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Visual function in patients implanted with Panoptix trifocal intraocular lens

Submission date	Recruitment status	[_] Prospectively registered
24/04/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2019	Eye Diseases	

Plain English summary of protocol

Background and study aims
Cataracts occur when changes in the lens of the eye cause it to become less clear, resulting in cloudy or misty vision. Cataract surgery involves removing the cloudy lens through a small incision in the eye and replacing it with a clear, plastic intraocular lens (IOL). IOL design is continuously changing in order to improve visual outcomes, increase patient satisfaction and achieve spectacle-independence after cataract surgery. Diffractive bifocal IOLs were designed with concentric rings which create a near and far focus to improve visual function and achieve adequate vision at all distances without spectacles. A drawback of bifocal IOLs is that intermediate performance is often below the requirements for activities such as computer use or looking at the dashboard while driving. Trifocal technology has been developed to create a true intermediate focus to overcome these difficulties. The new AcrySof PanOptix® trifocal IOL (Alcon Research, Fort Worth, TX, USA) has been developed to improve light transmission and distribution between the three focuses and to improve intermediate vision. So far there have been no reports on daily practice clinical outcomes with this new trifocal IOL. The aim of this study is to assess the clinical outcomes of patients implanted with the PanOptix lens.

Who can participate?
Patients over 18 years old with cataracts in both eyes who are scheduled to be implanted with the PanOptix lens

What does the study involve?
One month after undergoing cataract surgery and lens implantation, participants undergo a series of tests to determine their visual function for far, intermediate and near distances, as well as in different light settings.

What are the possible benefits and risks of participating?
Participants do not gain anything by participating, but the information obtained will help assess the clinical performance of the IOL so that in the future, ophthalmologists will be able to recommend the best IOL for each patient depending on their lifestyle and visual requirements. There are no known risks as all of the tests are non-invasive.

Where is the study run from?
Clinica Rementería (Spain)

When is the study starting and how long is it expected to run for?
January to October 2016

Who is funding the study?
Clinica Rementería (Spain)

Who is the main contact?
Dr Inés Contreras

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UCM-2016-01

Study information

Scientific Title
Visual function in pseudophakic patients with bilateral implantation of Acrysof IQ Panoptix Trifocal intraocular lens

Study objectives
Intraocular lens (IOL) design is continuously evolving in order to improve visual outcomes, increase patient satisfaction and achieve spectacle-independence after cataract surgery. Diffractive bifocal IOLs were designed with concentric rings which create a near and far focus;

pupillary changes help to adjust light distribution between both focuses to improve visual function. A drawback of bifocal IOLs is that intermediate performance is often below the requirements for activities such as computer use or correct dashboard perception while driving. Trifocal technology has been developed to create a true intermediate focus to overcome these difficulties. The new AcrySof PanOptix® trifocal IOL (Alcon Research, Fort Worth, TX, USA) has been developed to improve light transmission and distribution between the three focuses. Its design aims to decrease pupillary dependence for excellent performance and to improve intermediate vision. To the best of our knowledge, so far there have been no reports on daily practice clinical outcomes with this new trifocal IOL. The purpose of this study was to evaluate clinical outcomes in patients with bilateral PanOptix lens implantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Hospital Clínico San Carlos, Madrid, Spain, 16/03/2016, ref: UCM-2016-01

Study design
Single-center longitudinal interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Cataracts

Interventions
The study recruited over six months and followed each individual patient for one month after undergoing bilateral cataract surgery. Patients were not randomised, the decision to undergo surgery and the type of lens implanted was taken before entering the study, since the purpose was to characterise visual outcomes with the study intraocular lens

Candidates for cataract surgery underwent an extensive ophthalmic evaluation. After an in-depth discussion of the characteristics of monofocal and multifocal lens, the ophthalmologist recommended the intraocular lens best suited to the patient. If the recommended lens was the Panoptix IOL, the patient was considered for inclusion in the study. The purpose of the study was explained to patients with none of the exclusion criteria and patients agreeing to participate signed an informed written consent.

One month after surgery, the following specific explorations of the study were performed: monocular defocus curve; mono- and binocular uncorrected visual acuity in photopic and mesopic conditions, for far, intermediate and near distances; subjective refraction and binocular contrast sensitivity in photopic and mesopic conditions.

Intervention Type
Procedure/Surgery

Primary outcome measure
Mono- and binocular uncorrected visual acuity in photopic and mesopic conditions, for far, intermediate and near distances, measured at 1 month after surgery:
1.1. Distance visual acuity measured using a 22" LED liquid crystal display system (CC-100 HW 5.0 Series, Topcon) that can display ETDRS charts at 4 meters
1.2. Near visual acuity measured using the Logarithmic Visual Acuity Chart 2000 New ETDRS (Precision Vision, Lasalle, IL) at 33 centimeters
1.3. Intermediate visual acuity, measured with the same chart as near acuity (Logarithmic Visual Acuity Chart 2000 New ETDRS (Precision Vision, Lasalle, IL)) and the value adjusted for the 60 centimeter distance
For photopic visual acuity measurements, room luminance was 85 candelas [cd]/m2. Mesopic visual acuity measured after dark adaptation (10 minutes in the testing room under mesopic conditions) with the room luminance set to 3 cd/m2

Secondary outcome measures
1. Subjective refraction, performed with the ETDRS chart at 4 meters
2. The defocus curve, performed monocularly with the patients observing the ETDRS chart through lenses starting at -5.00 D and increasing in 0.50 D steps to +3.00 D
3. Binocular contrast sensitivity, measured at spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd) using the functional acuity contrast test (Test SV-1000) of the CC-100 HW 5.0 Series system
4. Binocular contrast sensitivity after dark adaptation (10 minutes in the testing room under mesopic conditions), measured at spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd) using the functional acuity contrast test (Test SV-1000) of the CC-100 HW 5.0 Series system
5. Visual function, assessed using Catquest 9-SF questionnaire
Measured at 1 month after surgery

Overall study start date
11/01/2016

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Patients over 18 years old
2. Candidates to bilateral cataract surgery
3. Planned bilateral Panoptix intraocular lens implantation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 patients

Key exclusion criteria
1. Presence of any ocular pathology which could compromise visual recovery
2. Preoperative astigmatism higher than 1.5 Diopters (D) on corneal topography
3. Abnormal iris
4. Intra- or postoperative complications

Date of first enrolment
01/04/2016

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
Spain

Study participating centre
Clinica Rementería
c/ Almagro 36 Entreplanta Dcha
Madrid
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Sponsor information

Organisation
Clinica Rementería

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b3d7291

Funder(s)

Funder type
Other

Funder Name
Clinica Rementería

Results and Publications

Publication and dissemination plan
A paper has been written and is under consideration for publication

Intention to publish date
24/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Inés Contreras

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/05/2017	29/01/2019	Yes	No