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Expert Consensus on the Use of the PRESERFLO™ MicroShunt Device in the Treatment of Glaucoma

A Modified Delphi Panel

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Expert Consensus on the Use of the PRESERFLO™ MicroShunt Device in the Treatment of Glaucoma: A Modified Delphi Panel

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ABSTRACT

Introduction: The implantation of the PRESERFLO™ MicroShunt (PMS) device has been shown to significantly lower increased intraocular pressure (IOP) in patients with primary open-angle glaucoma (POAG). However, guidelines on best practice for patient selection and

pre-/peri-/postoperative care management are lacking. The aim of this modified Delphi panel was to achieve expert consensus on the role of the PMS to treat patients with glaucoma in Europe.

Methods: Twelve European glaucoma surgeons experienced with the PMS procedure participated in a three-round modified Delphi panel. A targeted literature review and expert steering committee guided round 1 questionnaire development. Consensus was set at a pre-defined threshold of at least 70% of panellists selecting 'Strongly disagree'/'Disagree' or

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‘Strongly agree’/‘Agree’ for six-point Likert scale questions, or at least 70% selecting the same option for multiple-choice questions. Questions not reaching consensus were restated/revised for the next round, following guidance from free-text responses/scoping questions.

Results: Consensus was achieved for 60.3% ($n = 38/63$), 60.0% ($n = 18/30$), and 100.0% ($n = 11/11$) of Likert/multiple-choice questions in rounds 1, 2, and 3, respectively. There was agreement that the PMS procedure is effective at reducing IOP in patients with high-tension POAG (greater than 21 mmHg). Although surgical techniques may vary slightly, consensus was reached on several points, including the importance of posterior application of mitomycin C (MMC). Panellists agreed that the PMS postoperative follow-up appointment schedule is reasonably predictable and mostly characterised by fewer visits than with trabeculectomy, particularly in the early phase. Although panellists agreed that combined cataract/PMS surgery and the use of non-MMC wound-healing modulators/antifibrotics during the procedure are possible, further data are needed to determine efficacy.

Conclusion: The expert consensus reached in this panel will help inform best practice guidelines in the treatment of patients with glaucoma in Europe. Panellists also highlighted key areas for future research to improve understanding of the PMS in the treatment algorithm of glaucoma.

Keywords: Consensus; Delphi method; Europe; Glaucoma; MicroShunt; PRESERFLO™; Open-angle glaucoma

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Key Summary Points

Why carry out this study?

The implantation of the PRESERFLO™ MicroShunt (PMS) device has been shown to significantly lower increased intraocular pressure in patients with primary open-angle glaucoma.

As a relatively new implant made of a novel biocompatible material, guidelines on best practice for patient selection and care management are yet to be developed for the PMS.

The aim of this modified Delphi panel was to achieve expert consensus on the role of the PMS to treat patients with glaucoma in Europe.

What was learned from the study?

The study demonstrated that the expert panel of glaucoma surgeons were largely aligned on patient selection and pre-, peri-, and postoperative care management decisions for the PMS.

The information gathered from this consensus process can be used by surgeons to guide their use of the PMS in clinical practice.

Panellists also highlighted key areas for future research to improve understanding of the PMS in the treatment algorithm of glaucoma.

INTRODUCTION

In Europe, primary open-angle glaucoma (POAG) is the most common form of glaucoma and a leading cause of blindness [1]. Increased intraocular pressure (IOP) is a major risk factor for the development and progression of POAG [2, 3]. Furthermore, reducing IOP is key to slowing disease progression and is critical for

preserving vision and preventing further visual field loss in patients with glaucoma [4].

The first-line treatment for patients with POAG is most often topical IOP-lowering medications, such as prostaglandin analogues and beta-adrenergic antagonists [5]. However, forgetfulness, lack of confidence, and poor tolerance often results in non-adherence, with reported rates ranging from 30% to 80% [6]. Selective laser trabeculoplasty may also be offered as first-line treatment [7]. If medication and/or laser treatment does not achieve adequate IOP reduction, incisional surgeries are often needed [8].

Trabeculectomy and tube shunt surgery are frequently performed incisional glaucoma procedures. However, while these procedures are effective at lowering IOP, they are often associated with postoperative complications and frequently require follow-up interventions [9]. Minimally invasive glaucoma surgery (MIGS; also referred to as micro-invasive glaucoma surgery) procedures were developed as a less invasive alternative to traditional glaucoma surgeries, with the aim to improve safety outcomes and reduce postoperative management of patients. However, IOP reduction is often modest following MIGS procedures [10]. As such, MIGS procedures are indicated in patients with mild-to-moderate glaucoma.

The PRESERFLO™ MicroShunt (PMS; Santen SA; formerly known as the InnFocus MicroShunt) was developed as a subconjunctival glaucoma drainage device composed of poly(styrene-*block*-isobutylene-*block*-styrene [SIBS]), a highly biocompatible and inert material [11, 12]. In contrast to the XEN® 45 Gel Stent (Allergan Inc., Dublin, Ireland) which is a subconjunctival stent implanted using an ab interno approach [13], the PMS is placed using an ab externo approach to facilitate aqueous humour outflow to a bleb [12, 14]. Several clinical studies have shown that the PMS significantly lowers IOP in patients with POAG and has an acceptable safety profile [14–18].

Following these clinical studies demonstrating the long-term safety and efficacy of the PMS, the device has been available for clinical practice in Europe since 2019 [19]. As such, there are a growing number of surgeons with

real-world clinical expertise in treating patients with the PMS. There is an unmet need to collate this expert experience to develop guidelines on all aspects of patient selection and pre-, peri-, and postoperative management of the PMS for patients with glaucoma. The Delphi method is a systematic and robust technique to gather expert consensus on real-world knowledge, using iterative rounds of questions [20]. In this modified Delphi study, conducted between September and December 2021, we sought to establish expert consensus on the role of the PMS to treat patients with glaucoma in Europe.

METHODS

Delphi Panellists

Eligible panellists were glaucoma surgeons based in Europe with extensive experience treating patients with the PMS (more than 100 procedures) and with patients having at least 12 months follow-up (Supplementary Table S1). Panellists were invited via email and asked to respond in the affirmative if they wished to participate in the Delphi panel. Three panellists (APK, IS, and LAP) were invited by the sponsor (Santen SA) to form a steering committee (SC) to guide the development of the statements included in each round of the Delphi panel. One member of the SC was asked to act as the moderator (APK). The moderator critically reviewed questionnaire results and supported the development of subsequent rounds. To avoid potential bias, the moderator did not actively participate in the consensus process. In addition, the sponsor did not actively participate in the consensus process but reviewed the questionnaires to ensure technical accuracy and regulatory compliance. No patients were involved in the study and therefore ethical approval was not required.

Study Design

This study used a modified Delphi method which pre-specified that three or fewer questionnaire rounds would be conducted. The

decision whether to hold a third round was decided by the moderator and SC based on the nature of the results from previous rounds and an assessment of the potential benefits of holding this additional round. A virtual consensus panel meeting with all panellists was held following round 2 of the Delphi panel. This meeting allowed panellists to discuss statements that had not yet reached consensus and provide additional context and considerations for the statements that had reached consensus. Each questionnaire round was delivered through a bespoke web application for Delphi panels. This platform was designed to help enforce key methodological requirements for Delphi panels, such as preventing retrospective amendments to a questionnaire round once it has been opened. All responses provided during the Delphi rounds were anonymised.

Round 1 Questionnaire Development and Distribution

A targeted literature review (TLR) was conducted in July 2021 to collate published information on the PMS. Literature searches were carried out in MEDLINE and Embase (simultaneously via Ovid SP). The Cochrane Library database was also searched. Searches were date-limited from 2016 to present. The list of electronic databases and search terms used are presented in Supplementary Table S2. In addition, a pragmatic literature search of professional society websites and non-peer-reviewed ophthalmology-specific grey literature was carried out to identify any relevant treatment guidelines, expert opinion and/or trends surrounding the clinical application of the PMS.

Following the completion of the TLR, a teleconference call was held with SC members to discuss the results and to determine key objectives of the overall Delphi panel. Insights from the results of the TLR and SC discussions during this teleconference were used to develop the framework of the round 1 questionnaire. Questions were grouped into the following categories: patient selection and preoperative considerations, perioperative considerations, and postoperative considerations. The question

types posed in the survey were Likert scale, yes–no, multiple-choice, or scoping questions. Scoping questions were used to gather insight from panellists and to provide context that would be used to generate more specific questions in subsequent rounds. Answers to the Likert scale questions were provided on a six-point scale: strongly agree, agree, slightly agree, slightly disagree, disagree, or strongly disagree. For each Likert scale question, ‘do not wish to answer’ or ‘insufficient expertise’ options were also included. For each question, panellists were able to provide free-text comments to contextualise their response and/or suggest a change to the statement for the subsequent round.

Rounds 2 and 3 Questionnaire Development and Distribution

Questions that reached consensus in rounds 1 or 2 were removed from the subsequent round. Questions that did not reach consensus could be restated or rephrased in the subsequent round with a view to increasing the likelihood of achieving consensus. Whether to rephrase or restate a question was decided on the basis of the distribution of responses in the previous round, the free-text comments provided by panellists, and the advice of the moderator and SC. Statements that were posed in round 2 but did not reach consensus were discussed during the virtual consensus panel meeting. To encourage elicitation of consensus, for each restated/rephrased statement posed in rounds 2 and 3 panellists were able to view their individual response alongside a chart displaying anonymised summary statistics and all free-text comments provided for the question in the preceding round. Some statements that did not reach consensus in rounds 1 or 2 were not restated or rephrased for a subsequent round. This decision was made by the moderator and SC following an assessment of the level of agreement/disagreement with the statement, the content of free-text responses, and overall value of the statement to the consensus process.

Processing and Synthesis of Results

Results were exported directly from the online survey platform and analysed in Microsoft Excel[®]. The consensus was set at a pre-defined threshold of at least 70% of panellists selecting ‘Strongly disagree’/‘Disagree’ or ‘Strongly agree’/‘Agree’ for six-point Likert scale questions, or at least 70% selecting the same option for yes–no or multiple-choice questions. For Likert scale responses, ‘Slightly agree’ or ‘Slightly disagree’ were not included in the overall calculation of percentage of ‘agreement’ or ‘disagreement’ reported for a given statement. Instead, these responses were used to guide the approach to rephrasing the statement for the subsequent round, if appropriate. As such, for a given statement, the reported percentage of agreement and disagreement may not equal 100%, despite all participants answering the question. The consensus was not assessed for scoping questions or free-text responses.

RESULTS

Delphi Rounds

The round 1 questionnaire was open from 27 September to 4 October 2021; round 2 was open from 20 to 25 October 2021; the virtual consensus panel meeting took place on 18 November 2021; round 3 was open from 30 November to 6 December 2021 (Fig. 1). All 11 panellists eligible to participate completed the round 1, round 2, and round 3 questionnaires. Twelve panellists (including the moderator) attended the virtual consensus panel meeting. Panellists were all experienced glaucoma surgeons and familiar with the PMS implantation procedure.

Of the 78 statements included in the round 1 questionnaire, 15 (19.2%) were posed as scoping questions; for the remaining 63 questions, consensus was reached for 38 (60.3%), whereas 25 (39.7%) did not reach consensus. In total, 31 statements were included in round 2, with one posed as a scoping question (3.2%). Of the remaining 30 statements, 18 (60.0%) reached

consensus, and 12 (40.0%) did not reach consensus. Finally, all 11 statements included in round 3 reached consensus (100%) (Fig. 1).

Patient Selection and Preoperative Considerations

The complete results for statements relating to patient selection and preoperative considerations can be found in Table 1. Panellists agreed that the PMS can be used in patients with POAG to reduce or manage IOP levels, and the device effectively reduces IOP in patients with high-tension POAG (greater than 21 mmHg). Panellists agreed that the PMS is beneficial for the following individuals with POAG: receiving the maximum tolerated dose of glaucoma medication(s) with insufficient IOP control; with progressive visual field loss; and/or demonstrating poor adherence or intolerance to topical medications with topical and/or systemic side effects.

In addition, panellists agreed that the device might also be suitable for patients with off-label diagnoses of pigment dispersion and pseudoexfoliation (in line with conventional filtering surgery). However, on the basis of current evidence, the device should not be used in patients with neovascular glaucoma. The procedure may also be suitable for other forms of glaucoma, but further data will be required to demonstrate efficacy and safety. Although the PMS may be used for patients with high myopia, consensus was not reached on the use of the PMS for patients with the following: well-controlled uveitis without active inflammation; congenital glaucoma; high hyperopia; and normal-tension glaucoma. The following factors should be considered to determine the suitability of patients for the PMS: previous aqueous production limiting factors (e.g. cyclodestructive procedures); corneal endothelial cell count; condition of the conjunctiva; and anterior chamber depth.

Patients are often prepared for the PMS procedure in the same way as trabeculectomy with regards to the frequency of patient visits, assessments and testing, preoperative steroid use, alteration in systemic anti-coagulant and anti-aggregant therapy, and IOP-lowering

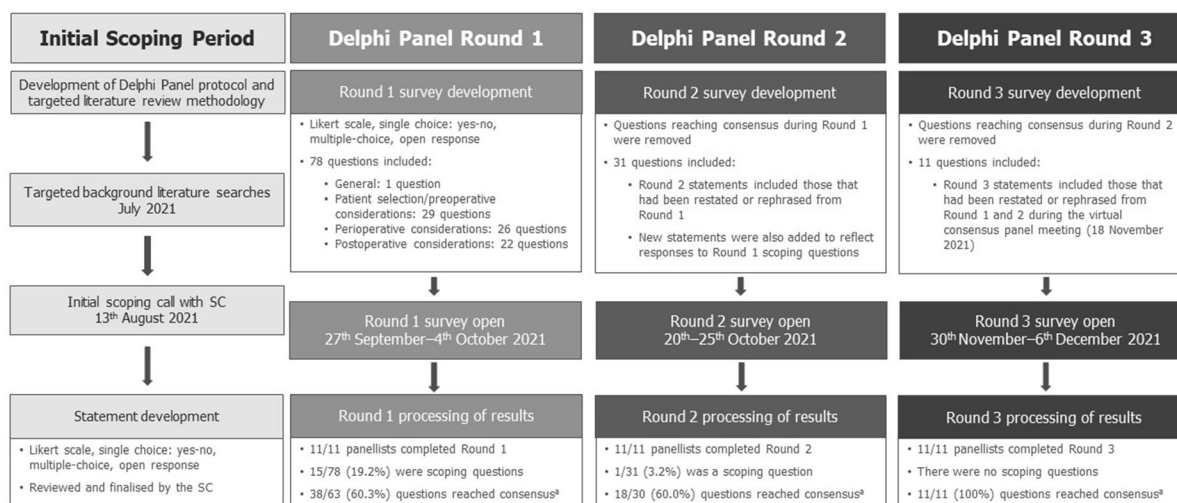


Fig. 1 Delphi panel study design. This study used a modified Delphi method which included an initial scoping period (targeted literature review and scoping call with the SC), three Delphi rounds and a virtual consensus panel meeting. *Consensus was set at a pre-defined threshold of at least 70% of panellists selecting ‘Strongly disagree’/

‘Disagree’ or ‘Strongly agree’/‘Agree’ for six-point Likert scale questions, or at least 70% selecting the same option for yes–no or multiple-choice questions; consensus was not assessed for scoping questions or free-text responses. SC steering committee

medication drop holiday. To optimise surgical outcomes, eligible patients should ideally not have had incisional glaucoma surgery or cataract surgery on the affected eye within the last 12 or 6 months, respectively. Although a shorter interval is possible in both cases, this may be associated with a reduced chance of surgical success. Panellists agreed that although in certain cases the PMS implantation procedure may be considered for patients who have had previous glaucoma surgery with subconjunctival drainage (provided there is a quadrant with the intact conjunctiva amenable to the implantation procedure), the outcome is expected to be less favourable than for primary surgery.

Perioperative Considerations

The full results for statements regarding perioperative considerations can be found in Table 2. Panellists agreed that the PMS is recommended for surgeons experienced and proficient with other filtering surgeries that require manipulation of the conjunctiva and Tenon’s capsule. For experienced surgeons, the procedure is relatively quick to learn. The device is

optimally implanted superiorly at 11 or 1 o’clock (to avoid the superior rectus muscle), using an ab externo approach and performed under local anaesthesia.

It was agreed that during the procedure, an anatomical assessment of Tenon’s capsule (e.g. deficiency, thickness, etc.) might prompt modification of the surgical technique, such as adjusting the mitomycin C (MMC) dose or placing a sclera-fixating suture. No consensus was reached on whether the following steps in the surgical procedure differed from a standard trabeculectomy: conjunctival and Tenon’s incision and dissection; and conjunctival and Tenon’s closure. However, it was agreed that although the size and morphology of the limbal incision may vary between surgeons, similar to trabeculectomy, the formation of a wide and deep posterior pocket is essential to maximise the chance of positive clinical outcomes. In addition, during the procedure particular attention is needed to avoid occlusion of the PMS during Tenon’s closure. It is feasible to perform cataract surgery in conjunction with the PMS, but further evidence on the efficacy of combined surgery is needed.

Table 1 Responses to statements on patient selection and preoperative considerations

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%) ^a	Delphi questionnaire round
The PRESERFLO™ MicroShunt can be used in patients with primary open-angle glaucoma to reduce or manage IOP levels	Agreement	100	Round 1
The PRESERFLO™ MicroShunt is effective at reducing IOP in patients with high-tension primary open-angle glaucoma (IOP > 21 mmHg)	Agreement	100	Round 1
The PRESERFLO™ MicroShunt is beneficial for patients with primary open-angle glaucoma:			
Receiving the maximum tolerated dose of glaucoma medication(s) with insufficient IOP control	Agreement	100	Round 1
With progressive visual field loss	Agreement	91	Round 1
Demonstrating poor adherence or intolerance to topical medications with topical or systemic side effects	Agreement	100	Round 1
The PRESERFLO™ MicroShunt is particularly valuable for those patients who would benefit from fewer follow-up appointments and monitoring ^b	No consensus reached	Agree (27) Disagree (9)	Round 1
Although the target patient population for the PRESERFLO™ MicroShunt are patients with primary open-angle glaucoma, with no other underlying eye disorders, the device can also be used in patients with the following:			
Pigment dispersion (off-label)	Agreement	82	Round 1
Neovascular glaucoma (off-label)	Disagreement	82	Round 1
Well-controlled uveitis without active inflammation (off-label) ^c	No consensus reached	Agree (36) Disagree (9)	Round 2
Congenital glaucoma (off-label)	No consensus reached	Agree (18) Disagree (18)	Round 1
High myopia (following satisfactory assessment of the conjunctiva) ^c	Agreement	73	Round 2
High hyperopia (providing there is sufficient anterior chamber depth) ^c	No consensus reached	Agree (27) Disagree (9)	Round 2

Table 1 continued

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%) ^a	Delphi questionnaire round
Normal-tension glaucoma with baseline IOP in the upper normal range ^c	No consensus reached	Agree (0) Disagree (18)	Round 2
The PRESERFLO™ MicroShunt implantation procedure may be suitable for other forms of open-angle glaucoma, but further data are required to examine this	Agreement	73	Round 2
In addition to patients with primary open-angle glaucoma, the PRESERFLO™ MicroShunt device may also be used in patients with pseudoexfoliation (off-label), in line with conventional filtering surgery	Agreement	Agree (82) Disagree (0)	Round 2
To determine the suitability of patients for the PRESERFLO™ MicroShunt, previous aqueous production limiting factors (e.g. cyclodestructive procedures) should be considered, if known	Agreement	73	Round 2
The PRESERFLO™ MicroShunt implantation procedure may be performed on patients that have had previous glaucoma surgery with sub-conjunctival drainage, provided there is a quadrant with the intact conjunctiva amenable to PRESERFLO™ MicroShunt implantation	No consensus reached	Agree (55) Disagree (18)	Round 2
The PRESERFLO™ MicroShunt implantation procedure may be performed on patients that have had previous glaucoma surgery with sub-conjunctival drainage, provided there is a quadrant with the intact conjunctiva amenable to PRESERFLO™ MicroShunt implantation. Although the outcome is expected to be less favourable than a primary surgery, it may be considered in certain cases	Agreement	82	Round 3
To optimise surgical outcomes, eligible patients for the PRESERFLO™ MicroShunt should not have had incisional glaucoma surgery on the affected eye ideally within the last 12 months. Although a shorter interval is possible and sometimes necessary due to clinical need, this may be associated with less chance of success	Agreement	100	Round 3

Table 1 continued

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%)^a	Delphi questionnaire round
To optimise surgical outcomes, eligible patients for the PRESERFLO™ MicroShunt should not have had cataract surgery on the affected eye ideally within the last 6 months. Although a shorter interval is possible and sometimes necessary due to clinical need, this may be associated with less chance of success	Agreement	100	Round 3
Multiple-choice	Consensus	Percentage (%)^a	Delphi questionnaire round
To optimise surgical outcomes, eligible patients for the PRESERFLO™ MicroShunt should not have had incisional glaucoma surgery on the affected eye within the past [x] months	Consensus not reached	1 month (0) 3 months (17) 6 months (50)	12 months (25) Round 2 Ever (8)
To optimise surgical outcomes, eligible patients for the PRESERFLO™ MicroShunt should not have had cataract surgery on the affected eye within the past [x] months	Consensus not reached	1 month (0) 3 months (33) 6 months (67)	12 months (0) Round 2 Ever (0)
Single choice—yes or no	Consensus yes/no	Percentage yes/no (%)^a	Delphi questionnaire round
Should the following ocular anatomy/physiology be considered to determine if patients are suitable for the PRESERFLO™ MicroShunt? Please detail any specific considerations.			
Endothelial cell count	Yes	82	Round 1
Condition of the conjunctiva	Yes	100	Round 1
Do you give consideration to the anterior chamber depth (i.e. consider requirement for phacoemulsification) when assessing a patient prior to PRESERFLO™ MicroShunt implantation?	Yes	100	Round 2

Table 1 continued

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%) ^a	Delphi questionnaire round
Do you prepare a patient for the PRESERFLO™ MicroShunt implantation procedure in the same way as trabeculectomy, with regards to:			
Frequency of preoperative patient visits	Yes	100	Round 1
Preoperative assessments and testing	Yes	91	Round 1
Preoperative steroid use	Yes	100	Round 1
Alteration in systemic anti-coagulant and anti-aggregant therapy	Yes	73	Round 1
IOP-lowering medication drop holiday	Yes	100	Round 1

IOP intraocular pressure. Delphi round questionnaires were developed using the findings from the targeted literature review, input from the steering committee and feedback provided by the panellists during each round

^aAnswers to Likert scale questions were provided on a six-point scale: strongly agree, agree, slightly agree, slightly disagree, disagree, or strongly disagree. For each Likert scale question, 'do not wish to answer' or 'insufficient expertise' options were also included. Consensus was set at a pre-defined threshold of at least 70% of panellists selecting 'Strongly disagree'/'Disagree' or 'Strongly agree'/'Agree' for six-point Likert scale questions, or at least 70% selecting the same option for multiple-choice questions. For Likert scale questions, 'Slightly disagree' were not included in the calculation of agreement/disagreement and therefore the overall percentage may not equal 100%

^bStatement was revised for round 2 and included in the postoperative section: 'The PRESERFLO™ MicroShunt implantation procedure has a reasonably predictable postoperative follow-up appointment schedule, with fewer unscheduled visits compared with trabeculectomy'

'Revised question for round 2: 'Although the target patient population from the PRESERFLO™ MicroShunt are patients with primary open-angle glaucoma, with no other underlying eye disorders, the device may also be suitable for patients with the following'

Table 2 Responses to statements on perioperative considerations

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%) ^a	Delphi questionnaire round
The use of the PRESERFLO™ MicroShunt is recommended for surgeons experienced and proficient with other filtering surgeries that require manipulation of conjunctiva and Tenon’s capsule	Agreement	100	Round 1
For experienced surgeons, the PRESERFLO™ MicroShunt implantation procedure has a quick learning curve	Agreement	82	Round 1
The PRESERFLO™ MicroShunt can be implanted using an ab externo approach and performed under local anaesthesia	Agreement	100	Round 1
Preferential implantation of the PRESERFLO™ MicroShunt is superiorly at 11 or 1 o’clock	Agreement	91	Round 1
One small suture at the end of the PRESERFLO™ MicroShunt may help to keep the device in place and prevent it from catching on Tenon’s flap	Consensus not reached	Agree (36) Disagree (18)	Round 1
When performing the PRESERFLO™ MicroShunt implantation procedure, an anatomical assessment of Tenon’s capsule (e.g. deficiency, thickness, etc.) may prompt modification of the surgical technique (e.g. adjusting MMC dose or placing a sclera-fixating suture)	Agreement	91	Round 3
While the size and morphology of the limbal incision during the PRESERFLO™ MicroShunt implantation may vary between surgeons, the formation of a wide and deep posterior pocket is important to maximise the chance of positive clinical outcomes	Agreement	100	Round 3
During PRESERFLO™ MicroShunt implantation, particular attention needs to be paid to Tenon’s closure to avoid occlusion of the PRESERFLO™ MicroShunt	Agreement	100	Round 3
Is it feasible to perform cataract surgery in conjunction with PRESERFLO™ MicroShunt implantation in select cases? ^b	Agreement	100	Round 2
It is feasible to perform cataract surgery in conjunction with PRESERFLO™ MicroShunt implantation. However, an extensive body of evidence is lacking on whether the efficacy is comparable to a standalone procedure ^c	Agreement	100	Round 3

Table 2 continued

Single choice—yes or no	Consensus yes/no	Percentage yes/no (%) ^a	Delphi questionnaire round
Would you consider implantation of the PRESERFLO™ MicroShunt in the sulcus in selected patients?	Yes	73	Round 1
For the following steps of the PRESERFLO™ MicroShunt implantation procedure, do you do anything differently from a standard trabeculectomy?			
Conjunctival and Tenon's incision and dissection	Consensus not reached	Yes (45) No (55)	Round 1
Conjunctival closure	Consensus not reached	Yes (36) No (64)	Round 1
Tenon's closure	Consensus not reached	Yes (45) No (55)	Round 1
When performing the PRESERFLO™ MicroShunt implantation procedure, do you perform any of the following differently from the manufacturer's surgical guidance?			
Preoperative procedure	No	100	Round 2
Sponge location/number	Consensus not reached	Yes (36) No (64)	Round 2
Wound healing medication ^d	Consensus not reached	Yes (45) No (55)	Round 1
Location of PRESERFLO™ MicroShunt	No	82	Round 2
Type of tenon/conjunctiva suture	No	100	Round 2

Table 2 continued

Likert scale	Consensus agreement/ disagreement	Percentage agreement/ disagreement (%) ^a	Delphi questionnaire round
Postoperative procedure	No	73	Round 2
<p><i>MMC mitomycin C. Delphi round questionnaires were developed using the findings from the targeted literature review, input from the steering committee and feedback provided by the panellists during each round</i></p> <p>^aAnswers to Likert scale questions were provided on a six-point scale: strongly agree, agree, slightly agree, slightly disagree, disagree, or strongly disagree. For each Likert scale question, ‘do not wish to answer’ or ‘insufficient expertise’ options were also included. Consensus was set at a pre-defined threshold of at least 70% of panellists selecting ‘Strongly disagree’/‘Disagree’ or ‘Strongly agree’/‘Agree’ for six-point Likert scale questions, or at least 70% selecting the same option for multiple-choice questions. For Likert scale questions, ‘Slightly agree’ and ‘Slightly disagree’ were not included in the calculation of agreement/disagreement and therefore the overall percentage may not equal 100%</p> <p>^bStatement was revised for round 3 as there was agreement during the consensus panel meeting that the statement would benefit from rewording to clarify the context</p> <p>^cRevised from round 2: ‘Is it feasible to perform cataract surgery in conjunction with PRESERFLO™ MicroShunt implantation in select cases?’</p> <p>^dResponse to round 1 question, ‘When performing the PRESERFLO MicroShunt implantation procedure, do you perform any of the following differently from the protocol in the manufacturers’ instructions for use?’</p>			

Mitomycin C

The full results for statements regarding MMC can be found in Table 3. MMC is recommended for use during the majority of procedures to reduce the risk of subconjunctival fibrosis and increase the chance of surgical success. Posterior application of MMC is equally as crucial for the PMS as it is for trabeculectomy. Assessment of the patient’s conjunctiva and Tenon’s capsule morphology influences MMC application, concentration, and duration used. Panellists do not approach the type of sponge, number of sponges, concentration, or duration of MMC application during this procedure differently from that of trabeculectomy. In addition to the standard use of MMC, the panellists agreed that other wound-healing modulators or antifibrotic strategies, such as beta-irradiation, fluorouracil (5-FU), or anti-vascular endothelial growth factor (VEGF), may be used at the surgeon’s discretion and as per previous experience with other filtering surgeries or trabeculectomy. However, further data are needed to determine the efficacy of these adjunct therapies.

Postoperative Considerations

The complete results for statements regarding postoperative considerations can be found in Table 4. There was agreement that the PMS has predictable safety outcomes with a reduced risk and frequency of postoperative complications, when compared with trabeculectomy. In addition, the procedure has consistent and predictable efficacy outcomes with regards to reduction in IOP from baseline and the discontinuation of glaucoma medications. Panellists agreed that the postoperative follow-up appointment schedule for the PMS procedure is reasonably predictable with, on average, fewer patient visits in the early postoperative phase compared with trabeculectomy. For a typical patient (i.e. one showing a positive response to treatment without any significant postoperative complications), postoperative care usually includes the following: 2–4 follow-up appointments in the first month; one appointment every month between months 2 and 4; one

Table 3 Responses to statements on MMC

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%) ^a	Delphi questionnaire round
The antifibrotic agent MMC is recommended for use during the majority of PRESERFLO™ MicroShunt implantation procedures to reduce the risk of subconjunctival fibrosis and increase the chance of surgical success	Agreement	100	Round 1
Other wound-healing modulators/antifibrotic strategies (e.g. beta-irradiation, fluorouracil [5-FU], anti-vascular endothelial growth factor [VEGF]) may be used in addition to MMC	Consensus not reached	Agree (55) Disagree (9)	Round 2
In addition to the standard use of MMC, other wound-healing modulators/antifibrotic strategies (e.g. fluorouracil [5-FU] or anti-vascular endothelial growth factor [VEGF]) may be used at the surgeons discretion and as per previous experience with other filtering surgeries/trabeculectomy. However, further data are needed to determine their efficacy	Agreement	100	Round 3
Posterior application of MMC is equally important for PRESERFLO™ MicroShunt implantation as it is for trabeculectomy	Agreement	100	Round 3
Single choice—yes or no	Consensus yes/no	Percentage yes/no (%) ^a	Delphi questionnaire round
Does your assessment of the patient's conjunctiva and Tenon's capsule morphology influence MMC application, concentration or duration used?	Yes	73	Round 2
Regarding the use of MMC during the PRESERFLO™ MicroShunt implantation procedure, do you approach any of the following differently as compared to trabeculectomy?			
Type of sponge	No	91	Round 1
Number of sponges	No	73	Round 1
Duration of application	No	91	Round 1
Do you position MMC-soaked sponges more posteriorly during the PRESERFLO™ MicroShunt implantation procedure as compared to trabeculectomy?	Consensus not reached	Yes (64) No (36)	Round 2

Table 3 continued

Single choice—yes or no	Consensus yes/no	Percentage yes/no (%) ^a	Delphi questionnaire round
Regarding the use of MMC during the PRESERFLO™ MicroShunt implantation procedure, do you use a different concentration of MMC as compared to trabeculectomy?	No	73	Round 2

MMC mitomycin C. Delphi round questionnaires were developed using the findings from the targeted literature review, input from the steering committee and feedback provided by the panellists during each round

^aAnswers to Likert scale questions were provided on a six-point scale: strongly agree, agree, slightly agree, slightly disagree, disagree, or strongly disagree. For each Likert scale question, ‘do not wish to answer’ or ‘insufficient expertise’ options were also included. Consensus was set at a pre-defined threshold of at least 70% of panellists selecting ‘Strongly disagree’/‘Disagree’ or ‘Strongly agree’/‘Agree’ for six-point Likert scale questions, or at least 70% selecting the same option for multiple-choice questions. For Likert scale questions, ‘Slightly agree’ and ‘Slightly disagree’ were not included in the calculation of agreement/disagreement and therefore the overall percentage may not equal 100%

appointment every 3 months between months 4 and 12 (these final follow-ups can be performed by a general ophthalmologist); and one appointment every 3–6 months beyond 12 months post-surgery.

Panellists indicated that they do not approach the postoperative use of antibiotics, steroids, or nonsteroidal anti-inflammatory drugs (NSAIDs) any differently as compared to trabeculectomy. Several methods can be used to manage postoperative increased IOP levels, including steroids, NSAIDs, open revision, and bleb needling. However, revision surgery is preferable to bleb needling, except in the case of cystic blebs. Although corneal endothelial decompensation is an uncommon side effect of the procedure (on the basis of currently available data), it is nevertheless important to monitor this in a similar fashion as one would following the implantation of other glaucoma drainage devices. There was agreement that an unsuccessful PMS procedure does not preclude a subsequent glaucoma surgery with subconjunctival drainage. Panellists indicated that trabeculectomy was a possibility for this subsequent surgery, but that MIGS should not be used. No consensus was reached for tube surgery or a second PMS implantation in a different quadrant.

DISCUSSION

There are currently no standard guidelines on best practice for patient selection and pre-, peri-, and postoperative care management for the PMS in the treatment of patients with POAG. This modified Delphi panel successfully achieved consensus from a group of glaucoma surgeons with extensive experience using the PMS on aspects of best practice for the use of this device to treat patients with glaucoma in Europe.

Patient Selection and Preoperative Considerations

Although the consensus panel agreed that the PMS is effective at reducing IOP in patients with high-tension POAG (greater than 21 mmHg),

Table 4 Responses to statements on postoperative considerations

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%) ^a	Delphi questionnaire round
The PRESERFLO™ MicroShunt has predictable safety outcomes with reduced risk and frequency of postoperative complications and interventions in comparison with trabeculectomy	Agreement	100	Round 1
The PRESERFLO™ MicroShunt has consistent and predictable efficacy outcomes with regards to reduction in IOP from baseline and discontinuation of glaucoma medications	Agreement	82	Round 1
The postoperative period of the PRESERFLO™ MicroShunt implantation requires fewer patient follow-up appointments and patient management compared with trabeculectomy ^b	Agreement	73	Round 1
Corneal endothelial cell monitoring is recommended for patients undergoing implantation of the PRESERFLO™ MicroShunt and other glaucoma drainage devices	Agreement	Agree (73) Disagree (9)	Round 2
Postoperative increased IOP levels can be managed through several methods including steroids, NSAIDs, open revision and bleb needling	Agreement	82	Round 2
In the case of an unsuccessful PRESERFLO™ MicroShunt implantation procedure, your next surgery would be:			
Trabeculectomy	Agreement	Agree (73) Disagree (27)	Round 1
Tube surgery	Consensus not reached	Agree (45) Disagree (18)	Round 1
Minimally invasive glaucoma surgery	Disagreement	82	Round 1
A second PRESERFLO™ MicroShunt in a different quadrant	Consensus not reached	Agree (18) Disagree (18)	Round 1
For a typical patient (i.e. a 'typical' patient exhibiting a positive response to treatment without any significant postoperative complications), postoperative care usually includes:	Agreement	91	Round 2
2–4 follow-up appointments in the first month			
1 appointment every month between months 2 and 4			
1 appointment every 3 months between months 4 and 12 (these final follow-ups can be performed by a general ophthalmologist)			
1 appointment every 3–6 months beyond 12 months post-surgery			

Table 4 continued

Likert scale	Consensus agreement/disagreement	Percentage agreement/disagreement (%) ^a	Delphi questionnaire round
If target IOP reduction is not sustained following PRESERFLO™ MicroShunt implantation, revision surgery is preferable to bleb needling, except in the case of cystic blebs	Agreement	91	Round 2
Corneal endothelial decompensation is an uncommon side effect of PRESERFLO™ MicroShunt implantation	Agreement	73	Round 2
The PRESERFLO™ MicroShunt implantation procedure has a reasonably predictable postoperative follow-up appointment schedule, with fewer unscheduled visits compared with trabeculectomy [‡]	Consensus not reached	Agree (55) Disagree (0)	Round 2
Patients with highly myopic eyes are at increased risk of hypotony following PRESERFLO™ MicroShunt implantation	Consensus not reached	Agree (45) Disagree (9)	Round 2
The risk of hypotony in patients following PRESERFLO™ MicroShunt implantation can be reduced by using a hypotony prevention suture	Consensus not reached	Agree (36) Disagree (9)	Round 2
The PRESERFLO™ MicroShunt implantation procedure has a reasonably predictable postoperative follow-up appointment schedule, with on average fewer visits in the early postoperative phase compared with trabeculectomy ^d	Agreement	91	Round 3
In the case of bleb failure following PRESERFLO™ MicroShunt implantation, revision surgery is preferable to bleb needling, except in the relatively uncommon case of cystic blebs	Agreement	100	Round 3
Single choice—yes or no			
Consensus yes/no			
Percentage yes/no (%)^a			
Delphi questionnaire round			
Following implantation of the PRESERFLO™ MicroShunt, do you approach any of the following postoperative considerations differently as compared with trabeculectomy?			
Use of antibiotics	No	91	Round 1
Use of steroids	No	91	Round 1
Use of nonsteroidal anti-inflammatory drugs	No	100	Round 1

Table 4 continued

Single choice—yes or no	Consensus yes/no	Percentage yes/no (%) ^a	Delphi questionnaire round
Does an unsuccessful PRESERFLO™ MicroShunt implantation procedure preclude a subsequent glaucoma surgery with subconjunctival drainage?	No	91	Round 1
Multiple-choice			
For bleb needling, do you primarily perform this:	Consensus not reached	In clinic with no overnight stay (36)	Round 1
In clinic with no overnight stay		In clinic with at least one overnight stay (0)	
In clinic with at least one overnight stay		In an operating theatre with no overnight stay (55)	
In an operating theatre with no overnight stay		In an operating theatre with at least one overnight stay (9)	
In an operating theatre with at least one overnight stay			
IOP intraocular pressure, <i>M/MC</i> mitomycin C, <i>NSAID</i> nonsteroidal anti-inflammatory drug. Delphi round questionnaires were developed using the findings from the targeted literature review, input from the steering committee and feedback provided by the panellists during each round			
^a Answers to Likert scale questions were provided on a six-point scale: strongly agree, agree, slightly agree, slightly disagree, disagree, or strongly disagree. For each Likert scale question, 'do not wish to answer' or 'insufficient expertise' options were also included. Consensus was set at a pre-defined threshold of at least 70% of panellists selecting 'Strongly disagree'/'Disagree' or 'Strongly agree'/'Agree' for six-point Likert scale questions, or at least 70% selecting the same option for multiple-choice questions. For Likert scale questions, 'Slightly agree' and 'Slightly disagree' were not included in the calculation of agreement/disagreement and therefore the overall percentage may not equal 100%			
^b Statement was revised for round 3 as there was agreement during the consensus panel meeting that the statement would benefit from rewording to clarify the context			
^c Statement was rephrased from the following statement included in the patient selection and preoperative consideration section in round 1: 'The PRESERFLO™ MicroShunt is particularly valuable for those patients who would benefit from fewer follow-up appointments and monitoring'			
^d Revised from round 2: 'The postoperative period of the PRESERFLO™ MicroShunt implantation requires fewer patient follow-up appointments and patient management compared with trabeculectomy'			

more evidence is needed to determine if the device is suitable for patients requiring the lowest target pressures. The panellists indicated that more evidence is also needed to determine if the device can be indicated for other forms of glaucoma and/or for patients with certain comorbidities, such as high hyperopia. However, there was consensus that the device might be suitable for patients with the off-label diagnosis of pseudoexfoliation, supporting recent research that has shown the PMS has similar efficacy for patients with POAG and those with pseudoexfoliation [21]. There was consensus that it is possible to perform the procedure in patients with high myopia, but there was some disagreement among the panellists regarding this approach. Some surgeons indicated that they had experienced positive outcomes for patients with high myopia and, in some cases, better outcomes as compared with trabeculectomy. However, other panellists urged caution with this approach, citing experience of patients presenting with high myopia at possibly greater risk of developing complications secondary to hypotony. These panellists further detailed that it may be more challenging to treat patients with PMS postoperatively with anterior chamber injection of viscoelastic, as this can cause sharp increases in IOP due to viscoelastic not easily passing through the PMS. However, there are several potential mitigation techniques to reduce the risk of IOP spikes in these patients, such as modifying the type of ophthalmic viscoelastic device (OVD) used and/or monitoring the patient closely for changes in IOP. In addition, several surgeons detailed that another potential method to reduce the risk of postoperative hypotony is to insert a ripchord suture in a releasable fashion during the PMS procedure (e.g. 10/0 nylon or 9/0 prolene). Overall, there was agreement that patients with high myopia are at a higher risk of postoperative complications regardless of the type of glaucoma surgery, and therefore these patients need to be monitored carefully during the postoperative period.

During the consensus meeting, the panellists discussed that in some cases it might be feasible to perform the PMS implantation procedure in patients who have had previous glaucoma

surgery. Panellists agreed that to optimise surgical outcomes, eligible patients should not have had incisional glaucoma surgery or cataract surgery on the affected eye for the 12 or 6 months prior, respectively. However, a shorter time frame is acceptable in both cases depending on the surgical need and there are practical advantages to choosing the PMS as a second surgery. In the case of a failed trabeculectomy, the surgeon may not have adequate space superiorly to perform a second trabeculectomy, but there may be space to insert the PMS. Recent evidence has shown that implantation of the PMS in patients with POAG after a failed trabeculectomy was safe and effective [22]. However, more data are required to ensure the safety and efficacy of such an approach. In addition, there was general discussion that it may be possible to implant a second PMS after a failed initial procedure. However, this decision is contingent on many factors such as the available quadrants and glaucoma severity; this approach did not reach consensus during the process.

Perioperative Considerations

The panellists agreed that for surgeons experienced and proficient with other filtering surgeries that require manipulation of conjunctiva and Tenon's capsule, the PMS implantation procedure (using an ab externo approach) has a short learning curve compared with trabeculectomy and tube surgery. As most surgeons are often already comfortable performing ab externo procedures, the PMS procedure is a valuable opportunity for widespread adoption to provide an additional treatment option for patients with glaucoma. MMC is recommended for use during PMS procedures to prevent excessive postoperative scarring and to increase the chance of surgical success. Surgeons also expressed that typically, their method of MMC use during the PMS procedure does not differ from that used during trabeculectomy (e.g. method of application [sponges or injection], concentration [typically between 0.2 and 0.4 mg/mL], and/or duration of application).

However, there were some key differences among the panellists in their approach to MMC use during the PMS procedure. Some surgeons detailed that they have experienced consistently more favourable results when using a higher concentration of MMC during the PMS procedure (0.4 mg/mL) than the concentration used during trabeculectomy. There was agreement that surgeons may approach MMC use during the PMS procedure differently from a trabeculectomy, and ultimately surgeons should use the MMC concentration that, in their experience, works best. In addition, the consensus panel agreed that the condition of Tenon's capsule guided their MMC use and may influence the duration of MMC application during the procedure; however, some panellists indicated that they would instead alter the concentration of MMC used. Regardless of the concentration and/or duration of MMC used, there was overall agreement that posterior application of MMC is equally important for the PMS procedure as it is for trabeculectomy. Regarding other wound-healing modulators and antifibrotic strategies, such as beta-irradiation, 5-FU, and anti-VEGF, surgeons should approach the use of these techniques during the PMS procedure in the same way as they would for trabeculectomy or other filtering surgeries. However, the consensus panel agreed that additional data are required to demonstrate the efficacy of these strategies.

Each surgeon has a slightly different surgical technique to achieve optimal results during trabeculectomy, and therefore there were some differences among the panellists regarding surgical approach to the PMS procedure. However, differences in surgical technique are to be expected and of no consequence if surgical outcomes are similar. For example, although surgeons may have different approaches to the conjunctival and Tenon's incision and dissection, the key outcome is the creation of a wide and deep pocket for the application of MMC and to reduce posterior resistance. In addition, some surgeons indicated that they closed differently between trabeculectomy and the PMS procedure. For the latter, it is crucial to avoid trapping the distal tip of the device in the Tenon's during conjunctival and Tenon's

closure. As such, the Tenon's capsule must be sufficiently stretched to avoid occluding the distal tip of the implant, and the closure needs to be watertight.

The panellists also discussed the safety and efficacy of performing cataract surgery in conjunction with PMS implantation. The consensus panel agreed that while it is possible to perform cataract surgery in combination with the PMS procedure, it is important to note that success rates may be compromised. Although there are promising preliminary data that show the efficacy and safety of a combined PMS and cataract procedure [23], further data are required to further understand the efficacy of combined surgical procedures and to identify any factors that may compromise outcomes, such as additional inflammation.

Postoperative Considerations

Overall, and in the experience of the consensus panel, the PMS has consistent and predictable efficacy outcomes with regards to reduction in IOP from baseline and discontinuation of glaucoma medications. In addition, for the 'typical' patient, the procedure has a reasonably predictable postoperative follow-up appointment schedule, with fewer unscheduled visits compared with trabeculectomy, which often requires frequent in-person follow-up appointments. One reason why patients implanted with the PMS tend to experience fewer postoperative visits compared with trabeculectomy is because there are no scleral flap sutures that need adjustment or removal. With fewer overall appointments, the PMS procedure may be particularly suitable for patients who are unable to attend a high frequency of appointments.

The PMS has a good safety profile, with minimal complications arising immediately after surgery [18, 24]. Complications are most often transient, of low severity, and resolve without intervention [15]. Specifically, surgeons indicated that, on the basis of their experience, corneal endothelial decompensation is uncommon in patients following the PMS procedure. However, it is important to note that current

experience with the device is, on average, relatively short-term (2–3 years), and endothelial cell decompensation is typically a late complication of surgery. To prevent any potential complications, it is crucial to place the PMS as far away from the corneal endothelium as possible.

Strengths and Limitations

The modified Delphi method is a widely used, systematic, and robust methodology to gather expert consensus using several rounds of iterative questionnaires [20]. This Delphi panel sought consensus from a diverse group of glaucoma surgeons from across Europe, each with substantial experience of using the PMS to treat patients with glaucoma. Each panellist brought their own unique experience and perspective to the process, thereby strengthening the overall results of the consensus. A limitation of the Delphi methodology is that there is often a high level of drop-off in participation between rounds as a result of the prolonged time commitment. However, this study was completed relatively quickly, with all three Delphi rounds and the consensus panel meeting taking place over a 3-month period. All panellists participated in each of the Delphi rounds and also attended the consensus panel meeting, ensuring that the overall results represent the experiences of the entire consensus panel.

A particular benefit of the Delphi methodology is that statements are updated between rounds following participant feedback provided through scoping questions and/or free-text responses. For this modified Delphi panel, the statements included in each round were also reviewed by the moderator and SC to ensure that the statements were clinically relevant and accurately worded.

One potential methodological issue with consensus processes is the tendency for participants to feel pressure to conform to the group view [25]. This issue was mitigated by using an online bespoke web application that maintained the anonymity of each panellist's responses while allowing for rapid collection, analysis and dissemination of each round of

results. Although the virtual consensus panel meeting that was held after the second Delphi round facilitated 'face-to-face' discussion, this meeting was crucial to provide the opportunity for the panellists to further discuss and contextualise the results ahead of the final round. As the PMS is a relatively new device, there were a limited number of surgeons in Europe who had the required experience in treating patients with the PMS to participate in this study. Gathering insight from a larger panel of surgeons would potentially increase the robustness of the consensus results. However, the panellists included in this study represent a wide range of nationalities and each bring their unique background and experiences, thereby strengthening the consensus process. As more surgeons gain experience with the PMS and additional research on efficacy and safety is published, it may be beneficial to revisit the results of this paper to ensure that the consensus remains consistent with current knowledge and experience of the device.

CONCLUSION

The study demonstrated that the consensus panel of glaucoma surgeons were largely aligned on patient selection and pre-, peri-, and post-operative care management decisions for the PMS. Furthermore, the panel identified evidence gaps that should be met to improve our future understanding of the PMS. The information gathered from this consensus study can be used to guide inexperienced surgeons in best practice while using the PMS to treat patients with glaucoma.

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Compliance with Ethics Guidelines. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

Data Availability. All data generated or analysed during this study are included in this published article/as supplementary information files.

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