



## **Educational Concerns About the Safety of Cataract Surgery During Residency: The E3CAPS Pedagogic Study**

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STUDY PROTOCOL

# Educational Concerns About the Safety of Cataract Surgery During Residency: The E3CAPS Pedagogic Study

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## ABSTRACT

**Introduction:** Cataract surgery is the most common surgical procedure performed in France. While the incidence of intraoperative complications affecting visual prognosis is

extremely low, given the large number of patients operated on, the absolute number of patients affected by complications is quite high. Complication rates are significantly higher when ophthalmology residents (ORs) perform the surgery. Although lack of experience remains the main risk factor, sleep deprivation may adversely affect ORs' successful surgery rate. The value of the EyeSi® surgical simulator in initial training has been demonstrated to

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increase cataract surgery safety through the transfer of surgical skills from the simulator to the operating room. However, there is no consensus regarding how much training is needed before the first-time ORs are allowed to operate. There is also no scientific evidence that sleep deprivation is associated with a decrease in surgical performance. Establishing a validated protocol for cataract surgery training using the EyeSi surgical simulator (referred to further as the EyeSi) and identifying risk factors for intraoperative complications related to sleep deprivation will improve cataract surgery safety and lead to the reorganization of our healthcare systems.

**Methods and Planned Outcomes:** This multi-centre educational cohort study will include two distinct axes which will both aim to reduce the risks of cataract surgery. Enrollment will include 16 first-year ORs for Axis 1 and 25 experienced residents for Axis 2, all from the University Hospitals of Nantes, Tours, Angers and Rennes. Axis 1 will focus on investigating the learning curve of first-year ORs using the EyeSi, following the training program recommended by the “College des Ophtalmologistes Universitaires de France” in order to set up a future “licence to operate.” Axis 2 will evaluate the impact of sleep deprivation on the surgical performance of experienced ORs using the EyeSi.

**Trial Registration:** ClinicalTrial.gov identifier: NCT05722080.

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**Keywords:** Cataract surgery; Simulation; Resident ophthalmologist’s learning; Learning curve; Sleep deprivation

### Key Summary Points

#### *Why carry out this study?*

Cataract surgery is the most common surgical procedure in France.

Intraoperative complications have been shown to increase when ophthalmology residents (ORs) perform the surgery owing to a lack of experience.

The aim of this study is to assess the learning curve of ORs using a surgical simulator and to investigate the relationship between sleep deprivation and surgical performance.

This study is intended to be the catalyst for a change in the way ORs are taught cataract surgery.

## INTRODUCTION

### Background

Cataract surgery is the most common surgical procedure in France, with 884,254 cataract surgeries in 2018) [1]. The procedure is performed under an operating microscope and requires high levels of precision and attention from the surgeon. Perfect mastery of the surgical technique is all the more important because surgical complications, especially posterior capsule rupture, can significantly alter the patient’s visual outcome [2].

Until recently, the main approach to learning cataract surgery was through shadowing and hands-on practice under the supervision of an experienced surgeon. The sole prerequisites were theoretical learning, observation of experienced surgeons in real life, and manipulation of pig eyes or artificial eyes during hands-on

work. However, while rehearsing surgical steps on a porcine or artificial eye is useful, it is insufficient in terms of preparing the surgeon for human eyes because of the significant differences in tissue thickness and resistance between the eyes of humans and artificial eyes or those of pigs. These learning modalities are valuable and are still used today but their limitations are well known [3, 4].

The incidence of posterior capsular rupture, the main vision-threatening intraoperative complication, is known to be higher in patients operated on by ophthalmologist residents (ORs) (incidence ranging from 5% to 17%) [5–8] than in those operated on by experienced surgeons (incidence ranging from 0.5% to 3.5%) [9]. While these complication rates are relatively low, when compared to the very high number of surgeries performed each year, they ultimately affect many patients.

Cataract surgery simulators are a valuable tool that can be used to reduce this excess of surgical risks related to training and to respect the “never the first time on a patient” principle recommended by the French National Health Agency [10]. The EyeSi® surgical simulator (VRMagic, Mannheim, Germany) is the most widely used simulator in France. It allows the ORs to perform most of the steps of cataract surgery virtually, modulating the difficulty and giving the student a qualitative and quantitative performance appraisal for each surgical step. Numerous studies have been conducted to evaluate the benefit of using the EyeSi surgical simulator in OR training. According to several authors [11–13], the score obtained on the simulator correlates with different surgical skill scores in the real-life situation, with the simulator able to differentiate between an experienced and a novice operator. The use of the simulator leads to acceleration of the learning curve, reduction of the rate of surgical complications, and to improved surgical skill scores of both the novice and the experienced surgeon.

However, there is no assessment of the amount of simulator training required before real surgery can be performed. The creation of a “licence to operate” with a simulator test is an objective set by the “Collège des Ophtalmologistes Universitaires de France” (COUF). The

COUF recommends four 2-h-long simulator sessions during the first year. Analysis of the learning curve in our study will help to improve the training program by determining whether additional training sessions are needed and identifying which steps are the most difficult and slowest for students to master.

In addition to high-precision surgery in a specific operating theater environment, the large number of patients to be operated on in the same operating theater, resulting in high turnover, requires mobilization of all the attentional, intellectual and gestural capacities of the ophthalmic surgeon. These capacities can be affected by sleep deprivation both in terms of professional activities (e.g., continuity of care, examinations, theoretical learning) or personal activities (e.g., parenthood, leisure). In particular, as university medical studies are among the longest academic programs, the proportion of medical students who are parents is one of the highest [14]. Finally, given their mixed status as students and hospital staff, ORs may need to reduce the amount of sleep they get in order to improve their theoretical knowledge. For example, in the field of aviation, fatigue is a main contributing factor in fatal accidents (e.g., estimated incidence of between 4% and 7% in the USA in 2001 [15]), with the main known risk factors being sleep deprivation, prolonged wakefulness, irregularity of circadian rhythm and heavy workload, among others.

These risk factors are the same as those identified in the medical environment and a fortiori in OR populations. The results of studies evaluating the effect of sleep deprivation on the technical and cognitive skills of non-ophthalmic surgeons under simulation conditions are not homogeneous and their validity is often limited by the presence of numerous biases (e.g. poorly assessed chronotype, lack of objective sleep measurement) [16].

To date, only one Canadian study by Erie et al., 2011, has examined the relationship between sleep deprivation and surgical performance on the Eyesi surgical simulator. No relationship was found, but only nine ORs were included [17] and the assessment of sleep quantity was declarative: there was no assessment of cognitive ability and, most

importantly, there was no calculation of the number of subjects required to demonstrate a possible decrease in surgical performance. We postulate that sleep deprivation decreases patient safety, but this risk has not yet been demonstrated.

To conclude, we have proposed hypotheses for addressing these unmet educational needs: for Axis 1, to establish the learning curve of the OR to improve the national training program and to set up a national “license to operate” in the short term; for Axis 2, to assess surgical performance of experienced ORs following sleep deprivation.

### Study Objectives

To confirm or reject these assumptions, the primary objectives are: for Axis 1, to establish the learning curve of novice ORs following the training program recommended by the COUF (4 sessions, each of 2-h duration, over a period of 1 year) for each surgical step and then for the entire surgery; for Axis 2, to assess changes in the surgical performance of experienced ORs after sleep deprivation. The secondary objectives are: for Axis 1, to assess just how representative are the learning curves of each surgical step of the global learning curve and how much the global learning curve is influenced by possible surgical practice biases of ORs; for Axis 2, to assess the relationship between sleep deprivation, sleepiness, cognitive performance, perceived fatigue, and surgical performance, and to assess whether perceived fatigue correlates with reduced surgical performance.

### Trial Design

This interventional longitudinal prospective study involved and will involve ORs from the University Hospital of Nantes, Tours, Angers and Rennes. The study started on 9 January 2023 and is scheduled to end in December 2024.

## METHODS

### Study Setting

For Axis 1, as recommended by the COUF, each OR will complete four 2-hour-long learning sessions over a period of 1 year under the supervision of an experienced cataract surgery educator at the university hospital centers mentioned above. Each OR will perform a standardized assessment at the beginning of the first session, collecting scores at each surgical step and calculating an average score, thereby simulating a complete surgery. This standardized assessment will then be repeated at the end of each of the four training sessions. These five points of measurement will allow the realization of a learning curve for each surgical step and for an average score simulating a complete surgery. Additional assessments will be performed at the beginning of the second, third and fourth session and will concern only the capsulorhexis step: this increases the number of assessments to eight points of measurement for the capsulorhexis step. The addition of a test at the beginning of the training session increases the accuracy of the measurement of student progress and, in particular, makes it possible to assess any loss of skill or knowledge since the end of the previous session. To avoid inducing fatigue or reducing the length of the training session, the capsulorhexis step was chosen because it is short, difficult to master, and responsible for critical surgical complications. Furthermore, it is slightly more representative of real-life techniques than phacoemulsification [18].

For both Axis 1 and 2, the experimental procedure will include the collection of the following data for each OR: demographic data, dominant hand, video game experience (none, limited, high), music instrument experience (none, limited, high), in vivo surgical experience (number of cataract procedures) and experience out of the operating room (number of previous simulations/training sessions on porcine and/or synthetic eyes). For Axis 2, data on chronotype assessment (the Horne and Östberg self-assessment morningness-eveningness

questionnaire validated in French [19]) and the sleep schedule 1 week before the first session will also be collected.

For Axis 1, in order to minimize the risk of bias associated with any previous surgical practices of the OR, the study population will include only novice ORs who are less than 3 months into their residency. To take account of any heterogeneity in the population for both Axis 1 and 2, data on surgical practice experience will be collected and quantified using a composite score adding up the following data: video game experience (none = 0 point; limited = 1 point; high = 2 points), music instrument experience (none = 0; limited = 1; high = 2), cataract surgery simulation sessions (1 point per hour of training with pig's eyes, synthetic eyes or a virtual simulator), and any tasks performed in the operating room (1 point per set of 5 attempts for each step of cataract surgery: incision, capsulorhexis, hydro maneuvers, phaco-emulsification, irrigation and aspiration, intra-ocular lens [IOL] insertion, viscous removal, hydro-suture).

In order to limit bias for Axis 2, we will ensure that the participants did not consume caffeine in the 24 h before each of the three phases and that they had a systematic breakfast before each session; in addition, each evaluation will be carried out at the same time in the morning between 9 and 11 am and in the afternoon between 1 and 3 pm. The three sessions will be carried out on three consecutive days to limit individual variability in any other factors influencing surgical performance, except for sleep deprivation. For both axes, the evaluation phase will be performed without any student/resident present in the room in order to limit competition bias.

The study flowchart for Axis 2 is shown in Table 1. The study design detailing enrollment and intervention is shown in Fig. 1 as the SPIRIT recommendation. The SPIRIT checklist, a guideline for the minimum content of a clinical trial protocol [20], has also been uploaded as electronic supplementary material (ESM; Table S1).

## Sample Selection

Sixteen novice ORs from the departments of ophthalmology in the University Hospitals of Nantes, Tours, Angers and Rennes, respectively, will be included in Axis 1. For Axis 2, the target population corresponds to ORs in the second half of their residency, i.e., in their fourth, fifth, and sixth year. Calculating the number of subjects required to demonstrate a 10% reduction in surgical performance after sleep deprivation allowed us to define a target of 25 ORs. The only exclusion criteria is the absence of consent to participate for Axis 1 or Axis 2. Written informed consent will be obtained from all study participants by a senior ophthalmologist surgeon.

## Measurement—Description of the Score Used

The EyeSi surgical simulator is a high-fidelity virtual reality simulator used for training and practicing various aspects of cataract surgery [21]. The device includes a platform on which is placed the dummy of a patient's head with, in place of the eye, a digital box consisting of numerous sensors, into which the OR inserts two handpieces. The virtual reality image of the virtual operating field is produced in high definition and stereoscopy through operating microscope eyepieces positioned above the platform. This set-up provides a highly realistic and immersive reproduction of real-life conditions. The EyeSi surgical simulator, which is specifically designed for cataract surgery, is a well-studied and unique tool and, to our knowledge, with no recognizable competitors. Thomsen et al. provided evidence that EyeSi simulator training significantly improves operating room competencies for beginning ORs [22]. This finding implies that the simulator serves as an instrumental asset for skills transfer.

Cataract skills training on the EyeSi cataract include surgery training modules for capsulorhexis, hydro maneuvers, phacoemulsification, irrigation and aspiration, IOL insertion, and posterior capsular rupture management. Training exercises can be customized based on



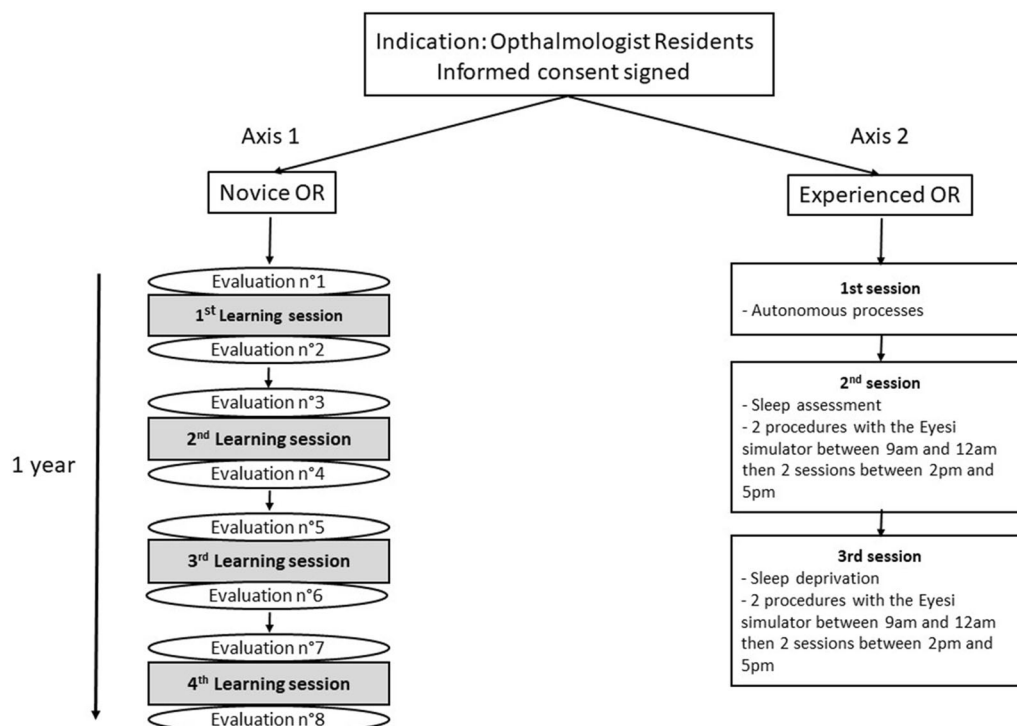
**Table 1** Flowchart for Axis 2

Session	Actions
First session: To include the so-called “experimented” ORs and to limit the learning curve bias of the cognitive tests and the surgical procedure	<ul style="list-style-type: none"> <li>- 3 normed self-report assessments to determine the average score for each OR</li> <li>- 3 administrations of TAP, with parallel versions to limit test–retest learning bias</li> </ul>
Second session: Absence of sleep deprivation	<ul style="list-style-type: none"> <li>- Sleep assessment by actimetry the night before the session (using the MotionWatch 8 medical-grade actigraphy watch [CamNTEch, Fenstanton, UK], validated as an alternative method to the reference method polysomnography)</li> <li>- Epworth Sleepiness Score</li> <li>- Visual analog scale for self-rated fatigue</li> <li>- 2 TAP tests between 9–12 am and 2–5 pm, respectively</li> <li>- 2 standardized assessments on the EyeSi® surgical simulator (VRMagic, Mannheim, Germany), between 9 am and 12 am and between 2 pm and 5 pm, respectively</li> </ul>
Third session: Sleep deprivation (< 7 h cumulative) after a day’s work	<ul style="list-style-type: none"> <li>- Sleep deprivation (&lt; 7 h cumulative) after a day’s work</li> <li>- Sleep assessment by actimetry the night before the session (MotionWatch 8©)</li> <li>- Epworth Sleepiness Score</li> <li>- Visual analog scale for self-rated fatigue</li> <li>- 2 TAP tests between 9 am and 12 am and between 2 pm and 5 pm, respectively</li> <li>- 2 standardized assessments on the EyeSi surgical simulator, between 9 am and 12 am and between 2 and 5 pm, respectively</li> </ul>

OR Ophthalmologist Resident, TAP Test for Attentional Performance

the desired skill level, specific technique to practice, and/or surgical challenges to address. During virtual surgery, cataract instruments, such as forceps, visco cannula, cystotome, and phaco probe, are available. A digital interface and a realistic two-axis phaco foot pedal allow the control of fluidics. The OR must select appropriate phaco parameters in order to safely and effectively complete the chosen surgical procedure.

Throughout the simulation, EyeSi can provide real-time feedback on various parameters, such as completion of tasks, amount of ultrasound delivered, eye tissue injury, inappropriate insertion of instruments, or eye shift. The simulator tracks and records performance metrics, allowing surgeons to measure their progress over time. Simulation tasks repeat and reinforce microsurgical motor skills, microscope handling, proper pivoting at the incision, and understanding of spatial boundaries. Using a



**Fig. 1** E3CAPS study design. OR Ophthalmologist Resident

specific numerical scale for each surgical step, including positive points for tasks completed and negative points for errors and inappropriate or dangerous gestures, the simulator awards a score of between 0 and 100 for each attempt.

In the present study, the standard test will take approximately 20–30 min and consists of the following exercises: capsulorhexis level 1, hydro maneuvers level 2, phaco divide and conquer level 6, irrigation and aspiration level 3, and IOL insertion level 3. Each exercise simulates the performance of a step of cataract surgery, and the sequence has been chosen to simulate a complete standard cataract surgery. For each exercise, the following data will be collected: EyeSi score (ranging from 0 to 100, where a higher score is positively correlated with a better performance), measurements of the distance traveled in the eye by the instruments (odynometry, in millimeters), and measurement of the completion time of the exercise.

To assess sleep, the chronotype will be determined using the Horne and Östberg morningness-eveningness questionnaire [19],

which allows five categories to be defined: complete morning; moderate morning; neutral; moderate evening; complete evening. Sleepiness is assessed using the Epworth sleepiness scale [23].

Attention is tested by five subtests of the TAP (Test for Attentional Performance) [24, 25]:

- Alertness (4 min 30 s). This test measures reaction time in two scenarios. First, it gauges simple reaction time by asking participants to press a key as swiftly as possible when a cross is displayed randomly on the screen, thereby assessing intrinsic alertness. The second scenario times responses to a critical stimulus following an auditory cue, thereby testing the timing of attentional focus.
- Divided attention (6 min). In this test, a visual and an auditory task will be processed in parallel asynchronously.
- Flexibility (3 min). This ‘set shifting’ task presents a letter-number pair on the screen. Participants will respond to alternating targets (letter-number-letter sequence).



Participants press a key depending on whether the target appears to the left or right of the screen's center.

- Incompatibility (3 min). This task examines stimulus–response incompatibility by displaying arrows pointing left or right at varying sides of a fixation point. Irrespective of where the arrow appears, participants must respond with an arrow corresponding to the arrow's direction.
- Working memory (5 min). This activity tests the handling and updating of data in working memory. A number sequence is shown to the participant, who must decide if each number matches its immediate predecessor or the second-last one, depending on the scenario.

For all participants, both the ability to complete the task and the reaction time will be recorded.

Sleep is assessed by actimetry using the MotionWatch 8 medical-grade actigraphy watch (CamNTEch, Fenstanton, UK), the use of which has been validated as an alternative to the reference method, polysomnography [26].

### Planned Outcomes

The main endpoint of Axis 1 is the EyeSi score collected for each exercise. A mean score for each timepoint is calculated. The mean score for all exercises simulates a complete surgery. Secondary endpoints are odynometry and completion time for each exercise. To model the learning curve, these normalized assessments will be repeated throughout the training program.

For Axis 2, we will measure the decrease in the mean score on a complete surgery after sleep deprivation (session 3) in comparison to the mean score before sleep deprivation (session 2). The aim of session 1 is to verify that the experienced ORs can successfully complete cataract surgery and to assess the baseline performance in order to reduce the learning bias. For the secondary outcomes (Axis 2), correlations will be made between the Epworth sleepiness score, visual analog fatigue scale, attention scores, and

surgical performance scores between session 2 and session 3.

### Data Management

The two coordinators of these study are committed to maintain the confidentiality of the OR involved in the study. In this respect, an anonymity code for each OR will be generated in order to create an electronic dataset without any information on OR identity. A separate document that links the anonymity code to the identify of each participant will be locked in a separate location and its access will be strictly restricted to these two coordinators. The presentation of the research results must exclude any direct or indirect identification.

### Data Analysis

For Axis 1, a learning curve will be derived from the plot of the score against the number of sessions: several functional forms will be tested in order to obtain the best fit to the data [27, 28]. The learning rate will be estimated for each surgical step and for the complete surgery based on this model. The model will be adjusted to possible surgical practice biases. To assess the extent to which the learning curves of each surgical step are representative of the global learning curve, we will assess the correlation between the overall mean score and the mean score for each step score using Pearson or Spearman's correlation. The percentage of ORs reaching the performance threshold (score of 80 out of 100) at the end of the training program and its 95% confidence interval will be estimated. A linear mixed model will be constructed to account for the repeated nature of the measurements for the Axis 2 criterion. The model will be fitted to the differences observed in the descriptive analysis with respect to video game experience (yes/no, 1 coefficient to be estimated), in vivo surgery (number of cataract procedures, 1 coefficient), and simulator experience (number of previous pig eye and synthetic eye simulations/trainings, 1 coefficient to be estimated) and the presence of chronic sleep deprivation (1 coefficient). The endpoint is the

difference in intercept between the two periods before and after. Statistical analyses will be performed using R (version 4.0.2; R Foundation for Statistical Computing, Vienna, Austria).

### Sample Size

For Axis 1, given the exploratory nature of this analysis, the sample selected will be a convenience sample, represented by the 16 newly nominated ORs in the participating University Hospitals.

For Axis 2, the proposed multivariate analysis will require the inclusion of five students per estimated coefficient ( $n = 4$ ), i.e., 20 students, given an alpha risk of 5% and a beta risk of 20% [29]. The repeated nature of the measurements leads to an increase in the sample of 25%, i.e., a total of 25 students, in order to maintain adequate power, assuming an intraclass correlation coefficient equal to 0.25 (conservative approach) [30].

## STRENGTHS AND LIMITATIONS OF THIS STUDY

This project is supported by the COUF, which highlights the great importance of the project for the safety of care in cataract surgery training. It will contribute to addressing the following challenges: promotion of multicenter projects for surgical education purposes; evaluation of simulation-based learning tools; improving safety for learners and patients; homogenization of surgical education practices at the national level; and creation of a national “license to operate.”

This project is also supported by the “Hopitaux Universitaires du Grand Ouest” (HUGO-Western University Hospitals) and the simulation centers of each participating University Hospital as it is a regional and structuring educational project.

To our knowledge, it will be the first pedagogical trial to assess the importance of sleep deprivation on both surgical and cognitive skills for cataract surgery. These findings will raise awareness on the importance of taking into

consideration continuity of care and residents’ lifestyle as risk factors for surgical complications.

The main limitation of our study is the relatively small size of the cohort for Axis 1 because of the restriction to enroll only novice residents.

## ETHICS AND DISSEMINATION

The project has won the competitive regional call for proposals “Recherche en simulation—2021” (Research in simulation–2021) of the “Groupement Interrégional de Recherche Clinique et d’Innovation du Grand Ouest” (GIRCI-GO) (Interregional Group on Clinical Research and Innovation of the ‘Grand Ouest’ region). The clinical study will be conducted in accordance with the Public Health Code of France, national and international Good Clinical Practice (GCP) guidelines, and the Declaration of Helsinki, each in the applicable version. This clinical study was approved by the Ethics Committee of Nantes University on 17 October 2022. At the time of writing, this trial had just started. The updated protocol is available as version 2 (28 January 2023). The first OR was enrolled in January 2023. The study will run until December 2024.

The trial results will be published in international peer-reviewed scientific journals and presented in national and international congresses. The investigators, who will share all the final trial dataset, will follow the rules and guidelines of the International committee for Medical Journal Editors (ICMJE) for authorship. The sponsor (CHU Nantes) and GIRCI-GO, which provides the grant, has to be cited in the publication.

## CONCLUSION

The simultaneous exploration of these two axes has the aims to evaluate surgical skills of both novice and experienced ORs. Due to the COVID crisis, the number of cataract surgeries and the accessibility to the operating room in university hospitals has decreased: this hinders the

training of ORs and makes the formalization of a simulator training program urgent. Furthermore, because the results will have implications for the safety of surgical care beyond specialists in ophthalmology, the implementation of the second axis on sleep deprivation is justified. French hospitals are currently facing serious organizational difficulties that affect the quality and safety of care: the current upheaval in the role of postgraduate students and the public hospital as a whole makes it necessary to obtain the results of these two axes rapidly and simultaneously.

Regarding safety of care, this study will make it possible to reduce surgical complications affecting visual outcome by improving the effectiveness and relevance of OR simulator learning. If the results obtained on the simulator are unsatisfactory, the OR's visualization of the average learning curve and his/her personal curve allows him/her to postpone practice on a real-life patient with confidence.

If a decrease in surgical performance is found after sleep deprivation, the study will accelerate the reorganization of care time by ORs, confirm the importance of safety rest, and finally make all ORs aware of the importance of getting sufficient sleep. Further investigations will be needed to evaluate the impact of sleep deprivation on senior surgeons' surgical performances as tolerance to sleep deprivation may be influenced by age and experience. These findings will spread beyond the field of ophthalmology and will highlight the need for all surgical specialties to study the impact of sleep deprivation on surgical skills.

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**Author Contribution.** Jean-Baptiste Ducloyer and Raoul Kanav Khanna designed the trial. Jean-Baptiste Ducloyer, Raoul Kanav Khanna, Alexandra Poinas, and Pierre Lebranchu wrote the protocol. Alexandra Poinas, Jean-Baptiste Ducloyer, and Raoul Kanav Khanna coordinated the submission and the follow-up of the GIRCI tender and the regulatory authorities, and are coordinating the trial. Pascal Caillet and Léa Duchesne wrote the methodological/statistical analyses section in the protocol. Alexandra Poinas wrote the manuscript, Raoul Kanav Khanna, Léa Duchesne, Pascal Caillet, Catherine Ivan, Corinne Lejus Bourdeau, Nadège Limousin, Thomas Desmidt, Frederic Mouriaux, Patrick Pladys, Pierre-Jean Pisella, Anne Bernard, Hubert Lardy, Philippe Gohier, Ludovic Martin, Pierre Lebranchu, and Jean-Baptiste Ducloyer assisted with the drafting of the manuscript. Raoul Kanav Khanna, Corinne Lejus Bourdeau, Philippe Gohier, and Jean-Baptiste Ducloyer participated in enrolling ORs and the follow-up in Axis 1.

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

**Ethical Approval.** The clinical study will be conducted in accordance with the Public Health Code of France, national and international Good Clinical Practice (GCP) guidelines, and the Declaration of Helsinki, each in the

applicable version. This clinical study was approved by the Ethics Committee of Nantes University on 17 October 2022.

**Conflict of Interest.** Jean-Baptiste Ducloyer, Alexandra Poinas, Léa Duchesne, Pascal Caillet, Catherine Ivan, Corinne Lejus-Bourdeau, Nadège Limousin, Thomas Desmidt, Patrick Pladys, Pierre-Jean Pisella, Anne Bernard, Hubert Lardy, Philippe Gohier, Ludovic Martin, Frederic Mouriaux, Pierre Lebranchu and Raoul Kanav Khanna have nothing to disclose.

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