Table C-28. Ongoing clinical trials of retina implant model Alpha/Bionic Eye (2 studies)

Clinicaltrials.gov Title Clinicaltrials.gov Identifier Sponsor	Study Design	Purpose	Start Date Expected Completion Date Estimated Enrollment	Primary Outcomes	Secondary Outcomes	Eye-specific Inclusion Criteria	Eye-specific Exclusion Criteria
Safety and Efficacy of Subretinal Implants for Partial Restoration of Vision in Blind Patients: A Prospective Multicenter Clinical Study Based on Randomized Intra-individual Implant Activation in Patients with Degenerative Retinal Diseases NCT01024803 Retina Implant AG	Single-masked (patient) randomized, interventional single-group assignment study with device (Retinal Implant Model Alpha, aka Bionic Eye) in ON/OFF modes	Study aims to determine whether patients who have hereditary retinal degeneration and receive a retinal implant experience a significant VA improvement when the device is ON compared to the OFF condition.	December 2009 March 2018 Recruiting patients n=45	Activities of daily living and mobility via activities of daily living tasks, recognition tasks, mobility, or a combination thereof through 1 year.	VA/light-perception and/or object-recognition via: FrACT/BaLM/ BaGA/VFQ-25 or a combination thereof through 1 year Patient long-term safety and stability of implant function through 1 year	Hereditary retinal degeneration of the outer retinal layers (i.e., photoreceptor rods and cones) Pseudophakia Angiography showing retinal vessels adequately perfused, despite pathological RP condition Blindness (at least monocular; i.e., visual functions not appropriate for localization of objects, self-sustained navigation, or orientation) Ability to read normal print in earlier life, optically corrected without magnifying glass	Period of appropriate visual functions approx. 12 years / lifetime Significant retinal edema and/or scar tissue within target region for implant Retina detected as too thin to expect required rest-functionality of inner retina Lack of inner-retinal function Heavy clumped pigmentation at posterior pole Any other ophthalmologic disease with relevant effect upon visual function (e.g., glaucoma, optic neuropathies, trauma, diabetic retinopathy, retinal detachment) Amblyopia earlier in life on eye to be implanted

Table C-28. Ongoing clinical trials of retina implant model Alpha/Bionic Eye (2 studies) (continued)

Clinicaltrials.gov Title Clinicaltrials.gov Identifier Sponsor	Study Design	Purpose	Start Date Expected Completion Date Estimated Enrollment	Primary Outcomes	Secondary Outcomes	Eye-specific Inclusion Criteria	Eye-specific Exclusion Criteria
Safety & Efficacy of Subretinal Implants for Partial Restoration of Vision in Blind Patients: A Prospective Mono- & Multicenter Clinical Study Based on Randomized Intra-individual Implant Activation in Degenerative Retinal Disease Patients NCT01497379 Retina Implant AG	Single-masked (patient) randomized interventional, single- group assignment study with device in ON/OFF modes	Patients who are legally blind, caused by retinal degeneration of photoreceptor rods and cones (e.g., RP), will receive a subretinal implant to partially restore vision.	October 2011 Completed January 2015 n=2	Safety at 1 year: treatment shows no permanent damage of function or structures that have been functional before surgery and no permanent damage to health and/or well-being of patients Efficacy at 1 year as measured by activities of daily living and mobility that are significantly improved with implant ON versus OFF, as shown via: Activities of Daily Living tasks, or Recognition tasks, or Mobility, or a combination of the above	Patient long-term safety: Stability of implant function Stability of body structure and function related to implant system and visual acuity/light-perception and/or object recognition significantly improved with implant ON vs. OFF as shown via: FrACT or BaLM or Grating test (e.g., BaGA) and/or quality of life or a combination of the above, measured at 1 year	Hereditary retinal degeneration of the outer retinal layers (i.e., photoreceptor rods and cones) Pseudophakia Retinal vessels adequately perfused, despite pathological RP condition Blindness (at least monocular; i.e., visual functions not appropriate for localization of objects, self-sustained navigation or orientation; impaired light localization or worse) Ability to read normal print in earlier life, optically corrected without magnifying glass	Period of appropriate visual functions <12 years/lifetime. Significant retinal edema and/or scar tissue within target region for implant Retina detected as too thin to expect required rest-functionality of inner retina Lack of inner-retinal function Heavy clumped pigmentation at posterior pole Any other ophthalmologic disease with relevant effect upon visual function (e.g., glaucoma, optic neuropathies, trauma, diabetic retinopathy, retinal detachment) Amblyopia earlier in life on eye to be implanted

BaGA=Basic Grating Acuity Test; BaLM= Basic Assessment of Light and Motion (test); FrACT=Freiburg Acuity and Contrast Test; RP=retinitis pigmentosa; VA=visual acuity; VFQ-25=(National Eye Institute) Visual Function Questionnaire