Planning of the site of subretinal implant in patients suffering from retinitis pigmentosa

Doctoral thesis

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INTRODUCTION

According to a WHO estimate there are more than 37 million people suffering from blindness worldwide. There are major differences between the reasons for blindness in the economically developed and underdeveloped countries. According to statistical data the incidence of blindness in Hungary is 59.1 in 100,000 people per year, meaning the number of blind people increases by 6000 annually. In the economically developed countries the main reason for blindness are retinal degenerative diseases. In 2000 the WHO initiated a program called „Vision 2020" with the aim of eradicating preventable blindness and significantly decreasing the number of people with visual impairment by 2020. Our research is linked to these very important objectives. Achieving these aims, however, is aggravated by the fact that due to the growth and ageing of the population incidence of blindness is on the increase.

In recent years the use of retinal chips has been a major breakthrough in curing blindness caused by hereditary retinal dystrophy (HDR). There are a number of groups involved in developing retinal implants. The operational principle of a given implant determines substantially the results that can be expected after the implantation.

At the end of the 1980s scientific research in microelectronics and engineering began attempting to simulate retinal functions with integrated circuits referred to as „silicon retina chips". This direction of research opened the way to treating patients with no measurable visual acuity and only minimal light sensitivity.

Clinical research and the development of retinal implants began in the 1990s. Researchers examined different types of retinal implants; at present research focuses on epi- and subretinal implants that differ in their placement in relation to the retina.

Our group researched the application of subretinal implants. We examined an implant containing more than 1500 intraocular microelectrodes. The wire starting from the chip located between the retina and the pigmentepithelium goes through the sclera and arrives in the orbit. From there through the suborbital margin it reaches the electronic power supply placed in the retroauricular region in the surface of the bony skull. The use of a power supply is inevitable because, according to common experience, without photoreceptors the

energy of the incoming light is not sufficient to generate a stimulus on the chip. Furthermore it is essential for the visual pathways to be intact.

We carried out our research on patients suffering from retinitis pigmentosa. The significance of this heredodegenerative condition in public health and clinical treatment is elevated by the fact that it can occur at any age and there is no effective treatment available for this condition to date. In case of a typical course of the condition visual impairment begins as early as adolescent age. At first visual acuity decreases at twilight and especially in peripheral visual fields and later progresses to the complete loss of vision, in some cases without any light sensation.

A major part of our research was to determine the position of the implant in the subretinal space. Furthermore we measured and evaluated the distance between the chip and the site of incision on the bulbus, taking into account the different morphological characteristics of the individual eyeballs.

AIMS

In 2007 we had the opportunity to join the research carried out by a workgroup at the Eberhard Karls University in Tübingen that was aimed at developing a retinal chip and improving its operational technique for implantation. Each of the ten research professionals working within the group had different responsibilities; my job was to determine the exact position of the implant.

1. Determining the position of the retinal implant preoperatively

Considering the fact that there is no reproducible preoperative methodology available for the evaluation of patients with end-stage retinitis pigmentosa and in order to optimize the potential function of the implant the following preoperative methods have been developed.

a. Classifying the pathomorphology of the fundus in unit areas with the help of a rectangular grid and a special computer program

Because the fundus of the bulbus is not homogeneous when determining the optimal place of the chip preoperatively our aim was to measure and evaluate the unit areal position and dimension of the disorders on the fundus in patients suffering from retinitis pigmentosa.

b. Comparing the planned and achieved position of the implant

Our aim was to compare the preoperatively determined places to the achieved chip position postoperatively with the help of the rectangular grid.

c. Preoperative definition of the length of the intraocular cable for the retinal implant

Preparing the necessary formulas and calculations to create a model to determine the intraocular cable length of the implant. Creating recommendations for using a guiding-foil that is inevitably necessary for the introduction of the subretinal chip.

2. Ultrasound method for measurements in the equatorial plane of the bulbus

Our aim was to determine the horizontal and vertical diameters of the bulbus in the equatorial plane. Furthermore we tested the reproducibility of the ultrasound measurements both using one examiner or multiple examiners, as well as validating these measurements along the axial axis with partial coherence interferometry (PCI) method.

METHODS

1. Developing methods for the preoperative determination of the implant position

Our method was used on ten patients (four females, six males) at the Eberhard Karls University, Tübingen. All patients were diagnosed with clinical signs of end stage retinitis pigmentosa and displayed typical signs of retinal mutation. Detailed examination of the anterior and posterior segments was conducted using regular ophthalmic diagnostic procedures. Digital fundus photography was performed using a Zeiss FF 450 (Carl Zeiss Meditec AG, Jena, Germany) camera. Fluorescein angiography images were also taken. Optical coherence tomography (OCT) scans were performed using a Zeiss Stratus OCT (Cirrus HD-OCT, Model 4000, Zeiss Meditec, Dublin, CA, USA), Topcon 3D OCT (v.2.12 Topcon Medical Systems, Inc., Oakland, CA, USA), or a Spectralis^{TM} OCT equipment (Spectralis Heidelberg Engineering GmbH, Heidelberg, Germany).

We developed an optical rectangular grid for the examination of the fundus picture using the principles of cylindrical projection introduced by Miller. With the help of this method we defined the position of the disorder and its distance from the fovea centralis on the fundus. Based on the results of the above mentioned measurements we determined the preoperative position of the implants using a software developed by our workgroup.

We investigated the thickness of the retina, the presence of small vessels, pathological disorders of the pigment epithelium of the retina including scars and atrophic degenerative changes. We defined the distances of the individual points of the rectangular grid from the fovea centralis. We evaluated and analyzed the results of the individual grids with the help of our custom made software.

We created a 3D model of the eyeball and then based on the results of the biometric measurements using this ellipsoid model we carried out calculations to determine the intraocular cable length using the software developed by our team.

We evaluated the calculations of the implant's placement by using mathematical methods as well. We compared the pre- and postoperative sensitivity data (g) with a calculation using the following formula:

$$g = \sum_{i=1}^{n} w_i f_i$$

where f_i is the i^{th} element of the sensitivity matrix and w_i is its corresponding weight factor that represents the proportion of the area covered by the chip. The acuity of the chip's placement was checked by the rectangular grid visually as well.

2. Developing a method for measuring the vertical and horizontal diameters of the eyeball in the equatorial plane with an ultrasound machine

We took measurements of 26 emmetropic people. After measuring the axial length of the eyeball by ultrasound technique and using partial coherence interferometry we measured the horizontal and vertical diameters of the bulbus at the equatorial plane. The results were analyzed with the help of a multifactor random model determining the intraclass correlation coefficient (ICC). We defined the Spearman-correlation as well as Bland-Altman analysis.

RESULTS

1. Defining the position of the implant preoperatively

We analyzed the location and distance of retinal lesions from the fovea. We studied the retinal thickness, the presence of small blood vessels of the retina; pathological lesions pigment epithelium, including scars and atrophic degenerative changes, as these can affect the degree of available visual improvement. The fundus image was prepared in each case before surgery for indicating the planned implant position.

Our hypothesis was that the closer the implant is to the fovea, the more likely a functional improvement can be achieved. The improvement is proportional to the increased light sensitivity elicited by the stimuli. The light sensing ability of the eye might also be affected by the pathological changes of the retina.

a. Comparison of the planned and achieved position of the implant

We defined a ratio (q) for the sensitivity calculated for the actual area covered by the chip and the proposed area, which was 90.79% on average, with a standard deviation of 11.39%. In two cases the actual position had an evaluation ratio of more than 1 due to the calculation technique, meaning that the sensitivity of the position achieved for these two patients was equal to that of the planned positions. In two cases evaluation was not possible because the final chip position was outside the 8 x 8 grid fields.

Axial length of the eyeball, with equatorial, horizontal and vertical diameters was measured in each case. We determined the insertion of the chip design and the distance between the position and the intraocular cable length. We measured the planned and achieved position of the distance between the centers of the chip, giving an average of 2.14 mm with a standard deviation of 1.37 mm.

b. Accuracy of the planning

To evaluate the accuracy of the implantations we have shown how the achieved sensitivity ratio changes in function of the distance of the planned and actual position. We

used all measurement data except for the outlier value of one patient, based on which we can state that dependence of the ratio q from the distance can be modeled adequately by quadratic function. Based on the results of our 10 patients, we found that to achieve a 95% sensitivity the offset between the planned and actually achieved chip position had to be less than 1.7 mm.

c. Preoperative determination of the individual intraocular cable length of the retina implant

The 3D model of the eyeball was created using our software. An ellipsoidal model was used thus allowing the preparation of implants with cable lengths corresponding to individual measurement results. Preoperative determination of cable length was found to be appropriate in all cases. The importance of this procedure is supported by our experience that inaccurate, longer cable increases the risk of surgical complications and usuration of the conjunctiva, while a shorter cable length makes the correct placement of the chip in the subretinal space impossible.

2. Ultrasound method for measurements in the equatorial plane of the bulbus

We have measured and compared the axial length using partial coherence interferometry (PCI) and ultrasound, as well as the horizontal and vertical diameters of the bulbus in the equatorial plane. A strong correlation was found between the results of the interferometric coherence and the ultrasonic axial measurements. The axial measurements performed using an IOL master (22.86 +/- 0.86 mm) correlated well with the results of the measurements carried out by ultrasound (22.813 +/- 0.85 mm).

The patients did not perceive the measurements carried out to be invasive and no complications were observed in any of the cases. The measurements were carried out easily with devices used in clinical practice and without any need for modification. Following statistical processing of the results a strong correlation was found between the results of the axial measurements performed using PCI and ultrasound technology. The correlation coefficient of the first examiner was r_{op1}=0.9963, while in the case of the second examiner

was r_{op2}=0.9910. Significant correlation was found between the mean values of the two examiners $p < 0.05$ (95% confidence interval). Consistency as well as absolute agreement showed a high degree of conformity with the definition of intraclass conformity (ICC).

CONCLUSIONS

1. Defining the position of the implant preoperatively

Our group was the first to have developed and applied a chip positioning system for subretinal implants internationally. The method allows the preoperative evaluation of individual retinal structures prior to implantation. The optimal location of the chip that will vary in each individual can thus be determined.

a. Classifying the pathomorphology of the fundus in unit areas with the help of a rectangular grid and a special computer program

We have categorized the different individual characteristics of the fundus for each retinitis pigmentosa patient and then, by analyzing the individual fields of the grid fitted onto the fundus, we evaluated each field according to each of the four categories. The categories included the distance from the fovea, the retinal thickness, the size of pigment deposits and lesions, as well as the vascular distribution. The chip, when implanted, should cover the most favorable fields identified on the basis of the analysis. An optimal site for the chip is considered to be the area closest to the fovea, without severe scarring and pigmentation disorders, and with good circulation and normal retinal thickness.

Based on our assessment, the optimal location of the chip in each case included the fovea itself. We believe that a chip placed in the vicinity of the fovea will produce the best improvement in light perception.

b. Comparing the planned and achieved position of the implant

With the help of the grid system it is possible to compare pre- and postoperative chip location. We have shown that the difference in distance between the planned and the actual site of the chip was 2.14 mm on average in the case of the 10 procedures examined. By implanting the chip a sensitivity ratio of 95% can be achieved, providing the distance between the planned and the actual positions is less than 1.7 mm.

c. Preoperative definition of the length of the individual intraocular cable for the retinal implant

Accurate positioning of the implant in the subretinal space is facilitated by the definition of the length of the chip's intraocular cable. We have determined for each of the procedures the necessary intraocular cable length by inserting the results of the MRI measurement sequences we have specifically developed into an ellipsoid model. The individually calculated values proved to be sufficiently accurate for performing the surgery successfully.

2. Ultrasound method for measurements in the equatorial plane of the bulbus

Our team was the first to develop a noninvasive preoperative method performed using ultrasound technology for measuring the horizontal and vertical diameters of the bulbus in the equatorial plane. No alteration to the device is necessary to perform the measurements in the equatorial regions. The method is highly reproducible, safe and cost effective. By using our ultrasound method, it is possible to determine the length of the implant's intraocular cable to a 1/10 mm precision.

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