

National Institute for Health and Care Excellence
IP1860 YAG laser vitreolysis for symptomatic vitreous floaters

IPAC date: 11 August 2022

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Royal College of Ophthalmologists	General	<p>The summary of evidence provided by NICE shows the lack of high-quality studies on YAG laser vitreolysis for disabling visual floaters. Efficacy of this intervention cannot be established from the current evidence. More importantly, safety data on vitreolysis for this condition is limited especially on incidence of complications such as cataract, raised IOP, retinal tears and haemorrhage, retinal detachment and uveitis. Other real world considerations not addressed include training requirements, device variations, and the need for repeated treatments.</p> <p>It should also be noted that in the UK, this procedure is only carried out in a private healthcare setting, which may further limit awareness of complications and regulation.</p> <p>The consensus from professional experts UK and Éire Glaucoma Society (UKEGS)) in this field is that this interventional procedure cannot be supported and should not be adopted by the NHS at present and that further high quality research is required.</p>	<p>Thank you for your comment.</p> <p>IPAC has considered this comment but decide not to include further details (such as training, device and repeated treatments) to the research recommendation, because the research ethics committees would oversee the procedure tested in research.</p>
2	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	1.1	<p>A Study being set up and led by Prof Stanga (The Retina Clinic London/UCL, London, UK) aims at addressing all the NICE Committee's questions, amongst others, Safety and Efficacy of YAG Laser Vitreolysis. This study will be submitted for IRAS approval within the next 3 months: VITREOUS STRUCTURE AND VISUAL FUNCTION IN MYOPIC VITREOPATHY (MV) OR WEISS RING (WR) SECONDARY TO PVD CAUSING VISION DEGRADING MYODESOPSIA (VDM) BEFORE AND AFTER YAG LASER VITREOLYSIS (YVL).</p>	<p>Thank you for your comment.</p> <p>NICE will consider this study when the guidance is updated.</p>

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3	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	1.2	<p>The Study VITREOUS STRUCTURE AND VISUAL FUNCTION IN MYOPIC VITREOPATHY (MV) OR WEISS RING (WR) SECONDARY TO PVD CAUSING VISION DEGRADING MYODESOPSIA (VDM) BEFORE AND AFTER YAG LASER VITREOLYSIS (YVL) led by Prof Stanga (The Retina Clinic London/UCL, London, UK) will report on, amongst others, details of patient selection (including type, size and location of floaters), degree of visual disturbance, and details of the procedure.</p> <p>Lumibird Medical (Quantel Medical - Ellex) has already agreed to support Prof. Stanga’s clinical studies.</p> <p>The study aims of Prof. Stanga’s study will be the following:</p> <ol style="list-style-type: none"> 1. Compare Ultrasound Imaging of Vitreous Structure and Assessments of Visual Function Pre vs. Post YVL in patients presenting MV and/or WR. Limited Vitrectomy Surgery (LVS) to be offered only to patients not satisfied with YVL 2. Quantification of Vitreous Opacification using Quantel's new ABSOLU ultrasound Technology and 20 MHz Annular Array Probe 3. Development of Quantitative Ultrasonography (QUS) specifically for new system (see 2.) 4. Correlation of QUS with Functional testing 5. Creation of a new and adequate classification of vitreous opacities 6. Identification of “Best Candidate Opacities” for YVL (those satisfied and not seeking LVS) 7. Creation of Guidelines for Management Options of Vitreous Opacities: No treatment vs. YVL vs. LVS 8. Creation of a Data Collection protocol to allow Quantel / Ellex to promote YVL treatment option in Vision Degrading Myodesopsia patients. 	<p>Thank you for your comment.</p> <p>NICE will consider this study when the guidance is updated.</p>

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			This will be a randomized controlled trial in patients with bilateral vitreous floaters where one eye will be randomized to treatment and the other to observation.	
4	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	1.3	We fully agree with this recommendation in the patient's best interest.	Thank you for your comment.
5	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	2.1	No additional comment.	Thank you for your comment.
6	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	2.2	No additional comment.	Thank you for your comment.
7	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	2.3	No additional comment.	Thank you for your comment.
8	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	2.4	No additional comment.	Thank you for your comment.

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9	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	2.5	<p>Clinical experience shows that part or the totality of some floaters can be segmented into smaller fragments that no longer interfere with vision.</p> <p>Prof. Stanga's study also aims at identifying anatomical and biochemical changes in vitreous floaters following YAG Laser Vitreolysis (YVL) with the use of novel high resolution 3D Ultrasound and OCT Imaging Technologies in vivo as well as Light and Electron Microscopy in experimental model ex-vivo (Assessment of the morphological and histological changes in cadaveric porcine vitreous following YVL).</p>	<p>Thank you for your comment.</p> <p>Section 2.5 has been changed to: <i>"The pupil is dilated and anaesthetic eye drops are administered. A specialised contact lens is placed on the cornea. Coaxial illumination is used. A laser microscope focuses on the front surface of the floater and creates short bursts of energy (nanosecond pulses). The laser energy usually starts at a low level, which is increased until it is high enough to break up the floater. The laser is stopped once all visually significant floaters are treated."</i></p>
10	Consultee 2 Lumibird Medical (Quantel Medical - Ellex)	2.6	No additional comment.	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."