Supplementary Table S1. FDA guidance regarding properties considered in review of PRO measures used in clinical trials

Component	Description as per FDA PRO guidance	What was reviewed?
Content validity	Evidence that the instrument measures the concept of interest, including evidence from qualitative studies that the items and domains of an instrument are appropriate, and comprehensive, relative to its intended measurement concept, population, and use.	• Item generation process for evidence of the inclusion of concept elicitation and cognitive debriefing of the draft measure with individuals with presbyopia • Development of the measure using input of individuals with presbyopia
Recall period	The choice of recall period that is most suitable depends on: the instrument's purpose and intended use; the variability, duration, frequency, and intensity of the concept measured; the disease or condition's characteristics; and the tested treatment. Items with short recall periods or items that ask patients to describe their current or recent state are usually preferable.	• Length of recall period
Reproducibility	Stability of scores over time when no change is expected in the concept of interest	• Intraclass correlation coefficient *(ICC ≥0.70 was considered acceptable)[1]*
Internal consistency	Extent to which items comprising a scale measure the same concept	• Cronbach's alpha for summary scores *(>0.70 but less than <0.95 was considered acceptable)[2]*
Construct validity	Evidence that relationships among items, domains, and concepts conform to *a priori* hypotheses concerning logical relationships that should exist with measures of related concepts or scores produced in similar or diverse patient groups	• Strength of correlation testing *a priori* hypotheses (discriminant and convergent validity) *(At least one Pearson's correlation coefficient (r) value categorized as moderate (0.25-0.50) or strong (>0.50) was considered acceptable)[3]* • Degree to which the PRO instrument can distinguish among groups hypothesized, *a priori,* to be different (known groups validity) *(A statistically significant (P < 0.05) difference in at least one comparison of patient subgroups with differing clinical features was considered acceptable)[2]*
Ability to detect change	Evidence that a PRO instrument can identify differences in scores over time in individuals or groups (similar to those in the clinical trials) who have changed with respect to the measurement concept	• Evidence of differences in within person change over time between groups who would be expected to differ in terms of changes (e.g. between stable and improved groups) *(A statistically significant (P < 0.05) change in scores following an intervention in at least one longitudinal validation study or one RCT in individuals with presbyopia was considered acceptable)*
Responder definition	The individual patient PRO score change over a predetermined time period that should be interpreted as a treatment benefit, derived using anchor-based methods	• Available MID (minimal important difference)/ responder definition in presbyopia

1. David L. Streiner GRN, and John Cairney. Health Measurement Scales: A practical guide to their development and use: Oxford University Press 1995.
2. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika* 1951;16(3):297-334.

3. Cohen EJ. Statistical power analysis for the behavioral sciences. Second ed: Lawrence Erlbaum Associates 1988.

Supplementary Table S2. Presbyopia studies identified from literature search

Reference	Patient (n) Demographic	Age	Study type	Treatments/ Intervention	PRO/Subjective Measurement	Result
Sivardeen, A., Laughton, D., & Wolffsohn, J. S. (2016). Investigating the utility of clinical assessments to predict success with presbyopic contact lens correction. Contact Lens and Anterior Eye, 39(5), 322-330.	35 Presbyopic participants with a prescribed reading addition	54.3	Randomized crossover trial	Crossover trial of Air Optix Aqua multifocal, PureVision 2 for Presbyopia, Acuvue OASYS for Presbyopia, Biofinity multifocal and monovision with Biofinity contact lenses	Near Activity Visual Questionnaire (NAVQ)	Better quality of life score was observed with the Biofinity compared to OASYS (p=0.047). No significant difference was found between scores of Air Optix Aqua, PureVision 2, and monovision lenses (p>0.05)
Luger, M. H. A., McAlinden, C., Buckhurst, P. J., Wolffsohn, J. S., Verma, S., & Arba Mosquera, S. (2015). Presbyopic LASIK using hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. American Journal of Ophthalmology, 160(3), 493-505.	32 Patients treated with the hybrid bi-aspheric micromonovision technique to correct presbyopia	51	Consecutive case series	Central presbyLASIK	Quality of Vision (QoV) NAVQ	QoV score worsened postoperatively (p=0.02), mainly with more patients experiencing haloes (p=0.002), blurred vision p=0.02), and double vision (p =0.01). NAVQ scores were found to be stable at 3 months follow-up time
Gupta, N., Naroo, S. A., & Wolffsohn, J. S. (2009). Visual comparison of multifocal contact lens to monovision. Optometry and Vision Science, 86(2), E98-E105.	20 Presbyopes without previous contact lens experience	55	Randomized prospective study	Bausch & Lomb PureVision multifocal contact lens vs. PureVision single vision contact lenses	NAVQ	No difference was observed in subjective assessment of near ability for both types of contact lens (p=0.52)
Gundersen, K. G., & Potvin, R. (2016). Comparison of visual outcomes and subjective visual	55 Patients with either trifocal or blended bifocal Intraocular lenses (IOLs)	59.5	Non-interventional two-arm diagnostic study	ReSTOR +2.5/+3.0 “blended bifocal” modality vs CZM AT LISA tri 839MP IOL	National Eye Institute Visual Function Questionnaire	No statistically significant difference in the scores of NEI VFQ and QoV were observed between

quality after bilateral implantation of a diffractive trifocal intraocular lens and blended implantation of apodized diffractive bifocal intraocular lenses. Clinical Ophthalmology, 10, 805-811.					(NEI VFQ)-near vision sub-scale only QoV	patients with trifocal and those with blended bifocal IOLs, during their single routine follow-up visit between 3 and 24 months after surgery Higher number of trifocal subjects reported observed visual disturbances as "bothersome" (p=0.05)
Gundersen, K. G., & Potvin, R. (2016). Comparison of visual outcomes after implantation of diffractive trifocal toric intraocular lens and a diffractive apodized bifocal toric intraocular lens. Clinical Ophthalmology, 10, 455-461.	22 Patients seeking presbyopia correction at the time of cataract surgery	66	Randomized prospective study	Bilateral implantation of a trifocal toric or a bifocal toric lens	NEI VFQ-25	No statistically significant differences by group were observed on NEI VFQ (p>0.26 in all cases) at 3 months postoperatively
Gundersen, K. G., & Potvin, R. (2013). Comparative visual performance with monofocal and multifocal intraocular lenses. Clinical Ophthalmology, 7, 1979-1985.	94 Patients with different binocular IOLs implanted	63.2	Post-intervention diagnostic study	Three groups of patients were studied: those with bilateral AcrySof IQ monofocal lenses implanted, those with bilateral AcrySof IQ ReSTOR +3.0 D lenses implanted, and those with bilateral AcrySof IQ ReSTOR +2.5 D lenses implanted	QoV NEI VFQ near vision sub-scale only	No significant difference was observed in the NEI VFQ scores by IOL (p>0.07) in patients returning for a single diagnostic visit between 3 and 6 months after surgery QoV scores on subscales of frequency, severity and bothersome were better/lower with the monofocal IOL and similar between the two multifocal IOLs
Wang Yin, G. H., McAlinden, C., Pieri,	69 Hyperopic presbyopes	53.8	Prospective cohort study	Presbyopic surgery by central	QoV	Visual side effects as assessed by QoV

E., Giulardi, C., Holweck, G., & Hoffart, L. (2016). Surgical treatment of presbyopia with central presbyopic keratomileusis: One-year results. Journal of Cataract and Refractive Surgery, 42(10), 1415-1423. .				presbyopic LASIK with corneal asphericity modulation by the Custom Q algorithm of the Wavelight EX500 wavefront-guided excimer laser (Alcon Surgical, Inc.).		were highest in frequency and severity at 1-month post-surgery, showed a decrease at 3 months before returning to close to baseline or preoperative level 12 months after surgery
Gierek-Ciaciura, S., Cwalina, L., Bednarski, L., & Mrukwa-Kominek, E. (2010). A comparative clinical study of the visual results between three types of multifocal lenses. Graefe's Archive for Clinical and Experimental Ophthalmology, 248(1), 133-140.	30 Patients with cataract, and corneal astigmatism of 1.5 diopters or less to undergo phacoemulsification with artificial multifocal lens implantation(correction of presbyopia)	56.3	Prospective, nonrandomized, comparative trial	Three different multifocal lenses: refractive ReZoom, diffractive and refractive Acrysof ReSTOR and diffractive Tecnis	Visual Function Index-14 (VF-14)	The results in the VF-14 test improved in 83% of patients, and did not vary significantly between patients with different multifocal lenses
Kidd Man, R. E., Fenwick, E. K., Sabanayagam, C., Li, L. J., Gupta, P., Tham, Y. C., .Lamoureux, E. L. (2016). Prevalence, Correlates, and Impact of Uncorrected Presbyopia in a Multiethnic Asian Population. American Journal of Ophthalmology, 168, 191-200.	7890 Presbyopes	57.1	Population-based cross-sectional study	None	Visual Function Index-11 (VF-11)	Uncorrected presbyopia was associated with significantly worse composite VF scores with reduced ability to perform vision-specific distance and near tasks ($p<0.05$)
Soler Tomas, J. R., Fuentes-Paez, G., & Burillo, S. (2015). Symmetrical versus asymmetrical	30 Hyperopic presbyopes	52.7	Longitudinal, comparative case series	Symmetrical Versus Asymmetrical PresbyLASIK	CataractTyPE Spec	After 18 months, no significant difference was observed between groups although patients in

PresbyLASIK: Results after 18 months and patient satisfaction. Cornea, 34(6), 651-65						asymmetrical presbyLASIK group reported greater vision satisfaction and less near vision difficulties.
Whitman, J., Hovanesian, J., Steinert, R. F., Koch, D., & Potvin, R. (2016). Through-focus performance with a corneal shape-changing inlay: One-year results. Journal of Cataract and Refractive Surgery, 42(7), 965-971.	30 Emmetropic patients with presbyopia	50.7	Prospective nonrandomized clinical trial	Raindrop Near Vision Inlay designed to modify the surface shape of the central cornea.	National Eye Institute - Refractive Error Quality Of Life Instrument – 42 (NEI RQL-42) Only a single item assessing patient satisfaction with correction was used	93% of patients were satisfied one year after surgery. Two patients indicated dissatisfaction in domains difficulty with reading and work or hobbies.
Whitman, J., Dougherty, P. J., Parkhurst, G. D., Olkowski, J., Slade, S. G., Hovanesian, J., Koch, D. D. (2016). Treatment of presbyopia in emmetropes using a shape-changing corneal inlay one-year clinical outcomes. Ophthalmology, 123(3), 466-475.	373 Emmetropic patients with presbyopia	51.3	Prospective nonrandomized clinical trial	Raindrop Near Vision Inlay	NEI RQL-42 Only a single item assessing patient satisfaction with correction was used	Compared to 66% before surgery, it was found that 92% of subjects post-surgery were either somewhat, very, or completely satisfied with their inlay vision
Blaylock, J. F., Si, Z., Aitchison, S., & Prescott, C. (2008). Visual function and change in quality of life after bilateral refractive lens exchange with the ReSTOR multifocal intraocular lens. Journal of Refractive Surgery, 24(3), 265-273.	30 Presbyopes including 19 myopes and11 hyperopes	55.9	Prospective non-interventional study	Bilateral implantation of the Acrysof SA60D3 ReSTOR IOL	NEI RQL-42	Overall, the 3 or 6 month postoperative mean scores on subscales of expectations, activity limitations, dependence on correction, appearance, and satisfaction were statistically significantly

						higher (p<0.05) compared to scores prior to surgery The scores of near vision and dependence on correction in hyperopes were significantly higher indicating greater improvement (p<0.05) compared to myopes at 3 or 6 months after surgery
Richdale, K., Mitchell, G. L., & Zadnik, K. (2006). Comparison of multifocal and monovision soft contact lens corrections in patients with low-astigmatic presbyopia. Optometry and Vision Science, 83(5), 266-273.	38 Low- Astigmatic Presbyopes	50.1	Randomized crossover study	Bausch & Lomb SofLens Multifocal (MF) vs monovision (MV) (SofLens 59)	NEI RQL-42	Compared to baseline (habitual correction), significant differences were observed on the subscales of Clarity of vision (pMF/MV=0.05) (worse with both multifocal and monovision contact lenses), Symptoms (pMF/M =0.99) (lesser symptoms at baseline), and Appearance (pMF/MV=0.05) (improvement with contact lenses)
Cochener, B., Fernandez-Vega, L., Alfonso, J. F., Maurel, F., Meunier, J., & Berdeaux, G. (2010). Spectacle independence and subjective satisfaction of ReSTOR multifocal intraocular lens after cataract or	304 Patients treated for bilateral presbyopia or age-related cataract using phaco-emulsification and bilateral implantation of the ReSTOR® IOL	65.6	Cross-sectional, noncomparative study	None	Freedom From Glasses Value Scale (FGVS)	Based on FGVS score, a global positive change in vision was noted in 93.1% of patients while 88.2% stated their vision had improved Sight problems were noted to be resolved in 78.0% of patients

presbyopia surgery in two European countries (pp. 81-89).						
Hipsley, A., Hall, B. (2017) Visual Outcomes 24 Months after LaserACE. Eye and Vision, 4:15.	26 Patients demonstrating loss of accommodative function	49.7	Prospective noncomparative study	LaserACE surgery	CatQuest 9SF Survey	There was significant improvement in the postoperative satisfaction score (p=0.000016) and near vision ability of the patients particularly in areas of doing handwork and reading text (p<0.025).
Labiris, G., … Kozobolis, V. P. (2017) Evaluation of activities of daily living following pseudophakic presbyopic correction. Eye Vis (Lond), 4:2.	122 Presbyopes	60.3	Prospective non-interventional study	Mini-monovision (MoG) cataract extraction and bilateral multifocal lenses implantation (MfG)	VF-14	The postoperative scores of MoG patients on the near vision subscale were worse compared to those with MfG (p=0.05)