NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1862 Ab interno canaloplasty for open-angle glaucoma**

Your information

Name:	Augusto Azuara-Blanco
Job title:	Clinical Professor of Ophthalmology and Honorary Consultant Ophthalmologist
Organisation:	Queen's University Belfast and Belfast Health and Social Care Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Ophthalmologists
Nominated/ratified by (if applicable):	Royal College of Ophthalmologists
Registration number (e.g. GMC, NMC, HCPC)	GMC 4388241

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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X I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

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Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I don't have experience this this procedure I have experience with similar procedures
	Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I am not certain, but I suspect that this procedure is done by a small minority of NHS surgeons It is only done by ophthalmologists with a special interest in glaucoma surgery My specialty (glaucoma) is the one dealing with patients with glaucoma.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. YES I have done research on this procedure in laboratory settings (e.g. device-related research). NO I have done clinical research on this procedure involving patients or healthy volunteers. NO I have published this research. NO I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is a minor variation of other glaucoma surgeries called “angle surgeries”. The novel approach is the use of an illuminated catheter. Alternatively a similar intervention can be done with a non-illuminated catheter or without any catheter. “Angle surgeries” are gaining popularity but not standard surgical practice Established practice and no longer new. NO A minor variation on an existing procedure, which is unlikely to alter the procedure’s safety and efficacy. YES Definitely novel and of uncertain safety and efficacy. NO The first in a new class of procedure. NO
4	Does this procedure/technology have the potential to replace current standard care or	It will not replace current standard glaucoma surgery. However it has the potential to be used in different scenarios with different goals, e.g., to reduce the need for glaucoma medications

	would it be used as an addition to existing standard care?	

Current management

5	Please describe the current standard of care that is used in the NHS.	Glaucoma is a chronic condition, most patients have open angle glaucoma and are treated with eye drops and laser. Standard glaucoma surgery, trabeculetomy, is an option for those with uncontrolled disease in spite of laser and medications (eye drops), particularly those with severe disease. This procedure under evaluation is part of a group of novel surgeries called MIGS (Minimally Invasive Glaucoma Surgeries) which are typically safer and less effective than trabeculectomy. MIGS are typically used at the time of cataract surgery.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Yes, there is a number of competing alternatives within the type of surgeries called MIGS. This intervention is described as angle surgery, or angle MIGS. They probably have similar efficacy profile, and there risk of severe complications is very small. Perhaps a detailed description is not needed in this document but please let me know if you want more information

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reduction of the number of glaucoma drops required to control the disease
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those undergoing cataract surgery or with a history of cataract surgery Those with mild or moderate glaucoma.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Glaucoma is a slowly progressive chronic condition. I don't think this technology will help reduce the number of people with severe vision loss because it is not very effective. But it will probably help to reduce the number of glaucoma medications which is of value. It may reduce marginally the need for standard glaucoma surgery but not substantially
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Considering that generic glaucoma medications are not expensive, I don't think the technology will result in cost saving
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Overall it is not going to make a huge difference in current resources
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	This technology would be used in the operating theatre, using standard equipment (e.g., microscope, instructions)

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, some training would be required, but it would be easy to learn for active glaucoma surgeons

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	The procedure has a good safety profile, with very small risk of severe complications. Perhaps the most common may be a minor bleeding in the eye which typically resolved without any serious consequence. There is poor evidence base, no RCT evidence, publications with high risk of bias See: Bicket AK, et al. Minimally Invasive Glaucoma Surgical Techniques for Open-Angle Glaucoma: An Overview of Cochrane Systematic Reviews and Network Meta-analysis. JAMA Ophthalmol. 2021 Sep 1;139(9):983-989.
15	Please list the key efficacy outcomes for this procedure/technology?	Intraocular pressure Number of glaucoma medications Need for additional glaucoma surgery Quality of life Cost-effectiveness
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	There is uncertainty about effectiveness, and particularly about comparative effectiveness among different novel glaucoma surgeries, e.g., angle MIGS

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Uncertainty about effectiveness
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. PROBABLY COULD BE DONE IN MOST HOSPITALS WITH EYE SURGEONS A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present. CORRECT

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Not aware of unpublished studies
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not aware of unpublished studies

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Thousands?
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No if there is evidence of its effectiveness and cost-effectiveness
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No. A RCT would help. Registry data or electronic medical record data would also be useful
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	**Beneficial outcome measures:** For short-term and long term: Intraocular pressure (part of standard care) Number of glaucoma medications Need for additional glaucoma surgery Quality of life: several instruments, some designed for evaluating novel glaucoma surgeries Disease progression (only long-term) Cost-effectiveness

		Adverse outcome measures: frequency and severity of complications

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	None

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	none		
Choose an item.			
Choose an item.			

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

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Print name:	**Augusto Azuara-Blanco**
Dated:	**02-02-2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1862 Ab interno canaloplasty for open-angle glaucoma**

Your information

Name:	Konstantinos Giannouladis
Job title:	Consultant Ophthalmologist – Special interest in Glaucoma
Organisation:	Nottingham University Hospitals
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Ophthalmologists
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC: 7023127

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1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have been doing procedures with the iTrack microcatheter since 2017 during my fellowship and then continued in 2018 as a consultant. I have been doing AbiC more over the last year but the majority of my procedures with the catheter are GATT (Gonioscopically assisted transluminal trabeculotomy). I have read the literature and I have used it in both straightforward and more complex cases. Due to the complexity of my work in Nottingham and the multitude of technologies/ Techniques available in my disposal (iStent, AbiC, GATT Preserflo, Trabeculectomy PAUL tube) Abic only forms as small part of procedures for the prescribed indication and patient population.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	- The technique as far as I am aware is only used in a handful of places. With regards to uptake I think the technique as described with the Ellex branded catheter isn't going to have a very quick uptake. There is a competitive system (OMNI) which effectively does the same thing that will see a much greater and quicker penetration in the market. Despite the differences of the system/device the technique in question (Canaloplasty through an ab interno approach) is the same. This is confirmed by the studies done with the OMNI system which are in agreement with previous studies with the catheter. - The illuminated catheter technology has a potential benefit in terms of safety which would be very relevant in more complex and paediatric cases. - As a glaucoma surgeon undertaking this procedure I would treat my own cases or cases referred to me. I currently do about 40 procedures a year using the illuminated microcatheter, however the majority are of the GATT variety and not AbiC.

	procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. – YES as part of personal research I have done research on this procedure in laboratory settings (e.g. device-related research). - NO I have done clinical research on this procedure involving patients or healthy volunteers. - NO I have published this research. – no I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	This is novel to the UK but has a long history of application in Europe and the US where it would be considered standard of care. Comparing to the traditional Trabeculectomy and Tube surgery in the UK environment it is novel, compared to the rest of the world and with new RCTs on the back of the OMNI device confirming pervious years of studies it is no longer new. Established practice and no longer new. - X A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	This would be used in addition to current standard care. This procedure is one of the true MIGS. It has a place in a wide range of cases and should be offered by a glaucoma surgeon trained in the full range of glaucoma surgery.

Current management

5	Please describe the current standard of care that is used in the NHS.	Currently the surgical standard of care would still be considered trabeculectomy surgery. However this is rapidly changing the last couple of years with the rapid uptake of the preserflo microshunt and procedures such as AbiC and GATT. Also many units are also using the istent or Hydrus and all this variation has to do with local peculiarities and preferences.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	The OMNI device has recently been approved. This is effectively offers the option to do the same procedures : canaloplasty and trabeculotomy. The difference is that AbiC traditionally is done with the Ellex illuminated microcatheter and there are certain benefits (illumination allows some greater feeling of safety and maybe useful in unusual anatomy – not applicable in standard open angle glaucoma). The OMNI however has lower costs in setup time and in theory the design of the catheter there should allow for safe guidance without illumination.(no safety issues reported on the studies). So the same procedure can be done quickly and with no assistant. In addition the same devices can be used for GATT which is more invasive but it is much more efficacious and it is gaining significant ground.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	There is a cohort of patients who would benefit greatly from this technology as it would reduce medication burden for several years and because it can be combined well with cataract surgery even in advanced cases it can be considered as a way to set a stage for later subconjunctival surgery. Inflammation after cataract surgery can last for up to 6 months which can cause issues with subconjunctival surgery.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	It can be used in most cases where the trabecular meshwork can be accessed.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Overall as a procedure the follow up is much less intensive than traditional trabeculectomy (requiring weekly appointments in the first month and 2-3 weekly until 3 months) This requires appointments at 1 week – 3-4 weeks then another 4-6 weeks depending on the eye pressure measured. Depending on patient selection 50% of patients can be medication free or have reduced medication at 3 to 5 years. In terms of onward surgery in this cohort with the addition of drops (if appropriate) more invasive surgery can be delayed for longer.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Overall it should be less, if we are comparing like for like. It is definitely less with regards to reducing medication burden and vision loss by allowing earlier intervention. It might be more if you account for higher use of the technology (ie since it is safe it will be used in more and earlier cases, which would be beneficial for the patients but would show as somewhat increased cost. However an economic analysis would be necessary to account for the reduced appointments and medications and anciliary costs)
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Less overall and also more patients can be treated.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Most departments should already have a tilting microscope(the majority of ophthalmic microscopes have this facility for the last 10 years) but there are also alternative lenses which can be used if they don't.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes training in a glaucoma unit undertaking the procedure is necessary, usually this is part of the fellowship. Alternatively, currently practicing glaucoma consultants can acquire the skill and knowledge through seminars and training attachments. From experience teaching the procedure it does require a certain level of skill and practice before undertaking it safely.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Descements detachment ~10% self limiting Microhyphema / hyphema ~ 10% self limiting usually clears within 1-2 weeks Transient refractive change that can last for 6 weeks ~20-30% not of practical significance unless refractive cataract surgery is considered at the same time, in which case the surgeon should be aware and time the measurements appropriately IOP spikes ~30% these can be significant and care is required particularly in advanced glaucoma cases. This is medically managed and lasts about a week. These do not effect the efficacy of the procedure, which is usually assessed at the 6 -8 week mark once the effect of the post operative steroid has started waning. Catheter entering a collector channel , intraoperative, noticed by the illumination and of no significance. Would require changing the approach and increase surgical time a bit. The illuminated catheter protects from this by noting the abnormal movement of the light, the OMNI device by being more rigid and avoid misdirection that way. There are case reports of the catheter entering the subretinal space and even reaching posteriorly towards the macular area. These are certainly cautionary tales but can be explained by either very complex and surgically challenging cases and/or poor technique. Fortunately I haven't encountered such problems but I can understand how it would be possible to do..
15	Please list the key efficacy outcomes for this procedure/technology?	For Abic in particular would be improve IOP with same or reduced medication burden.

16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	I would have concerns if someone tries to do the procedure with poor training as there is a certain learning curve. If a surgeon is already undertaking angle surgery then it is definitely easier and quick but it can be trickier than it looks. Efficacy is similar to currently approved procedures (istent, hydrus) with the benefit that a wider area of the drainage system is treated and no implant left in place. Case selection is critical.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	This is certainly not a “trab killer”. As a procedure it can treat a wider range of high IOP more predictably than the iStent (already NICE approved) without the need for leaving an implant. It is also a good option for MIGS in patients with angle closure glaucoma or pigmented irides where when TM implants are used there is a higher rate of failure at the 1-2 year mark due to synechiae/occlusion. Some surgeons feel that it “doesn’t” work, but I think that has to do more with case selection and expectations. I would personally consider AbiC a very good add-on when safety, quick visual recovery is required and some chance of reduced medication is appreciated. Again case selection is critical.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. **Fewer than 10 specialist centres in the UK.** Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature	I’m terribly sorry but I don’t have the time at the moment. I would advise you to also search for the studies done with the OMNI and VISCO360. There are now RCTs available with results consistent with previous research.

	searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not sure

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Judging from my cohort it can be 7-30% depending on the availability of istent/hydrus and patient / surgeon preference.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	It should be done by a trained glaucoma surgeon
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Until recently there wasn't any centres undertaking these procedures (GATT, AbiC) so training with the catheter wasn't possible. With the introduction of OMNI and stronger presence of competition and marketing this will change
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	In more complex cases the technique can have underwhelming or unexpected results, it isn't clear how it can be predicted clinically but surgeon experience helps. Also there is rational in using it in combination with angle closure cataract surgery but the studies are few. Longer term studies and reports would be helpful.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life	Beneficial outcome measures: -IOP reduction >20% from baseline short-long term - medication reduction short/medium term - stability of RNFL medium/long term

	measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	- stability of HVF long term Short= 3-6 months medium=12=24 months long term 36+months Adverse outcome measures: IOP spikes IOP >30% or >30 within 6 weeks of surgery. Descemets detachment >1mm from limbus or affecting vision. (1-2 weeks) .

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	In general it is a useful tool in modern glaucoma management. Choosing cases carefully is important and if there are resource issues (ie devices such as istent or hydrus aren't available) either ellex or omni can serve as multipurpose tools to address a wide spectrum of glaucoma disease starting from early to late particularly when both the option of Abic and GATT are considered. For Paediatric cases and complex anatomy the illuminated catheter may be preferable as there are more studies and experience.

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

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Print name:	**Konstantinos Giannouladis**
Dated:	**01/02/2022**

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Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1862 Ab interno canaloplasty for open-angle glaucoma**

Your information

Name:	Professor Sir Peng Tee Khaw
Job title:	Director of the UK National Institute for Health Research Biomedical Research Centre in Ophthalmology at Moorfields Eye Hospital and UCL Institute of Ophthalmology, Director of Research and Development at Moofields Eye Hospital, Consultant Ophthalmic Surgeon at Moofields Eye Hospital and Professor of Glaucoma Studies and Wound Healing at UCL Institute of Ophthalmology and Moorfields Eye Hospital
Organisation:	Moorfields Eye Hospital and University College London Institute of Ophthalmology
Email address:	p.khaw@nhs.net
Professional organisation or society membership/affiliation:	President of UK Paediatric Glaucoma Society (UKPGS); Master of the Oxford Ophthalmological Congress and Ophthalmology Foundation Board Member
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	GMC Registration Number 2636997

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Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Yes Variant used on patients with glaucoma particularly children where the success rate is high Cannulation of the schlemms microcanal requires considerable experience and we have been operating on this canal structure for 25+ years Not widely used at present Speed of uptake will depend on training and results in adult open angle glaucoma No

	− Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	Patient selection – currently mainly children
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. yes I have done research on this procedure in laboratory settings (e.g. device-related research). No I have done clinical research on this procedure involving patients or healthy volunteers. Only audit and not the full canaloplasty I have published this research. No I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	This generic procedure (cannulating the microscopic Schlemms canal which drains through the porous trabecular meshwork extending 360 degrees around the anterior chamber of the eye and is the main aqueous outflow passage) called trabecuLOTOMY as opposed to trabecuLECTOMY (drainage channel with flap) was first described many decades ago. However there have been small evolutions of this procedure using metal microscnnulas and adapted microstitches. The ab interno canaloplasty using the itack cannula differs in that it uses a fibreoptic microcannula that has a hollow lumen that can be used to inject viscoelastic gel into the canal to dilate it and also has a fibreoptic with a helium neon beam that aids visualisation for safety. A suture is tied onto the cannula and passed 360 degrees and tied opening up the canal. Alternatively The cannula can also be “ripped” out of the canal opening it up

		Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. **Definitely novel and of uncertain safety and efficacy. Jury still out on efficacy in adults** The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Cannot completely replace surgery making a new outflow channel (trabeculectomy) or tube drainage surgerywhich lowers pressure better

Current management

5	Please describe the current standard of care that is used in the NHS.	Pressure lowering eyedrops ist choice Latanoprost then add drops Laser trabeculoplasty to increase outflow through trabecular meshwork Possibly angle surgery (Multiple devices) Canaloplasty fits in here external filtration surgery via device or making a drainage flap
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?	

	If so, how do these differ from the procedure/technology described in the briefing?	

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Relatively less invasive than trabeculectomy filtering surgery the gold standard drainage surgery
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Not clear
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Not hugely Possible
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	More than trabeculectomy if itrack is used
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Cost more possibly safer but less pressure lowering
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Itrack cannula and training

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes skillful procedure needs training

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Significant Bleeding 10% cyclodialysis (tear at base iris) 1% retinal detachment (one case seen) >1/500
15	Please list the key efficacy outcomes for this procedure/technology?	Pressur lowering degree and drop usage
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term efficacy uncertain
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. **A minority of hospitals, but at least 10 in the UK.** Fewer than 10 specialist centres in the UK.

		Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	None recent
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not known

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Thousands
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Training and skill

23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Cost and efficacy
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Full trial
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Pressure lowering Cessation drop use Adverse outcome measures: Visual acuity loss visual field loss other complications

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Indirect	Advisory board santen which makes the preserflo drainage implant	**2021**	**2022**
Choose an item.			
Choose an item.			

X **Yes** I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**PROFESSOR SIR PENG TEE KHAW**
Dated:	**26 JANUARY 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1862 Ab interno canaloplasty for open-angle glaucoma**

Your information

Name:	Andrew Tatham
Job title:	Consultant Ophthalmologist
Organisation:	NHS Lothian
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Ophthalmologists
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC - 6054449

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

X I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I have performed 15 ab interno canaloplasty procedures in patients with glaucoma, all using the OMNI device. I started using the device in Spring 2021 and am still using it. I also perform other canal-based glaucoma procedures, including the Hydrus and iStent trabecular meshwork bypass procedures. I also perform most other types of glaucoma surgery, including trabeculectomy and glaucoma drainage device surgery. Ab interno canaloplasty has been around for at least 10 years and is particularly common in the United States. I am aware of two devices that allow ab interno canaloplasty, one uses an illuminated light pipe (iTrack, Ellex), the other a non-illuminated catheter (OMNI, Sight Sciences). The procedure does seem to be becoming more common in the UK, I think partly due to the improved ease of use of OMNI. Ab interno canaloplasty aims to decrease intraocular pressure (IOP) but opening Schlemm's canal and enhancing the conventional route of aqueous outflow. It involves ab interno passing a microcatheter through the trabecular meshwork into Schlemm's canal. The catheter is then passed through Schlemm's canal, usually over the entire length of the canal (360 degrees), either in one step (as with iTrack) or along 180 degrees, followed by the second 180 degrees (OMNI). As the catheter is withdrawn from the canal, viscoelastic is deposited within the canal. Viscoelastic also passes through the trabecular meshwork and into the proximal collector channels, in theory dilating the channels and improving outflow. The procedure is sometimes combined with ab interno trabeculotomy, which involves using the catheter to tear through the trabecular meshwork. This is a more invasive step than canaloplasty alone, increasing the risk of bleeding, but potentially increasing the chances of IOP reduction.

	procedure/technology, please indicate your experience with it.	While these procedures are still relatively uncommon in the UK, a survey of American Glaucoma Society members in 2019, which asked glaucoma surgeons to choose a glaucoma procedure they would prefer performed on themselves were they to be diagnosed with glaucoma, found ab interno trabeculotomy was the most preferred or second most preferred procedure depending on hypothetical pre-operative IOP level. The procedure may be performed by non-glaucoma specialist cataract surgeons, but I think it would be better performed by glaucoma specialists.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	I think the answer to this depends on the exact procedure performed. Overall I would say it is a minor variation of other canal-based glaucoma surgery. Ab interno canaloplasty alone (canulation and viscodilation of Schlemm's canal) is a more novel treatment than ab interno canaloplasty combined with trabeculotomy (tearing of the trabecular meshwork). There are several procedures that involve ab interno trabeculotomy, some of which NICE have already reviewed. These include Trabectome and Kahook Dual Blade. It is likely that the efficacy of ab interno canaloplasty combined with trabeculotomy is similar to these procedures. Ab interno canaloplasty without trabeculotomy is likely safer than these procedures as it doesn't involve tearing or removing tissue, but the efficacy compared to these procedures is uncertain. A potential advantage of ab interno canaloplasty is that allows 360 degrees of Schlemm's canal to be treated, whereas other procedures tend to treat 120 degrees at most. This is a difficult choice between - A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy.

		I would choose the former if combined with trabeculotomy and the latter if performed alone.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It has the potential to replace other ab interno minimally invasive glaucoma procedures.

Current management

5	Please describe the current standard of care that is used in the NHS.	The current similar procedures are ab interno trabeculotomy or ab interno minimally invasive glaucoma surgery procedures including Trabectome, Kahook Dual Blade, iStent, Hydrus. These tend to be offered either to reduce dependency on glaucoma medications, or to patients with mild to moderate glaucoma with suboptimal IOP. They are often combined with cataract surgery.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Discussed in answer to question 3.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Offers the potential for improved control of disease, with reduced dependency on topical medications. This may help overcome problems of medication side effects such as ocular surface disease, and problems associated with poor adherence. There is also the potential for patients to avoid the need for more invasive operations such as trabeculectomy.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those who are unable to instil eye drops or who have medication side effects or problems with adherence.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	The procedure could lead to fewer hospital visits, especially if it reduces the need for subsequent trabeculectomy. If the procedure provides better disease control, there is also the potential that fewer visits may be needed, and vision of affected individuals could be better preserved.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Likely to cost similar to other minimally invasive glaucoma procedures.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Likely to cost similar to other minimally invasive glaucoma procedures.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes to existing facilities.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Device specific training would be needed. The procedure should only be performed by specialist glaucoma surgeons, with results audited.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Bleeding is a potential concern, though this is less likely with ab interno canaloplasty alone, without trabeculotomy. Other adverse events include – IOP increase, Descemet's detachment, formation of peripheral anterior synechiae.
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in IOP, reduction in number of glaucoma medications, reduction in need for further glaucoma surgery, rate of visual field loss.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Ab interno canaloplasty is likely to have a good safety profile. The efficacy of the procedure is less certain, particularly long-term efficacy.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	I don't think so.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	The GEMINI study ClinicalTrials ID: NCT03861169 A prospective, multi-centre single-arm, historic-controlled, interventional clinical trial. Interim 6-month results have been reported.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	This is very difficult to estimate. Glaucoma has a high prevalence but only a small proportion need surgery. The procedure is most likely to be combined with cataract surgery.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The procedure is fairly easy to learn, especially for those already experienced in other minimally invasive glaucoma procedures.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	There are several observational studies and a large quantity of real-world data from the United States, but to the best of my knowledge no RCTs have been published. It would also be useful to have studies comparing ab interno canaloplasty to other minimally invasive glaucoma surgeries. Studies are also needed of standalone MIGS performed without cataract surgery.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Reduction in IOP – Percentage and absolute reduction in IOP 12 months after surgery compared to IOP immediately before surgery and peak IOP before surgery. Number of glaucoma medications – Reduction in glaucoma medications 12 months after surgery compared to before surgery. Change in visual field summary indices – Change in visual field mean deviation at 12 months, 24 months etc, compared to baseline visual field (rate of visual field change). PROMs could include a measure of ocular surface disease which is very prevalent in patients using glaucoma medications and is likely to be improved by reduced dependency on medications after this procedure. Adverse outcome measures: Reduction in visual acuity of ≥2 lines Need for reoperation for complication

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Speaker honorarium for a talk related to the OMNI device in September 2021 (Sight Sciences). Consultancy fee related to the Hydrus device for a meeting in November 2021 (Ivantis)	**September 2021**	**November 2021**
Non-financial personal	Member of the European Glaucoma Society Executive Committee	**December 2020**	**Ongoing**
Choose an item.			

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**ANDREW TATHAM**
Dated:	**23 Feb 2022**