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Successful pilot study into the function of the first retinal implant in the human eye

Retinal chip enables blind people to gain “useful impressions of vision”

(Reutlingen/Tübingen) – The medical technology company Retina Implant GmbH in Reutlingen has developed an active microelectronic retinal implant with the help of which it has for the first time been possible to successfully restore partial vision to completely blind patients at the University Eye Clinic in Tübingen.

5A press conference was held yesterday (Wednesday) to mark the conclusion of the sensational study. Professor Eberhart Zrenner, medical director of the University Eye Clinic in Tübingen, and Dr Walter-G. Wrobel, chairman of the board of directors of Retina Implant GmbH presented the results jointly.

In addition to Professor Dr Zrenner and Dr Wrobel, Professor Dr Karl Ulrich Bartz-10Schmidt from the University Eye Clinic in Tübingen and Professor Dr Helmut Sachs from the University Eye Clinic in Regensburg, both surgeons, and study participants Hartwig Lahann and Lothar Wüstner reported on the initial success.

“It is impressive when science fiction becomes fact“, said Dr Walter-G. Wrobel. “It is actu-15ally easier to fly to the moon than to develop a retinal implant“, added Prof Dr Eberhart Zrenner, in light of the 12 years so far spent on research and development. Nowhere have better results so far been achieved than in Tübingen, regardless of the approach used. The focus of the pilot study was on patients suffering from retinitis pigmentosa, a congenital disease of the retina that can be attributed to degenerate photoreceptors.

20Seven patients between the ages of 26 and 58 had been provided with artificial retinal implants since autumn 2005.

The chip measuring just 3mm by 3mm was implanted under the patients' retina, where it replaced dead photoreceptors. Film documentation played during the press conference 25described the visual results of the pilot study as a kind of test picture for blind people.

“The study has clearly proven the feasibility of our concept“, said Dr Walter-G. Wrobel.

“With the chip it is now possible to replace the eye's natural photoreceptors, i.e. the rods

and cones, with artificial ones.“ The patients were then able to see patterns, localise objects and describe sources of light. Patient Hartwig Lahann was still overwhelmed, “The impressions from the tests were worth far more than the risk associated with them“. He
30 will remember his participation in the month-long pilot study for many years to come.

1,500 electrodes on the chip generate the same number of picture elements (pixels), with each pixel containing an electronic amplifier that boosts the electrical signal of the photodiodes in such a way that the retina is stimulated.

An additional 16 direct-stimulus electrodes are mounted on a kind of tongue at the tip of
35 the implant, which works with the popular CMOS technology that can be found in the camera chips of mobile phones.

The external power supply necessary for the amplification was provided via a thin, flexible foil cable, explained Professor Dr Sachs from the University Eye Clinic in Regensburg. Inserted into the eye, this cable runs across the temple under the scalp, ending in a
40 plug behind the ear. The so-called transchoroidal operating method was specially developed at the University of Tübingen to place the chip near the optical nerve without harming the retina. This was not yet landing a man on the moon, but in view of the results of the study, one could speak of successfully manoeuvring a lunar probe into place, explained ophthalmic surgeon Professor Dr Bartz-Schmidt, taking up the same metaphor
45 introduced by Professor Dr Zrenner at the outset.

Within two year Retina Implant GmbH intends to introduce a fully functional chip to the market for around EUR 25,000. This is still less than the cost of a guide dog (EUR 30,000). “Thanks to the pilot study we now know what has to be done to achieve this goal“, said Dr Walter-G. Wrobel. The prototype of a wireless implant that works inductively – just like a transformer – has already been developed. CE approval is expected at
50 the end of 2008.

Until then the results of a multicentre study with, in addition to Tübingen, the participation of further clinics in Germany and other countries should bring the goal of a marketable product nearer. The next functional tests with a slightly revised chip are scheduled for
55 early summer

Market researchers forecast the worldwide market for retina implants to grow to several EUR 100 million in size over the next five to ten years, according to Dr Walter-G. Wrobel. The pilot test has proven that “real-life practical vision“ is possible with the retina implant. The implant's tolerability has been confirmed; in spite of the cable, the patients could still

60move their eyes free from tear fluid, inflammation and pain. The only thing that they could not say anything about was long-term stability due to the limited month-long study. However, the example of patient Lothar Wüstner, who has carried the implant at his own risk for 18 months without any complaints, shows that it is in principle possible for the chip to remain in the eye for a longer period. According to Wüstner, medical advances
65can only be made if blind people actively participate in research.

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About Retina Implant GmbH

The medical technology company has developed an electronic chip that can be implanted under the retina. This retinal implant is designed to restore partial vision to blind people who suffer from certain forms of degenerative retinal diseases (such as retinitis pigmentosa or age-related macular degeneration). At the heart of the development is a silicon chip containing photosensors that control electronic signals that – depending on light intensity - can stimulate the nerve cells in the retina with electrical impulses of varying strength. The electrical impulses are relayed via the optical nerve fibres to the brain, which is able to generate an image from these signals. The project entered the clinical trials phase in 2005 following many years of technical development. For the first time, previously completely blind patients could be successfully operated on.

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