Small and handy – tiny LED lights can improve eye surgeons’ work

A new lighting system for vitreoretinal surgery that uses small white light-emitting diode (LED) technology, promises to be safer for patients and more practical for surgeons. It will probably be three years before the idea is launched as a medical product. Prototypes need to be optimised, approved and then tested for safety and functionality at the University Eye Hospital in Frankfurt.

Dr. Christian Lingenfelder, CEO of the medical device manufacturer alamedics GmbH & Co. KG (Dornstadt, Germany), and his cooperation partners, Prof. Dr. Martin Heßling from the Ulm University of Applied Sciences and Prof. Frank Koch from the University Eye Hospital in Frankfurt, have come up with promising results. They have filed some patents, their experiments with porcine eyes have worked well, and they are now ready to test the new lighting system on human eyes.

The interdisciplinary team, which has recently also brought on board LED specialist EPIGAP Optronic GmbH, will now apply for funds from the “Central Innovation Programme for SMEs” (ZIM). These funds will be used to optimise the results and produce a medical device, test the prototype in a clinical trial and place the final product on the market. In September 2015, the cooperative project “SafeLED” received what is generally regarded as a high accolade among European retina specialists: the EURETINA Science & Medicine Innovation Award that comes with a purse of 20,000 euros. The jury consists of eight top international retina surgeons and the consortium sees the award as a clear sign to advance their project further.

“We want to make the life of eye surgeons as easy as possible,” says Lingenfelder describing the idea behind the consortium’s radically new approach. Lingenfelder, Heßling and Koch have developed the approach based on experience from their and other surgeons’ work in ophthalmic surgery and they have tested it on porcine eyes. In Germany alone (according to figures from the
German Federal Statistics Office), around 200,000 retinal and vitreous eye surgeries are performed every year.

The eyes need to be protected against specific light

Doctors who carry out eye surgery rely on a well illuminated work area. The human eye is very sensitive to blue, violet and UV light and is damaged when the light intensity is too strong. Light that comes too close to the eye can damage the eye thermally or photochemically even within the space of a few minutes. Great care needs to be taken to protect the human retina, a human tissue with one of the highest metabolisms. The DIN EN ISO/DIS 15004-2:2014 standard specifies the light hazard protection limits for the eye. Surgeons need to know the radiation power, angle of incidence and spectrum of the light source in order to determine the maximum duration of illumination without damaging the eye.

Xenon light sources and mercury vapour lamps are the preferred light sources for eye surgery and are usually used in combination with disposable optical fibres. Two different types of optical fibre are available; one type has rigid ends and is hand-held and the other has so-called chandelier endoilluminators. The optical fibres are introduced into the eye via small incisions in the eye’s “pars plana”, giving the surgeon a clear view of the surgical area. The cut is made in the front of the eyeball, which has no retina and no functional tissue.

Surgeons should be able to use both hands for surgery

However, the light probes of these fibres do usually not illuminate the whole intraocular space, so either several light probes or additional hand-held endoilluminators have to be used simultaneously, or the lights have to be repositioned during surgery. In many cases, this means that the surgeon holds the light with one hand and a surgical instrument with the other. It goes without saying that this is not ideal, the intervention takes longer and might not be as precise. Moreover, conventional light sources (xenon and mercury vapour lamps of between 100 to 300 W) are installed in large box-like apparatuses and are quite difficult to handle.

White LEDs are becoming very popular illumination systems and are used in smartphones and car headlights. In 2014, three Japanese
scientists were awarded the Nobel Prize in Physics for developing blue light-emitting diodes. Physicist Heßling believes that white LEDs are specifically suited for ophthalmic surgery; the light spectrum only has a few harmful blue light components and corresponds well with the sensitivity curve of the human eye. They are also relatively cheap and a great deal smaller than conventional lighting systems. LEDs (0.7 mm in diameter) provide only a thousandth of the power of conventional bulbs. This is no problem, as much of the light is lost as it passes through the optical fibres of the conventional bulbs.

Geometrically designed miniature LEDs fit into the eye and require only an electrical socket and a small button battery: Heßling, Koch and Lingenfelder have developed this key idea into two alternative approaches. The cooperation partners are of the opinion that an LED system that has been on the market since 2011 is far too inefficient and might damage the retina when the tip of the light fibres comes too close.

Smaller, safer, more efficient

The first alternative, a miniature LED endoilluminator with a light probe, has no optical fibres and provides much better intraocular illumination than conventional systems. The light probe has a conical tip that allows stable fixation within an incision. The surgeon can therefore use both hands for the intervention. Part of the light (up to 20 percent) penetrates through the sclera (outer layer of the eye), so that two light sources illuminate the eye relatively uniformly. As Lingenfelder sees it, the eye basically becomes a luminous element.

Since the emission range of LED is almost double that of comparable xenon lamps, the LED illuminator could potentially illuminate the eye for as long as 13 hours without photochemical damage. Heßling calculated that potential thermal damage was also well below existing threshold values (0.7 W/cm² compared to 0.1 mW/cm²). At the contact area between the eye and the LED, the measured temperature of 40.2°C was below the 47 to 57°C that is regarded as the critical value for retinal pigment epithelium.

The investigations were carried out using porcine eyes and LEDs of 0.1 W. The project partners hope that the new generation of chandelier LED endoilluminators will be more efficient and less photochemically hazardous than illuminators that are currently used for eye operations. Tiny LEDs 0.3 mm in diameter might even be able to reduce incision size. The ideas have been patented but not yet implemented as they require further investigations.

Illumination without incision

Future transscleral LED endoilluminators will also rely on incisions in the eye. The procedure is as follows: the LED is brought in front of the eye using an eyelid retractor, a standard tool in eye surgery. The non-invasive approach involves the use of a relatively weak white light diode, which does not emit light in the violet and UV spectral ranges that would damage the retina.
The LED is pressed to the eye, preferentially from the side at a site where there is no retina (“pars plana“). The light passes through the sclera and the choroid into the interior of the eye where it is partially absorbed and scattered. This approach takes advantage of the fact that the sclera is translucent. This unexpected finding was made with porcine eyes where a 10 to 15 percent light transmission was measured in the 400 to 750 spectral range. Light transmission increases with wavelength and pressure on the eye wall. The system has been designed as a disposable medical product that the surgeon receives in sterilised form and that sufficiently illuminates the surgical field for at least 30 minutes. This length of time would be a great improvement on many commercially available illumination systems which can only be applied for a much shorter period due to much higher photochemical retinal loads.

Upcoming tests with human eyes

Investigations using porcine eyes are broadly consistent with previously published results obtained with human eyes where a 15 to 20 percent sclera transmission was measured at a wavelength of just below 600 nm. Increasing pressure led to 40 to 50 percent transmission. Investigations of the transscleral approach on eye safety did not reveal any photochemical or thermal risk, even under very unfavourable assumptions. Thermal load (0.35 W/cm²) was around 50% lower than the threshold value, and the LED heated to around 30°C, which is not dangerous. The results were obtained using a surgical attachment lens on the lens of the porcine eye as no suitable eye contractors are available for porcine eyes. With a transmission value of 20 percent for the eye wall, Heßling believes that the new system will also achieve a relatively good illumination level inside the eye.

Further reading:
Further information

- Ulm University of Applied Sciences
- alamedics GmbH & Co. KG

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- Medical technology – serving healthcare