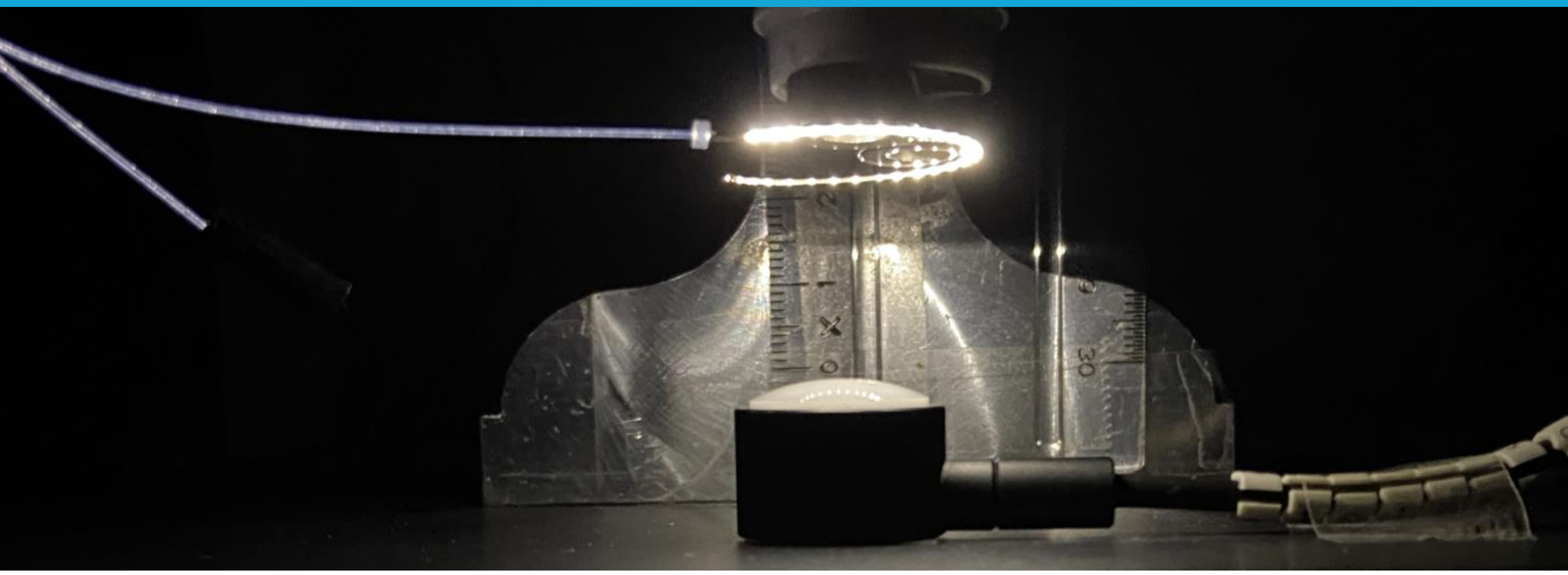
MSc thesis in Biomedical Engineering

Design & evaluation of a new intraocular illumination system for vitreoretinal surgery: the RingLight

Boyd Riemens

2022



TU Delft

DESIGN & EVALUATION OF A NEW INTRAOCULAR ILLUMINATION SYSTEM FOR VITREORETINAL SURGERY: THE RINGLIGHT

A thesis submitted to the Delft University of Technology in partial fulfillment of the requirements for the degree of

Master of Science in Biomedical Engineering

by

Boyd Riemens

June 2022

Boyd Riemens: *Design & evaluation of a new intraocular illumination system for vitreo-retinal surgery: the RingLight* (2022)

The work in this thesis was made in the:

MSc Biomedical Engineering
Track 2: Medical Devices & Bioelectronics
Faculty of Mechanical, Maritime & Materials Engineering
Delft University of Technology

Supervising Professor:	Dr. Dimitra Dodou
Supervisors	Drs. Koen van Overdam
	Prof. Dr. Benno Hendriks

ABSTRACT

Throughout history, different intraocular illumination methods for vitreoretinal surgery have been used and the most common limitations to the state-of-the-art intraocular illumination methods are the glare and reflections created by the illumination device and the relatively small illuminated area. A way to tackle these limitations could be by using a ring-light configuration, which produces diffuse scattered illumination for a full 360° around the object.

In this study, we developed and experimentally evaluated two ring-light configurations for intraocular illumination during vitreoretinal surgery: one for insertion through the pars plana (20 mm), and one for insertion through the cornea and placement in the posterior chamber (11 mm). Both prototypes are made from a 27 gauge Eckardt TwinLight (DORC, the Netherlands), placed inside a capillary tube cut in half through the length. Cuts were made in the fiber every 2 mm, perpendicular to the length of the fiber, to allow light to exit the fiber through the cladding.

By measuring the light intensity and illuminated area, we found that the ring-light configurations produce a lower light intensity but also a slightly larger illuminated area and a more diffuse and uniformly distributed illumination than the Eckardt TwinLight.

The placement of the ring-light in the posterior chamber proved to be unsafe and complex, since the installation procedure in ex-vivo porcine cadaver eyes could not be executed without damaging the lens bag, lens zonules, posterior iris and cornea, due to the lack of space in the posterior chamber, and the rigidity and sharp tip of the ring.

The ring-light configuration that is inserted through the pars plana also caused damage to the retina and lens bag, due to the ring's rigidity and its sharp tip. However, this configuration shows potential when the ring would be made from a more flexible material and has an incorporated pigtail curve a the distal end, which can be easily achieved in a future version of the prototype.

ACKNOWLEDGEMENTS

During my graduation project, many people have helped me. First of all, I would like to thank Koen van Overdam, my external supervisor from the Rotterdam Eye Hospital, and Dimitra Dodou, my supervisor from the TU Delft. I appreciate how the two of you guided me through this project with useful discussions and brainstorming sessions and providing me with information and the right equipment for this research. Furthermore, I appreciate how you both were willing to make time for helping me. Thank you Remi van Starkenburg and David Jager from DEMO (Dienst Elektronische en Mechanische Ontwikkeling) at the TU Delft for your time and help in producing the Ring Light prototypes. A special thanks to DORC (Dutch Ophthalmic Research Center), especially Mart Gahler, for allowing me to perform the installation procedure in ex-vivo porcine cadaver eyes in their showroom and providing me with the needed equipment for these procedures. Furthermore, I would like to thank Benno Hendriks for being part of the graduation assessment committee. Finally, I would like to thank my parents and my girlfriend for the endless support and for helping me where possible, brainstorming or proofreading.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

1 INTRODUCTION

1.1 INTRAOCULAR ILLUMINATION

Vitreoretinal surgery refers toa group of advanced procedures that are done in the interior eye where the vitreous and retina are located. Some of the main reasons vitreoretinal surgery is performed are: diabetic retinopathy, macular holes, macular pucker or retinal detachment or tears (Associated Retina Consultants [2022]). To perform these procedures in the best way possible, intraocular illumination is used to obtain a good view of the fundus.

Throughout the years, many different intraocular illumination techniques have been used to illuminate the retina during vitreoretinal surgery (for an overview see Figure 1.1). In the beginning of vitreoretinal surgery, standard procedures were performed with an external illumination source like coaxial or slit lamp illumination from the operating microscope (El Bayadi [1953]). These illumination methods did not require incisions since the light source is located outside the eye. However, when using external illumination sources, the illuminated area is restricted by the relatively small size of the pupil and since the light is projected through the cornea and the lens, reflections in these bodies are unavoidable (Charles [2008]).

After some years of using external illumination methods, surgeons started relying more on endoillumination devices. These devices enter the eye through an incision and illuminate the internal eye from inside the eye. The first endoillumination devices were vitreoretinal instruments with an integrated light source like vitrectomy cutters (Machemer [1974]) and retinal picks (Williams et al. [1989]). These endoilluminators evolved into separate endoillumination probes and although they could get close to the retina, they had a relatively small field of view of about 20 to 30 degrees of the retina (Koch et al. [1993]).

When Spitznas (1987) developed a wide-angle observation system called the binocular indirect ophthalmomicroscope (BIOM) for vitreous surgery, with an enlarged working field up to 150 degrees of the retina, the call for new illumination devices and techniques that allowed wider illumination angles increased. This call for a larger illuminated area was answered by the so-called ceiling lights or chandelier illumination systems that were placed in the intraocular pars plana region. By increasing the distance to the retina, the illuminated area of the retina was increased and the retinal phototoxicity decreased, but the light intensity was still insufficient. Therefore, Koch et al. [1991] presented the multiport illumination system (MIS), which was the first device to fully illuminate the working field of the BIOM, while accomplishing true bimanual surgery.

After the introduction of the MIS, new endoillumination probes with even wider angles of illumination (180°) were designed to compete with the MIS (Ryan [1997]; Peyman et al. [2002]). Simultaneously with the development of the wide-angle endoillumination probes, another intraocular illumination method arose. Transillumination is a form of external illumination in which vitreous, retinal and choroidal structures are illuminated indirectly through the sclera. The light scatter by small particles in the medium that is created by transillumination is called the Tyndall effect and can be increased by using triamcinolone (Peyman et al. [2000]). The first transillumination device was the external diaphanoscopic illuminator (DIL) by Schmidt et al. [2000], which could be used for transillumination as well as indentation device due to its rounded metallic tip that allows atraumatic movements on

top of the sclera. Some years later, Beltrame and Busatto [2006] and Veckeneer and Wong [2009] also developed a device for transillumination and indentation. They both used a standard optic fiber, which was available in the standard vitrectomy package, making the technique easier accessible. To increase the stiffness of the light pipe and reduce the risk of trauma to the sclera and conjunctiva, Veckeneer and Wong [2009] added a sleeve to the light fiber. While the transillumination devices did not require any incisions, they did require that all other lights within the operating field have to be turned off to ensure clear distinction between vitreous and retina and allowing complete removal of vitreous close to the retina.
During the development of the wide-angle endoilluminators and the transillumination devices, the chandelier illumination systems were concurrently being improved as well, mainly because some situations encountered during vitreoretinal surgery can be better managed using bimanual techniques, with both hands operating intraocular instruments, achieved by using a chandelier illumination system. Where previous endoillumination devices used 20 gauge fibers (a gauge to millimetre conversion chart is given in Appendix A), Eckardt [2003] developed a 25 gauge chandelier light called the Twin Lights, and Oshima et al. [2007] even achieved to develop a 27 gauge self-retaining chandelier endoilluminator, making them small enough to obtain a sutureless sclerotomy. Shortly thereafter, D.O.R.C. Company (Zuidland, the Netherlands) combined the self-retaining mechanism of Oshima et al. [2007] with the Twin Lights of Eckardt [2003] and created the 27 gauge self-retaining Twin-Light (Williams [2008]). An even smaller chandelier illumination system was developed by Sakaguchi et al. [2011], using a 30 gauge optic fiber and a 29 gauge trocar-cannula system.

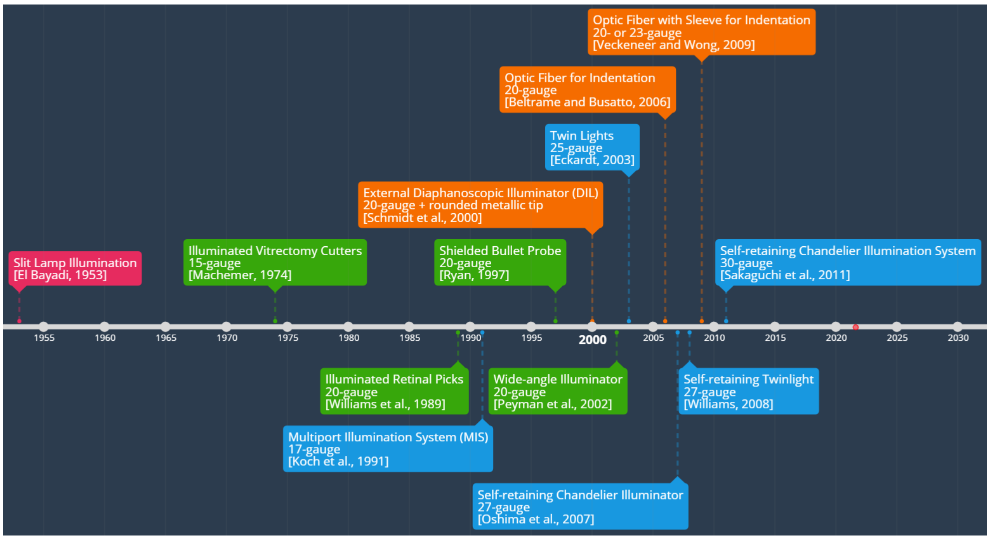
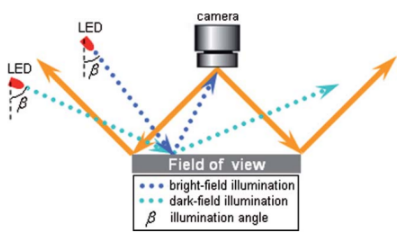


Figure 1.1: A historical timeline of the inventions of the discussed intraocular illumination instruments together with their inventor(s) and their size in gauge. The pink block indicates external illumination sources, the orange blocks indicate transillumination indentation devices, the green blocks indicate endoillumination probes and the blue blocks indicate chandelier endoillumination systems.

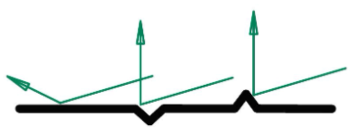
If one looks at the existing intraocular illumination methods and techniques, there is still no ideal intraocular illumination method. All aforementioned illumination methods have limitations. The most common limitations that are still encountered during vitreoretinal surgery regarding the illumination are the glare and reflections created by the illumination device. Also, the illuminated area could still be increased, since the TwinLight sometimes has to be steered in the right direction to obtain adequate illumination. Another concern is the visibility of fine vitreous structures, which are hard to visualise with chandelier illumination systems since the light is not as focused as with light probes and no Tyndall effect occurs.

1.2 RING LIGHT

To tackle the limitations of the current intraocular illumination systems, ways to better distribute the light need to be explored in order to reduce the glare and reflections and to increase the illuminated area. A way to obtain better light distribution and diffuse illumination could be a ring-light configuration. A ring-light configuration generally takes the form of a circular fiber optic light guide that produces diffuse scattered illumination for a full 360° around the object (Loughlin [1993]). In this configuration, the camera is placed behind the ring light and is able to view through the center of the ring light. This way shadows can be eliminated and diffuse illumination is produced, but specular reflection of light into the camera should be avoided. Therefore, to prevent specular reflection, a ring light configuration performs optimally when the object is several times smaller than the diameter of the ring light and is placed fairly close to it (Loughlin [1993]).
Ring lights are being used over the last decade in various professional fields. The even lighting is helpful for detail-oriented tasks like makeup application and streamers and influencers illuminate their faces with these lights while filming videos or taking pictures. In some branches of photography, like facial photography for aesthetic surgery, the ring lights are also preferred for their homogeneous soft illumination and to obtain well-lit photographs without loss of detail (Dölen and Çınar [2016]). The study by Lu et al. [2014] uses a ring light for video-assisted thoracic surgery and is the first to use a ring light for medical purposes. They show that the ring light greatly improves background lighting and imaging quality due to a more uniform illumination, which creates opportunities to implement this method in other medical field, e.g. vitreoretinal surgery.
With ring lights, a distinction can be made between two configurations, i.e. bright field and dark field illumination. With bright field illumination, the light source is placed at an illumination angle of 0° to 45°. As the name suggests, bright field illumination produces a brightly and uniformly illuminated surface, because the light is directly aimed at the surface and reflected back into the camera as illustrated in Figure 1.2a. With relatively low illumination angles this configuration might still produce specular reflections and since increasing the working distances results in a decreased illumination angle, a smaller working distance would be preferred for this configuration (Advanced illumination [2019]). Dark field illumination is the form of illumination where the light source is placed at an illumination angle of 45° to 90°. With a dark field ring light configuration at a large illumination angle (close to 90°), most of the light is reflected away from the camera and is thus not collected. This effect is shown in Figure 1.2a and is the reason we see a ”dark field”. However, the scattered light off any individual surface detail that reflects into the camera produces what is called feature-specific contrast and is illustrated in Figure 1.2b (Advanced illumination [2019]). This method could therefore probably be used to create a Tyndall effect in vitreoretinal surgery.



(a)



(b)

Figure 1.2: A schematic of the bright field illumination and dark field illumination configurations with the illumination angle (Dong et al. [2011]) (a) and a ray function diagram of the dark field configuration with the feature-specific contrast (Advanced illumination [2019]) (b).

1.3 PROBLEM STATEMENT AND GOAL OF THE RESEARCH

The first step to finding out if a ring light improves intraocular illumination compared with the existing methods is to design such a ring light. To design a ring light for intraocular illumination we first need to find out where and how it is going to be inserted into the eye. After the insertion, we need to find a way to deploy the light fiber into a ring and subsequently place it at the right location in the eye. Thereafter, some way of attaching the ring light in the eye has to be found to ensure the ring does not obstruct the surgeon during vitreoretinal surgery. Finally, we will try to develop a light fiber that emits light through the cladding over the length of the ring instead of only from its tip. Overall, the main goal of this study is: ***To develop and experimentally evaluate a ring light that can be inserted and placed inside the eye for intraocular illumination.***

The ring light configuration for intraocular illumination that is being designed in this study will from now on be referred to as ”the RingLight”.

1.4 STRUCTURE OF THE REPORT

The first part of this report, Chapter 2, lists the requirements for the design of the RingLight. Chapter 3 describes the conceptual design, which leads to two prototypes, whose production is presented in Chapter 4. The production of the prototypes is followed by the experimental evaluation of the installation of both prototypes in Chapter 5. Finally, Chapter 6 and 7 discuss and conclude the findings of the experimental evaluation, respectively.

2 PROGRAMME OF REQUIREMENTS

2.1 MUST HAVES

We have established a list of requirements for the design of the RingLight. These must-have requirements are necessary to create a functional and useful prototype while ensuring it is safe to use for a future version of the design to be suitable for clinical practice.

2.1.1 Safety

1. *Invasiveness (Number of incisions).* The RingLight should not need more than 2 incisions for the insertion and attachment of the device. This is the number of incisions needed for the TwinLight, and the RingLight should not need more incisions.

2. *Time related phototoxicity.* The RingLight should not cause any phototoxic damage to the retina, similar as the existing illumination method, i.e. a TwinLight with an LED light source. Retinal phototoxicity is dependent on the exposure time of the retina to the light source during vitreoretinal surgery. The exposure time necessary to reach the predefined ISO 15004-2 (2007) safety limit is called the retinal threshold time. The retinal threshold time for an LED light source at 0 mm distance from the retina is calculated to be 4.7 hours (Koelbl et al. [2019]). This retinal threshold time of 4.7 hours is the lower limit for an LED light source and the RingLight should at least allow for a retinal threshold time of 4.7 hours.

3. *Working distance related phototoxicity.* The working distance of the RingLight should be at least 15 mm from the macula, the center of the retina. This working distance of 15 mm is the working distance of normal endoilluminators according to (Koelbl et al. [2019]), whereas chandelier endoilluminators have a working distance of 18 mm. In their study, 15 mm was shown to be a safe working distance for endoilluminators with an LED light source. With the lower limit of 15 mm, the RingLight still has options to be placed further away from the macula and is not bound to a maximized working distance. Nevertheless, a larger working distance results in reduced risk of retinal phototoxicity and thus an increased retinal threshold time.

4. *Mechanical damage.* The RingLight should not cause mechanical damage, which is damage to the tissue in the eye caused by insertion and attachment of the RingLight. There are two levels of mechanical damage to the tissue, i.e., mechanical damage in micro level and mechanical damage on macro level. The mechanical damage on micro level is the permanent damage to the cells and the mechanical damage on macro level is in the form of tears in the tissue, both should be avoided.

5. *Thermal damage.* The RingLight should not cause thermal damage to the retina, the sclera or any other part of the eye. The temperature of the light fiber should not be raised more than 10 degrees Celsius, at which point irreversible damage to the cells occurs (Youssef et al. [2011]).

2.1.2 Dimensions

6. *Fiber size.* The light fiber used for the RingLight should be 27 gauge or smaller. Because of their small size, 27 gauge fibers allow for sutureless sclerotomies (Oshima et al. [2007]), meaning a self-sealing wound closure after removing the fibers. When an extra component is added to the fiber, increasing its size, the fiber itself should be smaller (29 or 30 gauge) to compensate for this increase, keeping the combined size at 27 gauge.

7. *Ring diameter.* There are certain limitations to the diameter of the RingLight that are set by the dimensions of the human eye. The RingLight can be placed in two different parts of the eye, e.g. in the vitreous chamber or in the posterior chamber of the eye (Figure 2.1). With the option of inserting the RingLight in different parts of the eye come different limitations to the size of its diameter.

   - When inserted in vitreous chamber, limitations to the diameter of the RingLight are set by the size of the human eye which is approximately 24.2 mm (transverse, horizontal); 23.7 mm (sagittal, vertical) with no significant difference between sexes and age groups (Bekerman et al. [2014]).
   - When inserted in posterior chamber, limitations to the diameter of the RingLight are set by the size of the posterior chamber which has a diameter of approximately 11.0 mm (Davis et al. [1991]) and a depth of 0.52 mm (Cronemberger et al. [2010]).

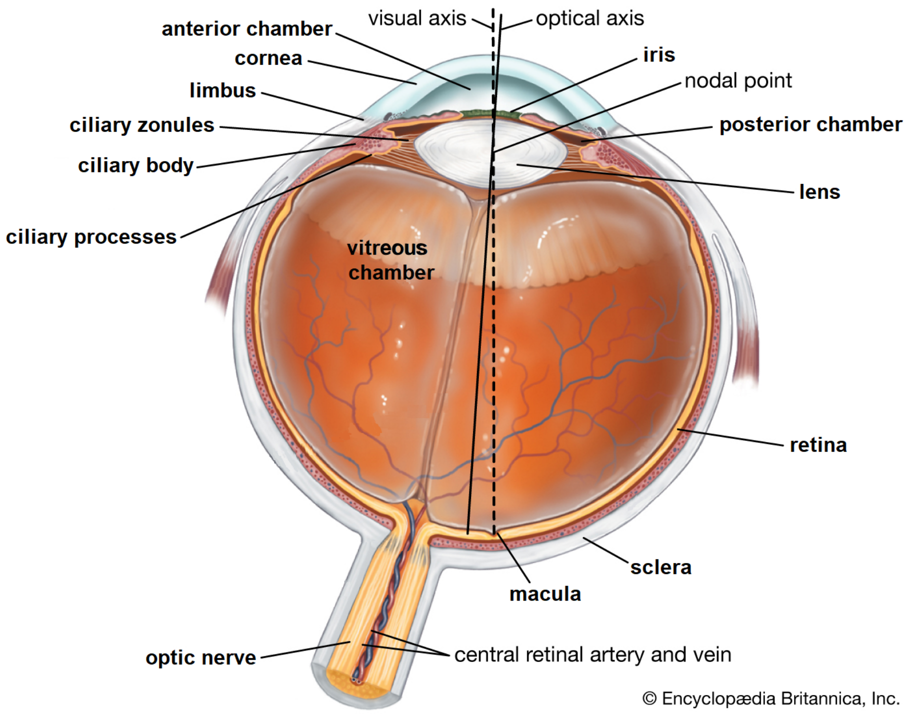


Figure 2.1: Cross section of the human eye with the names of different structures (adjusted from Davson and Perkins [2021]).

2.1.3 Performance

8. *Moving through vitreous humour.* The fiber should be able to move through the vitreous humour, as the RingLight is placed inside the eye before the vitrectomy and therefore the vitreous humour is still present inside the eye. Vitreous humour is a gel-like fluid with a relatively high viscosity due to hyaluronan and collagen, which are the major structural components of vitreous (Sebag [1994]). This is only for the case of insertion in the vitreous chamber since the vitreous chamber is filled with vitreous humour. In contrast to the vitreous chamber, the posterior chamber is filled with aqueous humour, which has has a lower viscosity and and consists 99.9% of water and 0.1% of sugars, vitamins, proteins and other nutrients (Vision Eye Institute [2017]).

9. *Installation complexity.* The installation procedure of the RingLight should have minimal added complexity compared to the existing illumination method. Considering that the installation of the TwinLight is a relatively simple procedure, the complexity of the installation procedure of the RingLight will probably be higher. This added complexity is allowed to some extent, assuming the operation will benefit from the RingLight.

10. *Installation steps.* The installation procedure of the RingLight should consist of as few steps as possible. The steps being insertion, deployment, placement, and attachment. All of these steps might be needed for the installation of the RingLight, but the fewer steps the better. If more steps are needed for the installation procedure, the complexity and duration of the installation will increase. The installation procedure of the TwinLight consist only of the insertion step and the attachment step, which is accomplished by adjusting the silicon cuff that ensures the self-retaining ability of the fiber (Oshima et al. [2007]; Williams [2008]; Sakaguchi et al. [2011]).

11. *Bending radius of the fiber.* The bending of the light fiber should not exceed the maximum bending radius of an optic fiber, which is 10 times its own diameter, i.e. 10×0.417 mm = 4.17 mm; bending to this radius would cause the fiber to break and light might exit through the cladding on places that are not desired (Essentra Components US [2019]).

12. *Attachment.* The RingLight should not get detached during the operation. When the device gets detached it might fall down and hang from the insertion location. It also might get entangled with other instruments present in the eye and obstruct the manipulation of those instruments.

13. *Obstruction of view.* The RingLight should not obstruct the surgeon's view of the retina during the operation. One of the purposes of this research is to improve the view of the retina by improving the intraocular illumination. Therefore the device should not block the view of the retina and thus conflict with the goal of improving the view of the retina.

14. *Obstruction of instruments.* The RingLight should not obstruct any other instrument during the operation, meaning it should be placed at such a location that the other instruments can move freely inside the eye.

2.2 NICE TO HAVES

The nice-to-have requirements are requirements that are not yet essential for the prototype of this study. They do not have to be fulfilled while designing the prototype, but should be met for a future version of the design to make it suitable for clinical practice. Although the prototype does not have to meet these nice-to-have requirements, they should not complicate the future design of the intraocular illumination method that is suitable for clinical practice.

15. *Biocompatible.* The intraocular illumination device should be made of materials that are not harmful to the human body and are biocompatible according to ISO 10993.
16. *Self retaining.* It is desired that the RingLight is self-retaining, meaning it can keep its insertion position without the use of sutures (Oshima et al. [2007]).
17. *Installation time.* It is desired that the installation of the RingLight takes less than 5 minutes. The installation procedure of the TwinLight takes about one minute, but when the RingLight improves the operating conditions the additional time for the installation can be compensated by reduced procedure duration.
18. *Dynamic adjustment of position.* It is desired to change the direction of the light during the operation, meaning some manoeuvrability of the RingLight to be able to create a Tyndall effect.

3 CONCEPTUAL DESIGN

3.1 STRUCTURAL CRITERIA

3.1.1 Where and how is it inserted into the eye?

INSERTION THROUGH THE PARS PLANA. One location for the insertion of the RingLight is through the pars plana, just like most of the existing intraocular illumination methods, e.g. chandelier endoilluminators. The pars plana is located between the the ciliary body and the peripheral retina and, as seen from the outside, 3.5 to 4 mm from the limbus through the sclera (Figure 2.1). The RingLight can be inserted through the pars plana with two different methods.
The first insertion method is by using a component that is present during the entire operation, such as a trocar. A trocar is placed in the pars plana and acts as a portal for the light fiber to enter the vitreous chamber. Only when the RingLight is extracted from the vitreous chamber can the trocar be removed as well.
The second insertion method is by using a component that is only temporarily needed for the insertion and can be removed directly after the insertion is completed. The most common way to accomplish this is by using a guidance needle, which is inserted into the pars plana and then carefully retracted to leave only the tip of the needle in the sclerotomy. Next the light fiber is placed into the trough of the needle and inserted through the trough at an angle of 10° to 20°, while at the same time retracting the needle (Williams [2008]).

INSERTION THROUGH THE CORNEA. Another location for the insertion of the RingLight is through the cornea. When inserted through the cornea, the RingLight can be placed in the posterior chamber of the eye. The posterior chamber is the space in the eye behind the iris and in front of the ciliary processes, which are part of the ciliary body (Figure 2.1). The RingLight can be placed in the posterior chamber via the pupil and onto the ciliary body, the sulcus. Placement of the RingLight into the posterior chamber needs to be done carefully to not damage the lens and ciliary zonules.
Another location for the RingLight after insertion through the cornea is in the pupil, using the method used in pupil expanders. This method inserts a small device through the cornea that is designed for mechanically dilating the pupil during operations (Graether [1996]; Bhattacharjee [2017]). This technique could be combined with a light fiber to dilate the pupil and illuminate the retina simultaneously.

3.1.2 How is it deployed inside the eye?

DEPLOYMENT WITH THE USE OF EXTRA COMPONENTS. Once the light fiber is inserted into the eye, it needs to be deployed into the shape of a ring. Since the fiber itself is straight but flexible, it can be manipulated by other components to obtain another shape.
One way to achieve this is by pushing the light fiber into the eye, while pulling the tip of the fiber back. By doing this, the tip of the light fiber is pulled back to the location of insertion while the rest of the light fiber is being inserted and bent into the shape of a circle. The simplest implementation of this method is by adding a small string to the tip of the fiber. Another implementation could be by using

magnets: one small magnet on the tip of the fiber and a strong magnet on the sclera. By inserting the fiber with one hand and manipulating the magnet with the other, the fiber could be pulled into a circular shape.
A second way to shape the light fiber into a ring is by adding a pre-defined shape to the fiber. Such a pre-defined shape could be like a capsular tension ring (CTR), a polymethylmethacrylate (PMMA) C-shaped device used to stabilize the capsular bag of the lens during cataract surgery in eyes with zonular defects (Menapace et al. [2000]). This component could already be added onto the design of the light fiber before insertion.
A small adaptation of the previous method is not to add a pre-defined shape to the fiber, but a pre-curved metal wire inspired by the studies about pre-curved needles used for biopsies (Warnock [1996]; Sze [2001]; Singh et al. [2008]). Because the metal wire is pre-curved and attached to the fiber, the fiber would become pre-curved. A pre-curved fiber is a fiber that is curved into the desired shape and slightly flexible so that it can be inserted into a rigid tube, temporarily straightening the fiber again. When inserting the tube, the fiber can be deployed into the eye and regain its desired shape.

DEPLOYMENT BY USING THE MECHANICS OF THE FIBER. To shape the light fiber into a ring without using extra components, we need to rely on the mechanics of the fiber itself. One way to achieve this is by folding the fiber into a cannula and let it fold out into a ring when inserted into the eye. This method relies on the mechanics of the fiber and can only function when the fiber is very flexible and does not have plastic deformation, otherwise it would not fold out into the desired shape again.

3.1.3 How is it placed in the desired position?

When the light fiber is deployed in the eye into the shape of a ring, it might not be in the right position yet. It might be that the ring is not yet in the right location or that it is lopsided. Therefore a step for small adjustments is added to ensure the RingLight is placed in the desired position.

PLACING THE RINGLIGHT IN THE RIGHT LOCATION BY USING OTHER COMPONENTS. After deployment of the RingLight, small adjustments to its location and rotation can be made by using magnets, with one magnet or a magnetic strip on the ring itself and an external magnet on the sclera to pull it into the desired location.
Another method is to make a handle, a straight rigid part added to the fiber, at the point where the fiber enters the eye to create a point on which the ring can pivot. By pivoting inside the eye, the ring can be placed horizontal above the macula or at a certain angle if desired. When the ring is either too close to or too far away from the desired location, the handle can be pulled further out of the eye or pushed further into the eye to reach the desired location. This handle could also be of use in the insertion phase for some extra grip and sturdiness to the fiber.

3.1.4 How is it attached?

ATTACHING THE RINGLIGHT WITH THE USE OF EXTRA COMPONENTS. Finally, when the light fiber is inserted into the eye, deployed into a ring and placed at the desired location and in the right position, it has to be fixed in that position and at that location. When using extra components for the attachment of the RingLight, a distinction can be made for methods that do not require additional incisions and methods that do.
One of the methods that does not require additional incisions is the one that uses magnets to attach the RingLight. With a limited number of magnets on the sclera (external magnets) and a magnetic strip on the light fiber (internal magnet), the

RingLight can be attached in the right location and easily be detached at the end of the surgery. Instead of using a magnetic strip as internal magnet, it is also possible to add a limited amount of internal magnets to the light fiber.
Another method that does not need additional incisions is by gluing the ring to the inside of the eye. However this sounds simple, it is an unorthodox way of attaching something in the eye and it might have more risks than it has advantages.
On the other hand, some methods for attaching the RingLight do need additional incisions. A method could be attaching the RingLight with sutures, inserted from the outside and attaching the fiber to the inside of the eye. However, this option will not be considered, since the procedure of getting the suture around the fiber from outside the eye is too complex.
Other methods would require not just an extra component, but a whole new instrument to make an attachment. By introducing a new instrument into the eye, the RingLight does not need to be attached to the eye itself. Instead, it can be attached to the new instrument and thus decrease the risk of damage to the eye. This can be realized by introducing an additional trocar into the eye. This trocar can be used to insert a mechanism that will hold the light fiber, like a clamp or a string.
Alternatively, a new instrument can be inserted directly into the eye without the use of a trocar. An example of such a method is by inserting a hook through the sclera on which the RingLight can be placed.

ATTACHING THE RINGLIGHT BY USING MECHANICS OF THE FIBER. Using the mechanics of the fiber to attach the fiber to the inside of the eye requires contact mechanics. By engraving the surface of the fiber with a pattern, it might be possible for the fiber to grasp the tissue and attach itself without using any extra components. This method would require a specifically modified fiber and further research as to not cause damage to the tissue of the eye.

ATTACHING THE RINGLIGHT BY UTILIZING COMPONENTS OR INSTRUMENTS THAT ARE ALREADY IN USE. Next to the use of extra components and the mechanics of the fiber, the fiber could also be attached by utilizing components that are already being used for other purposes. By adding a simple mechanism to such components or instruments, they could be used for multiple purposes.
Instruments that are generally present during all vitreoretinal surgeries are trocars. This would make them ideal instruments to add a mechanism for attachment to, without needing another insertion. The trocars could be adjusted in such a way that a foldable hook is attached to it on which the RingLight could be placed. Instead of hooks, other mechanisms like strings or magnets could be attached to the trocars to hold the RingLight in place. However, it should be kept in mind that the trocars will be manipulated during surgery to obtain the right angles for the inserted instruments and therefore the RingLight should be attached firmly to the mechanism to prevent detachment.

3.2 FUNCTIONAL CRITERIA

The functional criteria of the conceptual design consist of the degrees of freedom (DOF) of the RingLight. The degrees of freedom refer to the freedom of movement of the RingLight in the three-dimensional space. They are divided into degrees of freedom referring to change of position and change of orientation. Three degrees of freedom referring to the change of movement are forwards or backwards (surge), left or right (sway) and up or down (heave). Change of orientation can be achieved through rotation about the three axis, i.e. the normal axis (yaw, on the coronal/frontal plane), the longitudinal axis (roll, on the transverse/horizontal plane) and the transverse axis (pitch, on the saggital/vertical plane). The changes of position and orientation result in a combined total of six degrees of freedom and are shown in Figure 3.1 for clarification.

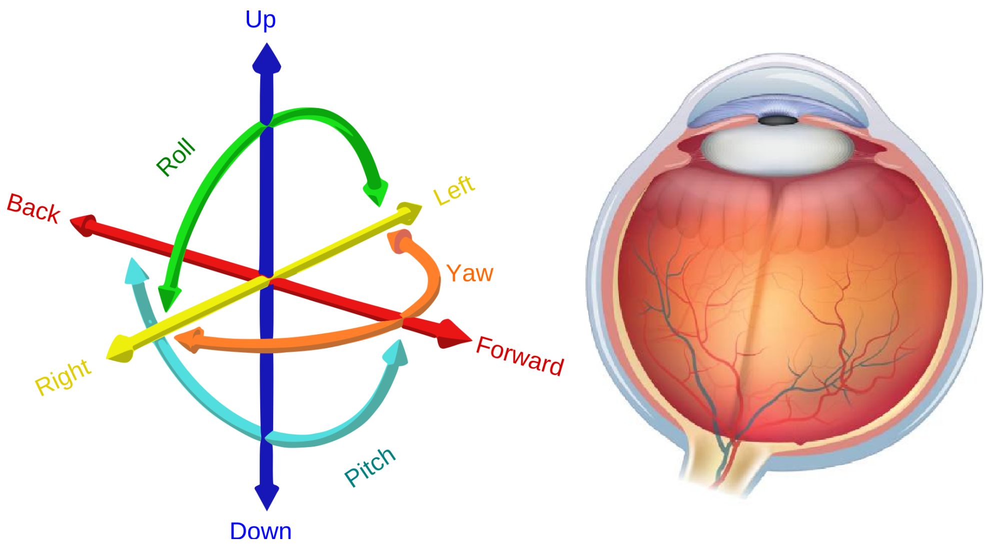


Figure 3.1: The six degrees of freedom with a cross-section of an eye as reference, meaning that up is in the direction of the pupil and the cornea and down in the direction of the macula.

3.2.1 In what directions is the RingLight maneuverable?

MOVING THE RINGLIGHT CLOSER TO OR FURTHER FROM THE MACULA (HEAVE) The RingLight could be moved closer to or further from the macula, i.e. changing the working distance. Moving the RingLight up and down could be used to highlight different areas. When the RingLight is positioned closer to the center of the retina, the macula will be better illuminated, due to a higher light intensity on the center of the retina. Meanwhile, the light intensity on the peripheral retina will decrease. When the RingLight is positioned further from the center of the retina, the peripheral retina and the vitreous base are highlighted, which is favored for vitreous shaving. On the other hand, the illuminated area will decrease if the RingLight is closer to the macula. To obtain a maximized illuminated area the RingLight should be positioned as far away from the macula as possible, trading off light intensity on the macula. Another consequence of moving the RingLight up or down is the change in working distance related phototoxicity, which also benefits from a large working distance.

TILTING THE RINGLIGHT TO THE LEFT OR RIGHT (ROLL), OR TO THE FRONT OR BACK (PITCH) Besides moving the ring up and down, the RingLight could also be tilted to the left or right (roll), or to the front or back (pitch). By tilting the RingLight in one of these directions or a combination of these directions, an angle can be created from which the retina is illuminated. This might be useful for surgeries where more peripheral areas of the retina need to be illuminated. An important implication of tilting is the risk for phototoxicity increase, since some parts of the ring will be closer to the retina.

3.2.2 How is the size of the diameter of the ring changeable (compared to the ideal placement: furthest from macula, fully deployed)?

INCREASING THE DIAMETER Since the eye is spherical, the diameter of the eye varies with the distance from the macula. This fact can be used to increase the diameter of the ring. When the RingLight is inserted as far away from the macula as possible, its diameter can only be increased by moving the ring closer to the macula at the point where the diameter of the eye is largest. Increasing the diameter of the RingLight reduces specular reflection of the light, because specular reflection is reduced to a minimum when the diameter of the RingLight is several times larger than the object and positioned fairly close to it Loughlin [1993].

DECREASING THE DIAMETER When the RingLight is fully deployed inside the eye, its diameter could be decreased by slightly redeploying the ring to make it more oval shaped in the left/right or back/forward directions. This is only possible for some deployment methods, e.g. by pulling the tip of the fiber back. Another way of decreasing the diameter of the RingLight is by external indentation, which is frequently done during vitreoretinal surgery. This has a similar effect on the shape of the ring as the previous method, meaning that the RingLight will more likely take the shape of an oval than a ring with decreased diameter on all sides. Decreasing the diameter of the RingLight might be beneficial in some cases where more focused light is required. A side effect of decreasing the diameter is that the RingLight results in more specular reflection and might hinder the surgeon's view.

3.2.3 Total degrees of freedom

From these functional criteria we can conclude that the RingLight could have a maximum of 5 degrees of freedom, i.e. roll, pitch, heave, sway and surge. However, the sway and surge can not actually be achieved by moving the whole ring on the frontal plane, but by changing its shape from circular to oval. Only when the diameter of the ring is smaller than the diameter of the eye, the whole ring could be moved on the frontal plane. Since the RingLight is not wireless, its light fiber has an internal part and an external part. Its movement is therefore being restricted by the location of insertion and because of this, the RingLight is not able to rotate around the normal axis (yaw). As we will see in Chapter 4, the degrees of freedom of the RingLight are strongly dependent on the chosen methods for installation (insertion location, deployment, placement and attachment) and the 5 degrees of freedom will not be achieved in most cases.

3.3 DESIGN CHOICES

In this section we will make the design choices for the RingLight based on a Harris Profile (see Appendix B). A Harris Profile is a way to visualize the strengths and weaknesses of different design concepts, by subjectively evaluating the methods and solutions on the basis of the Programme of Requirements. Besides the requirements set in Chapter 2, the concepts are also evaluated on innovativeness, with higher scores in innovativeness given to concepts that are not yet found in literature. The installation steps are being taken into account as well in this Harris Profile, since some methods do not require all installation steps. First a Harris Profile is made to choose the best method for insertion, deployment, placement and attachment of the RingLight (Appendix B Figure B.1). Consequently, a Harris Profile of the different solutions per chosen method is made to create a design for the prototypes (Appendix B Figure B.2).

3.3.1 Where and how is it inserted into the eye?

There are two possible locations for the insertion of the RingLight, through the pars plana and through the cornea. The pars plana seems like a perfect insertion location for intraocular illumination, since it is already being used in the existing intraocular illumination methods and meets almost all of the requirements. However, movement of the RingLight through the vitreous humour could create traction of the vitreous to the retina, resulting in retinal tears, making it not completely safe if the vitreous humour is not yet removed. Nonetheless, insertion via the cornea is more prone to mechanical damage, because the RingLight needs to be placed in the posterior chamber through the pupil without damaging the pupil and the lens. Furthermore, placement of the RingLight in the posterior chamber requires a smaller diameter. However, the insertion of the RingLight through the cornea is a very innovative method and placement in the posterior chamber does not require adjustments for placement and attachment, reducing the installation steps. Therefore, we have chosen to design two prototypes: one that is inserted through the cornea and placed in the posterior chamber and one that is inserted through the pars plana and placed in the vitreous chamber.

INSERTION THROUGH THE PARS PLANA The options for insertion through the pars plana are using a trocar or a guidance needle. Both are being used in modern-day vitreoretinal surgery and one is not more favorable than the other, but in this case a guidance needle is preferred since the guidance needle is removed after the insertion is completed. The insertion of the light fiber with a guidance needle needs to be done under an angle of about 30° and not perpendicular to the pars plana, which is illustrated in Figure 3.2. This way the RingLight does not have to make a sharp bend inside the eye and the entire diameter of the eye can be used.

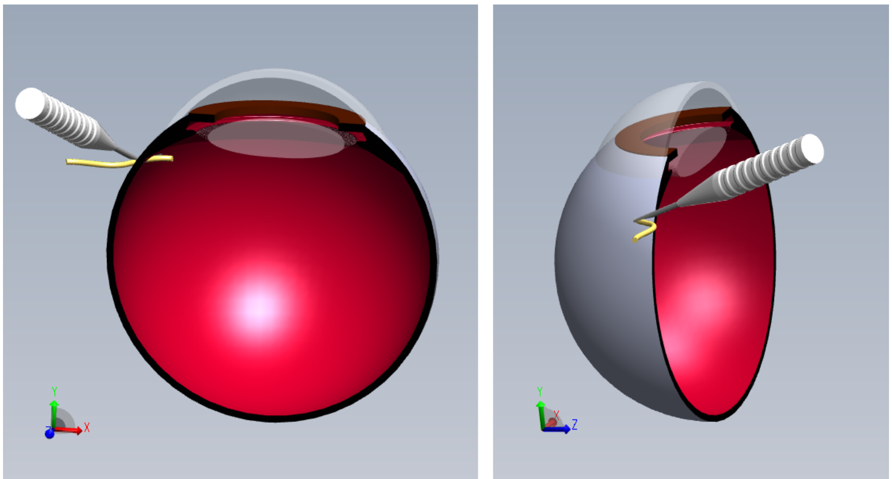
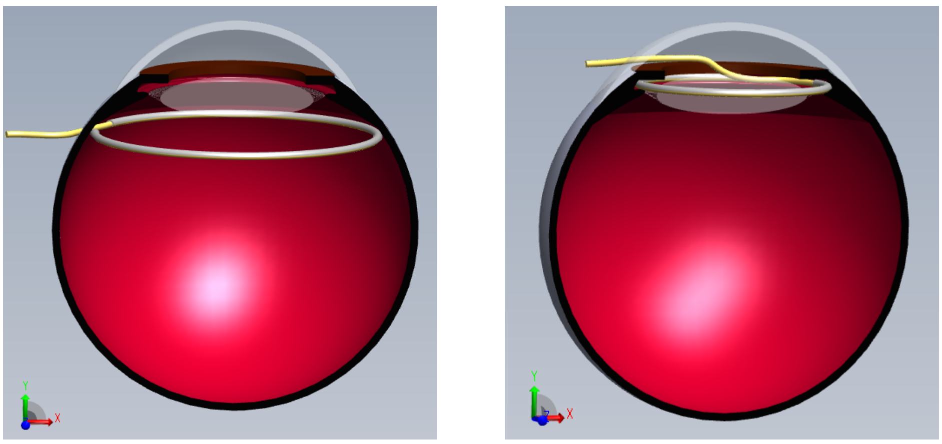


Figure 3.2: Sketches of the insertion of a light fiber through the pars plana at an angle of about 30° using a guidance needle.

INSERTION THROUGH THE CORNEA When the RingLight is inserted through the cornea, it can be placed in the posterior chamber or in the pupil as a pupil expander. Both options are prone to mechanical damage, e.g. to the iris, the lens and ciliary zonules when placed in the posterior chamber and to the iris and lens when placed as a pupil expander. Moreover, the diameter of the RingLight already has to be smaller when inserted through the cornea than through the pars plana due to the dimensions of the eye, but the pupil has an even smaller diameter than the posterior chamber, resulting in a smaller diameter of the RingLight. Since a ring-light configuration works optimal with a large diameter compared with the object that is illuminated, diameter size has high priority. Therefore, placement in the posterior chamber is preferred over placement in the pupil. However, with both configurations the intraocular instruments are inserted in the eye from beneath and thus outside the ring, probably creating shadows.

3.3.2 How is it deployed inside the eye?

Using the mechanics of the fiber for deployment of the RingLight inside the eye is not an option, because the fiber has plastic deformation and once bent in a particular shape, while exceeding the maximum bending radius, the fiber does not bend back.
Moreover, the deployment of the RingLight inside the eye faces one main problem, namely that it has to move through the vitreous. Because the vitreous is a gel-like fluid, it is more difficult to move the light fiber through vitreous than through water for instance. This is why the method that needs extra components is chosen for the deployment phase. These extra components can be used to strengthen the light fiber itself or to exert more force on the light fiber, like when pulling the tip back with a string.
To ensure rigidity of the light fiber, we have chosen to add a pre-defined shape to the light fiber instead of a pre-curved fiber. This pre-defined shape also ensures that the light fiber keeps the shape of a ring and the maximum bending radius will not be exceeded, whereas the method of pulling the tip of the fiber back is more prone to exceed the maximum bending radius. Besides, when adding a pre-defined shape on top of the ring, this material can also be used to reflect the light downwards and only illuminate the retina and prevent glare. The same method of deployment is chosen for the insertion through the cornea. Although the aqueous humour has a lower viscosity than the vitreous humour, this method is still preferred since the capsular tension rings are inserted in a similar way at a similar location.
Figure 3.3 shows the RingLight with an added pre-defined shape for both the insertion through the pars plana (Figure 3.3a) and the insertion through the cornea with placement in the posterior chamber (Figure 3.3b).



(a) (b)

Figure 3.3: Sketches of the deployment of the RingLight using a pre-defined shape when inserted through the pars plana (a) and when inserted through the cornea and placed in the posterior chamber (b).

3.3.3 How is it placed in the desired position?

Since the posterior chamber is such a small space in the eye, the position of the RingLight that is inserted through the cornea and placed in the posterior chamber does not need to be adjusted and therefore this phase is redundant for this configuration.
The placement phase for the insertion through the pars plana can only be accomplished by using extra components. To make these final adjustments to the location of the RingLight we compared the use of magnets with the use of a handle. With the use of magnets, the magnet has to be strong enough to pull the whole ring through the vitreous humour in the right location. Moreover, it might be a complex procedure to make small adjustments to the location and position of the RingLight with an internal and external magnet. Therefore, we have chosen to use a handle, which is illustrated in Figure 3.4. With this handle, the ring can be moved back and forth by pushing or pulling the handle further in or out of the eye. Furthermore, the ring can be moved to the left and right or at an angle by using the handle in the insertion point as a pivot. This method gives the surgeon the freedom to adjust the RingLight in the desired position and location.

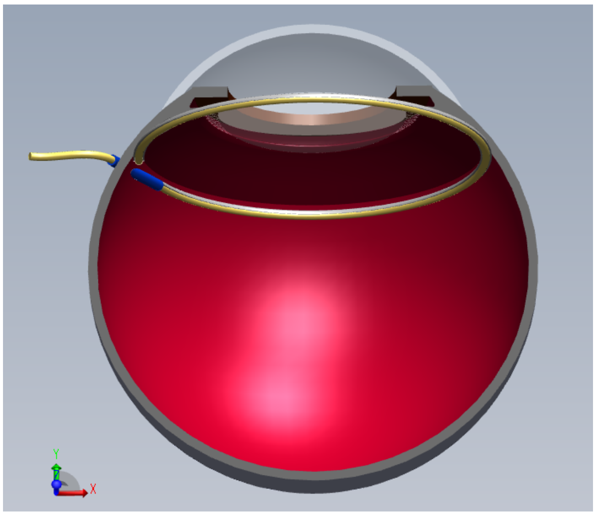


Figure 3.4: Sketch of the placement of the RingLight with a handle in the vitreous chamber. The handle is made of the same material as the pre-defined shape, but shown in blue for clarification, and is located at the proximal edge of the ring.

3.3.4 How is it attached?

Similar to the placement phase, the attachment phase is redundant for the RingLight that is placed in the posterior chamber since the RingLight rests on the ciliary body and cannot move in any other direction.
For the attachment in the vitreous chamber, the decisive factor in choosing the right solution is the risk of detachment, because the RingLight should under no circumstance get detached. Therefore, the attachment of the RingLight with magnets (extra component without additional incisions) and by using the mechanics of the fiber are not preferred, since both methods are prone to detachment. The methods of using extra components with additional incisions and the use of components that are already in use both have pretty reliable attachments and their solutions will be compared with each other to find the best attachment method.
The method of adding a mechanism to the trocars that are already in use is not preferred, since the installation is very complex and might take a lot of time. Besides the installation complexity, the trocars will be manipulated during surgery, meaning the RingLight will constantly be moving and could result in an unsteady

light source, which is not ideal. The additional hooks that could be inserted for attachment also increase the installation complexity and do not ensure a reliable attachment. Therefore, we have chosen to attach the RingLight in the eye with the use of an extra instrument/component through an additional trocar. This method ensures the most reliable attachment of the RingLight, although the installation will still be complex. We have chosen to insert a string through the additional trocar and create a noose through which the RingLight has to be placed (Figure 3.5). Once the RingLight is placed through the noose, it can be tightened from outside of the trocar.

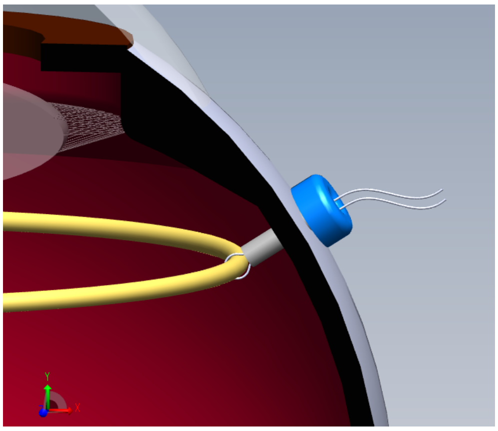


Figure 3.5: Sketch of the attachment of the RingLight with a string through an additional trocar, which is placed on the opposite side from where the RingLight is inserted.

There is one last option for attaching the RingLight. But this option is strongly dependent on the previously chosen methods of deployment and placement and is therefore not included in the Harris Profiles in Appendix B. If a handle is added to the RingLight like described in the placement phase, this handle could be fixed at such an angle that the ring itself does not need an attachment, provided that the RingLight has enough rigidity to remain in place (which is acquired by the added pre-defined shape for deployment). This technique is already being used for the self-retaining TwinLight, which is held in place and at the right angle by taping the fiber to the forehead of the patient. This method significantly decreases the installation complexity of the attachment and does not need additional incisions. Therefore this method will also be tested during the experiments.

4 PROTOTYPES

Two prototypes have been made according to the design choices of the previous chapter. The first prototype is the Ring Light that is inserted through the pars plana and placed in the vitreous chamber, and the second prototype is the Ring Light that is inserted through the cornea and placed in the posterior chamber. Both locations have different dimensions and therefore the two prototypes have some differences, but the basics are very similar. For both prototype, two back-ups were made in case one did not work or got broken. An overview of the specifications of both prototypes is shown in Table 4.1.

The first problem that is faced when trying to create a Ring Light from a light fiber is that light is only emitted from the tip of the fiber with normal light fibers. With a Ring Light, however, the light does not need to be emitted from the tip of the fiber but through the cladding of the fiber over the entire length of the ring. This way the light shines downward and illuminates the retina. In normal light fibers, total internal reflection occurs since the cladding has a lower refractive index than the core of the fiber, which does not allow light with small acceptance angles (45° or smaller) to exit the fiber through the cladding (Ivanov et al. [2006]). These fibers thus need to be modified in such a way that there is no total internal reflection, but some of the light gets emitted through the cladding.

As explained in Chapter 2, a light fiber has a maximum bending radius of 10 times its own diameter. If that maximum bending radius is exceeded, cracks will occur in the cladding and the light might escape through the cladding (Essentra Components US [2019]). With normal fibers this is a highly unwanted situation, but in the situation of the Ring Light this is just what we need. By making intended cuts into the cladding we could control where the light exits the fiber and therefore illuminate the retina with the Ring Light.

4.1 PROTOTYPE 1

The prototype consists of two parts: the light fiber and the added pre-defined shape. The used light fiber is the 27 gauge light fiber from the Eckardt TwinLight (DORC[1], the Netherlands). The TwinLight consists of two light fibers and therefore one of the fibers was sealed off with tape. The cuts in the fiber are made by cutting the fiber in the cladding up to the core of the fiber with a small knife, perpendicular to the length of the fiber. The cuts are made along the entire ring after every 2 mm, which is done before the fiber is made into the shape of a ring (Figure 4.1).

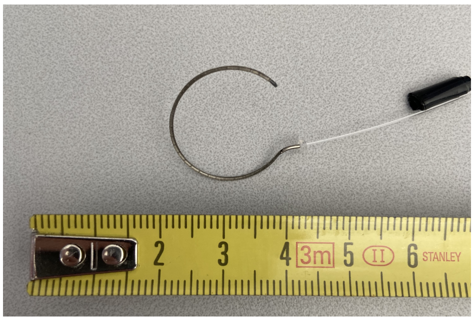
Figure 4.1: Light fiber with cuts through the cladding every 2 mm.

1 Dutch Ophthalmic Research Center

The cuts in the fiber need to be close to each other to resemble one light source when shaped into a ring and not individual small light sources. But when too much cuts are made in the fiber, too much light will exit through the cladding and the light intensity at the end of the ring is reduced, which can be seen in Figure 4.2b.
The second component of the prototype is the added pre-defined shape, which is made out of a metal capillary tube. The capillary tube is cut in half through the length, so that the fiber could be glued into the capillary tube with the cuts in the fiber on the open side of the halved capillary tube. Appendix C shows the technical drawings of the pre-defined shape. The inner diameter of the capillary tube had to be large enough for the 27 gauge fiber to fit into was therefore chosen to be 0.45 mm. The only available capillary tube with inner diameter of 0.45 mm had an outer diameter of 0.6 mm, making the prototype larger than the desired 27 gauge. The outer diameter of the ring for this prototype depends on the dimensions of the eye itself, which is 24.2 mm (transverse, horizontal) at its apex. Since the Ring Light will be placed further from the macula (at the height of the pars plana), the diameter is estimated to be 20 mm. This estimation is made using the sketches in SolidWorks, which are made using the real dimensions of the eye. Furthermore, an opening is added to the ring with an angle of 60°to simplify the insertion of the ring. Because the ring is made of a rigid material with low flexibility, a relatively large opening angle is required to allow the ring to be inserted into the eye.
To prevent the light from exiting the fiber through its tip, the end of the ring is glued shut with metal glue. This ensures the light is only directed to the macula (downwards) and not sideways through the tip. Finally, for the placement of the Ring Light, a small handle is added at the beginning of the ring. This handle is made out of the same capillary tube but this time not cut in half. The handle has a length of 4 mm to offer some stability and to act as a pivot but in the same time not to obstruct the surgeon and the instruments on the outside of the eye. The Ring light prototype 1 is shown in Figure 4.2a and 4.2b.
This prototype has a total of 4 degrees of freedom, viz. it can be moved back or forwards, left or right and it can be pitched and rolled. All of these four degrees of freedom can be achieved by using the handle as a pivot. On the other hand, the handle rules out the other two degrees of freedom since it restricts the Ring Light to be moved up or down and makes yawing impossible. Although these degrees of freedom allow for dynamic adjustment of position and rotation, it also increases the chance of traction of the vitreous humour on the retina and thus retinal tears when the RingLight is moved.

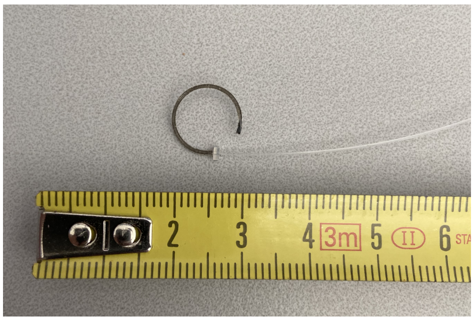
4.2 PROTOTYPE 2

The second prototype is made in a similar way as the first prototype, the only differences being the outer diameter of the ring and that this one has no handle. Because this prototype is placed in the posterior chamber of the eye, the diameter of the ring has to be smaller than that of the first prototype and depends on the dimensions of the posterior chamber. As stated in Chapter 2, the posterior chamber has a diameter of 11.0 mm and therefore this prototype has an outer diameter of 11 mm as well. The handle cannot be used for this prototype since the Ring Light has to be moved through the pupil after insertion through the cornea. The Ring Light prototype 2 is shown in Figure 4.2c and 4.2d, and Figure 4.2d clearly shows that the second prototype has a higher light intensity at the end of the ring than the first prototype (Figure 4.2b), because of a reduced number of cuts due to the smaller diameter of the ring.
Due to the small dimensions of the posterior chamber, this prototype has no degrees of freedom. After placement in the posterior chamber, the Ring Light is not able to move in any direction. Rotation is also not possible, partly due to the small dimensions and partly due to the absence of the handle.



(a) Ring Light prototype 1, light source off.

(b) Ring Light prototype 1, light source on.



(c) Ring Light prototype 2, light source off.

(d) Ring Light prototype 2, light source on.

Figure 4.2: The Ring Light prototype 1 (a) & (b) and the Ring Light prototype 2 (c) & (d).

Table 4.1: Overview of the specifications of the two Ring light prototypes.

	Location	**Ring diameter**	**Cuts interval**	**Opening angle**	**Handle**	**DOF**
Prototype 1	Vitreous chamber	20 mm	2 mm	60°	Yes	4
Prototype 2	Posterior chamber	11 mm	2 mm	60°	No	0

5 EVALUATION

5.1 GOAL OF THE EXPERIMENT

In a proof of concept experiment, the safety and complexity of the installation of both RingLight prototypes have been evaluated ex-vivo on porcine cadaver eyes. The evaluation was done on the basis of the list of requirements in Chapter 2.
Besides the safety and complexity of the installation of the RingLight prototypes, the light intensity and the illuminated area of the RingLight prototypes have been measured and compared with each other and the Eckardt TwinLight.

5.2 EXPERIMENTAL SETUP

5.2.1 Temperature increase of the RingLight

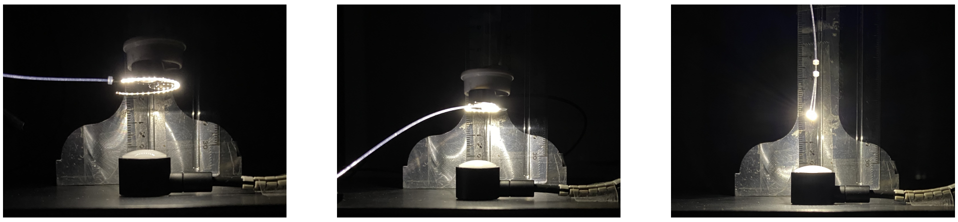
For measuring the temperature increase of the light fibers in the RingLight prototypes a FLIR thermal imaging camera (FLIR Systems, United States) was used. The RingLight prototypes were connected to the LEDStar (DORC, the Netherlands), which is a light source for light fibers that provides safe illumination (no toxic UV wavelengths) with different light intensities (0% to 100%) and different light colors (white to yellow).

5.2.2 Light intensity and illuminated area of the RingLight versus the TwinLight

LIGHT INTENSITY Figure 5.1 shows the setup for the light intensity measurements. Both RingLight prototypes and the Eckardt TwinLight were connected to the LEDStar alternately and placed 20 mm above a Konica Minolta illuminance meter T-10MA receptor head (Konica Minolta, Japan). The 20 mm was chosen to keep the working distance of the different illumination methods constant and because this is approximately the working distance of the chandelier illumination systems.

Figure 5.1: The setup for light intensity measurements with the LEDStar on the left, the Konica Minolta illuminance meter on the right and the Konica Minolta illuminance meter receptor head in the middle in front of a ruler with the Eckardt TwinLight placed 20 mm above it by using a small wooden plank.

The light intensity measurements were performed in a dark room for the best results with the illuminance meter and on a dark background to reduce reflections of the light. The RingLight prototypes were held in place above the illuminance meter receptor head by using a magnet glued to a long metal wire that was attached to a small wooden plank. This setup was required to maintain a constant working distance of 20 mm, since the Eckardt TwinLight could be attached to the wooden plank directly and just hang above the illuminance meter receptor head. Figure 5.2 shows this setup for both RingLight prototypes and the Eckardt TwinLight.



(a) (b) (c)

Figure 5.2: Setup of the light intensity measurements with the RingLight prototype 1 (a), the RingLight prototype 2 (b) and the Eckardt TwinLight (3) all placed 20 mm above the Konica Minolta illuminance meter receptor head.

ILLUMINATED AREA Almost the same setup as in Figure 5.1 was used for the measurements regarding the illuminated area, the only difference being that the Konica Minolta illuminance meter was removed and a dark background made of graph paper was added for a better indication of the size of the illuminated area (Figure 5.3).

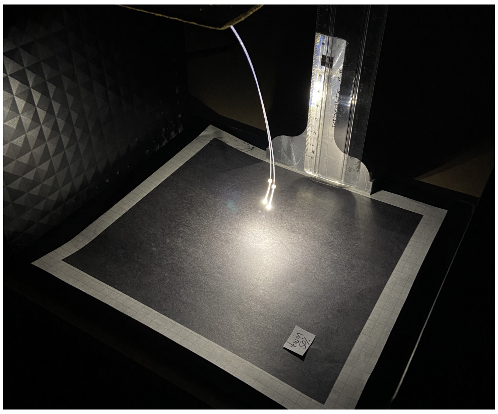


Figure 5.3: Setup for the illuminated area with the Eckardt TwinLight above a dark background made of graph paper for size indication.

5.2.3 Installation of the RingLight

The installation of the RingLight prototypes were tested ex-vivo on porcine cadaver eyes. The eyes were harvested immediately after killing the animal and transported in melting ice and kept in the fridge overnight. The time between eye harvesting and preparation was approximately one day. The porcine cadaver eyes were pinned on a rubber base and placed under a surgical microscope. The RingLight prototypes were connected to an EVA eye surgical system (DORC, the Netherlands), which has the same light module as the LEDStar included, at a power set point of 100%. In addition, the EVA eye surgical system can also be used to perform vitrectomies, which will be of use later on in the experimental procedure.

Figure 5.4: Setup for the installation of the RingLight prototypes with vitreoretinal surgeon Koen van Overdam in front of a porcine cadaver eye, about to insert one of the RingLight prototypes. The porcine cadaver eye is placed under a surgical microscope and the RingLight prototype is connected to the EVA eye surgical system on the right (also used for vitrectomies).

5.3 EXPERIMENTAL PROCEDURE

The complete test protocols for the temperature increase in the light fibers, the light intensity and the illuminated area and for the installation of the RingLights can be found in Appendix D and E respectively.

5.3.1 Temperature increase of the RingLight

The temperature increase in the light fibers of the RingLight prototypes was measured with a FLIR thermal imaging camera by pointing the thermal imaging camera at the fibers and showing the temperature of the center point of the image. First, the temperature of the fibers was measured with the light source (LEDStar) off, and then the temperature of the fibers was measured with the light source on at 100% after one minute to allow the fibers to heat up.

5.3.2 Light intensity and illuminated area of the RingLight versus the TwinLight

LIGHT INTENSITY With one of the RingLight prototypes or the Eckardt TwinLight at 20 mm above the illuminance meter receptor head, the light intensity was measured with the illuminance meter for 10%, 20%, 30%, 40% and 50% power set points of the LEDStar. This was done for all three different light fibers and repeated four times per power set point to obtain five measurements per light fiber per power set point. The light intensity was also measured when the light source was off to create a reference value to calculate the total light intensity that is produced by the light fibers itself.

ILLUMINATED AREA The illuminated area was captured with an iPhone 11 camera placed in a fixed position against the end of the small wooden plank, parallel to the illuminated surface, keeping the distance and the angle of the camera with respect to the illuminated surface constant for the RingLight prototypes and the Eckardt TwinLight. Pictures were taken for all three different light fibers for 10%, 20%, 30%, 40% and 50% power set points of the LEDStar. A small note was placed on the illuminated surface to differentiate the pictures during post-processing (Figure 5.3).

5.3.3 Installation of the RingLight

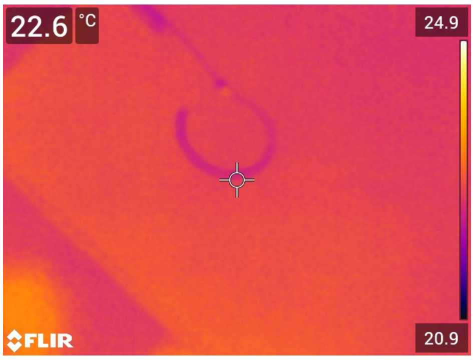
The installation procedure described in this section is the intended installation procedure as described in the test protocol (Appendix E). In reality, this installation procedure did not work out as planned, which will be described in Section 5.4.3.

Before the installation procedure, all RingLight prototypes are held under a surgical microscope to inspect the cuts that are made in the cladding.
The RingLight prototype 1 is inserted first, through the pars plana and with the help of a guidance needle. Another trocar is inserted on the opposite side of the eye for insertion of the string (prolene suture 10-0) for attaching the RingLight. With the help of the added pre-defined shape and the handle, the RingLight prototype 1 can be steered through the noose made with the string and brought to the right location. After tightening the noose, the RingLight prototype 1 is in place. This whole procedure is being timed with a stopwatch and all observations regarding the requirements are written down, i.e. how the ring moves through the vitreous, the complexity of the installation procedure, problems with bending radius, firmness of the attachment and damage to the tissue. These observations are made by Koen van Overdam, a vitreoretinal surgeon for the Rotterdam Eye Hospital, who also executed the installation procedures. Afterwards, the RingLight prototype 1 is removed from the eye by pulling the ring back as careful as possible and the procedure is repeated on two more porcine eyes. After installation in the last porcine eye, attaching the ring with the use of the handle will be attempted by removing the string and taping the handle in a fixed position to keep the ring horizontal. Finally, the RingLight prototype 1 is carefully removed after a short vitrectomy is performed to evaluate the obstruction to the view of the surgeon and the obstruction to other instruments of the RingLight.
On three other porcine eyes, the RingLight prototype 2 is inserted through the cornea and placed through the pupil into the posterior chamber. After making a small incision in the cornea, the RingLight prototype 2 is inserted and brought to the right location with the help of small tweezers. Once again, these procedures are being timed with a stopwatch and the same observations are written down, except for the movement through the vitreous since the ring does not move through the vitreous in these procedures. After the installation procedure in the third porcine eye, another short vitrectomy is performed before removing the RingLight prototype 2 for evaluation of the obstruction by the RingLight prototype 2.
When all prototypes are removed from the eyes, all six porcine eyes are carefully cut open with surgical scissors and a scalpel to further evaluate the damage done to the tissue during the installation procedure. Finally, the prototypes are inspected under the surgical microscope again to see if the installation procedures caused cracks in the cladding due to possible exceedance of the maximum bending radius.

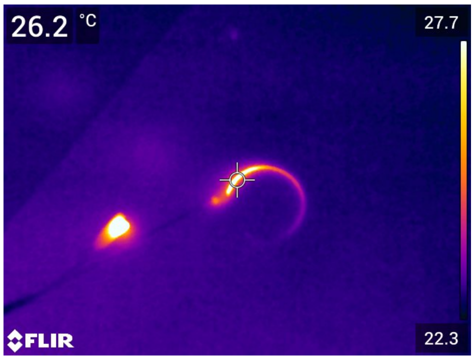
5.4 EXPERIMENTAL RESULTS

5.4.1 Temperature increase of the RingLight

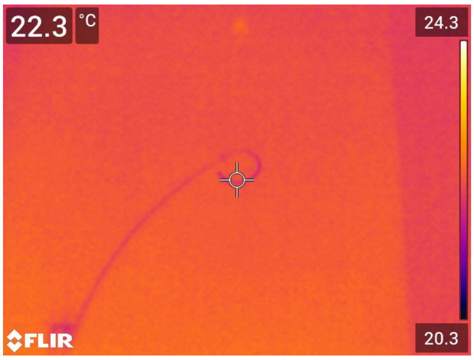
The temperature increase in the fibers is calculated by subtracting the temperature of the fiber when the light source is off from the temperature of the fiber when the light source has been on for one minute. Both temperature measurements for the RingLight prototype 1 and the RingLight prototype 2 are shown in Figure 5.5. The temperature increase is calculated at 3.6°C and 6.5°C for the RingLight prototype 1 and 2, respectively.



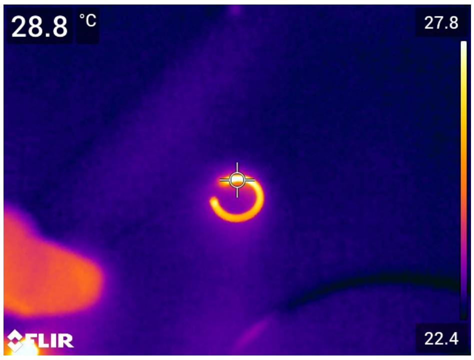
(a) RingLight prototype 1, light source off.



(b) RingLight prototype 1, light source on.



(c) RingLight prototype 2, light source off.



(d) RingLight prototype 2, light source on.

Figure 5.5: The temperatures of both RingLight prototypes with the light source off and with the light source at a power set point of 100% after 1 minute.

5.4.2 Light intensity and illuminated area of the RingLight versus the TwinLight

LIGHT INTENSITY The light intensity of the RingLight prototypes and the Eckardt TwinLight was measured with the Konica Minolta Illuminance meter T-10MA, which showed the light intensity in lux (lx). Lux is the luminous flux per unit area and is equal to one lumen per square metre. Every measurement was repeated four times and afterwards the average value for each measurement was calculated (Table 5.1). The reference value (light source off) was 0.15 lx, which is negligible, meaning the room was almost completely dark. The average values were put into a graph using MATLAB, which is shown in Figure 5.6 (the MATLAB code can be found in Appendix F).

Table 5.1: The average light intensity in lux for the two RingLight prototypes and the Eckardt TwinLight for power set points of 10%, 20%, 30%, 40% and 50%.

	Power set points				
	10%	**20%**	**30%**	**40%**	**50%**
Prototype 1	85.4	169.4	242.4	318.8	388.4
Prototype 2	84.6	168.4	240.8	316.4	385.2
TwinLight	2043	4054	5778	7592	9252

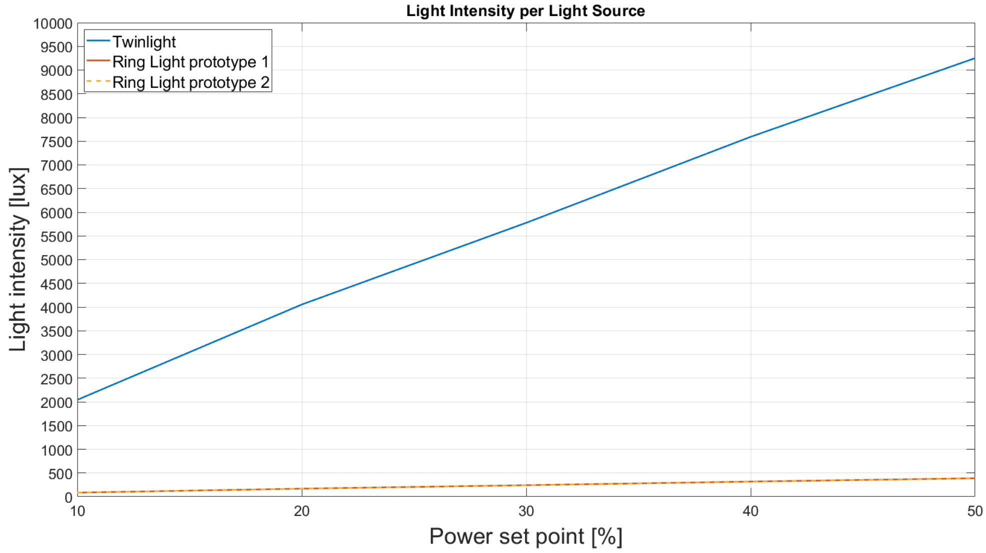


Figure 5.6: The light intensity of the standard TwinLight (27 gauge), the RingLight prototype 1 and the RingLight prototype 2 in lux.

ILLUMINATED AREA Figure 5.7 shows the color images of the illuminated area. These images were post-processed using MATLAB to create black and white images (Figure 5.8). All images were cropped to 3000 by 3000 pixels to obtain the same proportions and the illuminated areas could be compared with each other. With the help of the graph paper, we found that the 3000 pixels correspond to 12 cm and by using a MATLAB function to find the largest circle, we could calculate the area of the circle by converting the circle diameter from number of pixels to centimetre (the MATLAB code can be found in Appendix G). The area of each circle is shown in the bottom left of each corresponding image and the fitted circle is plotted as a blue circle. To obtain the correct fitted circle, the magnet that held the ring in place is edited out by covering it with a white circle and the white graph paper on each side of the images is also edited out.

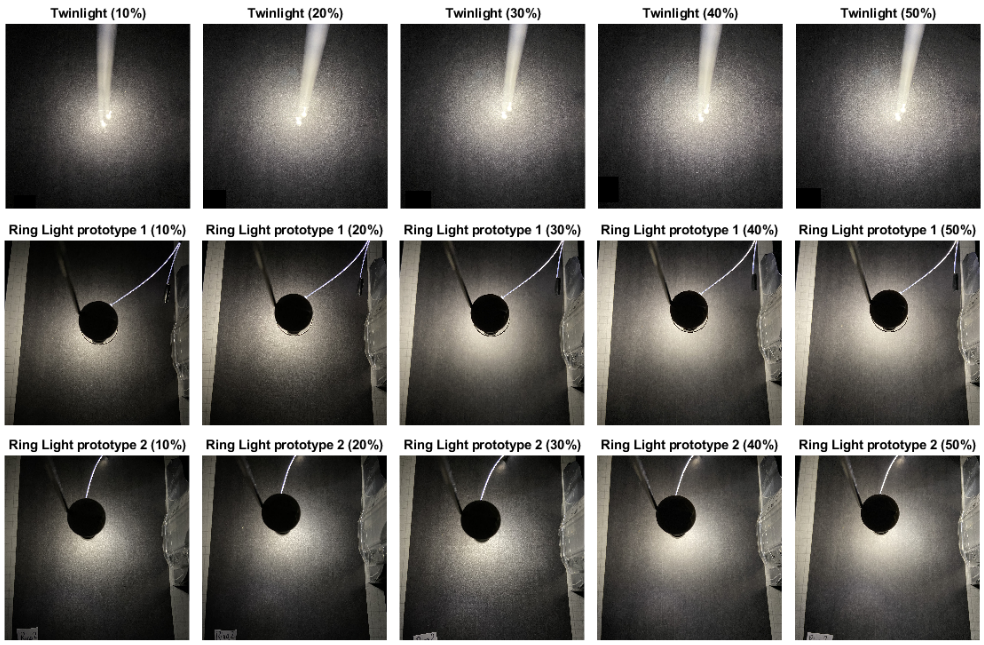


Figure 5.7: The illuminated area in color with the standard TwinLight (27 gauge), the RingLight prototype 1 and the RingLight prototype 2 for power set points of 10%, 20%, 30%, 40% and 50%.

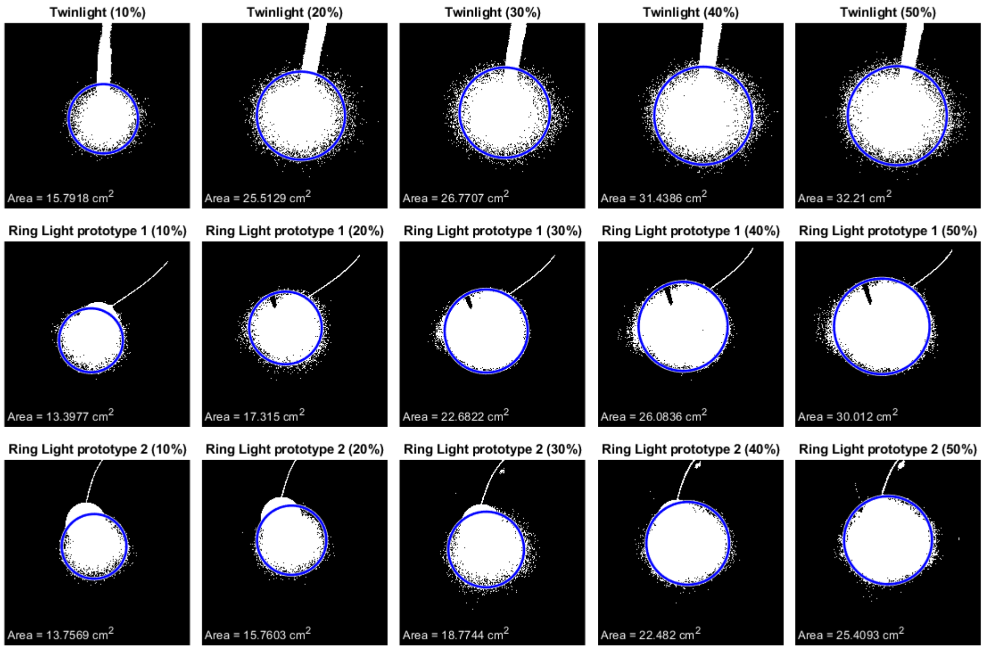


Figure 5.8: The illuminated area in black and white with the standard TwinLight (27 gauge), the RingLight prototype 1 and the RingLight prototype 2 for power set points of 10%, 20%, 30%, 40% and 50%. The blue circle is the fitted circle over the illuminated area, which is written down in cm^2 in the bottom left corner of each picture.

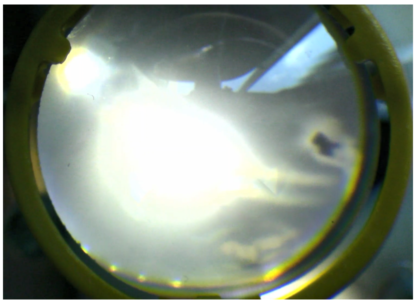
5.4.3 Installation of the RingLight

An overview of the observations made during the installation procedures of the RingLight prototype 1 and 2 is given in Table 5.2.

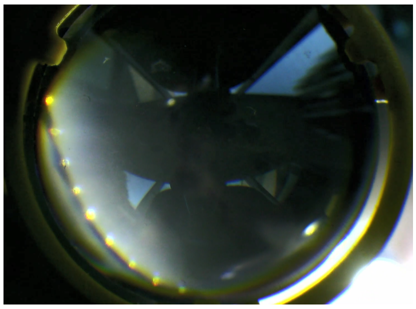
PROTOTYPE 1 The insertion phase of the first prototype was accomplished by cutting a relatively large incision in the pars plana instead of with a guidance needle like planned. The guidance needle was not an option anymore since the prototype got larger than the desired 27 gauge.
With the help of the added pre-defined shape, the RingLight prototype 1 was pushed further into the eye, and no problems were encountered to move the ring through the vitreous. However, the ring was too rigid and too sharp, which resulted in a punctured retina (Figure 5.9a) and a punctured lens bag. Therefore, manipulation with a forceps was needed to prevent the sharp tip from doing damage to the tissue. No problems were encountered with moving the forceps through the vitreous.
The placement phase with the handle was also difficult due to the short length of the handle (4 mm), because of this it was not possible to insert the ring further into eye and no good pivot was created. This was tried with one of the back-up prototypes with a longer handle (circa 10 mm) and this difference in handle length enabled the prototype to be better manipulated into the desired position.
The noose that was made out of the prolene suture 10-0 could not be found in the eye with the RingLight prototype 1 and made the attachment phase too complex. Therefore the attachment with the handle was used for the installation procedures and proved to be a better option. However, with the short handle the ring was too heavy to hold and the opposite side of insertion point fell down on the retina. When the handle was longer, the attachment was possible because of the law of the lever. By taping the 10 mm handle in the desired position, attachment of the RingLight prototype was possible without inserting any other components into the eye.

Removing the RingLight was done by carefully pulling back the ring the same way it was inserted. This time, the sharp tip did not puncture the retina, but the ring itself did get pulled against the retina. No retinal tears occurred during the withdrawal of the RingLight in these procedures, but there is a chance they might occur when the RingLight is not removed carefully.

In the end, the installation procedure of the RingLight prototype 1 was done twice instead of three times. Because the ring was too rigid and the tip was too sharp, too much damage was done to the tissue, making another repetition meaningless. The first installation procedure took 3 minutes and 46 seconds and the second attempt took 2 minutes and 22 seconds. Giving an average time of circa 3 minutes for the installation procedure of the RingLight prototype 1.
During the deployment phase, the maximum bending radius was not exceeded, since only the ring itself was inside the eye and the fiber was glued into the ring, making it impossible to further bend the fiber. Unfortunately, the images from the fiber made with the surgical microscope did not show enough details to show new cracks in the fiber, but since the maximum bending radius is not exceeded, this effect is not expected to occur.
Finally, the RingLight prototype only obstructed the view of the surgeon during the vitrectomy on the opposite side of insertion when the prototype with the short handle was used (Figure 5.9b). With the longer handle, the ring did not obstruct the view since it did not fall down. Furthermore, the RingLight prototype with the longer handle did not obstruct the vitrectomy instruments when installed correctly, and even removing the vitreous close to the ring was a success.



(a) Image showing the punctured retina: the black spot on the right.

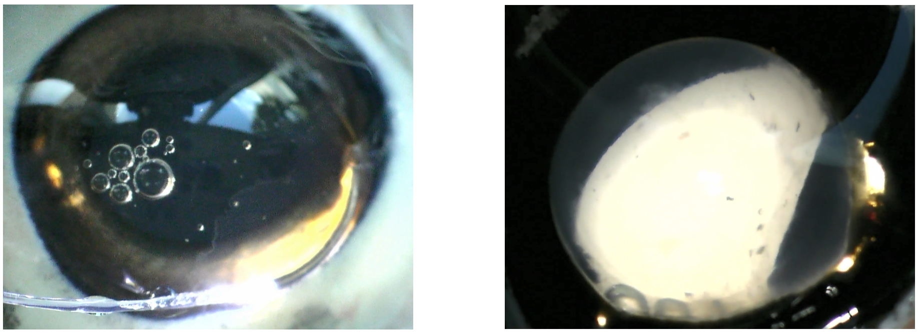


(b) Image showing the obstruction of view on the bottom left, when inserted from the right.

Figure 5.9: Images taken after the installation procedure of the RingLight prototype 1 of the damaged retina (a) and the obstruction of the view of the surgeon (b).

PROTOTYPE 2 The RingLight prototype 2 was inserted by making an incision in the cornea with a scalpel, a second incision was made for a small forceps. Inserting the ring proved to be more difficult than predicted. Due to the rigidity of the ring and the sharp tip, the tip of the ring damaged the inside of the cornea before being inserted completely. Once the RingLight prototype 2 was completely inserted into the anterior chamber, a small forceps was used to try and place the ring into the posterior chamber via the pupil. The lack of space in the posterior chamber in combination with the rigidity of the ring made the placement in the posterior chamber almost impossible. Figure 5.10a shows the RingLight prototype 2 placed partly in the posterior chamber, but the complete ring would not fit (right). Moreover, Figure 5.10a shows damage to the posterior iris at the location of the tip of the ring (left), which was caused by the sharp tip of the ring and the lack of space. Besides damage to the posterior iris and the inside of the cornea, the RingLight prototype 2 also damaged the ciliary zonules and the lens bag itself.

The installation procedure of the RingLight prototype 2 was only executed once, with no meaningful recorded time since the installation was not completed successfully. However, when the ring was (partly) in the posterior chamber, no problems were encountered regarding the bending radius and the fiber did not exceed the maximum bending radius. If the ring is placed in the desired position it will not move anywhere, eliminating the risk of detachment. Furthermore, the ring will not obstruct both the view of the retina and the vitrectomy instruments in this configuration. The last observation made with the installation procedure of this prototype is that the light was blocked by the ciliary body (Figure 5.10b) and therefore did not illuminate the retina at all.



(a) Image showing the damaged posterior iris on the left and the ring that could not be completely placed in the posterior chamber on the right.

(b) Image showing that the light is not emitted through the ciliary body, but only at the right side where the ciliary body was removed on purpose.

Figure 5.10: Images taken after the installation procedure of the RingLight prototype 2 of the damaged posterior iris (a) and the ciliary body blocking the light, seen from the side of the retina after cutting the eye open (b).

Table 5.2: An overview of the observations made during the installation procedures of both RingLight prototypes.

	Prototype 1	**Prototype 2**
Movement through vitreous	No problems encountered	Not applicable
Damage to tissue	Punctured retina; Punctured lens bag	Punctured inside of cornea; Damaged posterior iris; Damaged ciliary zonules; Punctured lens bag
Complexity of installation	Ring was too rigid and tip too sharp	Ring was too rigid and tip too sharp; Too little space
Installation time	Circa 3 minutes	No relevant time measured
Problems with bending radius	No problems encountered; Only ring was inside the eye, so fiber did not make any bends	No problems encountered; Bends made by the fiber to get ring into the posterior chamber were not exceeding maximum bending radius
Firmness of attachment	Noose was too complex; If handle was long enough, it could hold ring, otherwise ring fell on retina	When in the right location, ring could not move anymore
Obstruction of view	With short handle, ring fell in view; With longer handle, ring did not obstruct view	Ring did not obstruct view
Obstruction of instruments	Ring did not obstruct vitrectomy instruments when installed correctly	Ring did not obstruct vitrectomy instruments

6 DISCUSSION

The aim of this research was to develop and experimentally evaluate a ring light that can be inserted and placed inside the eye for intraocular illumination. We have designed two RingLight configurations: one for insertion through the pars plana (20 mm) and one for insertion through the cornea and placement in the posterior chamber (11 mm). Both prototypes are made from a 27 gauge Eckardt TwinLight, placed inside a capillary tube cut in half through the length. Cuts were made in the fiber every 2 mm, perpendicular to the length of the fiber, to allow light to exit the fiber through the cladding.
We have tested the two RingLight configurations on temperature increase by measuring their temperature with a FLIR thermal imaging camera with the light source off and on. Their light intensity was measured with an illuminance meter and the illuminated area was captured with a camera and both were compared to the Eckardt TwinLight. The installation procedures were performed to evaluate the safety and complexity of the procedures. These experiments were used to evaluate if the RingLight configurations meet all of the requirements of Chapter 2, which will be discussed in this chapter. Using these evaluations, the limitations to the prototypes and to the experiment will be discussed. Furthermore, we will give some recommendations for the next version of the RingLight prototype and some steps for continuation of this research.

6.1 INTERPRETATION OF THE RESULTS

6.1.1 Temperature increase of the RingLight

The temperature increase in both RingLight prototypes is less than the maximum allowed temperature increase of 10°C, with respect to the temperature with the light source off (Youssef et al. [2011]), preventing both rings from causing thermal damage to the sclera, internal pars plana or the ciliary sulcus. These are the locations that could make contact with the light fibers and therefore heat up the quickest when the temperature of the fibers increases. Because the retina is further away from the light fibers, the temperature increase in the retinal cells will increase even less, which makes it safe to say that both RingLight prototypes will not cause (photo)thermal damage.

6.1.2 Light intensity and illuminated area of the RingLight versus the TwinLight

LIGHT INTENSITY From Table 5.1 and Figure 5.6 it is obvious that both RingLight prototypes have a much lower light intensity than the Eckardt TwinLight. The RingLight prototype 1 has a slightly higher light intensity than the RingLight prototype 2, but this difference is almost negligible and could be caused by the measurement bias of the illuminance meter. One way to explain the large difference in light intensity between the prototypes and the Twinlight is that the prototypes are made from the same Eckardt TwinLight where one of the fibers is sealed off with tape. Because of this, half of the light goes to the fiber that is sealed off and half of the light goes to the RingLight itself. Thus, the power in the RingLight prototypes is in fact half the power delivered by the LEDStar and the power set point axis of the RingLights in Figure 5.6 should go from 5% to 25% instead of 10% to 50%. Although the light intensity of the RingLight prototypes would increase when the power is doubled, their light intensity would still not be as high as that of the TwinLight. With the Eckardt Twinlight, all of the light through the light fiber comes out of the fiber tip and is focused on one point, whereas the RingLights distribute the light over the entire ring resulting in more diffuse illumination with lower light intensity.

Although the light intensity of the RingLight prototypes is too low for illuminating structures like the vitreous humour during vitrectomy through a microscope, it might be just enough for the 3D visualization systems used for vitreoretinal surgery, which require a lower light intensity due to the better light sensitivity of the software and the High Dynamic Range (HDR) cameras (Ehlers et al. [2018]; Kumar et al. [2018]; Kantor et al. [2021]).

Additionally, the lower light intensity of the RingLight configurations reduce the risk of phototoxicity, since the phototoxicity is directly proportional to the light intensity (Solley and Sternberg Jr [1999]). The phototoxicity is also directly proportional to the exposure duration (Solley and Sternberg Jr [1999]) and has an inversed square proportionality with the working distance (Koelbl et al. [2019]), meaning that a doubled working distance results in nearly 4 times less phototoxicity and thus a 4 times longer retinal threshold time, which is also reported by Sakaguchi and Oshima [2012] and Chow [2014]. Furthermore, Aydin et al. [2014] reported that the maximum threshold time at a working distance of 5 mm is about 20 minutes. This would result in a maximum threshold time of about 180 minutes (3 hours) for a working distance of 15 mm, which is the minimum working distance for the RingLight set in Chapter 2. According to Koen van Overdam, vitreoretinal surgery at the Rotterdam Eye Hospital, the average duration of vitreoretinal surgery is 45 minutes with exceptions for complex surgeries, which can take up to 2 or 3 hours.

In summary, the time and working distance related phototoxicity will reduce with the use of the RingLight, although the risk of phototoxicity will never completely be eliminated during endoillumination. However, with the present-day techniques and light sources, the risk of phototoxicity is reduced to the point that surgery can be performed without thinking too much about the phototoxic hazards and now the same can be said for ring-light configurations.

ILLUMINATED AREA Figure 5.8 shows the illuminated areas of the RingLight prototypes and the Eckardt TwinLight. Both RingLights have a smaller illuminated area with respect to the TwinLight according to the black and white images from MATLAB, where we would have expected a larger illuminated area with the RingLights. This might be due to the lower light intensity of the RingLight prototypes. As discussed before, the power set points of 20% and 40% of the RingLights should be compared with the 10% and 20% power set point of the TwinLight, respectively. If we compare these areas, we see a slightly larger illuminated area with the RingLight prototype 1 than with the TwinLight and a slightly smaller illuminated area with the RingLight prototype 2. Another factor that might influence the calculated illuminated areas is the threshold value used for converting the color images to black and white. Due to the lower light intensity of the RingLight prototypes, the brightness of their illuminated areas might be lower than the brightness of the illuminated area of the Eckardt TwinLight. Consequently, a smaller area will be converted to white for the RingLight prototypes.

Another observation from Figure 5.8, which can also been seen in Figure 5.7, is that the RingLight prototypes have a more diffuse illumination than the TwinLight. The images of the upper row of Figure 5.7 all have a more granular illumiated area than the images in the other two rows. This is probably due to the specular reflection produced by the TwinLight. This granular effect is also illustrated in Figure 5.8, where the illuminated area of the RingLights falls more neatly inside the fitted circles and the illuminated area of the TwinLight has more white spots outside of the fitted circle.

6.1.3 Installation of the RingLight

PROTOTYPE 1 The main problem with the installation procedure of the RingLight prototype 1 was the rigidity of the ring and its sharp tip. Due to these aspects, the ring caused a lot of damage to the retina and the lens bag during the insertion. This problem was fixed during the experiment by guiding the tip of the ring with the help of a forceps, ensuring the sharp tip did not cause damage to any tissue. Although the vitreous was not yet removed, the movement of the forceps was not hindered. The installation procedure required only one incision, since the incision made for the insertion of the forceps could be reused for the vitrectomy instrument. Although the number of incisions was lower than with the Eckardt TwinLight, the size of the incision was larger due to the added capillary tube. Instead of 27 gauge, the prototype now had a size of 24 gauge.

A way to overcome these limitations is by making the capillary tube from a more flexible material such as polymethylmethacrylate (PMMA), which is used for capsular tension rings. Moreover, the tip if the ring should be more blunt to prevent it from puncturing the retina during insertion. For this solution we could mimic the CTR once more by incorporating a pigtail curve at the distal end of the ring, like illustrated in Figure 6.1. With such a pigtail curve and increased flexibility, a forceps might not be needed anymore to guide the fiber during deployment.

On the other hand, the rigidity of the ring guaranteed smooth movement through the vitreous. We also tested the movement through the vitreous with a normal light fiber, to see if this smooth movement was achieved by the rigidity of the capillary tube or if the fiber itself was rigid enough. We found that the fiber itself was rigid enough to ensure smooth movement through the vitreous, which implies that the added pre-defined shape does not need to be rigid at all. Moreover, the movement through the vitreous did not cause any visible traction of the vitreous humour on the retina and no retinal tears occurred.

As previously said, the attachment method of the string through an additional trocar was rejected immediately because this procedure was too complex. Mainly because the noose made in the string could not be found with the ring, because it was too close to the pars plana and could not be seen through the pupil. Luckily, the back-up method of taping the handle in a fixed position proved to be a good solution provided that the handle is long enough. This way of attaching the RingLight did not obstruct the view of the retina and the vitrectomy instruments and has even more advantages, since the position of the ring is easily adjustable and no additional incisions are required. On top of that, the handle could be used as a pivot to direct the light on a certain part of the retina.

The entire installation procedure consisted of 4 steps, i.e. the insertion through the pars plana, the deployment of the ring inside the eye with the use of forceps, adjusting the placement of the ring with the handle and attaching the ring. All in all, the duration of the installation procedure was circa 3 minutes, which is longer than the installation of the Eckardt TwinLight, but also not that long. These additional 2 minutes for the installation of the RingLight might be worthwhile, since the RingLight has other benefits over the TwinLight that might improve operating conditions, such as more diffuse illumination to reduce the reflection and overillumination. Furthermore, the time needed for installation will improve with a better prototype as well as with practice.

PROTOTYPE 2 The installation procedure with the RingLight prototype 2 was unsuccessful, partly due to the rigidity of the small ring and the sharp tip, but mostly due to the lack of space in the posterior chamber. With this lack of space and the complexity of the installation procedure, it is almost impossible to not damage the ciliary zonules, lens bag and the iris, even with a more flexible and blunt ring. On top of that, the light is not emitted through the ciliary body due to the highly pigmented retinal epithelium (Figure 5.10b), making this RingLight configuration even more unusable.
Because the installation procedure of the RingLight prototype 2 is so complex and the mechanical damage to the tissue caused by the installation procedure cannot be prevented, all other requirement do not matter anymore and are therefore not discussed.

6.2 LIMITATIONS

6.2.1 Limitations to the prototypes

A 27 gauge light fiber was used for the prototype, but in combination with the capillary tube this resulted in a 24 gauge ring. Due to this increased size, the ring could not be inserted with a guidance needle because the incision needed to be larger. Also the light intensity of the RingLight was not as high because the light was divided over two separate fibers. Moreover, the light intensity of the RingLight prototype 1 was not uniformly distributed over the entire ring, since less light was emitted from the distal end of the ring. This effect is shown in Figure 4.2b and is caused by the cuts in the cladding. The more cuts are made in the cladding, the more light is emitted from the light fiber before it reaches the end of the ring. Therefore, a balance needs to be found between the number of cuts and the distribution of light to ensure a more uniform distribution.
With regard to the installation of the prototype, the main limitations were the rigidity of the added pre-defined shape and the sharpness of the tip of the ring. These limitations made the installation procedure unsafe, although the safety was slightly increased by guiding the tip of the ring with forceps. Furthermore, the metal glue in the tip of the ring impeded the light to shine through the fiber tip, which made it difficult to locate the tip of the ring inside the eye. In this case, it would have been better if the metal glue was not added in the tip so the ring could more easily be found with the forceps.

6.2.2 Limitations to the experiment

The experiments of the light intensity and the illuminated area were not optimal because half of the power is used in the RingLights as discussed. Therefore the results of the RingLights cannot be compared with the Eckardt TwinLight directly. For the illuminated area, the black and white images limit the calculate the real illuminated are, because a certain threshold value is used. If the light intensity of the RingLights is lower than that of the TwinLight, the amount of pixels that are converted to white will be less for the RingLights. Consequently, both illumination methods could not be compared precisely and might differ more than found in this study.
The installation procedures were predominantly limited by the amount of damage to the tissue and their complexity. After the first installation procedure we could already conclude that the RingLight prototypes were too rigid with a sharp tip. If the installation procedure was repeated multiple times, similar results would be obtained. Therefore, an improved prototype is required to obtain more and better results and to continue this research.

6.3 FUTURE WORK

6.3.1 Recommendations

Although the RingLight prototype 1 shows potential, there are a lot of improvements that should be made to the prototype to continue this research. Firstly, the RingLight should be made from an individual light fiber instead of the Eckardt Twinlight to acquire twice as much power from the light source and thus twice as much light intensity.
Secondly, the RingLight should be made of a smaller fiber, so a smaller capillary tube could be used. Preferably a capillary tube with an outer diameter of 27 gauge to gain the self-retaining property of the 27 gauge chandelier endoilluminators. The smallest available light fibers are 29 gauge, meaning the thickness of the capillary tube can only be 0.036 mm. This might not be possible and therefore we should also look at other solutions to obtain the pre-defined shape. An option for this is to bend the fiber in the right shape, since it has some rigidity of itself. This way the light will be emitted not only downwards through the cladding but in all directions. To prevent the light from shining upwards towards the surgeon, a reflective coating could be added to the top of the ring. This was tried with a permanent marker after the installation procedures and worked.
If the pre-defined shape is still to be added, this should be made from a more flexible material like PMMA and the tip should have an incorporated pigtail curve to make the tip less sharp and thus eliminating the need of a forceps to guide the ring inside the eye. With such a flexible ring, the diameter of the ring could be made slightly larger than the used prototype and could clamp itself against the inside of the pars plana after insertion and no attachment would be needed at all. Lastly, the length of the handle should be increased to 10 mm so it can be used to create a better pivot. These recommendations are sketched in Figure 6.1.

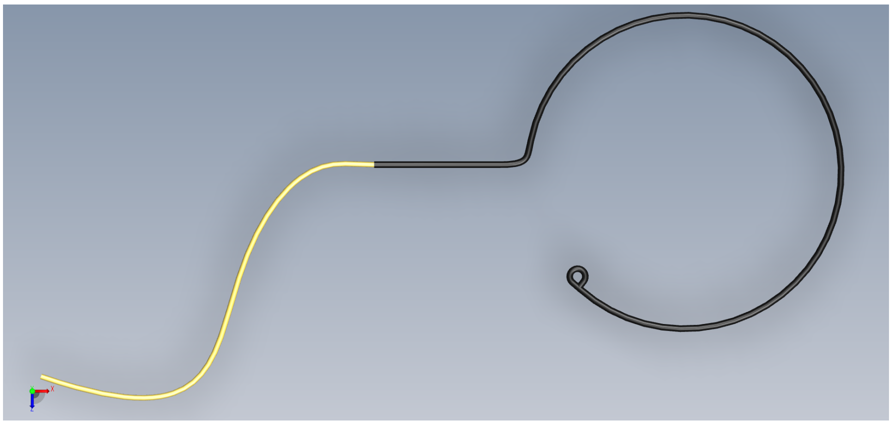


Figure 6.1: Sketch of an improved version of the prototype with a longer handle (10 mm) and an incorporated pigtail curve at the distal end of the ring. Moreover, this improved prototype uses a 29 gauge fiber resulting in a 27 gauge prototype when combined with the capillary tube. The handle, capillary tube and pigtail curve are all made from PMMA and coated with a dark (reflective) coating.

Other ideas for the prototype might be the pupil expander configuration that was suggested in Chapter 3. Since this configuration is placed in the pupil, it does not have the restricted space as in the posterior chamber. The benefit of this configuration is that it does not only illuminate the retina, but it also expands the pupil. This idea was, however, not worked out in this research since such a prototype would take too much time to be manufactured and first research needs to be done as to how the light is refracted through the lens and the influence of lens opacity in this configuration.

6.3.2 Towards clinical use

If the RingLight configuration is to be used for clinical use, a lot of things have to be done. Firstly, the previously recommended improvements need to be made to the prototype. The RingLight should be designed in such a way that it never causes damage to the tissue and the installation is less complex than it is now. Secondly, more experiments should be done, e.g., more installation procedures should be performed and by different vitreoretinal surgeons.

Furthermore, the biocompatibility of the RingLight should be tested according to to ISO 10993. On top of that, future research should be done to the sterilisation of the RingLight. If this is possible, the RingLight could be reused for multiple procedures instead of being a single-use illumination method.

7 CONCLUSION

In this work, we have presented the design and experimental evaluation of two different RingLight prototypes. We have shown that the RingLight configuration could be a good method for illuminating the retina during vitreoretinal surgery with a 3D visualization system due to its lower light intensity than the Eckardt TwinLight and a slightly larger illuminated area. On top of that, its diffuse and more uniform light distribution reduces the risk of overillumination, specular reflection and glare.
The evaluation of the installation procedures of the prototypes in ex-vivo porcine cadaver eyes showed that the placement of the RingLight in the posterior chamber is almost impossible without damaging the tissue, due to the limited space in the posterior chamber, and the rigidity and sharp tip of the prototype. The installation procedure of the first RingLight prototype also caused damage to the tissue, due to the rigidity and the sharp tip. Nevertheless, this RingLight configuration, inserted through the pars plana, shows potential when the ring would be made from a more flexible material such as PMMA, has an incorporated pigtail curve a the distal end of the ring, and has a longer handle at the proximal end of the ring.

BIBLIOGRAPHY

Advanced illumination (2019). Bright field vs. dark field illumination. Last accessed 6 April 2022 [online]. Available: https://www.advancedillumination.com/lighting-education/bright-field-dark-field-lighting/.

Associated Retina Consultants (2022). What is vitreoretinal surgery? Last accessed 1 June 2022 [online]. Available: https://associatedretinaconsultants.com/what-is-vitreoretinal-surgery/.

Aydin, B., Dinç, E., Yilmaz, Ş. N., Altiparmak, U. E., Yülek, F., Ertekin, S., Yilmaz, M., and Yakın, M. (2014). Retinal endoilluminator toxicity of xenon and light-emitting diode (led) light source: rabbit model. *Cutaneous and ocular toxicology*, 33(3):192–196.

Bekerman, I., Gottlieb, P., and Vaiman, M. (2014). Variations in eyeball diameters of the healthy adults. *Journal of ophthalmology*, 2014.

Beltrame, G. and Busatto, P. (2006). Double use of optic fiber during vitrectomy as a transilluminator and indenter instrument. *Retina*, 26(2):223–224.

Bhattacharjee, S. (2017). B-hex pupil expander: Pupil expansion redefined. *Indian Journal of Ophthalmology*, 65(12):1407.

Charles, S. (2008). Illumination and phototoxicity issues in vitreoretinal surgery.

Chow, D. R. (2014). The evolution of endoillumination. *Microincision Vitrectomy Surgery*, 54:77–86.

Cronemberger, S., Calixto, N., Andrade, A. O., and Mérula, R. V. (2010). New considerations on pupillary block mechanim. *Arquivos Brasileiros de Oftalmologia*, 73(1):9–15.

Davis, R. M., Campbell, D. M., and Jacoby, B. G. (1991). Ciliary sulcus anatomical dimensions. *Cornea*, 10(3):244–248.

Davson, H. and Perkins, E. S. (2021). Human eye. Last accessed 1 June 2022 [online]. Available: https://www.britannica.com/science/human-eye.

Dölen, U. C. and Çınar, S. (2016). Perfect lighting for facial photography in aesthetic surgery: ring light. *Aesthetic plastic surgery*, 40(2):319–326.

Dong, J.-t., Lu, R.-s., Shi, Y.-q., Xia, R.-x., Li, Q., and Xu, Y. (2011). Optical design of color light-emitting diode ring light for machine vision inspection. *Optical Engineering*, 50(4):043001.

Eckardt, C. (2003). Twin lights: a new chandelier illumination for bimanual surgery. *Retina*, 23(6):893–894.

Ehlers, J. P., Uchida, A., and Srivastava, S. K. (2018). The integrative surgical theater: combining intraoperative optical coherence tomography and 3d digital visualization for vitreoretinal surgery in the discover study. *Retina*, 38:S88–S96.

El Bayadi, G. (1953). New method of slit-lamp micro-ophthalmoscopy. *The British journal of ophthalmology*, 37(10):625.

Essentra Components US (2019). Fiber optics faqs: The advantages, bend radius explained and more. Last accessed 23 February 2022 [online]. Available: https://www.essentracomponents.com/en-us/news/product-resources/fiber-optics-faqs-the-advantages-bend-radius-explained-and-more.

Graether, J. M. (1996). Graether pupil expander for managing the small pupil during surgery. *Journal of Cataract & Refractive Surgery*, 22(5):530–535.

Ivanov, O. V., Nikitov, S. A., and Gulyaev, Y. V. (2006). Cladding modes of optical fibers: properties and applications. *Physics-Uspekhi*, 49(2):167.

Kantor, P., Matonti, F., Varenne, F., Sentis, V., Pagot-Mathis, V., Fournié, P., and Soler, V. (2021). Use of the heads-up ngenuity 3d visualization system for vitreoretinal surgery: a retrospective evaluation of outcomes in a french tertiary center. *Scientific Reports*, 11(1):1–11.

Koch, F. H. J., Pawlowski, D., and Spitznas, M. (1991). A multiport illumination system for panoramic bi-manual vitreous surgery. *Graefe's archive for clinical and experimental ophthalmology*, 229(5):425–429.

Koch, F. H. J., Schmidt, H. P., Mönks, T., Blumenröder, S. H., Haller, A., and Steinmetz, R. L. (1993). The retinal irradiance and spectral properties of the multiport illumination system for vitreous surgery. *American journal of ophthalmology*, 116(4):489–496.

Koelbl, P. S., Lingenfelder, C., Spraul, C. W., Kampmeier, J., Koch, F. H., Kim, Y. K., and Hessling, M. (2019). An intraocular micro light-emitting diode device for endo-illumination during pars plana vitrectomy. *European journal of ophthalmology*, 29(1):75–81.

Kumar, A., Hasan, N., Kakkar, P., Mutha, V., Karthikeya, R., Sundar, D., and Ravani, R. (2018). Comparison of clinical outcomes between "heads-up" 3d viewing system and conventional microscope in macular hole surgeries: a pilot study. *Indian Journal of Ophthalmology*, 66(12):1816.

Loughlin, C. (1993). *Sensors for industrial inspection*, page 284. Springer Science & Business Media.

Lu, M.-K., Chang, F.-C., Wang, W.-Z., Hsieh, C.-C., and Kao, F.-J. (2014). Compact light-emitting diode lighting ring for video-assisted thoracic surgery. *Journal of biomedical optics*, 19(10):105004.

Machemer, R. (1974). A new concept for vitreous surgery: 7. two instrument techniques in pars plana vitrectomy. *Archives of Ophthalmology*, 92(5):407–412.

Menapace, R., Findl, O., Georgopoulos, M., Rainer, G., Vass, C., and Schmetterer, K. (2000). The capsular tension ring: designs, applications, and techniques. *Journal of Cataract & Refractive Surgery*, 26(6):898–912.

Oshima, Y., Awh, C. C., and Tano, Y. (2007). Self-retaining 27-gauge transconjunctival chandelier endoillumination for panoramic viewing during vitreous surgery. *American journal of ophthalmology*, 143(1):166–167.

Peyman, G. A., Canakis, C., Livir-Rallatos, C., and Easley, J. (2002). A new wide-angle endoillumination probe for use during vitrectomy. *Retina*, 22(2):242.

Peyman, G. A., Cheema, R., D Conway, M., and Fang, T. (2000). Triamcinolone acetonide as an aid to visualization of the vitreous and the posterior hyaloid during pars plana vitrectomy. *Retina*, 20(5):554–555.

Ryan, E. H. (1997). Two shielded'bullet'probes for panoramic endoillumination. *Archives of Ophthalmology*, 115(1):125–126.

Sakaguchi, H. and Oshima, Y. (2012). Considering the illumination choices in vitreoretinal surgery. *Retinal Physician*, 9(2):26–31.

Sakaguchi, H., Oshima, Y., Nishida, K., and Awh, C. C. (2011). A 29/30-gauge dual-chandelier illumination system for panoramic viewing during microincision vitrectomy surgery. *Retina*, 31(6):1231–1233.

Schmidt, J. C., Nietgen, G. W., Hesse, L., and Kroll, P. (2000). External diaphanoscopic illuminator: a new device for visualization in pars plana vitrectomy. *Retina*, 20(1):103–106.

Sebag, J. (1994). Surgical anatomy of vitreous and the vitreo-retinal interface. *Clinical ophthalmology*, 6:1–36.

Singh, A. K., Leeman, J., Shankar, S., and Ferrucci, J. T. (2008). Core biopsy with curved needle technique. *American Journal of Roentgenology*, 191(6):1745–1750.

Solley, W. A. and Sternberg Jr, P. (1999). Retinal phototoxicity. *International ophthalmology clinics*, 39(2):1–12.

Spitznas, M. (1987). A binocular indirect ophthalmomicroscope (biom) for non-contact wide-angle vitreous surgery. *Graefe's archive for clinical and experimental ophthalmology*, 225(1):13–15.

Sze, D. Y. (2001). Use of curved needles to perform biopsies and drainages of inaccessible targets. *Journal of vascular and interventional radiology*, 12(12):1441–1444.

Veckeneer, M. and Wong, D. (2009). Visualising vitreous through modified trans-scleral illumination by maximising the tyndall effect. *British Journal of Ophthalmology*, 93(2):268–270.

Vision Eye Institute (2017). The aqueous humour. Last accessed 3 March 2022 [online]. Available: https://visioneyeinstitute.com.au/eyematters/aqueous-humour/#:~:text=The%20aqueous%20humour%20is%20a,gives%20the%20eye%20its%20shape.

Warnock, N. G. (1996). Curved needle technique for the avoidance of interposed structures in ct-guided percutaneous fine needle biopsy. *Journal of computer assisted tomography*, 20(5):826–828.

Williams, G. A. (2008). 27-gauge twinlight chandelier illumination system for bi-manual transconjunctival vitrectomy. *Retina*, 28(3):518–519.

Williams, G. A., Abrams, G. W., and Mieler, W. F. (1989). Illuminated retinal picks for vitreous surgery. *Archives of Ophthalmology*, 107(7):1086–1086.

Youssef, P. N., Sheibani, N., and Albert, D. M. (2011). Retinal light toxicity. *Eye*, 25(1):1–14.

A GAUGE TO MILLIMETRE

Table A.1: Conversion chart of gauge to millimetre.

Gauge	Millimetre
20	0.91
21	0.81
22	0.71
23	0.61
24	0.60
25	0.51
26	0.46
27	0.417
28	0.376
29	0.345

B HARRIS PROFILES

	Insertion		Deployment		Placement	Attachment			
Safety	Through pars plana	Through cornea	With extra components	Mechanics of the fiber	With extra components	With extra components (without incisions)	With extra components (with incisions)	Mechanics of the fiber	Components that are already in use
Invasiveness	1	1	N/A	N/A	N/A	1	2	1	2
Working distance related phototoxicity	1	1	N/A	N/A	N/A	2	2	2	1
Mechanical damage	1	2	N/A	N/A	N/A	1	1	2	1
Thermal damage	1	1	N/A	N/A	N/A	2	1	2	1
Dimensions	Through pars plana	Through cornea	With extra components	Mechanics of the fiber	With extra components	With extra components (without incisions)	With extra components (with incisions)	Mechanics of the fiber	Components that are already in use
Fiber size	1	1	2	2	N/A	2	1	2	1
Ring diameter	1	3	1	1	N/A	N/A	N/A	N/A	N/A
Performance	Through pars plana	Through cornea	With extra components	Mechanics of the fiber	With extra components	With extra components (without incisions)	With extra components (with incisions)	Mechanics of the fiber	Components that are already in use
Attachment	N/A	N/A	N/A	N/A	N/A	2	1	3	1
Obstruction of instruments	1	1	N/A	N/A	N/A	2	2	1	1
Obstruction of view	1	2	N/A	N/A	N/A	1	1	1	1
Moving to vitreous	N/A	N/A	2	3	2	N/A	N/A	N/A	N/A
Installation complexity	1	2	2	1	2	2	2	2	3
Installation steps	3	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Bending radius	1	2	1	3	N/A	N/A	N/A	N/A	N/A
Innovative	3	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Final choice	Through pars plana	Through cornea	With extra components		With extra components		With extra components (with incisions)		Components that are already in use

Level of risk:	
1	-> No risk/complexity at all
2	-> Risky/complex
3	-> Unwanted
N/A	-> Not applicable

Figure B.1: Harris profile of the different methods for installation of the Ring Light.

	Insertion				Deployment			Placement		Attachment		
Safety	pp: Trocar	pp: Guidance needle	c: Posterior chamber	c: Pupil expander	Pulling on tip	Pre-defined shape	Pre-curved	Magnet	Handle	Instrument through trocar	Inserted hook	Mechanism on trocar
Invasiveness	1	1	1	1	N/A	N/A	N/A	N/A	N/A	2	2	1
Working distance related phototoxicity	1	1	1	1	N/A	N/A	N/A	N/A	N/A	1	1	1
Mechanical damage	1	1	2	2	N/A	N/A	N/A	N/A	N/A	1	1	1
Thermal damage	1	1	1	1	N/A	N/A	N/A	N/A	N/A	1	1	1
Dimensions	pp: Trocar	pp: Guidance needle	c: Posterior chamber	c: Pupil expander	Pulling on tip	Pre-defined shape	Pre-curved	Magnet	Handle	Instrument through trocar	Inserted hook	Mechanism on trocar
Fiber size	1	1	1	1	1	2	2	N/A	N/A	1	1	1
Ring diameter	1	1	2	3	1	1	1	N/A	N/A	N/A	N/A	N/A
Performance	pp: Trocar	pp: Guidance needle	c: Posterior chamber	c: Pupil expander	Pulling on tip	Pre-defined shape	Pre-curved	Magnet	Handle	Instrument through trocar	Inserted hook	Mechanism on trocar
Attachment	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	2	2
Obstruction of instruments	1	1	1	1	1	1	1	N/A	N/A	1	2	1
Obstruction of view	1	1	2	2	1	1	1	N/A	N/A	1	1	1
Moving to vitreous	N/A	N/A	N/A	N/A	2	1	2	2	2	N/A	N/A	N/A
Installation complexity	1	1	2	2	2	1	1	2	1	2	3	3
Installation steps	3	3	1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Bending radius	1	1	1	2	2	1	1	N/A	N/A	N/A	N/A	N/A
Innovative	3	3	1	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Final choice	pp: Trocar	pp: Guidance needle	c: Posterior chamber			Pre-defined shape			Handle	Instrument through trocar		

Level of risk:	
1	-> No risk/complexity at all
2	-> Risky/complex
3	-> Unwanted
N/A	-> Not applicable

Figure B.2: Harris profile of the different solutions per chosen method for installation of the Ring Light. (pp = pars plana & c = cornea)

C RING PROTOTYPE

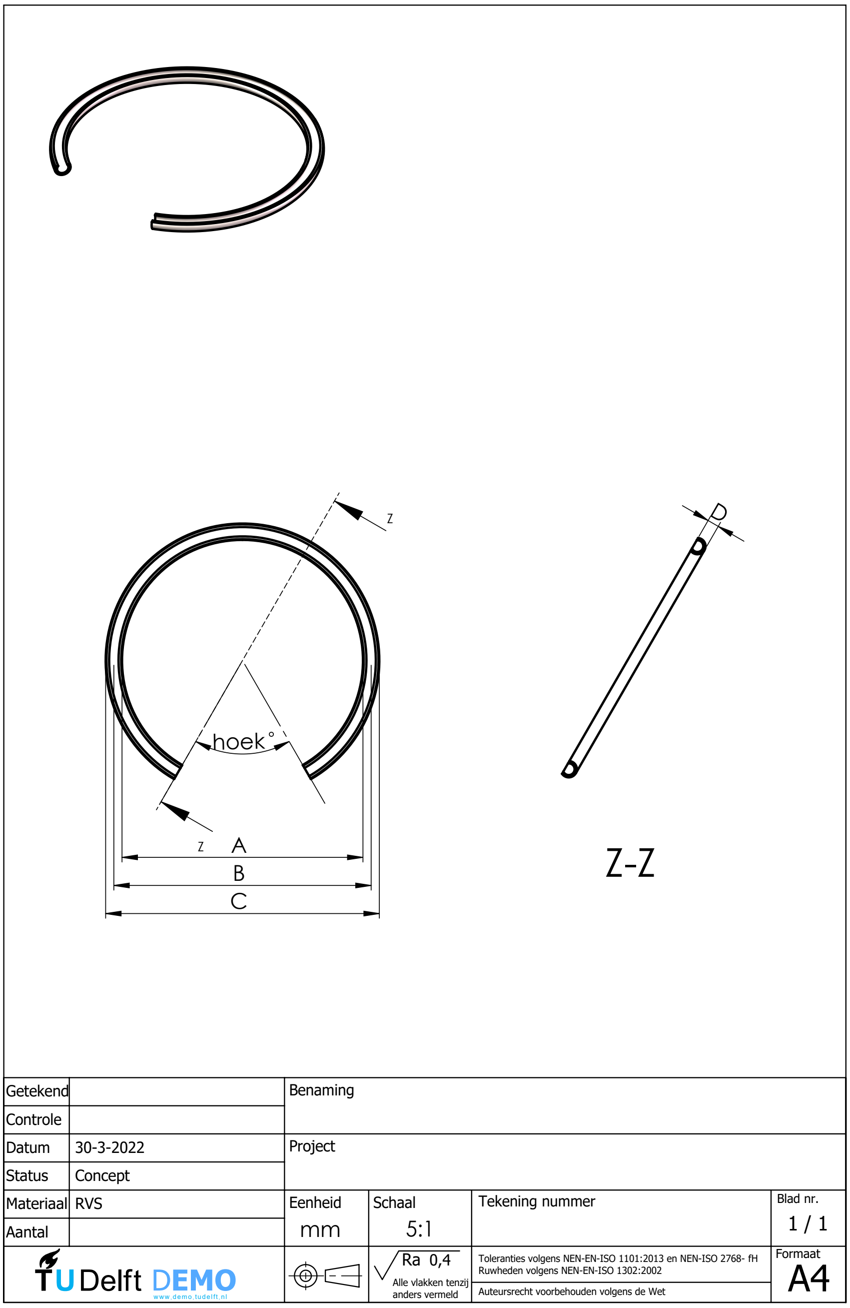


Figure C.1: Design of the pre-shaped ring made from a capillary tube cut in half, where A is the inner diameter of the ring, B the internal diameter of the ring, C the outer diameter of the ring and D the outer radius of the capillary tube. The "hoek" is the opening angle between the beginning and the end of the capillary tube ring.

D | TESTPROTOCOL TEMPERATURE & LIGHT INTENSITY OF THE RING LIGHT

I. Measurement for temperature increase in light fibers

Equipment:

- Ledstar light module for fibers with DORC connection
- Ring Light prototype 1
- Ring Light prototype 2
- Flir thermal imaging camera

1) Take an image of the Ring Light prototype 1 with the Flir thermal imaging camera when the Ledstar light module is off and write down the temperature in the table below.
2) Turn the Ledstar light module on at a power set point of 100% and take an image of the Ring Light prototype 1 with the Flir thermal imaging camera after 1 minute and write down the temperature in the table below.
3) Turn off the Ledstar light module.
4) Repeat steps 1 up to and including 3 for the Ring Light prototype 2.

Measured temperature in degrees Celsius of the different prototypes:

	Ring Light prototype 1	**Ring Light prototype 2**
Light source off		
Light source on (100%)		

II. Measurement of the light intensity

Equipment:

- Konica Minolta T-10MA Illuminance meter
- Ledstar light module for fibers with DORC connection
- Standard twinlight (27 gauge)
- Ring Light prototype 1
- Ring Light prototype 2

1) Place the illuminance meter on a table.
2) Make a setup from where the fibers (prototypes and twinlight) can hang at 2 cm (the working distance of light source to retina) distance to the illuminance meter.
3) Turn on the illuminance meter.
4) Measure the light intensity while the Ledstar is still off and write down in the table below.
5) Attach the standard twinlight to the made setup at 2 cm distance from the illuminance meter.
6) Connect the standard twinlight to the Ledstar light module.
7) Turn on the Ledstar light module.
8) Measure the light intensity of the standard twinlight for 10%, 20%, 30%, 40% and 50% power and write down in the table below.
9) Turn of the Ledstar and repeat steps 7 and 8 four times.
10) Repeat steps 4 up to and including 9 for the Ring Light prototypes 1 and 2.

Light intensity of the different light sources for different power percentages (in lux):

Light Source off					

	Standard twinlight					**Ring Light prototype 1**					**Ring Light prototype 2**				
Power[%]	10	20	30	40	50	10	20	30	40	50	10	20	30	40	50
Intensity #1															
Intensity #2															
Intensity #3															
Intensity #4															
Intensity #5															
Average															

III. Measurement of the illuminated area

Equipment:

- Dark room
- Ledstar light module for fibers with DORC connection
- Standard twinlight (27 gauge)
- Ring Light prototype 1
- Ring Light prototype 2
- Dark background
- Camera (phone)

1) In a dark room, make a setup from where the fibers (prototypes and twinlight) can hang at 2 cm (the working distance of light source to retina) distance to the dark background.
2) Attach the standard twinlight to the made setup at 2 cm distance from the dark background.
3) Connect the standard twinlight to the Ledstar light module.
4) Turn on the Ledstar light module.
5) Make a photo of the illuminated ared from a fixed position right above the illuminated area.
6) Turn off the Ledstar light module.
7) Repeat steps 2 up to and including 6 for the Ring Light prototype 1 and 2.
8) Compare the illuminated area per light source afterwards using MatLab.

E | TESTPROTOCOL INSTALLATION OF THE RING LIGHT

I. Preparing the porcine eyes

Equipment:

- Surgical gown
- Sterile gloves
- Porcine cadaver eyes (6)
- Rubber base to fix the porcine eyes (6)
- Hat pins
- Alcohol wipes

I. Put on a surgical gown and sterile gloves.
II. Fix all of the porcine cadaver eyes in the rubber bases with the hat pins.
III. Wipe the table clean with alcohol wipes afterwards.

II. Checking the cuts in the fiber of the prototypes under the microscope

Equipment:

- Ring Light prototype 1 (20mm ring)
- Ring Light prototype 2 (11mm ring)
- Microscope

1) Check the fiber of the Ring Light prototype 1 under the microscope and make a picture/screenshot of the cuts in the fiber.
2) Check the fiber of the Ring Light prototype 2 under the microscope and make a picture/screenshot of the cuts in the fiber.

III. Installation of the Ring Light prototype 1 in the porcine eyes.

Equipment:

- ○ Porcine eyes fixed in the rubber bases (3)
- ○ Microscope
- ○ EVA
- ○ Ring Light prototype 1
- ○ Stopwatch
- ○ Trocars
- ○ Prolene suture 10-0
- ○ Guidance needle
- ○ Tape

1) Put one of the fixed porcine eyes under the microscope.
2) Start the stopwatch.
3) Insert a trocar through the pars plana with the prolene suture 10-0 in a noose through it.
4) Insert the Ring Light prototype 1 (attached to the EVA) through the pars plana on the opposite side of the eye with the guidance needle.
5) Maneuver the Ring Light prototype 1 through the vitreous and through the noose of the prolene suture 10-0 and attach the Ring Light prototype 1 when it is in the right position by tightening the noose.
6) Stop the stopwatch and write down the time needed for inserting the Ring Light prototype 1 with the prolene suture 10-0 through the trocar in the table below.
7) Remove the Ring Light prototype 1 and repeat steps 1 up to and including 6 twice. Leave the Ring Light prototype 1 inside the third porcine eye after the last repetition.
8) Write down the difficulties that have been experienced during the installation of the Ring Light prototype 1.
9) Write down if the fiber had to make sharp bends during the installation and if the maximum bending radius might have been exceeded.
10) Write down how difficult it was to move the Ring Light prototype 1 through the vitreous.
11) Remove the prolene suture and try to attach the Ring Light prototype 1 with the use of a tape and the handle and compare these methods on firmness.

Notes for <u>movement through the vitreous</u> of the Ring Light prototype 1:

IV. Installation of the Ring Light prototype 2 in the porcine eyes.

Equipment:

- ○ Porcine eyes fixed in the rubber bases (3)
- ○ Microscope
- ○ EVA
- ○ Ring Light prototype 2
- ○ Stopwatch
- ○ Scalpel for insertion through the cornea

1) Put one of the fixed porcine eyes under the microscope.
2) Start the stopwatch.
3) Insert the Ring Light prototype 2 (attached to the EVA) through the cornea with the scalpel.
4) Place the Ring Light prototype 2 in the posterior chamber via the pupil.
5) Stop the stopwatch and write down the time needed for inserting the Ring Light prototype 2 in the posterior chamber in the table below.
6) Remove the Ring Light prototype 2 and repeat steps 1 up to and including 5 twice. Leave the Ring Light prototype 2 inside the third porcine eye after the last repetition.
7) Write down the difficulties that have been experienced during the installation of the Ring Light prototype 2.
8) Write down if the fiber had to make sharp bends during the installation and if the maximum bending radius might have been exceeded.

<u>Time needed for installing</u> the different prototypes:

	Ring Light prototype 1	**Ring Light prototype 2**
Time needed for installation		

Notes about the <u>complexity of the installation</u> of the different:

Ring Light prototype 1	**Ring Light prototype 2**

Notes about the <u>bending radius</u> of the different prototypes during installation:

Ring Light prototype 1	**Ring Light prototype 2**

V. (Short) vitrectomy

Equipment:

- ○ Both porcine eyes with inserted Ring Light prototypes 1 & 2
- ○ Microscope
- ○ Trocars
- ○ Vitrectomy instruments
- ○ EVA (with foot pedal)

1) Perform a short vitrectomy on the porcine eye with the inserted Ring Light prototype 1 and write down if and when the Ring Light prototype 1 obstructs the view of the retina and/or obstructs the vitrectomy instruments (take a picture if possible) and write down how firm the prototype is attached.
2) Stop the vitrectomy and do the same for the porcine eye with other prototype.

Firmness of the attachment:

	Ring Light prototype 1	**Ring Light prototype 2**
Firmness of attachment		

Notes about the obstruction by the different prototypes during the vitrectomy:

	Ring Light prototype 1	**Ring Light prototype 2**
Obstruction of view		
Obstruction of instruments		

VI. Removing the prototypes and checking the cuts in the fiber of the prototypes again under the microscope + checking the damage to the tissue.

Equipment:

- ○ Both porcine eyes with inserted Ring Light prototypes 1 & 2
- ○ Other 4 used porcine eyes
- ○ Microscope
- ○ Medical scissors

1) Remove the Ring Light prototype 1 as careful as possible from the porcine eye.
2) Check the fiber of the Ring Light prototype 1 under the microscope and make a picture/screenshot of the cuts in the fiber.
3) Repeat steps 1 and 2 for the Ring Light prototype 2.
4) Cut open all 6 porcine eyes as careful as possible to assess the damage to the tissue.
5) With the porcine eyes used for the Ring Light prototype 1: check is there is any damage to the inside of the eye or the retina and write down below.
6) With the porcine eyes used for the Ring Light prototype 2: check is there is any damage to the pupil, lens, ciliary sulcus or the lens zonules and write down below.

Notes for damage to the tissue in the eye:

	Ring Light prototype 1	**Ring Light prototype 2**
Damage to the tissue		

VII. Shutting down the equipment and cleaning up all materials

Equipment:

- ○ Alcohol wipes

1) Shut down all equipment and clean up the materials, wipe everything clean with the alcohol wipes afterwards.

F MATLAB CODE LIGHT INTENSITY

```
%%%% Light intensity per light source

clc
close all
clear all

%% Inserting measurement values:

% Light source off
off = [0.16 0.16 0.16 0.16 0.15];
off = mean(off);

% twinlight
twin_10 = [2012 2035 2061 2058 2049];
twin_10 = mean(twin_10);
twin_20 = [3920 4070 4110 4090 4080];
twin_20 = mean(twin_20);
twin_30 = [5640 5810 5830 5820 5790];
twin_30 = mean(twin_30);
twin_40 = [7440 7630 7640 7650 7600];
twin_40 = mean(twin_40);
twin_50 = [9100 9310 9320 9280 9250];
twin_50 = mean(twin_50);

% ring large (prototype 1)
ring1_10 = [86.2 86.3 84.6 84.9 85];
ring1_10 = mean(ring1_10);
ring1_20 = [172.2 167.9 168.3 169.2 169.3];
ring1_20 = mean(ring1_20);
ring1_30 = [245.5 240.3 241.8 242.1 242.3];
ring1_30 = mean(ring1_30);
ring1_40 = [323 316 318 318 319];
ring1_40 = mean(ring1_40);
ring1_50 = [393 385 387 388 389];
ring1_50 = mean(ring1_50);
% ring1_100 = 798

% ring small (prototype 2)
ring2_10 = [85 84.3 84.4 84.7 84.6];
ring2_10 = mean(ring2_10);
ring2_20 = [169 167.9 168.3 168.5 168.4];
ring2_20 = mean(ring2_20);
ring2_30 = [240.6 240.2 240.9 241 241.2];
ring2_30 = mean(ring2_30);
ring2_40 = [316 315 317 317 317];
ring2_40 = mean(ring2_40);
ring2_50 = [385 384 386 385 386];
```

```
ring2_50 = mean(ring2_50);
% ring1_100 = 777

%% Light intensity - Light off

twin_10 = twin_10 - off;
twin_20 = twin_20 - off;
twin_30 = twin_30 - off;
twin_40 = twin_40 - off;
twin_50 = twin_50 - off;

ring1_10 = ring1_10 - off;
ring1_20 = ring1_20 - off;
ring1_30 = ring1_30 - off;
ring1_40 = ring1_40 - off;
ring1_50 = ring1_50 - off;

ring2_10 = ring2_10 - off;
ring2_20 = ring2_20 - off;
ring2_30 = ring2_30 - off;
ring2_40 = ring2_40 - off;
ring2_50 = ring2_50 - off;

%% Making matrix for plot

intensity = [twin_10 twin_20 twin_30 twin_40 twin_50;
    ring1_10 ring1_20 ring1_30 ring1_40 ring1_50; ring2_10
    ring2_20 ring2_30 ring2_40 ring2_50];
intensity = transpose(intensity);

%% Plot

plot([10:10:50],intensity(1:end,1),'LineWidth',2)
hold on
plot([10:10:50],intensity(1:end,2),'LineWidth',2)
plot([10:10:50],intensity(1:end,3),'--','LineWidth',2)
grid on
title("Light Intensity per Light Source",'FontSize',38)
legend("Twinlight","Ring Light prototype 1","Ring Light
    prototype 2",'Location','northwest','FontSize',20)
ax = gca;
ax.FontSize = 18;
ylabel("Light intensity [lux]",'FontSize',28)
yticks(0:500:10000)
xlabel("Power set point [%]",'FontSize',28)
xlim([10 50])
xticks(0:10:50)
```

G MATLAB CODE ILLUMINATED AREA TO BLACK AND WHITE

```
% 3000 pixels = 12 cm
pix2cm = 12/3000;

%% TwinLight 10%
twin_10 = imread('area_TL_10.jpg');     % Import image
twin_bw10 = im2bw(twin_10,0.5);       % color -> black/white
    (0.5 is standard threshold)

figure(1)
subplot(3,5,1)
hold on

imshow(twin_bw10)
title('Twinlight (10%)')

% Find circle diameter
props_twin_10 = regionprops(twin_bw10, 'Area', 'EquivDiameter
    ');
allAreas_twin_10 = [props_twin_10.Area];
allDiameters_twin_10 = [props_twin_10.EquivDiameter];
[largestArea_twin_10, indexOfLargestArea_twin_10] = max(
    allAreas_twin_10);
largestDiameter_twin_10 = allDiameters_twin_10(
    indexOfLargestArea_twin_10);

center_twin_10 = [1600 1550];
radius_twin_10 = largestDiameter_twin_10/2;
radiuscm_twin_10 = radius_twin_10*pix2cm;
area_twin_10 = pi*radiuscm_twin_10^2;

% Plot circle
viscircles(center_twin_10, radius_twin_10,'Color','b');
legend_twin_10 = ['Area = ',num2str(area_twin_10),' cm^2'];
text(50,2800,legend_twin_10,'Color','w')

%%
% Same code for TwinLight 20%, 30%, 40% and 50%, except other
    imported image, other indexing and other position in
    subplot

%% Ring Light 1 10%
ring1_10 = imread('area_RL1_10(1).jpg');     % Import image
ring1_bw10 = im2bw(ring1_10,0.5);      % color -> black/white
    (0.5 is standard threshold)

subplot(3,5,6)
imshow(ring1_bw10)
```

```
title('Ring Light prototype 1 (10%)')

% Find circle diameter
props_ring1_10 = regionprops(ring1_bw10, 'Area', 'EquivDiameter');
allAreas_ring1_10 = [props_ring1_10.Area];
allDiameters_ring1_10 = [props_ring1_10.EquivDiameter];
[largestArea_ring1_10, indexOfLargestArea_ring1_10] = max(allAreas_ring1_10);
largestDiameter_ring1_10 = allDiameters_ring1_10(indexOfLargestArea_ring1_10);

center_ring1_10 = [1400 1600];
radius_ring1_10 = largestDiameter_ring1_10/2;
radiuscm_ring1_10 = radius_ring1_10*pix2cm;
area_ring1_10 = pi*radiuscm_ring1_10^2;

% Plot circle
viscircles(center_ring1_10, radius_ring1_10,'Color','b');
legend_ring1_10 = ['Area = ',num2str(area_ring1_10),' cm^2'];
text(50,2800,legend_ring1_10,'Color','w')

%%
% Same code for Ring Light 1 20%, 30%, 40% and 50%, except other imported image, other indexing and other position in subplot

%% Ring Light 2 10%
ring2_10 = imread('area_RL2_10(1).jpg');    % Import image
ring2_bw10 = im2bw(ring2_10,0.5);     % color -> black/white (0.5 is standard threshold)

subplot(3,5,11)
imshow(ring2_bw10)
title('Ring Light prototype 2 (10%)')

% Find circle diameter
props_ring2_10 = regionprops(ring2_bw10, 'Area', 'EquivDiameter');
allAreas_ring2_10 = [props_ring2_10.Area];
allDiameters_ring2_10 = [props_ring2_10.EquivDiameter];
[largestArea_ring2_10, indexOfLargestArea_ring2_10] = max(allAreas_ring2_10);
largestDiameter_ring2_10 = allDiameters_ring2_10(indexOfLargestArea_ring2_10);

center_ring2_10 = [1450 1400];
radius_ring2_10 = largestDiameter_ring2_10/2;
radiuscm_ring2_10 = radius_ring2_10*pix2cm;
area_ring2_10 = pi*radiuscm_ring2_10^2;

% Plot circle
viscircles(center_ring2_10, radius_ring2_10,'Color','b');
legend_ring2_10 = ['Area = ',num2str(area_ring2_10),' cm^2'];
text(50,2800,legend_ring2_10,'Color','w')
```

```
%%
% Same code for Ring Light 2 20%, 30%, 40% and 50%, except
    other imported image, other indexing and other position in
     subplot
hold off

%% Plot color images

figure(2)
subplot(3,5,1); imshow(twin_10); title('Twinlight (10%)')
hold on

subplot(3,5,2); imshow(twin_20); title('Twinlight (20%)')

subplot(3,5,3); imshow(twin_30); title('Twinlight (30%)')

subplot(3,5,4); imshow(twin_40); title('Twinlight (40%)')

subplot(3,5,5); imshow(twin_50); title('Twinlight (50%)')

subplot(3,5,6); ring1_10=imread('area_RL1_10.jpg'); imshow(
    ring1_10); title('Ring Light prototype 1 (10%)')

subplot(3,5,7); ring1_20=imread('area_RL1_20.jpg'); imshow(
    ring1_20); title('Ring Light prototype 1 (20%)')

subplot(3,5,8); ring1_30=imread('area_RL1_30.jpg'); imshow(
    ring1_30); title('Ring Light prototype 1 (30%)')

subplot(3,5,9); ring1_40=imread('area_RL1_40.jpg'); imshow(
    ring1_40); title('Ring Light prototype 1 (40%)')

subplot(3,5,10); ring1_50=imread('area_RL1_50.jpg'); imshow(
    ring1_50); title('Ring Light prototype 1 (50%)')

subplot(3,5,11); ring2_10=imread('area_RL2_10.jpg'); imshow(
    ring2_10); title('Ring Light prototype 2 (10%)')

subplot(3,5,12); ring2_20=imread('area_RL2_20.jpg'); imshow(
    ring2_20); title('Ring Light prototype 2 (20%)')

subplot(3,5,13); ring2_30=imread('area_RL2_30.jpg'); imshow(
    ring2_30); title('Ring Light prototype 2 (30%)')

subplot(3,5,14); ring2_40=imread('area_RL2_40.jpg'); imshow(
    ring2_40); title('Ring Light prototype 2 (40%)')

subplot(3,5,15); ring2_50=imread('area_RL2_50.jpg'); imshow(
    ring2_50); title('Ring Light prototype 2 (50%)')

hold off
```