Welcome Session - Welcome Addresses

8:45

Bernd Kirchhof, Cologne, Germany – The Retina Implant Foundation

Helma Gusseck, Bonn, Germany – The Retina Implant Foundation

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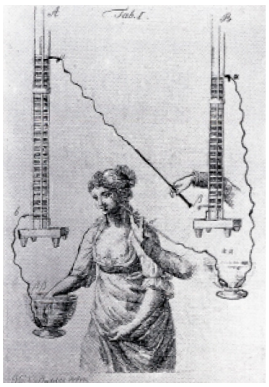
Introductory Lecture

9:00

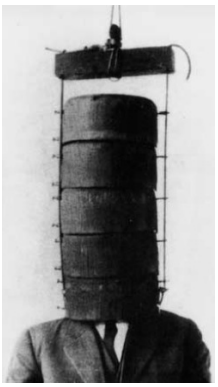
Heinrich Gerding, Olten, Switzerland

A brief Review on the History of Electrical Stimulation of the Human Eye

The principle idea to use electrical stimulation in order to cure visual system defects goes far back into the history of modern science. Electrical stimulation experiments were very popular in the Enlightenment. Before 1751 Benjamin Franklin performed stimulation experiments of the eye and as early as 1755 Le Roy tried to elicit electrically evoked phosphenes in blind people, nearly three decades before the description of bioelectric stimulation by Galvani (1786). Since then pioneers, eccentrics, and serious scientists have performed a colourful and sometimes curious series of electrical stimulation experiments in humans. Many of the ideas involved and the results achieved trend to be forgotten, but seem to be worth a deeper reflection. The idea of electrical stimulation by retina implants became reality with the project of Tassicker in 1956. He already performed long-term implantation trials in humans. In 1962 Brindley was evaluating the possibility of transscleral stimulation of the retina before developing his visual cortex approach. With major steps forward in microtechnology, microfabrication and vitreoretinal surgery a new area of retina implant development was entered in the last two decades.



Galvanic surgery, Bischoff 1801



Magnusson & Stevens, 1914

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Keynote Lecture

9:10

Heinz Wässle, Frankfurt/M, Germany

Molecular and genetic approaches to restore photosensitivity in retinal degeneration

Inherited degenerations of rods and cones, that result in blindness, affect 1 in 3000 humans worldwide. Mice carrying the retinal degeneration mutation (*rd1/rd1*) loose nearly all of their photoreceptors while inner retinal neurons and synaptic circuits survive. There are several recent attempts to make these surviving neurons intrinsically photosensitive and thus restore visual functions after photoreceptor degenerations. Bi et al. (Neuron 50, 23-33, 2006) injected adeno-associated viral vectors (AAV) into the vitreous and transfected inner retinal neurons with a microbial-type rhodopsin, channelrhodopsin2 (ChR2). Ganglion cells expressing ChR2 showed intrinsic light responses. Lagali et al. (Nature Neuroscience 11, 667-675, 2008) targeted ChR2 to retinal ON-bipolar cells in *rd1/rd1* mice. They showed that about 7% of the bipolar cells were transfected and could

elicit stable light responses. In behavioral studies the transfected mice showed visual responses. Lin et al. (PNAS 105, 16009-16014, 2008) used AAV injection into the vitreous of *rd1/rd1* mice to ectopically express melanopsin. Approximately 10% of the ganglion cells expressed melanopsin and stable light responses could be recorded from these cells. In behavioral studies visual responses were observed.

We crossed a transgenic mouse line, that expresses ChR2 in the central nervous system (Arenkiel et al. Neuron 54, 205-218, 2007) into an *rd1/rd1* background and approximately 30% of the ganglion cells were found to express ChR2. They gave stable light responses at light ON, and their sensitivity was only 30 - 100 times lower than the photopic cone sensitivity. The visual performance of the mice was tested in a two choice visual discrimination task. It was dependent on the residual number of cones and was not significantly improved by the expression of ChR2 in retinal ganglion cells. We would argue that changing all physiological classes of retinal ganglion cells into ON-cells "confuses" the visual cortex and, therefore, vision is not restored despite of the ganglion cell light responses.

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Basic Research

9:40

Bryan Jones, Robert Marc, Salt Lake City, USA

The dynamics of retinal degeneration

Motivation: Retinal remodeling and reprogramming are events triggered in all types of retinal degenerations in all species and are progressive, continuing to alter the fundamental architecture and function of the remnant retina throughout life. The mechanisms regulating these events are unknown, but most non-neural elements such as

Müller cells, retinal pigmented epithelium cells, microglia, vascular endothelial cells and possibly astrocytes interact to create a novel milieu for large-scale remodeling and reprogramming.

Results: Remodeling involves extensive revisions in connectivity and includes the abundant generation of new ectopic axon-like processes by survivor neurons. We are exploring the endogenous generations of retinoic acid as a regulator of de novo axonogenesis via retinoic acid receptor (RAR) signaling. A more challenging process is reprogramming in cone-sparing retinitis pigmentosa, where ON bipolar cells begin to express AMPA/KA ionotropic receptors, changing their polarity and gain. First discovered in human RP retina, we have now demonstrated it in the rhodopsin P347L transgenic rabbit, a model of human autosomal dominant RP. While only 30% of bipolar cells have OFF polarity in the normal retina, 70-90% (including all rod bipolar cells) have OFF response attributes in advanced adRP.

Conclusions: The implications of these findings are several. First, all of these alterations complicate every late intervention (genetic, cellular, bionic) in late stage (NLP) RP arising form photoreceptor gene defects. Second, genetic profiling of candidate patients may be necessary to properly stratify outcome statistics. Third, as we are learning the triggers of remodeling and reprogramming, we are also encountering possible interventions to improve the outcomes of genetic, cellular, bionic treatments for blinding diseases.

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10:00

Shelley Fried, Boston, USA

The distribution of voltage across the proximal axon underlies spike initiation in response to electric stimulation of retinal ganglion cells.

Purpose: We are studying the response of retinal neurons to electric stimulation in order to develop more effective methods of stimulation for use during clinical trials. Our recent

study indicates that a dense band of sodium channels in the proximal portion of the axon was the site at which activation thresholds were lowest, suggesting that this is also the site of spike initiation. We also showed that the property of the sodium channel band varies across types, suggesting that the response to stimulation will be different in each type as well. Here, we are studying which properties of the induced electric field across the band are most important for generating activity.

Methods: We measured the spatial profile of voltage elicited in response to 0.2 ms cathodic pulses from a conical platinum-iridium electrode (100 kΩ impedance). Then we moved the stimulating electrode to multiple sites around the ganglion cell and determined the threshold required to elicit an action potential at each location. Knowledge of the voltage profile allowed us to determine the voltage across the sodium channel band for each location of the stimulating electrode. From this, we could compare the profile across the band (the spike initiation site) for all 'successful' pulses. This allowed us to look for common feature(s) in pulses that activate spiking. We similarly compared the first and second derivatives of the voltage profile across the band as well.

Results: The magnitude of the second derivative across the band was the determining factor as to whether a given pulse would elicit a spike. In other words, if the second derivative of the voltage profile across the band exceeded a certain value, the cell was likely to generate an action potential. The absolute magnitude was different for different types of ganglion cells and was influenced by properties of the band (e.g. length, distance from the soma).

Conclusions: Our results indicate that we can predict the relative effectiveness of different stimulus configurations for eliciting spiking in retinal ganglion cells. This may help to reduce thresholds for eliciting clinical responses. Also, because the optimum profile was different for different types of ganglion cells, our findings suggest that methods to selectively activate individual types may be achievable. This would allow complex patterns of neural activity to be generated and likely result in improved clinical outcomes.

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10:20

Nicolas Cottaris, Detroit, USA

Cortical Assessment of Retinal Prosthetic Stimulation

Introduction One of the most challenging issues for epiretinal prosthetics is how to optimize multi-focal electric stimuli (MFES) so that they induce visual percepts with desired spatial characteristics. This is an intractable issue for experiments with human subjects due to the multi-dimensional stimulus space, time limitations, and subject fatigue and frustration. To address this problem, we developed an *in-vivo* animal (cat) model in which the spatial information transmitted by a MFES paradigm is assessed by decoding cortical (area V1) population responses. Our approach is based on the premise that MFES paradigms that maximize the spatial information transmitted to cat V1 are likely to be the most efficacious at producing visual percepts that correspond to the stimulation patterns.

Methods An 8x10 intracortical recording array inserted in V1 records multi-site local field potentials (ms-LFPs). The ms-LFP tuning for retinotopic location, orientation, and spatial frequency is determined using flashed (40 msec) visual stimuli. A Multi-Taper, Space-Frequency Singular Value Decomposition method is applied to the ms-LFP signal to identify dominant patterns of spatial coherence within different local frequency bands. This analysis also allows meaningful comparisons of visual vs. electric ms-LFP responses, which may differ in absolute latencies and/or durations. The spatial coherence patterns identified in a subset of the stimulation trials are used to train a Support Vector Machine (SVM) that learns to associate cortical response dynamics with inducing stimuli. Subsequently, the SVM is used to decode stimuli from the response dynamics induced in a non-overlapping subset of trials. This analysis computes the joint probability distribution between delivered and decoded stimuli, which determines the amount of information transmitted to V1. MFES are delivered via custom-made, thin-film 32-electrode arrays implanted epiretinally at the region providing input to the monitored V1 sites. Stimulating electrodes (flat-contact, 60 μm diameter platinum disks, separated by 65 μm), are arranged in a 6x6 grid (minus 4 corners), and the return electrode is on the animal's ear. Current pulses are charge-balanced, cathodic-first (typically: 0.25 msec x 4-12 μAmps). MFES are realized by delivering identical pulses to groups of electrodes along different orientations (0^o, 30^o, 60^o, 90^o, 120^o, 150^o). In this study, the inter-electrode pulse latency (IEPL) was varied to examine the dependence between temporal structure of MFES and

orientation information transmitted to V1.

Results (1) Spatial position, orientation, and spatial frequency of visual stimuli were all decoded with high resolution from the V1 ms-LFP. Thus, the V1 ms-LFP captures a large amount of the spatial information transmitted by the retina. (2) The orientation of MFES with IEPL=0 (simultaneous pulse injection) was not decoded accurately from the V1 ms-LFP signal. Conversely, the orientation of MFES with IEPLs of 3 and 5 msec was decoded accurately. Therefore, temporal dispersion of MFES is crucial for increasing the spatial information transmitted by an implant.

Conclusions: Objective assessments of the efficacy of different paradigms of retinal prosthetic stimulation are achievable using our cortical ms-LFP-decoding model. Further characterizations are feasible based on the correspondence between visual and electric ms-LFP responses.

Support: National Science Foundation grant to N.P.Cottaris (CBET-0756098) and Ligon Research Fund.

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10:40 – 11:15 Coffee Break

11:15

Rolf Eckmiller, Bonn, Germany

Learning of Image Encoding

Purpose: Simulation study of a novel retina implant with perceptual feedback, oculomotor feedback for simulated miniature eye movements (SM), and with optional feedback from spontaneous nerve impulses (NI) of the stimulated regions.

Methods: Simulations were performed with a novel retina encoder (RE-3) with a filter module (FM) consisting of an input array of 20 x 20 pixels for presentation of a pattern P1 and 100 spatio-temporal (ST) filters for generation of selective stimulation signals for 100 electrodes at the retinal output, a novel inverter module (IM-3) to mimic parts of the central visual system and to map the FM_{Ref} -output onto a simulated percept P2, and a dialog module (DM). DM simulated the perceptual feedback from a human user. SMs were generated on demand for movements of P1 by one pixel in a given direction to mimic typical eye movements during fixation. Spontaneous NI could be considered to avoid stimulus pattern disturbances: a) stimulation signals with NI-suppression capability and b) neural feedback from neural tissue to RE-3 via bi-directional electrode arrays for stimulation and recording.

Results: a-FM was specified as a regular distribution of three ST filter types to mimic receptive field properties of primate retinal ganglion cells. b-Both P1 and FM filter array were described as multi-dimensional vector matrices, which had several advantages, including easy changes of pixel numbers or filter numbers as well as FM-output calculation as matrix products. c-The software for IM-3 was designed to process the FM-output matrices with an efficient algorithm and to invert the partly ambiguous FM mapping with the help of SMs.

d-Due to the matrix structure, inversion of the FM-output by IM-3 could be processed in a single matrix run through all coefficients.

Conclusions: Since 'Gestalt' perception in humans requires active vision as a continuous interaction between sensory and oculomotor processes, a combination of neural-, oculomotor, and perceptual feedback may be important to optimize the function of bionic visual prostheses.

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11:35

Gislin Dagnelie, Baltimore, USA

Why isn't prosthetic vision like biological vision? Results from simulation studies

Background: As several groups have embarked on patient testing with epiretinal and subretinal implants over the last few years, the results have been at the same tie encouraging and disappointing. Clearly the patients are "seeing," yet the vision they describe and utilize does not match the simple simulations we envisaged a few years ago. Micro-anatomical studies have taught us the fundamental changes in signal processing in the degenerating retina, and we can begin to understand the patients' problems by adjusting our simulations, to understand what prosthesis wearers may see, and how much they can learn to understand through practice.

Objective: To adapt the prosthetic vision simulation environment, specifying the appearance of individual phosphenes and their temporal and spatial interactions, so they model the percepts reported by, and data collected from, prosthesis wearers; and to test this phosphene-based vision in sighted volunteers.

Methods: We have created a modeling environment that allows us to build in: 1. configuration information regarding different implants, which provide the spatial and temporal electric field properties at the tissue interface; 2. spontaneous "noise" backgrounds corresponding to the "light shows" described by many RP patients; 3. eye movement compensation so the "phosphenes" can be stabilized on the subject's retina; and 4. patient data from intraoperative experiments and early implant wearers, in particular threshold and dynamic range data. In this environment our subjects perform a series of recognition, localization, discrimination, and eye-hand coordination tasks.

Results: Over the past 3 years we have concentrated on visually guided task performance: mobility in a virtual building, a checkers game, and a maze tracing experiment. In each of these experiments subjects were trained to understand the impoverished reality of their "phosphene world" and to perform tasks never shown to them in unfiltered, free-viewing conditions. All subjects tested have been able to learn the tasks, and have substantially improved their performance, often through many hours of practice. Examples of tasks and performance will be shown.

Conclusion: While simulations can tell us much about the ability of the visual system to adapt to extremely adverse visual conditions, they can only provide a meaningful contribution to prosthetic vision rehabilitation if the image transformations presented to the subjects match the reality experienced by the prosthesis wearer. To this end, the basic

research of the transformed degenerated retina and the prosthesis recipients experience need to be fully integrated.

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Preclinical Development of Systems I

11:55

Daniel Palanker, Stanford, USA

High Resolution Photovoltaic Retinal Prosthesis

Purpose: Electronic retinal prostheses aim at restoring sight in blind patients with retinal degeneration by patterned electrical stimulation of surviving inner retinal neurons. Most designs use inductive or optical serial telemetry to wirelessly deliver power and data to implanted circuitry. The incoming signals are then decoded and electrical stimuli distributed to each pixel via an intraocular cable. We have designed and fabricated a photodiode-based prosthesis in which all pixels receive power and data optically in parallel and without the need for external circuitry or wiring, simplifying both the implant design and surgical procedures.

Methods: Processed camera images are projected onto the retinal implant by video goggles using pulsed infrared (905 nm) light. Silicon photodiodes convert this pulsed light into biphasic photovoltaic current. Each pixel has a central stimulating electrode surrounded by a photosensitive zone (covering 50% of the total area), and a peripheral return electrode. Trenches in 30 □m-thick monocrystalline silicon were etched to separate the pixels, leaving thin (~0.5□m) “springs” holding the array together. The resulting flexible implant conforms to the curvature of the eye, while the trenches electrically isolate neighboring pixels. Electrophysiological response of the retina to optoelectronic stimulation is being studied using multielectrode arrays.

Results: Single diode and three series diode implants were fabricated, with pixel sizes of 230, 115 and 58 □m containing 80, 40, and 20 □m diameter stimulation microelectrodes with corresponding pixel densities of 16, 64, and 256 pixels/mm^2. Implant sizes were 1x1.2 and 2x2 mm, for implantation into rat and cat eyes, respectively. Initial *in vitro* tests in phosphate buffered saline indicate a maximum charge injection of 1.7 mC/cm^2 per phase for SIROF microelectrodes. Surgical methods were developed, and successful subretinal implant placement evaluated using optical coherence tomography. Threshold light intensity for eliciting retinal response with 1ms pulses was 1 mW/mm^2.

Conclusions: A photovoltaic subretinal prosthesis has been fabricated and tested. Since each pixel operates independently, they do not need to be physically connected to each other. Thus, segments of the array may be separately placed into the subretinal space, allowing for enlargement of the stimulated field, and greatly simplifying surgery.

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12:15

Shawn Kelly, Cambridge, USA

The Boston Retinal Implant Project:
Progress on the Development and Testing of a Hermetic Retinal Prosthesis

The Boston Retinal Implant Project is developing and testing a chronically-implantable subretinal visual prosthesis. We showed the viability of the concept in a series of six acute epiretinal stimulation trials with blind volunteers between 1998 and 2000. We determined that a subretinal approach provides the safest and most stable placement for the stimulating electrode array and electronics, and have since pursued a chronically-implantable subretinal prosthesis that receives power and data wirelessly.

Our first generation retinal prosthesis was surgically implanted into three Yucatan minipigs, for more than seven months in the longest case. This device was assembled on a flexible

substrate which attached to the outside of the eye, deep in the orbit, and the thin-film polyimide flex array with iridium oxide stimulating electrodes entered the subretinal space via an incision in the sclera. Power and data telemetry coils rested on the temporal side of the eye, with the primary coils placed against the temple on the outside of the animal's head. The implanted device was coated with silicone to protect the electronics, but it was understood that this coating would eventually leak. Our next-generation prosthesis uses a hermetic titanium enclosure to protect the communication and stimulation circuitry. The next-generation Boston retinal prosthesis has been implanted in three minipigs, for more than four months in the longest case.

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12:35

Gregg J. Suaning, Sydney, Australia

The Australian Visual Prosthesis Project

The Australian Vision Prosthesis Group (AVPG), established at the University of New South Wales (Sydney, Australia) in 1997 by the presenter and his co-investigator, Professor Nigel Lovell has grown to become a large, multi-disciplinary team of researchers covering most areas of vision prosthesis research from basic vision science, to mathematical modelling of retinal activation, to the development of novel retinal neuroprostheses. The presentation will provide an overview of the AVPG research and achievements over the past three years and present specific, recent results in the following areas of research:

• *in vivo* evidence of localized cortical activation using bipolar stimulation in a hexagonal electrode matrix placed in the supra-choroidal space;
• improved mathematical models of stimulation of active retinal tissue;
• *in vitro* observations in response to subretinal stimulation in the rabbit indicating that

response profiles can be generalized into four classes with distinctive properties; and
• advancements in neuroprosthesis design and fabrication methods – particularly in hermetic encapsulation and electrode tissue interfaces.

Recently the Australian Government has budgeted funding of the order of € 25M to be distributed in a competitive grant process to produce a clinical, visual neuroprosthesis within four years. Should the AVPG be a recipient of these funds, capabilities towards human implantation will be substantially improved. Plans for the near future in the context of the recent research outcomes of the AVPG will be described by way of introducing the implant design that is intended to be taken forward to human trials. This device consists of a hybrid system that utilises a behind-the-ear implant similar to that of a cochlear implant that will manage data and power in a bi-directional, inductively-coupled, radio-frequency communications system. The behind-the-ear device is connected by way of a novel, two-wire interface to a substantially smaller, hermetically-sealed neurostimulator circuit connected to 98 stimulation channels placed within the suprachoroidal space. Performance of prototypes in vivo and in vitro shall be described.

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12:55

Vernon L. Towle, Phil Troyk, Chicago, USA

Toward an Effective Intracortical Visual Prosthesis

Our group has investigated the functional advantages and surgical and technical challenges of developing an intracortical visual prosthesis. We have conducted variety of human and primate studies which support the conclusion that implantation of an intracortical visual prosthesis in a human is functionally, technologically and surgically feasible. Through our primate studies we have developed insertion tools and procedures for implanting small independent stimulating modules over the occipital cortical surface which do not compromise the vascularity or functional integrity of cortex. Investigations of electrode tip size and composition have allowed us to protect both components of the electrode/tissue interface. Data from psychophysical testing of normally-sighted and low-vision subjects indicates that a prosthesis placed on the dorsolateral surface of the occipital lobe may permit adequately dense spatial resolution to elicit useful sensory input for individuals with blindness.

We have investigated the feasibility of cortically-induced artificial scoreboard vision by inducing punctate phosphenes through intracortical electrodes placed in the dorsolateral surface of the occipital lobe. Our psychophysical simulations have indicated that useful vision may be obtained from 300-600 stimulating electrodes that could be implanted within the superficial occipital cortex. Our system is based upon chips containing 16 wireless stimulation modules connected to penetrating iridium electrodes (Figure 1). The electrodes are formed from etched iridium wire and have tips coated with activated iridium oxide film. The shafts of the electrodes are insulated with Parylene-C, and the tips are exposed by laser ablation, yielding a surface area of 2,000^2 microns. The physical placement of the electrodes is maintained by mounting them in a ceramic platform which forms the interconnect structure for the wireless custom integrated chip. The modules will receive their power and transmit data via a transcutaneous magnetic link.

Using our planned placement of the intracortical electrodes, combined with the projected phosphene maps and associated psychophysical studies, it appears feasible to produce usable visual function with about 40 modules implanted over the dorsolateral surface of the occipital lobe. One striking aspect of our psychophysical studies is how impoverished the simulated phosphene displays appeared when viewing them abstractly through the virtual reality goggles. Yet, the subjects were quickly, and rather easily, able to learn to

use these scanned images as a means of performing eye-hand and mobility tasks. Since the subjects needed to rely upon memory while scanning the scene, one might ask if phosphenes produced by electrical stimulation might be stored in short-term memory as easily as the simulated phosphenes were. In order to effectively use scanning as a method of integrating the "scoreboard-like" patterns, the subjects needed to build up the perceptual information in constructing the mental image. It remains unclear to what extent this same integration might be accomplished using artificially–induced phosphenes via electrical stimulation. We have not yet demonstrated the emergence of higher-order percepts or objects (e.g., perceiving a line from a row of punctate phosphenes) in our primate or human studies. We consider this an important milestone for all approaches to a visual prosthesis. Despite these limitations, our assessment is that it is technologically and surgically feasible to implant intracortical electrodes within the human cortical visual system, and the psychophysical studies support the likelihood of prosthesis efficacy.

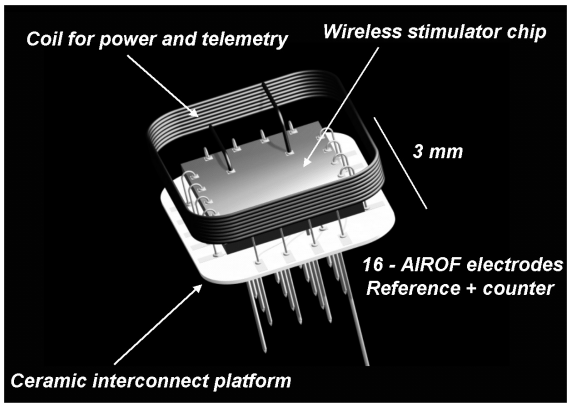

Fig. 1. Drawing of the wireless intracortical stimulation module

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13:15 – 14:25 Lunch Break

14:25

Welcome Address

Renate Reymann, Berlin, Germany –
President of the German Federation of Blind and Visually Impaired People

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Preclinical Development of Systems II

14:30

Raymond Iezzi, Paul Finlayson, Rochester, USA
Multichannel Neurotransmitter based Prosthesis

Most retinal prostheses in development today employ the use of electrical stimulation to modulate neuronal activity within the retina and create electrophosphenes. Fabrication of retinal prothesis electrodes and electrical stimulation chips has been made possible through decades of advances microelectronics fabrication technology. The primary mode of interneuronal communication within the retina is via neurotransmitter-ligand receptor interactions, however. These systems evolved to provide the visual system with information pathways. Retinal prostheses that employ the spatially and temporally controlled release of neurotransmitters may be able to uniquely communicate along these specialized visual sub-systems.
Our group has successfully characterized the neurotransmitter stimulation parameters required to modulate retinal ganglion cell activity in wholemount retinae of normal and retinitis pigmentosa phenotypes. Combined with computational models and methods for microfluidic manufacturing, the design and fabrication of multichannel neurotransmitter-based retinal prostheses is possible.

The purpose of this talk is to present our results with in-vitro neurotransmitter-based retinal stimulation and how these relate to the predicted models for retinal stimulation in normal and retinitis pigmentosa retinae in the context of designing a neurotransmitter-based

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14:50

Hum Chung, Seoul, South Korea

Multichannel visual cortical recording by three-dimensional electrode array

Purpose: Electrical stimulation of retina with microelectrode array (MEA) has been suggested as a possible method for retinal prosthesis. In our research, stimulation of retina was achieved by epiretinal or suprachoroidal application of three-dimensional MEA. For the epiretinal fixation of the MEA, PMMA microtack with grating was developed. To evaluate the tonotopicity of the retina onto the visual cortex on electrical retinal stimulation, multiple depth electrodes were used and the electrically evoked cortical potential (EEP) was recorded.

Methods: We designed PMMA(poly-methyl metharcylate) retinal tacks with barb-shaped scale bar which could act as an index in measuring the penetration depth. Using OCT, the scale bar was checked after insertion with 3D epiretinal electrode onto the rabbit's retina. The implanted electrode with retinal tack was harvested to confirm the biocompatibility and durability. And multichannel EEP's were recorded with 16 channel cortical electrode array in the rabbit's visual cortex using multichannel electrophysiological workstation after insertion of polyimide based MEA with 3D electrode into the suprachoroidal space.

Results: The scale bars of the retinal tack could be confirmed on Cirrus OCT evaluation. Through histologic examination, no inflammatory infiltrates was revealed. And 16 channel EEP recording provided two dimensional information of cortical responses on electrical retinal stimulation. We could confirm the different two dimensional patterns of EEP by electrical stimulation of different areas of retina.

Conclusions: The PMMA retinal tack was suitable to measure the penetration depth of an inserted 3D epiretinal electrode. And multichannel EEP recording could be used in topological evaluation of the visual cortical responses.

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15:10

Quishi Ren, Beijing, China

The C-Sight Project

Recently, a new type of visual prosthesis based on optic nerve stimulation with penetrating electrode array is developed by our group. In this presentation, we will describe the overall design principle, the technological development, and the experimental studies of the device. surgical approach to expose the optic nerve (ON), optimal site for electrode implantation, topographic distribution of the ON fibers, microvasculature distribution in ON, and biocompatibility of stimulating microelectrodes were investigated. The key issues and future challenges of visual prosthesis for blindness will also be discussed.

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15:30

Yasuo Terasawa, Nara, Japan

A visual prosthesis based on suprachoroidal-transretinal stimulation

We have been developing a visual prosthesis based on suprachoroidal-transretinal stimulation (STS). In STS, electrical stimulation is achieved by applying a current pulse between a stimulation electrode array implanted in the sclera and a return electrode placed in the vitreous cavity. The prime advantage of STS is its low-invasiveness to the eye due to the placement of the stimulation electrode array outside the eyeball.

In our system, an electrical circuit contained in a hermetic package is placed under the skin behind the patient's ear. Charge-balanced biphasic current pulses are sent from the circuit to the electrode array placed in suprachoroidal area via parylene-insulated, helically-wound cables. Each cable is directly welded to an electrode. The electrode array consists of bullet-shaped platinum electrodes and a substrate made from parylene to which the electrodes are fixed. The diameter and the height of each electrode are both 500 μm. The electrode array is curved to fit the eye. To check the long-term durability of the implant, a soak test in 37□ phosphate-buffered saline was conducted for 6 month and no device failure was observed. To examine the safety of electrical stimulation, testing of long-term stimulation of rabbits' eyes has been conducted using the above-mentioned bullet-shaped electrodes. Although this trial is still underway, preliminary results suggest that a charge injection of up to 0.7uC/phase does not show a significant correlation with the occurrence of tissue damage. Additionally, from histology, it can be inferred that an appropriate thickness of the residual sclera between the electrode array and choroid is critical for preventing damage to the retina.

Currently we are preparing for clinical study of a wirelessly-powered and -controlled device implanted for one month. At the same time, we are developing a next-generation device that includes a hermetic package small enough to be placed onto the eyeball. In addition, we are trying to improve the charge delivery capacity of the bullet-shaped electrodes by roughening their surfaces with electrochemical etching.

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15:50

Heinrich Gerding, Olten, Switzerland

The MiRi Project

Retina implants designed for epi- or subretinal stimulation are setting completely new challenges concerning the surgical management (critical anatomical sites of implantation, complex high risk interventions) and long-term biocompatibility of relatively large intraocular objects. Problems to be solved are mechanical implant stabilization, foreign body reaction, retinal long-term survival and the induction of proliferative reactions. It is the aim of the minimal invasive retinal implant project (miRI) to overcome the obvious disadvantages of large scale intraocular implant deposition by designing a new retina implant system. It is the principle of this new design that all components of the implant are deposited externally to the sclera and only the stimulating electrodes are penetrating the eye via sclera and choroid. Obviously this concept is in conflict with the general assumption that multiple ab externo penetration of the choroid might be a harmful procedure and that implants penetrating the eye permanentely would cause undesired tissue reactions. To evaluate the feasibility and principle design of implants for direct stimulation of the retina by penetrating electrodes a set of in vitro- and in vivo experimental series including eyes of rabbits and monkeys were performed. Results so far show that miRI-type devices can safely implanted by a minimal surgical approach without the necessity to perform a vitrectomy or any other intraocular manipulation beside of the penetration of stimulation electrodes.

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16:10 – 16:40 Coffee Break

Clinical Trials

16:40

Brian Mech, Robert Greenberg, Sylmar, USA

Preliminary Results from the Argus II Study: A 60 Electrode Epiretinal Prosthesis

Purpose: To provide a clinical update on Second Sight Medical Products Inc., (SSMP) Argus II (A-II) epiretinal prosthesis feasibility study.

Methods: As of July 2009, 32 subjects have been implanted at 11 centers. This abstract addresses the first 17 implanted subjects who had reached the six month time point by January 2009. Governmental and institutional approvals were obtained at all centers. All subjects had bare light perception or worse vision due to retinitis pigmentosa (see www.clinicaltrials.gov for more details). The A-II electronics were sutured episcleraly and then after a vitrectomy the electrode array was inserted through the pars plana and tacked to the retina in the macular region. Data from a glasses-mounted camera and power are transmitted wirelessly in real-time to the implant.

Results: The average age of the subjects has been 60 ± 9 years. The median surgical time has been 3:09 hours. All subjects were able to take the system, which included the glasses and battery-operated video processing unit, home for use outside the clinic. Subjects have been implanted an average of 14 ± 6 months. All subjects have reached the 6 month time point which is the data cutoff for this presentation. As of Janurary 2009, cumulatively, there have been nearly 20 subject-years of experience with the Argus II implant. The safety of the device has been acceptable and as expected for a new implant design. Most of the major adverse events occurred around the time of surgery (within one month post-operative) and all resolved by the six month endpoint. These major events include conjunctival erosion (n=5), hypotony (n=4) and endophthalmitis (n=3). There were no device failures and no explants. On the efficacy side, 100% of the subjects are seeing phosphenes. Significant improvements have also been shown in spatial localization, motion detection, orientation and mobility and other measures.

Conclusions: With six months follow-up on seventeen subjects, to our knowledge, this is the largest study of a visual prosthesis. The results to date confirm previous reports with the Argus I of phosphene production and the ability of the Argus device to provide visual information with a reasonable safety profile and good reliability.

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16:55

Ralf Hornig, Michaela Velikay-Parel, Gisbert Richard, Bonn, Graz, Hamburg, Germany, Austria

The IMI Trials

The “Intelligent Retinal Implant System” (IRIS^{TM}) has been developed with the aim of providing modest visual perception to blind patients suffering from retinal degeneration e.g. retinitis pigmentosa.

This epi-retinal prosthesis consists of an implantable part and two external parts. The implantable part is called the Retina Stimulator and is provided with energy wirelessly. The external components are the Visual Interface (VI) and the Pocket Processor (PP). The VI resembles a pair of sunglasses. A tiny camera is integrated within the Visual Interface to capture images from the patients’ surrounding and convert the image information into electronic signals. These signals are sent via a thin cable to the walkman sized Pocket Processor.. The PP processes the data and converts them into stimulation commands using very adaptable algorithms. The processed signals are then sent back via cable to the Visual Interface, where the signals are sent wirelessly to the implanted retina stimulator. The Retina Stimulator receives the data and generates the stimulation currents to activate the nerve cells of the retina. The stimulation currents are applied by an electrode array, which is placed epi-retinally onto the macular.

The implant is specially designed to allow ease of explants and potential replacement thereby allowing potentially allowing patients to benefit from future refinements in the technology. It is coated with a special surface material, which is biocompatible and does not adhere to the retinal tissue. Furthermore the implant is fixed with a special system that

allows the removal of the Retina Stimulator with low risk of retinal detachment.

A preliminary clinical trial revaluated the electrode array, which was implanted into humans during vitreoretinal surgeries. The retina was stimulated for maximum 45 minutes using a cable connected current source. The trial provided information relating to the optimum amount of current and electrode size.

The next step was a chronic study of prototype retinal stimulators. Selected patients from the first trial with low stimulation thresholds were enrolled. The Retina Stimulator was implanted into one eye and activated during several stimulation sessions. In this trial no camera was used. Stimulation signals were generated by a connected computer. Patients were able to localize phosphenes and to differentiate between different stimulation patterns.

In a further clinical trial an advanced system was used. In this trial the camera was used for the first time. Patients used the system in a series of stimulation sessions in the clinic. For the first time vision training was introduced in the Retina Implant treatment. This training proved to be critical and subsequently a patient could localize and grasp a ball.

IMI and the participating clinical sites are currently recruiting for the next step of clinical programme. The main objectives of the latest trial is to assess the real benefit of the device in the everyday life of patients and therefore patients will be encouraged to use the system in their normal daily surroundings.

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17:10

Eberhart Zrenner, Tübingen, Germany

Blind Retinitis Pigmentosa Patients Can Read Letters and Combine Them to Words

Purpose: Restoration of letter reading and stripe pattern recognition via subretinal electronic implants in blind RP patients.

Methods: Subretinal implants were placed transchoroidally near the macula, consisting of two arrays: 4 x 4 electrodes (100 x 100 µm), spaced 280 µm, controlled retroauricularly via a subdermal line for direct stimulation ("DS array") and a "chip" (3 x 3 x 0,1 mm) with 1500 electrodes (50 x 50 µm) of the same kind,each electrode being activated by light falling onto a neighboring micro-photodiode that controls the output of its subretinal amplifier (Details see presentation of Dr. Wrobel). Letters were presented to 3 patients either by stimulating retinal cells in 10ms steps via individual electrodes in a sequence patients had learned to write such letters or - via the light sensitive chip -by individual letters or stripe patterns steadily presented at a screen.

Results: On the DS array patients reported uniformly for each electrode that the sensation evoked by each individual pulse (0.5 - 4 ms, 0.1 V above threshold) consisted of a whitish round dot, clearly separated from its neighbor. Patterns consisting of such 4 x 4 dots correspond to letters of approximately 5 cm diameter presented at 60 cm distance.

Pat. 1 correctly (20/24) recognized the direction of the letter "U", presented with the opening in four different directions in in a 4 alternative forced choice (4AFC) mode.

Pat. 2 correctly (12/12) differentiated letters (e.g. C, O, I, L, Z, V) within few seconds, presented via DSelectrodes in random order (4AFC). With the light sensitive subretinal chip, he also correctly (22/24) differentiated without head movements letters (e.g. L,I,T,Z; 8,5 cm high, 1.7 cm line width) steadily presented on a screen at 62 cm distance with a red light (630nm cutoff) of 3.4 cd/m^2. Pat.3 recognized (15/20 correct, 4AFC) the direction of lines or stripe patterns with the chip, as did Pat.1 (11/14, 2AFC) and Pat.2 (11/12 4AFC) up to 0.35 cycles/deg. Regular ophthalmological tests with Landolt-C rings(4AFC) revealed a visual acuity of >20/1000 in Pat. 2 exceeding the limits of blindness according to German definitions.

Conclusions: Active subretinal multielectrode implants with currents close to recognition threshold (10 to 27 nC/electrode) produce retinotopically correct patterns that allow for the first time recognition of individual letters (8cm high, viewed in appr. 62 cm distance) even at low luminance levels. Stripe patterns of moderate luminance can be resolved up to 0.35

cycles/deg via the subretinal chip with visual acuity >20/1000 (Landolt-C ring). This clearly supports the feasibility of light sensitive subretinal multi-electrode devices for restoration of useful visual percepts in blind patients.

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17:25

Peter Walter, Wilfried Mokwa, Uwe Thomas, Aachen, Giessen, Germany

The EPIRET Trial

Between 2003 and 2006 the EPIRET 3 prototype was designed and fabricated. EPIRET 3 is a completely intraocular retinal stimulator with integrated electronics and inductive links for data and energy transfer, data handling, and pulse generation. Twenty five iridium oxide electrodes are mounted on a polyimide base. The implant is hermetically sealed and flexible enough to allow a minimal invasive implantation procedure. Animal experiments demonstrated the long term functionality and biocompatibility of the system. Cortical recordings and metabolic mapping of the visual cortex in cats implanted with the device showed that local activations occurred within the visual cortex corresponding to the area of stimulation in the retina. The system was implanted in six blind volunteers suffering from Retinitis pigmentosa. Lensectomy and vitrectomy were performed using standard techniques. The implant was inserted after enlargement of the corneal incision. The receiver module was inserted in the posterior chamber and transsclerally sutured. The stimulator module was placed on the retinal surface in the macula and retinal tacks were used for stable fixation. The surgery could be perfomed without intraoperative complications. Postoperatively, mild inflammatory responses were seen. The implant was left in place for four weeks. At three time points stimulus thresholds were determined for selected electrodes and perception patterns were recorded in comparison to the stimulation patterns. In all patients the implant could be activated using the inductive link. In all patients the implant was fully functional after the implantation procedure. In all

patients phosphenes were elicited. The phosphene patterns corresponded to the stimulus patterns and stimulus thresholds on average were 15 nC/cm². After four weeks the implants were removed and the patients were followed for five months. In one patient a retinal break occurred during the explant procedure. It was treated successfully with laser endocoagulation and silicone oil filling. In three patients tiny epiretinal membranes occurred during the follow-up in the tack areas. None of the volunteers lost their residual visual function. Angiograms showed no vascular changes.

In summary, the EPIRET 3 system proved that a completely implantable retinal implant system without any transscleral connections for data and energy can be fabricated and implanted.

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Free Communications

17:40

Jun Ohta, Nara, Japan

Light controlled retinal stimulator for large number of electrodes.

We present a retinal stimulator with a light-controlled function for subretinal implantation. The stimulator is based on a multiple-microchip architecture which has previously been developed to realize over 1000 stimulus electrodes by our group. The retinal stimulator can be controlled by the intensity of light through the light-controlled function embedded in each microchip. The fabricated stimulator was implanted in a rabbit eye and stimulated retinal cells. The EEP signals were successfully obtained.

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17:50

Thomas Schanze, Giessen, Germany

Neurophysics of retinal visual prostheses

Blinds subjects with end-stage photoreceptor degenerative diseases such as retinitis pigmentosa and age-related macular degeneration have retinal neurons that are still intact. Without visual input, retinal ganglion cells spontaneously generate action potentials that are transmitted by their axons to higher visual centers. However, such non-visually driven activity can change the properties of the visual cortex. The goal of a retinal implant is to evoke retinal activation patterns that can be perceived as phosphenes which should be useful for vision restoration in blind subjects with degenerated photoreceptors. Despite much scientific and technical progress some important neurophysical questions are still pending. 1. What is the optimal electrode-neuron interface for selective, safe/low-threshold, and long-term stable stimulation? 2. What spatial, temporal, and intensity/contrast resolutions are obtainable with current retinal implant technology and are these resolutions sufficient to provide a detection or recognition of static objects and motion in visual scenes? 3. What electronic pre-processing of camera captured visual scenes and electrical stimulation parameters are useful and necessary to activate retinal neurons physiologically adequate and long-term stable for vision restoration? We summarize results of experiments obtained from anesthetized cats with intact visual systems, especially results concerning stimulation threshold as well as temporal and spatial resolution. We compare some of these results with results obtained from a clinical study performed by the German EPI-RET group with blind retinitis pigmentosa patients and conclude with respect to current and upcoming issues concerning design and testing of retinal implants.

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18:00

Thomas Laube, Düsseldorf, Essen, Germany

Successful long-term* in vivo*-function of the wireless EPI RET3 retina implant system – Tests in Goettinger minipigs

Objective: To develop and establish surgical methods for safe implantation and explantation of wireless intraocular retina implant systems. To test the *in vivo*-function of active retina implants and to evaluate the tissue compatibility of epiretinal electrical stimulation.

Methods: Phacoemulsification and vitrectomy was performed at the right eye in 16 Goettinger minipigs under general anaesthesia. The implant consisting of an HF receiver coil and an electrode array was inserted through a scleral incision. The receiver coil was placed behind the iris and the electrode array was fixed onto the central retina with a retinal tack. Wireless electrical epiretinal stimulation experiments were performed in 12 minipigs using short biphasic charge-balanced charges of 0,9 mC/cm^2 or 2 mC/cm^2, respectively. Following successful start-up of the implant stimulation charges were applied for one hour. Animals were observed for a period of 14 days. After sacrificing, the eyes were enucleated and processed for histological evaluation. In separate explantation experiments the retinal tack was retained and the implant removed through a scleral incision.

Results: The implantation and explantation procedures could be well established and were safely performed. Intraoperatively a minor reversible punctiform bleeding of the retina occurred in one case and an iris bleeding in a second case. Stimulation artifacts were measured with subconjunctival needle electrodes in 11 eyes. Continuous *in vivo*-function of the implant was proved for a period of 24 months postoperatively. Electrical stimulation of the retina caused no tissue alterations at neither of the charges applied.

Conclusions: The performed surgical procedures are safe and effective. A long-term successful *in vivo*-function of the retina implants could be documented and charges of up to 2 mC/cm^2 are safely applicable to retinal tissue in a time range of 1 hour.

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18:10

Michaela Velikay-Parel, Graz, Austria

Mobility testing and its Repeatability in RP Patients with profound visual impairment: Learning effects, coping strategies and other influencing factors.

Purpose: We created a visual function test, the Graz mobility test (GMT) to document visual progress in artificial vision. In previous studies our visual function test adequately graded the low vision of patients with retinitis pigmentosa (RP). However in repeated testing the learning effect could contaminate the results after implantation. Therefore test and retests were performed in various time intervals on low vision RP patients.
The aim of this study was to investigate the consistency of the performance in patients in repeated testing and to study the learning effect for later use in artificial vision. Furthermore behavioral changes during retests were first time recorded and assessed.
Methods: 16 low vision RP-patients with a visual acuity from hand motion to 20/800voluntered. Repeated testing was performed in 1, 2, 3 and 6 months time intervals. The GM test consisted of four different, structurally similar mazes with 11 obstacles. The subjects passed through each course several times. A people tracking system with an integrated trajectory projection system was established to record horizontal and vertical scanning movements of people whilst walking through the test. Passage time, walking speed, number of contacts, frequency of scanning movements and average scanning angle were recorded.

Results: In repeated testing significant changes of the passage time were observed once the patients became familiar with the mobility test. The maximum learning effect was achieved within the first test session and was never exceeded in the following sessions. However further changes in the remaining parameters were observed in each patient, displaying behavioural changes correlating to the level of comfort during the task performance.

Conclusion: The GM proves to be reliable for repeated testing in low vision patients and the learning effect will not contaminate the results of visual function changes.

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18:20

Walter Wrobel, Reutlingen, Germany

Active subretinal implants: Design, functionality, and operational experience

The active subretinal implant has been designed based on MEA measurements with chicken retina samples. Threshold for excitation was determined to be 0.5 to 1 nC, with a dynamic range up to 10 nC/electrode. Achievable spatial resolution was estimated at 0.5°. In-vivo animal experiments in cats demonstrated cortical excitation with a resolution of approx. 1°.

The subretinal chip, designed and manufactured by IMS Stuttgart, is based on a CMOS camera technology, with 1500 Pixels on 3 x 3 mm², with a pixel size of 70 x 70 µm². Simulations of technically achievable visual results show a visual acuity of up to 0.1.

For initial testing purposes in a pilot study, the implant system also features an array of 4 x 4 electrodes, which are powered and controlled externally, allowing the exact determination of thresholds for visual sensations and electrode impedances. .

The chip has a dynamic sensitivity range which allows to process 2-3 decades of brightness. This characteristic can be shifted by an external control voltage between 0,001

lx und 100 klx, allowing an adaptation to different lighting conditions. The chip is also sensitive in the Near-IR, giving the patient some night-vision capabilities.

Electrodes are made from fractal TiN. External power from a battery power supply behind the patient's ear is transferred via silicone/gold cables and polyimide foils through the orbital cavity and the sclera to the subretinal chip. This external wiring did not limit the patients' operative eye motility.

Electric field simulations show that within large, homogeneously stimulated areas the electric field in the center is less compared to the boundaries, leading to the clinical observation of bright "picture frames".

Slight movements of the chip of typically < 100 µm within the subretinal space were observed post-op, without any detrimental effect on the retina.

Patients perceived brightness and observed thresholds were in good agreement with laboratory measurements of the chip's sensitivity characteristic. Most clinical testing was done at moderate light levels (10 – 1000 lx).

Patients were able to correctly discriminate grey levels, in accordance with chip characteristic. Landolt-C-testing was possible, with the smallest perceived structural details corresponding to a distance of 2-3 pixels only.

Correct functionality of the implant system can be checked by measuring the power consumption and the impedances at different chip connectors.

Chip function itself can be monitored by measuring ERG "artefacts", with artefact amplitude correlated to chip illumination level.

This implant has been clinically tested in 11 blind patients with promising results (see presentation of E. Zrenner et.al.).

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18:30

Akos Kusnyerik, Budapest, Hungary

Results of the preoperative planning procedure in subretinal prosthesis implantation

Background and Purpose: Replacing functionality of lost photoreceptor cells in case of retinal diseases is the basic idea behind retinal prosthesis. Therefore it is very important to accurately situate the prosthesis to stimulate living cells and not inert areas on the retina. Our purpose is to establish a standardized planning procedure and to preoperatively define the most appropriate location on the fundus for surgical implantation of a subretinal microphotodiode-array (MPDA).

Methods: Eye morphology and retinal structure of the eyeball has been assessed in 4 persons scheduled for prosthesis implantation. Imaging techniques were used to topographically assess individual eye morphology with geometrical dimensions of the eyeball (ultrasound, interferometry, and 3 Tesla MRI using high resolution measurements), and retinal structures with functions (photography, angiography, OCT, microperimetry).

The desired location of the MPDA was defined by means of a multimodal fundus-mapping system. An ellipsoid eye model was used to determine the optimal outcome parameters. For surgical planning the distance from incision to posterior pole and the angle of insertion was calculated and provided to the surgeons. A guiding-tool with a mm-scale was used for creating the channel for insertion

Results: The parameters given proved to be precise enough for subretinal placement in the proximity of the desired location. The fundus-mapping system proved to be a valuable adjunct to define a well-suited location on the posterior pole and was applied for preoperative calculations.

Conclusion: The preoperative evaluation provides a meaningful tool for planning the surgical implantation of a subretinal visual prosthesis and could be useful to other approaches as well (e.g. epiretinal prostheses). It is possible to determine the appropriate surgical approach for the optimal MPDA position preoperatively using a combination of MRI data and projection of geometrical measures onto the eye. After identifying the optimal location with preoperative planning, better functional results were noted in patients.

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