

# Comparing microscope light-associated glare and comfort between heads-up 3D digital and conventional microscopes in cataract surgery: a randomised, multicentre, single-blind, controlled trial

Vincent Gualino ,<sup>1</sup> Kevin Pierne,<sup>1</sup> Anthony Manassero,<sup>2</sup> Sébastien Bruneau,<sup>2</sup> Aude Couturier ,<sup>3</sup> Ramin Tadayoni<sup>2,3</sup>

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<sup>1</sup>Department of Ophthalmology, Clinique Honoré Cave, Montauban, France

<sup>2</sup>Department of Ophthalmology, Hôpital Fondation Adolphe De Rothschild, Paris, France

<sup>3</sup>Department of Ophthalmology, Université Paris Cité, AP-HP, Hôpital Lariboisière, Paris, France

## Correspondence to

Dr Vincent Gualino; [v.gual@hotmail.fr](mailto:v.gual@hotmail.fr)

## ABSTRACT

**Objective** To compare subjective levels of comfort and visual experiences related to microscope light in patients undergoing their first cataract surgery with topical anaesthesia using a digital microscope (the NGENUITY three-dimensional (3D) visualisation system) or a conventional microscope.

**Methods and analysis** A prospective, randomised, single-blinded, parallel-group, multicentre, interventional study. Patients (n=128) were randomly assigned to one of two treatment groups: the experimental group (n=63) had surgery using the digital microscope and the control group (n=65) had surgery with a conventional microscope. The primary outcome was patients' subjective experience of glare from the microscope light during surgery on a numerical scale from 0 to 10. Key secondary outcomes were patients' subjective levels of comfort and visual experiences related to the microscope light.

**Results** The experimental group reported significantly lower levels of glare; median levels were 1.0 (0.0–4.0) for the experimental group vs 3.0 (0.0–6.0) for the control group (p=0.027). They also reported higher levels of comfort; median ratings were 8.0 (6.5–10.0) in the experimental group and 7.0 (5.0–9.0) in controls (p=0.026). There were no group differences in ratings of subjective pain or visual disturbances. Median microscope light intensity was lower in the experimental group than controls; 3425.0 (2296.0–4300.0) Lux vs 24 279.0 (16 000.0–26 500.0) Lux (p<0.0001), respectively.

**Conclusion** Compared with conventional microscopes, the NGENUITY 3D visualisation system allows surgeons to operate with lower levels of light exposure, resulting in significantly less glare and improved comfort in patients undergoing cataract surgery.

**Trial registration number** NCT05085314.

## INTRODUCTION

Cataract is the world's leading cause of blindness, accounting for approximately 50% of all blindness in adults aged 50 years and older.<sup>1</sup> Age is the greatest risk factor for cataract and the WHO estimates that the number of people with cataract-related blindness

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Cataract-related blindness is a growing global health issue. Despite significant improvements in surgical techniques for cataract removal, management of patient flow remains a challenge for ophthalmology services.

## WHAT THIS STUDY ADDS

⇒ In this randomised, multicentre, single-blind, controlled trial in patients undergoing their first cataract surgery with topical anaesthesia, we found that those who were operated on using a digital heads-up visualisation system (NGENUITY three-dimensional (3D) HUVS) reported significantly less glare and higher levels of comfort, than those operated using a conventional microscope. Notably, the 3D HUVS enabled a significant (sevenfold) reduction in microscope light intensity during cataract surgery.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Performing cataract surgery at lower light levels using a 3D HUVS may facilitate patient flow by reducing glare and improving patient comfort.

will reach 40 million by 2025, as the ageing population continues to grow.<sup>2</sup> Although significant progress has been made in understanding the causes of this condition, there is no proven primary prevention and surgical cataract removal remains the only therapy.

During the last decade, surgical techniques for cataract removal have vastly improved and the duration of cataract surgery has been considerably reduced since the first phacoemulsification. However, management of patient flow remains a challenge for many ophthalmology services and there is an unacceptably high backlog of operable cataract blindness, particularly in the developing world.<sup>3 4</sup> In order to optimise and simplify

patient care, cataract patients are now treated almost exclusively as outpatients, and local anaesthesia with or without light intravenous sedation has become the gold standard method for cataract surgery. However, with this type of anaesthesia, the patient is more alert, more sensitive to his or her surroundings, and more stressed throughout the procedure. This can influence the surgeon's tranquillity and ultimately patient safety.

Microscope light plays a crucial role in cataract surgery, as it is essential for correct visualisation of ocular structures. Unfortunately, patients frequently complain of discomfort and visual disturbances related to light exposure during surgery.<sup>5</sup> Studies measuring subjective sensations of patients undergoing cataract surgery with topical anaesthesia have found that around one-fifth to one-quarter of patients find the microscope light to be very disturbing and uncomfortable.<sup>6,7</sup>

Heads-up surgery using three-dimensional (3D) digital visualisation is an evolving technique that is increasingly used in ophthalmology.<sup>8</sup> The heads-up NGENUITY 3D visualisation system (Alcon Laboratories, Fort Worth, Texas, USA) allows surgeons to replace conventional surgical microscope eyepieces with high-resolution stereoscopic cameras that retransmit an image directly on a single screen. Importantly, the highly sensitive camera sensors coupled with real-time digital processing, allow a significant reduction in intraoperative light intensity while maintaining satisfactory visualisation.<sup>9–13</sup> In this way, the digital 3D visualisation system may offer better comfort than conventional microscopes for patients undergoing eye surgery.

We set out to investigate this by comparing subjective levels of comfort and visual experiences related to microscope light in patients undergoing a first cataract surgery with topical anaesthesia, using either the NGENUITY 3D visualisation system or a conventional microscope.

## MATERIALS AND METHODS

### Study design and participants

The Comfort Operative Ocular Light study is a prospective, randomised (1:1), single-blinded, parallel-group, interventional study carried out between two centres in France; the Adolphe de Rothschild Foundation hospital in Paris and the Honoré Cave Clinic in Montauban. Patients were recruited during preoperative consultation for cataract surgery. Participation in the study did not interfere with the standard care of patients and did not require any extra hospital visits. The key inclusion criteria were (1) patients >18 years of age; (2) referred for a first cataract surgery (any eye) under topical anaesthesia with or without an intravenous sedative and (3) who were either members or beneficiaries of a social security scheme. Patients were excluded from the study if they (1) had comprehension difficulties or did not understand French; (2) were pregnant or breast feeding; (3) were subject to legal protection measures or (4) had received another type of surgery (such as a vitrectomy combined with cataract surgery) at the operated eye side.

### Randomisation and blinding

Balanced 1:1 randomisation was carried out centrally using computer-generated permuted blocks of size four and six. Randomisation was stratified by centre. Patients were randomised to undergo cataract surgery with topical anaesthesia using either the NGENUITY 3D visualisation system (Alcon Laboratories) (experimental group) or a conventional microscope system (control group). They were blinded to their treatment group allocation and were simply informed of their date of surgery, as per standard care.

### Surgical procedure

Surgery was performed using a halogen-illuminated Leica M844 microscope (Leica Microsystems, Bannockburn, Illinois, USA) at the Honoré Cave Clinic in Montauban, and with a xenon-illuminated OPMI LUMERA 700 microscope (Carl Zeiss Meditec, Jena, Germany) at the Adolphe de Rothschild Foundation hospital in Paris. Microscope oculars were left in place for the control group and replaced by the NGENUITY 3D visualisation system (V.1.3.3 in Paris and V.1.4 in Montauban) for the experimental group.

Prior to the operation, the surgeon adjusted the microscope settings. For the Leica M844 microscope, illumination settings were at 20% peripheral illumination and 10% central illumination for surgery with NGENUITY and at 45% peripheral illumination and 20% central illumination for surgery without NGENUITY. For the OPMI LUMERA 700 microscope, illumination settings were at 15% for surgery with NGENUITY and at 60% for surgery without NGENUITY.

For the NGENUITY 3D visualisation system, the gain was at its lowest setting: 1 or 2. The opening of the diaphragm was set at 80%. At the beginning of each surgical day, auto white balance was used to define the colour temperature of the light source. The three primary colours were unmodified at 100. Brightness was somewhat decreased to between 41 and 46.5 (47.8 on the default setting). The contrast was increased to between 56 and 60 (54.90 on the default setting). The gamma was increased to between 1.5 and 1.65 (1.20 on the default setting). Hue and saturation were unmodified (at 2 and 90). The surgeon had the possibility of increasing the power of the microscope during the surgery; any changes in power were recorded.

All surgeries were performed by phacoemulsification and posterior chamber implantation with corneal incision. Topical anaesthesia was administered using oxybuprocaine drops. The surgeon had the option of performing an intracameral injection of tropicamide, with phenylephrine, and lidocaine (Mydrane), if desired. Intravenous sedation was possible and followed an identical single protocol for all patients: propofol (20 mg if <70 kg, 30 mg if ≥70 kg) 1 min before opening the blepharostat. The anaesthetist was called for supplementary sedation, when necessary.

## Outcome measures

Patients were interviewed by the clinical study technician within 1–2 hours of completion of surgery and asked to answer four questions from a standardised questionnaire. For each question, patients had to answer on a numerical scale from 0 (no, not at all) to 10 (yes, extremely).

The primary outcome, assessed by the first question of the standardised questionnaire, was patients' experience of glare associated with the microscope light during cataract surgery.

Secondary outcomes were patients' subjective level of comfort and visual experiences related to the microscope light, the levels of light intensity required during surgery, the duration of surgery, the frequency and type of complications occurring during surgery, and the frequency of interventions requiring additional intravenous sedation. Subjective levels of comfort and visual experiences were assessed by questions 2–4 of the standardised questionnaire. Light intensity (in lux) was measured at the beginning of surgery using a calibrated lux metre (Voltcraft MS-1300-ISO luxmeter calibrated (ISO) 0.1–50 000 lx), placed at focal length under the microscope. Surgery duration (in minutes) was measured from the moment the microscope was switched on above the patient with the blepharostat open, until the moment when the surgeon removed the microscope from the operating field. Data on intraoperative complications, type of anaesthesia (topical anaesthesia alone or with intravenous sedation) and any further demand for supplementary intravenous sedation administered by an anaesthetist, were collected throughout the procedure.

## Sample size calculation

The sample size calculation was based on an expected difference of 2 points in the mean response to the first question of the standardised questionnaire between the two groups. With a level of significance  $\alpha=5\%$ , a power of  $1-\beta=90\%$ , an SD of 3.2 and an estimated dropout rate of 20%, it was calculated that a total sample size of 130 patients (65 per group) was required to confirm a difference of 2 points.

## Statistical analyses

The results are presented according to Consolidated Standards of Reporting Trials (CONSORT) recommendations.<sup>14</sup> Continuous variables were described as mean ( $\pm$ SD) or median (IQR), as appropriate, and categorical variables as numbers and percentages. Primary analysis was conducted on the intention-to-treat population. Randomised patients who completed the questionnaire were analysed according to their treatment arm. Student's t-test or Wilcoxon-Mann-Whitney test (as appropriate) were used to compare answers to each of the standardised questions, light intensity and duration of surgery between the experimental and control groups.  $\chi^2$  test or Fisher's exact test (as appropriate) were used to compare frequencies of intraoperative complications and requests for additional intravenous sedative from an

anaesthetist, between the two groups. All tests were two sided and the level of significance was set at 0.05. Statistical analyses were conducted using R,<sup>15</sup> V.4.2.0.

## Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

## RESULTS

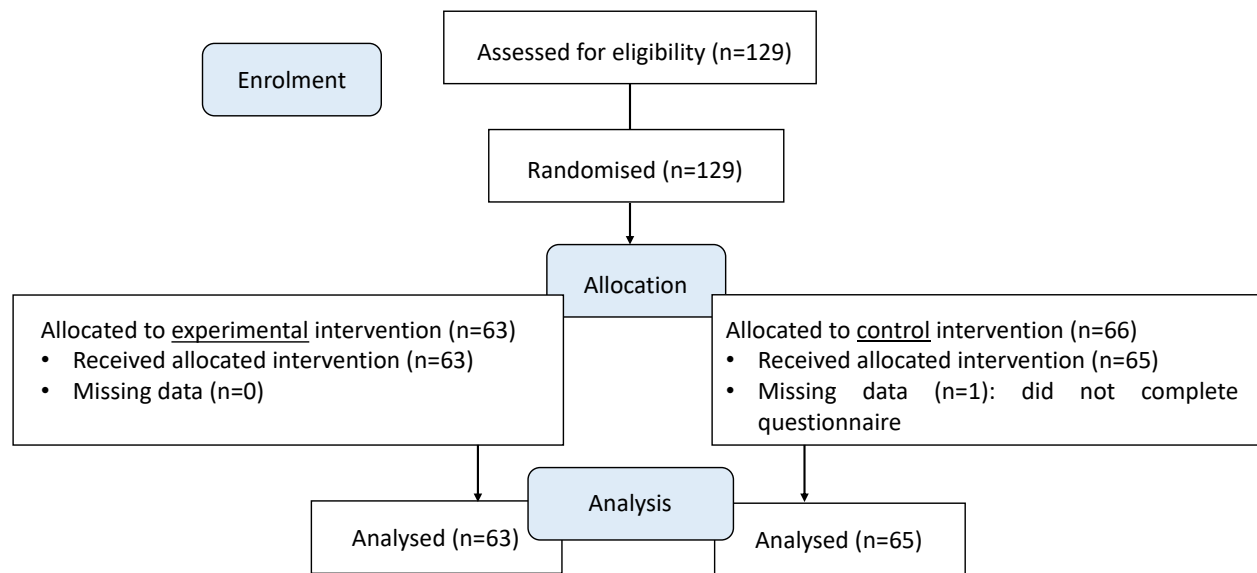
The study flow chart is illustrated in figure 1. Patients were recruited between October 2021 and April 2022, and cataract surgery was performed between October 2021 and May 2022. A total of 129 patients were enrolled in the study and randomised; 104 patients at the Honoré Cave clinic in Montauban and 25 patients at the Adolphe de Rothschild Foundation hospital in Paris. In the experimental group (n=63), all patients received the allocated treatment, completed the questionnaire and were subsequently analysed. In the control group (n=66), 65 patients received the allocated treatment, completed the questionnaire and were analysed. One patient randomised in the control arm did not complete the questionnaire and was therefore excluded from the final analysis.

Patient characteristics at baseline are presented in table 1. The majority of patients (63.3%, 81/128) were female and the mean age ( $\pm$ SD) was 72.7 (9.6) years. There were slightly more patients operated on the right eye (53.9%, 69/128) than the left eye (46.1%, 59/128).

Patients in the experimental group reported feeling significantly less dazzled by the microscope light than those in the control group. Median levels of subjective glare were 1.0 (0.0–4.0) in the experimental group compared with 3.0 (0.0–6.0) in controls (p=0.027).

The experimental group reported higher levels of comfort than controls when the microscope light was on during the operation; median subjective comfort ratings were 8.0 (6.5–10.0) in the experimental group vs 7.0 (5.0–9.0) in controls (p=0.026). There were no group differences in ratings of subjective pain during surgery; median ratings were 0.0 (0.0–3.0) in the experimental group compared with 0.0 (0.0–2.0) in controls (p=0.759). Similarly, there were no differences in ratings of visual disturbances related to glare, following surgery; median ratings were 0.0 (0.0–2.5) in the experimental group vs 0.0 (0.0–1.0) in controls (p=0.378). Data on patients' response to the standardised questionnaire are presented in table 2.

Table 3 presents light characteristics of the experimental (NGENUITY 3D Visualisation system) and conventional microscopes used during surgery. Median light intensity, measured at the beginning of surgery, was significantly lower in the experimental group: 3425.0 (2296.0–4300.0) Lux compared with the control group: 24279.0 (16000.0–26500.0) Lux (p<0.0001). The median microscope luminosity at the beginning of surgery, and median maximal luminosity during surgery, were also notably lower in the experimental



**Figure 1** Study flow chart.

group. Median luminosity was 21.0 (17.0–25.0) in the experimental group compared with 50.0 (50.0–55.0) in controls ( $p<0.0001$ ). Similarly, maximal luminosity was 25.0 (17.0–25.0) in the experimental group compared with 50.0 (50.0–55.0) in controls ( $p<0.0001$ ). Online supplemental figure 1 shows a surgical image obtained using the NGENUITY visualisation system.

The mean duration of surgery was longer in the experimental group: surgery lasted on average 9.0 (3.0) min in the experimental group compared with 8.0 (2.2) min in the control group ( $p=0.055$ ). There were no surgical complications, and no reported undesirable effects

associated with either the microscope or anaesthesia in both groups.

All patients undergoing cataract surgery received a topical anaesthesia (table 4). The majority, 86.7% (111/128) received intravenous sedation with no difference between the two groups; 88.9% (56/63) in the experimental group and 84.6% (55/65) in controls ( $p=0.48$ ). Supplementary sedation was given to three patients in the experimental group and six in the control group ( $p=0.49$ ).

## DISCUSSION

Here, we evaluated, for the first time, subjective visual experiences and comfort associated with microscope light in patients undergoing cataract surgery with topical anaesthesia, using either a heads-up digital NGENUITY 3D visualisation system or a conventional microscope. We found that, compared with conventional microscopes, the NGENUITY 3D heads-up visualisation system (HUVS) allowed significantly lower levels of light exposure during surgery, resulting in less glare and improved comfort in patients.

A number of previous investigations have also demonstrated the utility of 3D HUVS in reducing light exposure during ophthalmic surgery. A study of Japanese patients undergoing surgery for cataract alone or cataract with either glaucoma or vitrectomy ( $n=54$ , 72 eyes), found that surgeons were comfortable operating at endoillumination levels of 2%–8% of the maximum output when using a digital 3D HUVS.<sup>16</sup> A separate analysis of Japanese patients undergoing consecutive cataract surgery

**Table 1** Baseline characteristics of patients in the COOL study

Variables	Experimental group (n=63)	Control group (n=65)	Total (n=128)
Age (years)			
Mean (SD)	72.9 (9.5)	72.5 (9.7)	72.7 (9.6)
Range	51–91	44–96	44–96
Gender, n (%)			
Male	24 (38.1)	23 (35.4)	47 (36.7)
Female	39 (61.9)	42 (64.6)	81 (63.3)
Study eye, n (%)			
Right	31 (49.2)	38 (58.5)	69 (53.9)
Left	32 (50.8)	27 (41.5)	59 (46.1)
COOL, Comfort Operative Ocular Light.			

**Table 2** Patients' subjective responses to a standardised questionnaire

Questions	Experimental group (n=63)	Control group (n=65)	P value
1. Were you dazzled by the microscope light during the operation?			
Median (Q1–Q3)	1.0 (0.0–4.0)	3.0 (0.0–6.0)	0.027*
2. Were you comfortable when the light was on during your operation?			
Median (Q1–Q3)	8.0 (6.5–10.0)	7.0 (5.0–9.0)	0.026*
3. Did you experience any pain during the operation?			
Median (Q1–Q3)	0.0 (0.0–3.0)	0.0 (0.0–2.0)	0.759*
4. Do you still feel any visual disturbance due to glare from the microscope light, after the operation?			
Median (Q1–Q3)	0.0 (0.0–2.5)	0.0 (0.0–1.0)	0.378*

Patients responded to all questions on a scale of 0 (no, not at all) to 10 (yes, extremely).  
\*P values are based on the Wilcoxon-Mann-Whitney test.

with a 3D HUVS (n=45 eyes) or a conventional eyepiece (n=46 eyes), found that the minimum light intensity required for safe surgery was significantly lower in the digital group (5500±2000lux) than in the standard eyepiece group (11 900±1800lux; p<0.001).<sup>9</sup> Similarly, in a sample of New York patients undergoing femtosecond laser-assisted cataract surgery, the mean light intensity required for safe surgery was significantly less in a group using a 3D HUVS (18.5%±1.5%, n=27 eyes) than in the conventional microscope group (43.3%±3.7%, n=24 eyes; p<0.001).<sup>11</sup> Comparable results were also found in studies of vitreoretinal surgery.<sup>12 17–19</sup>

Lower endoillumination levels may facilitate patient flow by improving patients' well-being and cooperation during cataract surgery. Similar to our findings, previous studies have shown that reducing light intensity during cataract surgery with a 3D HUVS, can reduce patients' complaints of photophobia and lower patient stress at the beginning of surgery.<sup>9 20</sup> Accordingly, a recent case report of a patient with severe photophobia found that reduced luminance levels with a 3D HUVS enabled this patient to have retinal surgery under local anaesthesia.<sup>21</sup> There is also some evidence that lower surgical light levels may result in better post-operative visual outcomes. Rosenberg *et al* found that patients who underwent cataract

surgery using a digital microscope with low light intensity, achieved a postoperative day 1 visual acuity that was within 2 lines of the postoperative month 1 visual acuity a greater percentage of time than patients who were operated using a conventional microscope (81.5% of eyes vs 54.2% of eyes, p=0.04).<sup>11</sup> Similarly, Sandali *et al* reported that cataract patients who were operated on at low light intensity using a 3D HUVS, were more able to detect hand motion or count fingers immediately after surgery, than patients operated using a conventional microscope.<sup>20</sup> Lastly, retinal phototoxicity is a rare but recognised risk of ocular surgery. Operating at lower light intensity may decrease the risk of phototoxicity to retinal pigmented epithelium cells and photoreceptors.<sup>22</sup>

The ability to control the settings of the NGENUITY 3D HUVS is an essential element for optimising light intensity.<sup>23</sup> As surgeons have different preferences, it is difficult to have universal settings, and there are several possible strategies for lowering microscope brightness while maintaining good image quality. Here, we chose to open the iris aperture wide to 80%, which greatly increased the amount of light arriving at the camera sensors and allowed a significant reduction in microscope light intensity. Although the NGENUITY system provides a much greater depth of field than conventional microscopes,<sup>24</sup>

**Table 3** Light characteristics of the operating microscopes

Variables	Experimental group (n=63)	Control group (n=65)	P value
Light intensity* (Lux)			
Median (Q1–Q3)	3425.0 (2296.0–4300.0)	24 279.0 (16 000.0–26 500.0)	<0.0001†
Luminosity* (%)			
Median (Q1–Q3)	21.0 (17.0–25.0)	50.0 (50.0–55.0)	<0.0001†
Maximal luminosity‡ (%)			
Median (Q1–Q3)	25.0 (17.0–25.0)	50.0 (50.0–55.0)	<0.0001†

\*Light intensity and luminosity were measured at the beginning of surgery.  
†P values are based on the Wilcoxon-Mann-Whitney test.  
‡Maximal luminosity was measured during surgery.

**Table 4** Anaesthesia characteristics

Variables	Experimental group (n=63)	Control group (n=65)	P value
Topical anaesthesia, n (%)	63 (100.0)	65 (100.0)	>0.99*
Oral anxiolytic presurgery, n (%)	0 (0.0)	2 (3.1)	0.50*
Intracameral injection of xylocaine, n (%)	19 (30.2)	22 (33.8)	0.65†
Intravenous sedation, n (%)	56 (88.9)	55 (84.6)	0.48†
If intravenous sedation, compliance with recommended protocol, n (%‡)	55 (98.2*)	55 (100.0*)	0.60*
Anaesthetist called for supplementary sedation, n (%)	3 (4.8)	6 (9.2)	0.49*

\*P values were calculated using Fisher's exact test.  
†P values were calculated using  $\chi^2$  test.  
‡Percentage of patients with intravenous sedation who complied with the protocol.

increasing the aperture led to a loss of depth of field. This required adjusting the focus during surgery when necessary. Since cataract surgery requires less depth of field than other types of ophthalmic surgery such as vitreoretinal surgery, this was not an issue for surgeons in our study. Other parameters of the NGENUITY system could also be modified to decrease the light intensity of the microscope. Slightly lowering the brightness in our settings may seem counterintuitive. However, we found that doing so, in combination with our other selected settings, allowed us to have a less bland image.

To ensure a noise-free image of optimal quality, we left the gain at a minimum of 1 or 2. The gamma was increased to between 1.5 and 1.65, which significantly increased the clarity of the image and also lowered the light intensity of the microscope. Although the default setting of 1.20 is more suitable for posterior segment surgery in order to avoid areas of over and under exposure to the focal endoillumination light source, this is not the case for cataract surgery which uses a diffuse light source that does not move. We found that the decrease in brightness and the increase in contrast made it possible to have a sharper image and to better differentiate transparent structures (such as the rhexis and the nucleus of the lens) from one other. We did not touch the saturation and the hue during the study but it is conceivable that completely lowering the saturation until reaching black and white, may be an interesting way to lower the brightness even more without losing the information required for cataract surgery. One of the problems in black and white would be the difficulty in localising the limbal area, as the limbal vessels tend to disappear with the use of this setting.

Despite using lower light levels with the NGENUITY system, surgical efficacy and safety were maintained in our study; high quality visualisation was obtained, there were no intraoperative complications and no reported undesirable side effects associated with either the microscope or anaesthesia. This is in line with previous studies showing comparable efficacy and safety of the NGENUITY system and conventional microscopes, for cataract surgery.<sup>9 11 24–27</sup> Surgery duration times were significantly

longer in the 3D HUVS group than the conventional microscope group. This may be due to a steeper learning curve using the digital system whose use remains recent for surgeons.<sup>28</sup> Notably, with the NGENUITY 3D HUVS, there is a 0.09s delay between the image shown on the monitor and the surgeon's hand motion. This lag period is thought to have a more pronounced impact in anterior segment surgeries, due to higher instrumental speed while operating.<sup>23 29</sup> Accordingly, some surgeons report needing more time to adjust to using a 3D HUVS for cataract surgery than for vitreoretinal surgeries.<sup>30</sup>

The current investigation has a number of limitations. The choice of microscope light intensity was made subjectively by the surgeon and so it is difficult to know if this choice was comparable between the two groups. It is assumed that factors affecting choice of light intensity were similar between groups, and the absence of complications in each group seems to support this, however, additional studies may be required for confirmation. Patient anaesthesia may also influence results. Sedation levels for cataract surgery can range from no intravenous sedation to deep intravenous sedation. Here, we chose a low dose of intravenous sedation which is commonly used so that patients remain sedated but alert during surgery. The results of our study should be confirmed with different anaesthesia protocols. Nevertheless, our findings suggest that lowering levels of light exposure using a digital 3D HUVS, may improve patient well-being during cataract surgery. This may offer greater comfort to both surgeons and patients, and thereby facilitate patient flow.

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**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involved human participants and was approved by the research ethics committee (Comité de Protection des Personnes Est IV, Ref: CPP 21/53/ RIPHG no 21.00703.000001) and the French National Agency for Medicines and Health Products Safety. Participants gave informed consent to participate in the study before taking part.

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**Data availability statement** All data relevant to the study are included in the article or uploaded as online supplemental information.

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#### ORCID iDs

Vincent Gualino <http://orcid.org/0000-0002-3941-1304>

Aude Couturier <http://orcid.org/0000-0001-8549-7455>

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