Appendix A. Search Strategies

Resources Searched

ECRI Institute information specialists searched the following databases for relevant information. Search terms and strategies for each resource appear below. Two sets of search results were reviewed for this topic. Searches for information on retinal prosthesis devices were conducted in all of the resources listed below. A second search (corresponding to Key Questions 1B and 1C) to identify literature on psychometric properties of outcome measures in a broader patient population (i.e., patients with low vision) and for a longer time period, was conducted in selected bibliographic databases as indicated below.

Search strategy for Questions 1B and 1C

Name	Date Limits	Platform/Provider
The Cochrane Central Register of Controlled Trials (CENTRAL)	2000 through September 17, 2015	Wiley
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	2000 through September 17, 2015	Wiley
Cumulative Index of Nursing and Allied Health Literature (CINAHL)	2000 through September 30, 2015	EBSCOhost
Database of Abstracts of Reviews of Effects (DARE) (part of the Cochrane Library)	2000 through September 17, 2015	Wiley
EMBASE (Excerpta Medica)	2000 through September 30, 2015 1990 through December 2, 2015 (for KQ1C)	Embase.com
Health Technology Assessment Database (HTA) (part of the Cochrane Library)	2000 through September 17, 2015	Wiley
MEDLINE	2000 through September 30, 2015 1990 through December 1, 2015 (for KQ1C)	Embase.com OVIDSP
PUBMED (PreMEDLINE)	Searched September 17, 2015 Searched December 4, 2015 (for KQ1C)	NLM
U.K. National Health Service Economic Evaluation Database (NHS EED) (part of the Cochrane Library)	2000 through September 17, 2015	Wiley
PsycINFO	1990 through December 1, 2015 (for KQ1C)	OVIDSP
Associations and Societies [websites and meeting abstracts]		
American Academy of Ophthalmology	2013 through September 4, 2015	http://www.aao.org/
American Society of Retinal Specialists	2013 through September 4, 2015	https://www.asrs.org/
ARVO	2013 through September 4, 2015	http://www.arvo.org/
Retina Society	2013 through September 4, 2015	http://www.retinasociety.org/
Other Gray Literature Resources		
ClinicalTrials.gov	Searched September 3, 2015	NIH
Centers for Medicare and Medicaid (CMS) - Medicare Coverage Database	Searched September 9, 2015	CMS

Search strategy for Questions 1B and 1C (continued)

Name	Date Limits	Platform/Provider
ECRI Institute Library Catalog	Searched September 9, 2015	ECRI Institute
ECRI Institute Members Website	Searched September 4, 2015	ECRI Institute
Health Devices	Searched September 4, 2015	ECRI Institute
Healthcare Standards	2000 through September 4, 2015	ECRI Institute
Internet	Searched September 10, 2015	Google; Bing
Manufacturers	Searched September 8, 2015	Google; Bing; individual manufacturer websites
MediRegs	Searched September 15, 2015	Wolters Kluwer
MedlinePlus	Searched September 9, 2015	National Library of Medicine
Medscape	Searched September 9, 2015	WebMD
National Guideline Clearinghouse™ (NGC)	Searched September 4, 2015	AHRQ
National Institute for Health and Care Excellence (NICE) UK	Searched September 4, 2015	NHS
TRIP Database	2000 through September 9, 2015	
U.S. Food and Drug Administration (FDA), including Medical Device databases	Searched September 3, 2015	FDA

Reimbursement

The following Web sites were searched for reimbursement policies: Aetna, Anthem Blue Cross Blue Shield (BCBS), BCBS Alabama, BCBS of Massachusetts, BCBS of North Carolina, BCBS of Tennessee, CIGNA, Harvard Pilgrim, HealthPartners, Humana, Independence Blue Cross, Medica, Regence BCBS, United Healthcare, Wellmark BCBS.

Hand Searches of Journal and Gray Literature

Journals and supplements maintained in ECRI Institute's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

Topic-specific Search Terms

The search strategies employed combinations of free-text keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. Strategies for each bibliographic database follow this table.

Topic-specific Search Terms

Concept	Controlled Vocabulary	Keywords
Retinal Prostheses	**EMBASE (EMTREE)** 'ophthalmological prosthesis'/exp 'ophthalmological implant'/exp 'retinal implant'/exp retina/exp 'visual prosthesis'/exp **MEDLINE(MeSH)** Exp "prostheses and implants"/ Exp retina/ Exp visual prosthesis/ **CINAHL** (MH "prostheses and implants+") (MH "retina+) **PsycINFO** exp prostheses/ exp retina/	Alpha IMS Argus Artificial silicon retinal microchip ASR Epi-ret Bionic Bionics Institute Bionic Vision Boston retinal implant project electrode epiretinal "intelligent medical implants implant implants implanted implanting IRIS microchip Nidek Okayama ophthalmologic Optobionics OUReP photovoltaic pixium PRIMA prosthetic prosthesis retina retinal second sight STS Suprachoroidal transretinal stimulation Suprachoroidal retinal prosthesis Visus
Vision impairment	**EMBASE (EMTREE)** 'blindness'/exp 'low vision'/exp 'retina disease'/exp 'retinitis pigmentosa'/exp 'retinitis'/exp 'retina degeneration'/exp 'retina pigment degeneration'/exp 'visual impairment'/exp	Blindness degenerat* impair* loss 'low vision' macular degeneration retina degeneration retinitis sight vision

Concept	Controlled Vocabulary	Keywords
	MEDLINE (MeSH) exp blindness/ exp retinal degeneration exp retinal diseases/ exp retinitis pigmentosa/ exp vision disorders/ exp vision, low/ exp visually impaired persons/ **CINAHL** (MH "blindness+") (MH "Retinitis Pigmentosa+") (MH "vision disorders+") (MH "vision, subnormal+") **PsycINFO** exp vision disorders/ exp blind/ exp eye disorders/	visual
Selected Outcomes	**EMBASE (EMTREE)** 'quality of life'/exp 'quality of working life'/exp 'daily life activity'/exp 'adl disability'/exp 'visual system function'/exp **MEDLINE (MeSH)** exp "Quality of Life"/ exp "activities of daily living"/ exp "quality-adjusted life years"/ exp "disability evaluation"/ **CINAHL** (MH "activities of daily living+") (MH "rehabilitation of vision impaired+") (MH "Quality of Life+") (MH "Quality of Working Life") **PsycINFO** Exp "quality of life"/ Exp "quality of work life"/ Exp "activities of daily living"/ Exp "self care skills"/ exp visual perception/	activities of daily living adl bathe bathing bathroom cook cooking daily activity dress dressing drive driving eat eating hrqol iadl mobility orientation orienting phone quality of life qol shop shopping toilet* visual adaptation visual function

Concept	Controlled Vocabulary	Keywords
		visual orientation walk walking
Measurement terms	**EMBASE (EMTREE)** 'assessment of humans'/exp 'eye disease assessment'/exp 'functional status assessment'/exp 'general health status assessment'/exp 'outcome assessment'/exp 'psychologic test'/exp psychometry/exp 'quality of life assessment'/exp 'quality of life index'/exp 'visual system parameters'/exp **MEDLINE (MeSH)** exp Patient Outcome Assessment/ exp "Outcome Assessment (Health Care)"/ exp psychometrics/ exp psychological tests/ exp sickness impact profile/ exp questionnaires/ exp vision tests/ **CINAHL** (MH "disability evaluation+") (MH "Psychometrics") (MH "Measurement Issues and Assessments+") (MH "Outcome Assessment") (MH "Clinical Assessment Tools+") (MH "Functional Assessment+") (MH "Ferrans and Powers Quality of Life Index") (MH "Psychological Tests+") (MH "Questionnaires+") **PsycINFO** Exp disability evaluation/ Exp psychometrics Exp measurement/ Exp inventories/ Esp questionnaires/	assess assessment clinometric clinimetric index instrument* inventory inventories measure* psychometric* questionnaire* scale scales test tests
Named Measurement Tools		Activity Inventory Basic Assessment of Light and Motion Basic Grating Acuity Brief Symptom Inventory"

Concept	Controlled Vocabulary	Keywords
		Daily Living Tasks Dependent on Vision (DLTV) Daily task performance questionnaire Freiburg VA test Functional Low-Vision Observer Rated Assessment (FLORA) Form Vision Assessment Functioning Questionnaire (VA LV VFQ) Goldmann visual field test Grating acuity test (GAT) Impact of Vision Impairment (IVI) Landolt-C rings test Low Luminance Questionnaire (LLQ) Low Vision Letter Acuity Macular Disease Quality of Life (MacDQoL) Macular Disease Society Questionnaire (MDSQ) National Eye Institute Visual Function Questionnaire (NEI-VFQ) NEI-VF1-25 Nine item questionnaire Night vision questionnaire (NVQ) Retinopathy Dependent Quality of Life measure (RetDQOL) Self Report and Observation of Performance Seven item questionnaire Spatial Mapping of Stimulated Visual Phosphene Fields Thirty-five item questionnaire VisQOL vision-related quality of life Veterans Affairs Low Vision Visual
Reliability/Validity	**EMBASE (EMTREE)** 'discriminant analysis'/exp 'measurement precision'/exp reliability/exp reproducibility/exp validity/exp 'Rasch analysis'/exp 'Validation study'/exp 'comparative study'/exp psychometry/exp 'outcomes research'/exp 'observer variation'/exp reproducibility/exp	Agreement ceiling effect clinimetric clinometric concordance consistency computer adaptive testing correlation cronbach's alpha dependability discriminative equivalence factor analysis

Concept	Controlled Vocabulary	Keywords
		floor effect
	MEDLINE (MeSH)	generalizability
	Exp "Reproducibility of Results"/	homogeneity
	Exp "Validation study"/	homogeneous
	Exp "Comparative Study"/	indicator
	Exp "observer variation"/	instrumentation
	Exp "Health Status Indicators"/	intra-examiner
	Exp "reproducibility of results"/	inter-examiner
	Exp "discriminant analysis"/	inter-observer
		intra-observer
	CINAHL	inter-rater
	(MH "Precision")	intra-rater
	(MH "Reliability and Validity+")	interscale
	(MH "Reproducibility of Results")	intra-technician
		inter-technician
	PsycINFO	inter-tester
	exp Test Validity/	intra-tester
	exp Statistical Validity/	item bank
	exp test reliability/	kappa
	exp Statistical Reliability/	known group
	exp Interrater Reliability/	methods
	exp item response theory/	multitrait
		observer variation
		outcome
		precision
		qualitative*
		rasch
		reliable
		reliability
		repeatable
		repeatability
		reproducible
		reproducibility
		responsive*
		stability
		test-retest
		uncertainty
		valid*
		variability

SEARCH STRATEGIES FOR RETINAL PROSTHESIS SYSTEMS (KEY QUESTIONS: 1A, 1B, 2-5)

EMBASE/MEDLINE (searched via Embase.com)

Set Number	Concept	Search Statement
1	Retinal prostheses	('retinal implant'/exp OR (('visual prosthesis'/exp OR 'ophthalmological prosthesis'/exp OR 'ophthalmological implant'/exp) AND (retina/exp OR retina/de)) OR (implant* OR prosthes* OR prosthet* OR stimluat* OR microchip* OR electrode* OR photovoltaic*) NEAR/3 (retina OR retinal OR epiretina* OR subretina* OR transretina* OR suprachoroidal)
2	Named Devices	(Argus* OR (alpha next/2 IMS) OR (epi next/1 ret) OR "second sight" OR "intelligent medical implants" OR pixium OR "sts" OR "suprachoroidal transretinal stimulation" OR nidek OR "suprachoroidal retinal prosthesis" OR "bionics institute" OR "bionic vision" OR bionicvision OR "bionic eye" OR "boston retinal implant project" OR visus OR optobionics OR "asr" OR "artificial silicon retinal microchip" OR IRIS OR PRIMA OR "photovoltaic retinal prosthesis" OR OUReP OR okayama) AND ('retinal implant'/exp OR 'visual prosthesis'/exp OR 'ophthalmological prosthesis'/exp OR 'ophthalmological implant'/exp OR ((implant* OR prosthes* OR prosthet* OR stimluat* OR microchip* OR electrode* OR photovoltaic*) NEAR/3 (retina OR retinal OR epiretina* OR subretina* OR transretina* OR ophthalmologic)))
3	Combine sets	1 OR 2
4	Limit by publication type	3 NOT (book OR editorial OR erratum OR letter OR note OR 'short survey')/de OR (book OR editorial OR erratum OR letter OR note OR 'short survey'):it OR (book:pt)
5	Apply Limits	4 AND Limits: Py:2000-2015; humans

EMBASE.com Syntax:

* = truncation character (wildcard)

NEAR/*n* = search terms within a specified number (*n*) of words from each other in any order

NEXT/*n* = search terms within a specified number (*n*) of words from each other in the order specified

/ = search as a subject heading

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

mj = denotes a term that has been searched as a major subject heading

:de = search in the descriptors field (controlled terms and keywords)

:lnk = floating subheading

/lim = limiter

:it,pt. = source item or publication type

:ti. = limit to title

:ti,ab. = limit to title and abstract fields

PubMed (PreMEDLINE)

English language, human

Set Number	Concept	Search Statement
1	Retinal prostheses	("Visual Prosthesis"[Mesh] OR "Prostheses and Implants"[Mesh]) AND "Retina"[Mesh] OR (implant*[tiab] OR prosthes*[tiab] OR prosthet*[tiab] OR stimluat*[tiab] OR microchip*[tiab] OR electrode*[tiab] OR photovoltaic*[tiab]) AND (retina[tiab] OR retinal[tiab] OR epiretina*[tiab] OR subretina*[tiab] OR transretina*[tiab])
2	Named devices	(Argus* OR "alpha ims OR "alpha-ims" OR "epi ret" OR "epi-ret" OR "second sight" OR "intelligent medical implants" OR pixium OR "sts" OR "suprachoroidal transretinal stimulation" OR nidek OR "suprachoroidal retinal prosthesis" OR "bionics institute" OR "bionic vision" OR bionicvision OR "bionic eye" OR "boston retinal implant project" OR visus OR optobionics OR "asr" OR "artificial silicon retinal microchip" OR IRIS OR PRIMA OR "photovoltaic retinal prosthesis" OR OUReP OR okayama) AND ("Visual Prosthesis"[Mesh] OR ((implant*[tiab] OR prosthes*[tiab] OR prosthet*[tiab] OR stimluat*[tiab] OR microchip*[tiab] OR electrode*[tiab] OR photovoltaic*[tiab]) AND (retina[mh] OR retina[tiab] OR retinal[tiab] OR epiretina*[tiab] OR subretina*[tiab] OR transretina*[tiab] OR ophthalmologic[tiab])))
3	Combine sets	1 OR 2
4	Limit to Subfile	3 AND ("in process" [sb] OR publisher[sb])

PubMed Syntax:

* = truncation character (wildcard)

[mh]/[MeSH] = controlled vocabulary term

[sb] = subset

[ti] = limit to title field

[tiab] = limit to title and abstract fields

[tw] = text word

CINAHL

English language, human, exclude MEDLINE records

Set Number	Concept	Search Statement
1	Retinal prostheses	(MH "prostheses and implants+") AND (MH "retina+") OR (implant* OR prosthes* OR prosthet* OR stimluat* OR microchip* OR electrode* OR photovoltaic*) N3 (retina OR retinal OR epiretina* OR subretina* OR transretina*)
2	Named Devices	(Argus* OR (alpha n2 IMS) OR "epi ret" OR "epi-ret" OR "second sight" OR "intelligent medical implants" OR pixium OR "sts" OR "suprachoroidal transretinal stimulation" OR nidek OR "suprachoroidal retinal prosthesis" OR "bionics institute" OR "bionic vision" OR bionicvision OR "bionic eye" OR "boston retinal implant project" OR visus OR optobionics OR "asr" OR "artificial silicon retinal microchip" OR IRIS OR PRIMA OR "photovoltaic retinal prosthesis" OR OUReP OR okayama) AND (implant* OR prosthes* OR prosthet* OR stimluat* OR microchip* OR electrode* OR photovoltaic*) AND (retina OR retinal OR epiretina* OR subretina* OR transretina* OR ophthalmologic)))
3	Combine sets	1 OR 2
4	Exclude Medline records	

CINAHL Syntax:

* = truncation character (wildcard)

N*n* = search terms within a specified number (*n*) of words from each other in any order

TI = limit to title field

AB = limit to title and abstract fields

MH = MeSH heading

MJ = MeSH heading designated as major topic

PT = publication type

SEARCH STRATEGIES FOR RELIABLE AND VALID PSYCHOMETRIC PROPERTIES IN PATIENTS WITH LOW VISION (KEY QUESTION 1C)

MEDLINE/PSYCINFO (searched via Ovid)

Set Number	Concept	Search Statement
1	Low vision/blindness terms	
	MeSH	exp blindness/ OR exp retinitis pigmentosa/ OR exp vision disorders/ OR exp vision, low/ OR exp visually impaired persons/ OR exp retinal degeneration OR exp retinal diseases/
		OR
	PsycInfo	exp vision disorders/ OR exp blind/ OR exp eye disorders/
		OR
	Keywords	blindness OR 'low vision' OR ((vision OR sight) ADJ2 (impair* OR loss OR low)) OR retinitis OR ((retina* OR macula*) AND degenerat*) OR (retinitis ADJ1 pigment*)
2	Selected Outcomes	
	MeSH	exp "Quality of Life"/ OR exp "activities of daily living"/ OR exp "disability evaluation"/ OR exp "quality-adjusted life years"/
		OR
	PsycINFO	exp "quality of life"/ OR exp "quality of work life"/ OR exp "activities of daily living"/ OR exp "self care skills"/ OR exp visual perception/
	Keywords	OR
		"quality of life" OR "qol" OR "hrqol" OR (activity ADJ3 "daily living") OR (activities ADJ3 "daily living") OR "adl" OR "iadl" OR (daily ADJ3 activity) OR ((vision OR visual) ADJ3 (function* OR orient* OR adapt* OR acquity)) OR walk OR walking OR bathe OR bathing OR dress OR dressing OR eat OR eating OR bathroom OR toilet* OR cook OR cooking OR drive OR driving OR phone OR shop OR shopping OR mobility OR orientation OR orienting OR reading OR ((facial OR feature* OR color* OR pattern*) ADJ2 (recognition OR recogniz*))
3	Measurement terms	
	MeSH	exp *Patient Outcome Assessment/ or exp *"Outcome Assessment (Health Care)"/ or exp *psychometrics/ or exp *psychological tests/ or exp *sickness impact profile/ or exp *questionnaires/
		OR
	PsycINFO	exp *disability evaluation/ or exp *psychometrics/ or exp *measurement/ or exp *inventories/ or exp *questionnaires/
		OR
	Keywords	(((psycho* or clinimetr* or clinometr* or disability or disabled) and (test or tests or scale or scales or instrument* or index or indices or measure* or assessment or assess OR property OR properties OR characteristic*)) or (function* adj2 assess*) or (measure* adj2 propert*) or (measure* adj3 characteristic*) or questionnaire*).ti,ab.

Set Number	Concept	Search Statement
4	Named Measurement tools	"Daily Living Tasks Dependent on Vision" OR "DLTV" OR "Macular Disease Quality of Life" OR "MacDQoL" OR "Impact of Vision Impairment" OR "IVI" OR "Veterans Affairs Low Vision Visual Functioning Questionnaire" OR "VA LV VFQ" OR "Activity Inventory" OR "National Eye Institute Visual Function Questionnaire" OR "NEI-VFQ*" OR "Macular Disease Society Questionnaire" OR "MDSQ" OR "Low Luminance Questionnaire" OR "LLQ" OR "Retinopathy Dependent Quality of Life measure" OR "RetDQOL" OR "Night vision questionnaire" OR "NVQ" OR (item ADJ questionnaire) OR "Daily task performance questionnaire" OR "Functional Low Vision Observer Rated Assessment" OR "FLORA" OR ("Self Report" ADJ "Observation of Performance") OR "Goldmann Visual Field test" OR "VisQOL" OR "grating acuity" OR "GAT" OR "Brief Symptom Inventory" OR "Freiburg VA test" OR ("Basic Assessment of Light" ADJ Motion) OR "BaLM" OR "Basic Grating Acuity" OR (landolt ADJ2 ring*) OR "NEI-VF1-25" OR "vision-related quality of life" OR "Low Vision Letter Acuity" OR "Spatial Mapping of Stimulated Visual Phosphene Fields" OR "Form Vision Assessment" OR "logMAR" OR (Freiberg ADJ3 acuity) OR "FrACT" OR (("early diabetic retinopathy study" OR "ETDRS") ADJ1 acuity) OR ((Farnsworth OR chow) ADJ2 color) OR "brief symptom inventory"
5	Combine Sets	3 OR 4

Set Number	Concept	Search Statement
6	Reliability/Validity/Reproducibility/ Responsiveness MeSH PsycINFO Keywords	 exp "Reproducibility of Results"/ OR exp "Validation study" OR exp "Comparative Study"/ OR exp "observer variation"/ OR exp "Health Status Indicators"/ OR exp "reproducibility of results"/ OR exp "discriminant analysis"/ OR exp Test Validity/ OR exp Statistical Validity/ OR exp test reliability/ OR exp Statistical Reliability/ OR exp Interrater Reliability/ OR exp item response theory/ OR clinimetr* OR clinometr* OR (outcome ADJ1 measure*) OR "observer variation" OR "health status indicator" OR reproducib* OR unreliab* OR valid* OR coefficient OR homogeneity OR homogeneous OR "internal consistency" OR (cronbach* AND (alpha OR alphas)) OR (item AND (correlation* OR selection* OR reduction*)) OR agreement OR precision OR imprecision OR "precise values" OR (test ADJ1 retest) OR (reliab* AND (test OR retest)) OR stability OR interrater OR inter-rater OR intrarater OR intra-rater OR intertester OR inter-tester OR intratester OR intra-tester OR interobserver OR inter-observer OR intraobserver OR intraobserver OR intertechnician OR inter-technician OR intratechnician OR intra-technician OR interexaminer OR inter-examiner OR intraexaminer OR intra-examiner OR interindividual OR inter-individual OR intraindividual OR intra-individual OR interparticipant OR inter-participant OR intraparticipant OR intra-participant OR kappa OR kappas OR repeatab* OR ((replicab* OR repeated) AND (measure OR measures OR findings OR result OR results OR test OR tests)) OR generaliza* OR generalisa* OR concordance OR (intraclass AND correlation*) OR discriminative OR "known group" OR "factor analysis" OR "factor analyses" OR dimension* OR subscale* OR (multitrait AND scaling AND (analysis OR analyses)) OR "item discriminant" OR (interscale ADJ correlation) OR "individual variability" OR (variability AND (analysis OR values)) OR (uncertainty AND (measurement OR measuring)) OR "standard error of measurement" OR sensitivity OR responsiveness OR ((minimal OR minimally OR clinical OR clinically) AND (important OR significant OR detectable) AND (change OR difference)) OR (small* AND (real OR detectable) AND (change OR difference)) OR "meaningful change" OR "ceiling effect" OR "floor effect" OR "item response model" OR Rasch OR "Differential item functioning" OR "computer adaptive testing" OR "item bank" OR "cross-cultural equivalence"
7	Combine sets	1 AND 2 AND 5 AND 6
8	Remove unwanted publication types	7 NOT (("column/opinion" OR "comment/reply" OR dissertation OR editorial OR letter OR book).dt. OR book.pt. OR (letter/ or editorial/ or news/ or comment/ or case report or case reports/ or note/ or conference paper/) or (letter or editorial or news or comment or case reports or conference abstract*).pt.)
9	Apply limits	Limits: Py:1990-2015; humans; English language
10	Remove duplicates	

OVID Syntax:

* = truncation character (wildcard)

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication type

.ti. = limit to title

.tw. = limit to title and abstract fields

EMBASE (searched via Embase.com)

Set Number	Concept	Search statement
1	Low vision/blindness terms	'blindness'/exp OR 'low vision'/exp OR 'retina disease'/exp OR 'retinitis pigmentosa'/exp OR 'retinitis'/exp OR 'retina degeneration'/exp OR 'retina pigment degeneration'/exp OR 'visual impairment'/exp OR blindness OR 'low vision' OR ((vision OR sight) NEAR/2 (impair* OR loss OR low)) OR retinitis OR ((retina* OR macula*) AND degenerat*) OR (retinitis NEAR/1 pigment*)
2	Selected Outcomes	'quality of life'/exp OR 'quality of working life'/exp OR 'daily life activity'/exp OR 'adl disability'/exp OR 'visual system function'/exp OR "quality of life" OR "qol" OR "hrqol" OR (activity NEAR/3 "daily living") OR (activities NEAR/3 "daily living") OR "adl" OR "iadl" OR (daily NEAR/3 activity) OR ((vision OR visual) NEAR/3 (function* OR orient* OR adapt* OR acuity)) OR walk OR walking OR bathe OR bathing OR dress OR dressing OR eat OR eating OR bathroom OR toilet* OR cook OR cooking OR drive OR driving OR phone OR shop OR shopping OR mobility OR orientation OR orienting OR reading OR ((facial OR feature* OR color* OR pattern*) NEAR/2 (recognition OR recogniz*))
3	Measurement terms	'assessment of humans'/exp/mj OR 'eye disease assessment'/exp/mj OR 'functional status assessment'/exp/mj OR 'general health status assessment'/exp/mj OR 'outcome assessment'/exp/mj OR 'psychologic test'/exp/mj OR psychometry/exp/mj OR 'quality of life assessment'/exp/mj OR 'quality of life index'/exp/mj OR 'visual system parameters'/exp/mj OR 'questionnaire'/exp/mj OR (((psycho* or clinimetr* or clinometr* or disability or disabled) and (test or tests or scale or scales or instrument* or index or indices or measure* or assessment or assess OR property OR properties OR characteristic*)) or (function* NEAR/2 assess*) or (measure* NEAR/2 propert*) or (measure* NEAR/3 characteristic*) or questionnaire*):ti,ab

Set Number	Concept	Search statement
4	Named Measurement tools	"Daily Living Tasks Dependent on Vision" OR "DLTV" OR "Macular Disease Quality of Life" OR "MacDQoL" OR "Impact of Vision Impairment" OR "IVI" OR "Veterans Affairs Low Vision Visual Functioning Questionnaire" OR "VA LV VFQ" OR "Activity Inventory" OR "National Eye Institute Visual Function Questionnaire" OR (NEI NEXT/1 VFQ*) OR "Macular Disease Society Questionnaire" OR "MDSQ" OR "Low Luminance Questionnaire" OR "LLQ" OR "Retinopathy Dependent Quality of Life measure" OR "RetDQOL" OR "Night vision questionnaire" OR "NVQ" OR (item NEAR/1 questionnaire) OR "Daily task performance questionnaire" OR "Functional Low Vision Observer Rated Assessment" OR "FLORA" OR ("Self Report" NEXT/1 "Observation of Performance") OR "Goldmann Visual Field test" OR "VisQOL" OR "grating acuity" OR "GAT" OR "Brief Symptom Inventory" OR "Freiburg VA test" OR ("Basic Assessment of Light" NEAR/1 Motion) OR "BaLM" OR "Basic Grating Acuity" OR (landolt NEAR/2 ring*) OR "NEI-VF1-25" OR "vision-related quality of life" OR "Low Vision Letter Acuity" OR "Spatial Mapping of Stimulated Visual Phosphene Fields" OR "Form Vision Assessment" OR "logMAR" OR (Freiberg NEAR/3 acuity) OR "FrACT" OR (("early diabetic retinopathy study" OR "ETDRS") NEAR/1 acuity) OR ((Farnsworth OR chow) NEAR/2 color) OR "brief symptom inventory"
5	Combine Sets	3 OR 4

Set Number	Concept	Search statement
6	Reliability/Validity/Reproducibility/ Responsiveness	'discriminant analysis'/exp OR 'measurement precision'/exp OR reliability/exp OR reproducibility/exp OR validity/exp OR 'Rasch analysis'/exp OR 'Validation study'/exp OR 'comparative study'/exp OR 'outcomes research'/exp OR 'observer variation'/exp OR clinimetr* OR clinometr* OR (outcome NEAR/1 measure*) OR "observer variation" OR "health status indicator" OR reproducib* OR unreliab* OR valid* OR coefficient OR homogeneity OR homogeneous OR "internal consistency" OR (cronbach* AND (alpha OR alphas)) OR (item AND (correlation* OR selection* OR reduction*)) OR agreement OR precision OR imprecision OR "precise values" OR (test NEAR/1 retest) OR (reliab* AND (test OR retest)) OR stability OR interrater OR inter-rater OR intrarater OR intra-rater OR intertester OR inter-tester OR intratester OR intra-tester OR interobserver OR inter-observer OR intraobserver OR intraobserver OR intertechnician OR inter-technician OR intratechnician OR intra-technician OR interexaminer OR inter-examiner OR intraexaminer OR intra-examiner OR interindividual OR inter-individual OR intraindividual OR intra-individual OR interparticipant OR inter-participant OR intraparticipant OR intra-participant OR kappa OR kappas OR repeatab* OR ((replicab* OR repeated) AND (measure OR measures OR findings OR result OR results OR test OR tests)) OR generaliza* OR generalisa* OR concordance OR (intraclass AND correlation*) OR discriminative OR "known group" OR "factor analysis" OR "factor analyses" OR dimension* OR subscale* OR (multitrait AND scaling AND (analysis OR analyses)) OR "item discriminant" OR (interscale NEAR correlation) OR "individual variability" OR (variability AND (analysis OR values)) OR (uncertainty AND (measurement OR measuring)) OR "standard error of measurement" OR sensitivity OR responsiveness OR ((minimal OR minimally OR clinical OR clinically) AND (important OR significant OR detectable) AND (change OR difference)) OR (small* AND (real OR detectable) AND (change OR difference)) OR "meaningful change" OR "ceiling effect" OR "floor effect" OR "item response model" OR Rasch OR "Differential item functioning" OR "computer adaptive testing" OR "item bank" OR "cross-cultural equivalence"
7	Combine sets/apply limits	1 AND 2 AND 5 AND 6 AND ([humans]/lim AND [english]/lim AND [1990-2016]/py)
8	Limit to EMBASE only records	7 AND [EMBASE]/lim
9	Limit to MEDLINE only records	7 AND [MEDLINE]/lim
10	Remove Medline records (captured in the Ovid search), limit to articles, articles in press (excludes publications from conferences, books, notes, editorials, short surveys)	8 NOT 9 AND ([article]/lim OR [article in press]/lim OR [review]/lim)

EMBASE.com Syntax:

*	=	truncation character (wildcard)
NEAR/*n*	=	search terms within a specified number (*n*) of words from each other in any order
NEXT/*n*	=	search terms within a specified number (*n*) of words from each other in the order specified
/	=	search as a subject heading
exp	=	"explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)
mj	=	denotes a term that has been searched as a major subject heading
:de	=	search in the descriptors field (controlled terms and keywords)
:lnk	=	floating subheading
:it,pt.	=	source item or publication type
:ti.	=	limit to title

PubMed (PreMedline)

Set Number	Concept	Search Statement
1	Low vision	Blindness[mh] OR "Retinitis Pigmentosa"[Mesh] OR vision disorders[mh] OR "Vision, Low"[Mesh] OR "visually impaired persons"[Mesh] OR "retinal degeneration"[Mesh] OR "retinal diseases"[Mesh] OR blindness[tiab] OR "low vision"[tiab] OR (vision[tiab] OR visual[tiab] OR sight[tiab]) AND (loss[tiab] OR impaired[tiab] OR impairment[tiab]) OR retinitis[tiab] OR ((retina*[tiab] OR macular[tiab]) AND degenerat*[tiab])
2	Outcomes	"Quality of Life"[Mesh] OR "activities of daily living"[Mesh] OR "disability evaluation"[Mesh] OR "quality-adjusted life years"[Mesh] OR "quality of life" OR "qol" OR "hrqol" OR "activities of daily living" OR "adl" OR "iadl" OR "daily activities" OR ((vision[tiab] OR visual[tiab]) AND (function*[tiab] OR orient*[tiab] OR adapt*[tiab])) OR walk[tiab] OR walking[tiab] OR bathe[tiab] OR bathing[tiab] OR dress[tiab] OR dressing[tiab] OR eat[tiab] OR eating[tiab] OR bathroom[tiab] OR toilet*[tiab] OR cook[tiab] OR cooking[tiab] OR drive[tiab] OR driving[tiab] OR phone[tiab] OR shop[tiab] OR shopping[tiab] OR mobility[tiab] OR orientation[tiab] OR orienting[tiab] OR reading[tiab] OR ((facial[tiab] OR feature*[tiab] OR color*[tiab] OR pattern*[tiab]) AND (recognition[tiab] OR recogniz*[tiab]))
3	Measurements	"Patient Outcome Assessment"[Mesh] OR "Outcome Assessment (Health Care)"[Mesh] OR psychometrics[Mesh] OR psychological tests[Mesh] OR questionnaires[Mesh] OR "sickness impact profile"[Mesh] OR "vision tests"[Mesh] OR "functional assessment" OR scale[tiab] OR scales[tiab] OR instrument*[tiab] OR index[tiab] OR measure*[tiab] OR assessment[tiab] OR assess[tiab] OR psychometric*[tiab] OR inventory[tiab] OR inventories[tiab] OR questionnaire*[tiab] OR test[tiab] OR tests[tiab]
4	Named Measurement Tools	"Daily Living Tasks Dependent on Vision" OR "DLTV" OR "Macular Disease Quality of Life" OR "MacDQoL" OR "Impact of Vision Impairment" OR "IVI" OR "Veterans Affairs Low Vision Visual Functioning Questionnaire" OR "VA LV VFQ" OR "Activity Inventory" OR "National Eye Institute Visual Function Questionnaire" OR "NEI-VFQ" OR "Macular Disease Society Questionnaire" OR "MDSQ" OR "Low Luminance Questionnaire" OR "LLQ" OR "Retinopathy Dependent Quality of Life measure" OR "RetDQOL" OR "Night vision questionnaire" OR "NVQ" OR "item questionnaire" OR "Daily task performance questionnaire" OR "Functional Low Vision Observer Rated Assessment" OR "FLORA" OR ("Self Report" AND "Observation of Performance") OR "Goldmann Visual Field test" OR "VisQOL" OR "grating acuity" OR "GAT" OR "Brief Symptom Inventory" OR "Freiburg VA test" OR "Basic Assessment of Light" OR "BaLM" OR "Basic Grating Acuity" OR ((landolt[tiab] AND (ring[tiab] OR rings[tiab])) OR "NEI-VF1-25" OR "vision-related quality of life" OR "Low Vision Letter Acuity" OR "Spatial Mapping of Stimulated Visual Phosphene Fields" OR "Form Vision Assessment" OR "logMAR" OR (Freiberg[tiab] AND acuity) OR "FrACT" OR (("early diabetic retinopathy study" OR "ETDRS") AND acuity) OR ((Farnsworth[tiab] OR chow[tiab]) AND color) OR "brief symptom inventory"
5	Combine sets	3 OR 4

Set Number	Concept	Search Statement
6	Reliability/Validity/ Reproducibility	"Reproducibility of Results"[Mesh] OR "validation study"[Mesh] OR "comparative study"[Mesh] OR "observer variation"[Mesh] OR "Health Status Indicators"[Mesh] OR "reproducibility of results"[Mesh] OR "discriminant analysis"[Mesh] OR clinimetr* OR clinometr* OR (outcome AND measure*) OR "observer variation" OR "health status indicator" OR reproducib* OR unreliab* OR valid* OR coefficient OR homogeneity OR homogeneous OR "internal consistency" OR (cronbach* AND (alpha OR alphas)) OR (item AND (correlation* OR selection* OR reduction*)) OR agreement OR precision OR imprecision OR "precise values" OR (test AND retest) OR (reliab* AND (test OR retest)) OR stability OR interrater OR inter-rater OR intrarater OR intra-rater OR intertester OR inter-tester OR intratester OR intra-tester OR interobserver OR inter-observer OR intraobserver OR intraobserver OR intertechnician OR inter-technician OR intratechnician OR intra-technician OR interexaminer OR inter-examiner OR intraexaminer OR intra-examiner OR interindividual OR inter-individual OR intraindividual OR intra-individual OR interparticipant OR inter-participant OR intraparticipant OR intra-participant OR kappa OR kappas OR repeatab* OR ((replicab* OR repeated) AND (measure OR measures OR findings OR result OR results OR test OR tests)) OR generaliza* OR generalisa* OR concordance OR (intraclass AND correlation*) OR discriminative OR "known group" OR "factor analysis" OR "factor analyses" OR dimension* OR subscale* OR (multitrait AND scaling AND (analysis OR analyses)) OR "item discriminant" OR (interscale AND correlation) OR "individual variability" OR (variability AND (analysis OR values)) OR (uncertainty AND (measurement OR measuring)) OR "standard error of measurement" OR sensitivity OR responsiveness OR ((minimal OR minimally OR clinical OR clinically) AND (important OR significant OR detectable) AND (change OR difference)) OR (small* AND (real OR detectable) AND (change OR difference)) OR "meaningful change" OR "ceiling effect" OR "floor effect" OR "item response model" OR Rasch OR "Differential item functioning" OR "computer adaptive testing" OR "item bank" OR "cross-cultural equivalence"
7	Combine sets	1 AND 2 AND 5 AND 6
8	Remove unwanted publication types, non-human studies	7 NOT (comment[pt] OR editorial[pt] OR letter[pt] OR news[pt] OR "Textbooks" [pt] OR "Book Reviews"[pt] OR "Book Illustrations"[pt] OR animal*[tiab] OR rat[tiab] OR rats[tiab] OR mouse[tiab] OR mice[tiab] OR goat*[tiab] OR pig[tiab] OR pigs[tiab] OR cadaver*[tiab] OR dog[tiab] OR dogs[tiab] OR monkey*[tiab] OR ape[tiab] OR apes[tiab])
9	Limit to inprocess citations	8 AND ("inprocess"[sb] OR publisher[sb] OR pubmednotmedline[sb])

PubMed Syntax:

* = truncation character (wildcard)

[mh]/[MesH] = controlled vocabulary term

[sb] = subset

[ti] = limit to title field

[tiab] = limit to title and abstract fields

[tw] = text word

Appendix B. Excluded Studies

Abateneh A, Tesfaye M, Bekele S, et al. Vision loss and psychological distress among Ethiopians adults: a comparative cross-sectional study. PLoS ONE. 2013;8(10):e78335. Also available: http://dx.doi.org/10.1371/journal.pone.0078335. PMID: 24205202. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Ahmadian L, Massof R. Does functional vision behave differently in low-vision patients with diabetic retinopathy? A case-matched study. Invest Ophthalmol Vis Sci. 2008 Sep;49(9):4051-7. Also available: http://dx.doi.org/10.1167/iovs.07-1507. PMID: 18552389. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Ahmadian L, Massof R. Impact of general health status on validity of visual impairment measurement. Ophthalmic Epidemiol. 2008 Sep-Oct;15(5):345-55. Also available: http://dx.doi.org/10.1080/09286580802227402. PMID: 18850472. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Ahmed I. October Consultation # 9. J Cataract Refract Surg. 2006 Oct;32(10):1600-1. Also available: http://dx.doi.org/10.1016/j.jcrs.2006.08.007. Not relevant RPS

Ahn SJ, Legge GE, Luebker A. Printed cards for measuring low-vision reading speed. Vision Res. 1995 Jul;35(13):1939-44. No patient-centered outcome

Ahuja AK, Behrend MR. The Argus II retinal prosthesis: Factors affecting patient selection for implantation. Prog Retin Eye Res. 2013;1-23. Also available: http://dx.doi.org/10.1016/j.preteyeres.2013.01.002. PMID: 23500412. No patient-centered outcome

Ahuja AK, Dorn JD, Caspi A, et al. Blind subjects implanted with the Argus II retinal prosthesis are able to improve performance in a spatial-motor task. Br J Ophthalmol. 2011 Apr;95(4):539-43. Also available: http://dx.doi.org/10.1136/bjo.2010.179622. PMID: 20881025. Duplicate data

Ahuja AK, Yeoh J, Dorn JD, et al. Factors affecting perceptual threshold in Argus II retinal prosthesis subjects. Transl Vis Sci Technol. 2013 Apr;2(4):1. Also available: http://dx.doi.org/10.1167/tvst.2.4.1. PMID: 24049718. No patient-centered outcome

Akeo K, Hiida Y, Saga M, et al. Correlation between contrast sensitivity and visual acuity in retinitis pigmentosa patients. Ophthalmologica. 2002 May-Jun;216(3):185-91. PMID: 12065855. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Al Yaman M, Al Atabany W, Bystrov A, et al. FPGA design for dual-spectrum Visual Scene Preparation in retinal prosthesis. Conf Proc IEEE Eng Med Biol Soc. 2014;2014:4691-4. Also available: http://dx.doi.org/10.1109/EMBC.2014.6944671. PMID: 25571039. Technical report without human data

Alcubierre N, Rubinat E, Traveset A, et al. A prospective cross-sectional study on quality of life and treatment satisfaction in type 2 diabetic patients with retinopathy without other major late diabetic complications. Health Qual Life Outcomes. 2014;12:131. Also available: http://dx.doi.org/10.1186/s12955-014-0131-2. PMID: 25138117. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Allen P, Ayton L, Yeoh J, et al. First-in-human clinical trial of a suprachoroidal retinal prosthesis. Neuromodulation. 2014 Jul;17(5). Also available: http://dx.doi.org/10.1111/ner.12232. Duplicate data

Allen P, Yeoh J, Briggs R, et al. Suprachoroidal retinal prostheses: A preliminary clinical trial of three patients. Clin Experiment Ophthalmol. 2014 Nov;42(Suppl 1):60. Also available: http://dx.doi.org/10.1111/ceo.12448. Duplicate data

Alteheld N, Roessler G, Vobig M, et al. The retina implant new approach to a visual prosthesis. Biomed Tech. 2004 Apr;49(4):99-103. Narrative review

Alteheld N, Roessler G, Walter P. Towards the bionic eye--the retina implant: surgical, opthalmological and histopathological perspectives. Acta Neurochir Suppl. 2007;97(Pt 2):487-93. PMID: 17691339. Technical report without human data

Althin R, Lundstrom M, Roos P. A new index approach to measure lost benefits from progression to blindness. Int J Technol Assess Health Care. 2002;18(3):635-44. PMID: 12391956. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Al-Zboon E, Smadi J. Self-determination of women with disabilities. Europ J Spec Needs Educ. 2015 Jul 3;30(3):412-21. Also available: http://dx.doi.org/10.1080/08856257.2015.1009704. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Anderson AJ, Johnson CA, Werner JS. Measuring visual function in age-related macular degeneration with frequency-doubling (matrix) perimetry. Opt Vis Sci. 2011 Jul;88(7):806-15. Also available: http://dx.doi.org/10.1097/OPX.0b013e31821861bd. PMID: 21478785. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Andrade LC, Souza GS, Lacerda EM, et al. Influence of retinopathy on the achromatic and chromatic vision of patients with type 2 diabetes. BMC Ophthalmol. 2014;14:104. Also available: http://dx.doi.org/10.1186/1471-2415-14-104. PMID: 25174264. No patient-centered outcome

Arimura E, Matsumoto C, Nomoto H, et al. Correlations between M-CHARTS and PHP findings and subjective perception of metamorphopsia in patients with macular diseases. Invest Ophthalmol Vis Sci. 2011 Jan;52(1):128-35. Also available: http://dx.doi.org/10.1167/iovs.09-3535. PMID: 20739469. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Aslam T, Mahmood S, Balaskas K, et al. Repeatability of visual function measures in age-related macular degeneration. Graefes Arch Clin Exp Ophthalmol. 2014 Feb;252(2):201-6. Also available: http://dx.doi.org/10.1007/s00417-013-2421-5. PMID: 23884391. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Ayton LN, Apollo NV, Varsamidis M, et al. Assessing residual visual function in severe vision loss. Invest Ophthalmol Vis Sci. 2014 Mar;55(3):1332-8. Also available: http://dx.doi.org/10.1167/iovs.13-12657. PMID: 24481260. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Ayton LN, Blamey PJ, Guymer RH, et al. First-in-human trial of a novel suprachoroidal retinal prosthesis. PLoS ONE. 2014 Dec 18;9(12):e115239. Also available: http://dx.doi.org/10.1371/journal.pone.0115239. PMID: 25521292. Duplicate data

Ayton LN, Luu CD, Allen PJ, et al. The importance of multidisciplinary collaborations in the future of bionic vision. Expert Rev Ophthalmol. 2013 Feb;8(1):9-11. Also available: http://dx.doi.org/10.1586/eop.12.71. Editorial

Azoulay L, Chaumet-Riffaud P, Jaron S, et al. Threshold levels of visual field and acuity loss related to significant decreases in the quality of life and emotional states of patients with retinitis pigmentosa. Ophthalmic Res. 2015 Sep;54(2):78-84. Also available: http://dx.doi.org/10.1159/000435886. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Babizhayev MA. Glare disability and driving safety. Ophthalmic Res. 2003 Jan-Feb;35(1):19-25. PMID: 12566859. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Bach M, Wilke M, Wilhelm B, et al. Basic quantitative assessment of visual performance in patients with very low vision. Invest Ophthalmol Vis Sci. 2010 Feb;51(2):1255-60. Also available: http://dx.doi.org/10.1167/iovs.09-3512. PMID: 19850846. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Barnes N, Walker J, Lieby P, et al. The impact of environment complexity on mobility performance for prosthetic vision using the visual representation of depth. Clin Experiment Ophthalmol. 2011 Nov;29-30. Also available: http://dx.doi.org/10.1111/j.1442-9071.2011.02690.x. Not relevant RPS

Barry JA, Folkard A, Denniston AK, et al. Development and validation of quality-of-life questionnaires for birdshot chorioretinopathy. Ophthalmology. 2014 Jul;121(7):1488-9.e2. Also available: http://dx.doi.org/10.1016/j.ophtha.2014.01.007. PMID: 24576888. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Barteselli G, Gomez ML, Doede AL, et al. Visual function assessment in simulated real-life situations in patients with age-related macular degeneration compared to normal subjects. Eye (Lond). 2014 Oct;28(10):1231-8. Also available: http://dx.doi.org/10.1038/eye.2014.189. PMID: 25081294. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Beausencourt E, Elsner AE, Hartnett ME, et al. Quantitative analysis of macular holes with scanning laser tomography. Ophthalmology. 1997 Dec;104(12):2018-29. PMID: 9400761. No patient-centered outcome

Bechtel B. Small firm development offers big promise to retinal medicine. Ocular Surg News. 2011 Jun 10;29(11):1-14. Editorial

Berdeaux G, Mesbah M, Bradley C. Metric properties of the MacDQoL, individualized macular-disease-specific quality of life instrument, and newly identified subscales in French, German, Italian, and American populations. Value Health. 2011 Jan;14(1):110-20. Also available: http://dx.doi.org/10.1016/j.jval.2010.10.027. PMID: 21211493. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Besch D, Sachs H, Szurman P, et al. Extraocular surgery for implantation of an active subretinal visual prosthesis with external connections: Feasibility and outcome in seven patients. Br J Ophthalmol. 2008 Oct;92(10):1361-8. Also available: http://dx.doi.org/10.1136/bjo.2007.131961. PMID: 18662916. Not relevant RPS

Bhagat N, Zarbin M. Recent Innovations in Medical and Surgical Retina. Asia Pac J Ophthalmol (Phila). 2013 Jul-Aug;2(4):244-52. Also available: http://dx.doi.org/10.1097/APO.0b013e31829d3dbf. PMID: 26106919. Narrative review

Bhagat N, Zarbin M. Recent Innovations in Medical and Surgical Retina. Asia Pac J Ophthalmol (Phila). 2015 May-Jun;4(3):171-9. Also available: http://dx.doi.org/10.1097/APO.0000000000000121. PMID: 26065505. Not relevant RPS

Bibby SA, Maslin ER, McIlraith R, et al. Vision and self-reported mobility performance in patients with low vision. Clin Exp Optom. 2007 Mar;90(2):115-23. PMID: 17311573. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Bionic eye? Home Healthc Nurse. 2001 Aug 1;19(8):465-6. Editorial

Biro A. Gene therapy, retinal implants may help restore sight in blind patients. Ocular Surg News. 2012 Aug 10;30(15):8-10. Editorial

Biro A. Subretinal implant provides some vision in patients with hereditary retinal degenerative disease... including commentary by Regillo CD. Ocular Surg News. 2012 Sep 25;30(18):1-3. Narrative review

Bittner AK, Gould JM, Rosenfarb A, et al. A pilot study of an acupuncture protocol to improve visual function in retinitis pigmentosa patients. Clin Exp Optom. 2014 May;97(3):240-7. Also available: http://dx.doi.org/10.1111/cxo.12117. PMID: 24773463. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Bittner AK, Haythornthwaite JA, Diener West M, et al. Worse-than-usual visual fields measured in retinitis pigmentosa related to episodically decreased general health. Br J Ophthalmol. 2013 Feb;97(2):145-8. Also available: http://dx.doi.org/10.1136/bjophthalmol-2012-302116. PMID: 23212205. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Bittner AK, Ibrahim MA, Haythornthwaite JA, et al. Vision test variability in retinitis pigmentosa and psychosocial factors. Opt Vis Sci. 2011 Dec;88(12):1496-506. Also available: http://dx.doi.org/10.1097/OPX.0b013e3182348d0b. PMID: 21946786. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Bokinni Y, Shah N, Maguire O, et al. Performance of a computerised visual acuity measurement device in subjects with age-related macular degeneration: Comparison with gold standard ETDRS chart measurements. Eye (Lond). 2015 Aug 14;29(8):1085-91. Also available: http://dx.doi.org/10.1038/eye.2015.94. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Bologna G, Deville B, Diego Gomez J, et al. Toward local and global perception modules for vision substitution. Neurocomputing. 2011 Mar 15;74(8):1182-90. Also available: http://dx.doi.org/10.1016/j.neucom.2010.07.022. Not relevant RPS

Bonotto LB, Moreira AT, Chuffi S, et al. Comparative study of visual functions in premature pre-school children with and without retinopathy of prematurity. Arq Bras Oftalmol. 2014 Jan-Feb;77(1):34-9. PMID: 25076371. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Bourbakis N. Sensing surrounding 3-D space for navigation of the blind. A prototype system featuring vibration arrays and data fusion provides a near real-time feedback. IEEE Eng Med Biol Mag. 2008 Jan-Feb;27(1):49-55. PMID: 18270050. No patient-centered outcome

Boyle EL, Harcharek A, Hasson M, et al. Retinal implant holds potential for end-stage AMD patients... Retina 2011, Ka'anapali, Maui, Hawaii, January 16-21... including commentary by Regillo CD. Ocular Surg News. 2011 Feb 25;29(4):24-5. Editorial

Brabyn JA, Schneck ME, Lott LA, et al. Night driving self-restriction: vision function and gender differences. Optom Vis Sci. 2005 Aug;82(8):755-64. PMID: 16127342. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Brendler C, Pour Aryan N, Rieger V, et al. A Substrate Isolated LDO for an Inductively Powered Retinal Implant. Biomed Tech (Berl). 2013 Sep 7. Also available: http://dx.doi.org/10.1515/bmt-2013-4367. PMID: 24043082. Technical report without human data

Brennan Ing M, Boerner K, Horowitz A, et al. The vision-specific optimization in primary and secondary control (OPS) scale. Eur J Ageing. 2013 Dec;10(4):345-52. PMID: 24443648. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Briesen S, Roberts H, Finger RP. The impact of visual impairment on health-related quality of life in rural Africa. Ophthalmic Epidemiol. 2014 Oct;21(5):297-306. Also available: http://dx.doi.org/10.3109/09286586.2014.950281. PMID: 25133670. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Brody BL, Roch-Levecq AC, Gamst AC, et al. Self-management of age-related macular degeneration and quality of life: a randomized controlled trial. Arch Ophthalmol. 2002 Nov;120(11):1477-83. PMID: 12427060. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Brose LS, Bradley C. Psychometric development of the individualized Retinopathy-Dependent Quality of Life Questionnaire (RetDQoL). Value Health. 2010 Jan-Feb;13(1):119-27. Also available: http://dx.doi.org/10.1111/j.1524-4733.2009.00589.x. PMID: 19695003. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Brose LS, Bradley C. Psychometric development of the retinopathy treatment satisfaction questionnaire (RetTSQ). Psychol Health Med. 2009 Dec;14(6):740-54. Also available: http://dx.doi.org/10.1080/13548500903431485. PMID: 20183546. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Brown B. Visual psychophysics and clinical assessment of abnormal vision. Curr Opin Ophthalmol. 1990;1(6):660-664. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Brown CM, Wong EY, O'Connor PM, et al. Measurement of quality of life for people with diabetic retinopathy impairment. Expert Rev Ophthalmol. 2009 Dec;4(6):587-93. Also available: http://dx.doi.org/10.1586/eop.09.57. No patient-centered outcome

Brown GC, Brown MM, Kertes PJ, et al. Comparative effectiveness and cost-effective analyses: 17.3% and counting!. Evid Based Ophthalmol. 2011 Apr;12(2):108-14. Also available: http://dx.doi.org/10.1097/IEB.0b013e318212d334. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Bruijning J, van Nispen R, Knol D, et al. Low vision rehabilitation plans comparing two intake methods. Optom Vis Sci. 2012 Feb;89(2):203-14. PMID: 22198794. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Bruijning J, van Nispen R, Verstraten P, et al. A Dutch ICF version of the Activity Inventory: results from focus groups with visually impaired persons and experts. Ophthalmic Epidemiol. 2010 Dec;17(6):366-77. Also available: http://dx.doi.org/10.3109/09286586.2010.528133. PMID: 21090911. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Bruijning JE, van Rens G, Fick M, et al. Longitudinal observation, evaluation and interpretation of coping with mental (emotional) health in low vision rehabilitation using the Dutch ICF Activity Inventory. Health Qual Life Outcomes. 2014;12:182. Also available: http://dx.doi.org/10.1186/s12955-014-0182-4. PMID: 25539603. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Bruijning JE, van Rens G, Knol D, et al. Psychometric analyses to improve the Dutch ICF Activity Inventory. Opt Vis Sci. 2013 Aug;90(8):806-19. Also available: http://dx.doi.org/10.1097/OPX.0b013e318282cdce. PMID: 23518676. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Bruijning JE, van Rens GH, Fick M, et al. Longitudinal observation, evaluation and interpretation of coping with mental (emotional) health in low vision rehabilitation using the Dutch ICF Activity Inventory. Health Qual Life Outcomes. 2014 Dec 24;12(1). Also available: http://dx.doi.org/10.1186/s12955-014-0182-4. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Cacho I, Dickinson CM, Smith HJ, et al. Clinical impairment measures and reading performance in a large age-related macular degeneration group. Opt Vis Sci. 2010 May;87(5):344-9. Also available: http://dx.doi.org/10.1097/OPX.0b013e3181d9515c. PMID: 20386356. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Cacho-Martinez P, Garcia-Munoz A, Ruiz-Cantero MT. Is there any evidence for the validity of diagnostic criteria used for accommodative and nonstrabismic binocular dysfunctions? J Optom. 2014 Jan-Mar;7(1):2-21. Also available: http://dx.doi.org/10.1016/j.optom.2013.01.004. PMID: 24646897. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Camparini M, Cassinari P, Ferrigno L, et al. ETDRS-fast: implementing psychophysical adaptive methods to standardized visual acuity measurement with ETDRS charts. Invest Ophthalmol Vis Sci. 2001 May;42(6):1226-31. PMID: 11328731. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Cao KY, Markowitz SN. Residual stereopsis in age-related macular degeneration patients and its impact on vision-related abilities: a pilot study. J Optom. 2014 Apr-Jun;7(2):100-5. Also available: http://dx.doi.org/10.1016/j.optom.2013.12.003. PMID: 24766867. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Cappello E, Virgili G, Tollot L, et al. Reading ability and retinal sensitivity after surgery for macular hole and macular pucker. Retina. 2009 Sep;29(8):1111-8. Also available: http://dx.doi.org/10.1097/IAE.0b013e3181a3b832. PMID: 19491726. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Carignan M, Rousseau J, Gresset J, et al. Content validity of a home-based person-environment interaction assessment tool for visually impaired adults. J Rehabil Res Dev. 2008;45(7):1037-51. PMID: 19165693. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Carta A, Braccio L, Belpoliti M, et al. Self-assessment of the quality of vision: association of questionnaire score with objective clinical tests. Curr Eye Res. 1998 May;17(5):506-11. PMID: 9617546. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Caspi A, Dorn JD, McClure KH, et al. Feasibility study of a retinal prosthesis: Spatial vision with a 16-electrode implant. Arch Ophthalmol. 2009 Apr;127(4):398-401. Also available: http://dx.doi.org/10.1001/archophthalmol.2009.20. PMID: 19365014. Not relevant RPS

Caspi A, Zivotofsky AZ. Assessing the utility of visual acuity measures in visual prostheses. Vision Res. 2015 Mar 1;77-84. Also available: http://dx.doi.org/10.1016/j.visres.2015.01.006. PMID: 25637855. Duplicate data

Caspi A, Zivotofsky AZ. Assessing the utility of visual acuity measures in visual prostheses. Vision Res. 2015 Mar 1;77-84. Also available: http://dx.doi.org/10.1016/j.visres.2015.01.006. PMID: 25637855. Not relevant RPS

Chader GJ, Weiland J, Humayun MS. Artificial vision: needs, functioning, and testing of a retinal electronic prosthesis. Prog Brain Res. 2009;175:317-32. PMID: 19660665. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Chader GJ. Beyond basic research for inherited and orphan retinal diseases: Successes and challenges. Retina. 2005 Dec;25(8). PMID: 16374318. Narrative review

Chan TL, Perlmutter MS, Andrews M, et al. Equating visual function scales to facilitate reporting of Medicare functional G-code severity/complexity modifiers for low-vision patients. Arch Phys Med Rehabil. 2015 Oct 1;96(10):1859-65. Also available: http://dx.doi.org/10.1016/j.apmr.2015.06.013. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Chang MH, Kim HS, Shin JH, et al. Facial identification in very low-resolution images simulating prosthetic vision. J Neural Eng. 2012 Aug;9(4). Also available: http://dx.doi.org/10.1088/1741-2560/9/4/046012. PMID: 22766585. Not relevant RPS

Chen SJ, Mahadevappa M, Roizenblatt R, et al. Neural responses elicited by electrical stimulation of the retina. Trans Am Ophthalmol Soc. 2006;252-8. PMID: 17471346. Not relevant RPS

Cheong AC, Lovie-Kitchin JE, Bowers AR. Determining magnification for reading with low vision. Clin Exp Optom. 2002 Jul;85(4):229-37. PMID: 12135415. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Chia EM, Chia EM, Rochtchina E, et al. Utility and validity of the self-administered SF-36: findings from an older population. Ann Acad Med Singapore. 2006 Jul;35(7):461-7. PMID: 16902721. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Chia EM, Wang JJ, Rochtchina E, et al. Impact of bilateral visual impairment on health-related quality of life: the Blue Mountains Eye Study. Invest Ophthalmol Vis Sci. 2004 Jan;45(1):71-6. PMID: 14691156. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Chiang PP, Fenwick E, Marella M, et al. Validation and reliability of the VF-14 questionnaire in a German population. Invest Ophthalmol Vis Sci. 2011 Nov;52(12):8919-26. Also available: http://dx.doi.org/10.1167/iovs.11-7702. PMID: 22025576. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Chiang PP, Zheng Y, Wong TY, et al. Vision impairment and major causes of vision loss impacts on vision-specific functioning independent of socioeconomic factors. Ophthalmology. 2013 Feb;120(2):415-22. Also available: http://dx.doi.org/10.1016/j.ophtha.2012.07.077. PMID: 23149127. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Childs AL. Responsiveness of the SF-36 health survey to changes in visual acuity among patients with subfoveal choroidal neovascularization. Am J Ophthalmol. 2004 Feb;137(2):373-5. PMID: 14962442. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Chow AY. Retinal Prostheses Development in Retinitis Pigmentosa Patients-Progress and Comparison. Asia Pac J Ophthalmol (Phila). 2013 Jul-Aug;2(4):253-68. Also available: http://dx.doi.org/10.1097/APO.0b013e3182a0b4fe. PMID: 26106920. Narrative review

Christiaan Stronks H, Barry MP, Dagnelie G. Electrically elicited visual evoked potentials in argus II retinal implant wearers. Invest Ophthalmol Vis Sci. 2013;54(6):3891-901. No patient-centered outcome

Chuang AT, Margo CE, Greenberg PB. Retinal implants: A systematic review. Br J Ophthalmol. 2014 Jul;98(7):852-6. Also available: http://dx.doi.org/10.1136/bjophthalmol-2013-303708. PMID: 24403565. Narrative review

Cimberle M. Research on retinal implants progresses. Ocular Surg News. 2003 Jan 15;21(2):74-5. Unable to obtain

Cimberle M. Subretinal electronic chip shows encouraging results, further improvements. Ocular Surg News. 2011 Oct 25;29(20):49-51. Narrative review

Cimberle M. Subretinal implant shows promise to restore vision in some patients. Ocular Surg News. 2007 Nov 1;25(21):109-10. Narrative review

Claesson L, Blomstrand J, Eklund K, et al. Comparison of visual acuity charts identifying visual impairment among older people outside the eye clinic. Disabil Rehabil. 2013 Aug;35(16):1394-400. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Clemons TE, Chew EY, Bressler SB, et al. National Eye Institute Visual Function Questionnaire in the Age-Related Eye Disease Study (AREDS): AREDS Report No. 10. Arch Ophthalmol. 2003 Feb;121(2):211-7. PMID: 12583787. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Clemson L, Bundy A, Unsworth C, et al. Validation of the modified assessment of living skills and resources, an IADL measure for older people. Disabil Rehabil. 2009 Mar;31(5):359-69. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Conrad R, Geiser F, Kleiman A, et al. Temperament and character personality profile and illness-related stress in central serous chorioretinopathy. Sci World J. 2014;2014:631687. Also available: http://dx.doi.org/10.1155/2014/631687. PMID: 24696654. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Correa M, Fox C, Hasson M. Useful vision restored in retinitis pigmentosa patients who received subretinal implant. Ocular Surg News. 2013 May 25;31(10):42-3. Narrative review

Cunningham S, Tjan B, Bao P, et al. Tactile-Evoked V1 responses in Argus II Retinal Prosthesis Patients assessed with fMRI: A Case Study. J Vis. 2015 Sep 1;15(12):359. Also available: http://dx.doi.org/10.1167/15.12.359. PMID: 26326047. No patient-centered outcome

Dagnelie G, Keane P, Narla V, et al. Real and virtual mobility performance in simulated prosthetic vision. J Neural Eng. 2007 Mar 1;4(1). Also available: http://dx.doi.org/10.1088/1741-2560/4/1/S11. PMID: 17325421. Not relevant RPS

Dagnelie G. Visual perfromance under simulated conditions of prosthetic vision. J Vis. 2002;2(10):4a. No patient-centered outcome

Dahlin Ivanoff S, Sonn U, Svensson E. Development of an ADL instrument targeting elderly persons with age-related macular degeneration. Disabil Rehabil. 2001 Jan;23(2):69-79. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Davison JA. October consultation # 6. J Cataract Refract Surg. 2008 Oct;34(10):1624-6. Also available: http://dx.doi.org/10.1016/j.jcrs.2008.08.008. Not relevant RPS

Day H, Jutai J. Measuring the psychosocial impact of assistive devices: The PIADS. Can J Rehabil. 1996;9(3):159-168. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

De Balthasar C, Patel S, Roy A, et al. Factors affecting perceptual thresholds in epiretinal prostheses. Invest Ophthalmol Vis Sci. 2008 Jun;49(6):2303-14. Also available: http://dx.doi.org/10.1167/iovs.07-0696. PMID: 18515576. Not relevant RPS

de Boer MR, de Vet HC, Terwee CB, et al. Changes to the subscales of two vision-related quality of life questionnaires are proposed. J Clin Epidemiol. 2005 Dec;58(12):1260-8. PMID: 16291470. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

de Boer MR, Moll AC, de Vet HC, et al. Psychometric properties of vision-related quality of life questionnaires: a systematic review. Ophthalmic Physiol Opt. 2004 Jul;24(4):257-73. PMID: 15228503. No psychometric property data reported, or study was not primarily designed to measure psychometrics

de Boer MR, Terwee CB, de Vet HC, et al. Evaluation of cross-sectional and longitudinal construct validity of two vision-related quality of life questionnaires: the LVQOL and VCM1. Qual Life Res. 2006 Mar;15(2):233-48. PMID: 16468079. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

DeCcarlo DK, Scilley K, Wells J, et al. Driving habits and health-related quality of life in patients with age-related maculopathy. Optom Vis Sci. 2003 Mar;80(3):207-13. PMID: 12637832. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Dell SJ. February consultation #2. J Cataract Refract Surg. 2010 Feb;36(2):354-5. Also available: http://dx.doi.org/10.1016/j.jcrs.2009.12.003. Not relevant RPS

Demers L, Monette M, Descent M, et al. The Psychosocial Impact of Assistive Devices Scale (PIADS): translation and preliminary psychometric evaluation of a Canadian-French version. Qual Life Res. 2002 Sep;11(6):583-92. PMID: 12206579. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Denny F, Marshall AH, Stevenson MR, et al. Rasch analysis of the daily living tasks dependent on vision (DLTV). Invest Ophthalmol Vis Sci. 2007 May;48(5):1976-82. PMID: 17460249. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Dev MK, Paudel N, Joshi ND, et al. Impact of visual impairment on vision-specific quality of life among older adults living in nursing home. Curr Eye Res. 2014 Mar;39(3):232-8. Also available: http://dx.doi.org/10.3109/02713683.2013.838973. PMID: 24144491. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Dev MK, Paudel N, Joshi ND, et al. Psycho-social impact of visual impairment on health-related quality of life among nursing home residents. BMC Health Serv Res. 2014;14:345. Also available: http://dx.doi.org/10.1186/1472-6963-14-345. PMID: 25128378. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Dickson G, Chesser A, Woods NK, et al. Time required for screening for visual impairment in primary care: a randomized comparison of 3 common visual tests. J Prim Care Community Health. 2012 Jul 1;3(3):174-9. Also available: http://dx.doi.org/10.1177/2150131911429824. PMID: 23803778. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Dixon P, Dakin H, Wordsworth S. Generic and disease-specific estimates of quality of life in macular degeneration: mapping the MacDQoL onto the EQ-5D-3L. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2015 Oct 1. Also available: http://dx.doi.org/10.1007/s11136-015-1145-x. PMID: 26462812. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Djafari F, Gresset JA, Boisjoly HM, et al. Estimation of the misclassification rate of self-reported visual disability. Can J Public Health. 2003 Sep-Oct;94(5):367-71. PMID: 14577747. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Dobson V, Quinn GE, Biglan AW, et al. Acuity card assessment of visual function in the cryotherapy for retinopathy of prematurity trial. Invest Ophthalmol Vis Sci. 1990 Sep;31(9):1702-8. PMID: 2211019. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Dorn JD, Ahuja AK, Caspi A, et al. The detection of motion by blind subjects with the epiretinal 60-electrode (Argus II) retinal prosthesis. JAMA Ophthalmol. 2013 Feb;131(2):183-9. Duplicate data

Dougherty BE, Bullimore MA. Comparison of scoring approaches for the NEI VFQ-25 in low vision. Optom Vis Sci. 2010 Aug;87(8):543-8. Also available: http://dx.doi.org/10.1097/OPX.0b013e3181e61bd8. PMID: 20526224. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Dougherty BE, Martin SR, Kelly CB, et al. Development of a battery of functional tests for low vision. Opt Vis Sci. 2009 Aug;86(8):955-63. Also available: http://dx.doi.org/10.1097/OPX.0b013e3181b180a6. PMID: 19593240. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Dowling JE. Restoring vision to the blind: Introduction. Transl Vis Sci Technol. 2014;3(7) Also available: http://dx.doi.org/10.1167/tvst.3.7.2. Editorial

Dreer LE, McGwin G Jr, Scilley K, et al. Development of a nursing home vision-targeted health-related quality of life questionnaire for older adults. Aging Ment Health. 2007 Nov;11(6):722-33. PMID: 18074260. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Dubuc S, Wittich W, Gomolin JE, et al. Beyond visual acuity: functional outcome and patient satisfaction following treatment for age-related macular degeneration. Can J Ophthalmol. 2009 Dec;44(6):680-5. Also available: http://dx.doi.org/10.3129/i09-163. PMID: 20029487. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Dunbar HM, Crossland MD, Rubin GS. Fixation stability: a comparison between the Nidek MP-1 and the Rodenstock scanning laser ophthalmoscope in persons with and without diabetic maculopathy. Invest Ophthalmol Vis Sci. 2010 Aug;51(8):4346-50. Also available: http://dx.doi.org/10.1167/iovs.09-4556. PMID: 20335616. No psychometric property data reported, or study was not primarily designed to measure psychometrics

El Miedany Y, El Gaafary M, Toth M, et al. Falls risk assessment score (FRAS): Time to rethink. J Clin Gerontol Geriatr. 2011 Mar;2(1):21-6. Also available: http://dx.doi.org/10.1016/j.jcgg.2011.01.002. No patient-centered outcome

Elliott AF, Dreer LE, McGwin G Jr, et al. The personal burden of decreased vision-targeted health-related quality of life in nursing home residents. J Aging Health. 2010 Jun;22(4):504-21. Also available: http://dx.doi.org/10.1177/0898264310361368. PMID: 20231730.

Eng JG, Agrawal RN, Tozer KR, et al. Morphometric analysis of optic nerves and retina from an end-stage retinitis pigmentosa patient with an implanted active epiretinal array. Invest Ophthalmol Vis Sci. 2011 Jun;52(7):4610-6. Also available: http://dx.doi.org/10.1167/iovs.09-4936. PMID: 21296811. No patient-centered outcome

Faria BM, Duman F, Zheng CX, et al. Evaluating contrast sensitivity in age-related macular degeneration using a novel computer-based test, the SPAETH/RICHMAN Contrast sensitivity test. Retina. 2015 Jul;35(7):1465-73. Also available: http://dx.doi.org/10.1097/IAE.0000000000000474. PMID: 25658175. No patient-centered outcome

Fellman RL. June Consultation # 2. J Cataract Refract Surg. 2007 Jun;33(6):944-7. Also available: http://dx.doi.org/10.1016/j.jcrs.2007.04.003. Not relevant RPS

Fenwick EK, Ong PG, Sabanayagam C, et al. Assessment of the psychometric properties of the Chinese Impact of Vision Impairment questionnaire in a population-based study: findings from the Singapore Chinese Eye Study. Int J Qual Life. 2015 Sep 29. Also available: http://dx.doi.org/10.1007/s11136-015-1141-1. PMID: 26420045. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Fenwick EK, Pesudovs K, Khadka J, et al. Evaluation of item candidates for a diabetic retinopathy quality of life item bank. Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation. 2013 Sep;22(7):1851-8. Also available: http://dx.doi.org/10.1007/s11136-012-0307-3. PMID: 23135924. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Fenwick EK, Pesudovs K, Khadka J, et al. The impact of diabetic retinopathy on quality of life: qualitative findings from an item bank development project.[Erratum appears in Qual Life Res. 2012 Dec;21(10):1783]. Qual Life Res. 2012 Dec;21(10):1771-82. PMID: 22290480. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Fenwick EK, Pesudovs K, Rees G, et al. Republished article: The impact of diabetic retinopathy: understanding the patient's perspective. Postgrad Med J. 2012 Mar;88(1037):167-75. Also available: http://dx.doi.org/10.1136/pgmj.2010.191312rep. PMID: 22343937. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Fenwick EK, Pesudovs K, Rees G, et al. Republished article: The impact of diabetic retinopathy: Understanding the patient's perspective. Postgrad Med J. 2012;88(1037):167-75. Also available: http://dx.doi.org/10.1136/pgmj.2010.191312rep. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Fenwick EK, Pesudovs K, Rees G, et al. The impact of diabetic retinopathy: understanding the patient's perspective. Br J Ophthalmol. 2011 Jun;95(6):774-82. Also available: http://dx.doi.org/10.1136/bjo.2010.191312. PMID: 20940313. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Fenwick EK, Xie J, Pesudovs K, et al. Assessing disutility associated with diabetic retinopathy, diabetic macular oedema and associated visual impairment using the Vision and Quality of Life Index. Clin Exp Optom. 2012 May;95(3):362-70. Also available: http://dx.doi.org/10.1111/j.1444-0938.2012.00742.x. PMID: 22537275. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Fernandes RA, Diniz B, Ribeiro R, et al. Artificial vision through neuronal stimulation. Neurosci Lett. 2012 Jun 25;519(2):122-8. Also available: http://dx.doi.org/10.1016/j.neulet.2012.01.063. PMID: 22342306. Narrative review

Feucht M, Laube T, Bornfeld N, et al. Development of an epiretinal prosthesis for stimulation of the human retina. Ophthalmologe. 2005 Jul;102(7):688-91. Also available: http://dx.doi.org/10.1007/s00347-005-1186-6. PMID: 15770506. Narrative review

Fevzi A, Aysegul Y. Psychometric performance of the National Eye Institute 25-Item Visual Function Questionnaire: In Turkish diabetic retinopathy patients. Patient. 2008;1(2):115-25. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Finger RP, Fenwick E, Chiang PP, et al. The impact of the severity of vision loss on vision-specific functioning in a German outpatient population - an observational study. Graefes Arch Clin Exp Ophthalmol. 2011 Aug;249(8):1245-53. Also available: http://dx.doi.org/10.1007/s00417-011-1646-4. PMID: 21465288. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Finger RP, Fenwick E, Marella M, et al. The impact of vision impairment on vision-specific quality of life in Germany. Invest Ophthalmol Vis Sci. 2011 May;52(6):3613-9. Also available: http://dx.doi.org/10.1167/iovs.10-7127. PMID: 21357395. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Finger RP, Fenwick E, Owsley C, et al. Visual functioning and quality of life under low luminance: evaluation of the German Low Luminance Questionnaire. Invest Ophthalmol Vis Sci. 2011 Oct;52(11):8241-9. Also available: http://dx.doi.org/10.1167/iovs.11-7858. PMID: 21908584. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Finger RP, Fenwick E, Pesudovs K, et al. Rasch analysis reveals problems with multiplicative scoring in the macular disease quality of life questionnaire. Ophthalmology. 2012 Nov;119(11):2351-7. Also available: http://dx.doi.org/10.1016/j.ophtha.2012.05.031. PMID: 22968142. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Finger RP, Fleckenstein M, Holz FG, et al. Quality of life in age-related macular degeneration: a review of available vision-specific psychometric tools. Int J Qual Life. 2008 May;17(4):559-74. Also available: http://dx.doi.org/10.1007/s11136-008-9327-4. PMID: 18365767. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Finger RP, Guymer RH, Gillies MC, et al. The impact of anti-vascular endothelial growth factor treatment on quality of life in neovascular age-related macular degeneration. Ophthalmology. 2014 Jun;121(6):1246-51. Also available: http://dx.doi.org/10.1016/j.ophtha.2013.12.032. PMID: 24518613. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Finger RP, Kortuem K, Fenwick E, et al. Evaluation of a vision-related utility instrument: the German vision and quality of life index. Invest Ophthalmol Vis Sci. 2013 Feb;54(2):1289-94. Also available: http://dx.doi.org/10.1167/iovs.12-10828. PMID: 23341011. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Fitzke FW, Crabb DP, McNaught AI, et al. Image processing of computerised visual field data. Br J Ophthalmol. 1995 Mar;79(3):207-12. PMID: 7703195. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Fornos AP, Sommerhalder J, da Cruz L, et al. Temporal properties of visual perception on electrical stimulation of the retina. Invest Ophthalmol Vis Sci. 2012 May;53(6):2720-31. Also available: http://dx.doi.org/10.1167/iovs.11-9344. PMID: 22447863. Duplicate data

Fornos AP, Sommerhalder J, Pelizzone M. Reading with a simulated 60-channel implant. Front Neurosci. 2011. Also available: http://dx.doi.org/10.3389/fnins.2011.00057. PMID: 21625622. Not relevant RPS

Friedman DS, Munoz B, Massof RW, et al. Grating visual acuity using the preferential-looking method in elderly nursing home residents. Invest Ophthalmol Vis Sci. 2002 Aug;43(8):2572-8. PMID: 12147587. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

From the field. Retinal prosthesis study recruitment partially completed. J Vis Impair Blind. 2008 Mar 1;102(3):179-80. Editorial

Frost NA, Sparrow JM, Durant JS, et al. Development of a questionnaire for measurement of vision-related quality of life. Ophthalmic Epidemiol. 1998 Dec;5(4):185-210. PMID: 9894804. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Frost NA, Sparrow JM, Hopper CD, et al. Reliability of the VCM1 Questionnaire when administered by post and by telephone. Ophthalmic Epidemiol. 2001 Feb;8(1):1-11. PMID: 11262678. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Fujikado T, Morimoto T, Kanda H, et al. Evaluation of phosphenes elicited by extraocular stimulation in normals and by suprachoroidal-transretinal stimulation in patients with retinitis pigmentosa. Graefes Arch Clin Exp Ophthalmol. 2007 Oct;245(10):1411-9. Also available: http://dx.doi.org/10.1007/s00417-007-0563-z. PMID: 17342502. Not relevant RPS

Gabrielian A, Hariprasad SM, Jager RD, et al. The utility of visual function questionnaire in the assessment of the impact of diabetic retinopathy on vision-related quality of life. Eye (Lond). 2010 Jan;24(1):29-35. Also available: http://dx.doi.org/10.1038/eye.2009.56. PMID: 19325572. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gall R, Wick B, Bedell H. Vergence facility: establishing clinical utility. Optom Vis Sci. 1998 Oct;75(10):731-42. PMID: 9798213. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Gallagher P, Mulvany F. Levels of ability and functioning: Using the WHODAS II in an Irish context. Disabil Rehabil. 2004 May 6;26(9):506-17. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Garcia S, Petrini K, Rubin GS, et al. Visual and non-visual navigation in blind patients with a retinal prosthesis. PLoS ONE. 2015;10(7):e0134369. Also available: http://dx.doi.org/10.1371/journal.pone.0134369. PMID: 26225762. Duplicate data

Garcia-Munoz A, Carbonell-Bonete S, Cacho-Martinez P. Symptomatology associated with accommodative and binocular vision anomalies. J Optom. 2014 Oct-Dec;7(4):178-92. Also available: http://dx.doi.org/10.1016/j.optom.2014.06.005. PMID: 25323640. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Gekeler F, Kopp A, Sachs H, et al. Visualisation of active subretinal implants with external connections by high-resolution CT. Br J Ophthalmol. 2010 Jul;94(7):843-7. Also available: http://dx.doi.org/10.1136/bjo.2009.170654. PMID: 20606022. No patient-centered outcome

Gekeler F, Messias A, Ottinger M, et al. Phosphenes electrically evoked with DTL electrodes: A study in patients with retinitis pigmentosa, glaucoma, and homonymous visual field loss and normal subjects. Invest Ophthalmol Vis Sci. 2006 Nov;47(11):4966-74. Also available: http://dx.doi.org/10.1167/iovs.06-0459. PMID: 17065515. Not relevant RPS

Gerding H. Development of a minimally invasive retinal implant system. Ophthalmologe. 2008 May;105(5):463-73. Also available: http://dx.doi.org/10.1007/s00347-007-1631-9. PMID: 18369640. Technical report without human data

Giacomelli G, Volpe R, Virgili G, et al. Contrast reduction and reading: assessment and reliability with the Reading Explorer test. Eur J Ophthalmol. 2010 Mar-Apr;20(2):389-96. PMID: 19882511. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Globe DR, Levin S, Chang TS, et al. Validity of the SF-12 quality of life instrument in patients with retinal diseases. Ophthalmology. 2002 Oct;109(10):1793-8. PMID: 12359596. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Goldstein JE, Chun MW, Fletcher DC, et al. Visual ability of patients seeking outpatient low vision services in the United States. JAMA Ophthalmol. 2014 Oct;132(10):1169-77. Also available: http://dx.doi.org/10.1001/jamaophthalmol.2014.1747. PMID: 25073745. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Goodrich GL, Kirby J. A comparison of patient reading performance and preference: optical devices, handheld CCTV (Innoventions Magni-Cam), or stand-mounted CCTV (Optelec Clearview or TSI Genie). Optometry. 2001 Aug;72(8):519-28. PMID: 11519714. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Gopal L. Update on vitreo retinal surgery. J Int Med Sci Acad. 2010 Jul-Sep;23(3):165-8. Narrative review

Gothwal VK, Bagga DK, Sumalini R. Rasch analysis of the Indian vision function questionnaire. Br J Ophthalmol. 2012 May;96(5):619-23. Also available: http://dx.doi.org/10.1136/bjophthalmol-2011-300092. PMID: 22308172. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Bagga DK. Andhra Pradesh Eye Disease Study - Visual Function Questionnaire: further improvements in psychometric properties using Rasch analysis. Ophthalmic Epidemiol. 2012 Oct;19(5):306-16. Also available: http://dx.doi.org/10.3109/09286586.2012.712192. PMID: 22978532. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Bagga DK. Utility values in the visually impaired: comparing time-trade off and VisQoL. Opt Vis Sci. 2013 Aug;90(8):843-54. Also available: http://dx.doi.org/10.1097/OPX.0b013e318291063a. PMID: 23628757. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Bagga DK. Vision and Quality of Life Index: validation of the Indian version using Rasch analysis. Invest Ophthalmol Vis Sci. 2013 Jul;54(7):4871-81. Also available: http://dx.doi.org/10.1167/iovs.13-11892. PMID: 23800765. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Lovie-Kitchin JE, Nutheti R. The development of the LV Prasad-Functional Vision Questionnaire: a measure of functional vision performance of visually impaired children. Invest Ophthalmol Vis Sci. 2003 Sep;44(9):4131-9. PMID: 12939337. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Reddy SP, Sumalini R, et al. National Eye Institute Visual Function Questionnaire or Indian Vision Function Questionnaire for visually impaired: a conundrum. Invest Ophthalmol Vis Sci. 2012 Jul;53(8):4730-8. Also available: http://dx.doi.org/10.1167/iovs.11-8776. PMID: 22700705. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Srinivas M, Rao GN. A new look at the WHOQOL as health-related quality of life instrument among visually impaired people using Rasch analysis. Qual Life Res. 2013 May;22(4):839-51. Also available: http://dx.doi.org/10.1007/s11136-012-0195-6. PMID: 22648162. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Sumalini R, Bharani S, et al. The second version of the L. V. Prasad-functional vision questionnaire. Opt Vis Sci. 2012 Nov;89(11):1601-10. Also available: http://dx.doi.org/10.1097/OPX.0b013e31826ca291. PMID: 23069725. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Gothwal VK, Sumalini R, Irfan SM, et al. Rasch analysis of Impact of Vision Impairment for Children questionnaire. Opt Vis Sci. 2013 Aug;90(8):820-7. Also available: http://dx.doi.org/10.1097/OPX.0b013e3182956c1f. PMID: 23748842. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Grabow HB. October Consultation # 3. J Cataract Refract Surg. 2006 Oct;32(10):1596-7. Also available: http://dx.doi.org/10.1016/j.jcrs.2006.08.002. Not relevant RPS

Greenberg R. Cooperation between private and public sectors leads to an intraocular retinal implant. Retina. 2005 Dec;25(8). PMID: 16374342. Editorial

Greenwald SH, Horsager A, Humayun MS, et al. Brightness as a function of current amplitude in human retinal electrical stimulation. Invest Ophthalmol Vis Sci. 2009 Nov;50(11):5017-25. Also available: http://dx.doi.org/10.1167/iovs.08-2897. PMID: 19608533. Not relevant RPS

Gusseck H. Retinal implants. Patients' expectations. Ophthalmologe. 2005 Oct;102(10):950-6. Also available: http://dx.doi.org/10.1007/s00347-005-1262-y. PMID: 16132993. Narrative review

Guthrie DM, Pitman R, Stolee P, et al. Reliability of standardized assessment for adults who are deafblind. J Rehabil Res Dev. 2011;48(5):545-54. PMID: 21674404. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Guttman KC. Subretinal implant benefits retinitis pigmentosa cases. Ophthalmol Times. 2015 Jun 15;40(10):15-6. Narrative review

Guttman Krader C, Rizzo S. Epiretinal prosthesis outcomes remain encouraging for retinitis pigmentosa. Ophthalmol Times. 2014 Nov 1;39(20):40-1. Editorial

Haegerstrom-Portnoy G, Schneck ME, Verdon WA, et al. Clinical vision characteristics of the congenital achromatopsias. II. Color vision. Optom Vis Sci. 1996 Jul;73(7):457-65. PMID: 8843125. No patient-centered outcome

Hafed ZM, Stingl K, Bartz-Schmidt KU, et al. Oculomotor behavior of blind patients seeing with a subretinal visual implant. Vision Res. 2014 Aug 21. Also available: http://dx.doi.org/10.1016/j.visres.2015.04.006. PMID: 25906684. Duplicate data

Hafed ZM, Stingl K, Bartz-Schmidt KU, et al. Oculomotor behavior of blind patients seeing with a subretinal visual implant. Vision Res. 2014 Aug 21. Also available: http://dx.doi.org/10.1016/j.visres.2015.04.006. PMID: 25906684. No patient-centered outcome

Hahm BJ, Shin YW, Shim EJ, et al. Depression and the vision-related quality of life in patients with retinitis pigmentosa. Br J Ophthalmol. 2008 May;92(5):650-4. Also available: http://dx.doi.org/10.1136/bjo.2007.127092. PMID: 18356260. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Hallum LE, Dagnelie G, Suaning GJ, et al. Simulating auditory and visual sensorineural prostheses: A comparative review. J Neural Eng. 2007;4(1):S58-S71. Narrative review

Hanout M, Horan N, Do DV. Introduction to microperimetry and its use in analysis of geographic atrophy in age-related macular degeneration. Curr Opin Ophthalmol. 2015 May;26(3):149-56. Also available: http://dx.doi.org/10.1097/ICU.0000000000000153. PMID: 25784112. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Harper R, Doorduyn K, Reeves B, et al. Evaluating the outcomes of low vision rehabilitation. Ophthal Physiol Opt. 1999 Jan;19(1):3-11. PMID: 10615433. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Hart PM, Stevenson MR, Montgomery AM, et al. Further validation of the Daily Living Tasks Dependent on Vision: identification of domains. Br J Ophthalmol. 2005 Sep;89(9):1127-30. PMID: 16113365. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Hartnett ME, Rodier DW, McColm JR, et al. Long-term vision results measured with Teller Acuity Cards and a new Light Perception/Projection Scale after management of late stages of retinopathy of prematurity. Arch Ophthalmol. 2003 Jul;121(7):991-6. PMID: 12860803. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Hassan SE, Massof RW. Measurements of street-crossing decision-making in pedestrians with low vision. Accid Anal Prev. 2012 Nov;49:410-8. Also available: http://dx.doi.org/10.1016/j.aap.2012.03.009. PMID: 23036420. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Hassell JB, Weih LM, Keeffe JE. A measure of handicap for low vision rehabilitation: the impact of vision impairment profile. Clin Experiment Ophthalmol. 2000 Jun;28(3):156-61. PMID: 10981786. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Hasson M, Mullin DW. Subretinal implant allows stable images with eye movement in pilot study of blind patients. Ocular Surg News. 2010 Jun 10;28(11):20-1. Narrative review

Hasson M. Subretinal implant provides stable percepts synchronized with eye movement. Ocular Surg News. 2010 Aug 10;28(15):24-5. Narrative review

Hayes JS, Yin VT, Piyathaisere D, et al. Visually guided performance of simple tasks using simulated prosthetic vision. Artif Organs. 2003 Nov;27(11):1016-28. Also available: http://dx.doi.org/10.1046/j.1525-1594.2003.07309.x. PMID: 14616520. Not relevant RPS

Haymes S, Guest D, Heyes A, et al. Mobility of people with retinitis pigmentosa as a function of vision and psychological variables. Optom Vis Sci. 1996 Oct;73(10):621-37. PMID: 8916133. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Haymes SA, Chen J. Reliability and validity of the Melbourne Edge Test and High/Low Contrast Visual Acuity chart. Optom Vis Sci. 2004 May;81(5):308-16. PMID: 15181355. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Haymes SA, Johnston AW, Heyes AD. A weighted version of the Melbourne Low-Vision ADL Index: a measure of disability impact. Optom Vis Sci. 2001 Aug;78(8):565-79. PMID: 11525547. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Haymes SA, Johnston AW, Heyes AD. Relationship between vision impairment and ability to perform activities of daily living. Ophthal Physiol Opt. 2002 Mar;22(2):79-91. PMID: 12014491. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Haymes SA, Johnston AW, Heyes AD. The development of the Melbourne low-vision ADL index: a measure of vision disability. Invest Ophthalmol Vis Sci. 2001 May;42(6):1215-25. PMID: 11328730. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Head DN, Babcock JL, Goodrich GL, et al. A geriatric assessment of functional status in vision rehabilitation. J Vis Impair Blind. 2000;94(6):357-71. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Heintz E, Wirehn AB, Peebo BB, et al. QALY weights for diabetic retinopathy--a comparison of health state valuations with HUI-3, EQ-5D, EQ-VAS, and TTO. Value Health. 2012 May;15(3):475-84. Also available: http://dx.doi.org/10.1016/j.jval.2011.11.031. PMID: 22583458. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Hensil J, Whittaker SG. Visual reading versus auditory reading by sighted persons and persons with low vision. J Vis Impairm Blindn. 2000;94:762-70. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Hernandez Trillo A, Dickinson CM. The impact of visual and nonvisual factors on quality of life and adaptation in adults with visual impairment. Invest Ophthalmol Vis Sci. 2012;53(7):4234-41. Also available: http://dx.doi.org/10.1167/iovs.12-9580. PMID: 22599581. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Hewitt AW, Jeganathan VS, Kidd JE, et al. Influence of photodynamic therapy for age related macular degeneration upon subjective vision related quality of life. Graefes Arch Clin Exp Ophthalmol. 2006 Aug;244(8):972-7. PMID: 16411103. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Holbrook EA, Stevens SL, Kang M, et al. Validation of a talking pedometer for adults with visual impairment. Med Sci Sports Exerc. 2011 Jun;43(6):1094-9. Also available: http://dx.doi.org/10.1249/MSS.0b013e318205e2d6. PMID: 21085034. No patient-centered outcome

Horiguchi M, Suzuki H, Kojima Y, et al. New visual acuity chart for patients with macular hole. Invest Ophthalmol Vis Sci. 2001 Nov;42(12):2765-8. PMID: 11687515. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Horowitz A, Reinardt JP. Development of the Adaptation to age-related Vision Loss Scale. J Vis Impair Blind. 1998 Jan;92(1):30-41. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Horsager A, Boynton GM, Greenberg RJ, et al. Temporal interactions during paired-electrode stimulation in two retinal prosthesis subjects. Invest Ophthalmol Vis Sci. 2011 Jan;52(1):549-57. Also available: http://dx.doi.org/10.1167/iovs.10-5282. PMID: 20720224. Not relevant RPS

Horsager A, Greenberg RJ, Fine I. Spatiotemporal interactions in retinal prosthesis subjects. Invest Ophthalmol Vis Sci. 2010 Feb;51(2):1223-33. Also available: http://dx.doi.org/10.1167/iovs.09-3746. PMID: 19741248. Not relevant RPS

Horsager A, Greenwald SH, Weiland JD, et al. Predicting visual sensitivity in retinal prosthesis patients. Invest Ophthalmol Vis Sci. 2009 Apr;50(4):1483-91. PMID: 19098313. Not relevant RPS

Hossain P, Seetho IW, Browning AC, et al. Science, medicine, and the future: Artificial means for restoring vision. Br Med J. 2005 Jan 1;330(7481):30-3. PMID: 15626803. Narrative review

Huang Q, Chowdhury V, Coroneo MT. Evaluation of patient suitability for a retinal prosthesis using structural and functional tests of inner retinal integrity. J Neural Eng. 2009;6(3). Also available: http://dx.doi.org/10.1088/1741-2560/6/3/035010. PMID: 19458395. No patient-centered outcome

Hudson C, Flanagan JG, Turner GS, et al. Short-wavelength sensitive visual field loss in patients with clinically significant diabetic macular oedema. Diabetologia. 1998 Aug;41(8):918-28. PMID: 9726594. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Humayun Mark S. Prosthesis team leader outlines components, procedure, follow-up... [corrected] [published erratum appears in OPHTHALMOL TIMES 2013; 38(12):14]. Ophthalmol Times. 2013 Mar 1;38(5):10-2. Editorial

Humayun MS, Dorn JD, Ahuja AK, et al. Preliminary 6 month results from the Argus II epiretinal prosthesis feasibility study. Conf Proc IEEE Eng Med Biol Soc. 2009. PMID: 19963839. Duplicate data

Humayun MS, Weiland JD, Fujii GY, et al. Visual perception in a blind subject with a chronic microelectronic retinal prosthesis. Vision Res. 2003 Nov;43(24):2573-81. Also available: http://dx.doi.org/10.1016/S0042-6989(03)00457-7. PMID: 13129543. Not relevant RPS

Humayun MS. Intraocular retinal prosthesis. Trans Am Ophthalmol Soc. 2001;271-300. PMID: 11797315. Technical report without human data

Idil A, Ozen M, Atak N, et al. Validity and reliability study of Turkish version on low vision with quality of life questionnaire. Int J Ophthalmol. 2011 Nov;11(11):1880-5. Also available: http://dx.doi.org/10.3969/j.issn.1672-5123.2011.11.004. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Idil SA, Caliskan D, Idil NB. Development and validation of the Turkish version of the MNREAD visual acuity charts. Turk J Med Sci. 2011;41(4):565-70. Also available: http://dx.doi.org/10.3906/sag-1008-1. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

In the journals. Ocular Surg News. 2011 Jan 25;29(2):20, 22, 24 passim. Not relevant RPS

Ivastinovic D, Koch M, Langmann A, et al. Evaluation of a new mobility test and a visual acuity test for assessment of visual function. Spektr Augenheilkunde. 2006;20(4):180-4. No patient-centered outcome

Iyigun E, Bayer A, Tastan S, et al. Validity and reliability study for the NEI-VFO-39 scale in chronic ophthalmic diseases--Turkish version. Acta Ophthalmol. 2010 Jun;88(4):e115-9. Also available: http://dx.doi.org/10.1111/j.1755-3768.2009.01810.x. PMID: 20346083. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Jabr F. Bionic eye. Sci Am. 2012 May;306(5):44-5. PMID: 22550922. Not relevant RPS

Javaheri M, Hahn DS, Lakhanpal RR, et al. Retinal prostheses for the blind. Ann Acad Med Singapore. 2006 Mar;35(3):137-44. PMID: 16625261. Narrative review

Jayasundera T. Use of retinal prosthesis system helps shape vision for retinitis pigmentosa. Ophthalmol Times. 2014 Oct 1;39(18):26-9. Narrative review

Kamel HK, Guro-Razuman S, Shareeff M. The activities of daily vision scale: a useful tool to assess fall risk in older adults with vision impairment. J Am Geriatr Soc. 2000 Nov;48(11):1474-7. PMID: 11083326. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Kay S, Ferreira A. Mapping the 25-item National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) to EQ-5D utility scores. Ophthalmic Epidemiol. 2014 Apr;21(2):66-78. Also available: http://dx.doi.org/10.3109/09286586.2014.888456. PMID: 24568628. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Keane PA, Patel PJ, Ouyang Y, et al. Effects of retinal morphology on contrast sensitivity and reading ability in neovascular age-related macular degeneration. Invest Ophthalmol Vis Sci. 2010 Nov;51(11):5431-7. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Keeffe JE, McCarty CA, Hassell JB, et al. Description and measurement of handicap caused by vision impairment. Aust N Z J Ophthalmol. 1999 Jun-Aug;27(3-4):184-6. PMID: 10484186. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Keseru M, Feucht M, Bornfeld N, et al. Acute electrical stimulation of the human retina with an epiretinal electrode array. Acta Ophthalmol. 2012 Feb;90(1):e1-8. Also available: http://dx.doi.org/10.1111/j.1755-3768.2011.02288.x. PMID: 22067614. Not relevant RPS

Khadka J, McAlinden C, Pesudovs K. Quality assessment of ophthalmic questionnaires: review and recommendations. Optom Vis Sci. 2013 Aug;90(8):720-44. Also available: http://dx.doi.org/10.1097/OPX.0000000000000001. PMID: 23873034. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Kim CY. August consultation #4. J Cataract Refract Surg. 2010;36(8):1439-40. Also available: http://dx.doi.org/10.1016/j.jcrs.2010.06.050. Not relevant RPS

Kinoshita T, Imaizumi H, Miyamoto H, et al. Changes in metamorphopsia in daily life after successful epiretinal membrane surgery and correlation with M-CHARTS score. Clin Ophthalmol. 2015 Feb 4;225-33. Also available: http://dx.doi.org/10.2147/OPTH.S76847. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Kiral-Kornek FI, Savage CO, O'Sullivan-Greene E, et al. Embracing the irregular: a patient-specific image processing strategy for visual prostheses. Conf Proc IEEE Eng Med Biol Soc. 2013;3563-6. Also available: http://dx.doi.org/10.1109/EMBC.2013.6610312. PMID: 24110499. Not relevant RPS

Kitiratschky VB, Stingl K, Wilhelm B, et al. Safety evaluation of "retina implant alpha IMS" a prospective clinical trial. Graefes Arch Clin Exp Ophthalmol. 2015 Mar 1;253(3):381-7. PMID: 25219982. Duplicate data

Klein BE, Moss SE, Klein R, et al. Associations of visual function with physical outcomes and limitations 5 years later in an older population: the Beaver Dam eye study. Ophthalmology. 2003 Apr;110(4):644-50. PMID: 12689880. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Klein M, Birch DG. Psychophysical assessment of low visual function in patients with retinal degenerative diseases (RDDs) with the Diagnosys full-field stimulus threshold (D-FST). Doc Ophthalmol. 2009 Dec;119(3):217-24. Also available: http://dx.doi.org/10.1007/s10633-009-9204-7. PMID: 19885692. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Koenraads Y, Braun KP, van der Linden DC, et al. Perimetry in young and neurologically impaired children: the Behavioral Visual Field (BEFIE) Screening Test revisited. JAMA Ophthalmol. 2015 Mar;133(3):319-25. Also available: http://dx.doi.org/10.1001/jamaophthalmol.2014.5257. PMID: 25541916. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Kontodimopoulos N, Pappa E, Tadros C, et al. Dimensional sensitivity of the 15D multiattribute utility instrument in diabetic retinopathy. Appl Res Qual Life. 2014 Jun;9(2):413-27. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Kotecha A, Zhong J, Stewart D, et al. The Argus II prosthesis facilitates reaching and grasping tasks: a case series. BMC Ophthalmol. 2014;14:71. Also available: http://dx.doi.org/10.1186/1471-2415-14-71. PMID: 24885164. Duplicate data

Kovac B, Vukosavljevic M, Djokic Kovac J, et al. Validation and cross-cultural adaptation of the National Eye Institute Visual Function Questionnaire (NEI VFQ-25) in Serbian patients. Health Qual Life Outcomes. 2015 Sep 15;13(1). Also available: http://dx.doi.org/10.1186/s12955-015-0330-5. PMID: 26370558. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Kowalski JW, Rentz AM, Walt JG, et al. Rasch analysis in the development of a simplified version of the National Eye Institute Visual-Function Questionnaire-25 for utility estimation. Qual Life Res. 2012 Mar;21(2):323-34. Also available: http://dx.doi.org/10.1007/s11136-011-9938-z. PMID: 21814877. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Krader CG, Humayun MS. FDA approval of retinal prosthesis brings limited sight to individuals with retinitis pigmentosa. Ophthalmol Times. 2013 Mar 1;38(5):1-9. Editorial

Krezel AK, Hogg RE, Azuara-Blanco A. Patient-reported outcomes in randomised controlled trials on age-related macular degeneration. Br J Ophthalmol. 2015 Nov 1;99(11):1560-4. Also available: http://dx.doi.org/10.1136/bjophthalmol-2014-306544. PMID: 25934846. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Kriechbaum K, Prager F, Geitzenauer W, et al. Association of retinal sensitivity and morphology during antiangiogenic treatment of retinal vein occlusion over one year. Ophthalmology. 2009 Dec;116(12):2415-21. PMID: 19744723. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Krisch I, Hosticka BJ. Restoring visual perception using microsystem technologies: engineering and manufacturing perspectives. Acta Neurochir Suppl. 2007;97(Pt 2):473-80. PMID: 17691337. Technical report without human data

Kronemyer B. Retinal prosthesis system allows patients to identify letters, words. Ocular Surg News. 2013 May 25;31(10):36-8. Editorial

Kuo HK, Kuo MT, Tiong IS, et al. Visual acuity as measured with Landolt C chart and Early Treatment of Diabetic Retinopathy Study (ETDRS) chart. Graefes Arch Clin Exp Ophthalmol. 2011 Apr;249(4):601-5. Also available: http://dx.doi.org/10.1007/s00417-010-1461-3. PMID: 20658145. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Kusnyerik A, Greppmaier U, Wilke R, et al. Positioning of electronic subretinal implants in blind retinitis pigmentosa patients through multimodal assessment of retinal structures. Invest Ophthalmol Vis Sci. 2012 Jun;53(7):3748-55. Also available: http://dx.doi.org/10.1167/iovs.11-9409. PMID: 22562517. No patient-centered outcome

Labiris G, Katsanos A, Fanariotis M, et al. Psychometric properties of the Greek version of the NEI-VFQ 25. BMC Ophthalmol. 2008;8:4. PMID: 18325083. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Chong EW, Thumboo J, et al. Vision impairment, ocular conditions, and vision-specific function: the Singapore Malay Eye Study. Ophthalmology. 2008 Nov;115(11):1973-81. Also available: http://dx.doi.org/10.1016/j.ophtha.2008.05.005. PMID: 18584873. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Hassell JB, Keeffe JE. The determinants of participation in activities of daily living in people with impaired vision. Am J Ophthalmol. 2004 Feb;137(2):265-70. PMID: 14962415. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Hassell JB, Keeffe JE. The impact of diabetic retinopathy on participation in daily living. Arch Ophthalmol. 2004 Jan;122(1):84-8. PMID: 14718300. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Lamoureux EL, Pallant JF, Pesudovs K, et al. Assessing participation in daily living and the effectiveness of rehabiliation in age related macular degeneration patients using the impact of vision impairment scale. Ophthalmic Epidemiol. 2008 Mar-Apr;15(2):105-13. PMID: 18432494. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Pallant JF, Pesudovs K, et al. The effectiveness of low-vision rehabilitation on participation in daily living and quality of life. Invest Ophthalmol Vis Sci. 2007 Apr;48(4):1476-82. PMID: 17389474. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Pallant JF, Pesudovs K, et al. The impact of vision impairment questionnaire: an assessment of its domain structure using confirmatory factor analysis and rasch analysis. Invest Ophthalmol Vis Sci. 2007 Mar;48(3):1001-6. PMID: 17325138. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Pallant JF, Pesudovs K, et al. The impact of vision impairment questionnaire: an evaluation of its measurement properties using Rasch analysis. Invest Ophthalmol Vis Sci. 2006 Nov;47(11):4732-41. PMID: 17065481. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Pesudovs K, Pallant JF, et al. An evaluation of the 10-item vision core measure 1 (VCM1) scale (the Core Module of the Vision-Related Quality of Life scale) using Rasch analysis. Ophthalmic Epidemiol. 2008 Jul-Aug;15(4):224-33. Also available: http://dx.doi.org/10.1080/09286580802256559. PMID: 18780255. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Pesudovs K, Thumboo J, et al. An evaluation of the reliability and validity of the visual functioning questionnaire (VF-11) using Rasch analysis in an Asian population. Invest Ophthalmol Vis Sci. 2009 Jun;50(6):2607-13. Also available: http://dx.doi.org/10.1167/iovs.08-2359. PMID: 19182258. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Tai ES, Thumboo J, et al. Impact of diabetic retinopathy on vision-specific function. Ophthalmology. 2010 Apr;117(4):757-65. Also available: http://dx.doi.org/10.1016/j.ophtha.2009.09.035. PMID: 20122736. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lamoureux EL, Tee HW, Pesudovs K, et al. Can clinicians use the PHQ-9 to assess depression in people with vision loss? Opt Vis Sci. 2009 Feb;86(2):139-45. Also available: http://dx.doi.org/10.1097/OPX.0b013e318194eb47. PMID: 19156007. No patient-centered outcome

Lange C, Feltgen N, Junker B, et al. Resolving the clinical acuity categories "hand motion" and "counting fingers" using the Freiburg Visual Acuity Test (FrACT). Graefes Arch Clin Exp Ophthalmol. 2009 Jan;247(1):137-42. Also available: http://dx.doi.org/10.1007/s00417-008-0926-0. PMID: 18766368. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Langelaan M, van Nispen RM, Knol DL, et al. Visual Functioning Questionnaire: reevaluation of psychometric properties for a group of working-age adults. Optom Vis Sci. 2007 Aug;84(8):775-84. PMID: 17700340. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Langelaan M, Wouters B, Moll AC, et al. Intra- and interrater agreement and reliability of the Functional Field Score. Ophthalmic Physiol Opt. 2005 Mar;25(2):136-42. PMID: 15713205. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Latham K, Baranian M, Timmis MA, et al. Difficulties with goals of the Dutch ICF Activity Inventory: Perceptions of those with retinitis pigmentosa and of those who support them. Invest Ophthalmol Vis Sci. 2015 Apr;56(4):2381-91. Also available: http://dx.doi.org/10.1167/iovs.14-16237. PMID: 25766586. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lauritzen TZ, Harris J, Mohand-Said S, et al. Reading visual braille with a retinal prosthesis. Front Neurosci. 2012;6:168. PMID: 23189036. Duplicate data

Le Gargasson JF, Rigaudiere F, Guez JE, et al. Contribution of scanning laser ophthalmoscopy to the functional investigation of subjects with macular holes. Doc Ophthalmol. 1994;86(3):227-38. PMID: 7813374. No patient-centered outcome

Legge GE, Beckmann PJ, Tjan BS, et al. Indoor navigation by people with visual impairment using a digital sign system. PLoS ONE. 2013;8(10):e76783. Also available: http://dx.doi.org/10.1371/journal.pone.0076783. PMID: 24116156. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Leissner J, Coenen M, Froehlich S, et al. What explains health in persons with visual impairment? Health Qual Life Outcomes. 2014;12:65. Also available: http://dx.doi.org/10.1186/1477-7525-12-65. PMID: 24886326. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Leplege A, Schemann JF, Diakite B, et al. A new condition specific quality of life measure for the blind and the partially sighted in Sub-Saharan Africa, the IOTAQOL: methodological aspects of the development procedure. Qual Life Res. 2006 Oct;15(8):1373-82. PMID: 16826435. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lepri BP. Is acuity enough? Other considerations in clinical investigations of visual prostheses. J Neural Eng. 2009 Jun;6(3):035003. PMID: 19458402. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Lesmes LA, Lu ZL, Baek J, et al. Bayesian adaptive estimation of the contrast sensitivity function: The quick CSF method. J Vis. 2010 Mar 30;10(3). No psychometric property data reported, or study was not primarily designed to measure psychometrics

Lewis PM, Ackland HM, Lowery AJ, et al. Restoration of vision in blind individuals using bionic devices: A review with a focus on cortical visual prostheses. Brain Res. 2015 Jan 21;51-73. Also available: http://dx.doi.org/10.1016/j.brainres.2014.11.020. Narrative review

Li X, Chen J, Xu G, et al. Development of an elderly low vision quality of life questionnaire for less-developed areas of China. Int J Qual Life. 2015 Oct 14;24(10):2403-13. Also available: http://dx.doi.org/10.1007/s11136-015-0970-2. PMID: 26174361. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lin JC, Chie WC. Psychometric validation of the Taiwan Chinese version of the 25-Item National Eye Institute Visual Functioning Questionnaire.[Erratum appears in J Eval Clin Pract. 2010 Oct;16(5):1024]. J Eval Clin Pract. 2010 Jun;16(3):619-26. Also available: http://dx.doi.org/10.1111/j.1365-2753.2009.01253.x. PMID: 19712207. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lin JC, Chie WC. Psychometric validation of the Taiwan Chinese version of the 25-Item National Eye Institute Visual Functioning Questionnaire: Corrigenda. J Eval Clin Pract. 2010 Oct;16(5):1024. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Lin JC, Yu JH. Assessment of quality of life among Taiwanese patients with visual impairment. J Formos Med Assoc. 2012 Oct;111(10):572-9. Also available: http://dx.doi.org/10.1016/j.jfma.2011.09.021. PMID: 23089693. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Lin TC, Chang HM, Hsu CC, et al. Retinal prostheses in degenerative retinal diseases. J Chin Med Assoc. 2015 Sep;78(9):501-5. Also available: http://dx.doi.org/10.1016/j.jcma.2015.05.010. PMID: 26142056. Narrative review

Lindblad AS, Clemons TE. Responsiveness of the National Eye Institute Visual Function Questionnaire to progression to advanced age-related macular degeneration, vision loss, and lens opacity: AREDS Report no. 14. Arch Ophthalmol. 2005 Sep;123(9):1207-14. PMID: 16157800. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Linder M, Chang TS, Scott IU, et al. Validity of the visual function index (VF-14) in patients with retinal disease. Arch Ophthalmol. 1999 Dec;117(12):1611-6. PMID: 10604665. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lipshitz I, Jacob S, Lamba M, et al. Mirror telescopic intraocular lens for age-related macular degeneration. Design and preliminary clinical results of the Lipshitz macular implant. J Cataract Refract Surg. 2008 Jan;34(1):87-94. Not relevant RPS

Little B. October consultation #2. J Cataract Refract Surg. 2009 Oct;35(10):1836-7. Also available: http://dx.doi.org/10.1016/j.jcrs.2009.08.003. Not relevant RPS

Liu X, Makino H, Kobayashi S, et al. An indoor guidance system for the blind using fluorescent lights--relationship between receiving signal and walking speed. Conf Proc IEEE Eng Med Biol Soc. 2006;1:5960-3. PMID: 17946350. No patient-centered outcome

Lloyd AJ, Loftus J, Turner M, et al. Psychometric validation of the Visual Function Questionnaire-25 in patients with diabetic macular edema. Health Qual Life Outcomes. 2013;11:10. Also available: http://dx.doi.org/10.1186/1477-7525-11-10. PMID: 23347793. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lodha N, Westall CA, Brent M, et al. A modified protocol for the assessment of visual function in patients with retinitis pigmentosa. Adv Exp Med Biol. 2003;533:49-57. PMID: 15180247. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Loewenstein A, Malach R, Goldstein M, et al. Replacing the Amsler grid: a new method for monitoring patients with age-related macular degeneration. Ophthalmology. 2003 May;110(5):966-70. PMID: 12750099. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Loizos K, Lazzi G, Lauritzen JS, et al. A multi-scale computational model for the study of retinal prosthetic stimulation. Conf Proc IEEE Eng Med Biol Soc. 2014;2014:6100-3. Also available: http://dx.doi.org/10.1109/EMBC.2014.6945021. PMID: 25571389. Not relevant RPS

Longworth L, Yang Y, Young T, et al. Use of generic and condition-specific measures of health-related quality of life in NICE decision-making: a systematic review, statistical modelling and survey. Health Technol Assess. 2014 Feb;18:1-224. Also available: http://dx.doi.org/10.3310/hta18090. PMID: 24524660. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lopez-Miguel A, Coco-Martin MB, Martinez-Fernandez R, et al. Patient-reported outcomes in Spanish patients diagnosed with bilateral age-related macular degeneration. Ophthalmologica. 2013;230(2):69-75. Also available: http://dx.doi.org/10.1159/000351652. PMID: 23886949. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Lovie-Kitchin JE, Bevan JD, Hein B. Reading performance in children with low vision. Clin Exp Optom. 2001 May;84(3):148-154. PMID: 12366326. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lu Y, Wang J, Wu H, et al. Recognition of objects in simulated irregular phosphene maps for an epiretinal prosthesis. Artif Organs. 2014 Feb;38(2). Also available: http://dx.doi.org/10.1111/aor.12174. PMID: 24117959. Not relevant RPS

Luna B, Dobson V, Biglan AW. Development of grating acuity in infants with regressed stage 3 retinopathy of prematurity. Invest Ophthalmol Vis Sci. 1990 Oct;31(10):2082-7. PMID: 2211005. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Lundstrom M, Wendel E. Assessment of vision-related quality of life measures in ophthalmic conditions. Expert Rev Pharmacoecon Outcomes Res. 2006 Dec;6(6):691-724. Also available: http://dx.doi.org/10.1586/14737167.6.6.691. No patient-centered outcome

Luo YH, Da Cruz L. A review and update on the current status of retinal prostheses (bionic eye). Br Med Bull. 2014 Mar;109(1):31-44. Also available: http://dx.doi.org/10.1093/bmb/ldu002. PMID: 24526779. Narrative review

Luo YH, Zhong JJ, da Cruz L. The use of Argus® II retinal prosthesis by blind subjects to achieve localisation and prehension of objects in 3-dimensional space. Graefes Arch Clin Exp Ophthalmol. 2015 Nov;253(11):1907-14. Epub 2014 Dec 31. Also available: http://dx.doi.org/10.1007/s00417-014-2912-z. PMID: 25547618. Duplicate data

MacKenzie D. Electronic device restores sight in the blind. N Sci. 2010 Nov 6;208(2785):1-2. Also available: http://dx.doi.org/10.1016/S0262-4079(10)62725-X. Editorial

Mackenzie PJ, Chang TS, Scott IU, et al. Assessment of vision-related function in patients with age-related macular degeneration. Ophthalmology. 2002 Apr;109(4):720-9. PMID: 11927429. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mahadevappa M, Weiland JD, Yanai D, et al. Perceptual thresholds and electrode impedance in three retinal prosthesis subjects. IEEE Trans Neural Syst Rehabil Eng. 2005 Jun;13(2):201-6. Also available: http://dx.doi.org/10.1109/TNSRE.2005.848687. PMID: 16003900. Not relevant RPS

Malkin AG, Goldstein JE, Perlmutter MS, et al. Responsiveness of the EQ-5D to the effects of low vision rehabilitation. Opt Vis Sci. 2013 Aug;90(8):799-805. Also available: http://dx.doi.org/10.1097/OPX.0000000000000005. PMID: 23851303. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mallinson T. Why measurement matters for measuring patient vision outcomes. Optom Vis Sci. 2007 Aug;84(8):675-82. PMID: 17700332. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Mangione CM, Berry S, Spritzer K, et al. Identifying the content area for the 51-item National Eye Institute Visual Function Questionnaire: results from focus groups with visually impaired persons. Arch Ophthalmol. 1998 Feb;116(2):227-33. PMID: 9488276. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mangione CM, Lee PP, Gutierrez PR, et al. Development of the 25-item National Eye Institute Visual Function Questionnaire. Arch Ophthalmol. 2001 Jul;119(7):1050-8. PMID: 11448327. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mangione CM, Lee PP, Pitts J, et al. Psychometric properties of the National Eye Institute Visual Function Questionnaire (NEI-VFQ). NEI-VFQ Field Test Investigators. Arch Ophthalmol. 1998 Nov;116(11):1496-504. PMID: 9823352. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mansfield JS, Legge GE, Bane MC. Psychophysics of reading. XV: Font effects in normal and low vision. Invest Ophthalmol Vis Sci. 1996 Jul;37(8):1492-501. PMID: 8675391. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Maples WC. Test-retest reliability of the College of Optometrists in Vision Development Quality of Life Assessment short form. J Optom Vision Dev. 2002 Summer;33(2):126-34. PMID: 11016247. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Marella M, Gothwal VK, Pesudovs K, et al. Validation of the visual disability questionnaire (VDQ) in India. Opt Vis Sci. 2009 Jul;86(7):E826-35. Also available: http://dx.doi.org/10.1097/OPX.0b013e3181ae1b3f. PMID: 19543138. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Marella M, Pesudovs K, Keeffe JE, et al. The psychometric validity of the NEI VFQ-25 for use in a low-vision population. Invest Ophthalmol Vis Sci. 2010 Jun;51(6):2878-84. Also available: http://dx.doi.org/10.1167/iovs.09-4494. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Markowitz SN, Reyes SV. Microperimetry and clinical practice: an evidence-based review. Can J Ophthalmol. 2013 Oct;48(5):350-7. Also available: http://dx.doi.org/10.1016/j.jcjo.2012.03.004. PMID: 24093179. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Marmeleira J, Laranjo L, Marques O, et al. Criterion-related validity of the short form of the International Physical Activity Questionnaire in adults who are blind. J Vis Impair Blind. 2013 Sep-Oct;107(5):375-81. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Marton K, Kovi Z, Farkas L, et al. Everyday functions and needs of individuals with disability: a reliability and validity study based on the principles of the ICF. Psychiatr Hung. 2014;29(4):398-409. PMID: 25569829. No patient-centered outcome

Marx MS, Werner P, Cohen-Mansfield J, et al. Visual acuity estimates in noncommunicative elderly persons. Invest Ophthalmol Vis Sci. 1990 Mar 1;31(3):593-6. PMID: 2318597. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW, Ahmadian L, Grover LL, et al. The Activity Inventory: an adaptive visual function questionnaire. Optom Vis Sci. 2007 Aug;84(8):763-74. PMID: 17700339. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW, Ahmadian L. What do different visual function questionnaires measure? Ophthalmic Epidemiol. 2007 Jul-Aug;14(4):198-204. PMID: 17896298. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW, Fletcher DC. Evaluation of the NEI visual functioning questionnaire as an interval measure of visual ability in low vision. Vision Res. 2001 Feb;41(3):397-413. PMID: 11164454. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW, Hsu CT, Baker FH, et al. Visual disability variables. I: the importance and difficulty of activity goals for a sample of low-vision patients. Arch Phys Med Rehabil. 2005 May;86(5):946-53. PMID: 15895341. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW, Hsu CT, Baker FH, et al. Visual disability variables. II: The difficulty of tasks for a sample of low-vision patients. Arch Phys Med Rehabil. 2005 May;86(5):954-67. PMID: 15895342. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW. A systems model for low vision rehabilitation. II. Measurement of vision disabilities. Optom Vis Sci. 1998 May;75(5):349-73. PMID: 9624700. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW. An interval-scaled scoring algorithm for visual function questionnaires. Optom Vis Sci. 2007 Aug;84(8):689-704. PMID: 17700325. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW. Application of stochastic measurement models to visual function rating scale questionnaires. Ophthalmic Epidemiol. 2005 Apr;12(2):103-24. PMID: 16019693. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW. Likert and Guttman scaling of visual function rating scale questionnaires. Ophthalmic Epidemiol. 2004 Dec;11(5):381-99. PMID: 15590585. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Massof RW. The measurement of vision disability. Optom Vis Sci. 2002 Aug;79(8):516-52. PMID: 12199545. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Mathew R, Sivaprasad S. Environmental Amsler test as a monitoring tool for retreatment with ranibizumab for neovascular age-related macular degeneration. Eye (Lond). 2012 Mar;26(3):389-93. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mazella A, Albaret JM, Picard D. Haptic-2D: A new haptic test battery assessing the tactual abilities of sighted and visually impaired children and adolescents with two-dimensional raised materials. Res Dev Disabil. 2016 Jan 1;103-23. Also available: http://dx.doi.org/10.1016/j.ridd.2015.10.012. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

McCabe P, Nason F, Demers Turco P, et al. Evaluating the effectiveness of a vision rehabilitation intervention using an objective and subjective measure of functional performance. Ophthalmic Epidemiol. 2000 Dec;7(4):259-70. PMID: 11262673. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

McCarthy C, Barnes N. Time-to-contact maps for navigation with a low resolution visual prosthesis. Conf Proc IEEE Eng Med Biol Soc. 2012;2780-3. PMID: 23366502. Not relevant RPS

McCarthy C, Walker JG, Lieby P, et al. Mobility and low contrast trip hazard avoidance using augmented depth. J Neural Eng. 2015 Feb 1;12(1). Also available: http://dx.doi.org/10.1088/1741-2560/12/1/016003. Not relevant RPS

McClure ME, Hart PM, Jackson AJ, et al. Macular degeneration: do conventional measurements of impaired visual function equate with visual disability? Br J Ophthalmol. 2000 Mar;84(3):244-50. PMID: 10684832. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

McGregor LN, Chaparro A. Visual difficulties reported by low-vision and nonimpaired older adult drivers. Hum Factors. 2005;47(3):469-78. PMID: 16435689. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

McKean-Cowdin R, Varma R, Wu J, et al. Severity of visual field loss and health-related quality of life. Am J Ophthalmol. 2007 Jun;143(6):1013-23. Also available: http://dx.doi.org/10.1016/j.ajo.2007.02.022. PMID: 17399676. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Melillo P, Orrico A, Attanasio M, et al. A pilot study for development of a novel tool for clinical decision making to identify fallers among ophthalmic patients. BMC Med Inform Decis Mak. 2015;15 Suppl 3:S6. Also available: http://dx.doi.org/10.1186/1472-6947-15-S3-S6. PMID: 26391731. No patient-centered outcome

Messias K, Jagle H, Saran R, et al. Psychophysically determined full-field stimulus thresholds (FST) in retinitis pigmentosa: relationships with electroretinography and visual field outcomes. Doc Ophthalmol. 2013 Oct;127(2):123-9. Also available: http://dx.doi.org/10.1007/s10633-013-9393-y. PMID: 23733195. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Miller KM. August consultation #5. J Cataract Refract Surg. 2008 Aug;34(8):1234-5. Also available: http://dx.doi.org/10.1016/j.jcrs.2008.06.006. Not relevant RPS

Misajon R, Hawthorne G, Richardson J, et al. Vision and quality of life: the development of a utility measure. Invest Ophthalmol Vis Sci. 2005 Nov;46(11):4007-15. Also available: http://dx.doi.org/10.1167/iovs.04-1389. PMID: 16249474. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Miskala PH, Bressler NM, Meinert CL. Relative contributions of reduced vision and general health to NEI-VFQ scores in patients with neovascular age-related macular degeneration. Arch Ophthalmol. 2004 May;122(5):758-66. PMID: 15136325. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Miskala PH, Hawkins BS, Mangione CM, et al. Responsiveness of the National Eye Institute Visual Function Questionnaire to changes in visual acuity: findings in patients with subfoveal choroidal neovascularization--SST Report No. 1.[Erratum appears in Arch Ophthalmol. 2003 Oct;121(10):1513]. Arch Ophthalmol. 2003 Apr;121(4):531-9. PMID: 12695250. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mitchell J, Bradley C. Design of an individualised measure of the impact of macular disease on quality of life (the MacDQoL). Qual Life Res. 2004 Aug;13(6):1163-75. PMID: 15287282. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mitchell J, Bradley C. Psychometric evaluation of the 12-item Well-being Questionnaire for use with people with macular disease. Qual Life Res. 2001;10(5):465-73. PMID: 11763208. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mitchell J, Bradley C. Quality of life in age-related macular degeneration: a review of the literature. Surrey (UK): Royal Holloway, University of London; 2006 Oct 20. 63 p. Also available: http://amdalliance.org/documents/White%20Paper%20%20references%20updated%20and%20standardised%20261006.pdf. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Mitchell J, Wolffsohn J, Woodcock A, et al. The MacDQoL individualized measure of the impact of macular degeneration on quality of life: reliability and responsiveness. Am J Ophthalmol. 2008 Sep;146(3):447-54. Also available: http://dx.doi.org/10.1016/j.ajo.2008.04.031. PMID: 18547542. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mitchell J, Wolffsohn JS, Woodcock A, Anderson SJ, McMillan CV, Ffytche T, Rubinstein M, Amoaku W, Bradley C. +Psychometric evaluation of the MacDQoL individualised measure of the impact of macular degeneration on quality of life. Health Qual Life Outcomes. 2005;3:25. PMID: 15831093. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Mitchell P, Bressler N, Tolley K, et al. Patient-reported visual function outcomes improve after ranibizumab treatment in patients with vision impairment due to diabetic macular edema: randomized clinical trial. JAMA Ophthalmol. 2013 Oct;131(10):1339-47. Also available: http://dx.doi.org/10.1001/jamaophthalmol.2013.4592. PMID: 23974915. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Miwa M, Iwanami M, Oba MS, et al. Comparison of LogMAR Eye charts with angular vision for visually impaired: the Berkeley rudimentary vision test vs LogMAR One target Landolt ring Eye chart. Graefes Arch Clin Exp Ophthalmol. 2013 Dec;251(12):2761-7. Also available: http://dx.doi.org/10.1007/s00417-013-2469-2. PMID: 24057176. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Moganeswari D, Thomas J, Srinivasan K, et al. Test re-test reliability and validity of different visual acuity and stereoacuity charts used in preschool children. J Clin Diagn Res. 2015 Nov 1;9(11). Also available: http://dx.doi.org/10.7860/JCDR/2015/14407.6747. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Monge M, Raj M, Nazari MH, et al. A fully intraocular high-density self-calibrating epiretinal prosthesis. IEEE Trans Biomed Circuits Syst. 2013 Dec;7(6):747-60. Also available: http://dx.doi.org/10.1109/TBCAS.2014.2298334. PMID: 24473540. Technical report without human data

Morrow T. Retinal implant brings some sight to profound retinitis pigmentosa patients. Manag Care. 2013 May;22(5):54-5. PMID: 23757835. Editorial

Nanduri D, Fine I, Horsager A, et al. Frequency and amplitude modulation have different effects on the percepts elicited by retinal stimulation. Invest Ophthalmol Vis Sci. 2012 Jan;53(1):205-14. Also available: http://dx.doi.org/10.1167/iovs.11-8401. PMID: 22110084. Not relevant RPS

Nanduri D, Humayun MS, Greenberg RJ, et al. Retinal prosthesis phosphene shape analysis. Conf Proc IEEE Eng Med Biol Soc. 2008;1785-8. PMID: 19163027. Not relevant RPS

Nau A, Bach M, Fisher C. Clinical tests of ultra-low vision used to evaluate rudimentary visual perceptions enabled by the brainport vision device. Transl Vis Sci Technol. 2013;2(3). Also available: http://dx.doi.org/10.1167/tvst.2.3.1. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Nau AC, Pintar C, Fisher C, et al. A standardized obstacle course for assessment of visual function in ultra low vision and artificial vision. J Vis Exp. 2014;(84):e51205. Also available: http://dx.doi.org/10.3791/51205. PMID: 24561717. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Nayagam DA, Durmo I, McGowan C, et al. Techniques for processing eyes implanted with a retinal prosthesis for localized histopathological analysis: Part 2 Epiretinal implants with retinal tacks. J Vis Exp. 2015;(96). Also available: http://dx.doi.org/10.3791/52348. PMID: 25798628. Technical report without human data

Nelson PA, Dial JG, Joyce A. Validation of the cognitive test for the blind as an assessment of intellectual functioning. Rehabil Psychol. 2002;47(2):184-93. Also available: http://dx.doi.org/10.1037. No patient-centered outcome

Nevyas-Wallace A. February consultation #3. J Cataract Refract Surg. 2010 Feb;36(2):355-6. Also available: http://dx.doi.org/10.1016/j.jcrs.2009.12.004. Not relevant RPS

Niederlander C, Wahlster P, Kriza C, et al. Registries of implantable medical devices in Europe. Health Policy. 2013 Nov;113(1):20-37. Also available: http://dx.doi.org/10.1016/j.healthpol.2013.08.008. PMID: 24075007. Narrative review

Novack GD. Fill size for ophthalmic products. Ocul Surf. 2013 Oct;11(4):285-7. Also available: http://dx.doi.org/10.1016/j.jtos.2013.07.002. PMID: 24112231. Editorial

Novak CB, Mackinnon SE, Williams JI, et al. Development of a new measure of fine sensory function. Plast Reconstr Surg. 1993 Aug;92(2):301-10. PMID: 8337281. No patient-centered outcome

Nutheti R, Shamanna BR, Nirmalan PK, et al. Impact of impaired vision and eye disease on quality of life in Andhra Pradesh. Invest Ophthalmol Vis Sci. 2006 Nov;47(11):4742-8. PMID: 17065482. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

OConnor PM, Lamoureux EL, Keeffe JE. Predicting the need for low vision rehabilitation services. Br J Ophthalmol. 2008 Feb;92(2):252-5. PMID: 18227205. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

OConnor PM, Scarr BC, Lamoureux EL, et al. Validation of a quality of life questionnaire in the Pacific Island. Ophthalmic Epidemiol. 2010 Dec;17(6):378-86. Also available: http://dx.doi.org/10.3109/09286586.2010.528134. PMID: 21080810. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Ohta J, Tokuda T, Kagawa K, et al. Silicon LSI-based smart stimulators for retinal prosthesis: A flexible and extendable microchip-based stimulator. IEEE Eng Med Biol Mag. 2006 Sep-Oct;25(5):47-59. PMID: 17020199. Technical report without human data

Opie NL, Ayton LN, Apollo NV, et al. Optical coherence tomography-guided retinal prosthesis design: model of degenerated retinal curvature and thickness for patient-specific devices. Artif Organs. 2014 Jun;38(6):E82-94. Also available: http://dx.doi.org/10.1111/aor.12287. PMID: 24689741. Technical report without human data

Orr P, Rentz AM, Margolis MK, et al. Validation of the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) in age-related macular degeneration. Invest Ophthalmol Vis Sci. 2011 May;52(6):3354-9. Also available: http://dx.doi.org/10.1167/iovs.10-5645. PMID: 21282568. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Orticio LP. Measuring health-related quality of life among older visually impaired adults: a preview to instrument construction. Insight. 2007 Jul-Sep;32(3):8-12. PMID: 17953321. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Owsley C, Huisingh C, Clark ME, et al. Comparison of visual function in older eyes in the earliest stages of age-related macular degeneration to those in normal macular health. Curr Eye Res. 2015 Mar 17. Also available: http://dx.doi.org/10.3109/02713683.2015.1011282. PMID: 25802989. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Owsley C, McGwin G Jr, Scilley K, et al. Development of a questionnaire to assess vision problems under low luminance in age-related maculopathy. Invest Ophthalmol Vis Sci. 2006 Feb;47(2):528-35. PMID: 16431946. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Pach J, Gekeler F. Therapeutic approaches for retinitis pigmentosa. Klin Monbl Augenheilkd. 2013;230(5):512-8. Also available: http://dx.doi.org/10.1055/s-0032-1328471. PMID: 23695848. Narrative review

Parikh N, Itti L, Humayun M, et al. Performance of visually guided tasks using simulated prosthetic vision and saliency-based cues. J Neural Eng. 2013 Apr;10(2). Also available: http://dx.doi.org/10.1088/1741-2560/10/2/026017. PMID: 23449023. Not relevant RPS

Parikh NJ, McIntosh BP, Tanguay AR, et al. Biomimetic image processing for retinal prostheses: peripheral saliency cues. Conf Proc IEEE Eng Med Biol Soc. 2009;4569-72. PMID: 19963840. Not relevant RPS

Park RI. The bionic eye: Retinal prostheses. Int Ophthalmol Clin. 2004 Fall;44(4):139-54. Also available: http://dx.doi.org/10.1097/00004397-200404440-00011. PMID: 15577569. Narrative review

Park Y, Shin JA, Yang SW, et al. The relationship between visual impairment and health-related quality of life in Korean adults: The Korea national health and nutrition examination survey (2008-2012). PLoS ONE. 2015 Jul 20;10(7). Also available: http://dx.doi.org/10.1371/journal.pone.0132779. PMID: 26192763. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Patel PJ, Chen FK, Da Cruz L, et al. Test-retest variability of reading performance metrics using MNREAD in patients with age-related macular degeneration. Invest Ophthalmol Vis Sci. 2011 May;52(6):3854-9. PMID: 21421873. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Paudel P, Khadka J, Burnett A, et al. Papua New Guinea vision-specific quality of life questionnaire: A new patient-reported outcome instrument to assess the impact of impaired vision. Clin Experiment Ophthalmol. 2015 Apr 1;43(3):202-13. Also available: http://dx.doi.org/10.1111/ceo.12413. PMID: 25132289. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Payakachat N, Summers KH, Pleil AM, et al. Predicting EQ-5D utility scores from the 25-item National Eye Institute Vision Function Questionnaire (NEI-VFQ 25) in patients with age-related macular degeneration. Qual Res Life. 2009 Sep;18(7):801-13. Also available: http://dx.doi.org/10.1007/s11136-009-9499-6. PMID: 19543808. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Paz SH, Globe DR, Wu J, et al. Relationship between self-reported depression and self-reported visual function in Latinos. Arch Ophthalmol. 2003 Jul;121(7):1021-7. PMID: 12860807. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Paz SH, Slotkin J, McKean-Cowdin R, et al. Development of a vision-targeted health-related quality of life item measure. Qual Res Life. 2013 Nov;22(9):2477-87. Also available: http://dx.doi.org/10.1007/s11136-013-0365-1. PMID: 23475688. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Penrod WM, Petrosko J. Spatial organization skills of the blind in large outdoor places. RE:view. 2003 Winter;34(4):155-64. No patient-centered outcome

Peters AY, Locke KG, Birch DG. Comparison of the Goldmann-Weekers dark adaptometer and LKC Technologies Scotopic Sensitivity tester-1. Doc Ophthalmol. 2000 Jul;101(1):1-9. PMID: 11128963. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Peters T, Klingberg S, Zrenner E, et al. Emotional wellbeing of blind patients in a pilot trial with subretinal implants. Graefes Arch Clin Exp Ophthalmol. 2013 Jun;251(6):1489-93. Also available: http://dx.doi.org/10.1007/s00417-012-2210-6. PMID: 23192236. Duplicate data

Petrillo J, Cano SJ, McLeod LD, et al. Using classical test theory, item response theory, and Rasch measurement theory to evaluate patient-reported outcome measures: a comparison of worked examples. Value Health. 2015 Jan;18(1):25-34. Also available: http://dx.doi.org/10.1016/j.jval.2014.10.005. PMID: 25595231. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Pezaris J. A novel approach to visual prosthetics. Neurosci Lett. 2011 Jul. Also available: http://dx.doi.org/10.1016/j.neulet.2011.05.130. Not relevant RPS

Picaud S, Sahel JA. Retinal prostheses: Clinical results and future challenges. C R Biol. 2014 Mar;337(3):214-22. Also available: http://dx.doi.org/10.1016/j.crvi.2014.01.001. Narrative review

Piermarocchi S, Varano M, Parravano M, et al. Quality of Vision Index: a new method to appraise visual function changes in age-related macular degeneration. Eur J Ophthalmol. 2011 Jan-Feb;21(1):55-66. PMID: 20640999. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Posey VK, Henderson BW. Comprehensive adult student assessment systems braille reading assessment: an exploratory study. J Vis Impair Blind. 2012 Aug;106(8):488-99. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Rahimy E, Reddy S, Decroos FC, et al. Prospective evaluation of visual acuity agreement between standard early treatment diabetic retinopathy study chart and a handheld equivalent in eyes with retinal pathology. Retina. 2015 Aug 7;35(8):1680-7. Also available: http://dx.doi.org/10.1097/IAE.0000000000000518. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Rees G, Ponczek E, Hassell J, et al. Psychological outcomes following interventions for people with low vision: A systematic review. Expert Rev Ophthalmol. 2010 Jun;5(3):385-403. Also available: http://dx.doi.org/10.1586/eop.10.32. No patient-centered outcome

Rees G, Xie J, Holloway EE, et al. Identifying distinct risk factors for vision-specific distress and depressive symptoms in people with vision impairment. Invest Ophthalmol Vis Sci. 2013 Nov;54(12):7431-8. Also available: http://dx.doi.org/10.1167/iovs.13-12153. PMID: 24150757. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Reeves BC, Langham J, Walker J, et al. Verteporfin photodynamic therapy cohort study: report 2: clinical measures of vision and health-related quality of life. Ophthalmology. 2009 Dec;116(12):2463-70. Also available: http://dx.doi.org/10.1016/j.ophtha.2009.10.031. PMID: 19948277. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Regillo CD. Retinal implant shows promising early results in clinical trial. Ocular Surg News. 2009 Oct 10;27(19):57-9. Technical report without human data

Reischies FM, Geiselmann B. Age-related cognitive and vision impairment affecting the detection of dementia syndrome in old age. Br J Psychiatry. 1997 Nov;171:449-51. No patient-centered outcome

Restoring vision to the blind: Evaluating visual function, endpoints. Transl Vis Sci Technol. 2014;3(7):63-9. Also available: http://dx.doi.org/10.1167/tvst.3.7.10. Narrative review

Restoring vision to the blind: The new age of implanted visual prostheses. Transl Vis Sci Technol. 2014;3(7) Also available: http://dx.doi.org/10.1167/tvst.3.7.3. Narrative review

Retinal implant offers the potential for sight to blind patients. Ocular Surg News. 2009 Nov 10;27(21):22-3. Editorial

Revicki DA, Rentz AM, Harnam N, et al. Reliability and validity of the National Eye Institute Visual Function Questionnaire-25 in patients with age-related macular degeneration. Invest Ophthalmol Vis Sci. 2010 Feb;51(2):712-7. Also available: http://dx.doi.org/10.1167/iovs.09-3766. PMID: 19797233. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Rieger V, Aryan NP, Brendler C, et al. Benefit of spatial filtering for visual perception with a subretinal implant. Conf Proc IEEE Eng Med Biol Soc. 2014;2014:6112-5. Also available: http://dx.doi.org/10.1109/EMBC.2014.6945024. PMID: 25571392. Technical report without human data

Rizzo III JF, Wyatt J, Loewenstein J, et al. Methods and perceptual thresholds for short-term electrical stimulation of human retina with microelectrode arrays. Invest Ophthalmol Vis Sci. 2003 Dec;44(12):5355-61. Also available: http://dx.doi.org/10.1167/iovs.02-0819. PMID: 14638738. Not relevant RPS

Rizzo III JF, Wyatt J, Loewenstein J, et al. Perceptual efficacy of electrical stimulation of human retina with a microelectrode array during short-term surgical trials. Invest Ophthalmol Vis Sci. 2003 Dec;44(12):5362-9. Also available: http://dx.doi.org/10.1167/iovs.02-0817. PMID: 14638739. Not relevant RPS

Rock T, Bartz-Schmidt KU, Bramkamp M, et al. Influence of axial length on thickness measurements using spectral-domain optical coherence tomography. Invest Ophthalmol Vis Sci. 2014 Nov 1;55(11):7494-8. Also available: http://dx.doi.org/10.1167/iovs.14-14043. PMID: 25298411. No patient-centered outcome

Roentgen UR, Gelderblom GJ, de Witte LP. The development of an indoor mobility course for the evaluation of electronic mobility aids for persons who are visually impaired. Assist Technol. 2012;24(3):143-54. PMID: 23033732. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Roets Merken LM, Zuidema SU, Vernooij Dassen MJ, et al. Screening for hearing, visual and dual sensory impairment in older adults using behavioural cues: A validation study. Int J Nurs Stud. 2014 Nov;51(11):1434-40. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Rohrschneider K, Bultmann S, Gluck R, et al. Scanning laser ophthalmoscope fundus perimetry before and after laser photocoagulation for clinically significant diabetic macular edema. Am J Ophthalmol. 2000 Jan;129(1):27-32. PMID: 10653409. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Rohrschneider K, Springer C, Bultmann S, et al. Microperimetry--comparison between the micro perimeter 1 and scanning laser ophthalmoscope--fundus perimetry. Am J Ophthalmol. 2005 Jan;139(1):125-34. PMID: 15672526. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Rosenberg R. Low vision. Curr Opin Ophthalmol. 1992;3(1):102-7. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Rosenfeld JV, Lewis P. Progress in bionic vision devices. Stereotact Funct Neurosurg. 2013 May. Also available: http://dx.doi.org/10.1159/000351783. Narrative review

Rossi GC, Milano G, Tinelli C. The Italian version of the 25-item National Eye Institute Visual Function Questionnaire: translation, validity, and reliability. J Glaucoma. 2003 Jun;12(3):213-20. PMID: 12782838. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Rovner BW, Casten RJ, Tasman WS. Effect of depression on vision function in age-related macular degeneration. Arch Ophthalmol. 2002 Aug;120(8):1041-4. PMID: 12149057. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Rozanski C, Haythornthwaite JA, Dagnelie G, et al. Applying theories and interventions from behavioral medicine to understand and reduce visual field variability in patients with vision loss. Med Hypotheses. 2014 Aug;83(2):190-5. Also available: http://dx.doi.org/10.1016/j.mehy.2014.04.031. PMID: 24854574. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Rubin GS, Bandeen-Roche K, Huang GH, et al. The association of multiple visual impairments with self-reported visual disability: SEE project. Invest Ophthalmol Vis Sci. 2001 Jan;42(1):64-72. PMID: 11133849. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Rubin GS, West SK, Munoz B, et al. A comprehensive assessment of visual impairment in a population of older Americans. The SEE Study. Salisbury Eye Evaluation Project. Invest Ophthalmol Vis Sci. 1997 Mar;38(3):557-68. PMID: 9071208. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Rubin GS. Measuring reading performance. Vision Res. 2013 Sep 20;90:43-51. Also available: http://dx.doi.org/10.1016/j.visres.2013.02.015. PMID: 23506967. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Ryan B, Court H, Margrain TH. Measuring low vision service outcomes: Rasch analysis of the seven-item National Eye Institute Visual Function Questionnaire. Optom Vis Sci. 2008 Feb;85(2):112-21. PMID: 18296928. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Sabariego C, Oberhauser C, Posarac A, et al. Measuring disability: Comparing the impact of two data collection approaches on disability rates. Int J Environ Res Public Health. 2015 Aug 25;12(9):10329-51. Also available: http://dx.doi.org/10.3390/ijerph120910329. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Sabbah N, Authie CN, Sanda N, et al. Importance of eye position on spatial localization in blind subjects wearing an argus II retinal prosthesis. Invest Ophthalmol Vis Sci. 2014 Nov 20;55(12):8259-66. Also available: http://dx.doi.org/10.1167/iovs.14-15392. Duplicate data

Sakaguchi H, Kamei M, Fujikado T, et al. Artificial vision by direct optic nerve electrode (AV-DONE) implantation in a blind patient with retinitis pigmentosa. J Artif Organs. 2009 Sep;12(3):206-9. Not relevant RPS

Saunders AL, Williams CE, Heriot W, et al. Development of a surgical procedure for implantation of a prototype suprachoroidal retinal prosthesis. Clin Experiment Ophthalmol. 2014 Sep 1;42(7):665-74. Also available: http://dx.doi.org/10.1111/ceo.12287. Technical report without human data

Sawa M, et al. Question and answer sessions with Dr. George O. Waring, III. Ophthalmologica. 2003;217:45-7. Also available: http://dx.doi.org/10.1159/000073749. Not relevant RPS

Sawa Y, Tatsumi E, Funakubo A, et al. Journal of artificial organs 2009: The year in review. J Artif Organs. 2010 Apr;13(1):1-9. Also available: http://dx.doi.org/10.1007/s10047-010-0497-9. PMID: 20309714. Narrative review

Schemann JF, Leplege A, Keita T, Resnikoff S. From visual function deficiency to handicap: measuring visual handicap in Mali. Ophthalmic Epidemiol. 2002 Apr;9(2):133-48. PMID: 11821978. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Schmier JK, Halpern MT, Covert D. Validation of the Daily Living Tasks Dependent on Vision (DLTV) questionnaire in a U.S. population with age-related macular degeneration. Ophthalmic Epidemiol. 2006 Apr;13(2):137-43. PMID: 16581618. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Schulze-Bonsel K, Feltgen N, Burau H, et al. Visual acuities "hand motion" and "counting fingers" can be quantified with the freiburg visual acuity test. Invest Ophthalmol Vis Sci. 2006 Mar;47(3):1236-40. PMID: 16505064. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Schweitzer KD, Eneh AA, Hurst J, et al. Validation of patient symptom diary in acute posterior vitreous detachment. Saudi J Ophthalmol. 2011 Apr-Jun;25(2):181-6. Also available: http://dx.doi.org/10.1016/j.sjopt.2011.01.007. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Scilley K, Owsley C. Vision-specific health-related quality of life: content areas for nursing home residents. Qual Life Res. 2002;11(5):449-62. PMID: 12113392. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Scott IU, Schein OD, West S, et al. Functional status and quality of life measurement among ophthalmic patients. Arch Ophthalmol. 1994 Mar;112(3):329-35. PMID: 8129657. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Scott IU, Smiddy WE, Schiffman J, et al. Quality of life of low-vision patients and the impact of low-vision services. Am J Ophthalmol. 1999 Jul;128(1):54-62. PMID: 10482094. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Second human trial under way with retina implants for retinitis pigmentosa. Ocular Surg News. 2012 Jun 25;30(12):12-3. Editorial

Sengupta S, Nguyen AM, van Landingham SW, et al. Evaluation of real-world mobility in age-related macular degeneration. BMC Ophthalmol. 2015;15:9. Also available: http://dx.doi.org/10.1186/1471-2415-15-9. PMID: 25636376. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Serafano D. August Consultation # 9. J Cataract Refract Surg. 2007 Aug;33(8):1360-1. Also available: http://dx.doi.org/10.1016/j.jcrs.2007.06.010. Not relevant RPS

Sharma S, Oliver-Fernandez A. Age-related macular degeneration and quality of life: how to interpret a research paper in health-related quality of life. Curr Opin Ophthalmol. 2004 Jun;15(3):227-31. PMID: 15118510. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Shaw A, Gold D. Development of a tool for the assessment of employment preparedness specifically for persons who are blind or partially sighted. Work. 2011;39(1):49-62. Also available: http://dx.doi.org/10.3233/WOR-2011-1150. PMID: 21673428. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Shivdasani MN, Sinclair NC, Dimitrov PN, et al. Factors affecting perceptual thresholds in a suprachoroidal retinal prosthesis. Invest Ophthalmol Vis Sci. 2014;55(10):6467-81. Also available: http://dx.doi.org/10.1167/iovs.14-14396. No patient-centered outcome

Shrestha GS, Kaiti R. Visual functions and disability in diabetic retinopathy patients. J Optom. 2014 Jan-Mar;7(1):37-43. Also available: http://dx.doi.org/10.1016/j.optom.2013.03.003. PMID: 24646899. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Siepser SB. August consultation #8. J Cataract Refract Surg. 2008 Aug;34(8):1237-8. Also available: http://dx.doi.org/10.1016/j.jcrs.2008.06.009. Not relevant RPS

Sight restored. N Sci. 2010 Dec 11;208(2790):7. Technical report without human data

Simunovic MP. Metamorphopsia and its quantification. Retina. 2015 Jul;35(7):1285-91. Also available: http://dx.doi.org/10.1097/IAE.0000000000000581. PMID: 26049620. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Sin M, Rehak M, Chrapek O, et al. [Contemporary possibilities of artificial vision in blind patients using artificial neuro-prosthesis--review]. Cesk Slov Oftalmol. 2011 Feb;67(1):3-6. PMID: 21648144. Narrative review

Singer MA, Amir N, Herro A, et al. Improving quality of life in patients with end-stage age-related macular degeneration: Focus on miniature ocular implants. Clin Ophthalmol. 2011 Dec 29;6(1):33-9. PMID: 22259233. Narrative review

Slater KD, Sinclair NC, Nelson TS, et al. NeuroBi: a highly configurable neurostimulator for a retinal rrosthesis and other applications. IEEE J Transl Eng Health Med. 2015. Also available: http://dx.doi.org/10.1109/JTEHM.2015.2455507. Not relevant RPS

Smith J, Ward D, Michaelides M, et al. New and emerging technologies for the treatment of inherited retinal diseases: A horizon scanning review. Eye (Lond). 2015 Sep 11;29(9):1131-40. Also available: http://dx.doi.org/10.1038/eye.2015.115. Narrative review

Smith SC. Eye on research: retinal microchip implants. Insight. 2002 Jul-Sep;27(3). PMID: 12371259. Editorial

Smith TM. Refinement of the Low Vision Independence Measure: A qualitative study. Phys Occup Ther Geriatr. 2013 Sep;31(3):182-96. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Smretschnig E, Falkner-Radler CI, Binder S, et al. Vision-related quality of life and visual function after retinal detachment surgery. Retina. 2015 Oct 27. Also available: http://dx.doi.org/10.1097/IAE.0000000000000817. PMID: 26509221. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Snyder ME. August consultation #2. J Cataract Refract Surg. 2008 Aug;34(8):1231-3. Also available: http://dx.doi.org/10.1016/j.jcrs.2008.06.003. Not relevant RPS

Sommerhalder J, Rappaz B, De Haller R, et al. Simulation of artificial vision: II. Eccentric reading of full-page text and the learning of this task. Vision Res. 2004 Jun;44(14):1693-706. Also available: http://dx.doi.org/10.1016/j.visres.2004.01.017. PMID: 15136004. Editorial

Sonn U. Longitudinal studies of dependence in daily life activities among elderly persons. Scand J Rehabil Med Suppl. 1996;34:1-35. PMID: 96290155. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Sorensen MS, Andersen S, Henningsen GO, et al. Danish version of Visual Function Questionnaire-25 and its use in age-related macular degeneration. Dan Med Bull. 2011 Jun;58(6):A4290. PMID: 21651879. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Srinivasan K, Ramesh SV, Babu N, et al. Efficacy of a remote based computerised visual acuity measurement. Br J Ophthalmol. 2012 Jul;96(7):987-90. Also available: http://dx.doi.org/10.1136/bjophthalmol-2012-301751. PMID: 22539747. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Stacey A, Li Y, Barnes N. A salient information processing system for bionic eye with application to obstacle avoidance. Conf Proc IEEE Eng Med Biol Soc. 2011;5116-9. PMID: 22255490. Not relevant RPS

Stelmack J, Szlyk JP, Stelmack T, et al. Use of Rasch person-item map in exploratory data analysis: a clinical perspective. J Rehabil Res Dev. 2004 Mar;41(2):233-41. PMID: 15558377. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Stelmack J. Quality of life of low-vision patients and outcomes of low-vision rehabilitation. Optom Vis Sci. 2001 May;78(5):335-42. PMID: 11384011. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Stelmack JA, Massof RW. Using the VA LV VFQ-48 and LV VFQ-20 in low vision rehabilitation. Optom Vis Sci. 2007 Aug;84(8):705-9. PMID: 17700334. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Stelmack JA, Szlyk JP, Stelmack TR, et al. Measuring outcomes of vision rehabilitation with the Veterans Affairs Low Vision Visual Functioning Questionnaire. Invest Ophthalmol Vis Sci. 2006 Aug;47(8):3253-61. PMID: 16877389. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Stelmack JA, Szlyk JP, Stelmack TR, et al. Psychometric properties of the Veterans Affairs Low-Vision Visual Functioning Questionnaire. Invest Ophthalmol Vis Sci. 2004 Nov;45(11):3919-28. PMID: 15505037. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Stelmack JA, Tang XC, Reda DJ, et al. Outcomes of the Veterans Affairs Low Vision Intervention Trial (LOVIT). Arch Ophthalmol. 2008 May;126(5):608-17. PMID: 18474769. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Stelmack JA, Tang XC, Reda DJ, et al. The Veterans Affairs Low Vision Intervention Trial (LOVIT): design and methodology. Clin Trials. 2007;4(6):650-60. PMID: 18042574. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Stingl K, Bartz KU, Gekeler F, et al. Functional outcome in subretinal electronic implants depends on foveal eccentricity. Invest Ophthalmol Vis Sci. 2013 Nov 19;54(12):7658-65. Also available: http://dx.doi.org/10.1167/iovs.13-12835. PMID: 24150759. Duplicate data

Stingl K, Bartz-Schmidt KU, Besch D, et al. Artificial vision with wirelessly powered subretinal electronic implant alpha-IMS. Proc Biol Sci. 2013 Apr 22;280(1757):20130077. Also available: http://dx.doi.org/10.1098/rspb.2013.0077. PMID: 23427175. Duplicate data

Stingl K, Bartz-Schmidt KU, Besch D, et al. What can blind patients see in daily life with the subretinal Alpha IMS implant?: Current overview from the clinical trial in Tubingen. Ophthalmologe. 2012 Feb;109(2):136-41. Also available: http://dx.doi.org/10.1007/s00347-011-2479-6. PMID: 22350550. Duplicate data

Stingl K, Gekeler F, Bartz-Schmidt KU, et al. Fluorescein angiographic findings in eyes of patients with a subretinal electronic implant. Curr Eye Res. 2013 May;38(5):588-96. Also available: http://dx.doi.org/10.3109/02713683.2013.767349. PMID: 23410193. Not relevant RPS

Submacular Surgery Trials Research Group. Evaluation of minimum clinically meaningful changes in scores on the National Eye Institute Visual Function Questionnaire (NEI-VFQ) SST Report Number 19. Ophthalmic Epidemiol. 2007 Jul-Aug;14(4):205-15. PMID: 17896299. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Subramanian A, Dickinson C. Spatial localization in visual impairment. Invest Ophthalmol Vis Sci. 2006 Jan;47(1):78-85. PMID: 16384947. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Sugawara T, Sato E, Baba T, et al. Relationship between vision-related quality of life and microperimetry-determined macular sensitivity in patients with retinitis pigmentosa. Jpn J Ophthalmol. 2011 Nov;55(6):643-6. Also available: http://dx.doi.org/10.1007/s10384-011-0080-9. PMID: 21863221. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Suner IJ, Kokame GT, Yu E, et al. Responsiveness of NEI VFQ-25 to changes in visual acuity in neovascular AMD: validation studies from two phase 3 clinical trials. Invest Ophthalmol Vis Sci. 2009 Aug;50(8):3629-35. PMID: 19255158. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Suzukamo Y, Oshika T, Yuzawa M, et al. Psychometric properties of the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25), Japanese version. Health Qual Life Outcomes. 2005 Oct 26. Also available: http://dx.doi.org/10.1186/1477-7525-3-65. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Szlyk JP, Arditi A, Bucci PC, et al. Self-report in functional assessment of low vision. J Vis Impair Blind. 1990 Feb;84(2):61-6. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Szlyk JP, Coffey B, Arditi A, et al. Self-report in functional assessment of low vision. J Vis Impairm Blindn. 1990;84(2):61-6. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Szlyk JP, Fishman GA, Alexander KR, et al. Relationship between difficulty in performing daily activities and clinical measures of visual function in patients with retinitis pigmentosa. Arch Ophthalmol. 1997 Jan;115(1):53-9. PMID: 9006425. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Szlyk JP, Seiple W, Fishman GA, et al. Perceived and actual performance of daily tasks: relationship to visual function tests in individuals with retinitis pigmentosa. Ophthalmology. 2001 Jan;108(1):65-75. PMID: 11150266. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Szlyk JP, Stelmack J, Massof RW, et al. Performance of the Veterans Affairs low vision visual functioning questionnaire. J Vis Impair Blind. 2004 May;98(5):261-75. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Szlyk JP, Stelmack J, Massof RW, et al. Performance of the Veterans Affairs Low Vision Visual Functioning Questionnaire. J Vis Impairm Blindn. 2004 May;98(5):261-75. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Tabrett DR, Latham K. Factors influencing self-reported vision-related activity limitation in the visually impaired. Invest Ophthalmol Vis Sci. 2011 Jul;52(8):5293-302. Also available: http://dx.doi.org/10.1167/iovs.10-7055. PMID: 21613370. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Tadic V, Cooper A, Cumberland P, et al. Development of the functional vision questionnaire for children and young people with visual impairment: the FVQ_CYP. Ophthalmology. 2013 Dec;120(12):2725-32. Also available: http://dx.doi.org/10.1016/j.ophtha.2013.07.055. PMID: 24120327. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Tamaki M, Matsuo T. Optical coherence tomographic parameters as objective signs for visual acuity in patients with retinitis pigmentosa, future candidates for retinal prostheses. J Artif Organs. 2011 Jun;14(2):140-50. Also available: http://dx.doi.org/10.1007/s10047-011-0557-9. PMID: 21505820. Not relevant RPS

Tejeria L, Harper RA, Artes PH, et al. Face recognition in age related macular degeneration: perceived disability, measured disability, and performance with a bioptic device. Br J Ophthalmol. 2002 Sep;86(9):1019-26. PMID: 12185131. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Tosh J, Brazier J, Evans P, et al. A review of generic preference-based measures of health-related quality of life in visual disorders. Value Health. 2012 Jan;15(1):118-27. Also available: http://dx.doi.org/10.1016/j.jval.2011.08.002. PMID: 22264979. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Tranos PG, Topouzis F, Stangos NT, et al. Effect of laser photocoagulation treatment for diabetic macular oedema on patient's vision-related quality of life. Curr Eye Res. 2004 Jul;29(1):41-9. PMID: 15370366. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Trauzettel-Klosinski S, Biermann P, Hahn G, et al. Assessment of parafoveal function in maculopathy: a comparison between the Macular Mapping Test and kinetic Manual Perimetry. Graefes Arch Clin Exp Ophthalmol. 2003 Dec;241(12):988-95. PMID: 14618339. No patient-centered outcome

Tregear SJ, Ripley LG, Knowles PJ, et al. Automated tritan discrimination sensitivity: A new clinical technique for the effective screening of severe diabetic retinopathy. Int J Psychophysiol. 1994 May;16(2-3):191-8. No patient-centered outcome

Trento M, Passera P, Trevisan M, et al. Quality of life, impaired vision and social role in people with diabetes: a multicenter observational study. Acta Diabetol. 2013 Dec;50(6):873-7. Also available: http://dx.doi.org/10.1007/s00592-013-0470-1. PMID: 23526056. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Tunay ZO, Caliskan D, Oztuna D, et al. Validation and reliability of the CardiffVisual Ability Questionnaire for children using Rasch analysis in a Turkish population. Br J Ophthalmol. 2015 Aug 18. Also available: http://dx.doi.org/10.1136/bjophthalmol-2015-307122. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Turano KA, Geruschat DR, Stahl JW, et al. Perceived visual ability for independent mobility in persons with retinitis pigmentosa. Invest Ophthalmol Vis Sci. 1999 Apr;40(5):865-77. PMID: 10102283. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Turco PD, Connolly J, McCabe P, et al. Assessment of functional vision performance: a new test for low vision patients. Ophthalmic Epidemiol. 1994 Mar;1(1):15-25. PMID: 8790609. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Unver YB, Yavuz GA, Sinclair SH. Interactive, computer-based, self-reported, visual function questionnaire: the PalmPilot-VFQ. Eye (Lond). 2009 Jul;23(7):1572-81. Also available: http://dx.doi.org/10.1038/eye.2009.101. PMID: 19478821. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Uppal G, Milliken A, Lee J, et al. New algorithm for assessing patient suitability for macular translocation surgery. Clin Experiment Ophthalmol. 2007 Jul;35(5):448-57. PMID: 17651250. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Users of retinal prosthesis system accumulate implant time since FDA approval. Ocular Surg News. 2014 Feb 25;32(4):32-3. Narrative review

Van De Put MA, Vehof J, Hooymans JM, et al. Postoperative metamorphopsia in macula-off rhegmatogenous retinal detachment: Associations with visual function, vision related quality of life, and optical coherence tomography findings. PLoS ONE. 2015 Apr 8;10(4). Also available: http://dx.doi.org/10.1371/journal.pone.0120543. No psychometric property data reported, or study was not primarily designed to measure psychometrics

van Nispen RM, de Boer MR, van Rens GH. Additional psychometric information and vision-specific questionnaires are available for age-related macular degeneration. Qual Life Res. 2009 Feb;18(1):65-9. Also available: http://dx.doi.org/10.1007/s11136-008-9425-3. PMID: 19067235. No psychometric property data reported, or study was not primarily designed to measure psychometrics

van Nispen RM, Knol DL, Langelaan M, et al. Applying multilevel item response theory to vision-related quality of life in Dutch visually impaired elderly. Optom Vis Sci. 2007 Aug;84(8):710-20. PMID: 17700335. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

van Nispen RM, Knol DL, Langelaan M, et al. Re-evaluating a vision-related quality of life questionnaire with item response theory (IRT) and differential item functioning (DIF) analyses. BMC Med Res Methodol. 2011;11:125. Also available: http://dx.doi.org/10.1186/1471-2288-11-125. PMID: 21888648. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

van Nispen RM, Knol DL, Mokkink LB, et al. Vision-related quality of life Core Measure (VCM1) showed low-impact differential item functioning between groups with different administration modes. J Clin Epidemiol. 2010 Nov;63(11):1232-41. Also available: http://dx.doi.org/10.1016/j.jclinepi.2009.12.010. PMID: 20413266. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Velikay-Parel M, Ivastinovic D, Georgi T, et al. A test method for quantification of stimulus-induced depression effects on perceptual threshold in epiretinal prosthesis. Acta Ophthalmol. 2013 Dec;91(8):e595-e602. Also available: http://dx.doi.org/10.1111/aos.12179. PMID: 24112756. Not relevant RPS

Velikay-Parel M, Ivastinovic D, Hornig R, et al. Retina implant: Up date on artificial vision. Spektr Augenheilkunde. 2006;20(5):211-4. Narrative review

Velozo CA, Warren M, Hicks E, et al. Generating clinical outputs for self-reports of visual functioning. Opt Vis Sci. 2013 Aug;90(8):765-75. Also available: http://dx.doi.org/10.1097/OPX.0000000000000007. PMID: 23839700. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Verdugo MA, Prieto G, Caballo C, et al. Factorial structure of the quality of life questionnaire in a Spanish sample of visually disabled adults. Eur J Psychol Assess. 2005;21(1):44-55. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Viola MV, Patrinos AA. A neuroprosthesis for restoring sight. Acta Neurochir Suppl. 2007;97:481-6. PMID: 17691338. Narrative review

Virgili G, Rubin G. Orientation and mobility training for adults with low vision. Cochrane Database Syst Rev. 2003;(4):CD003925. PMID: 14583999. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Vurro M, Baselli G, Orabona F, et al. Simulation and assessment of bioinspired visual processing system for epi-retinal prostheses. Conf Proc IEEE Eng Med Biol Soc. 2006;3278-81. PMID: 17945764. Not relevant RPS

Wang J, Wu X, Lu Y, et al. Face recognition in simulated prosthetic vision: Face detection-based image processing strategies. J Neural Eng. 2014 Aug 1;11(4). Also available: http://dx.doi.org/10.1088/1741-2560/11/4/046009. PMID: 24921713. Not relevant RPS

Wang LL, Liu WJ, Liu HY, et al. Single-site baseline and short-term outcomes of clinical characteristics and life quality evaluation of Chinese wet age-related macular degeneration patients in routine clinical practice. Chin Med J. 2015 May 5;128(9):1154-9. Also available: http://dx.doi.org/10.4103/0366-6999.156083. PMID: 25947396. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Waninge A, van Wijck R, Steenbergen B, et al. Feasibility and reliability of the modified Berg Balance Scale in persons with severe intellectual and visual disabilities. J Intellect Disabil Res. 2011 Mar;55(3):292-301. Also available: http://dx.doi.org/10.1111/j.1365-2788.2010.01358.x. PMID: 21155916. No patient-centered outcome

Warrian KJ, Katz LJ, Myers JS, et al. A comparison of methods used to evaluate mobility performance in the visually impaired. Br J Ophthalmol. 2015 Jan;99(1):113-8. Also available: http://dx.doi.org/10.1136/bjophthalmol-2014-305324. PMID: 25138757. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Warrian KJ, Lorenzana LL, Lankaranian D, et al. Assessing age-related macular degeneration with the ADREV performance-based measure. Retina. 2009 Jan;29(1):80-90. Also available: http://dx.doi.org/10.1097/IAE.0b013e318187f160. PMID: 18854790. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Warrian KJ, Lorenzana LL, Lankaranian D, et al. The assessment of disability related to vision performance-based measure in diabetic retinopathy. Am J Ophthalmol. 2010 May;149(5):852-60.e1. Also available: http://dx.doi.org/10.1016/j.ajo.2009.12.028. PMID: 20399929. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Watson GR, De lAune W, Long S, et al. Veterans' use of low vision devices for reading. Optom Vis Sci. 1997 May;74(5):260-5. PMID: 9219283. No patient-centered outcome

Watson GR, Wright V, Long S, et al. A low vision reading comprehension test. J Vis Impair Blind. 1996 Nov-Dec;90(6):486-94. No patient-centered outcome

Weger M, Pichler T, Franke GH, et al. Assessment of vision-related quality of life in patients with central retinal artery occlusion. Retina. 2014 Mar;34(3):539-45. Also available: http://dx.doi.org/10.1097/IAE.0b013e3182a0e42e. PMID: 23958843. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Weih LM, Hassell JB, Keeffe J. Assessment of the impact of vision impairment. Invest Ophthalmol Vis Sci. 2002 Apr;43(4):927-35. PMID: 11923230. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Weiland JD, Humayun MS. A biomimetic retinal stimulating array. IEEE Eng Med Biol Mag. 2005 Sep-Oct;24(5):14-21. Also available: http://dx.doi.org/10.1109/MEMB.2005.1511496. PMID: 16248113. Technical report without human data

Weiland JD, Parikh N, Pradeep V, et al. Smart image processing system for retinal prosthesis. Conf Proc IEEE Eng Med Biol Soc. 2012;2012:300-3. Also available: http://dx.doi.org/10.1109/EMBC.2012.6345928. PMID: 23365889. Not relevant RPS

Weiland JD, Yanai D, Mahadevappa M, et al. Visual task performance in blind humans with retinal prosthetic implants. Conf Proc IEEE Eng Med Biol Soc. 2004;6:4172-3. Also available: http://dx.doi.org/10.1109/IEMBS.2004.1404164. PMID: 17271222. Not relevant RPS

Weitz AC, Behrend MR, Ahuja AK, et al. Interphase gap as a means to reduce electrical stimulation thresholds for epiretinal prostheses. J Neural Eng. 2014 Feb 1;11(1). Also available: http://dx.doi.org/10.1088/1741-2560/11/1/016007. PMID: 24654269. No patient-centered outcome

Weleber RG, Smith TB, Peters D, et al. VFMA: Topographic Analysis of Sensitivity Data From Full-Field Static Perimetry. Transl Vis Sci Technol. 2015 Apr;4(2):14. Also available: http://dx.doi.org/10.1167/tvst.4.2.14. PMID: 25938002. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

West CG, Gildengorin G, Haegerstrom-Portnoy G, et al. Vision and driving self-restriction in older adults. J Am Geriatr Soc. 2003 Oct 1;51(10):1348-55. PMID: 14511153. No psychometric property data reported, or study was not primarily designed to measure psychometrics

West SK, Rubin GS, Broman AT, et al. How does visual impairment affect performance on tasks of everyday life? The SEE Project. Salisbury Eye Evaluation. Arch Ophthalmol. 2002 Jun;120(6):774-80. PMID: 12049583. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Wilke R, Gabel VP, Sachs H, et al. Spatial resolution and perception of patterns mediated by a subretinal 16-electrode array in patients blinded by hereditary retinal dystrophies. Invest Ophthalmol Vis Sci. 2011 Jul;52(8):5995-6003. Also available: http://dx.doi.org/10.1167/iovs.10-6946. PMID: 21693599. Not relevant RPS

Williams RA, Brody BL, Thomas RG, et al. The psychosocial impact of macular degeneration. Arch Ophthalmol. 1998 Apr;116(4):514-20. PMID: 9565052. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Wittich W, Overbury O, Kapusta MA, et al. Visual function assessment and metamorphopsia after macular hole surgery. Ophthal Physiol Opt. 2005 Nov;25(6):534-42. PMID: 16343129. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Wolffe KE, Ajuwon PM, Kelly SM. Working with visual impairment in Nigeria: A qualitative look at employment status. J Vis Impair Blind. 2013 Nov-Dec;107(6):425-36. No patient-centered outcome

Wolffsohn JS, Cochrane AL, Watt NA. Implementation methods for vision related quality of life questionnaires. Br J Ophthalmol. 2000 Sep;84(9):1035-40. PMID: 10966961. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Wolffsohn JS, Cochrane AL. Design of the low vision quality-of-life questionnaire (LVQOL) and measuring the outcome of low-vision rehabilitation. Am J Ophthalmol. 2000 Dec;130(6):793-802. PMID: 11124300. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Wolffsohn JS, Jackson J, Hunt OA, et al. An enhanced functional ability questionnaire (faVIQ) to measure the impact of rehabilitation services on the visually impaired. Int J Ophthalmol. 2014;7(1):77-85. Also available: http://dx.doi.org/10.3980/j.issn.2222-3959.2014.01.14. PMID: 24634868. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Woodcock A, Bradley C, Plowright R, et al. The influence of diabetic retinopathy on quality of life: interviews to guide the design of a condition-specific, individualised questionnaire: the RetDQoL. Patient Educ Couns. 2004 Jun;53(3):365-83. PMID: 15186876. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Wooten BR, Renzi LM, Moore R, et al. A practical method of measuring the human temporal contrast sensitivity function. Biomed Opt Express. 2010;1(1):47-58. PMID: 21258445. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Wrobel WG, Banzhaf A, Blaess G, et al. A new system for the treatment of retinal degeneration. Biomed Tech. 2011 Oct;56(5):277-82. PMID: 21867451. Not relevant RPS

Wu AW, Coleson LC, Holbrook J, et al. Measuring visual function and quality of life in patients with cytomegalovirus retinitis. Development of a questionnaire. Studies of Ocular Complication of AIDS Research Group. Arch Ophthalmol. 1996 Jul;114(7):841-7. PMID: 96269316. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Wu Z, Guymer RH, Finger RP. Low luminance deficit and night vision symptoms in intermediate age-related macular degeneration. Br J Ophthalmol. 2015 Aug 6. Also available: http://dx.doi.org/10.1136/bjophthalmol-2015-306621. PMID: 26250520. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Wu Z, Guymer RH, Jung CJ, et al. Measurement of Retinal Sensitivity on Tablet Devices in Age-Related Macular Degeneration. Transl Vis Sci Technol. 2015 Jun;4(3):13. Also available: http://dx.doi.org/10.1167/tvst.4.3.13. PMID: 26175959. No patient-centered outcome

Wulsin LR, Jacobson AM, Rand LI. Psychosocial adjustment to advanced proliferative diabetic retinopathy. Diabetes Care. 1993 Aug;16(8):1061-6. PMID: 93387075. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Xia Y, Peng X, Ren Q. Retinitis pigmentosa patients' attitudes toward participation in retinal prosthesis trials. Contemp Clin Trials. 2012 Jul;33(4):628-32. Also available: http://dx.doi.org/10.1016/j.cct.2012.03.007. PMID: 22465307. No patient-centered outcome

Yamamoto S, Sugawara T, Murakami A, et al. Topical isopropyl unoprostone for retinitis pigmentosa: microperimetric results of the phase 2 clinical study. Ophthalmol Ther. 2012 Dec;1(1):5. Also available: http://dx.doi.org/10.1007/s40123-012-0005-9. PMID: 25135585. No patient-centered outcome

Yanai D, Lakhanpal RR, Weiland JD, et al. The value of preoperative tests in the selection of blind patients for a permanent microelectronic implant. Trans Am Ophthalmol Soc. 2003;223-30. PMID: 14971581. Not relevant RPS

Yanai D, Weiland JD, Mahadevappa M, et al. Visual performance using a retinal prosthesis in three subjects with retinitis pigmentosa. Am J Ophthalmol. 2007 May;143(5):820-7.e2. Also available: http://dx.doi.org/10.1016/j.ajo.2007.01.027. PMID: 17362868. Not relevant RPS

Yingyong P. Evaluation of the Thai, Low Vision Quality-of-Life Questionnaire (LVQOL). J Med Assoc Thai. 2007 Dec;90(12):2658-61. PMID: 18386717. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Yochim BP, Beaudreau SA, Fairchild JK, et al. Verbal Naming Test for use with older adults: Development and initial validation. J Int Neuropsychol Soc. 2015 Mar;21(3):239-48. PMID: 25801537. No patient-centered outcome

Yuzawa M, Fujita K, Tanaka E, et al. Assessing quality of life in the treatment of patients with age-related macular degeneration: Clinical research findings and recommendations for clinical practice. Clin Ophthalmol. 2013;1325-32. Also available: http://dx.doi.org/10.2147/OPTH.S45248. PMID: 23836961. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Zapf MP, Boon MY, Matteucci PB, et al. Towards an assistive peripheral visual prosthesis for long-term treatment of retinitis pigmentosa: Evaluating mobility performance in immersive simulations. J Neural Eng. 2015 Jun;12(3):036001. Also available: http://dx.doi.org/10.1088/1741-2560/12/3/036001. PMID: 25782059. Not relevant RPS

Zebehazy KT, Zigmond N, Zimmerman GJ. Ability or access-ability: Differential item functioning of items on alternate performance-based assessment tests for students with visual impairments. J Vis Impair Blind. 2012 Jun;106(6):325-38. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Zhang XJ, Wang AP, Yin AC. The impact of psychosocial adaptation status on quality of life for Chinese patients with visual impairments. J Clin Nurs. 2014 Jan;23(1-2):75-81. Also available: http://dx.doi.org/10.1111/jocn.12041. PMID: 23228059. No psychometric property data reported, or study was not primarily designed to measure psychometrics

Zhang XJ, Wang AP. Development of a psychosocial adaptation questionnaire for Chinese patients with visual impairments. J Clin Nurs. 2011 Oct;20(19-20):2822-9. Also available: http://dx.doi.org/10.1111/j.1365-2702.2011.03813.x. PMID: 21902740. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Zou H, Zhang X, Xu X, et al. Development and psychometric tests of the Chinese-version Low Vision Quality of Life Questionnaire. Qual Life Res. 2005 Aug;14(6):1633-9. PMID: 16110942. Either <67% of the patients had low vision retinal degenerative conditions, or it was unclear whether patients had low vision retinal degenerative conditions

Zrenner E, Bartz Schmidt KU, Gekeler F, et al. What retinitis pigmentosa patients can see with the new subretinal wireless implant alpha-IMS. Doc Ophthalmol. 2012 Jun;124(1). Also available: http://dx.doi.org/10.1007/s10633-012-9332-3. Duplicate data

Zrenner E, Bartz-Schmidt KU, Chee C, et al. (16:45) Visual outcome in 26 blind retinitis pigmentosa patients after receiving electronic subretinal implant Alpha-IMS. Doc Ophthalmol. 2014 Aug;129(1). Also available: http://dx.doi.org/10.1007/s10633-014-9441-2. Duplicate data

Zrenner E, Bartz-Schmidt KU, Gekeler F, et al. The subretinal implant alpha IMS to deliver useful vision in photoreceptor disease. Doc Ophthalmol. 2013 Oct;127(1). Also available: http://dx.doi.org/10.1007/s10633-013-9410-1. Duplicate data

Zrenner E, Benav H, Bruckmann A, et al. Electronic implants provide continuous stable percepts in blind volunteers only if the image receiver is directly linked to eye movement. Doc Ophthalmol. 2010 Dec;121(1):18-9. Also available: http://dx.doi.org/10.1007/s10633-010-9254-x. Not relevant RPS

Zrenner E. The subretinal implant: can microphotodiode arrays replace degenerated retinal photoreceptors to restore vision? Ophthalmologica. 2002;216 Suppl 1:8-20; discuss. PMID: 12207119. Narrative review

Appendix C. Evidence Tables

Table C-1. General information about studies included for Key Question 1B

Study	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Geruschat et al. 2015[1]	U.S.; Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD	26	26	Enrolled in the Argus II Retinal Prostheses System clinical trial. Not explanted, and accepted participation in this pilot study of FLORA (assessment instrument)	NR	Argus II	Half had been followed for an average of 3.3 years, and half for an average of 1.7 years
Bittner et al. 2011[2]	U.S.; Lions Vision Center, Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD	20	20	Represented in a database of previous research subjects at the center and from referrals by the Low Vision Clinic. Lived within 1.5 hour drive, not undergoing treatment for eye disease, vision likely to remain stable through 3 months	NR	None	3 months
Chow et al. 2010[3]	U.S.; Rush University Medical Center in Chicago, IL	18	18	Acuity 20/200 or worse in the better eye, and/or visual field diameter 20 degrees or less as measured by Goldmann perimetry or Humphrey field analyzer. Medically stable vision during 2–4 months of followup.	NR	None	4 months
Kiser et al. 2005[4]	U.S.; Lions Vision Center, Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD	78	78 but some data points had fewer patients	Legally blind, best corrected visual acuity 20/200 or worse in the better eye, and/or visual field diameter 20 degrees or less, informed consent, judgment that their condition would not change over the 4–5 month study period.	NR	None	5 months

FLORA=Functional Low-Vision Observer Rated Assessment; NR=not reported

Table C-2. Patient characteristics in studies included for Key Question 1B

Study	Diagnosis	Age	Sex (% male)	Race	Prior Treatments	Baseline Visual Acuity	Baseline Visual Field
Geruschat et al. 2015[1]	All RP except one patient had choroideremia	NR	NR	NR	NR	NR	NR
Bittner et al. 2011[2]	8 had RP, 5 had ARMD, 2 had ON, 1 had cone-rod dystrophy, 1 had retinal vein occlusion, 1 had glaucoma, 1 had diabetic retinopathy, and for 1 the condition was not reported. The non-RP patients were grouped together as "other retinal disease" (OR)	Mean 69, range 39 to 90	50%	6 were black, 13 were white, and 1 was Hispanic	NR	32 of 40 eyes met the criteria for legal blindness, best corrected visual acuity 20/200 or worse in the better eye, and/or visual field diameter 20 degrees or less as determined by either Goldmann or Humphrey visual field test	At least 32 eyes had VF<20 degrees
Chow et al. 2010[3]	5 had RP, 5 had ARMD, 1 had DR, 2 had congenital ON, 1 had cone-rod dystrophy, 2 had retinal vein occlusion, and 1 had severe glaucoma	Mean 69, range 39 to 90	52%	NR	NR	Mean 1.29 logMAR (range 0.32 to 2.0)	NR
Kiser et al. 2005[4]	26 had RP, 16 had MD, 3 had ON, 11 had OR, 4 had DR, and 18 had normal vision 20/25 or better (control group)	Mean 61, range 20 to 90	NR	NR	NR	Patients with RP were divided into 3 groups of visual acuity (RP-I had VA better than 20/40 [4 patients]; RP-II had VA between 20/40 and 20/199 [12 patients]; RP-III had VA between 20/200 and 20/1000 [10 patients]). Patients with MD were divided into 2 groups of visual acuity (MD-I had VA between 20/200 and 20/500 [8 patients], and MD-II had VA worse than 20/500 [8 patients]). The other 3 patient groups (ON, OR, DR) all had VA worse than 20/200.	NR

ARMD=age-related macular degeneration; DR=diabetic retinopathy; logMAR=logarithm of the minimum angle of resolution**;** MD=macular degeneration; NR=not reported; ON=optic neuropathy; OR=other retinopathies; RP=retinitis pigmentosa; VA=visual acuity; VF=visual field

Table C-3. Measures tested in studies included for Key Question 1B

Study	Measure	Details About the Measure	Reported Reliability Data	Reported Validity Data	Reported Responsiveness Data
Geruschat et al. 2015[1]	Functional Low-Vision Observer Rated Assessment (FLORA)	FLORA includes three sections: (1) self report that includes 14 open-ended questions (e.g., "What would you like me to know about how the system has affected you?") and any of them can be skipped if the assessor decides to skip; (2) observation of performance in 35 activities, in which the assessor observes the patient performing common activities of daily living, both with and without the Argus device turned ON and any of the activities can be skipped if the assessor decides to skip, and each task was rated as impossible/difficult/moderate/easy and also estimated how much vision was needed to accomplish the task (no vision, or some vision, or vision only); (3) case summary, which is a narrative case report summarizing the assessor's findings.		✓	
Bittner et al. 2011[2]	Grating acuity test (GAT)	For each stimulus, the lines were horizontal, vertical, diagonal right, or diagonal left. Researchers determined each person's acuity threshold, twice per visit, and again over 1–2 additional visits.	✓	✓	
Bittner et al. 2011[2]	ETDRS visual acuity test	Standard acuity test was administered.	✓		
Chow et al. 2010[3]	Grating acuity test (GAT)	For each stimulus, the lines were horizontal, vertical, diagonal right, or diagonal left. Researchers determined each person's acuity threshold 3–4 times over 3–4 visits.	✓	✓	
Chow et al. 2010[3]	Chow Color Test (CCT)	Developed to be more sensitive than the standard low color vision testing which is called the PV-16. The CCT is composed of both high-saturation (CHS) and low-saturation (CLS) discs. Researchers determined each person's color ability 3–4 times over 3–4 visits. The best possible score is 40.	✓	✓	
Kiser et al. 2005[4]	ETDRS visual acuity test, regular	Standard test, regular illumination in a dark room. Researchers determined each person's visual acuity and contrast sensitivity. Data were captured over 4–5 visits per person at monthly intervals (1 test per visit).	✓		
Kiser et al. 2005[4]	ETDRS visual acuity test, dim	Standard test, dim illumination in a dark room. Researchers determined each person's visual acuity and contrast sensitivity. Data were captured over 4–5 visits per person at monthly intervals (1 test per visit).	✓		

CCT=Chow Color Test; ETDRS=Early Treatment of Diabetic Retinopathy Study test; FLORA=Functional Low-Vision Observer Rated Assessment; GAT=grating acuity test

Table C-4. Psychometric data reported in studies included for Key Question 1B

Study	Measure and Psychometric Property	Description of Analysis	Result
Geruschat et al. 2015[1]	Functional Low-Vision Observer Rated Assessment (FLORA), ***Face validity***	Initial item generation	A team of experts in blind and low vision rehabilitation met to draft a first assessment. Multiple rounds of revision in the suggested FLORA process. The team reviewed commonly-accepted instruments and tailored FLORA to the challenges of this population. Face validity is suggested by the fact that the participants were experts in this clinical area, as well as the various steps they undertook.
Geruschat et al. 2015[1]	Functional Low-Vision Observer Rated Assessment (FLORA), ***Face validity***	Whether the self-report questions were used by most assessors	For 22/26 patients, all 14 questions were answered. In the other 4, an average of 12 questions were answered.
Geruschat et al. 2015[1]	Functional Low-Vision Observer Rated Assessment (FLORA), ***Face validity***	Whether the part 2 activities were used by most assessors	The average number of patients assessed per activity was 20 out of a possible 26 (see Table 1 of the article). This indicates that assessors tended to ask patients to perform most of the FLORA activities of daily living.
Bittner et al. 2011[2]	Grating Acuity Test (GAT), ***Construct Validity***	Separately for the 8 patients with RP and the 12 patients with OR, authors computed the correlation between the newly developed GAT and the standard and "well-validated" test, ETDRS. Perfect validity would be indicated by (1) strong correlation, (2) a slope of 1.0 and (3) an intercept of 0.	GAT demonstrated this type of construct validity for patients with RP, but not for patients with OR (Figure 2 in the article). The correlations, slopes, and intercepts were not reported. For RP, the correlation was strong, the slope was near 1.0, and the intercept was near 0. For OR, however, the correlation was weak, the slope was greater than 1, and the intercept was about 0.75. This means that for patients with OR, the newly developed GAT consistently overestimated patients' visual acuity.
Bittner et al. 2011[2]	Grating acuity test (GAT), ***Reliability***	Test-retest reliability. Authors computed each patient's coefficient of reliability, $CR_{.95}$. This was done both within-visit and between-visit. A low $CR_{.95}$ indicates good test-retest reliability, since it indicates the degree of difference between 2 tests that one might expect (a test with perfect test-retest reliability would have a $CR_{.95}$ of 0). Data were on the log-unit scale.	For RP, the median test-retest $CR_{.95}$ of GAT was 0.17 for within-visit and 0.16 for between-visit (log-unit scale, see Figure 5). For OR, the median test-retest $CR_{.95}$ of GAT was 0.11 for within-visit and 0.11 for between-visit (log-unit scale, see Figure 5 of the article).
Bittner et al. 2011[2]	ETDRS visual acuity test, ***Reliability***	Test-retest reliability, same as above	For RP, the median test-retest $CR_{.95}$ of ETDRS was 0.10 for between-visit (log-unit scale, see Figure 5 in the article). For OR patients, it was 0.16.

Table C-4. Psychometric data reported in studies included for Key Question 1B (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Chow et al. 2010[3]	Grating Acuity Test (GAT), ***Construct Validity***	Authors computed the correlation between the newly developed GAT and the standard and "well-validated" test, ETDRS. Perfect validity would be indicated by (1) strong correlation, (2) a slope of 1.0, and (3) an intercept of 0.	For RP specifically, correlation was strong (r=0.92), the slope estimate was 0.92, and intercept not reported (but appeared to be about 0.02 from Figure 35 in the article). Thus, good results for RP. For AMD and other retinopathies, however, GAT consistently underestimated logMAR (i.e., overestimated visual acuity). The mean logMAR for patients with AMD was 1.4 as measured by the gold standard ETDRS but was only 0.89 as measured by GAT. For OR, the mean logMAR as measured by ETDRS was 1.37 as compared to 0.98 for GAT. Thus, for non-RP patients, GAT has poor validity.
Chow et al. 2010[3]	Grating Acuity Test (GAT), ***Reliability***	Test-retest reliability. Authors computed each patient's coefficient of reliability, $CR_{.95}$. This was done both within-visit and between-visit. A low $CR_{.95}$ indicates good test-retest reliability. Data were on the log-units scale.	The mean test-retest $CR_{.95}$ of GAT was 0.16 for between-visit. For RP patients specifically, the mean test-retest $CR_{.95}$ of GAT was 0.15 for between-visit and 0.10 for within-visit.
Chow et al. 2010[3]	Chow Color Test (CCT), ***Construct Validity***	Authors computed the correlation between the newly developed CCT and the standard test called the PV-16. The tests are on different scales, so only the strength of correlation is a relevant measure for construct validity. Because higher scores on the CCT mean better color vision, whereas higher scores on the PV-16 mean worse color vision, good validity would be indicated by a large negative correlation.	The correlation between CCT and PV-16 was r=-0.77. Patients averaged 22.5 out of 40 on the CCT, and they averaged 315 on the PV-16.
Chow et al. 2010[3]	Chow Color Test (CCT), ***Reliability***	Test-retest reliability. Authors computed each patient's coefficient of reliability, $CR_{.95}$. This was done only between-visit. A low $CR_{.95}$ indicates good test-retest reliability. Data were on the same scale as the CCT, which is 0 (lowest possible color vision) and 40 (best possible color vision).	The mean test-retest $CR_{.95}$ of CCT was 6.1 for between-visit. For the 5 patients with AMD, it was 3.9; for the 5 patients with RP, it was 4.8; for the other 7 patients it was 8.7. The 3 groups' mean scores on the CCT were AMD, 30; RP, 13; and other, 24. Thus for an average RP patient, if their color vision testing was at 13 out of 40 at one visit, then the next visit would be expected (with 95% confidence) to be between 8 and 18 out of 40.
Kiser et al. 2005[4]	ETDRS visual acuity test, regular, ***Reliability***	Test-retest reliability. Authors computed each patient's coefficient of reliability, $CR_{.95}$. This was done only between-visit. A low $CR_{.95}$ indicates good test-retest reliability, because it indicates the degree of difference between 2 tests that one might expect (a test with perfect test-retest reliability would have a $CR_{.95}$ of 0). Data were on the log-unit scale.	Median values of $CR_{.95}$ were: 0.13 for RP-I, 0.23 for RP-II, 0.26 for RP-III 0.27 for MD-I, 0.21 for MD-II 0.18 for DR 0.20 for OR See Figure 3 of the article

Table C-4. Psychometric data reported in studies included for Key Question 1B (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Kiser et al. 2005[4]	ETDRS visual acuity test, dim, ***Reliability***	Test-retest reliability, same as above	Median values of $CR_{.95}$ were: 0.12 for RP-I, 0.41 for RP-II, 0.18 for RP-III 0.33 for MD-I, 0.20 for MD-II 0.27 for DR 0.19 for OR See Figure 3 of the article.

AMD=age-related macular degeneration; DR=diabetic retinopathy; ETDRS=Early Treatment of Diabetic Retinopathy Study (test); logMAR=logarithm of the minimum angle of resolution**;** MD=macular degeneration (I, II indicate better to worse visual acuity); OR=other retinopathies; RP=retinitis pigmentosa (I, II, III indicate better to worse visual acuity)

Table C-5. Risk-of-bias of data reported in studies included for Key Question 1B

Study	Psychometric Property	Risk-of-bias Considerations[a]	Risk-of-bias Category	Comments
Geruschat et al. 2015[1]	Face validity	Did they assess whether all items are relevant to what they are trying to measure? Did they assess whether all items are relevant for the purpose of the instrument? Did they assess whether the items comprehensively reflect what they are trying to measure? Any important flaws?	Low	Unclear whether the list of key activities was comprehensive, but probably it was.
Bittner et al. 2011[2]	Test-retest reliability	Percentage of missing items given? Adequate sample size? At least 2 measurements available? Were administrations independent? Was time interval stated? Were patients stable in the interim? Was time interval appropriate? Were test conditions similar for the 2 measurements? Any important flaws?	Moderate	Only 20 patients, and some did not have a retinal condition of interest.
Bittner et al. 2011[2]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Moderate	Used a statistical measure for this psychometric property. Only 20 patients, which may be too low.
Chow et al. 2010[3]	Test-retest reliability	Percentage of missing items given? Adequate sample size? At least 2 measurements available? Were administrations independent? Was time interval stated? Were patients stable in the interim? Was time interval appropriate? Were test conditions similar for the 2 measurements? Any important flaws?	Moderate	Only 18 patients, and some did not have a retinal condition of interest.
Chow et al. 2010[3]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Moderate	Used a statistical measure for this psychometric property. Only 18 patients, which may be too low.
Kiser et al. 2005[4]	Test-retest reliability	Percentage of missing items given? Adequate sample size? At least 2 measurements available? Were administrations independent? Was time interval stated? Were patients stable in the interim? Was time interval appropriate? Were test conditions similar for the 2 measurements? Any important flaws?	Low	3 had optic neuropathies, but this represents only 5% of the patients with low vision

Risk-of-bias considerations were based on the COSMIN manual.[5]

Table C-6. General information about studies included for Key Question 1C

Study	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Finger et al. 2014[6]	Australia; Center for Eye Research Australia, Royal Victorian Eye and Ear Hospital	201	201	Adults, legally blind (visual acuity 20/200 or worse in the better eye, and/or binocular visual field diameter 10 degrees or less), gave informed consent	NR	None	NA
Finger et al. 2014[7]	Australia; Center for Eye Research Australia, Royal Victorian Eye and Ear Hospital	40	40	Adults, legally blind (visual acuity 20/200 or worse in the better eye, and/or binocular visual field diameter 10 degrees or less), gave informed consent	NR	None	NA
Bittner et al. 2011[2]	U.S.; Lions Vision Center, Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD	20	20	Represented in a database of previous research subjects at the center and from referrals by the Low Vision Clinic. Lived within 1.5 hour drive, not undergoing treatment for eye disease, vision likely to remain stable through 3 months	NR	None	3 months
McKnight and Babcock-Parziale 2007[8]	U.S.; Southwestern Blind Rehabilitation Center (SWBRC), Tucson, AZ	NR, but 81 provided complete version of both forms	NR, but 81 provided complete version of both forms	Legally blind veterans (acuity 20/200 or worse), attending the SWBRC inpatient blind rehabilitation program	Active major depression, cognitive loss, active eye disease with further loss of vision, serious health condition	Blind rehabilitation service	6 weeks
Kiser et al. 2006[9]	U.S.; Lions Vision Center, Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD	77	77 but some data points had fewer patients	Acuity 20/200 or worse in the better eye, and/or visual field diameter 20 degrees or less, informed consent, judgment that their condition would not change over the 4–5 month study period	NR	None	5 months

Table C-6. General information about studies included for Key Question 1C (continued)

Study	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Babcock-Parziale et al. 2005[10]	U.S.; Southwestern Blind Rehabilitation Center, Tucson, AZ	190	190	Legally blind veterans (acuity 20/200 or worse), attending the SWBRC inpatient blind rehabilitation program between Dec 2000 and July 2002. Patient had to be represented as a record in 2 databases, VA-13 and Functional Assessment of Self-Reliance on Tasks (FAST).	NR	Blind rehabilitation service	6 weeks
Kiser et al. 2005[4]	U.S.; Lions Vision Center, Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD	78	78 but some data points had fewer patients	Legally blind, best corrected visual acuity 20/200 or worse in the better eye, and/or visual field diameter 20 degrees or less, informed consent, judgment that their condition would not change over the 4–5 month study period.	NR	None	5 months
Stelmack et al. 2002[11]	U.S.; Blind Rehabilitation Center (BRC) at Hines VA Medical Center in Hines, IL	77	77	Legally blind, in the BRC program, best corrected visual acuity 20/200 or worse in the better eye, and/or visual field diameter 20 degrees or less as measured by Goldmann perimetry	Severe cognitive or hearing deficits, completed the rehabilitation program	Low vision rehabilitation program with interdisciplinary specialists	Average program duration 42 days

NA=not applicable; NR=not reported, VA-13=Veterans' Administration-13

Table C-7. Patient characteristics in studies included for Key Question 1C

Study	Diagnosis	Age	Sex (% male)	Race	Prior Treatments	Baseline Visual Acuity	Baseline Visual Field
Finger et al. 2014[6]	50% had AMD, 14% had RP, 12% had OR, 7.5% had glaucoma, 16% had other eye conditions	72 (SD 16)	42%	NR	Mean number of visual aids used was 7.73 (SD 3.58)	22% had between 20/200 and counting fingers; 63% had between counting fingers and light perception; 14% had worse than light perception	NR
Finger et al. 2014[7]	Rod-cone dystrophy, and >80% had RP	Mean 53	53%	NR	NR	Mean 2.3 logMAR (SD 1.0)	70% had <10 degrees
Bittner et al. 2011[2]	8 had RP, 5 had ARMD, 2 had ON, 1 had cone-rod dystrophy, 1 had retinal vein occlusion, 1 had glaucoma, 1 had DR, and for 1 the condition was NR. The non-RP patients were grouped together as "other retinal disease" (OR).	Mean 69, range 39 to 90	50%	6 were black, 13 were white, and 1 was Hispanic	NR	32 of 40 eyes met the criteria for legal blindness, best corrected visual acuity 20/200 or worse in the better eye, and/or visual field diameter 20 degrees or less as determined by either Goldmann or Humphrey visual field test	At least 32 eyes had VF<20 degrees
McKnight and Babcock-Parziale 2007[8]	ARM-EX 54.5%, ARM-NE 16.1%, glaucoma 9.8%, optic atrophy 5.4%, diabetic retinopathy 4.5%, RP 1.8%, maculopathy 1.8%, other 6.1%	Mean 74	94%	81% white, 10% black, 8% Hispanic	NR	Better eye mean logMAR 1.09	NR
Kiser et al. 2006[9]	33 had RP, 14 had MD, 4 had ON, 9 had OR, 5 had DR, and 12 had normal vision 20/25 or better (CTL).	CTL group mean age 50 (range 22 to 74); patient groups mean age 61 (range 20 to 90)	48%	NR	NR	RP patients were divided into 4 groups of visual acuity (RP-I had VA better than 20/40 (8 patients); RP-II had VA between 20/40 and 20/199 (8 patients); RP-III had VA between 20/200 and 20/1000 (12 patients); RP-IV had VA worse than 20/1000 (5 patients)). MD patients were divided into 2 groups of visual acuity (MD-I had VA between 20/200 and 20/500 [12 patients], and MD-II had VA worse than 20/500 [2 patients]). The other 3 patients groups (ON, OR, DR) all had VA worse than 20/200.	NR

Table C-7. Patient characteristics in studies included for Key Question 1C (continued)

Study	Diagnosis	Age	Sex (% male)	Race	Prior Treatments	Baseline Visual Acuity	Baseline Visual Field
Babcock-Parziale et al. 2005[10]	ARMD 66%, glaucoma 10%, DR 7%, RP 4%, other 13%	Median 77 (range 42-96)	93%	85% white	NR	Better eye mean logMAR 1.3	55% had central field loss, 10% peripheral loss, 14% both central and peripheral loss, and 21% no field loss
Kiser et al. 2005[4]	26 had RP, 16 had MD, 3 had ON, 11 had OR, 4 had DR, and 18 had normal vision 20/25 or better (CTL).	Mean 61 range 20 to 90	NR	NR	NR	RP patients were divided into 3 groups of visual acuity (RP-I had VA better than 20/40 [4 patients]; RP-II had VA between 20/40 and 20/199 [12 patients]; RP-III had VA between 20/200 and 20/1000 [10 patients]). MD patients were divided into 2 groups of visual acuity (MD-I had VA between 20/200 and 20/500 [8 patients], and MD-II had VA worse than 20/500 [8 patients]). The other 3 patients groups (ON, OR, DR) all had VA worse than 20/200.	NR
Stelmack et al. 2002[11]	66% had MD, 16% had DR, 12% had glaucoma, NR the remaining 6%.	72 (range 38-88)	93.5%	NR	NR	Mean 1.00 logMAR	NR, but many of them must have had VF<20 degrees, since they were all legally blind, and many had VA>20/200

AMD, ARMD=age-related macular degeneration; ARM-EX=age-related macular degeneration exudative; ARM-NE=age-related macular degeneration non-exudative; CTL=control group; DR=diabetic retinopathy; logMAR=logarithm of the minimum angle of resolution**;** MD=macular degeneration; NR=not reported; ON=optic neuropathy; OR=other retinal disease; RP=retinitis pigmentosa; SD=standard deviation; VA=visual acuity; VF=visual field

Table C-8. Measures tested in studies included for Key Question 1C

Study	Measure	Details About the Measure	Reported Reliability Data	Reported Validity Data	Reported Responsive-ness Data
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire	Authors started with 37 items from the original IVI. Based on their analyses, they deleted 9 items that did not contribute to the identified 2 subscales (these subscales were the activities of daily living, mobility, and safety [ADLMS] and emotional well-being [EWB]). For both subscales, higher numbers indicate higher quality of life.	✓	✓	
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV)	Adaption of several existing scales for ADL, but tailored to those with very low vision	✓	✓	
Bittner et al. 2011[2]	Grating contrast sensitivity (GCS)	For each stimulus, the lines were horizontal, vertical, diagonal right, or diagonal left. Researchers determined each person's acuity threshold, twice per visit, and again over 1–2 additional visits. GCS gratings were 4 times larger than Grating Acuity Test gratings.	✓	✓	
Bittner et al. 2011[2]	Pelli-Robson (PR) contrast sensitivity test	Standard contrast sensitivity test	✓		
McKnight and Babcock-Parziale 2007[8]	FAST (Functional Assessment of Self-Reliance on Tasks), clinician-completed	Clinician-completed assessment of both pre-treatment and post-treatment abilities. There are 11 items, and a team of clinicians (consensus rating) completes it at both admissions to the program (pre) and discharge (post). Prior field testing indicated that FAST measures "functional ability."		✓	✓
McKnight and Babcock-Parziale 2007[8]	FAST (Functional Assessment of Self-Reliance on Tasks), patient-completed	Patient-completed assessment of both pre-treatment and post-treatment abilities. There are 11 items, and patients were interviewed by telephone both before and after low vision rehabilitation		✓	✓
Kiser et al. 2006[9]	Light perception test: Dark adaptometry	Researchers determined each person's threshold for detecting faint light (lower dB thresholds indicate greater sensitivity). Also they measured the amount of time it took to determine the person's threshold (shorter time indicates greater sensitivity). Data were captured over 4–5 visits per person at monthly intervals (1 test per visit).	✓	✓	
Kiser et al. 2006[9]	Light perception test: Dark-adapted Humphrey perimetry	After being dark-adapted, patients fixated on a red LED in the middle of a 4 x 4 square. Researchers determined each person's threshold for detecting faint light over the visual field. Data were on a dB scale, with higher dB indicating greater sensitivity. Data were captured over 4–5 visits per person (monthly intervals), and there were 2 tests per visit. Data were reported in 3 ways: (1) rod-based sensitivity using blue-green stimuli (500 nm); (2) cone-based sensitivity using red stimuli (650 nm); (3) rod-cone sensitivity ratios	✓	✓	
Kiser et al. 2006[9]	Light perception: Full-field	2 flashes appeared (1 at maximum attenuation, the other to	✓	✓	

Table C-8. Measures tested in studies included for Key Question 1C (continued)

Study	Measure	Details About the Measure	Reported Reliability Data	Reported Validity Data	Reported Responsive-ness Data
	flash test	determine the patient's threshold for detecting faint light). Higher dB thresholds indicate greater sensitivity. Data were captured over 4–5 visits per person at monthly intervals (1 test per visit).			
Babcock-Parziale et al. 2005[10]	VA-13	Patient-completed functional assessment of both pre-treatment abilities and post-treatment abilities. Patients completed VA-13 once, at 4–6 weeks after discharge form the program. It is a 13-item instrument measuring “the frequency of, and independence in, and satisfaction with performing specific tasks.” Prior field testing indicated that VA-13 measures "functional independence." Subjects were asked about (1) current health (which is the post-test measurement) and (2) their memory about their health before treatment.	✓	✓	✓
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), clinician-completed	Clinician-completed assessment of both pre-treatment abilities and post-treatment abilities. There are 11 items, and a team of clinicians (consensus rating) completes it at both admission to the program (pre) and discharge (post). Prior field testing indicated that FAST measures “functional ability.”	✓	✓	✓
Kiser et al. 2005[4]	Pelli-Robson (PR) contrast sensitivity test, regular	Standard test, regular illumination in a fully lit room. Researchers determined each person's visual acuity and contrast sensitivity. Data were captured over 4–5 visits per person at monthly intervals (1 test per visit).	✓		
Kiser et al. 2005[4]	Pelli-Robson (PR) contrast sensitivity test, dim	Standard test, dim illumination in a fully lit room. Researchers determined each person's visual acuity and contrast sensitivity. Data were captured over 4–5 visits per person at monthly intervals (1 test per visit).	✓		
Kiser et al. 2005[4]	Pelli-Robson contrast sensitivity test, glare	Standard test, glare illumination in a fully lit room. Researchers determined each person's visual acuity and contrast sensitivity. Data were captured over 4–5 visits per person at monthly intervals (1 test per visit).	✓		
Stelmack et al. 2002[11]	Modified NEI-VFQ-25 plus supplement	Authors started with 39 items (25 plus 14 supplement). 2 main modifications: Directions were modified to add consideration of low vision devices, and directions were repeated if necessary because veterans frequently forgot the instructions. Of 39 items, 5 were removed from the final analysis (3 involved driving questions 15, 16, and A10, and the 2 on vision-related health A1 and A2).		✓	✓

ADL=activities of daily living; dB=decibel; LED=light-emitting diode; NEI-VFQ-25=National Eye Institute Visual Function Questionnaire 25 item, VA-13=Veteran’s Administration-13

Table C-9. Psychometric data reported in studies included for Key Question 1C

Study	Measure and Psychometric Property	Description of Analysis	Result
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Construct Validity***	Response category thresholds (could participants discriminate between items) (between 0.7 and 1.3 is acceptable).	Response category thresholds: The original version had 3 items misfit. After determining the 2 domains, these 3 items were removed, along with 6 other items. The resulting 28-item instrument had no misfit items.
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Face validity***	Focus group discussions and telephone interviews with vision-impaired patients, healthy controls, and professionals.	Focus group discussions reduced an initial item pool from 76 to 52 items. Then 198 legally blind people were interviewed by telephone to reduce the 52 to 37. Eliminations were based on a floor effect (tasks too easy to bother asking about). Rephrasing of questions, and changing of response options.
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Reliability***	Separation reliability, PSI, which is how well the instrument classified respondents into different levels of the trait (PSI >2 is considered acceptable).	PSI: Met their criteria for acceptability.
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Reliability***	Internal consistency reliability. Person reliability, which reflects the spread of the underlying trait in the sample (person reliability >0.8 is considered acceptable).	Person reliability: Met their criteria for acceptability.
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Reliability***	Internal consistency reliability, same as above.	IR: Met their criteria for acceptability
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Construct Validity***	A test of unidimensionality based on the residuals of the first factor in principal components analyses (>50% is considered acceptable).	Unidimensionality: Residuals of first factor: Met their criteria for acceptability. There was no evidence of multidimensionality.
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Construct Validity***	Another test of unidimensionality, based on the first contrast of residuals (<2.5 eigenvalues is considered acceptable).	Unidimensionality: eigenvalues of first contrast: Met their criteria for acceptability. There was no evidence of multidimensionality.
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Construct Validity***	Targeting, which is whether the items adequately target the ability of respondents (a difference of less than 1.0 logits is considered acceptable).	Targeting: "slightly suboptimal", but "still well within acceptable levels."
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Construct Validity***	Differential item functioning, which is whether sample subgroups with similar underlying ability (e.g., of different age, sex, etc.) have different scores on the instrument.	Differential Item Functioning: None of the items showed this. Neither ADLMS nor EWB subscores were statistically significantly correlated with age, sex, marital status, living situation, employment, or education (see Table 3 of the article).

Table C-9. Psychometric data reported in studies included for Key Question 1C (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Construct Validity***	Whether their responses are associated with their eye conditions	Association with eye conditions (see Table 3 of the article). The ADLMS subscores varied among patients with different diagnoses, but the EWB subscores did not. For ADLMS, the means for RP, AMD, OR, glaucoma, and other were 0.15, -0.27, -0.37, -0.19, and 0.19, respectively (overall p=0.018). Thus the poorest ADLMS was found among those with AMD and glaucoma. For EWB, the means for RP, AMD, OR, glaucoma, and other were 0.24, 0.21, 0.45, 0.11, and 0.48 (overall p=0.685).
Finger et al. 2014[6]	Modified Impact of Vision Impairment (IVI) questionnaire, ***Construct Validity***	Whether their responses are associated with other health aspects.	Association with other health problems. Both ADLMS and EWB subscores correlated with 4 other measures of health (general health, other health problems, do other health problems interfere, and anxiety/depression). As expected, higher ADLMS and EWB subscores were predictive of better health responses to these questions.
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV), ***Face validity***	Focus group discussions and telephone interviews with patients with impaired vision, healthy controls, and professionals.	Authors began with 296 items from existing ADL tools. These were decreased to 25 general activities based on importance rankings with 62 participants with severe low vision. A panel of low vision experts then reduced the 25 activities to 11, which were comprised of 53 specific tasks. Tasks included "table and shelf searches for cutlery and crockery items, clock face and symbol recognition, signature placement, drink pouring, clothes sorting, and the understanding of hand gestures" (see Table 1 of the article for a complete list of the 53 tasks). The 53 tasks were all submitted to construct validity testing among 40 study participants.
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV), ***Construct Validity***	Response category thresholds (could participants discriminate between items) (between 0.7 and 1.3 is acceptable).	Response category thresholds: The original version (53 tasks) had 5 misfit items. A second version (27 tasks) had 2 misfit items. The final version (23 tasks) had 0 misfit items.
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV), ***Reliability***	Separation reliability, PSI, which is how well the instrument classified respondents into different levels of the trait (PSI >2 is considered acceptable).	PSI: Final version met their criteria for acceptability. Both the 1st and 2nd versions also met their criteria.
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV), ***Reliability***	Internal consistency reliability. Person reliability, which reflects the spread of the underlying trait in the sample (person reliability >0.8 is considered acceptable).	Person reliability: Final version met their criteria for acceptability. Both the 1st and 2nd versions also met their criteria.

Table C-9. Psychometric data reported in studies included for Key Question 1C (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV), ***Construct Validity***	A test of unidimensionality based on the residuals of the 1st factor in principal components analyses (>50% is considered acceptable).	Unidimensionality: Variance of first factor: Initial version (53 tasks) was 70.7%. Second version (27 tasks) was 71.6%, and the final version (23 tasks) was 77.5%.
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV), ***Construct Validity***	Another test of unidimensionality, based on the 1st contrast of residuals (<2.5 eigenvalues is considered acceptable).	Unidimensionality: eigenvalues of 1st contrast: The initial version had severe multidimensionality (eigenvalue for the first contrast 7.1). Even the final version did not meet their criteria for acceptability (eigenvalue for the 1st contrast 4.7). This was because there were 5 underlying factors, not just 1. Authors did not attempt to list the 5, but they did state that the 23 final tasks were related to 6 activities: table search, recognition of symbols, clock reading, signature placement, clothes sorting, and recognition of hand gestures.
Finger et al. 2014[7]	Very Low Vision Instrumental Activities of Daily Living (IADL-VLV), ***Construct Validity***	Whether their responses are associated with age or sex (which they ideally would not be).	Association with age/sex. After controlled for cognitive impairment and depression, there was no association between scores on the final instrument and age or sex. However, they are associated with both cognitive impairment and depression.
Bittner et al. 2011[2]	Grating contrast sensitivity (GCS), ***Construct Validity***	Separately for the 8 patients with RP and the 12 with OR, authors computed the correlation between the newly developed GCS and the standard and "well-validated" test called the Pelli-Robson chart. Perfect validity would be indicated by (1) strong correlation, (2) a slope of 1.0 and (3) an intercept of 0.	GCS did not demonstrate validity for patients with either RP or OR (Figure 4 in the article). Using the Pelli-Robson test as the gold standard, GCS overestimated patients' contrast sensitivity. For some patients with RP, it was not possible to obtain values using the gold standard. Even leaving out those patients, GCS overestimated contrast sensitivity.
Bittner et al. 2011[2]	Grating contrast sensitivity (GCS), ***Reliability***	Test-retest reliability, same as above	For RP, the median test-retest $CR_{.95}$ of GCS was 0.13 for within-visit and 0.15 for between-visit (log-unit scale, see Figure 5 in the article). For OR patients with vision worse than 20/350, the median test-retest $CR_{.95}$ of GCS was 0.13 for within-visit and 0.34 for between-visit (log-unit scale, see Figure 5 in the article). For OR patients with vision etter than 20/350, the median test-retest $CR_{.95}$ of GCS was 0.15 for within-visit and 0.41 for between-visit (log-unit scale, see Figure 5 in the article).
Bittner et al. 2011[2]	Pelli-Robson (PR) contrast sensitivity test, ***Reliability***	Test-retest reliability, same as above	For RP, the median test-retest $CR_{.95}$ of PR was 0.14 for between-visit (log-unit scale, see Figure 5 in the article). For OP patients, it was 0.24.
McKnight and Babcock-Parziale 2007[8]	FAST (Functional Assessment of Self-Reliance on Tasks), clinician-completed ***Responsiveness***	Responsiveness, as measured by the difference in scores between admission to the program and discharge from the program.	As shown in Figure 2 of the article, discharge scores were consistently much higher than admission scores. Authors did not quantify the size of the difference.

Table C-9. Psychometric data reported in studies included for Key Question 1C (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
McKnight and Babcock-Parziale 2007[8]	FAST (Functional Assessment of Self-Reliance on Tasks), patient-completed ***Responsiveness***	Responsiveness, as measured by the difference in scores between admission to the program and discharge from the program.	As shown in Figure 2 of the article, discharge scores were consistently much higher than admission scores. Authors did not quantify the size of the difference.
McKnight and Babcock-Parziale 2007[8]	FAST (Functional Assessment of Self-Reliance on Tasks), clinician-completed, vs. patient-completed, **Construct validity**	Whether the difficulty of items (as judged by Rasch analysis) was similar for clinician-completed vs. patient-completed forms	As shown in Figure 1 of the article, there was a near linear relationship between the two versions of FAST with respect to item difficulty. The single exception was reading, which was judged to be easier for patients when clinicians judged it as compared to when patients judged it.
McKnight and Babcock-Parziale 2007[8]	FAST (Functional Assessment of Self-Reliance on Tasks), clinician-completed, vs. patient-completed, **Construct validity**	Whether patients' abilities (as judged by Rasch analysis) were similar for clinician-completed vs. patient-completed forms	When the clinician-completed form was used to try to predict the patient-completed form, there was a relatively weak relationship. The slope was only 0.35, and only 55% of the variance in patient scores were explained by clinician scores. However, a multiple regression (Table 1 of the article) found that the timing of administration (at admission or at discharge) was the primary explanatory factor. These data indicate moderate construct validity for the 2 versions of the forms.
Kiser et al. 2006[9]	Light perception test: dark adaptometry, ***Reliability***	Test-retest reliability. The metric was the CoV, which is the SD of the time required to reach the person's light perception threshold divided by the average time the person required to reach the threshold. CoV is on the percentage scale, and lower numbers indicate greater test-retest reliability.	Only 16 of 33 RP patients could actually complete this test. All 32 other patients with other eye conditions could complete it. Most patient groups averaged about CoV of 10% to 20% (see Figure 3 in the article for curves for separate groups of patients). Authors did not report means for the different groups or across groups.
Kiser et al. 2006[9]	Light perception test: dark-adapted Humphrey perimetry: rod-based sensitivity using blue-green stimuli (500 nm), ***Reliability***	Test-retest reliability. Authors computed each patient's $CR_{.95}$. This was done both between-visit and within-visit. A low $CR_{.95}$ indicates good test-retest reliability. $CR_{.95}$ is on the same scale as the perimetry testing, which is dB.	Only 15 of 33 patients with RP could both do this test and provide sensible results. For patients with other conditions, 19 of 32 could both do the test and provide sensible results. For available results for RP-I patients, the median $CR_{.95}$ was 5 for between-visit and 1.5 for within-visit. For available results for RP-II patients, the $CR_{.95}$ was 1 for between-visit and 1 for within-visit. For available results for RP-III patients, the $CR_{.95}$ was 2 for between-visit and 2 for within-visit. For available results for MD-I patients, the $CR_{.95}$ was 5.5 for between-visit and 3.5 for within-visit. For available results for OR patients, the $CR_{.95}$ was 6 for between-visit and 2.5 for within-visit.

Table C-9. Psychometric data reported in studies included for Key Question 1C (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Kiser et al. 2006[9]	Light perception test: dark-adapted Humphrey perimetry: cone-based sensitivity using red stimuli (650 nm), ***Reliability***	Test-retest reliability, same as above	Only 15 of 33 patients with RP could both do this test and provide sensible results. For patients with other conditions, 19 of 32 could both do the test and provide sensible results. For available results for RP-I patients, the median $CR_{.95}$ was 3 for between-visit and 1 for within-visit. For available results for RP-II patients, the median $CR_{.95}$ was 4.5 for between-visit and 1.5 for within-visit. For available results for RP-III patients, the median $CR_{.95}$ was 6 for between-visit and 2 for within-visit. For available results for MD-I patients, the $CR_{.95}$ was 10 for between-visit and 2 for within-visit. For available results for OR patients, the $CR_{.95}$ was 5.5 for between-visit and 2.5 for within-visit.
Kiser et al. 2006[9]	Light perception test: dark-adapted Humphrey perimetry: rod-cone sensitivity ratios, ***Reliability***	Test-retest reliability, same as above	Only 15 of 33 patients with RP could both do this test and provide sensible results. For patients with other conditions, 19 of 32 could both do the test and provide sensible results. For available results for RP-I patients, the $CR_{.95}$ was 3 for between-visit and 2 for within-visit. For available results for RP-II patients, the $CR_{.95}$ was 5 for between-visit and 3 for within-visit. For available results for RP-III patients, the $CR_{.95}$ was 5 for between-visit and 5 for within-visit. For available results for MD-I patients, the $CR_{.95}$ was 6.5 for between-visit and 5 for within-visit. For available results for OR patients, the $CR_{.95}$ was 5 for between-visit and 2.5 for within-visit.
Kiser et al. 2006[9]	Light perception: Full-field flash test, ***Reliability***	Test-retest reliability, same as above	All but 2 of 77 patients could perform this test and provide sensible results (authors did not report the eye conditions of these 2). RP-I patients had a mean of 43 dB with a $CR_{.95}$ of 6 dB. This means that a typical RP-I patient had a threshold of 43 dB, and one would expect with 95% probability that a retest would be between 37dB and 49 dB. RP-II patients had a mean of 39 dB with a $CR_{.95}$ of 7dB. RP-III patients had a mean of 26 dB with a $CR_{.95}$ of 9 dB. RP-IV patients had a mean of 19 dB with a $CR_{.95}$ of 12dB. MD-I patients had a mean of 60 dB with a $CR_{.95}$ of 8dB. MD-II patients had a mean of 64 dB with a $CR_{.95}$ of 6 dB. OR patients had a mean of 50 dB with a $CR_{.95}$ of 10dB. DR patients had a mean of 48 dB with a $CR_{.95}$ of 16 dB.
Kiser et al. 2006[9]	Light perception test: dark adaptometry and full-field flash test, ***Construct Validity***	Correlation between results of dark adaptometry (threshold dB) and full-field flash test (threshold dB)	The correlation was only r=0.37, and the slope was 2.6, which clearly indicates that the 2 tests are measuring different traits. Authors theorized that the problem was that adaptometry was limited by the device ("limited response range of the SST") and caused a ceiling effect, which "limits the thresholds compared with those of the full-field flash test."

Table C-9. Psychometric data reported in studies included for Key Question 1C (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Kiser et al. 2006[9]	Light perception test: dark-adapted Humphrey perimetry and full-field flash test, ***Construct Validity***	Correlation between results of full-field flash test (threshold dB) and Humphrey perimetry	The correlation was 0.60 and the slope was -1.42. Authors theorized that the problem was MD-I patients were hampering the analysis. When they excluded MD-I patients, the correlation rose to 0.8 and the slope became -1.31.
Babcock-Parziale et al. 2005[10]	VA-13, ***Responsiveness***	Responsiveness. A comparison of Rasch-based person abilities, pretreatment vs. post-treatment	Patients had improved about 0.63 logit, which is less than typically observed in this field (2 or even 4 logits according to the authors), and so the authors stated that VA-13 instrument was under-responsive. Authors noted a ceiling effect in VA-13 responses.
Babcock-Parziale et al. 2005[10]	VA-13, ***Face validity***	Whether the distribution of pre-treatment item difficulty (Rasch-based analysis) was "the same order of difficulty that is observed in clinical practice at admission or in pre-test self-reports."	Two specific items were disordered: according to the VA-13, reading of newspapers/magazine was easier for patients than reading mail, however according to the authors' clinical expertise, the reverse is true. All remaining items were ordered as the authors expected. Thus 11/13 items achieved the expected ordering.
Babcock-Parziale et al. 2005[10]	VA-13, ***Construct Validity***	A comparison of Rasch-based item difficulties abilities, pretreatment vs. post-treatment	Item difficulty would not be expected to change pre vs post. Only 2 of 13 items seem to have changed in difficulty after treatment (reading mail, which became easier, and watching TV, which became more difficult) (see Figure 1 of the article). The authors interpreted this as evidence for the construct validity of the VA-13.
Babcock-Parziale et al. 2005[10]	VA-13, ***Construct Validity***	Response category thresholds: authors considered values between 0.6 and 1.4 as acceptable	Response category thresholds: data for both pre-test and post-test met the authors' criteria for acceptability.
Babcock-Parziale et al. 2005[10]	VA-13, ***Reliability***	Internal consistency reliability as measured by Cronbach's alpha. Item reliability.	For items, Cronbach's alpha was 0.81 for the retrospective pre-test and 0.76 for the post-test, indicating good internal consistency reliability.
Babcock-Parziale et al. 2005[10]	VA-13, ***Reliability***	Internal consistency reliability as measured by Cronbach's alpha. Person reliability.	For person reliability estimates, Cronbach's alpha was 0.71 for the retrospective pre-test and 0.27 for the post-test. This latter value of 0.27 was deemed by the authors to be poor.
Babcock-Parziale et al. 2005[10]	VA-13, ***Reliability***	Separation reliability (2 or more is considered acceptable).	For the retrospective pre-test this was only 1.57, and for the post-test it was only 0.60. The authors deemed these values unacceptably low.
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), ***Responsiveness***	Responsiveness. A comparison of Rasch-based person abilities, pre-treatment vs post-treatment	Acceptably responsive. The logit change was of 2.5 logits corresponded to a large effect size of d=1.8.

Table C-9. Psychometric data reported in studies included for Key Question 1C (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), ***Face validity***	Whether the distribution of pre-treatment item difficulty (Rasch-based analysis) was "the same order of difficulty that is observed in clinical practice at admission or in pre-test self-reports."	Distribution of item difficulties was consistent with the authors' opinion.
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), ***Construct Validity***	A comparison of Rasch-based item difficulties abilities, pre-treatment vs. post-treatment	Item difficulty would not be expected to change pre vs post. Only 3 of 11 items seem to have changed in difficulty after treatment (reading, which became easier, and home maintenance and fine motor dexterity, both of which became harder) (see Figure 3 of the article). The authors interpreted this as evidence for the construct validity of the VA-13.
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), ***Construct Validity***	Response category thresholds: authors considered values between 0.6 and 1.4 as acceptable	Response category thresholds: data for both pre-test and post-test met the authors' criteria for acceptability
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), ***Reliability***	Internal consistency reliability as measured by Cronbach's alpha. Item reliability	For items, Cronbach's alpha was 0.97 for the pre-test and 0.95 for the post-test, indicating good internal consistency reliability for items.
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), ***Reliability***	Internal consistency reliability as measured by Cronbach's alpha. Person reliability	For person reliability estimates, Cronbach's alpha was 0.90 for the pre-test and 0.85 for the post-test, indicating good internal consistency reliability for person abilities.
Babcock-Parziale et al. 2005[10]	FAST (Functional Assessment of Self-Reliance on Tasks), ***Reliability***	Separation reliability (2 or more is considered acceptable).	For pre-test the value was 2.9, and for post-test it was 2.37. Both meet criteria for acceptability.
Kiser et al. 2005[4]	Pelli-Robson (PR) contrast sensitivity test, regular, ***Reliability***	Test-retest reliability, same as above	Median values of $CR_{.95}$ were: 0.30 for RP-I, 0.31 for RP-II, 0.49 for RP-III, 0.48 for MD-I, 0.47 for MD-II, 0.46 for DR, and 0.19 for OR. See Figure 4 of the article
Kiser et al. 2005[4]	Pelli-Robson (PR) contrast sensitivity test, dim, ***Reliability***	Test-retest reliability, same as above	Median values of $CR_{.95}$ were: 0.22 for RP-I, 0.50 for RP-II, 0.38 for RP-III, 0.58 for MD-I, 0.27 for MD-II, 0.30 for DR, and 0.30 for OR. See Figure 4 of the article
Kiser et al. 2005[4]	Pelli-Robson (PR) contrast sensitivity test, glare, ***Reliability***	Test-retest reliability, same as above	Median values of $CR_{.95}$ were: 0.25 for RP-I, 0.68 for RP-II, 0.10 for RP-III, 0.59 for MD-I, 0.58 for MD-II, 0.30 for DR, and 0.47 for OR. See Figure 4 of the article

Table C-9. Psychometric data reported in studies included for Key Question 1C (continued)

Study	Measure and Psychometric Property	Description of Analysis	Result
Stelmack et al. 2002[11]	Modified NEI-VFQ-25 plus supplement, ***Responsiveness***	For each of 34 items, they compared the pre-treatment item difficulty to the post-item difficulty, and the difference was responsiveness. Item difficulty was based on the Rasch model. Thus, they measured whether certain visual tasks become easier after treatment.	7 of 34 items became statistically significantly easier after treatment (items 5, 6, 8, 14, A3, A4, and A8) (Figures 6 and 7a of the article). Item 5 is "How much difficulty do you have reading ordinary print in newspapers?". Item 6 is "How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools?". Item 8 is "How much difficulty do you have reading street signs or the names of stores?". Item 14 is "Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events?". Item A3 is "Wearing glasses, how much difficulty do you have reading the small print in a telephone book, on a medicine bottle, or on legal forms?" (item A3 was edited to include low vision devices as well as glasses). Item A4 is "Because of your eyesight, how much difficulty do you have figuring out whether bills you receive are accurate?". Item A8 is "Because of your eyesight, how much difficulty do you have seeing and enjoying programs on TV?"
Stelmack et al. 2002[11]	Modified NEI-VFQ-25 plus supplement, ***Responsiveness***	For each of 77 patients, they compared the pre-treatment visual ability to the post-treatment ability, and the difference was responsiveness. Visual ability was based on the Rasch model. Thus, they measured whether certain patients became more able after treatment.	69 of 77 patients had a higher estimate of visual ability after treatment vs. before treatment (Figure 9 in the article). The typical amount of improvement corresponded to a 4-line improvement in visual acuity.
Stelmack et al. 2002[11]	Modified NEI-VFQ-25 plus supplement, ***Construct Validity***	Authors used Rasch analysis to determine construct validity. Each item received a weighted fit statistic, and they determined whether the fit statistics before treatment were independent from fit statistics after treatment.	For item difficulty, the data demonstrate construct validity, as there was no relation between pre-intervention and post-intervention fit statistics (Figure 4a of the article). They found the same result for person ability estimates (Figure 4c of the article)

ADL=activities of daily living; ADLMS=activities of daily living mobility and safety; AMD=age-related macular degeneration; CoV=coefficient of variation; $CR._{95}$=coefficient of reliability; dB=decibel; EWB=emotional well-being; IR=internal reliability; MD=macular dystrophy (I, II designate disease severity); NEI-VFQ-25=National Eye Institute Visual Function Questionnaire 25 item; OR=other retinal dystrophy; PSI=person separation index; RP=retinitis pigmentosa (I–IV designate disease severity); SD=standard deviation; SST=Suprachoroidal Transretinal Stimulation device , VA-13=Veteran's Administration-13

Table C-10. Risk of bias of data reported in studies included for Key Question 1C

Study	Psychometric Property	Risk-of-Bias Considerations[a]	Risk-of-Bias Category	Comments
Finger et al. 2014[6]	Internal consistency reliability	Percentage of missing items given? Adequate sample size? Checked unidimensionality? Separate internal consistency reliability statistic for each unidimensional subscale? Any important flaws?	Low	Authors provided separate internal consistency reliability statistics for both item difficulty and person ability
Finger et al. 2014[6]	Separation reliability	Percentage of missing items given? Adequate sample size? Checked unidimensionality? Separate internal consistency reliability statistic for each unidimensional subscale? Any important flaws?	Low	Used a statistical measure for this psychometric property.
Finger et al. 2014[6]	Face validity	Did they assess whether all items are relevant to what they are trying to measure? Did they assess whether all items are relevant for the purpose of the instrument? Did they assess whether the items comprehensively reflect what they are trying to measure? Any important flaws?	Low	Unclear whether the list of key activities was comprehensive, but probably it was.
Finger et al. 2014[6]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Low	Used a statistical measure for this psychometric property.
Finger et al. 2014[7]	Internal consistency reliability	Percentage of missing items given? Adequate sample size? Checked unidimensionality? Separate internal consistency reliability statistic for each unidimensional subscale? Any important flaws?	Moderate	Authors provided separate internal consistency reliability statistics for both item difficulty and person ability. Only 40 patients tested, which may be too low.
Finger et al. 2014[7]	Separation reliability	Percentage of missing items given? Adequate sample size? Checked unidimensionality? Separate internal consistency reliability statistic for each unidimensional subscale? Any important flaws?	Moderate	Used a statistical measure for this psychometric property. Only 40 patients tested, which may be too low.
Finger et al. 2014[7]	Face validity	Did they assess whether all items are relevant to what they are trying to measure? Did they assess whether all items are relevant for the purpose of the instrument? Did they assess whether the items comprehensively reflect what they are trying to measure? Any important flaws?	Low	Unclear whether all items were truly important to the patients
Finger et al. 2014[7]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Moderate	Used a statistical measure for this psychometric property. Only 40 patients, which may be too low.
Bittner et al.	Test-retest	Percentage of missing items given? Adequate sample size?	Moderate	Only 20 patients, and some did not have a retinal

Table C-10. Risk of bias of data reported in studies included for Key Question 1C (continued)

Study	Psychometric Property	Risk-of-Bias Considerations[a]	Risk-of-Bias Category	Comments
2011[2]	reliability	At least 2 measurements available? Were administrations independent? Was time interval stated? Were patients stable in the interim? Was time interval appropriate? Were test conditions similar for the 2 measurements? Any important flaws?		condition of interest.
Bittner et al. 2011[2]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Moderate	Used a statistical measure for this psychometric property. Only 20 patients, which may be too low.
McKnight and Babcock-Parziale 2007[8]	Responsiveness	Percentage of missing items given? Adequate sample size? Longitudinal design with at least 2 measurements? Time interval stated? Hypotheses about changes made a priori? Comparator instrument to determine true responsiveness? Any important flaws?	Moderate	Authors did not indicate whether the measured pre-post difference was sufficiently large for the measures to be considered responsive.
McKnight and Babcock-Parziale 2007[8]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Low	Used a statistical measure for this psychometric property.
Kiser et al. 2006[9]	Test-retest reliability	Percentage of missing items given? Adequate sample size? At least two measurements available? Were administrations independent? Was time interval stated? Were patients stable in the interim? Was time interval appropriate? Were test conditions similar for the two measurements? Any important flaws?	Low	4 had optic neuropathies, but this only represents 6% of the low-vision patients
Kiser et al. 2006[9]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Moderate	Some patients could not complete 2 of the 3 tests; missing data was a problem. Unclear whether the correlation among the remaining patients is relevant.
Babcock-Parziale et al. 2005[10]	Internal consistency reliability	Percentage of missing items given? Adequate sample size? Checked unidimensionality? Separate internal consistency reliability statistic for each unidimensional subscale? Any important flaws?	Low	Authors provided separate internal consistency reliability statistics for both item difficulty and person ability.
Babcock-Parziale et al. 2005[10]	Separation reliability	Percentage of missing items given? Adequate sample size? Checked unidimensionality? Separate internal consistency reliability statistic for each unidimensional subscale? Any important flaws?	Low	Used a statistical measure for this psychometric property.

Table C-10. Risk of bias of data reported in studies included for Key Question 1C (continued)

Study	Psychometric Property	Risk-of-Bias Considerations[a]	Risk-of-Bias Category	Comments
Babcock-Parziale et al. 2005[10]	Face validity for VA-13	Did they assess whether all items are relevant to what they are trying to measure? Did they assess whether all items are relevant for the purpose of the instrument? Did they assess whether the items comprehensively reflect what they are trying to measure? Any important flaws?	High	Pretest assessment relies on patients' potentially faulty memory of their abilities before treatment. Sparse assessment of whether this instrument applies well to patients with very low vision
Babcock-Parziale et al. 2005[10]	Face validity for Functional Low-Vision Observer Rated Assessment (FAST)	Did they assess whether all items are relevant to what they are trying to measure? Did they assess whether all items are relevant for the purpose of the instrument? Did they assess whether the items comprehensively reflect what they are trying to measure? Any important flaws?	Moderate	Sparse assessment of whether this instrument applies well to patients with very low vision
Babcock-Parziale et al. 2005[10]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Low	Used a statistical measure for this psychometric property.
Babcock-Parziale et al. 2005[10]	Responsiveness	Percentage of missing items given? Adequate sample size? Longitudinal design with at least 2 measurements? Time interval stated? Hypotheses about changes made a priori? Comparator instrument to determine true responsiveness? Any important flaws?	Moderate	No comparator instrument to determine true responsiveness.
Kiser et al. 2005[4]	Test-retest reliability	Percentage of missing items given? Adequate sample size? At least 2 measurements available? Were administrations independent? Was time interval stated? Were patients stable in the interim? Was time interval appropriate? Were test conditions similar for the 2 measurements? Any important flaws?	Low	3 had optic neuropathies, but this represents only 5% of the patient with low vision
Stelmack et al. 2002[11]	Construct validity	Percentage of missing items given? Adequate sample size? Was an accepted statistical measure used, with standard thresholds for acceptability? If authors reported a comparator measure, would this comparator be expected to correlate with the tested measure? Any important flaws?	Low	Used a statistical measure for this psychometric property, and provided data separately for person ability and item difficulty.
Stelmack et al. 2002[11]	Responsiveness	Percentage of missing items given? Adequate sample size? Longitudinal design with at least 2 measurements? Time interval stated? Hypotheses about changes made a priori? Comparator instrument to determine true responsiveness? Any important flaws?	Moderate	No comparator instrument to determine true responsiveness.

VA-13=Veteran's Administration-13
Risk-of-bias considerations were based on the COSMIN manual.[5]

Table C-11. Description of study design, selection criteria, and treatment

Study	Study Design	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Arevalo et al. 2015[12,13]	Retrospective case series of 8 patients with RP	Saudi Arabia: King Khaled Eye Specialist Hospital and Amsterdam	10	8	Patients who had been implanted with the Argus II device starting in February 2013	NR	Argus II implantation	1.3–2.0 years
Ho et al. 2015 and other authors[14-22] Argus II	Multicenter, single arm, unmasked prospective study with the system turned ON and OFF.	10 centers in the United States and Europe	30	29	Confirmed diagnosis of RP (in U.S.) or outer retinal degeneration (Europe), bare or no LP in both eyes, functioning ganglion cells or optic nerve, and a history of useful form vision. Age was initially >50 but later changed to 25 years in the U.S. and Switzerland and 18 years in France and U.K.	Diseases or conditions that affect retinal or optic nerve function, ocular strictures, or conditions that could prevent successful implantation, and an inability to tolerate the surgery.	Argus II implantation including core and peripheral vitrectomy. Phakic subjects had the crystalline lens removed via phacoemulsification	Subjects (excluding 3 who have been explanted) have been implanted an average of 6.2±0.9 years (range of 5.2–7.4).

Table C-11. Description of study design, selection criteria, and treatment (continued)

Study	Study Design	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Stingl et al. 2015, 2013[23,24] Alpha IMS	International multicentered single (patient) blind prospective study in a group of 29 patients with RP or cone-rod dystrophy, with stimulator ON versus OFF comparisons presented in random order.	University of Tubingen, Germany; National University Health System, Singapore; Oxford Eye Hospital, U.K.; Katharinenhospital, Stuttgart, Germany; King's College Hospital and King's College London, U.K.; Olgahospital, Stuttgart, Germany; Semmelweis University, Hungary; Klinikum Dresden Friedrichstadt University Teaching Hospital, Germany; University of Hong Kong, Hong Kong; Oxford University Hospital, U.K.	29	29	Rod-cone or rod-cone degeneration and at least monocular blindness, meaning an inability to localize light and objects and lack of independent visual mobility in space or no LP or only an ability to distinguish light and darkness and unable to correctly localize a light source. Patients were required to have a fully developed and functioning central visual pathway with some useful vision up to age 12 years and who had learned to read and move independently. Also, electrically evoked phosphenes by corneal stimulation were a requirement. The retinal vascular still allows sufficient perfusion of inner retinal layer which was measured with fluorescein angiography.	No additional ophthalmologic disease. Patients without a clear optic media, inner retinal disease, or disease of the optic nerve were excluded. Patients with AMD were also excluded. Patients with edema or an extremely atrophic retina based on OCT were excluded. Also patients with heavily clumped pigmentation in the area to be implanted were excluded. Health conditions that would limit a patient's ability to withstand a 6- to 8-hour operation under general anesthesia, pregnancy, nursing, or age younger than 18 years or older than 78 years were excluded. No neurologic or psychiatric problems.	Subretinal implant Alpha IMS implanted in 1 eye plus cataract removal, vitrectomy, and a silicone oil tamponade. Appropriate refraction correction as needed. Explantation occurred at 1 year followup or earlier, based on the wish of the patient or device malfunction. Handheld unit allows patients to adjust contrast and brightness.	1 year
Ayton et al. 2014[25]	1st-in-human trial with the device in the OFF	Australia Royal Victorian Eye and Ear	3	3	Age ≥18 years, any sex, confirmed	Co-existing ocular disease with the	Suprachoroidal retinal prosthesis	12 months reported in this

Table C-11. Description of study design, selection criteria, and treatment (continued)

Study	Study Design	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Bionic Vision	position as the comparator	Hospital			history of other retinal degenerative disease such as RP or choroideremia, remaining VA of bare LP or less in both eyes, a functional inner retina (ganglion cells and optic nerve) as shown by ability to perceive light and/or measurable corneal electrically evoked visual response, at least 10 years of useful form vision in the worse seeing eye, willing and able to comply with study visits including preferably living within 1.5 hours of the investigational site, informed consent.	exception of mild cataract, inability to visualize the retina due to corneal or other ocular media opacities (corneal degenerations, dense cataracts, trauma, lid malposition) ocular conditions that predispose patients to eye rubbing, cognitive deficiencies including dementia or progressive neurological disease, psychiatric disorders including depression, deafness or significant hearing loss or the presence of a cochlear implant, poor general health or pregnancy that would exclude the use of a general anesthetic	without vitrectomy, patients continued with use of guide dogs. Due to a hemorrhage in the 1st implanted patient, patients 2 and 3 were also treated with Botox injections to minimize eye movements.	publication, study ongoing for a total of 2 years' followup

Table C-11. Description of study design, selection criteria, and treatment (continued)

Study	Study Design	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Rizzo et al. 2014[26] Argus II	Single center Interventional case series	Italy, Azienda Ospedaliero-Universitaria Pisana	6	5	RP, age ≥25 years, some visual memory, no electroretinographic response, residual LP, axial length between 20.5 and 26.0 mm, and reasonable expectations for the device's efficacy.	Other ocular disease that could interfere with device function or inhibit postoperative device visualization, history of cystic macular edema, pregnancy, desire to become pregnant, deafness, and uncontrollable systemic disease	Argus II following intervention protocol of Argus II feasibility study, including cataract extraction	12 months
Fujikado et al. 2011[27] Suprachoroidal Transretinal Stimulation	Case report of 2 patients with advanced RP. Their performance on a series of tests was compared with chance.	Osaka, Japan, Osaka University	2	2	NR	NR	For 5 and 7 weeks respectively, the 2 patients had a retinal prosthesis placed in the scleral pocket with the reference electrode in the vitreous cavity and they were treated with STS.	5 and 7 weeks, respectively, at which time the implant was removed
Klauke et al. 2011 and other authors[28-32] EPIRET3	Case series of 6 volunteers with RP	Aachen, Germany, Aachen University; and Essen, Germany, University of Duisburg-Essen	6	6 patients through 6-month followup; 5 through 2-year followup (1 patient died of breast cancer during the follow-up period)	18–80 years of age, RP, VA in better eye less than 1/50	Any other severe ocular disease, history of intraocular surgery except cataract, severe systemic or mental illness, other active implant, pregnancy, ability to read in childhood	EPIRET3 Implantation after removal of the lens, or if present, removal of an artificial intraocular lens and vitreous	1 month with device implanted followed by implant extraction. Followup was 6 months for efficacy and safety and 2 years for quality of life.

Table C-11. Description of study design, selection criteria, and treatment (continued)

Study	Study Design	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Zrenner et al. 2011[33] Alpha IMS	Proof-of-concept, pilot study. Report of last 3 volunteer patients who received the most current version of the device. Comparison was between stimulator ON and OFF presented randomly and without the patients' knowledge. 1 masked outcome assessor was used for all standardized tests.	Germany, University of Tübingen	3	3	Hereditary retinal degeneration of the outer retinal layers with the retinal vessels retaining perfusion and pigments of mild to moderate density, age 18–78 years, at least monocular blindness or visual function insufficient for navigation/ orientation, period of appropriate visual functions >12 years, and VA ≥20/400 earlier in life.	Any other ophthalmic disease with relevant effects on visual function, systemic diseases that might imply considerable risks with regard to the surgery or anesthesia, neurologic or psychiatric disease, hypersensitivity to any ingredients of the study device, pregnant, nursing, women of child bearing age not using contraception.	RPS Alpha IMS was implanted. All patients underwent cataract surgery and implantation of a posterior chamber lens in preparation for study prior to implantation in order to achieve the best possible optic media and prevent a secondary cataract due to use of silicone oil. Patients practiced using the device for 4–6 hours per day at home. Device was explanted at 4 months.	4 months

Table C-11. Description of study design, selection criteria, and treatment (continued)

Study	Study Design	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Chow et al 2010, Beruschat et al.[3,34] Extension study Artificial Silicon Retina (ASR)	Quasi-experimental, prospective, single-group study with the nonimplanted eye serving as the control condition; pre-operative and post-operative data were collected and compared.	U.S., Rush University Medical Center, Johns Hopkins University School of Medicine, and Central DuPage Hospital	6 (2 patients 5 and 6 from pilot study and 4 additional patients) Note for the orientation and mobility assess-ment only, 8 patients were tested (4 patients from the 1st trial and 4 from the extension study)	6	The 2 patients from the original pilot study who were able to read ETDRS. Additionally, 4 more RP patients with better VA received the implant under the expanded FDA-approved IDE protocol. All 4 of the newly enrolled patients were able to perform CGAT and ETDRS at some level.	NR	ASR microchip surgery with cataract removal in patients to facilitate viewing of the implant during surgery.	7 years

Table C-11. Description of study design, selection criteria, and treatment (continued)

Study	Study Design	Country/Site	Number of Patients Enrolled	Number of Patients at Final Followup	Patient Inclusion Criteria	Patient Exclusion Criteria	Treatment	Study Duration
Chow et al. 2004[35] Artificial Silicon Retina (ASR)	Quasi-experimental, prospective, single-group study of patients with RP, with the nonimplanted eye serving as the control condition. Pre-operative and post-operative data were collected and compared. 1 masked investigator for the 9-sector visual field test.	U.S., Rush University Medical Center, Johns Hopkins University School of Medicine, and Central DuPage Hospital	6	6	Age ≥40 years, diagnosis of RP Patients had to have a Snellen VA of 20/800 OU or worse and/or15° or less of remaining central visual field measured by Humphrey automated perimetry (loss >10dB, size III white static, and 31.5 apostilb background illumination). Patients also had to be able to perceive electrically induced phosphenes produced by contact lens electrical stimulation.	Free of other significant eye or medical diseases such as uveitis, diabetes, glaucoma, cystoid macular edema, or cardiac conditions. Unrealistic expectations of the study, unstable personality, or other significant psychiatric conditions.	ASR microchip. surgery with cataract removal in 3 patients to facilitate viewing of the implant during surgery. 1 patient underwent secondary anterior chamber intraocular lens implantation 1 month after the ASR implantation and 2 others were left aphakic	Study was scheduled to span postoperative days1 through month 24 but actual patient followup was between 6 and 18 months

AMD=age-related macular degeneration; ASR=Artificial Silicon Retina; CGAT=Chow Grading Acuity Test; dB=decibel; ETDRS=Early Treatment Diabetic Retinopathy Study test; FDA=U.S. Food and Drug Administration; IDE=investigational device exemption; LP=light perception; NR=not reported; OCT=optical coherence tomography; OU=both eyes; RP=retinitis pigmentosa; RPS=retinal prosthesis system; STS=Suprachoroidal Transretinal Stimulation; VA=visual acuity

Table C-12. Baseline demographics

Study	Diagnosis	Age at Diagnosis	Age at Implantation	Eye Implanted (% right)	Time from Implantation to Study Participation	Sex (% male)	Race	Prior Treatments	VA in Study Eye
Arevalo et al. 2015[12,13]	RP	NR	Range: 29–64 years; 1.5 years after implantation	75%	1.3–2.0 years	NR	NR	NR	7 LP, 1 L projection
Ho et al. 2015 and other authors[14-22] Argus II	RP (including 1 with Leber congenital amaurosis) 29 patients, choroideremia 1 patient	NR	Mean: 58 years Range: 28–77 years	NR, but typically worse seeing eye	Implantation is part of the study	70%	NR	NR	Bare LP in both eyes (29 patients), 1 no LP
Stingl et al. 2015, 2013[23,24] Alpha IMS	25 RP, 4 rod-cone dystrophy	NR	Mean: 53.8±8.2 years Range: 35–71 years	NR, but worse eye was implanted eye	Implantation is part of the study	55%	NR	NR	LP without projection (20 patients), no LP (9 patients) VA measured by standard flashlight test manually by direct illumination of the eye from 5 directions.
Ayton et al. 2014[25] Bionic Vision	End-stage RP (2 patients rod cone dystrophy, 1 patient Bardet-Beidl syndrome)	NR, but 2 patients had 20 years LP and 1 patient had 8–10 years LP	Mean: 55 years Range: 49–63 years	NR	Implantation is part of this study	66.6%	NR	Guide dog users at the time of study participation	LP: 3 patients
Rizzo et al. 2014[26] Argus II	RP: 6 patients	NR	Mean: 45.0±10.9 years Range: 36–59 years	66.6%	Implantation is part of the study	83%	NR	5 patients were pseudophakic and 1 was phakic and required a lens extraction	Monocular logMAR acuity that was immeasurable and worse than 2.9

Table C-12. Baseline demographics (continued)

Study	Diagnosis	Age at Diagnosis	Age at Implantation	Eye Implanted (% right)	Time from Implantation to Study Participation	Sex (% male)	Race	Prior Treatments	VA in Study Eye
Fujikado et al. 2011[27] STS	Advanced RP	26 years and 55 years	Mean: 69.5 years Range: 67–72 years	0% (left eyes chosen because in both patients, the threshold current to elicit phosphenes by transcorneal electrical stimulation was lower than in the right eye)	Implantation is part of the study	0%	NR	NR	Bare LP: 2 patients How VA measured: NR
Klauke et al. 2011 and other authors[28-32] EPIRET3	RP	NR Duration of legal blindness ranged from 2 to 8 years	Mean: 52.8 years Range: 35–69 years	NR	Implantation is part of this study	33.3%	NR	Artificial lens: 2 patients	LP: 4 patients No LP: 1 patient HM: 1 patient How VA was measured: NR
Zrenner et al. 2011[33] Alpha IMS	RP: 2 patients, choroideremia: 1 patient	Disease onset: 6, 6, and 16 years	Mean: 40.7 years Range: 38–44 years	NR	Implantation is part of the study	66.7%	NR	NR	Blind (bright light stimulation mediated some limited LP without any recognition of shapes) How VA measured: NR

Table C-12. Baseline demographics (continued)

Study	Diagnosis	Age at Diagnosis	Age at Implantation	Eye Implanted (% right)	Time from Implantation to Study Participation	Sex (% male)	Race	Prior Treatments	VA in Study Eye
Chow et al. 2010, Geruschat at al.[3,34] Extension study ASR	RP: autosomal dominant (2 patients), autosomal dominant Usher type 2 (1 patient), Isolated (2 patients), X-linked (1 patient)	NR	Mean: 54 years Range: 41–68 years	100%	Implantation part of study for 4 patients, other 2 patients were enrolled in pilot study for 6 months before taking part in this extension study	83%	83% Cauca-sian	Patient 5 from the pilot trial had cataract removal at time of implantation and an anterior chamber intraocular lens implantation 1 month post ASR implantation. This information was NR for the remaining patients. Use of a long cane (n=4) and guide dog (n=1) were reported by the patients taking part in the orientation and mobility assessment.	CF at 1– 2 feet HM at 4–5 feet HM at 2–3 feet HM at 1–2 feet HM at 5–6 feet HM at 5 feet

Table C-12. Baseline demographics (continued)

Study	Diagnosis	Age at Diagnosis	Age at Implantation	Eye Implanted (% right)	Time from Implantation to Study Participation	Sex (% male)	Race	Prior Treatments	VA in Study Eye
Chow et al. 2004[35] ASR	RP: Isolated without any family history (patient 1), extensive vertical autosomal dominant family history with multiple affected family members (patient 2), autosomal dominant with an affected sibling and child (patient 3), type 2 Usher syndrome with no family history of this condition (patient 4), autosomal dominant RP and a vertical family history (patients 5 and 6 were siblings)	NR	Range: 45–76 years	100%	Implantation was part of study	83%	NR	Posterior chamber intraocular lens (2 patients), anterior chamber intraocular lens (2 patients), uncorrected aphakia (2 patients)	ETDRS letters in either eye at 0.5 m (0 letters OD, 0–3 letters OS) (1 patient), no letters (2 patients), bare to no LP (1 patient), HM at 1 foot (1 patient), CF at 1–2 feet (1 patient)

ASR=Artificial Silicon Retina; CF=counting fingers; ETDRS=Early Treatment of Diabetic Retinopathy Study test; HM=hand motion; logMAR=logarithm of the minimum angle of resolution; L projection=light projection; LP=light perception; NR=not reported; OD=*oculus dexter*, right eye; OS=*oculus sinister*, left eye; RP=retinitis pigmentosa; STS=Suprachoroidal Transretinal Stimulation; VA= visual acuity

Table C-13. Visual acuity outcomes

Study	Outcomes	Comparator	Post-implantation VA	Change
Arevalo et al. 2015[12,13] Argus II	Grating visual acuity	Pre-implantation: 1 L projection, 7 LP	Post-implantation: 4 HM, 2 L projection, 2 LP	A majority of patients improved. Study did not report how many improved.
Arevalo et al. 2015[12,13] Argus II	Square localization	Stimulator OFF: NR	Stimulator ON: NR	80% of patients performed better with the stimulator ON than OFF
Arevalo et al. 2015[12,13] Argus II	Direction of motion	Stimulator OFF: NR	Stimulator ON: NR	40% of patients improved with the stimulator ON vs. OFF, 40% did slightly better, and 20% stayed the same
Ho et al. 2015 and other authors[14-22] Argus II	Square localization: percentage of subjects whose system ON results were significantly better than system OFF	Stimulator OFF	Stimulator ON Year 1 (n=16 patients): 93.8% did significantly better than with the stimulator OFF Year 3 (n=28): 89.3% did significantly better than with the stimulator OFF	Proportion of subjects with significantly better system ON than OFF results was not significantly different between 1 and 3 years for this test. Performance has remained better with the system ON than OFF on all visual tests, with these results sustained out beyond 5 years of chronic use.
Ho et al. 2015 and other authors[14-22] Argus II	Direction of motion: percentage of subjects whose system ON results were significantly better than system OFF	Stimulator OFF	Stimulator ON Year 1 (n=16 patients): 62.5% did significantly better than with the stimulator OFF Year 3 (n=27): 55.6% did significantly better than with the stimulator OFF	Proportion of subjects with significantly better system ON than OFF results was not significantly different between 1 and 3 years for this test. Performance has remained better with the System ON than OFF on all visual tests, with these results sustained out beyond 5 years of chronic use.
Ho et al. 2015 and other authors[14-22] Argus II	Grating visual acuity: percentage of subjects who scored between 2.9 and 1.6 logMAR with the system ON. None of the subjects scored with the system OFF	Stimulator OFF/Fellow eye: No subject could score on the scale at baseline.	Stimulator ON Year 1 (n=29 patients): 48.2% did significantly better than with the stimulator OFF Year 3 (n=27): 33.3% did significantly better than with the stimulator OFF	Proportion of subjects with significantly better system ON than OFF results was not significantly different between 1 and 3 years for this test. Performance has remained better with the System ON than OFF on all visual tests, with these results sustained out beyond 5 years of chronic use.

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Ho et al. 2015 and other authors[14-22] Argus II	Letter recognition in force choice test. Letters were divided into 3 groups (Group A only horizontal and vertical components, Group B oblique components, Group C oblique or curved element involving half the letter height. (n=21)	Stimulator OFF Mean % correct Group A: 17.7±12.9% Group B: 11.8±10.7% Group C: 15.3±7.4% Mean time in seconds for correctly identified letters Group A: NR Group B: NR Group C: NR	Stimulator ON Mean % correct Group A: 72.3±24.6% Group B: 55.0±27.4% Group C: 51.7±28.9% Mean time in seconds for correctly identified letters Group A: 47.7 s Group B: 68.6 s Group C: 63.9 s	Stimulator ON vs. OFF for all groups of letters p<0.001
Ho et al. 2015 and other authors[14-22] Argus II	Letter size reduction test: Given to subjects who correctly identified at least 50% of letters in each group of letters in the letter identification task within 60 seconds took part in this test. Test used ETDRS letter set and layout with a True Type Century Gothic font but, unlike ETDRS letters, were presented 1 at a time in white on a black background (n=6)	Stimulator OFF No eye patching Mean total letters identified correctly 2 (SE:0.5)	Stimulator ON Scrambled, both eyes patched Mean total letters identified correctly 1.0 (SE:0.25) Scrambled, no eyes patched Mean total letters identified correctly 3.0 (SE: :2) No eyes patched Mean total letters identified correctly 46.0 (SE:30) Both eyes patched Mean total letters identified correctly 45.0 (SE:30)	Scrambled mode was no better than Stimulator OFF condition, suggesting letter identification is not primarily dependent on head scanning, light detection, and inference but uses spatial information in the percept. Significant differences were found for the OFF condition vs. ON no patching and for ON scrambled with no patching vs. ON no patching (p<0.05).

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Ho et al. 2015 and other authors[14-22] Argus II	Word recognition test presented to subjects who completed letter recognition and letter size reduction test successfully. 10 words per trial were presented (n=4)	Stimulator OFF Patients correctly identified between 0 and 2 two-letter words, between 0 and 1 three-letter words, and between 0 and 1 four-letter words	Stimulator ON Scrambled and unpatched Patients correctly identified between 0 and 1 two-letter words, 0 and 2 three-letter words, and 0 and 1 four-letter words Scrambled and patched Patients correctly identified between 0 and 1 two-letter words, 0 three letter words, and 0 and 1 four-letter words Standard mode and unpatched Patients correctly identified between 5 and 10 two-letter words, 5 to 8 three letter words, and 3 and 10 four-letter words Standard mode and patched Patients correctly identified between 7 and 10 two-letter words, 5 to 9 three letter words, and 4 and 9 four-letter words	Patients benefited from the stimulator in STANDARD mode over SCRAMBLED or OFF mode.

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Stingl et al. 2015, 2013[23,24] Alpha IMS	BaLM test: Light threshold perception, light source localization, and motion detection of dot patterns were tested on a 60 cm distant screen as 2- or 4-AFC tests in 8 or 12 trials each. 1st test speed was 3.3 degrees per second and was increased if participants passed (75% responses light source localization, AFC) or 62.5% responses (localization and motion, 4 AFC) correct were required to pass the test.	Stimulator OFF LP percentage of patients passing test Month 1 (n=27) 10% Month 3 (n=22) 3% Month 6 (n=17) 10% Month 9 (n=11) 0% Month 12 (n=10) 0% Light localization, percentage of patients passing test Month 1 (n=26) 0% Month 3 (n=19) 0% Month 6 (n=15) 0% Month 9 (n=11) 0% Month 12 (n=7) 0% Movement, percentage or patients passing test Month 1 (n=22) 0% Month 3 (n=17) 0% Month 6 (n=15) 9% Month 9 (n=9) 0% Month 12 (n=6) 0%	Best achieved results: 86% (25/29 patients) passed the light test, 59% (17/29 but test only administered to 28 patients) passed the location task, and 21% (6/29 but test only administered to 25 patients) passed the motion task. LP percentage of patients passing test Month 1 (n=27) 78% Month 3 (n=22) 82% Month 6 (n=17) 70% Month 9 (n=11) 38% Month 12 (n=10) 41% At every time point all comparisons were statistically significant Light localization, percentage of patients passing test Month 1 (n=26) 38% Month 3 (n=19) 31% Month 6 (n=15) 25% Month 9 (n=11) 17% Month 12 (n=7) 12% Only months 1 through 3 were statistically significant Movement, percentage of patients passing test Month 1 (n=22) 14% Month 3 (n=17) 12% Month 6 (n=15) 8% Month 9 (n=9) 0% Month 12 (n=6) 0% No comparison at any time point was statistically significant	At all visits implant ON was significantly better than implant OFF for LP. For light localization, implant ON was significantly better than implant OFF for visits months 1, 2, and 6. For motion. The highest speed for which motion was correctly recognized was 3 to 35 degrees for implant ON. When the implant was OFF, 1 patient passed the motion test in 3.3 degrees per second in a 4 AFC test once.

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Stingl et al. 2015, 2013[23,24] Alpha IMS	Grating acuity and VA with standardized Landolt C-rings in contrast reversal (white ring/black background) were tested on 60 cm distant screen as 2- or 4-AFC in 8–12 trials. Patients had to report the orientation of the grating and the direction of the C-ring gap. At least 75% (2 AFC) or 62.5% (4 AFC) were required to pass the tests.	Stimulator OFF Grating acuity, percentage of patients passing test Month 1 (n=22) 15% Month 3 (n=17) 8% Month 6 (n=15) 0% Month 9 (n=10) 0% Month 12 (n=6) 0% Landolt C-rings, percentage of patients passing test Month 1(13) 0% Month 3 (n=9) 0% Month 6 (n=4) 0% Month 9 (n=4) 0% Month 12 (n=1) 0%	Best achieved results: Grating acuity: 48% passed test (14/29 but only administered to 25 patients) Best achieved results: Landolt C-ring VA: 14% passed (4/29 but only administered to 15 patients) Grating acuity, percentage of patients passing test Month 1 (n=22) 50% Month 3 (n=17) 46% Month 6 (n=15) 20% Month 9 (n=10) 30% Month 12 (n=6) 18% Only comparisons at months 1–3 were statistically significant Landolt C-rings, percentage of patients passing test Month 1 (n=13) 17% Month 3 (n=9) 22% Month 6 (n=4) 0% Month 9 (n=4) 0% Month 12 (n=1) 0% No time points showed statistically significant comparisons	Significantly better for implant ON versus OFF for visits months 1–3. Grating acuity resolutions with the implant ON ranged from 0.1 to 3.3 cycles per degree. 5 patients passed the grating acuity test with the implant OFF but all 5 patients had higher percentage of correct responses with the implant ON. 4 patients completed standardized VA testing with contrast reversal Landolt C-rings with VA of v20/2000, 20/2000, 20/606, and v320/546 with the implant ON.

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Stingl et al. 2015, 2013[23,24] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Letters: Read white letters on a black background, so a 26 AFC test with a response rate above 52% considered a passing grade. Letter size subtended a visual angle of up to 10 degrees. Timeout of each letter reading was 2 minutes.	Stimulator OFF Percent of patients passing test Month1 (n=16) 0% Month 3 (n=10) 0% Month 6 (n=8) 0% Month 9 (n=7) 14% Month 12 NR	Best achieved results: 14% passed (5/29 but only administered to 19 patients) Percent of patients passing test Month1 (n=16) 25% Month 3 (n=10) 11% Month 6 (n=8) 13% Month 9 (n=7) 15% Month 12 NR No comparisons were statistically significant	No statistically significant advantage to having the stimulator ON versus OFF. 4 patients passed the test at least once and could read letters. 1 patient passed the test with both the stimulator ON and OFF at visit month 9 but was unable to read any letters at study enrollment.
Ayton et al. 2014[25] Bionic Vision	Phosphene percepts (light): stimulation of the electrode array commenced for weekly psychophysics sessions of between 2 and 5 hours. The first stimulation session was held 55 days, 87 days and 37 days postoperatively, respectively, for the 3 patients. Stimulation was delivered using a custom-built neurostimulator that allowed direct stimulation of the individual electrodes via connection with the percutaneous connector and is designed to allow flexible configuration of testing parameters. The stimulator delivered charge-balanced biphasic current pulses with pulse widths ranging from 100 to 1,000 ms per phase. The electrodes were capacitively coupled and shorted between current pulses to remove any potentially damaging residual charge. Unless otherwise stated, the electrodes were stimulated in a monopolar electrode configuration using one of the 2 mm diameter platinum electrodes as the return.	NR	Reliable phosphene percepts: 3/3 patients Patients varied in the number of pulses per second required to experience percepts	NA

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Ayton et al. 2014[25] Bionic Vision	Visual acuity was assessed with the Landolt C optotype recognition subtest from FrACT, presented in a darkened room (108–114 lux) using a 30-inch computer monitor placed at 57 cm viewing distance. Testing incorporated a head-mounted video camera with a manufacturer stated field-of-view of 67°650.25° (Arrington Research, Inc., Scottsdale, AZ) and a pixel dimension of 320 by 240 pixels. Within the implant, the 20 stimulating electrodes are arranged in a staggered grid measuring 3.5 mm 63.46 mm, corresponding to a visual field projection on the retina of 12.4°612.2°. Floor effect (unable to estimate VA lower than 3.24 logMAR).	Device OFF no optotypes were seen (n=1)	Device ON: 2.62 mean logMAR, Rng 2.35–3.02 across 19 sessions (n=1)	Wilcoxon Rank-Sum Test z= -2.280, p=0.010 in favor of the device ON condition, n=1 patient (who was enrolled in the trial the longest)
Ayton et al. 2014[25] Bionic Vision	Light localization subtask of the BaLM test presented to subjects in a darkened room (108–114 lux) using a 30-inch computer monitor placed at 57 cm viewing distance. The BaLM test was completed with all subjects. Testing incorporated a head-mounted video camera with a manufacturer-stated field of view of 67°650.25° and a pixel dimension of 320 by 240 pixels. Within the implant, the 20 stimulating electrodes are arranged in a staggered grid measuring 3.5 by 63.46 mm, corresponding to a visual field projection on the retina of 12.4°612.2°. The BaLM test involves detection of a light wedge in 1 of 4 quadrants, and assesses the ability of the device to improve light localization skills. Given that the response options were 4 alternative forced choices (4 AFC), the chance rate was 25% and the criterion cutoff for success set at 62.5%. The device ON setting used a vision processing algorithm called Lanczos2 filter to ensure artefacts from such down-sampling do not appear, such as a flickering which may result from making small head movements with the camera viewing fine detail. This makes objects appear more consistent in their appearance.	Device OFF percentage correct was 27.8%, 25%, and 25%, respectively	Device ON: percentage correct was 97.5%, 71.4%, and 66.7%, respectively	Difference was p<0.0001 in all 3 patients
Rizzo et al. 2014[26]	Square localization was tested with both eyes open and device ON (mean distance from target center)	Pre-implantation: Mean 7.34 cm	Post-implantation 3 months: mean 4.42 cm 6 months: 4.68 cm 12 months: 4.6 cm	4/5 patients improved

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Rizzo et al. 2014[26]	Direction of motion was tested with both eyes open and device ON (number of correct responses)	Pre-implantation: Mean 21.8	Post-implantation 3 months: mean 18.2 6 months: 19 12 months: 29.4	3/5 patients improved
Rizzo et al. 2014[26]	Grating acuity was tested only in implanted eye with the device ON	Pre-implantation: 0 patients could identify gratings	Post-implantation: 1 patient was able to identify gratings, grating VA 2.2 logMAR in the operative eye with stimulator ON	1 patient improved
Fujikado et al. 2011[27] STS	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were blinded to stimulation because the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Object detection with head scanning: A white box was set randomly to the left or right of the center of the board and patients were asked to locate it.	Stimulator off performance was less than chance level 2/2 patients	Better than chance (50%): 2/2 patients	2/2 patients scored better than chance
Fujikado et al. 2011[27]	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were blinded to stimulation because the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Experiment 2: Object discrimination with head scanning 2 white bars of different widths were presented at the center of the board and patients were asked to tell the examiner whether the thicker bar was on the left or right.	Stimulator OFF performance was less than chance level 2/2 patients	Better than chance (50%): 2/2 patients	2/2 patients scored better than chance

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Fujikado et al. 2011[27]	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were blinded to stimulation as the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Experiment 3: Detection of direction of motion Patients were asked to keep their heads stationary. The rectangular white box was placed in front of the patients and was moved horizontally or vertically. The patients were asked to tell whether the bar moved horizontally or vertically.	Stimulator off performance was less than chance level 2/2 patients	Better than chance: 1 patient	1 patient scored 90% which was better than chance while the second patient scored 60% which was not better than chance
Fujikado et al. 2011[27]	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were blinded to stimulation as the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Ability to perceive 2 distinct phosphenes when stimuli were delivered through 2 channels	BLP	1/2 patients	NA
Fujikado et al. 2011[27]	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were blinded to stimulation as the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Ability to perceive phosphenes	BLP	2/2 patients	NA

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Klauke et al. 2011 and other authors[28-32] EPIRET3	Visual percepts as a result of electrical stimulation of different pulse amplitudes and durations on days 7, 14, and 27 after implantation. Catch trials with stimulation commands sent but no current applied were used to identify false positives. Subjects were blinded to which stimuli were used/which stimuli parameters were varied and electrode stimulation order was randomly presented.	LP: 4 patients No LP: 1 patient HM: 1 patient	NR	Visual percepts seen: 6 patients Visual percepts in all stimulation sessions: 4 patients Positive response to first stimulation pulses: 4/6 patients False positives: 6% Ability to differentiate between different spatiotemporal patterns: 5 patients Although not consistently reported, the authors presented examples of patients recognizing patterns and differentiating between stimulation sites
Zrenner et al. 2011[33] Alpha IMS	Light detection and localization using BaLM, 2 to 4 AFC, including light detection, basic temporal resolution (2 flashes of light), object localization, and movement detection.	Stimulator OFF Flash test: 50%, 37%, and 62.5% (3/3 failed) Localization test: 1/3 failed with 38% correct and 2/3 not tested. Movement test (4 AFC): 2/3 failed, with 17% and 50% correct and 1 not tested. Grid direction detection: Large grids 3/3 failed; 1 patient was tested at the next difficulty level and failed with 12.5% correct responses	Stimulator ON Flash test (2 AFC) percentage correct: 81.3%, 100%, 100% Localization test: 1/2 patients passed with 87.5% correct, 1 failed with 25% correct responses, and 1 patient was not tested. Movement test: passed by 1 patient (63% correct), 1 patient failed with 25%, 1 patient not tested Grid direction detection (4 AFC) For large grids 2/3 passed with 11/14 and 100% correct responses and 1/3 almost passed with 60% correct responses. 1 patient was tested at the next level of difficulty and passed with 62.5% correct responses	Flash test ON vs. OFF, n=16, p=0.00005

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Zrenner et al. 2011[33] Alpha IMS	Optional test: Single letter recognition	Stimulator OFF The patient who passed with the stimulator ON was tested with stimulator OFF and failed with 29% correct	Stimulator ON 1 patient passed with 100% correct responses, 2 patients not tested	1 patient benefited with device in ON mode
Zrenner et al. 2011[33] Alpha IMS	Standardized FrACT test with Landolt C optotypes and an up and down staircase procedure. If Landolt C was passed, single letters were used subsequently.	Stimulator OFF Only presented to patient who passed with the stimulator ON: patient failed	1/3 could see the Landolt C rings and discern letters with VA logMAR 1.69, 2 patients failed (but one of these patients reported seeing the Landolt ring gap clearly)	1/3 passed test
Zrenner et al. 2011[33] Alpha IMS	Visual percept	Stimulator OFF	DS Array Perception of a single electrical pulse at a single electrode: 3/3 patients showed stronger pupil constrictions in the stimulator ON position and reported simultaneous light perception. Single pulse, row of 4 electrodes: 3/3 recognized the correct orientation and 2/3 saw dark spots between the dots Single-pulse oblique line: 2/3 passed Pattern U in 4 directions (4 AFC): 2/3 passed Multiple letters: 1/3 passed, 1/3 partly seen, and 1/3 failed Sequential stimulation clockwise vs. counterclockwise	NA
Zrenner et al. 2011[33] Alpha IMS	Recognition of single letters cut out of paper and presented on a table 5–8 cm (16 AFC)	Stimulator OFF The patient who passed was tested with the stimulator OFF and failed with 0% correct responses (5 AFC)	Stimulator ON 1 patient tested and passed with 61% correct responses, 2 patients not tested	1 patient benefited

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Chow et al. 2010 and Geruschat et al.[3,34] Extension study ASR	CGAT: The CGAT test was developed because ETDRS testing even at ½-m distance is limited in the low vision range by the largest letter size of 20/1600 (logMAR 1.9). CGAT extends this range and tested from 20/125 (logMAR 0.8) to 20/6400 (logMAR 2.5). All vision testing was conducted with full cycloplegia applied at least 40 minutes before testing and full refractive correction for the test distance. The test is a 4 AFC test. Subjects had to identify the orientation of the grating (vertical, horizontal, diagonal left, diagonal right).	NA	This testing starting at 2.5 years postoperatively and by the final followup 6/6 patients had mean CGAT scores that were higher in the implanted than in the nonimplanted eye. Patient 5 Implanted 20/165 Nonimplanted 20/225 Patient 6 Implanted 20/585 Nonimplanted 20/4050 Patient 7 Implanted 20/200 Nonimplanted 20/300 Patient 8 Implanted 20/2420 Nonimplanted 20/2600 Patient 9 Implanted 20/328 Nonimplanted 20/3140 Patient 10 Implanted 20/796 Nonimplanted 20/2503	6/6 improved in implanted over nonimplanted eye.

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Chow et al. 2010 and Geruschat et al.[3,34] Extension study ASR	ETDRS acuity testing was performed at ½ m with 6 different charts, using 3 charts per eye and averaged. Cycloplegic agents with appropriate correction for refractive error at ½ m were used and subjects read letters in a forced choice manner.	Implanted eyes performed similarly to control eyes in the pre-operative period (6 patients). Patient 5 Implanted eye: 21.0 (16–25) letters Nonimplanted 25.7 (24–28) letters Patient 6 Implanted 0 (0–0) letters Nonimplanted 1.8 (0–3) letters Patient 7 Implanted 0 (0–0) letters Nonimplanted 0 (0–0) letters Patient 8 Implanted 0 (0–0) letters Nonimplanted 23 (17–27) letters Patient 9 Implanted 0 (0–0) letters Nonimplanted 0 (0–0) letters Patient 10 Implanted 0 (0–0) letters Nonimplanted 0.2 (0–1) letters	After implantation, through 8 years of followup, 4/6 patient's implanted eyes outperformed unimplanted eyes and 2/6 did not. 8 year or final followup Patient 5 Implanted 22.7 (17–29) Nonimplanted 9.3 (6–12) Patient 6 Implanted 5.0 (3–9) letters Nonimplanted 1.7 (1–2) letters Patient 7 Implanted 1 (0–2) letters Nonimplanted 0.3 (0–1) letters Patient 8 Implanted 0.7 (0–1) letters Nonimplanted 1.3 (0–3) letters Patient 9 Implanted 0–1.5 letters Nonimplanted 0–1.5 letters Patient 10 Implanted 0.7 (0–1) letters Nonimplanted 0 (0–0) letters	4/6 patients improved from pre- to post-operative period.

Table C-13. Visual acuity outcomes (continued)

Study	Outcomes	Comparator	Post-implantation VA	Change
Chow et al. 2004[35] ASR	Letter recognition	ETDRS: VA measured using standard back-illuminated ETDRS charts at 0.5 m with cycloplegia and BCVA with a retinoscopic refraction at 0.5 m. If neither of the top 2 lines of letters could be identified, visual acuity of HM, CF, and LP was recorded in 9 visual field sectors. Patients 1–4: 0 letters Patient 5: 16–25 letters OD, 24–28 letters OS Patient 6: 0 letters OD, 0 to 3 letters OS	ETDRS Patients 1 through 4: 0 letters (3 patients), able to see some of the largest letters OD only (20/1280 to 20/1600) at 12–18 month followup (1 patient) Patient 5 at 6-month followup: 35–41 letters OD, 21–28 letters OS Patient 6 at 6-month followup: 25–29 letters OD, 0 letters OS	3/6 patients experienced some improvement

AFC=alternative forced choice; ASR=Artificial Silicon Retina; BaLM=Basic Assessment of Light and Movement; BCVA=best corrected visual acuity; BLP=bare light perception; cd=candela; CF=count fingers; CGAT= Chow grating acuity test; DS=direct stimulation; ETDRS=Early Treatment Diabetic Retinopathy Study; FrACT=Freiburg visual acuity test; HM=hand motion; L projection=light projection; LP=light perception; logMAR=logarithm of the minimal angle of resolution; NA=not applicable; NR=not reported; OD=*oculus dexter*, right eye; OS=*oculus sinister*, left eye; Rng=range; SE=standard error; STS=Suprachoroidal Transretinal Stimulation; VA=visual acuity

Table C-14. Visual field

Study	Outcomes	Comparator	Post Implantation Visual Field	Change
Rizzo et al. 2014[26] Argus II	Goldmann visual field was tested in the operated eye with the device switched OFF	Pre-implantation	Post-implantation	Improved in all patients
Chow et al. 2004[35] ASR	Visual field measurements: Humphrey visual field analyzer II was conducted using III and V white static spot sizes in 30-2 (30-degree radius) and 60-4 (30- to 60-degree radius) protocols as well as a custom protocol with a 30-degree radius and a 4-degree spot separation.	Central Humphrey visual field: Patients 1 through 4: No consistent response to size V white static target Patients 5 and 6: Consistently positively responded to size V white static target	Patient 1 through 4 and patient 6: No improvement Patient 5: Demonstrated improved central and paracentral visual fields (30–2) in the right eye on multiple tests	1/6 improved but authors indicate this test was not applicable for 5 patients
Chow et al. 2004[35] ASR	Because Humphrey visual field is limited by the brightness of the instrument target, visual field light threshold testing was conducted in 9 visual field sectors (9 sector test) in a 3x3 grid with less than 0.1 foot-candle of background room illumination.	Patient1: Unoperated eye Patient 2: Subjective visual field was bare to no LP in study eye Patient 3: Unoperated eye	Patient1: Threshold sensitivity improved by 1,000% to 1,500% in all sectors Patient 2: Consistent LP in multiple sectors of the operated eye Patient 3: Threshold sensitivity in right-middle, right-lower, and middle-lower sectors improved by approximately 5,000% to 10,000%	3/6 improved, authors indicate this test was not applicable to the other 3 patients.
Chow et al. 2004[35] ASR	Subjective visual field	NR	Patients 2 through 5 indicated perception of light sensation to infrared light in the projected visual field of the implant during testing	4/6

ASR=Artificial Silicon Retina; LP=light perception; NR=not reported

Table C-15. Color vision

Study	Outcomes	Comparator	Post Implantation Color Vision	Change
Chow et al. 2004[35] ASR	Pseudoisochromatic color plate test	Patients 1 through 6: no patient was able to perceive or discriminate color	Patient 1 through 4 and patient 6: No change Patient 5: Could correctly identify blue and orange dots of the control isochromatic plate and the red and green dots on the test plate using the operated eye. The unoperated eye did not see any color.	1/6 improved

ASR=Artificial Silicon Retina

Table C-16. Laboratory function

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[14-22] Argus II	Reading Braille with the Argus II creating percepts in the form of Braille letters to be read visually rather than tactually. Single-letter tests were 8 or 9 AFC and short words were simulated 1 letter at a time in an open-choice test. Subject did not receive training before testing.	Chance level and assumption of a 100% correct identification rate for tactile Braille	Postimplantation: 1 patient who was an experienced Braille reader pre-implantation was tested and had 89% (SD:NR) correct responses for individual letters at 500 ms and 60 to 80% (SD:NR) correct responses for short words.	Single-letter recognition was significantly above chance level ($p<0.001$)
Ho et al. 2015 and other authors[14-22] Argus II	Meander Maze Tracing, or the labyrinth experiment, in which patient uses a touchscreen and tries to complete the maze without going off the path. The first test (2-AFC; n=21) involved a path with a right angle; those who passed that test or performed well with native vision (n=16) performed the mixed angle, single-turn test, and again those who did well went on to the final test, a 2-turn test. This test aimed to determine if prosthesis use could guide fine hand movements.	Stimulator OFF	Stimulator ON	Across all tests, Stimulator ON condition significantly reduced the error in tracing by 60% ($p<0.001$) and increased trace time by 211% ($p<0.001$).
Ho et al. 2015 and other authors[14-21] Argus II	Find the door	Stimulator OFF	Stimulator ON Month 6 (n=30) Mean percentage success: System ON 54%, (SD:NR) System OFF 27% (SD:NR) Year 1 (n=28 patients): Mean percentage success ON: 53.0% (SD 5.5%) Mean percentage success OFF 30.8% (SD 4.8%) Year 3 (n=28): Mean percentage success ON: 54.2% (SD 6.2%) Mean percentage success OFF 19.0% (SD 4.3%)	Performance remained better with the system ON than OFF on all visual tests, with these results sustained out beyond 5 years of chronic use. Month 6: $p=0.0001$

Table C-16. Laboratory function (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[14-21] Argus II	Follow the line	Stimulator OFF	Stimulator ON Month 6 (n=29) mean percentage success: System ON 68% System OFF 23% Year 1 (n=28 patients) mean percentage success: System ON: 72.8% (SD 5.7%) System OFF 17.1% (SD 4.2%) Year 3 (n=28) mean percentage success System ON: 67.9% (SD 6.5%) System OFF 14.3% (SD 3.8%)	Performance has remained better with the system ON than OFF on all visual tests, with these results sustained out beyond 5 years of chronic use. Month 6: p<0.0001
Ho et al. 2015 and other authors[14-21] Argus II	Object prehension (locate, reach, and grasp) and localization in 3-dimension space completed by 5 subjects at 1 site. Patient movements were tracked with a computer system. Lights were attached to patient's finger to help them visualize their finger.	Stimulator OFF Successful prehension Finger switch ON: 0, Finger switch OFF 0	Stimulator ON Successful prehension Finger switch ON: 71.3±27.1% Finger switch OFF 77.5±24.5%	Difference between finger marker ON and OFF not significant; but for stimulator ON vs. OFF (74.4±23.4% and 0) the difference was statistically significant, p=0.04
Stingl et al. 2015, 2013[23,24] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Clock task: white clock hands were placed at angles of 0 degrees, 90 degrees, or 180 degrees to each other indicating a clock time, presenting a 16 AFC test. Response rates greater than 53% were consider passing. Patents were asked to tell the time with a 2-minute timeout. This task was repeated 12 times.	Stimulator OFF Percent of patients passing the test Month1 (n=19) 0% Month 3 (n=13) 0% Month 6 NR Month 9 (n=8)13% Month 12 NR	Best achieved results: 17% passed test (4/29 but only administered to 22 patients) Percent of patients passing the test Month1 (n=19) 17% Month 3 (n=13) 25% Month 6 NR Month 9 (n=8) 11% Month 12 NR No comparisons were statistically significant	No statistically significant advantage of having the stimulator ON vs. OFF. 5 patients passed the test at least once. Only 1 participant passed this test with the stimulator OFF.

Table C-16. Laboratory function (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Stingl et al. 2015, 2013[23,24] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Gray levels: intermediate gray level presented on half the screen and 1 of 6 different levels of gray on the other half. Each of the 6 combinations was presented 3 times in random order. Patients had to say which side of the screen was brighter. A combination distinguished correctly 2 times counted as a recognized response. A full screen of the intermediate gray served as the control. Total correct responses were tallied. There was no timeout for this test.	Stimulator OFF Percentage of patients passing test Month 1 (n=15) 37.5% Month 3 (n=10) 35% Month 6 (n=8) 27% Month 9 (n=7) 0% Month 12 (n=6) 15%	Best achieved results: 52% passed test (15/29 but only administered to 19 patients) Percentage of patients passing test Month 1 (n=15) 67.5% Month 3 (n=10) 70% Month 6 (n=8) 25% Month 9 (n=7) 30% Month 12 (n=6) 68% Months 1 and 12 were only statistically significant comparisons.	Significantly better with the stimulator ON vs. OFF for gray level recognition at months 1, 2, and 12. 15 participants recognized at least 1 gray level and up to 6 gray levels with the stimulator ON while 8 patients recognized up to 3 gray levels with the stimulator OFF.

Table C-16. Laboratory function (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Stingl et al. 2015, 2013[23,24] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Table setup: Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. 4 dining objects were placed around a large white plate in front of the patient, who was not informed about the number of objects. Patient had to report the number, localize them, and identify them with a timeout of 4 minutes. Correct responses were tallied.	Stimulator OFF Month 1 (n=24) How many shapes 0.4 Where shapes 0.1 What shapes 0.025 Table how many 0.55 Table where 0.25 Table what 0.05 Month 3 (n=19) How many shapes 0.8 Where shapes 0.5 What shapes 0.2 Table how many 0.4 Table where 0.35 Table what 0 Month 6 ((n=15) How many shapes 1.2 Where shapes 1.1 What shapes 0.2 Table how many 0.75 Table where 0.4 Table what 0.1 Month 12: (n=8) How many shapes 0.7 Where shapes 0.2 What shapes 0 Table how many 1.2 Table where 1.0 Table what 0	Stimulator ON Month 1 (n=24) How many shapes 2.7 Where shapes 2.5 What shapes 1.1 Table how many 2.45 Table where 2.4 Table what 0.8 All comparisons statistically significant Month 3 (n=19) How many shapes 2.5 Where shapes 2.1 What shapes 0.7 Table how many 2.25 Table where 2.2 Table what 0.65 All comparisons statistically significant Month 6 (n=15) How many shapes 1.75 Where shapes 1.55 What shapes 0.3 Table how many 1.95 Table where 1.9 Table what 0.5 Table (how many and where) were the only statistically significant comparisons Month 12 (n=8) How many shapes 1.75 Where shapes 1.4 What shapes 0.4 Table how many 1.5 Table where 1.0 Table what 0 Shapes (where) were the only statistically significant comparison.	Significantly better with the implant ON vs. OFF in the first 3 months. From month 6 through 12, the statistical significance decreased (p>0.05) for most ON-OFF comparisons.

Table C-16. Laboratory function (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Stingl et al. 2015, 2013[23,24] Alpha IMS	Recognition and activities of daily living were performed on a black table using white objects with luminance around 200 to 600 cd/m^2 and the black table cloth below 30 cd/m^2. Geometric shapes: 4 objects of about 5-degree visual angle each were placed in front of the patient, who was not informed about the number of objects. Patient had to report on the number of objects, point to the objects, describe, by shape description and localization, what they were with a timeout of 4 minutes. Correct responses were tallied.	Stimulator OFF	Stimulator ON	Significantly better with the implant power ON vs. OFF during the first 3 months. For month 6 through 12, the statistical significance decreased ($p>0.05$) for most ON-OFF comparisons.
Rizzo et al. 2014[26] Argus II	Patient mobility, which consisted of asking the subject to locate a bright light on the corridor ceiling and to walk along a dark line (30 cm wide) on the pavement.	No comparator	All patients could locate light and walk on stripe on floor at 1 week followup	All patients could locate light and walk on stripe on floor at 1 week followup
Fujikado et al. 2011[27] STS	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were masked to stimulation because the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Experiment 4: Grasping objects A white object was set randomly either to the left or the right of the center of the board. The patient was asked to grasp the object with her right hand.	Stimulator OFF performance was less than chance level 1/1 patients	Better than chance: 1/1 patient	Only 1 patient performed this test and outperformed chance with a score of 90%.

Table C-16. Laboratory function (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Fujikado et al. 2011[27] STS	The system was tested 2 times per week from 1 week after implantation for 4 weeks. Threshold currents were increased until patients could recognize and localize phosphenes 50% of the time. Patients indicated the location of a perceived phosphene by pointing to spots on a plastic board. Patients were blinded to stimulation as the sequence of presentation was randomized. Efforts were made to identify false positives (stimulator off but buzzer on). Experiment 5: Touch panel A white rectangular bar was presented randomly either on the left or right of the center of a touch-panel screen that was connected to the computer. The patient was asked to touch the white bar with her right index finger. The position touched was recorded and analyzed by the computer. Depending on whether the patient touched the correct position, a different sound was emitted by the computer.	Stimulator OFF: less than chance 1/1 patient	Stimulator ON: The touch panel task was also applied to only 1 patient. The subjective phosphene was perceived shifted slightly to the right of the bar when presented on the right side and shifted to the left of the bar when presented on the left side. The success rate increased with repeated testing.	1/1 patient better with stimulator ON vs. stimulator OFF
Zrenner et al. 2011[33] Alpha IMS	Recognition of geometric of objects on a table (4 AFC)	Stimulator OFF The patient who passed with the stimulator in ON mode was tested with the stimulator OFF and failed with 0% correct responses	Stimulator ON 1 patient passed with 100% correct responses, 2 patients failed	1 patient benefited from the device in ON mode
Zrenner et al. 2011[33] Alpha IMS	Localization of dishes/flatware (3, 4, 2 AFC, respectively per patient)	Stimulator OFF The patient who passed was tested with the stimulator ON failed with 0% correct responses with stimulator OFF	Stimulator ON 3/3 patients passed	All patients benefited with the stimulator in ON mode
Zrenner et al. 2011[33] Alpha IMS	Recognition of hands on a clock (12 AFC)	Stimulator OFF The patient who passed with the stimulator in ON mode was tested with stimulator OFF and failed with 8% correct responses	Stimulator ON 1 patient passed with 92% correct responses, 2 patients not tested	1 patient benefited from the device in ON mode
Zrenner et al.	Recognition of 9 shades of gray (2	Stimulator OFF	Stimulator ON 1 patient passed with	1 patient benefited from the device in

Table C-16. Laboratory function (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
2011[33] Alpha IMS	AFC)	The patient who passed with the stimulator ON was tested with the stimulator OFF mode and failed with 40% correct responses	78% correct responses, 2 patients not tested	ON mode
Chow et al. 2010, Geruschat et al[3,34] Extension study ASR	Controlled mobility course was comprised of an indoor straight hallway 18.29 m long and 1.4 m wide illuminated with 150 foot-candle, painted off white with light gray carpet and seeded with obstacles either suspended or placed on the floor. Subjects also had to navigate through the hospital cafeteria. Subjects were not permitted to use guide dogs or long canes for this assessment. Tasks were performed with the implanted eye, the nonimplanted eye, and binocularly.	Preimplantation, 6 patients completed monocular testing due to personal safety concerns and 8 completed binocular testing. Subjects were divided into worse and better vision groups. At baseline, a statistically significant (p=0.005) larger number of obstacles was found in the binocular and treated eye conditions but not in the control eye condition between subjects with worse and better visual acuity and visual fields. There were no statistically significant differences in time to complete the course in the binocular, treated, or control eye when comparing those with worse and better vision at baseline. 3/5 subjects in the worse vision group could not complete the cafeteria task at baseline or the 3- or 6-month followup. The other 2 subjects in this group could complete the task at baseline but needed to go slowly. The 2 subjects had more difficulty at the 3- and 6-month followup, corresponding to a vision reduction in the better eye (20/100 to 20/550 and 20/720 to 20/1600, respectively). Patients in the better vision group did not show a change in ability to complete the cafeteria task over time.	Monocular testing (6 patients completed this task due to safety concerns) or binocular (8 subjects completed this task) after implantation	On the controlled mobility course, no significant group differences were observed pre- vs. post-implantation for obstacle contact or time to walk the course for both eyes, or treated or control eye only conditions, suggesting the ASR device does not aid independent orientation and mobility.

AFC=alternative forced choice; cd/m^2=candela per square meter; NR=not reported; p=p-value; SD=standard deviation; STS=Suprachoroidal Transretinal Stimulation

Table C-17. Day-to-day function

Study	Outcomes	Comparator	Post Implantation Function	Change
Ho et al. 2015 and other authors[14-21] Argus II	FLORA	Pre-implant period	Year 1 % (n=15) reporting positive or mild positive experience 80%, percentage prior positive and neutral 20% Negative 0% Year 3 (n=23) percentage reporting positive or mild positive experience 65.2%, percentage prior positive and neutral 34.8% Negative 0%	A majority of patients reported a positive experience with the device.
Stingl et al. 2015, 2013[23,24] Alpha IMS	Patient reports on their visual experiences in their home and daily life. Patients used the implant usually 2–3 hours per day.	NA	13 patients described device as useful (see shapes and details), 8 as a little useful (localize objects but could not recognize shapes or details), 8 as not useful. Examples of useful vision include seeing the shape of a person's head, house outlines, pavement lines, car lights moving at night, sunflower stalk, silhouette in the mirror, picture frame on the wall.	Several patients reported a slight improvement in their remaining LP with the implant OFF but, according to study authors, "none of them could see objects without the implant power being switched ON."
Chow et al. 2010 and Geruschat et al. 2012[3,34] Extension study ASR	Subjective (patient) impression of visual acuity	Subjective impression preimplantation not measured, but at baseline 5 could distinguish HM and 1 patient CF.	Following implantation, through 8 years of followup, 6/6 patients reported an improvement in subjective perceptions including seeing divider line on a highway and seeing objects around the house (1), sees objects around the house, sees darkness at night instead of light gray, uses operated eye to navigate as it is now the better eye (1) sees clock on oven, can watch son play basketball, sees shapes in photos, saw color of stoplights (1), can see image of people on television, can now navigate visually through house, can locate children and pets in house, sees color of objects, at night sees darkness instead of light gray (1)	6/6 patients improved from pre- to post-operative period.

Table C-17. Day-to-day function (continued)

Study	Outcomes	Comparator	Post Implantation Function	Change
Chow et al. 2004[35] ASR	Subjective vision measured as follows: patients described their visual perceptions for 7 aspects of visual function (brightness, contrast, color, shape, resolution, movement, and visual field size). Comparison was to nonimplanted eye and that eye was given a rating of 10 (e.g., if implanted eye brightness was twice that of the left eye the patient was instructed to give it a rating of 10).	Patient 1 right/left eyes: brightness 5:10, visual field 2:10 Patient 2 right/left: no LP/LP Patient 3 right/left: HM to LP OU, brightness 7:10, shape 10:10, resolution 10:10, movement 10:10, and visual field size 10:10 Patient 4 right/left: brightness 10:10, contrast 10:10, shape 10:10, and visual field size 10:10, overall rating of visual function 10. Patient 5 right/left: 10/10 for all 7 aspects of visual function Patient6 right/left: 10:10 for all 7 aspects of visual function.	Results at 6 months for 3 patients and 18 months for the remaining 3 patients Patient 1: brightness 7:10, visual fields 15:10, visual field subjectively 750% larger than at baseline, no need to turn head to see light coming from right side. Patient 2: brightness 8:10, contrast 10:10, shape 10:10, visual field size 8:10, able to see shadows of people with right eye. Patient 3: 30:10, 35:10, 50/10, 50:10, 50:10, 50:10 (which domains these refer to not reported), patient also reported they can now use a nightlight for navigation at night and can see movement on television screen. Patient 4: brightness 15:10, contrast 17:15, shape 17:10, visual field size 13:10, movement 2:10, and reports overall visual function 25, patient can now navigate yard without a cane and can tell which lights are on at night. Patient 5: brightness 17:10, contrast 30/12, color 17:10, shape 15:10, resolution 35:10, movement 13:10, and visual field size 11:10, patient reports he can now more easily discern denominations of money, use utensils, and recognize faces. Patient 6: brightness 20:10, contrast 25:10, color 20/10, shape 20/10, resolution 20/10, movement 20/10, and visual field size 18:10, and these values are for patient on his best days. Patient reported he can now recognize denominations of money, sometimes differentiate the color of traffic lights, locate cars on street, and find cup at meals.	6/6 improved

ASR=Artificial Silicon Retina; CF=count fingers; FLORA=Functional Low-Vision Observer Rated Assessment; HM=hand motion; LP=light perception; NA=not applicable; OU=both eyes

Table C-18. Quality of life

Study	Outcome	Baseline QOL	Followup	Change
Klauke et al. 2011 and other authors[28-32] EPIRET3	Quality of life: National Eye Institute Visual Function Questionnaire (NEI-VFQ-25) composite scores (German version, which has not been validated in retinitis pigmentosa population)	Pre-implantation: 22±7	3 weeks post-implantation: 22±7 6 months post-implantation: 20±5 27–29 months post-implantation: 22±5	Repeated measures ANOVA (analysis of variance) p=0.63, suggesting no statistically significant change in quality of life occurred during the study period of 2 years, despite implantation and explanation of the device.

Table C-19. Risk-of-bias assessment for visual acuity

Study and Risk-of-Bias Item	Arevalo et al. 2015, 2015[12,13] Argus II	Ho et al. 2015 and other authors[14-21] Argus II	Stingl et al. 2015, 2013[23,24] Alpha IMS	Ayton et al. 2014[25]	Rizzo et al. 2014[26] Argus II	Fujikado et al. 2011[27] STS	Klauke et al. 2011 and other authors[28-32] EPIRET3	Zrenner et al. 2011[33] Alpha IMS	Chow et al. 2010 and Geruschat 2012[3,34] ASR	Chow et al. 2004[35] ASR
Does the design or analysis control or account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?	NR	No	No	NR	No	NR	No	No	No	No
Did the study maintain fidelity to the intervention protocol?	NR	No	No	No	Yes	Yes	Yes	No	Yes	Yes

Table C-19. Risk-of-bias assessment for visual acuity (continued)

Study and Risk-of-Bias Item	Arevalo et al. 2015, 2015[12,13] Argus II	Ho et al. 2015 and other authors[14-21] Argus II	Stingl et al. 2015, 2013[23,24] Alpha IMS	Ayton et al. 2014[25]	Rizzo et al. 2014[26] Argus II	Fujikado et al. 2011[27] STS	Klauke et al. 2011 and other authors[28-32] EPIRET3	Zrenner et al. 2011[33] Alpha IMS	Chow et al. 2010 and Geruschat 2012[3,34] ASR	Chow et al. 2004[35] ASR
If attrition (overall or differential nonresponse, dropout, loss to followup, or exclusion of participants) was a concern, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Were the outcome assessors blinded to the intervention or exposure status of participants?	NR	No	No	NR	NR	NR	NR	Yes	NR	NR
Were the outcomes assessed/defined using valid and reliable measures and implemented consistently across all study participants?	Yes	Yes	Yes	NR	Yes	NR	NR	NR	Yes	Yes
Were the potential outcomes prespecified by the researchers? Are all prespecified outcomes reported?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Rating	High	High	High	High	Moderate	Moderate	Moderate	Moderate	Moderate	High

ASR=Artificial Silicon Retina; NR=not reported; STS=suprachoroidal transretinal stimulation

Table C-20. Risk-of-bias assessment for visual field

Study and Risk-of-Bias Item	Rizzo et al. 2014[26] Argus II	Chow et al. 2004[35] ASR
Does the design or analysis control or account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?	Yes	Yes
Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?	No	No
Did the study maintain fidelity to the intervention protocol?	Yes	Yes
If attrition (overall or differential nonresponse, dropout, loss to followup, or exclusion of participants) was a concern, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?	Yes	No
Were the outcome assessors blinded to the intervention or exposure status of participants?	NR	NR
Were the outcomes assessed/defined using valid and reliable measures and implemented consistently across all study participants?	NR	NR
Were the potential outcomes prespecified by the researchers? Are all prespecified outcomes reported?	Yes	Yes
Rating	Moderate	High

ASR=Artificial Silicon Retina; NR=not reported

Table C-21. Risk-of-bias assessment for color vision

Study and Risk-of-Bias Item	Chow et al. 2004[35] ASR
Does the design or analysis control or account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?	Yes
Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?	No
Did the study maintain fidelity to the intervention protocol?	Yes
If attrition (overall or differential nonresponse, dropout, loss to followup, or exclusion of participants) was a concern, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?	No
Were the outcome assessors blinded to the intervention or exposure status of participants?	NR
Were the outcomes assessed/defined using valid and reliable measures and implemented consistently across all study participants?	NR
Were the potential outcomes prespecified by the researchers? Are all prespecified outcomes reported?	Yes
Rating	High

ASR=Artificial Silicon Retina; NR=not reported

Table C-22. Risk-of-bias assessment for laboratory function

Study and Risk-of-Bias Item	Ho et al. 2015 and other authors[14-21] Argus II	Stingl et al. 2015, 2013[23,24] Alpha IMS	Rizzo et al. 2014[26] Argus II	Fujikado et al. 2011[27] STS	Zrenner et al. 2011[33] Alpha IMS	Chow et al. 2010 and Geruschat et al. 2012[3,34] ASR
Does the design or analysis control or account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?	Yes	Yes	Yes	Yes	Yes	Yes
Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?	No	No	No	NR	No	No
Did the study maintain fidelity to the intervention protocol?	No	No	Yes	Yes	No	Yes
If attrition (overall or differential nonresponse, dropout, loss to followup, or exclusion of participants) was a concern, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?	Yes	Yes	Yes	Yes	Yes	Yes
Were the outcome assessors blinded to the intervention or exposure status of participants?	No	No	NR	NR	Yes	NR
Were the outcomes assessed/defined using valid and reliable measures and implemented consistently across all study participants?	NR	NR	NR	NR	NR	NR
Were the potential outcomes prespecified by the researchers? Are all prespecified outcomes reported?	Yes	Yes	Yes	Yes	Yes	Yes
Rating	High	High	Moderate	Moderate	Moderate	Moderate

ASR=Artificial Silicon Retina; NR=not reported; STS=suprachoroidal transretinal stimulation

Table C-23. Risk-of-bias assessment for day-to-day function

Study and Risk-of-Bias Item	Ho et al. 2015 and other authors[14-21] Argus II	Stingl et al. 2015, 2013[23,24] Alpha IMS	Chow et al. 2010 and Geruschat et al. 2012[3,34] ASR	Chow et al. 2004[35] ASR
Does the design or analysis control or account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?	Yes	No	No	No
Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?	No	No	No	No
Did the study maintain fidelity to the intervention protocol?	No	No	Yes	Yes
If attrition (overall or differential nonresponse, dropout, loss to followup, or exclusion of participants) was a concern, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?	Yes	Yes	Yes	No
Were the outcome assessors blinded to the intervention or exposure status of participants?	No	No	No	No
Were the outcomes assessed/defined using valid and reliable measures and implemented consistently across all study participants?	Yes	No	No	No
Were the potential outcomes prespecified by the researchers? Are all prespecified outcomes reported?	Yes	Yes	Yes	Yes
Rating	High	High	High	High

ASR=Artificial Silicon Retina

Table C-24. Risk-of-bias assessment for quality of life

Study and Risk-of-Bias Item	Klauke et al. 2011 and other authors[28-32] EPIRET3
Does the design or analysis control or account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?	Yes
Did researchers rule out any impact from a concurrent intervention or an unintended exposure that might bias results?	No
Did the study maintain fidelity to the intervention protocol?	Yes
If attrition (overall or differential nonresponse, dropout, loss to followup, or exclusion of participants) was a concern, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?	Yes
Were the outcome assessors blinded to the intervention or exposure status of participants?	No
Were the outcomes assessed/defined using valid and reliable measures and implemented consistently across all study participants?	NR
Were the potential outcomes prespecified by the researchers? Are all prespecified outcomes reported?	Yes
Rating	Moderate

NR=not reported

Table C-25. Adverse events

Study	Adverse Event	Result
Arevalo et al. 2015[12,13]	SAE	0/5
Arevalo et al. 2015[12,13]	Device-related AE	0/5
Arevalo et al. 2015[12,13]	Elevated IOP at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[12,13]	Pain at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[12,13]	Suture irritation at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[12,13]	Conjunctival erosion at 1.3 to 2.0 year followup	1/8
Arevalo et al. 2015[12,13]	Edema at 1.3 to 2.0 year followup	2/8
Ho et al. 2015 and other authors[14-22] Argus II	SAE: Conjunctival erosion	1 year 3 patients, 3 years 4 patients
Ho et al. 2015 and other authors[14-22] Argus II	SAE: Hypotony	1 year 2 patients, 3 years 4 patients
Ho et al. 2015 and other authors[14-22] Argus II	SAE: Conjunctival dehiscence	1 year 3 patients, 3 years 3 patients
Ho et al. 2015 and other authors[14-22] Argus II	SAE: Presumed endophthalmitis	1 year 3 patients, 3 years 3 patients
Ho et al. 2015 and other authors[14-22] Argus II	SE: Re-tack	1 year 2 patients, 3 years 2 patients
Ho et al. 2015[14-22] Argus II	SAE (cumulative): Corneal opacity	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	SAE(cumulative): Retinal detachment, rhegmatogenous	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	SAE (cumulative): Retinal detachment, tractional and serous	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	SAE(cumulative): Retinal tear	1 year 1 patient, 3 years 1 patient

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[14-22] Argus II	SAE (cumulative): Uveitis	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	SAE (cumulative): Keratitis, infective	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	SAE (cumulative): Corneal melt	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	SAE (cumulative): Enucleation	1 year 0 patients, 3 years 0 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Epiretinal membrane	1 year 5 patients, 3 years 11 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Conjunctival congestion	1 year 10 patients, 3 years 10 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Ocular pain	1 year 5 patients, 3 years 9 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Hypotony	1 year 7 patients, 3 years 7 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Elective revision surgery	1 year 2 patients, 3 years 7 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Suture irritation	1 year 6 patients, 3 years 6 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Choroidal detachment	1 year 5 patients, 3 years 6 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Uveitis	1 year 4 patients, 3 year 5 patients

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative) cystoid macular edema	1 year 1 patient, 3 years 5 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Retinal thickening without cystic changes	1 year 4 patients, 3 years 4 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Ocular inflammation	1 year 3 patients, 3 years 4 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Vitreous hemorrhage	1 year 3 patients, 3 years 3 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Conjunctivitis inflammatory	1 year 2 patients, 3 year 3 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Epiphora	1 year 2 patients, 3 years 3 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Hyphema	1 year 2 patients, 3 year 3 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Headache	1 year 2 patients, 3 years 2 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Keratic precipitates	1 year 2 patients, 3 years 2 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Corneal vascularization	1 year 1 patient, 3 years 2 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): High IOP	1 year 1 patient, 3 years 2 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Ptosis	1 year 1 patient, 3 years 2 patients

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Conjunctival erosion	1 year 0 patients, 3 years 2 patients
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): 360 circumferential vitreous band traction	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Choroidal effusion	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Conjunctival dehiscence	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Corneal abrasion	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Corneal dryness	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Decrease in light perception	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Filamentary keratitis	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Irregular pupil	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Nausea	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Nystagmus increase	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Proliferative vitreoretinopathy	1 year 1 patient, 3 years 1 patient

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Rubeosis	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE: Scleritis	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Vertigo	1 year 1 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Conjunctival cyst	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Corneal epithelial defect	1 year 0 patient, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Corneal fold	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Broken corneal suture	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Fibrosis around tack	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Foreign body sensation	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Ocular fibrin	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Retinal break/tear	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Retinal detachment tractional	1 year 0 patients, 3 years 1 patient

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Retinoschisis	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Non-SAE (cumulative): Scleral patch displacement	1 year 0 patients, 3 years 1 patient
Ho et al. 2015 and other authors[14-22] Argus II	Device failure (cumulative)	1 year 0 patients, 3 years 0 patients
Ho et al. 2015 and other authors[14-22] Argus II	Safety and device functioning	6.2 years of followup: Safety remained acceptable and 24 patients still had implanted and functioning devices.
Ho et al. 2015 and other authors[14-22] Argus II	Retinal tack extractions (first 4 Argus II subjects requiring tack extraction for removal or repositioning of electrode array)	0/4 AEs through 18 months post-tack extraction
Ho et al. 2015 and other authors[14-22] Argus II	MRI 1.5 Tesla brain scan AEs	0/2 patients negatively affected by MRI testing 0/2 Argus II devices functioning affected 2/2 implants produced local moderate paramagnetic artifacts (50x50 mm) that precluded clear visualization of intraorbital contents causing loss of signal return and anatomical distortion but areas farther away from implant were unaffected.
Stingl et al. 2015, 2013[23,24] Alpha IMS	Intraoperative AE	Injury to the optic nerve with subsequent optic disc swelling (1 patient)
Stingl et al. 2015, 2013[23,24] Alpha IMS	SAEs	IOP increase to 46 mm Hg successfully treated without sequel (1 patient), retinal detachment immediately following explantation of the device treated surgically and resolved but with remaining local retinal fibrotic changes (1 patient)
Stingl et al. 2015, 2013[23,24] Alpha IMS	Postoperative adverse events	Retinal edema (1 patient)
Stingl et al. 2015, 2013[23,24] Alpha IMS	Device malfunction	Technical failure (1 patient), retinal perfusion problem overlying device (1 patient), retinal edema leading to device not functioning (1 patient), injury to the optic nerve with subsequent optic nerve swelling leading to device malfunction (1 patient), infraorbital cable part breaks due to stress from eye movements (NR but occurred in the first few patients in the trial)
Ayton et al. 2014[25] Bionic Vision	AEs during surgery	0/3 patients

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Ayton et al. 2014[25] Bionic Vision	Adverse events in immediate post-operative period	Subretinal hemorrhage on day 3 to 4 post-operatively which resolved without intervention in 55 days,101 days and 13 days respectively in the 3 study patients (3/3 patients) Pain: 3/3 with 1 patient requiring morphine Mild intraocular inflammation: 3/3 patients Intraocular pressure change: 0/3 patients Mild to moderate limitation in the abduction of implanted eye (1 patient) but improved over duration of study without lingering cosmetic or functional difficulty
Ayton et al. 2014[25] Bionic Vision	Device-related (with a direct or indirect causal link between surgery and AE); SAEs (requiring altered or increased medical management such as hospitalization or surgery)	*Staphylococcus aureus* infection at percutaneous connector on day 59 post-implantation which required a 3-day hospitalization and was determined to be device related. (1 patient) Device related SAE associated with the intraocular electrode array (0/3 patients)
Rizzo et al. 2014[26] Argus II	Elevated IOP	1 patient
Rizzo et al. 2014[26] Argus II	Choroidal detachment	1 patient
Rizzo et al. 2014[26] Argus II	Intraoperative AEs	Ciliary body touched and pulled (1 patient)
Rizzo et al. 2014[26] Argus II	Explantation	0 patients
Rizzo et al. 2014[26] Argus II	SAE	0 patients
Rizzo et al. 2014[26] Argus II	Endophthalmitis	0 patients
Rizzo et al. 2014[26] Argus II	Retinal detachment	0 patients
Rizzo et al. 2014[26] Argus II	Chronic intraocular inflammation	0 patients
Rizzo et al. 2014[26] Argus II	Proliferative vitreoretinopathy	0 patients
Rizzo et al. 2014[26] Argus II	Epiretinal membrane formation	0 patients
Rizzo et al. 2014[26] Argus II	Device malfunction	0 patients

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Fujikado et al. 2011[27] STS	Any AE in the 5- to 7-week period after implantation	Retinal detachment 0/2 patients Retinal/vitreous hemorrhage 0/2 patients Eye-movement restriction in all directions: 2/2 patients
Fujikado et al. 2011[27] STS	Any adverse event during or following explanation	VA: 0/2 patients maintained LP VA Eye restriction in all directions: 2/2 patients experienced recovered ability to move eyes in all directions
Klauke et al. 2011 and other authors[28-32] EPIRET3	Implant intraoperative AEs	None
Klauke et al. 2011 and other authors[28-32] EPIRET3	Post-operative implantation AEs	Mild transient inflammatory response (2), significant inflammatory reaction with a 1.5 mm painless hypotony without chemosis (1), hypotony due to permanent finger manipulations by the patient and a flat anterior chamber, inflammation and an epiretinal proliferation at the central tack (1)
Klauke et al. 2011 and other authors[28-32] EPIRET3	Intraoperative explantation AEs	Tacks removed because they were found to be loose (1), removal of a loose tack led to a central retinal defect (1)
Klauke et al. 2011 and other authors[28-32] EPIRET3	AEs during the 6-month followup period	Mild epiretinal gliosis formation at the tack fixation site (4), VA dropped from HM to LP in the patient with the central retinal defect but returned to HM at the 3-month followup (1), retinal detachments (0), choroidal neovascularization (0), new cystoid macular edema after 4 weeks (0)
Klauke et al. 2011 and other authors[28-32] EPIRET3	AEs during 2-year followup period	Conjunctivitis >1 year after implantation successfully treated with medication (1) Inflammatory reaction due to corneal sutures successfully treated with medication (1) Patient reported slight decline in residual visual perception in both eyes and a minor choroidal atrophy in the area where the retinal tacks were placed as well as some atrophy resulting from the laser photocoagulation at the posterior pole in the study eye was noted (1) Slight decline in visual perception following retinal defect repair in study eye due to tack removal (1) Posterior segments stable without clinically relevant progression of gliosis, no vascular abnormalities or leakages seen, and no intraretinal fluid around remaining tacks, all patients had clear corneas and were aphakic Nonprogressive gliosis present in study eye at 2-year followup (4 patients)
Zrenner et al. 2011[33] Alpha IMS	Serious adverse events Preretinal bleeding Persistent IOP increase Intraocular inflammation Retinal detachment Retinal neovascularization	0/3 patients

Table C-25. Adverse events (continued)

Study	Adverse Event	Result
Zrenner et al. 2011[33] Alpha IMS	Intraoperative complication	Small circumscribed area of subretinal bleeding at the posterior pole with complete reabsorption by day 10 (1)
Zrenner et al. 2011[33] Alpha IMS	Explantation	Mild skin infection of the retroauricular cable exit with restitutio ad integrum after a few days (1)
Chow et al. 2004[35] ASR	AEs in the immediate postoperative requiring intervention	IOP elevation to >25 mm Hg which required IOP lowering medication and steroid taper (3)
Chow et al. 2004[35] ASR	Scratchiness in the eye	Resolved after 6 weeks once external absorbable sutures dissolved (several patients, N not specified)
Chow et al. 2004[35] ASR	Aniseikonia between his aphakic ASR implanted eye and unoperated eye when using glasses	Anterior chamber intraocular lens relieved symptoms (1)
Chow et al. 2004[35] ASR	Syneresis of images seen in the implanted eye believed to be related to syneresis of a previously implanted posterior chamber intraocular lens	Symptoms substantially improved after replacement of the syneretic posterior chamber intraocular lens with a stable anterior chamber intraocular lens (1)
Chow et al. 2004[35] ASR	Final followup Infection Prolonged inflammation or discomfort Neovascularization Implant rejection Implant migration Implant erosion through the retina Retinal detachment	0 patients

AE=adverse event; ASR=Artificial Silicon Retina; HM=hand motion; IOP=intraocular pressure; LP=light perception; MRI=magnetic resonance imaging; SAE=serious adverse event; STS=Suprachoroidal Transretinal Stimulation; VA=visual acuity

Table C-26. Ongoing clinical trials of Argus II studies (6 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
Argus II Retinal Prosthesis System Dry AMD Feasibility Study Protocol NCT02227498 Second Sight Medical Products	Prospective, Phase I, nonrandomized single-group assignment study	In this study, 5 subjects with severe dry AMD who are legally blind will be implanted with the Argus II System. The study will evaluate the safety of the device and surgery, as well as functioning of the system and the extent of any restored vision. Each subject will be monitored for 3 years, with their eye health and visual function tested at multiple time points.	June 2015 June 2019 Recruiting patients n=5	The number of adverse events in implanted subjects through 1 year. The effect of the Argus II System on monocular (implanted eye) and binocular visual function, as measured by a suite of visual function tests through 1 year of followup.	NR	Subject must have diagnosed dry AMD; severely sight impaired and meets the following additional criteria: Visual acuity of logMAR 1.0 (6/60) or worse in both eyes, Hand motion or worse central vision in the eye to be implanted, geographic atrophy, and central scotoma in the central 20 degrees or more, pseudophakic with an intraocular lens successfully implanted in the study eye at least 2 weeks before baseline testing, or aphakic with a clear capsule. If applicable, posterior laser capsulotomy may be performed 2 weeks before baseline testing is performed.	Ocular diseases or conditions that could prevent the Argus II implant from working (e.g., optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma) Evidence of active sub-macular CNV in implanted eye Ocular structures or conditions that could prevent the successful implantation of the Argus II Implant or adequate healing from surgery (e.g., extremely thin conjunctiva; axial length <20.5 mm or >26 mm; corneal ulcers; abnormalities in the typical curvature of the retina like staphyloma, and all causes of significant protrusions or depressions in the area centralis that could compromise the optimal position of the electrode array, active or severe blepharitis) Ocular diseases or conditions (other than cataracts) that prevent adequate visualization of the inner structures of the

Table C-26. Ongoing clinical trials of Argus II studies (6 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
							eye (e.g., corneal opacity) An Implantable Miniature Telescope in either eye Predisposition to eye rubbing
Post-Market Study of the Argus® II Retinal Prosthesis System – France NCT02303288 Second Sight Medical Products	Multicenter, prospective observational cohort study	This is a post-market study of the Argus II Retinal Prosthesis System. The study is being conducted in France. The objective of the study is to obtain data to further demonstrate the effectiveness and evaluate the safety of Argus II System in patients with RP who have a bare light perception or worse in both eyes.	November 2014 November 2018 Recruiting patients n=18	The impact of the Argus II on subjects' lives (in terms of functional vision and quality of life) as measured by the Functional Low-vision Observer Rated Assessment (FLORA) at 2 years; incidence of procedure- and device-related adverse events through 2 years	Patient satisfaction and ease of use of the system through 2 years Visual function through 2 years will be assessed using the following tests: square localization, direction of motion, and grating visual acuity. Subjects' performance on the 3 tests above will be compared: Pre-vs. post-implant and. With the Argus II System ON vs. OFF Functional Vision through 2 years measured with NEI-VFQ-25. Incidence of all procedure- and device-related adverse events throughout 2 year follow-up	Patients with RP who have bare light perception or worse in both eyes, previous history of useful form vision. If the subject has no residual light perception, the retina must be able to respond to electrical stimulation.	Ocular diseases or conditions that could prevent Argus II from working (e.g., optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma, severe strabismus) Ocular structures or conditions that could prevent the successful implantation of the Argus II Implant or adequate healing from surgery (e.g., extremely thin conjunctiva; axial length <20.5 mm or >26 mm; corneal ulcers; CNV in the area of the intended tack location) Ocular diseases or conditions (other than cataracts) that prevent adequate visualization of the inner structures of the eye (e.g., corneal opacity); predisposition to eye rubbing

Table C-26. Ongoing clinical trials of Argus II studies (6 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
Argus® II Retinal Prosthesis System Post-Market Surveillance Study NCT01490827 Second Sight Medical Products	Prospective observational cohort study.	This post-market surveillance study is conducted in the European Economic Area where Argus II has been CE certified for use in patients with outer retinal degeneration. This study is being conducted to monitor the use of Argus II in a larger population than available within premarket approval studies. Safety data will be monitored to ensure continued acceptability of risks to study participants, and an attempt will be made to include all eligible and willing participants implanted with Argus II. Measures of visual function	November 2011 May 2016 Recruiting patients Record last updated March 2015 n=45	Adverse events up to 3 years from time of implantation	Visual function up to 3 years from time of implantation	Subjects will be selected from eligible patients in whom the Argus II retinal prosthesis has been implanted at the enrolling center with severe to profound outer retinal degeneration (not including AMD) Have some residual light perception. If no residual light perception remains, the retina must be able to respond to electrical stimulation; have previous history of useful form vision Had an Argus II Retinal Prosthesis surgically implanted 14 days (±7 days) before enrollment (at baseline visit) in the study	Ocular diseases or conditions that could prevent Argus II from working (e.g., optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma, severe strabismus) Ocular structures or conditions that could prevent the successful implantation of the Argus II Implant or adequate healing from surgery (e.g., extremely thin conjunctiva; axial length <20.5 mm or >26 mm; corneal ulcers; CNV in the area of the intended tack location) Ocular diseases or conditions (other than cataracts) that prevent adequate visualization of the inner structures of the eye (e.g., corneal opacity) Predisposition to eye rubbing

Table C-26. Ongoing clinical trials of Argus II studies (6 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
		that may contribute to device improvements will also be gathered and evaluated.					

Table C-26. Ongoing clinical trials of Argus II studies (6 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
New Enrollment Post-Approval Study of the Argus® II Retinal Prosthesis System NCT01860092 Second Sight Medical Products	Prospective observational cohort study.	This post-approval study is being implemented to monitor the use of Argus II System in a larger U.S. population than available within pre-approval studies. An attempt will be made to include all eligible and willing subjects implanted with Argus II System in the United States. Safety data will be monitored to ensure continued acceptability of risks to study subjects. The utility (i.e., visual function and functional vision) and reliability of Argus II System will also be evaluated.	January 2014 August 2018 Recruiting patients n=53	Safety (i.e., adverse event rates), with the main safety analysis performed when all subjects have reached 2 years post-implant.	Visual function will be measured using the following tests: Square localization, direction of motion and grating visual acuity (GVA). In addition to these tests, a photographic flash test will be performed with the system OFF only to determine whether subjects' native residual vision is bare light perception or no light perception. Functional vision will be assessed using the Functional Low-Vision Observer Rated Assessment (FLORA). A utilization questionnaire will also be administered to track how subjects are using the Argus II system Device reliability time frame for secondary outcomes 5 years	Have severe to profound RP Bare light or no light perception in both eyes; if the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed Have previous history of useful form vision Aphakic or pseudophakic. (if the patient is phakic prior to implant, the natural lens will be removed during the implant procedure)	Ocular diseases or conditions that could prevent Argus II System from working (e.g., optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma, severe strabismus) Ocular structures or conditions that could prevent the successful implantation of the Argus II Implant or adequate healing from surgery (e.g., extremely thin conjunctiva, axial length <20.5 mm or >26 mm, corneal ulcers) Ocular diseases or conditions (other than cataracts) that prevent adequate visualization of the inner structures of the eye (e.g., corneal opacity) Predisposition to eye rubbing
Argus® II Retinal	Interventional	The objective of	September 2006	Visual acuity and	Activities of daily	A confirmed history of RP (all	Optic nerve disease

Table C-26. Ongoing clinical trials of Argus II studies (6 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
Stimulation System Feasibility Protocol NCT00407602 Second Sight Medical Products Collaborator NEI	, open label, single group assignment study with pre-implantation serving as comparator.	this feasibility study is to evaluate the safety and utility of the Argus II Retinal Stimulation System in providing visual function to blind subjects with severe to profound RP.	August 2019 Ongoing but not recruiting patients n=30	safety through 5 years	living, quality of life, orientation and mobility, spatial vision, stability of implant, system functionality, all through 5 years	centers) or outer retinal degeneration (France, U.K., Switzerland, Mexico only) with remaining visual acuity of bare light perception (all centers) or 2.3 logMAR (France, U.K., Switzerland, Mexico only) or worse in both eyes. Functional ganglion cells and optic nerve as determined by a measurable electrically evoked response or documented light perception A history of former useful form vision in the worse-seeing eye	History of glaucoma Optic neuropathy or other confirmed damage to optic nerve or visual cortex damage Diseases or conditions that affect retinal function, including central retinal artery/vein occlusion (CRAO or CRVO) End-stage diabetic retinopathy Retinal detachment or history of retinal detachment Trauma Infectious or inflammatory retinal diseases Diseases or conditions that prevent adequate visualization of the retina, including corneal degeneration that cannot be resolved before implant Diseases or conditions of the anterior segment that prevent the ability to adequately perform the physical examination, including trauma or lid malpositions Diseases of the ocular surface including keratitis sicca An ocular condition that predisposes the subject to eye rubbing Conjunctival thinning which may predispose the subject

Table C-26. Ongoing clinical trials of Argus II studies (6 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
							to conjunctival erosion in the area where the implant will be installed extra-ocularly Axial eye length <21.5 mm or >26.0 mm in the implanted eye as measured by ultrasound (U.S. only)
Observational Study of the Argus® II Retinal Prosthesis System NCT01999049 University Health Network, Toronto: Collaborator Foundation Fighting Blindness	Prospective Observational single group assignment study	The Argus II Retinal Implant is a revolutionary new device, which offers vision to patients who are blind from retinal degeneration – RP. These patients have no alternatives. Patients typically can achieve ambulatory vision.	April 2014 January 2017 Recruiting patients n=10	Safety through 1 year after implantation. Safety will be assessed by calculating the proportion of subjects who experience individual procedure- and device-related adverse events. The proportion of subjects who experience a significant ocular event will also be reported.	Visual function at 1 year. Visual function will be measured using the following tests: square localization; direction of motion; grating visual acuity (GVA). Functional vision will be assessed using the Functional Low-Vision Observer Rated Assessment (FLORA). A utilization questionnaire will also be administered to track how subjects are using the Argus II System.	Patients with severe to profound outer retinal degeneration but some residual light perception. If no residual light perception remains, the retina must be able to respond to electrical stimulation and have history of useful form vision.	Ocular diseases or conditions that could prevent the Argus II System from working (e.g., optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma, severe strabismus). Ocular structures or conditions that could prevent the successful implantation of the Argus II Implant or adequate healing from surgery (e.g., extremely thin conjunctiva, axial length <20.5 mm or >26 mm, corneal ulcers, choroidal neovascularization in the area of the intended tack location) Ocular diseases or conditions (other than cataracts) that prevent adequate visualization of the inner structures of the eye (e.g., corneal opacity) Predisposition to eye rubbing

AMD=age-related macular degeneration; CE=Conformité Européenne; CNV=choroidal neovascularization; logMAR=logarithm of the minimum angle of resolution; NR=not reported; RP=retinitis pigmentosa

Table C-27. 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-27. 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

Table C-28. Ongoing clinical trials of IRIS (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
Extended Pilot Study to Evaluate Pattern Recognition with a Chronic Retinal Implant System (IRIS) NCT00427180 Intelligent Medical Implants GmbH	Open-label, non-randomized, interventional, single-group assignment study	To investigate whether blind subjects that fulfill the patient criteria provided with a retinal implant can differentiate between simple patterns like horizontal bar, vertical bar, and cross.	December 2006 December 2010 Recruitment status unknown; record last updated March 2010 n=20	Investigate whether blind subjects that fulfill the patient criteria provided with a retinal implant are able to differentiate between simple patterns, such as horizontal bar, vertical bar, and cross, through 18 months	Further evaluation of stimulation parameters Light localization with use of camera Safety Verification of stimulation parameters through 18 months	RP, choroideremia, or rod-cone dystrophy Visual field less than 40 degrees (if measurable) Visual acuity not better than (1/50), (logMAR≥1.7) Visual function stable for a duration of at least 1 year (according to subject statement) Normal eye pressure (9–21 mm Hg) Bulbus length (AP) between 21 and 25 mm	NR
Restoring Vision with the Intelligent Retinal Implant System (IRIS V1) in Patients with Retinal Dystrophy (Title in France: Compensation of Vision with the Intelligent Retinal Implant System [IRIS V1] in Patients with Retinal Dystrophy) NCT01864486 Pixium Vision SA	Open-label, single-group assignment interventional study	To evaluate the safety and effectiveness of the Intelligent Retinal Implants System (IRIS V1)	April 2013 June 2017 (estimated primary completion; full completion date NR) Recruiting patients n=20	Number of adverse events as a measure of safety and tolerability through 18 months after implantation All subjects will undergo ophthalmological examinations in predefined intervals after implantation, including funduscopy, slit lamp examination, and optical coherence tomography. All adverse events are recorded and analyzed.	Probable benefit through 18 months after implantation A series of vision test including grating visual acuity, light localization, and contrast sensitivity will be performed before and after implantation of the device.	Has a confirmed diagnosis of RP, choroideremia, or cone-rod dystrophy Has a visual acuity of logMAR 2.3 or worse in both the eyes as determined by a square grating scale Has functional ganglion cells and optic nerve activity Has a memory of former useful form vision Has AP eye dimensions that are appropriate with the dimensions of the implant (In Germany: Has an AP eye dimension between 20.5 and 25 mm)	Has a history of severe glaucoma, uveitis, optic neuropathy, or any confirmed damage to the optic nerve and/or visual cortex Has any disease (other than study-allowed diseases) or condition that affects retinal function of the study eye (e.g., central retinal artery/vein occlusion, end-stage diabetic retinopathy, current or prior retinal detachment, infectious or inflammatory retinal disease) Has any disease or condition that prevents adequate visualization of the retina of the study eye, including corneal degeneration that cannot be resolved before implantation

Table C-28. Ongoing clinical trials of IRIS (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
							Has any disease or condition of the anterior segment of the study eye that prevents adequate physical examination (e.g., ocular trauma) Has severe nystagmus, Has any ocular condition that leads to eye rubbing Presents with hypotony in the study eye Has active cancer or a history of intraocular, optic nerve, or brain cancer and metastasis In Germany: chronic inflammation of the skin in the area of the eye (e.g., dermatitis, rosacea, infection of the skin, herpes zoster) Chronic inflammation in the area of the eye (e.g., herpes of cornea and/or conjunctiva, recurrent blepharoconjunctivitis, horedeolum, chalazion)

AP=anterior-posterior; logMAR=logarithm of minimum angle of resolution; NR=not reported; RP retinitis pigmentosa

Table C-29. Ongoing clinical trials of implantable miniature telescope (3 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
Five Year Follow up of IMT-002 Patients; A Long-Term Monitoring Study of IMT-002 Patients NCT00976235 VisionCare Ophthalmic Technologies, Inc.	Open label, non-randomized single group assignment study	This is a 5-year study of patients who have received the Implantable Miniature Telescope (IMT by Dr. Isaac Lipshitz) under Protocol IMT-002. All patients in whom the telescope prosthesis has been implanted who enrolled in the IMT-002 trial were asked to participate in this study to monitor long-term safety. Patients will undergo examinations at 6-month intervals up to a total of 5 years after implantation.	June 2006 Completed n=129	Every 6 months, manifest refraction, visual acuity, IOP, slit lamp examination, endothelial cell density, device failures, complications and adverse events will be assessed.	NR	Patients must have participated in the IMT-002 trial.	Patients who have not participated in the IMT-002 trial.
Post-approval Study of VisionCare's Implantable Miniature Telescope (by Dr. Isaac Lipshitz) in Patients with Bilateral Severe to Profound Central Vision Impairment	Open-label, single-group assignment study	The objective of the PAS-01 study is to assess the safety of the intraocular implant as measured by the cumulative incidence of patients who within 5 years	August 2010 December 2028 Enrolling subjects by invitation only n=770	At investigative sites participating in the ECD Sub-Group study, corneal endothelial cell density will be measured by noncontact specular microscopy in a	NR	Stable severe vision impairment caused by bilateral central scotomas associated with end-stage AMD, retinal findings of geographic atrophy or disciform scar with foveal involvement Visually significant cataract, achieve at least a 5-letter	Stargardt's macular dystrophy Anterior chamber depth <3.0 mm Presence of corneal guttate Do not meet minimum age and ECD requirements Evidence of CNV or treatment of CNV within the past 6 months, previous intraocular or

Table C-29. Ongoing clinical trials of implantable miniature telescope (3 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
Assoc. With End-stage Age-related Macular Degeneration NCT01757132 VisionCare Ophthalmic Technologies, Inc.		after implantation experience persistent vision-impairing corneal edema (corneal edema leading to persistent loss of best corrected distance visual acuity >2 lines from pre-surgery baseline level). The study will test the null hypothesis that the percentage of patients who experience persistent vision-impairing corneal edema is >17% against the alternative that the percentage is <17%. The null hypothesis will be rejected if the upper bound of the two-sided 95% confidence integral for the observed percentage is <17%.		subgroup of 150 patients enrolled in the IMT-PAS-01 in the eye scheduled for and implanted with the intraocular telescope through 60 months		improvement with external telescope Have adequate peripheral vision in the eye not scheduled for surgery	corneal surgery of any kind in operative eye, including any type of surgery for either refractive or therapeutic purposes Have prior or expected ophthalmic-related surgery within 30 days preceding intraocular telescope surgery History of steroid-responsive rise in IOP, uncontrolled glaucoma, or preoperative IOP >22 mm Hg while on maximum medication History of eye rubbing or an ocular condition that predisposes eye rubbing Myopia >6.0 D hyperopia >4.0 D Axial length <21 mm Narrow angle (i.e., <Schaffer grade 2 cornea stromal or endothelial dystrophies, including guttate inflammatory ocular disease) Zonular weakness/instability of crystalline lens, or pseudoexfoliation, diabetic retinopathy Untreated retinal tears Retinal vascular disease Optic nerve disease History of retinal detachment Intraocular tumor RP

Table C-29. Ongoing clinical trials of implantable miniature telescope (3 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
A Prospective Multicenter Clinical Study of the Implantable Miniature Telescope* in Patients with Central Vision Impairment Associated with AMD: IMT-UK Protocol (*IMT by Dr. Isaac Lipshitz) NCT00555165 VisionCare Ophthalmic Technologies, Inc.	Open-label, single-group assignment study	Evaluation of pre- and post-implantation management of patients with end-stage AMD in whom the implantable telescope (IMT) has been implanted under CE mark indicated use. This study is designed to evaluate in particular the optimal parameters for patient selection for use of this device in routine clinical practice.	November 2007 Completed n=18	Best-corrected visual acuity through 1 year	Quality of life through 1 year	Bilateral visual impairment due to geographic atrophy or disciform scars Evidence of cataract	Active CNV (or wet AMD) Prior cataract or refractive surgery in the study eye

AMD=age-related macular degeneration; CE=Conformité Européenne; CNV=choroidal neovascularization; D=diopter; ECD=endothelial cell density; logMAR=logarithm of the minimum angle of resolution; IOP=intraocular pressure; NR=not reported; RP=retinitis pigmentosa

Table C-30. Ongoing clinical trials of encapsulated human NTC-201 cells releasing ciliary neurotrophic factor (CNTF) implant (5 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
A Phase II Study of Implants of Encapsulated Human NTC-201 Cells Releasing Ciliary Neurotrophic Factor (CNTF), in Participants with Visual Acuity Impairment Associated with Atrophic Macular Degeneration NCT00447954 Neurotech Pharmaceuticals	Double-masked (patient, outcome assessor) randomized, parallel-assignment, interventional study with a sham comparator	The purpose of this study is to look at the safety and effectiveness of CNTF implants on vision in participants with atrophic macular degeneration. This research is being done because there are no effective therapies for people with atrophic macular degeneration.	January 2007 Completed n=48	The increase in BCVA using EVA technology from baseline to 1 year	Change in BCVA over the 18-month followup period, change in ERG between baseline and months 12 and 18, change in area of geographic atrophy from baseline to months 12 and 18, change in area of drusen from baseline to months 12 and 18, change in retinal thickness from baseline to months 12 and 18, and change in quality of life between baseline and months 12 and 18 using NEI-VFQ-25	Diagnosis of age-related macular degeneration with the presence of geographic atrophy Visual acuity no better than 20/63 and no worse than 20/160 History of recent visual acuity loss	Age-related macular degeneration with new blood vessel growth, other eye diseases including advanced cataract
A Phase II/III Study of Encapsulated Human NTC-201 Cell Implants Releasing Ciliary Neurotrophic Factor (CNTF) for Participants with Retinitis Pigmentosa Using Visual Field Sensitivity as the Primary Outcome NCT00447980 Neurotech	Double-masked (patient, outcome assessor) randomized, parallel-assignment interventional study comparing high-dose with low-dose implants.	To look at the safety and effectiveness of CNTF implants on vision in persons with RP, Usher syndrome type 2 or 3, or choroideremia. This research is being done because no effective therapies exist for people with these	January 2007 Completed n=60	Change in Humphrey visual field sensitivity from baseline to month 12	Change in visual field sensitivity through 24 months, change in BCVA through 24 months, change in ERG through 24 months, change in OCT through 24 months, change in inflammation through 24 months, change in vision-related quality of	Diagnosis of RP, Usher syndrome type 2 or 3, or choroideremia Visual acuity no worse than 20/63 Experience with at least 2 full-threshold Humphrey visual field 30-2 tests, 1 completed within the year before enrolling in this study	RP caused by a classic syndrome, including Usher syndrome type 1 Other eye diseases including advanced cataract

Table C-30. Ongoing clinical trials of encapsulated human NTC-201 cells releasing ciliary neurotrophic factor (CNTF) implant (5 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
Pharmaceuticals		retinal degenerations. The implant is a small capsule that contains human retinal pigment epithelium cells. These cells have been given the ability to make CNTF and release it through the capsule membrane into the surrounding fluid. In this study, 2 CNTF dose levels will be used: a high dose and a low dose in 1 eye, as well as a sham (or placebo) surgery in the other eye.			life through 24 months		
A Phase II/III Study of Encapsulated Human NTC-201 Cell Implants Releasing Ciliary Neurotrophic Factor (CNTF) for Participants with Retinitis Pigmentosa Using Visual Acuity as the Primary Outcome NCT00447993 Neurotech Pharmaceuticals	Double-masked (patient, outcome assessor) randomized, parallel-assignment interventional study comparing high-dose to low-dose implants	To look at the safety and effectiveness of CNTF implants on vision in persons with RP, Usher syndrome type 2 or 3, or choroideremia This research is being done because no effective therapies exist for people with these	January 2007 Completed n=60	Change in BCVA using EVA technology at month 12	Longer-term observations of change in visual acuity, disease modification, BCVA, ERG, OCT, inflammation, and vision-related quality of life (NEI-VFQ-25) through 18 months	Diagnosis of RP, Usher syndrome type 2 or 3, or choroideremia Visual acuity no better than 20/63 and no worse than 20/320 Reduced electrical responses from the retina (ERG) and loss of peripheral vision	RP caused by a classic syndrome, including Usher syndrome type 1 Other eye diseases, including advanced cataract

Table C-30. Ongoing clinical trials of encapsulated human NTC-201 cells releasing ciliary neurotrophic factor (CNTF) implant (5 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
		retinal degenerations. This study will assess 2 CNTF dose levels (high and low dose) in 1 eye, as well as a sham (or placebo) surgery in the other eye.					
Photoreceptor Structure in A Phase 2 Study of Encapsulated Human NTC-201 Cell Implants Releasing Ciliary Neurotrophic Factor (CNTF) for Participants with Retinitis Pigmentosa Using Rates of Change in Cone Spacing and Density NCT01530659 Neurotech Pharmaceuticals Collaborator: University of California, San Francisco	Triple-masked (patients, investigator, and outcome assessor) single-group assignment study	A single-site clinical trial for participants who have early stage RP or Usher syndrome (type 2 or 3).	January 2012 August 2019 Recruiting patients n=30	Cone photoreceptor preservation through 24 months after implantation, evaluation of the changes (if present) in cone photoreceptor preservation in the CNTF-treated eye vs. the sham eye as measured by AOSLO	Change(s) in ocular function through 30 months after implantation Change(s) in visual acuity and change in perimetry assessed by: BCVA, changes in visual field using perimetry Changes in the outer nuclear layer thickness as measure by sdOCT Changes in full-field ERG from baseline through 24 months after implantation The presence of peri-implant fibrosis that blocks the visual axis or affects the lens or retina	Participant must have a diagnosis of RP or Usher syndrome type 2 or 3 (without profound deafness or cochlear implants) BCVA must be no worse than 20/63 (at least 59 letters) Participants must have clear natural lenses Participants must have less than 6 diopters myopia Participants must have reproducible baseline AOSLO image Participants must have interocular symmetry of disease severity Participant's clinical diagnosis must be consistent with retinal degeneration in the set of RP dystrophies	Participant who has any of the following lens opacities: cortical opacity > standard 3, posterior subcapsular opacity > standard 3, or a nuclear opacity > standard 3; or participant is pseudophakic or aphakic Participant has history of corneal opacification or lack of optical clarity Participant has undergone LASIK surgery or other refractive surgery for either eye Participant has nystagmus Participant has greater than 6 diopters myopia Participant has cystoid macular edema with cysts present within 4 degrees of the foveal center that prevent acquisition of at least 7 regions of interest with clear images of cone photoreceptors Participant has fewer than 7 regions of interest present on baseline AOSLO image montages

Table C-30. Ongoing clinical trials of encapsulated human NTC-201 cells releasing ciliary neurotrophic factor (CNTF) implant (5 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
					Adverse events affecting ocular function which are thought to be potentially related to the implant Toxicity through 30 months after implantation Safety will be evaluated by the presence or absence of local and/or systemic toxicities.		Participant with a history of ocular herpes zoster Participant in whom, as an infant, amblyopia was diagnosed and treated
A Phase I Study of NT-501-10 and NT-501-6A.02, Implants of Encapsulated Human NTC-210 Cells Releasing Ciliary Neurotrophic Factor (CNTF), in Patients with Retinitis Pigmentosa (RP) NCT00063765 NEI	Phase I, single-group assignment study	To evaluate the safety of a CNTF implant placed in the eye to allow the release of CNTF directly on the retina. The results of this study may lead to a larger investigation of CNTF implants to treat RP.	June 2003 Completed n=10	Safety	Anterior chamber cell scale and vitreous haze grading to measure inflammation, which may be caused by the implant. Also, visual acuity, visual fields, ERG, and OCT (OCT3) to determine retinal thickness.	Participant diagnosis consistent with RP characterized by the following features: Progressive photoreceptor dysfunction and death Clinical degeneration of the outer retina Intraretinal “bone-spicule” pigment Visual field constriction Night blindness Major reduction of both rod and cone ERG responses The first 2 participants have 20/400 vision or worse in the implant (study) eye with the same or better in the fellow eye, while the remainder of the participants will have visual acuity of 20/100 or worse	Participant has glaucoma Participant has cataract, and it interferes with the assessment of the posterior segment inflammation using a standard slit- lamp examination Participant has undergone intra-ocular lens replacement less than 6 months before enrollment Participant is on ocular medications known to be toxic to the lens, retina, or optic nerve Participant with retinal inflammatory diseases or with macula edema

Table C-30. Ongoing clinical trials of encapsulated human NTC-201 cells releasing ciliary neurotrophic factor (CNTF) implant (5 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
						Participant has an ERG less than 2 MV (28-32 Hz flicker) Participant with central visual field of 40 degrees diameter or less with the Goldmann V 4e stimulus (independent of a peripheral crescent of any size)	

AOSLO=adaptive optics scanning laser ophthalmoscopy; BCVA=best corrected visual acuity; CNTF=ciliary neurotrophic factor; ERG=electroretinography; EVA=Electronic Visual Acuity; NEI-VFQ-25: National Eye Institute Visual Function Questionnaire 25 item; OCT=optical coherence tomography; sdOCT=spectral domain optical coherence tomography; RP=retinitis pigmentosa

Table C-31. Ongoing clinical trials of brimonidine intravitreal implant (3 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
An Exploratory Study to Evaluate the Safety of Brimonidine Intravitreal Implant in Patients with Retinitis Pigmentosa NCT00661479 Allergan	Single-masked, non-randomized sham-controlled (fellow eye; patient), single-group assignment study	This exploratory, 12-month, ascending-dose study will evaluate the safety and effects on visual function of a single injection of brimonidine intravitreal implant in 1 eye of patients with RP	June 2008 Completed n=21	Change from baseline in BCVA in the study eye through month 6	Change from baseline in contrast sensitivity in the study eye through month 6 measured using a Pelli-Robson contrast sensitivity chart at 1 meter	RP in both eyes, Visual acuity between 20/40 and count fingers	Growth of new blood vessels in the eye Any intraocular surgery or laser in either eye in the last 6 months before screening visit or between the screening visit and day 1 Any ocular disease that can interfere with diagnosis and assessment of disease progression Significant near-sightedness
Safety and Efficacy of Brimonidine Intravitreal Implant in Patients with Geographic Atrophy Due to AMD NCT00658619 Allergan	Double-masked (patient, outcome assessor) randomized, parallel-group assignment study with a sham control (1 or both eyes)	Stage 1 is a patient-masked, dose-escalation, safety evaluation of brimonidine intravitreal implant. Patients will receive implant in 1 eye and sham in the fellow eye. Stage 2 will begin after 1 month of safety has been evaluated. Stage 2 is a randomized, double-masked, dose-response, sham-controlled evaluation of the safety and efficacy of brimonidine	May 2008 Completed n=119	Change from baseline in size of geographic atrophy lesion area in the study eye through month 12	Change from baseline in size of geographic atrophy lesion area in the study eye, based on fundus photography through month 24 Change from baseline in BCVA in the study eye through month 24 Change from baseline in contrast sensitivity through month 24, measured	Geographic atrophy in both eyes due to AMD Visual acuity between 20/40 and 20/320	Uncontrolled systemic disease or infection of the eye, recent eye surgery

Table C-31. Ongoing clinical trials of brimonidine intravitreal implant (3 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
		intravitreal implant in patients with geographic atrophy from AMD. Patients will be followed for up to 2 years.			with Pelli-Robson contrast sensitivity chart at 1 meter Change from baseline in reading speed in the study eye through month 24 measured with modified Bailey-Lovie word charts		
A Safety and Efficacy Study of Brimonidine Intravitreal Implant in Geographic Atrophy Secondary to Age-related Macular Degeneration (BEACON) NCT02087085 Allergan	Triple-masked (patient, investigator, outcome assessor), randomized parallel-assignment, sham-controlled study	This study will assess the safety and efficacy of the brimonidine intravitreal implant in patients with geographic atrophy due to AMD.	May 2014 February 2019 Recruiting patients n=300	Change from baseline in atrophic lesion area in the study eye through month 24	Change from baseline in low luminance BCVA in the study eye through month 24, change from baseline in retinal sensitivity in the study eye through month 24	Geographic atrophy due to AMD in the study eye Visual acuity better than or equal to 20/80 in the study eye and 20/200 in the fellow eye	Cataract surgery or LASIK in the study eye in the past 3 months Infection in either eye in the past 3 months

AMD=age-related macular degeneration; BCVA=best-corrected visual acuity; LASIK=laser assisted in-situ keratomileusis; RP=retinitis pigmentosa

Table C-32. Ongoing clinical trials of other treatments on the horizon (3 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
Transcorneal Electrical Stimulation Therapy for Retinal Disease - A Randomized, Single-blind Pilot Study NCT00804102 Okuvision GmbH	Single-masked, randomized, parallel- group assignment study comparing TES and DTL-electrode attached without energy	TES may enable neurons to survive degeneration processes via enhanced secretion of neurotrophic substances and direct stimulation of neurons	January 2008 Completed n=80	Enhanced field of vision, enhanced visual acuity, lower threshold for electrical evoked phosphenes Time frame: 3 years	NR	RP, macula off, primary open- angle glaucoma, hereditary macular degeneration, treated retinal detachment, retinal artery occlusion, retinal vein occlusion, nonarthritic-anterior-ischemic optic-neuropathy, hereditary autosomal dominant optic atrophy, dry AMD, ischemic macula edema	Severe other disease such as nonproliferative diabetic retinopathy, exudative AMD
Modulating Ocular/Retinal Blood Flow and Visual Function in Retinitis Pigmentosa NCT02086890 Nova Southeastern University. Collaborator: National Eye Institute	Phase I and II triple-masked (patient, investigator, outcome assessor), randomized crossover study assessing the following procedures: electro-acupuncture, laser acupuncture, TES, sham electro-acupuncture, sham laser acupuncture, sham TES	To gain a better understanding of possible changes in ocular and retinal blood flow and measures of vision in patients with RP receiving 2 promising therapies, electro-acupuncture and TES	August 2014 June 2016 Ongoing but not recruiting subjects n=21	Significant changes from baseline in ocular and retinal blood flow through 12 weeks after intervention	Significant changes from baseline in dark adaptation function through 12 weeks after intervention using the AdaptDx by Maculogix Significant changes from baseline in multifocal electro-retinogram through 12 weeks after intervention initiation Significant changes from baseline in Goldmann visual field area through 12 weeks after intervention initiation Significant	Diagnosis of RP BCVA better than 20/400 in at least 1 eye More than 20% loss of Goldmann visual field area (III4e test target) in at least 1 eye	Very severe vision losses in both eyes (e.g., hand motions or light perception only) with difficulty performing the proposed vision tests Vision loss due to ocular diseases other than RP, cystoid macular edema, or cataracts Previous acupuncture or TES treatment for RP

Table C-32. Ongoing clinical trials of other treatments on the horizon (3 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
					changes from baseline in best-corrected ETDRS visual acuity through 12 weeks after intervention initiation Significant changes from baseline in contrast sensitivity through 12 weeks after intervention initiation OCT through 12 weeks after intervention initiation Changes in macular edema		
A Phase I/IIa, Open-Label, Single-Center, Prospective Study to Determine the Safety and Tolerability of Sub-retinal Transplantation of Human Embryonic Stem Cell Derived Retinal Pigmented Epithelial (MA09-hRPE) Cells in Patients with Advanced Dry Age-related Macular Degeneration (AMD)	Open-label single-group assignment study	To evaluate the safety and tolerability of MA09-hRPE cellular therapy in patients with advanced dry AMD To evaluate the safety of the surgical procedures when used to implant MA09-hRPE cells To assess the number of hRPE cells to be transplanted in future studies To evaluate on an	September 2012 April 2016 Recruiting patients n=12	Safety of HeSC-derived RPE cells at 12 months, with none of the following: Any grade 2 (NCI grading system) or greater adverse events related to the cell product Any evidence that the cells are contaminated with an	Change in the mean of BCVA Autofluorescence photography Reading speed Evidence of successful engraftment will include: Structural evidence (OCT imaging, FA, slit lamp examination with fundus photography) that cells have been implanted in the	Clinical findings consistent with advanced dry AMD with evidence of 1 or more areas of >250 microns of GA involving the central fovea (GA defined as attenuation or loss of RPE as observed by biomicroscopy, OCT, and FA) No evidence of current or prior CNV in the treated eye The BCVA of the eye to receive the transplant will be no better than 20/400 BCVA of the eye that is NOT to receive the transplant will be no worse than 20/400	Presence of active or inactive CNV in the eye to be treated Presence or history of retinal dystrophy, RP, chorioretinitis, central serious choroidopathy, diabetic retinopathy, or other retinal vascular or degenerative disease other than AMD History of optic neuropathy Macular atrophy due to causes other than AMD Presence of glaucomatous optic neuropathy in the study eye Uncontrolled IOP, or use of 2 or more agents to control IOP Cataract of sufficient severity likely to necessitate surgical

Table C-32. Ongoing clinical trials of other treatments on the horizon (3 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
NCT01674829 CHABiotech Co., Ltd		exploratory basis potential efficacy endpoints to be used in future studies of MA09-hRPE cellular therapy.		infectious agent Any evidence that the cells show tumorigenic potential	correct location, electro-retinographic evidence (mfERG) showing enhanced activity in the implant location	Electrophysiological findings consistent with advanced dry AMD	extraction within 1 year History of retinal detachment repair in the study eye Axial myopia of greater than -8 diopters Axial length greater than 28 mm Any other sight-threatening ocular disease Any history of retinal vascular disease (compromised blood-retinal barrier) Glaucoma, uveitis, or other intraocular inflammatory disease Significant lens opacities or other media opacity Ocular lens removal within previous 3 months Ocular surgery in the study eye in the previous 3 months

AMD=age-related macular degeneration; BCVA=best corrected visual acuity; CNV=choroidal neovascularization; DTL= Dawson-Trick-Litzkow; ETDRS=Early Treatment Diabetic Retinopathy Study (test); FA=fluorescein angiography; GA=geographic atrophy; HeSC=human embryonic stem cell; IOP=intraocular pressure; NR=not reported; OCT=optical coherence tomography; RP=retinitis pigmentosa; RPE=retinal pigment epithelium; TES=transcorneal electrical stimulation

Table C-33. Ongoing clinical trials of genetic issues (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
Molecular Genetics of Retinal Degenerations NCT00231010 National Eye Institute	Diagnostic case series	To investigate in a multinational study the inheritance of genetic retinal degeneration in families of different nationalities and ethnic backgrounds to identify the genes that, when altered, cause retinal degeneration. The findings of this study should help improve diagnosis and methods of treatment for these disorders	September 2005 NR Recruiting patients n=5,000	Linkage will be determined using the LOD score method and mutations in specific genes will be assessed using a combination of residue conservation, BLOSUM score, and molecular modeling. Association will be determined using chi-square and Fisher exact tests. Biochemical, metabolic, and physiological effects will be individualized to the specific assay.	NR	Individuals or family members of individuals with retinal degenerations, either congenital, childhood, or age-related	Diseases, infections, or trauma that mimic primary retinal degenerations
Natural History and Genetic Studies of Usher Syndrome NCT00106743 National Eye Institute	Prospective, observational study	To explore clinical and genetic aspects of Usher syndrome	March 2005 NR Ongoing but not recruiting n=237	Affected participants will be phenotypically categorized in 1 of the 3 clinical types, based on audiology and vestibular findings.	NR	Documented neurosensory hearing loss and retinitis pigmentosa and fulfill the clinical characteristics for Usher syndrome type 1, 2, or 3 as defined by the Usher syndrome consortium or be unaffected family members of a proband with Usher syndrome, primarily parents and siblings. Family members will be considered unaffected by history if they	Had intrauterine infection, perinatal/ congenital infections, or intrauterine and birth complications. These conditions can result in damage to both the auditory and visual system. Have concurrent inherited or acquired conditions that affect the visual and/or auditory system and significantly alter the phenotype

Table C-33. Ongoing clinical trials of genetic issues (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
						have had previous normal ophthalmologic and hearing examinations and if they don't have decreased night or peripheral vision.	

NR=not reported

Reference List for Evidence Tables

1. Geruschat DR, Flax M, Tanna N, et al. FLORA: Phase I development of a functional vision assessment for prosthetic vision users. Clin Exp Optom. 2015 Jul;98(4):342-7. Also available: http://dx.doi.org/10.1111/cxo.12242. PMID: 25675964.

2. Bittner AK, Jeter P, Dagnelie G. Grating acuity and contrast tests for clinical trials of severe vision loss. Optom Vis Sci. 2011 Oct;88(10):1153-63. Also available: http://dx.doi.org/10.1097/OPX.0b013e3182271638. PMID: 21747309.

3. Chow AY, Bittner AK, Pardue MT. The artificial silicon retina in retinitis pigmentosa patients (an american ophthalmological association thesis). Trans Am Ophthalmol Soc. 2010 Dec;108:120-54. PMID: 21212852.

4. Kiser AK, Mladenovich D, Eshraghi F, et al. Reliability and consistency of visual acuity and contrast sensitivity measures in advanced eye disease. Optom Vis Sci. 2005 Nov;82(11):946-54.

5. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation. 2010 May;19(4):539-49. Also available: http://dx.doi.org/10.1007/s11136-010-9606-8. PMID: 20169472.

6. Finger RP, Tellis B, Crewe J, et al. Developing the impact of vision impairment-very low vision (IVI-VLV) questionnaire as part of the LoVADA protocol. Invest Ophthalmol Vis Sci. 2014 Oct;55(10):6150-8. Also available: http://dx.doi.org/10.1167/iovs.14-14731. PMID: 25190656.

7. Finger RP, McSweeney SC, Deverell L, et al. Developing an instrumental activities of daily living tool as part of the low vision assessment of daily activities protocol. Invest Ophthalmol Vis Sci. 2014 Dec;55(12):8458-66. Also available: http://dx.doi.org/10.1167/iovs.14-14732.

8. McKnight PE, Babcock-Parziale J. Respondent impact on functional ability outcome measures in vision rehabilitation. Optom Vis Sci. 2007 Aug;84(8):721-8.

9. Kiser AK, Mladenovich D, Eshraghi F, et al. Reliability and consistency of dark-adapted psychophysical measures in advanced eye disease. Invest Ophthalmol Vis Sci. 2006 Jan;47(1):444-52.

10. Babcock-Parziale J, McKnight PE, Head DN. Evaluating psychometric properties of a clinical and a self-report blind rehabilitation outcome measure. J Rehabil Res Dev. 2005 Jul-Aug;42(4):487-98.

11. Stelmack JA, Stelmack TR, Massof RW. Measuring low-vision rehabilitation outcomes with the NEI VFQ-25. Invest Ophthalmol Vis Sci. 2002 Sep;43(9):2859-68. PMID: 12202503.

12. Arevalo JF, Al Rashaed S, Kahtani ES, et al. The Argus II retinal prosthesis in RP patients: surgical and functional outcomes from the KKESH Collaborative Retina Study Group [slide presentation]. [internet]. Baltimore (MD): Johns Hopkins Medicine, Wilmer Eye Institute; 2015 Nov 15. 27 slides.

13. Arevalo JF, Mura M, Al Rashaed S. The Argus II retinal prosthesis: surgical and functional outcomes in younger retinitis pigmentosa (RP) patients [poster PO267; slide set]. In: American Academy of Ophthalmology 2015 annual meeting; 2015 Nov 14-17; Las Vegas (NV). American Academy of Ophthalmology (AAO); 2015. Also available: http://aao.scientificposters.com.

14. Ho AC, Humayun MS, Dorn JD, et al. Long-term results from an epiretinal prosthesis to restore sight to the blind. Ophthalmology. 2015 Aug;122(8):1547-54. Also available: http://dx.doi.org/10.1016/j.ophtha.2015.04.032. PMID: 26162233.

15. Luo YH, Zhong JJ, da Cruz L. The use of Argus® II retinal prosthesis by blind subjects to achieve localisation and prehension of objects in 3-dimensional space. Graefes Arch Clin Exp Ophthalmol. 2015 Nov;253(11):1907-14. Epub 2014 Dec 31. Also available: http://dx.doi.org/10.1007/s00417-014-2912-z. PMID: 25547618.

16. De Juan Jr E, Spencer R, Barale PO, et al. Extraction of retinal tacks from subjects implanted with an epiretinal visual prosthesis. Graefes Arch Clin Exp Ophthalmol. 2013 Oct;251(10):2471-6. Also available: http://dx.doi.org/10.1007/s00417-013-2452-y. PMID: 24013578.

17. Humayun MS, Dorn JD, da Cruz L, et al. Interim results from the international trial of Second Sight's visual prosthesis. Ophthalmology. 2012 Apr;119(4):779-88. PMID: 22244176.

18. Greenberg RJ, Humayun MS, da Cruz L, et al. Five-year data from the Argus II retinal prosthesis system clinical trial. Invest Ophthalmol Vis Sci. 2015 Jun;56(7):754. Also available: http://iovs.arvojournals.org/article.aspx?articleid=2336475&resultClick=1.

19. Luo YH, Davagnanam I, Dacruz L. MRI brain scans in two patients with the Argus II retinal prosthesis. Ophthalmology. 2013 Aug;120(8):1711-1711..e8. Also available: http://dx.doi.org/10.1016/j.ophtha.2013.04.021 . PMID: 23916083.

20. Lauritzen TZ, Harris J, Mohand-Said S, et al. Reading visual braille with a retinal prosthesis. Front Neurosci. 2012;6:168. PMID: 23189036.

21. Da Cruz L, Coley BF, Dorn J, et al. The Argus II epiretinal prosthesis system allows letter and word reading and long-term function in patients with profound vision loss. Br J Ophthalmol. 2013 May;97(5):632-6. Also available: http://dx.doi.org/10.1136/bjophthalmol-2012-301525. PMID: 23426738.

22. Barry MP, Dagnelie G. Use of the Argus II retinal prosthesis to improve visual guidance of fine hand movements. Invest Ophthalmol Vis Sci. 2012 Aug;53(9):5095-101. Also available: http://dx.doi.org/10.1167/iovs.12-9536. PMID: 22661464.

23. Stingl K, BartzSchmidt KU, Besch D, et al. Subretinal visual implant alpha IMS - clinical trial interim report. Vision Res. 2015 Jun;111(Pt B):149-60. Also available: http://dx.doi.org/10.1016/j.visres.2015.03.001. PMID: 25812924.

24. Stingl K, Bach M, Bartz-Schmidt KU, et al. Safety and efficacy of subretinal visual implants in humans: methodological aspects. Clin Exp Optom. 2013 Jan;96(1):4-13. Also available: http://dx.doi.org/10.1111/j.1444-0938.2012.00816.x. PMID: 23173814.

25. Ayton LN, Blamey PJ, Guymer RH, et al. First-in-human trial of a novel suprachoroidal retinal prosthesis. PLoS ONE. 2014 Dec 18;9(12):e115239. Also available: http://dx.doi.org/10.1371/journal.pone.0115239. PMID: 25521292.

26. Rizzo S, Belting C, Cinelli L, et al. The Argus II retinal prosthesis: 12-month outcomes from a single-study center. Am J Ophthalmol. 2014 Jun;157(6):1282-90. Also available: http://dx.doi.org/10.1016/j.ajo.2014.02.039. PMID: 24560994.

27. Fujikado T, Kamei M, Sakaguchi H, et al. Testing of semichronically implanted retinal prosthesis by suprachoroidal-transretinal stimulation in patients with retinitis pigmentosa. Invest Ophthalmol Vis Sci. 2011 Jun;52(7):4726-33. Also available: http://dx.doi.org/10.1167/iovs.10-6836. PMID: 21436271.

28. Klauke S, Goertz M, Rein S, et al. Stimulation with a wireless intraocular epiretinal implant elicits visual percepts in blind humans. Invest Ophthalmol Vis Sci. 2011 Jan;52(1):449-55. Also available: http://dx.doi.org/10.1167/iovs.09-4410. PMID: 20861492.

29. Menzel-Severing J, Laube T, Brockmann C, et al. Implantation and explantation of an active epiretinal visual prosthesis: 2-year follow-up data from the EPIRET3 prospective clinical trial. Eye (Lond). 2012 Apr;26(4):502-9. Also available: http://dx.doi.org/10.1038/eye.2012.35. PMID: 22422033.

30. Roessler G, Laube T, Brockmann C, et al. Implantation and explantation of a wireless epiretinal retina implant device: observations during the EPIRET3 prospective clinical trial. Invest Ophthalmol Vis Sci. 2009;50(6):3003-8. Also available: http://dx.doi.org/10.1167/iovs.08-2752. PMID: 19420330.

31. Roessler G, Laube T, Brockmann C, et al. Angiographic findings following tack fixation of a wireless epiretinal retina implant device in blind RP patients. Graefes Arch Clin Exp Ophthalmol. 2011 Sep;249(9):1281-6. Also available: http://dx.doi.org/10.1007/s00417-011-1653-5. PMID: 21465287.

32. Mokwa W, Goertz M, Koch C, et al. Intraocular epiretinal prosthesis to restore vision in blind humans. Conf Proc IEEE Eng Med Biol Soc. 2008;2008:5790-3. Also available: http://dx.doi.org/10.1109/IEMBS.2008.4650530. PMID: 19164033.

33. Zrenner E, Bartz-Schmidt KU, Benav H, et al. Subretinal electronic chips allow blind patients to read letters and combine them to words. Proc Biol Sci. 2011 May 22;278(1711):1489-97. Epub 2010 Nov 3. PMID: 21047851.

34. Geruschat DR, Bittner AK, Dagnelie G. Orientation and mobility assessment in retinal prosthetic clinical trials. Optom Vis Sci. 2012 Sep;89(9):1308-15. PMID: 22902422.

35. Chow AY, Chow VY, Packo KH, et al. The artificial silicon retina microchip for the treatment of vision loss from retinitis pigmentosa. Arch Ophthalmol. 2004;122(4):460-9.