting. |
| Hirsch L, Cotliar J, Vold S, et al. (2021) Canaloplasty and trabeculotomy ab interno with the OMNI system combined with cataract surgery in open-angle glaucoma: 12-month outcomes from the ROMEO study. <i>Journal of cataract and refractive surgery</i> 47(7):907-15 | n=81 FU=12 months | The OMNI system provided effective IOP reduction, sustained IOP control, and meaningful medicine reduction for up to 12 months postoperative. | Combined use of canaloplasty and trabeculotomy. |
| Kazerounian S, Zimbelmann M, Lortscher M et al. (2021) Canaloplasty ab interno (AbiC) - 2-Year-Results of a Novel Minimally Invasive Glaucoma Surgery (MIGS) Technique. <i>Klinische Monatsblätter für Augenheilkunde</i> 238(10):1113-9 | n=23 people, 25 eyes FU=24 months | Ab interno canaloplasty performed independently or combined with cataract surgery seems to be a safe and effective MIGS-technique with good long-term regulation of IOP and low risk profile. | Studies with more people included. |
| Körper N. (2018) Ab interno canaloplasty for the treatment of glaucoma: a case | n=20 people, 20 eyes | Findings from this study indicate that ab interno canaloplasty is comparable to | Studies with more people or longer follow up included. |

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| Article | Number of patients/ follow up | Direction of conclusions | Reasons for non-inclusion in summary of key evidence section |
|--|---------------------------------------|---|---|
| series study. Spektrum der Augenheilkunde : Zeitschrift der Osterreichischen Ophthalmologischen Gesellschaft, OOG 32(6) | FU=12 months | conventional canaloplasty in lowering IOP and medicine dependency. Long-term follow up in a large cohort is required to confirm the efficacy of this minimally invasive glaucoma procedure | |
| Porsia L and Nicoletti M. (2020) Combined viscodilation of schlemm's canal and collector channels and 360degree ab-interno trabeculotomy for congenital glaucoma associated with sturge-weber syndrome. International Medical Case Reports Journal 13:217-20 | n=1 FU=10 months | Successful treatment of glaucoma in an infant. Through 10 months of follow-up, intraocular pressure was adequately controlled without the need for adjunctive medical therapy. | Studies with more people or longer follow up included. |
| Pyfer MF, Gallardo M, Campbell A, et al. (2021) Suppression of diurnal (9am-4pm) IOP fluctuations with minimally invasive glaucoma surgery: An analysis of data from the prospective, multicenter, single-arm GEMINI study. Clinical Ophthalmology 15:3931-8 | n=128 people FU=12 months | This study shows that eyes with open-angle glaucoma can benefit from an overall decreased IOP and degree of IOP fluctuations for as long as 12 months after surgical treatment with canaloplasty and trabeculotomy. | Combined use of canaloplasty and trabeculotomy. |
| Villa KRM, Agudelo N, Rubio B, et al. (2019) Ab interno canaloplasty after failed trabeculectomy in uncontrolled open-angle glaucoma. | n=7 people, 9 eyes FU=6 months | In people with uncontrolled open-angle glaucoma after failed trabeculectomy ab interno canaloplasty appears to be a safe and effective procedure. At 6 | Conference abstract. Studies with more people or longer follow up included. |

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| Article | Number of patients/ follow up | Direction of conclusions | Reasons for non-inclusion in summary of key evidence section |
|---|--|---|--|
| Investigative Ophthalmology and Visual Science 60(9) | | months follow up reduction in IOP remain stable and reduction in glaucoma medicines was significantly reduced. | |
| Vizzari G and Bordin P. (2018) Mid and long-term outcomes of viscodilation associated with trabeculotomy using the VISCO360 microinvasive device for the treatment of open angle glaucoma. Investigative Ophthalmology and Visual Science 59(9) | n=37 people, 55 eyes FU=12 months | Viscodilation and trabeculotomy achieved a high percentage of surgical success during the whole follow up time and was effective in preventing the most serious immediate complications of other most invasive surgeries. | Conference abstract. Combined use of canaloplasty and trabeculotomy. |
| Vold SD, Williamson, BK, Hirsch L, et al. (2021) Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: The ROMEO Study. Ophthalmology Glaucoma 4(2):173-81 | n=48 FU=12 months | The sequential combination of canaloplasty followed by trabeculotomy performed as stand-alone procedures using the OMNI system in pseudophakic patients with open-angle glaucoma provides effective IOP reduction or sustained IOP control and meaningful medicine reduction for up to 12 months postoperatively. | Combined use of canaloplasty and trabeculotomy. |