Validation of the Dutch Patient-Reported Spectacle Independence Questionnaire (PRSIQ)

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21890

Source
NTR

Brief title
PRSIQ-NL

Health condition

cataract

Sponsors and support

Primary sponsor: Relationship between spectacle dependency, as assessed with PRSIQ-NL, and visual functioning, as assessed with Catquest-9SF-NL, after cataract surgery.
Source(s) of monetary or material Support: Wetenschapsfonds Amphia (Amphia en MSB-A)

Intervention

Outcome measures

Primary outcome

Validation of the Dutch version of the PRSIQ by means of Rasch analysis and item response

theory (IRT) analysis and test-retest reliability.

Secondary outcome

Differences in Rasch and IRT scores between groups of patients with different types of IOLs, patients with different set refractive targets and healthy subjects.

Study description

Background summary

Whether a patient will use spectacles after cataract surgery typically depends on the type of intraocular lens (IOL) implanted, any remaining refractive error, and personal preference of the patient. The Patient-Reported Spectacle Independence Questionnaire (PRSIQ) is a patient-reported outcome measure (PROM) that evaluates what patients say about their need for spectacles, what they use in daily life, and how they function without spectacles. More specifically, it contains a total of 11 questions on the need, use, and wear of spectacles to see at far, intermediate, and near. It is available in the English language and has been validated for use in the United States. Recently, we developed a formal Dutch translation of the questionnaire. Our main objective is to validate the Dutch translation of the PRSIQ and assess its test-retest reliability. Our secondary objective is to evaluate any differences in spectacle dependency between patients with different types of IOLs and healthy subjects of different ages. Our tertiairy objective is to assess the relationship between spectacle dependency and experienced visual functioning after cataract surgery, assessed with the Catquest-9SF-NL PROM.

Study objective

The PRSIQ-NL is a valid questionnaire to assess the need, use, and wear of spectacles to see at far, intermediate, and near in patients with cataract and healthy subjects.

Study design

Preoperatively and postoperatively.

Intervention

Cataract patients will fill in the PRSIQ-NL questionnaire before and 3 months after surgery. Half of them will fill in a second PRSIQ-NL questionnaire, both preoperatively and postoperatively, to assess reproducibility. Healthy subjects will fill in on PRSIQ-NL questionnaire. Half of them will fill in a second PRSIQ-NL questionnaire to test reproducibility. In addition, automated refractometry will be performed in healthy subjects to assess their refractive error.

Contacts

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Eligibility criteria

Inclusion criteria

Cataract patients: age of at least 18 years, diagnosis of cataract in both eyes, having consented to and is planned to undergo cataract surgery in both eyes, expected best-corrected distance Snellen decimal visual acuity of 0.7 or better in each eye, planned for implantation in both eyes of a a) non-toric monofocal IOL with target emmetropia, b) non-toxic monofocal IOL with target mild myopia, c) toric monofocal IOL with target emmetropia, d) non-toric enhanced far-focus IOL, e) extended depth of focus IOL with target emmetropia or monovision, f) trifocal IOL with target emmetropia, willing and able to participate in both preoperatieve and postoperative examination, and agreeing to sign the consent form. Healthy subjects: age of at least 18 years, no ocular or visual complaints (other than using spectacles or contact lenses), no significant history of ocular disease (including cataract, corneal disease, glaucoma, and posterior segment eye disease), no history of ocular surgery (including cataract surgery and corneal refractive surgery), willing and able to participate in examinations, and agreeing to sign the consent form.

Exclusion criteria

Cataract patients: insufficient understanding of the Dutch language to comply with study procedures, best-corrected distance Snellen decimal visual acuity of <0.7 in either eye after cataract surgery, any comorbidity (other than cataract) that may significantly affect visual function, influence subjective ocular visual symptoms, or prolong visual recovery after surgery, such as significant macular degeneration, glaucoma, diabetic eye disease, ocular surface disease, corneal dystrophy, corneal opacification, significant vitreous opacities (such as asteroid hyalosis and clinically significant floaters), and history of cerebral vascular accident, a history of ocular surgery (e.g., corneal refractive surgery), an increased risk of

complicated cataract surgery, such as lens subluxation or (phaco)iridodonesis, brunescens cataract, rubra cataract, ingrains cataract, or posterior pole cataract, history of ocular trauma, and a complication, either perioperatively or postoperatively, that significantly affects vision and has not resolved before 3 months after surgery.
Healthy subjects: insufficient understanding of the Dutch language to comply with study procedures.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8815
Other	MEC-U : Not yet appointed

Study results