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The PRIS-Tool. Preparing for clinical studies.

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Abstract: The entoptic view of the retina is a fascinating phenomenon that is caused by light stimulation. Over the course of the past two years, we have been developing our Purkinje Retinal Image Stabilizer (PRIS) method to simplify entoptic testing for retinal examinations. Our non-invasive method is intended as a retinal function test and to make disease-related changes in the retina or the retinal blood vessels visible to the user. Technically, we have implemented it in a small light stimulator, the PRIS-Tool. In a next step, clinical studies have to be conducted to verify the reliability and safety of the PRIS method as an ophthalmic screening tool for medical applications. We are focused on its use for the early detection of diabetic retinopathy worldwide and for the preoperative assessment of retinal function in cataract patients in low-income countries. For clinical studies, enhancements and new functions have been implemented in the redesigned PRIS-Tool device to facilitate handling and optimize in-house assembly. We also present our approach for assessing photobiological safety in accordance with IEC/EN 62471.

Keywords: entoptic, retinal, vessel, Purkinje, diabetes, retinopathy, ophthalmic, non-invasive, PRIS

1 Introduction

In order to proof the principle of our Purkinje Retinal Image Stabilization (PRIS) method, we have developed a diagnostic benchtop device for image perception of retinal blood vessels, as presented previously in [1], based on the Purkinje vascular entoptic test. Under particular light stimulation conditions, the central retinal vessels appear highly magnified as a stable image, known as the Purkinje tree. In preliminary PRIS experiments, it was observed that green light elicits a highly pleasant perception. This was followed by investigations to identify optimal stimulation parameters (e.g. brightness, geometries) using green light.

Subsequently, the method underwent miniaturization into the ergonomically designed PRIS-Tool, as outlined in [2]. It is battery-powered and microcontroller-based and was reduced to the key functions of the desktop device. It provides defined light stimulation and offers flexibility for improving device parameters or implementing new functionalities. For the entoptic eye examination, the light source-equipped tip of the PRIS-Tool is placed laterally on the closed eyelid. The light source, comprised of five bright light-emitting diodes (LEDs) arranged in a circular configuration, simulates a rotating light spot movement.

As a next step in developing the method, clinical studies will be conducted to test reliability and safety as an ophthalmic screening tool for diverse medical applications. These applications include its use as a diagnostic tool for the early detection of diabetic retinopathy worldwide and for the preoperative assessment of retinal function in cataract patients in low-income countries.

We estimated that 50 devices will be required at different facilities for clinical trials over the next twelve months; consequently, enhancements and new functions have been implemented in a redesigned version of the PRIS-Tool to facilitate device handling and optimize in-house assembly. Moreover, we have verified and documented conformity with fundamental requirements of international standards and guidelines for safe use on humans. We present our approach to assess the photobiological safety of the device by radiance determination to ensure that there is no risk to the retina from blue light hazard according to IEC/EN 62471.

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2 Materials & methods

2.1 Photobiological safety

Solid angle of a LED

Determining the radiance of a light source and comparing it with emission limit values from regulatory standards is the methodical approach to estimate the risk of photobiological hazards to the retina. To calculate the radiance of a light source from irradiance measurements, the solid angle Ω has to be known, as radiance is irradiance per solid angle.

The PRIS-Tool is equipped with five light-stimulating NSPG300D LEDs (Nichia Corp., USA), each with a focusing lens for a small radiation angle α, resulting in a narrow light beam. The modelling of the circular light cone considers the LED as a point source located at the apex. The cone is defined by Ω and its height. However, the focusing lens introduces a distortion in the LED position. According to [3], the concept of the virtual point source, marking the apex in an apparent distance of *X* behind the LED, had to be applied, as shown in **Figure 1**.

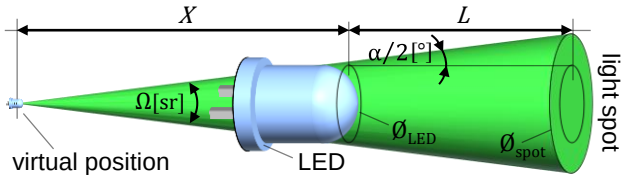

Figure 1: Modelling for solid angle calculation

To calculate *X*, the spot diameter $Ø_{spot}$ of the light beam at the distance *L* is required:

$$Ø_{spot} = Ø_{LED} + 2 \cdot L \cdot \tan(\alpha/2) \quad (1)$$

$$X = Ø_{LED} \cdot L \cdot (Ø_{spot} - Ø_{LED})^{-1} \quad (2)$$

To simplify the calculation of Ω, the spherical spot area is assumed to be flat, which is acceptable for small solid angles:

$$\Omega\,[sr] = \pi \cdot Ø_{spot}^2/4 \cdot (X + L)^{-2} \quad (3)$$

Application-specific assumptions

Based on the functionality and application of the PRIS-Tool, we defined application-specific assumptions that are fundamental for a reliable assessment of photobiological safety. These include the following:

- each LED is perceived as one source,
- each LED covers a large field of vision,
- each LED illuminates a different part of the retina,
- LED cannot be assumed to be a point light source,
- α is specified for 50% of the maximum luminosity,
- radiance analysis on single LEDs (*L* = 1 mm),
- we always assume the worst case: open eyes.

To determine $Ø_{spot}$, *X* and Ω, summarized in **Table 1**, we refer to the manufacturer's LED specifications for α and the LED diameter $Ø_{LED}$.

Table 1: PRIS-Tool application-specific parameters needed for radiance determination from irradiance measurements.

parameter	calculated value	equation
light spot diameter $Ø_{spot}$	3.25 mm	(1)
virtual distance *X*	20.86 mm	(2)
solid angle Ω	0.0175 sr	(3)

LED diameter $Ø_{LED}$ = 3.1 mm [4], radiation angle α* = 8.5° [4], LED to light spot distance *L* = 1.0 mm, *incl. 50% of the maximum luminosity.

Configuration for irradiance measurements

A X13 hazard light meter connected to a XD-45-HB blue light hazard detector (both Gigahertz Optik GmbH), compatible with the IEC/EN 62471 standard for irradiance measurements, were used to assess the photobiological hazard that may affect a human eye, looking directly into a light source at a distance of *L* = 200 mm. In accordance with its intended application, the PRIS-Tool LEDs are placed in contact with the closed eyelid (*L*→0), which differs significantly from the test setup specified in IEC/EN 62471. Preliminary tests on the influence of the distance between the LED and XD-45-HB detector revealed, that a maximum irradiance was achieved at *L* = 1 mm, a distance that is comparable to the intended use of the PRIS-Tool. For setting this short distance, the LED under test was positioned using a spacer. The light spot was centered on the detector, see **Figure 3A**.

Irradiance measurements were conducted, varying the supply voltage to identify a suitable LED operating range, that would not result in a blue light hazard. Radiance was calculated from irradiance values, with respect to the application-specific parameters in **Table 1**. To consider the worst case scenario, the light-protective effect of the eyelid was not included. Similar to the PRIS-Tool electronics, the LED under test was current-limited by a series resistor (10 Ω) connected to a regulated DC power supply. Supply and forward voltages were measured with a Keithley 2000 multimeter (Keithley Instruments, Inc., USA) to document operating point of each LED individually but also to evaluate the current-setting technique. All LEDs were investigated by using the same test setup.

2.2 Device properties

Electronics: A comprehensive revision has been conducted on the electronics primary to enhance device usability with the

introduction of new functions to enable more flexible configuration of light parameters and to simplify the manufacturing process.

Brightness adjustment: The PRIS-Tool was initially equipped with a push-button to adjust brightness in four intensity levels [2]. However, since we found that in most cases the default setting (70% PWM) is perceived as ideal, the need for brightness adjustment has been discussed. Entoptic tests with deactivated brightness adjustment were performed.

Battery discharge status: Fully charged devices are capable of continuous operation for up to 15 hours. However, a battery level indicator would improve the usability of the device, allowing the user to recharge the battery before it is empty. It was requested that no additional display components should be integrated.

Manufacturing: The digital light processing (DLP) UV printer ASIGA PRO 4K45 is continued to be used for additive manufacturing of the 2-shell housing and the small light source cap that encapsulates the LEDs at the tip, see **Figure 2**. The 3D printing processing parameters were optimized to ensure constant manufacturing quality. Consequently, the two housing shells are currently printed vertically, initiated at the rear side. This approach has been found to markedly reduce the necessity for mechanical post-processing, as the two shells are designed to align seamlessly even after UV curing. The assembly of the light cap in **Figure 2A**, which encloses the lower section of the LED housings, was modified to embed with certified non-cytotoxic 2-component adhesive Epoxy Resin L with Hardener S (R&G Faserverbundwerkstoffe GmbH).

3 Results & discussion

3.1 Measurement results

Figure 3B presents the LED radiance as a function of the applied supply voltage in a box plot. Despite the short distance to the detector, the NSPG300D LEDs (n = 25) do not exceed the radiance limit of 100 $Wm^{-2}sr^{-1}$ for blue light hazards specified in IEC/EN 62471. Under the application-specific assumptions made above, the usage of these LEDs can therefore be classified in risk group RG0 (no risk) for all tested LEDs and for all tested supply voltages, including the currently used 3.05 V. Compared to the effective irradiance for blue light the amount of UV-A and red light measured with the detector was considered as negligible, which is consistent within the manufacturer's specifications in [4] concerning the narrow wavelength range of the LEDs. The light-protective eyelid has not been considered, assuming the worst case scenario that the user does not keep the eyes closed as instructed, but rather inadvertently looks directly at the light-stimulating LEDs. Nevertheless, in the wavelength range of the green-emitting LEDs, eyelids have a light transmission of 2% or less [5]. In addition, their focused light beam will be diffused through the eyelid. However, it should be assumed that pressing the LEDs gently towards the closed eyelid significantly increases light transmission of the skin.

Two limitations must be mentioned: (1) The XD-45-HB detector is not a spectroradiometer and is therefore only used to estimate the photobiological hazard under the assumptions made. (2) The illumination of the diffusing disk of the detector was not homogeneous, due to the short LED distance.

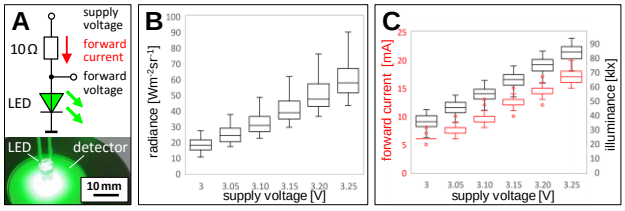

Figure 3: LED radiance and forward current *vs.* supply voltage

Forward current *vs.* supply voltage: Forward currents in **Figure 3C** differ significantly, though the same test setups was used for all tested LEDs (n = 25). Some values were even detected as outliers in box plot. A direct correlation of the forward current to the irradiance was not determined, but to the illuminance also measured with the detector, underlayed in **Figure 3C**.

3.2 Improved device handling

Improved design: As seen in **Figure 2**, the housing has been redesigned, with primarily: (1) The cut-outs have been adapted to improve device resistance to the ingress of solid foreign objects, to be compliant with IP4X. (2) The cut-out for the brightness button has been removed. (3) The two holes for the charging status LEDs have been replaced by transparent material thinning. (4) The time-consuming device labeling technology was replaced by laboratory adhesive labels.

Improved electronics: The electronics architecture as described in [2] remained basically unchanged. The PCB layout of the carrier board, which is responsible for carrying and electrically connecting all components and electronic modules, underwent a redesign process.

Fixed brightness: The device no longer offers brightness adjustment. Brightness is fixed to 70% PWM. The removal of the brightness button simplifies not only device handling, but also the technical complexity of the housing and electronics.

Battery level indicator: To improve device usability, it was equipped with a battery level indicator implemented by electronics and software modifications. As a result, the battery status is displayed intuitively by the number of illuminated light-stimulating LEDs representing a level meter of five segments. The indicator is activated for seconds: (1) After switching the device on, and (2) if the battery voltage falls below a threshold value during continuous operation. In both cases, PRIS light stimulation subsequently starts automatically. The threshold value was set to a remaining operating time of at least one hour.

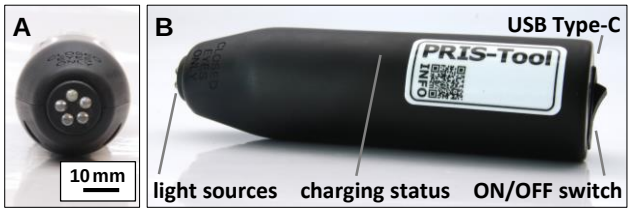

Figure 2: Redesigned PRIS-Tool

4 Conclusion

According to IEC/EN 62471, the photobiological safety of the LEDs used in the PRIS-Tool could be classified in risk group RG0 (no risk) under the assumptions made. Modelling the LED configuration by introducing the virtual LED position was an essential step for application-specific parameter determination including the solid angle Ω, needed for radiance calculation from irradiance measurements. To consider the worst case scenario, the light-protective effect of the eyelid was not included. The parameters listed in **Table 1** were calculated using the manufacturer's LED specifications, as experimental methods as described in [3] were not applicable.

The described improvements in the electronics and the housing by adding new features and streamlining the design have increased device usability. Furthermore, the in-house assembly has been simplified by further enhancements.

The evaluation of the LED forward currents showed that the resulting current varies even with a stable supply voltage. This is because we operate the LEDs, due to their high luminosity, below their nominal operation range, which exponentially increases the influence of the dynamic resistance of the LED at lower forward currents. This makes the current-setting technique with series resistor sensitive to any influence, e.g. from supply voltage changes or LED tolerances, potentially resulting in some luminosity variations. For comparative purposes, we will test constant current drivers. Actually, we avoid variations by carrying out pre-assembly test measurements.

An assisting app running on mobile devices is supposed to support the user in performing the Purkinje test with information and instructions, but also to help in reliably detecting and documenting retinal changes or abnormalities. The app is currently under development using Swift (Apple Inc., USA).

Our PRIS method is notable for its simplicity, which can greatly facilitate a medical application. We have recently designed a clinical trial to further evaluate the method in diabetes patients, pending ethical approval. Therefore, the PRIS-Tool as a non-invasive ophthalmic instrument has been improved for clinical studies. Subsequently, comparative studies on a larger scale involving multiple research centers will be initiated.

Author Statement

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