



Subretinale Implantate für Blinde: Was ist technisch erreichbar?

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Vorstand Technologie, Retina Implant AG

InnoPlanT.NET Netzwerktreffen, Erlangen, 23.02.2017

Retina Implant AG - Historie

- 1995 – 2003 BMBF-Verbundprojekt SUBRET
- 2003 Gründung Retina Implant AG
- 2005 Pilotstudie
- 2008 zertifizierter Medizinprodukte-Hersteller
- 2010 – 2013 Klinische Studie
- 2013 CE-Kennzeichen ALPHA IMS
- 2014 – 2017 Multizentrische Klinische Studie
- 2016 CE-Kennzeichen ALPHA AMS

» 45 Mitarbeiter

Produkte für Menschen, die an Retinitis Pigmentosa erkrankt sind

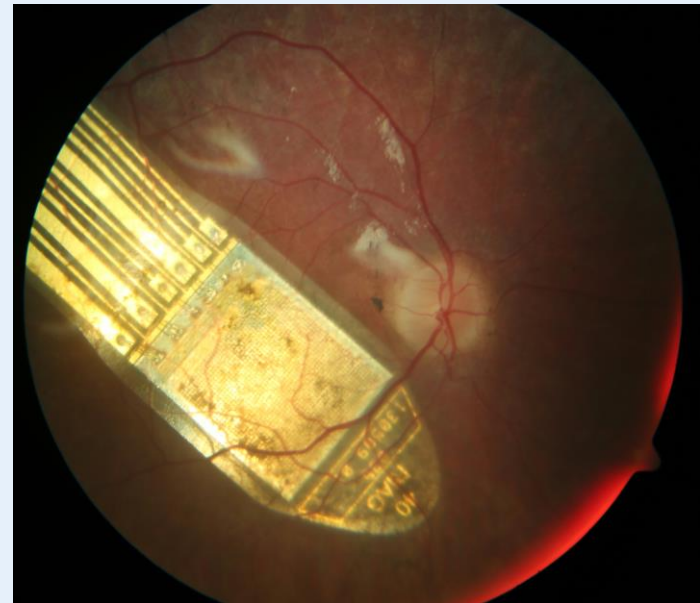
OkuStim

Elektrostimulationstherapie

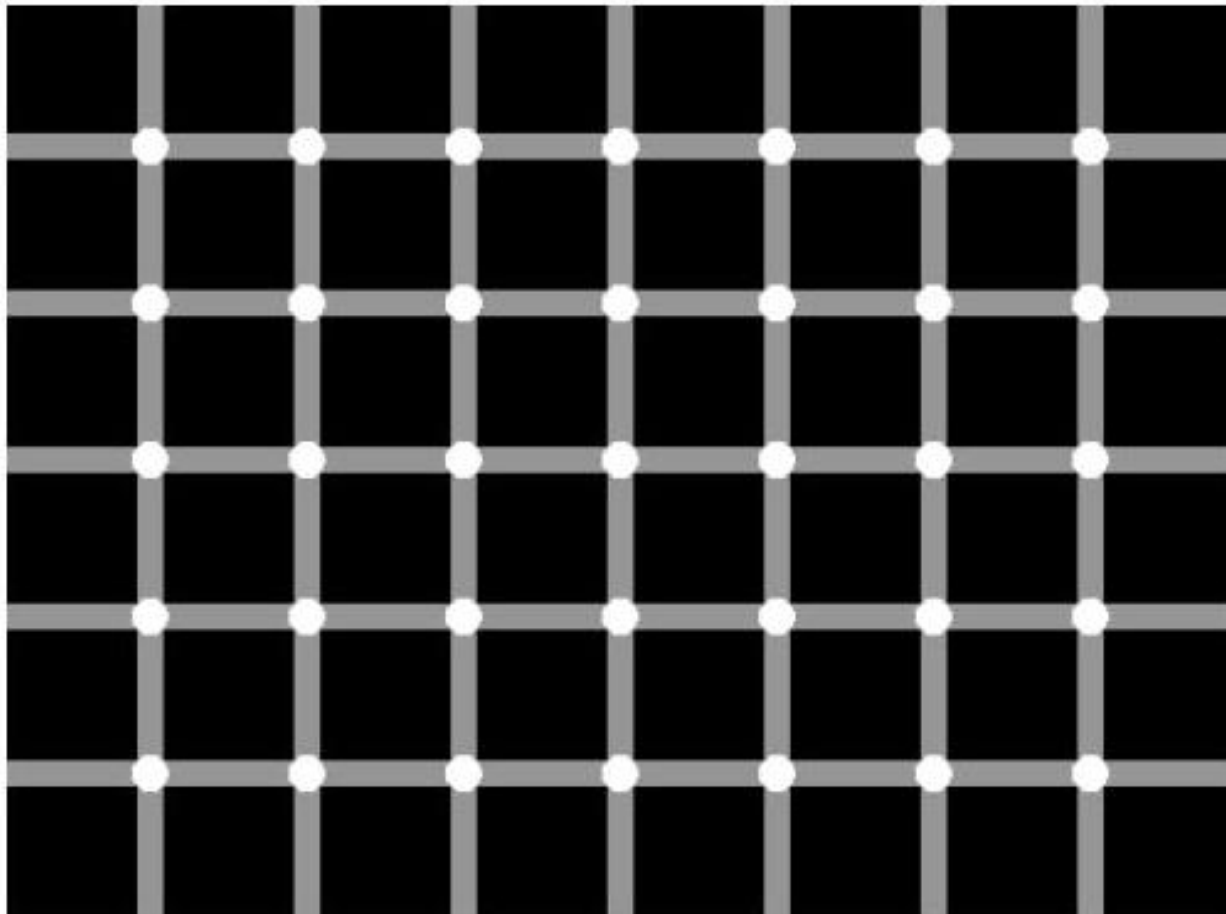


Retina Implant Alpha AMS

Subretinales Implantat

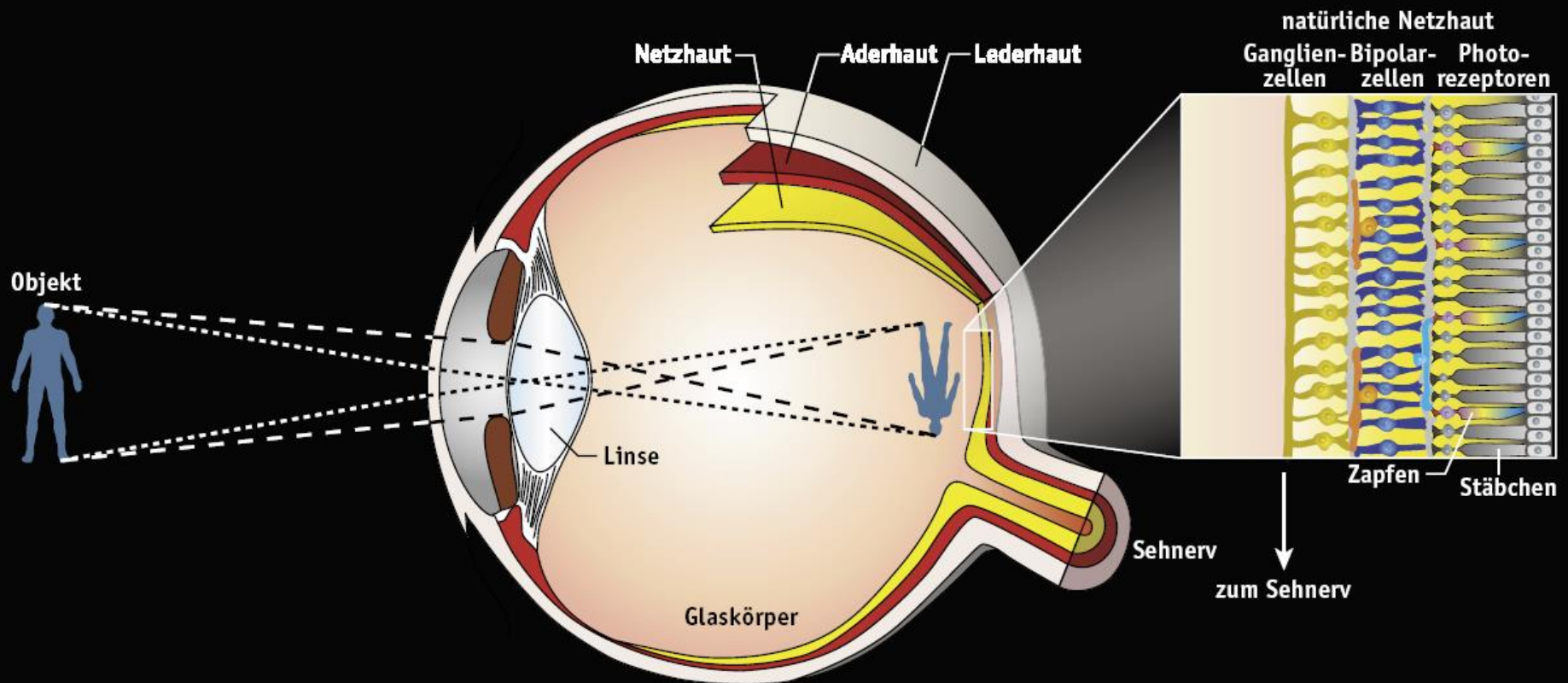




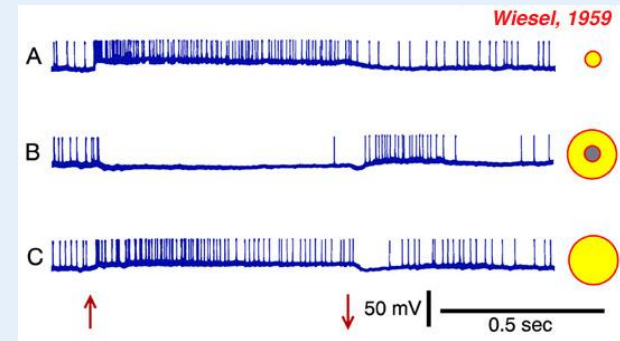
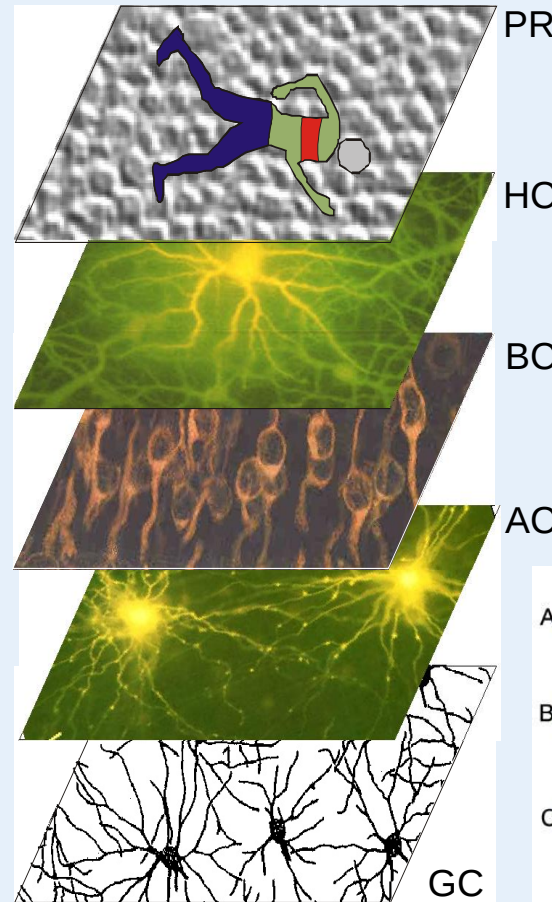
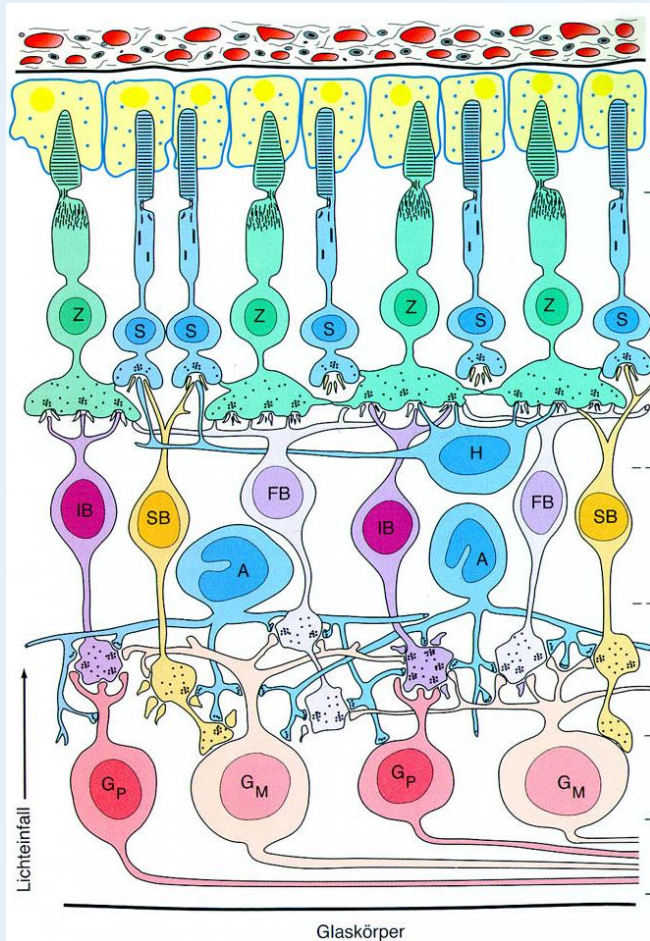


Zählen Sie die schwarzen Punkte!

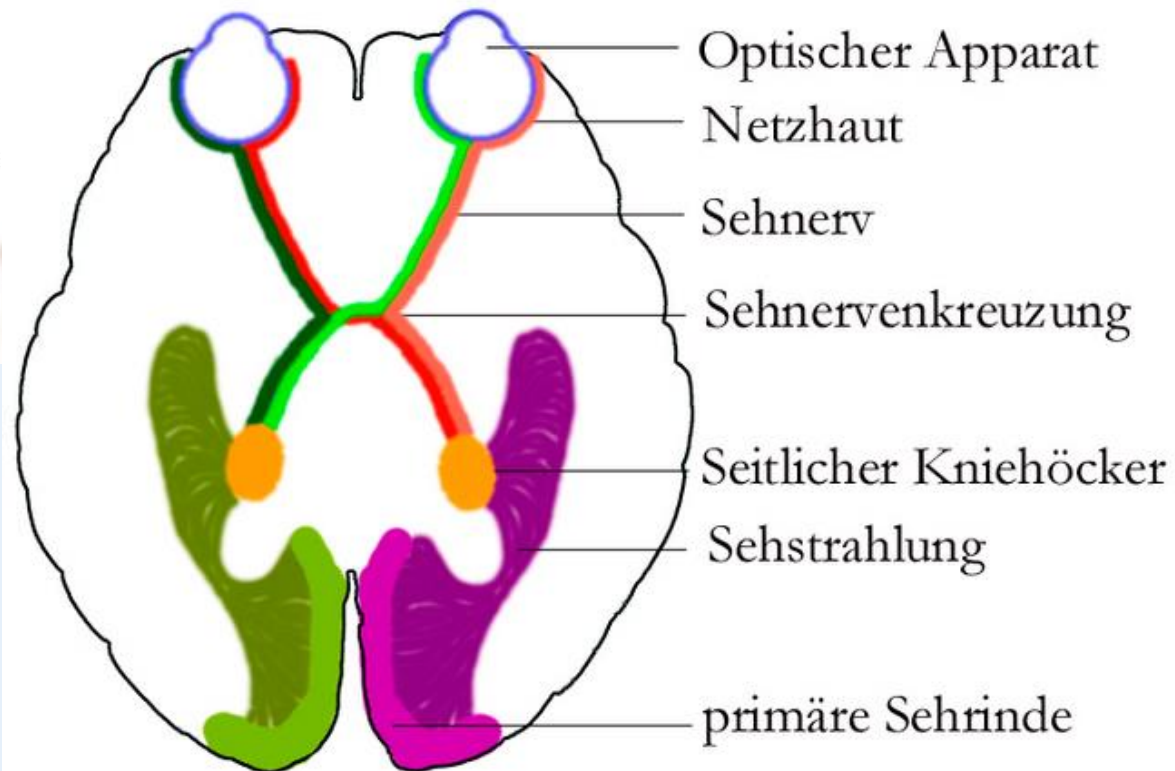
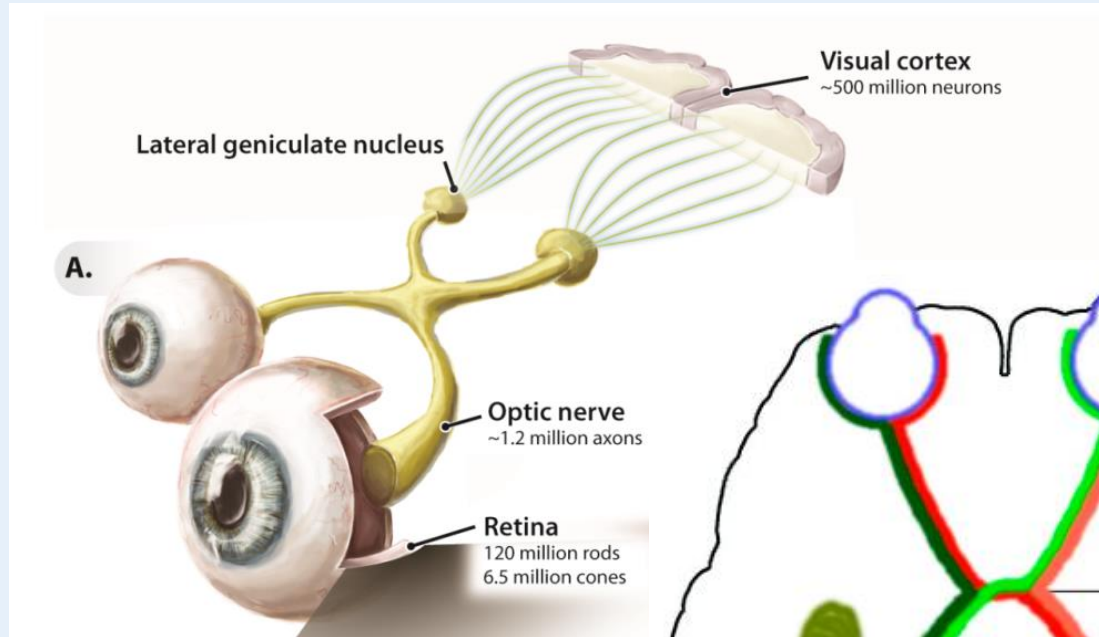
Sehen und Wahrnehmung



Signalverarbeitung in der Retina

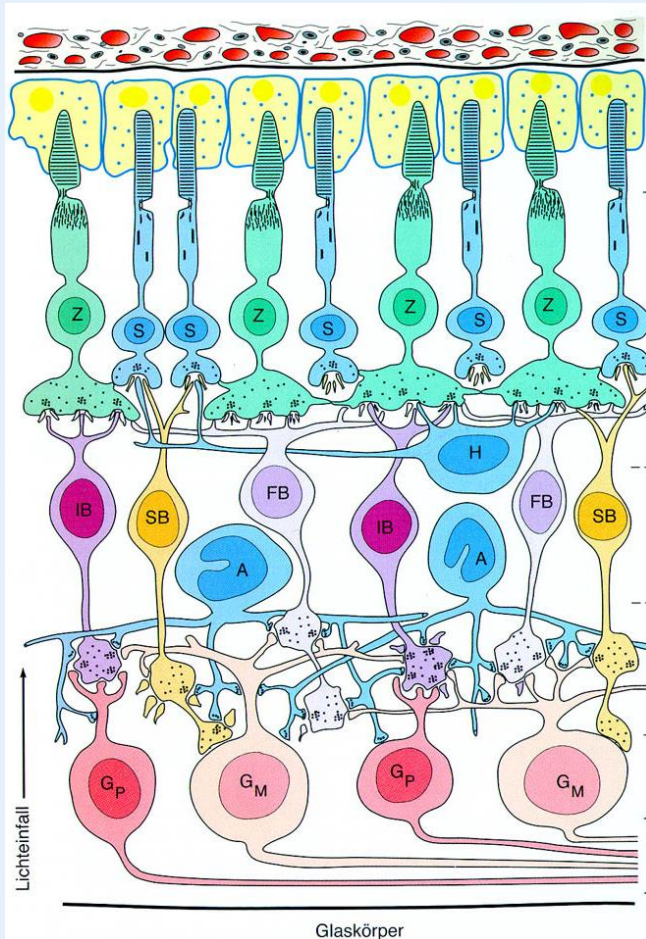


Aktionspotentiale der Ganglienzellen



Retinitis Pigmentosa

Blindheit durch Verlust der Photorezeptoren

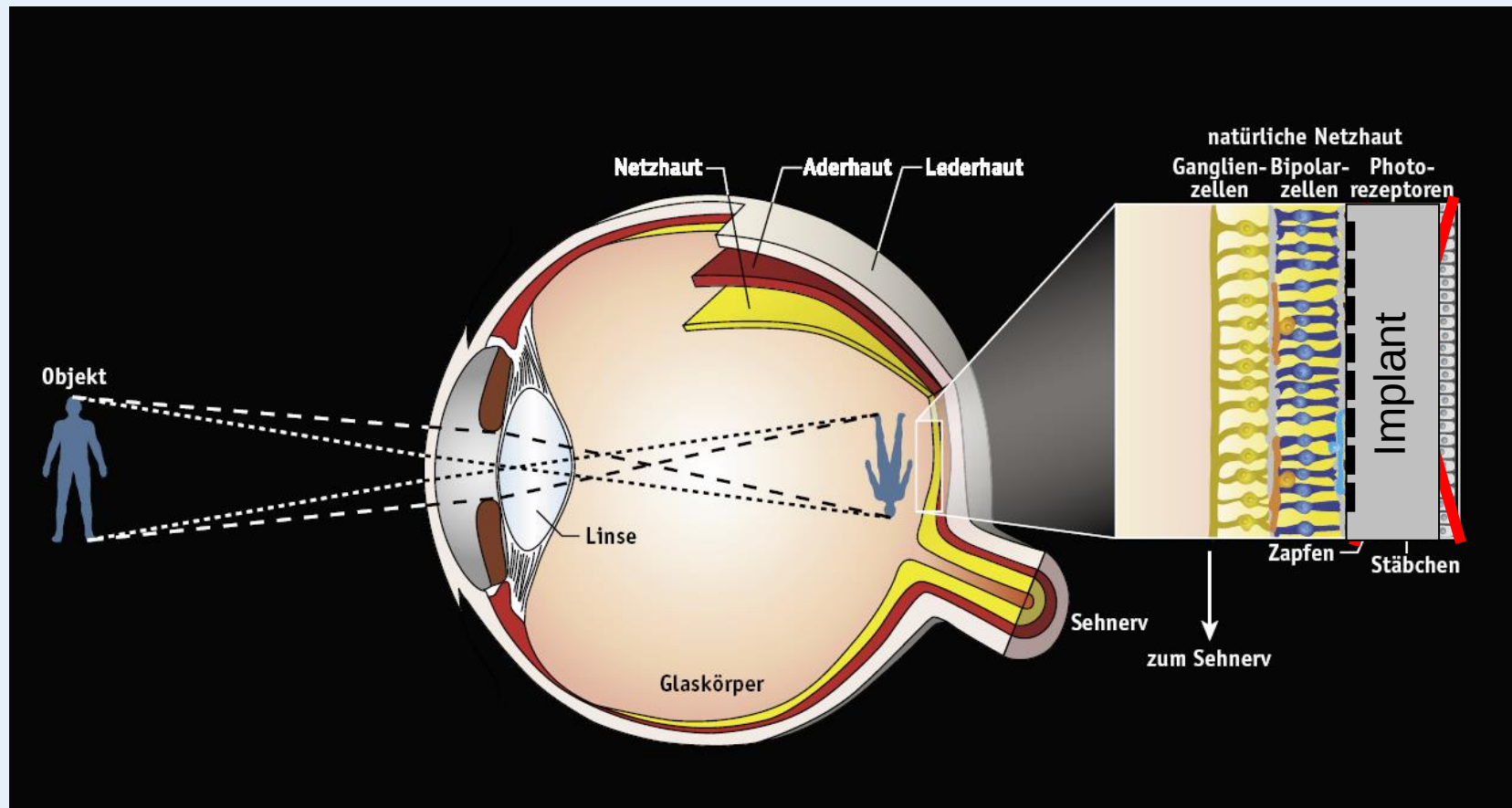


Ca. 30.000 bis 40.000 Betroffene in D



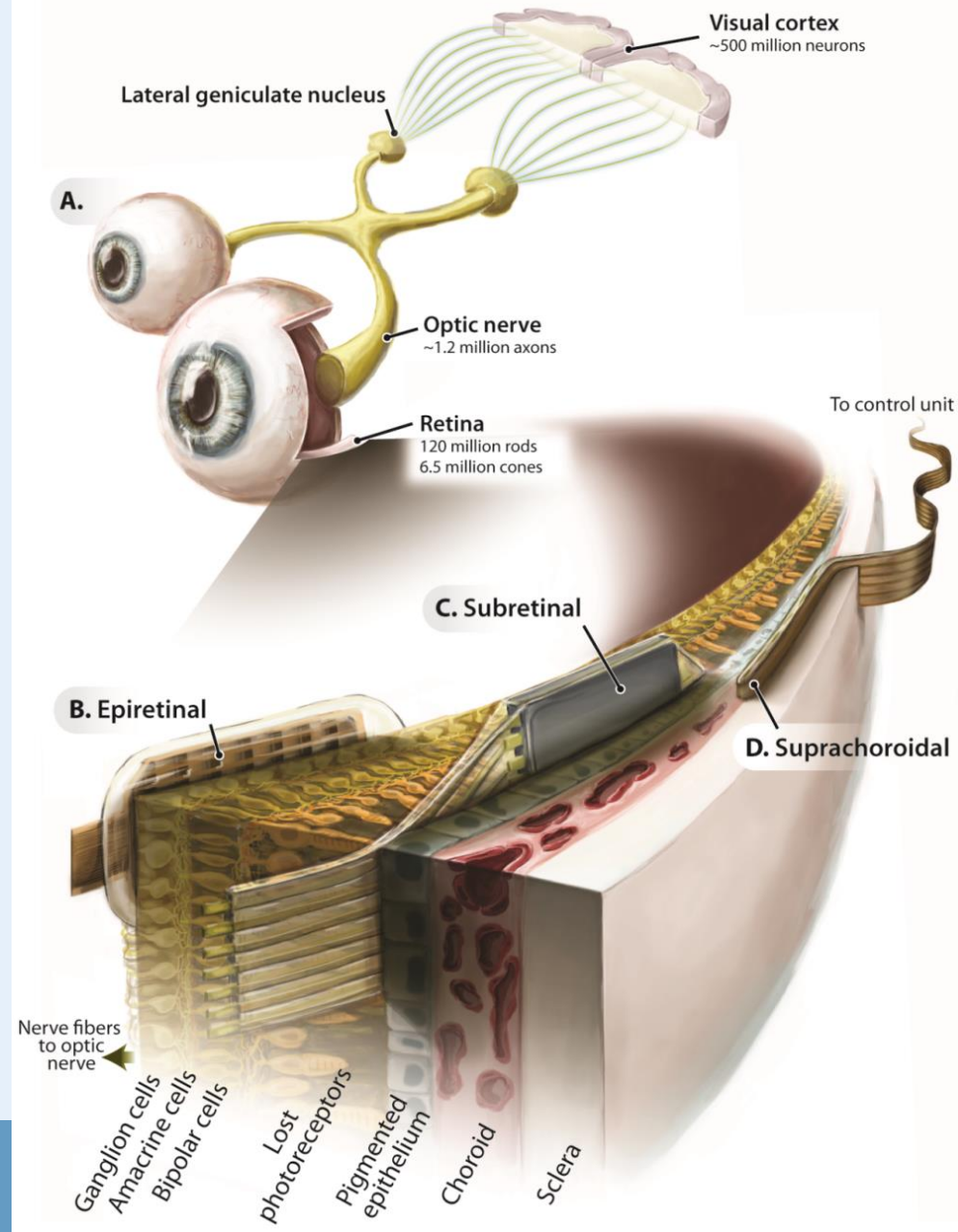
Netzhaut-Implantat

Wiederherstellung der Sehfunktion mit einem Chip in der Netzhaut



Sehimplantate

- **Subretinal**
 - Retina Implant Alpha AMS
- **Epiretinal**
 - Argus II, Second Sight
 - IRIS II, Pixium Vision
- **Suprachoroidal**
- **Optic nerve cuffs**
- **Kortikale Implantate**



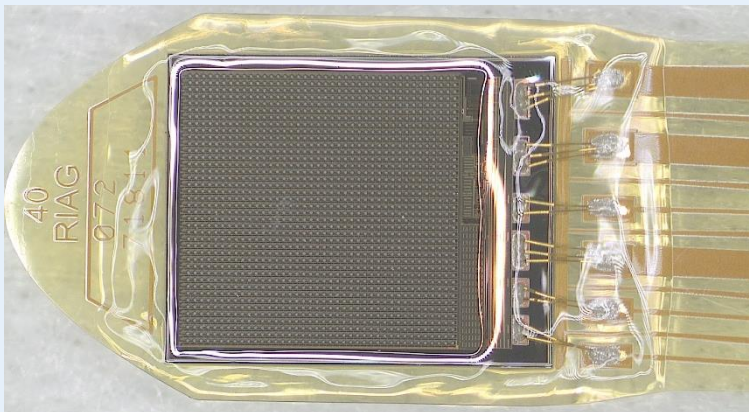
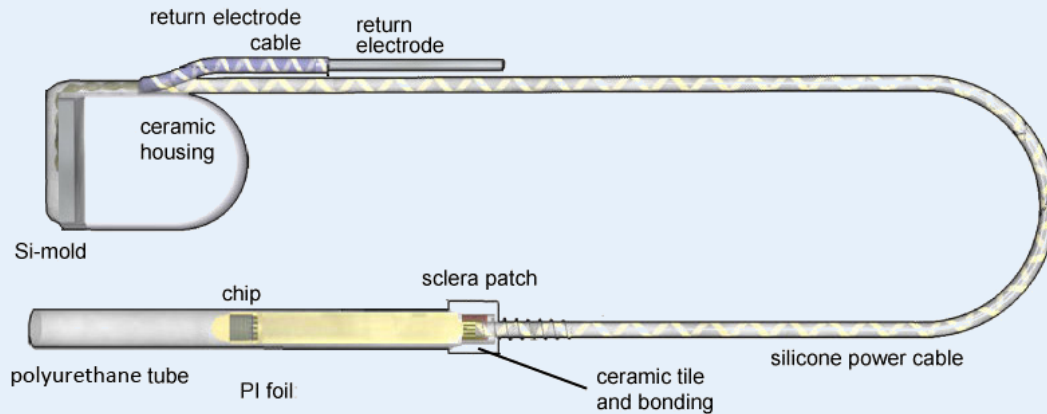
Subretinales Implantat

Herausforderungen

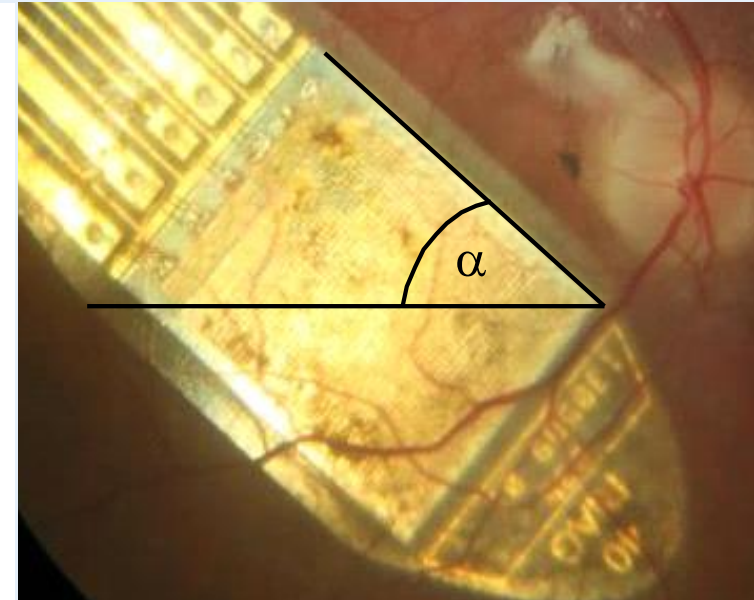
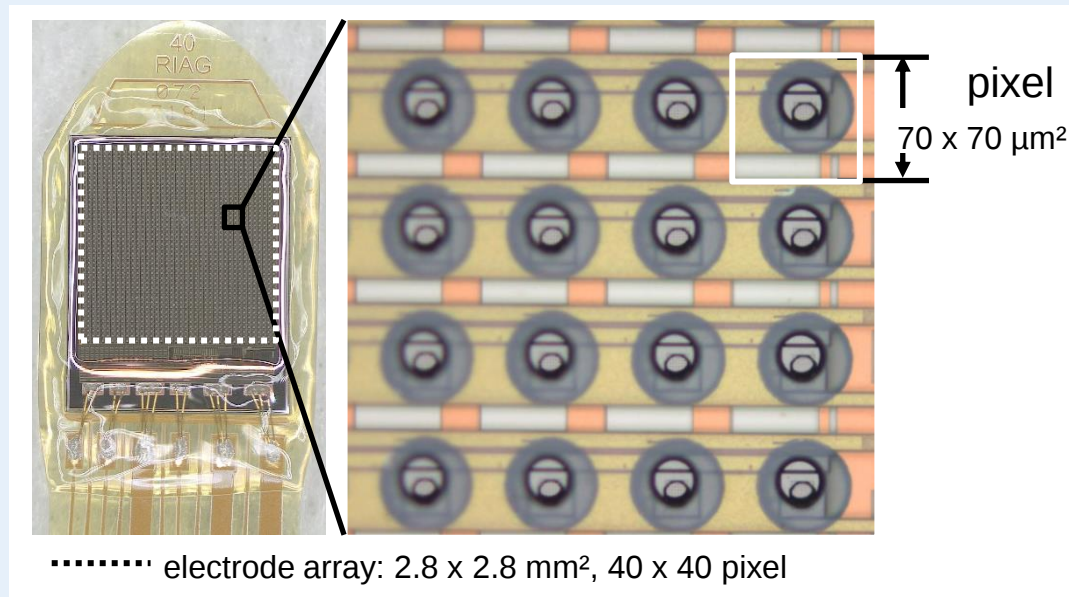
- Technisches System
 - Hohe räumliche / zeitliche Auflösung
 - Lebensdauer, Langzeitstabilität
 - Anwenderfreundlich, nicht stigmatisierend
- Chirurgisches Verfahren
 - einfach, schonend, sicher (auch im postoperativen Verlauf)
 - standardisiert
- Sehqualität
 - Hilfreiche Seh wahrnehmungen
 - Patientennutzen im Alltag

Retina Implant Alpha AMS

CE mark 2016



Räumliche Auflösung

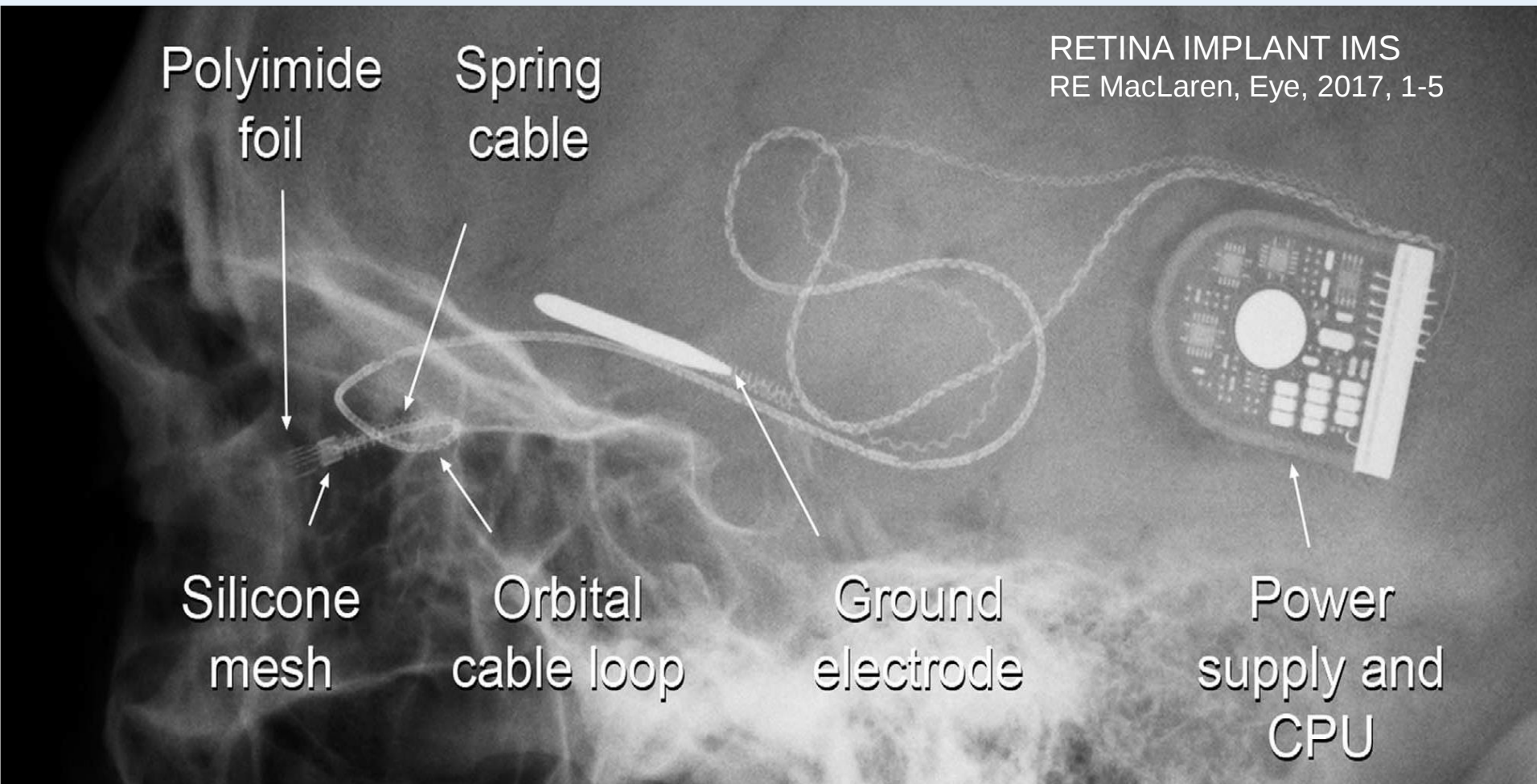


- Kleinster auflösbarer Sehwinkel: 14'
- Theoretisch möglicher Visus: 20/280 (0,07)
Klinik: 20/546
(gesetzlich blind: 0,02)
- Theoretisch mögliche Gitterauflösung: 2,1 cpd
- Gesichtsfeld: 13°

Normalsehend: 20"
20/20

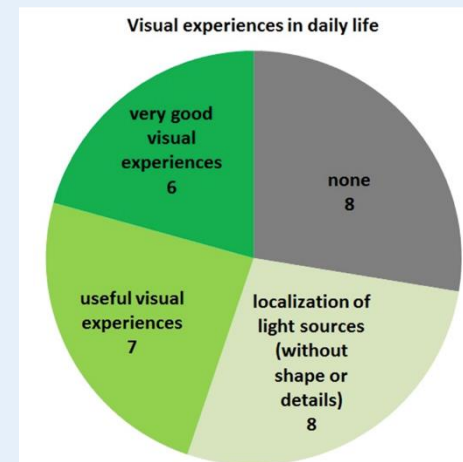
bis zu 60 cpd

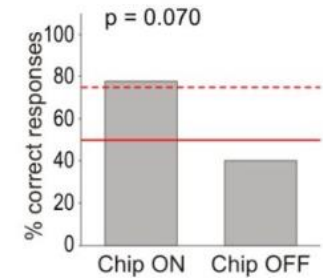
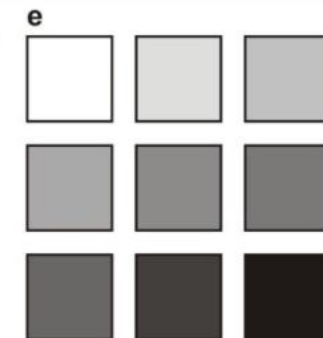
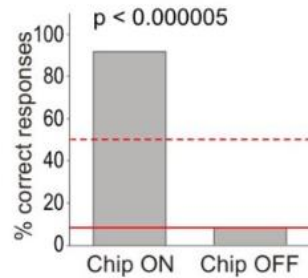
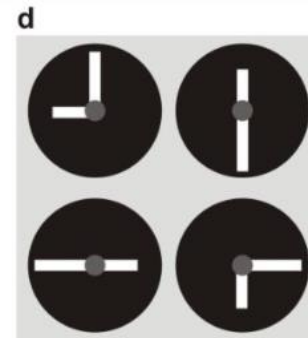
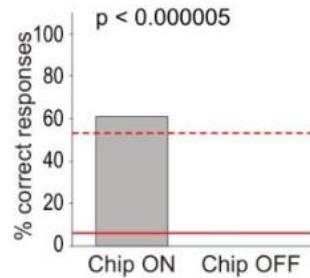
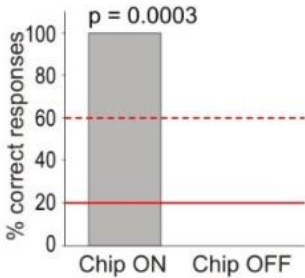
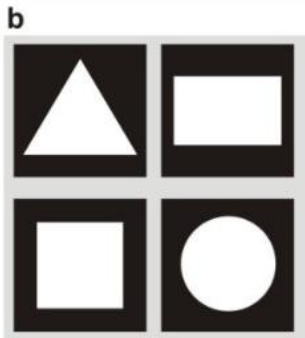
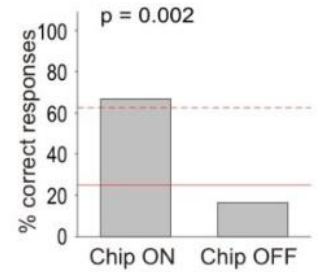
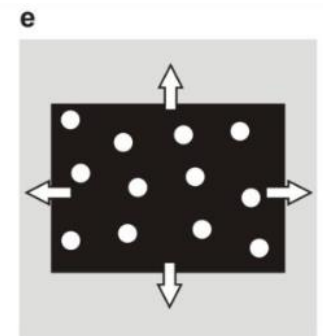
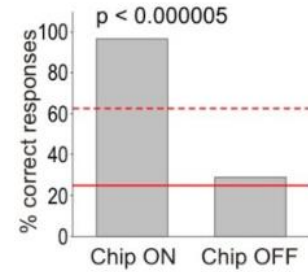
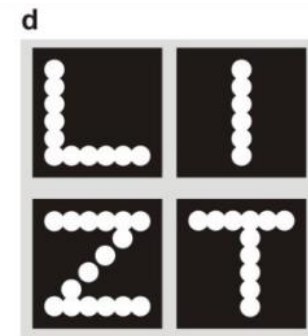
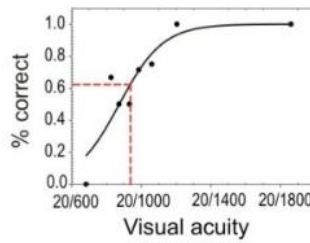
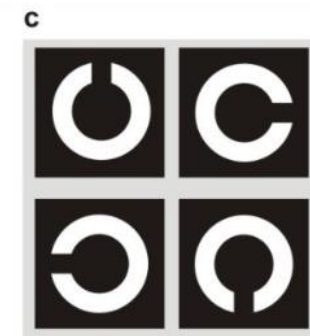
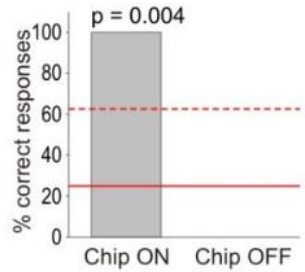
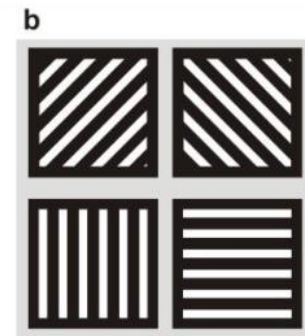
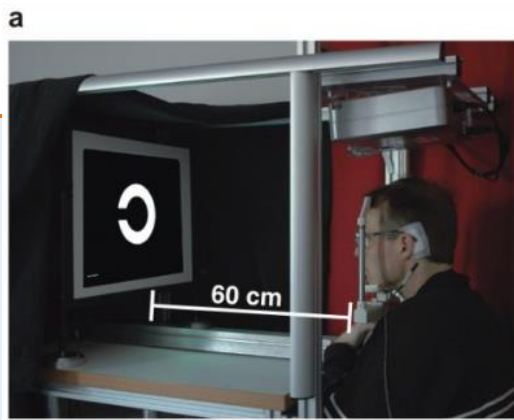
Kabel und Chip implantiert



Retina IMPLANT Alpha IMS: Multi-center clinical trial

- Clinical trial 2010 - 2013
- 29 subjects
- hereditary retinal degeneration, RP
- In 7 centers worldwide
(London, Oxford, Budapest, Dresden, Tübingen, Hong Kong, Singapur)

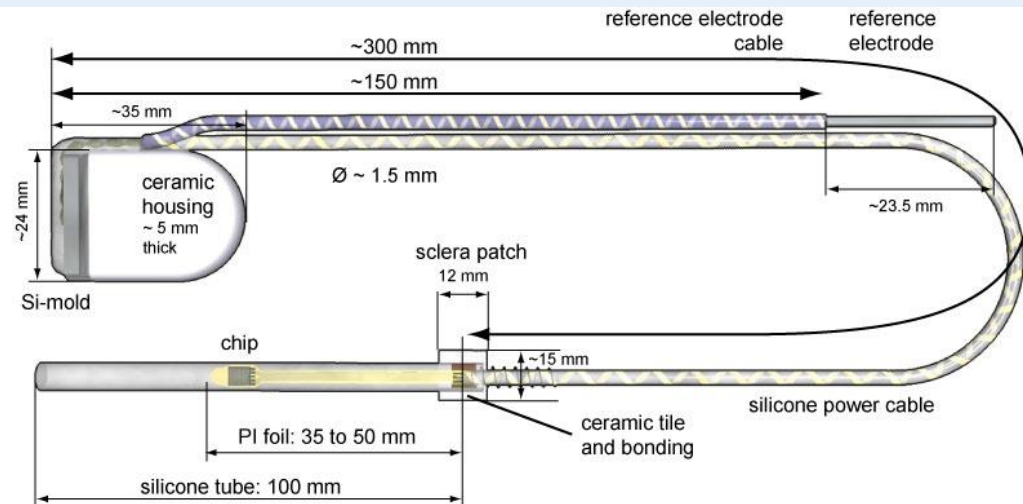
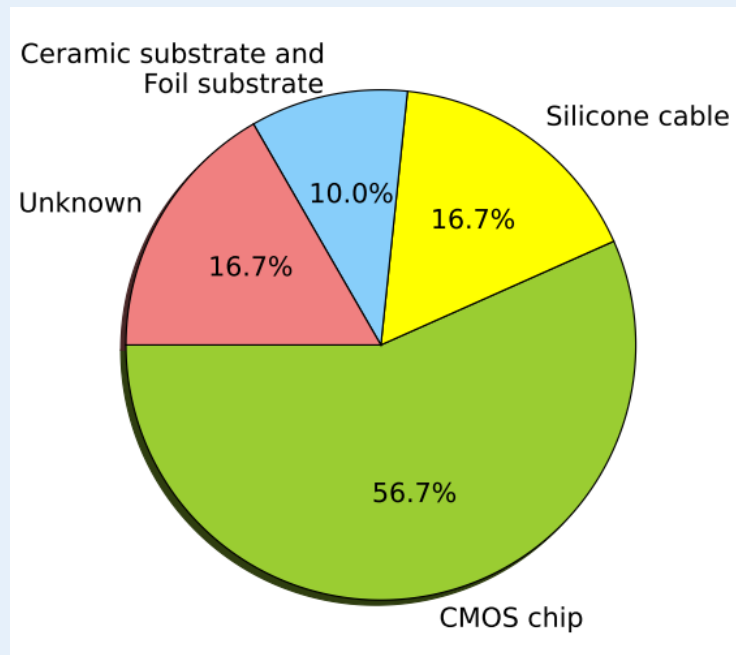




Zrenner E. et al. Subretinal electronic chips allow blind patients to read letters and combine them to words. Proc. R. Soc. B (2011) 278, 1489–1497

Ausfallursachen Alpha IMS

- Mittlere Lebensdauer: 7 Monate (Median)
- Analyse der Explantate



R. Daschner et al., Laboratory and clinical reliability of conformally coated subretinal implants, Biomed Microdevices, (2017) 19:7

Funktionsdauer der Systemkomponenten

- Beschleunigte Alterungstests mit Alpha IMS und Alpha AMS**

Component	Alpha IMS τ [years]	Alpha AMS τ [years]
CMOS chip	1.22 (50%)	6.04 (50%)
Foil substrate	3.05 (50%)	12.7 (50%)
Silicone cable	1.57 (50%)	7.04 (50%)
Total median system lifetime $S = 50\%$	0.7 years 8 months	4.7 years 56 months
Clinical study	7 months	?

Daschner R. et al. (2017). Laboratory and clinical reliability of conformally coated subretinal implants. Biomed Microdevices (2017) 19:7; DOI 10.1007/s10544-017-0147-6

Zusammenfassung: Retina Implant Alpha AMS

- Neurotechnologisch einzigartige Bauweise (ungehäuster Chip mit 1600 Elektroden)
- Kann alltagspraktische Sehleistungen von Menschen, die an Retinitis Pigmentosa erblindet sind, zu einem gewissen Grad wieder herstellen
- System ist sicher implantierbar und explantierbar.

