ISRCTN35178162 https://doi.org/10.1186/ISRCTN35178162

Comparison of peripheral iridectomy operating methods for posterior chamber phakic intraocular lens implantation in patients with brown irises

Submission date
04/03/2013

Recruitment status
No longer recruiting

Registration date
14/03/2013

Overall study status
Completed

Last Edited
06/05/2016

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The implantable contact lens (ICL) implantation is one of the major recent innovations in eye surgery. An effective peripheral iridectomy PI (surgical removal of a portion of the iris) could effectively prevent pupillary block and the subsequent high intraocular pressure (IOP) after ICL implantation. Currently, most surgeons apply preoperative YAG PI (a laser peripheral iridectomy). However, the majority of previous surgeries were performed on European patients, whose irises are mainly either blue or gray and thus contain less pigment than those of Asians, and the irises of Europeans are generally thinner than those of Asians and are easier to drill via laser drilling. Thus, in the Asian population, it is difficult to simultaneously drill two large and unblocked holes because the eye pigment dispersion can be severe. Surgical PI was performed by some surgeons on patients with dark-brown irises, and achieved good results. This study only wanted to compare the complications and the vision recovery between the YAG PI and Surgical PI when they were performed in patients with brown irises in ICL implantations, and to find which is more suitable.

Who can participate?
From January of 2011 to June of 2012, 46 patients (92 eyes) with high myopia who underwent an ICL implantation were enrolled in this study, including 26 males and 20 females who all had dark brown irises and were aged between 19 and 41.
The preoperative diopter was between -9.50 D and -22.0 D (spherical equivalent). The anterior chamber depth was greater than 2.8 mm. The anterior chamber angle was open. The endothelial cell count was greater than 2,500 cells/mm2. The peripheral retina was normal. The exclusion criteria were the presence of other eye disorders and systemic disorders.

What does the study involve?
All the patients were randomized to three groups. Among these participants, YAG PI and Surgical PI were performed two weeks before the ICL implantation and intraoperative PI was performed during ICL implantation. All of the YAG PI procedures were performed by the same

surgeon, and all of the preoperative PI and ICL implantations were performed by the same surgeon.
Follow-up examinations were performed during the 1 day, 1 week, and 1 and 3 months after the ICL implantation. The possible complications were compared among the three iridectomy approaches. The visual disturbance questionnaire was administered to the study patients to inquire whether they experienced any visual disturbances. The operation duration was also compared among the three iridectomy approaches. The postoperative recovery of visual acuity and the patients acceptance and satisfaction were assessed.

What are the possible benefits and risks of participating?
All participants had received ICL implantation performed by a high-level surgeon to treat the myopia. And all the follow-up examinations were free.
In this study the surgery methods including YAG PI and surgerical PI were all widely performed in the whole world for a long time, and the safety and effectiveness to humans were all confirmed. All participants had the same risks of the possible complications including iris bleeding, iris prolapses, pigment dispersion, visual disturbances, increased IOP and loss of visual acuity.

Where is the study run from?
Department of Ophthalmology, ChengDu Military General Hospital, ChengDu, China,.

When is the study starting and how long is it expected to run for?
The study started in January of 2011 and ended in June of 2012.

Who is funding the study?
Research funding from Chengdu Military General Hospital, China

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of peripheral iridectomy operating methods for posterior chamber phakic intraocular lens implantation in patients with brown irises: a prospective randomized controlled trial

Study objectives
An effective peripheral iridectomy (PI) could effectively prevent pupillary block and the subsequent high intraocular pressure (IOP) after an phakic posterior chamber implantable contact lens (ICL) implantation. Currently, most surgeons apply preoperative neodymium: yttrium-aluminum-garnet (Nd:YAG) laser peripheral iridectomy (YAG PI), which is also recommended by STAAR Surgical Company. But for most Asians which have dark-brown and thick irises, therefore, it is difficult to drill two unblocked and large holes with a YAG laser at one time. Then, surgical PI maybe more suitable for a ICL implantation for the treatment of high myopia in patients with brown irises.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of ChengDu Military General Hospital, 29/12/2010

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Refractive operation

Interventions
In this study the main interventions were three different PI methods.

YAG PI: The two iridectomy holes were drilled at the 10:30 oclock and 1:30 oclock positions, separated by approximately 90 degrees. The standard argon laser settings (0.1 to 0.2 second duration, 50 mm spot size, 700 to 1500 mW) were initially used to form a crater in the iris stroma. After deep stromal iris penetration or the first plume of iris pigment epithelium release, the Nd:YAG laser was immediately used to achieve iris perforation and remove the iris pigment epithelium. The complete penetration of the pigment epithelium was confirmed by transillumination.

Surgical PI: First, a 4-mm incision was cut at the 12:00 oclock position of the conjunctival edge. Subsequently, a 3-mm corneal incision was made at the corneal limbus. Then, the peripheral iris was grasped and pulled out using iris forceps and then removed. For patients receiving the two aforementioned PI approaches, a 3.2-mm main incision was positioned at the temporal side of the transparent corneal limbus for the ICL implantation. Two auxiliary penetrations were made at the 12:00oclock and 6:00oclock positions. A routine implantation of the ICL lens was applied, which was followed by a carbachol application for miosis.

Intraoperative PI during ICL Implantation: A 3.2-mm main incision was made at the 12:00 oclock position during the ICL implantation surgery. Two auxiliary penetrations were made at the 3:00 o clock and 9:00 oclock positions. The ICL was implanted through the main incision and then rotated to a horizontal orientation. After miosis with carbachol, the PI was performed at the 12: 00oclock position.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. The incidence of the complications of the three PI groups. Iris bleeding, iris prolapses and pigment dispersion, measured using slit-lamp examination.
2. The visual disturbance, measured using questionnaire
3. Increased IOP, measured using non contact tonometers

Secondary outcome measures
1. The operation duration of ICL implantation
2. The postoperative recovery of visual acuity, measured using logarithm of the minimum angle of resolution [LogMAR]

Measured during the day 1 and 1 and 2 weeks after pre-operative YAG PI and surgical PI. And after the ICL implantation the follow-up examinations were performed during the d 1ay, 1 week, and 1 and 3 months.

Overall study start date
01/01/2011

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. The preoperative diopter was between -9.50 D and -22.0 D (spherical equivalent)
2. The anterior chamber depth was greater than 2.8 mm
3. The anterior chamber angle was open. The endothelial cell count was greater than 2,500 cells /mm2. The peripheral retina was normal.
4. Men and women, age range from 19 to 41

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
46

Key exclusion criteria
The presence of other eye disorders and systemic disorders

Date of first enrolment
01/01/2011

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
China

Study participating centre
270 Tianhui Road
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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https://ror.org/01bk73674

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chengdu Military General Hospital (China) - research funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/05/2016		Yes	No