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A modified surgical approach for treating lower eyelid inversion (entropion) in Asian patients

Submission date
18/03/2020

Recruitment status
No longer recruiting

Registration date
10/05/2020

Overall study status
Completed

Last Edited
18/05/2020

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Lower eyelid involutional entropion causes the eyelid margin and eyelashes to rotate inward and irritate the eye. It usually occurs in individuals above 50 years of age. Many surgical methods have been designed to correct the contributing factors, but even so, recurrence is still a troublesome complication. To reduce the risk for recurrence, surgeons have modified the procedures according to the patients. The type of surgical procedure to be adopted should also be determined according to racial anatomical differences. Therefore, researchers have proposed a new surgical method modified from the Quickert procedure. This surgical design can cover most of the triggering causes in Asians. The aim of this study is to review the outcomes of patients who have undergone this surgery during the past five years (from January 2012 to October 2017).

Who can participate?
Patients aged over 55 years who had been diagnosed with involutional entropion and underwent the new surgical technique for repair

What does the study involve?
Information is collected from each patient's medical record including surgical success, complications and recurrence. All surgical procedures and examinations are performed by a single oculoplastic surgeon (CY Chen) using consistent techniques.

What are the possible benefits and risks of participating?
The surgical procedure was modified from the Quickert procedure in some steps, and the Quickert procedure has been well confirmed in the correction of lower lid entropion. The modified surgical procedure is thought to be safe and effective, and result in less recurrence, overcorrection and complication.

Where is the study run from?
Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
July 2018 to January 2019

Who is funding the study?
Chang Gung Memorial Hospital (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
201801039B0D001

Study information

Scientific Title
Using a modified Quickert procedure combined with prolapsed fat removal to correct involutional lower eyelid entropion in Asians

Study objectives
The researchers propose a new surgical method modified from Quickert procedure. This surgical design can cover most of the triggering causes in Asians.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/07/2018, Chang Gung Medical Foundation Institutional Review Board (199, Tung Hwa North Road, Taipei, Taiwan, 10507, Republic Of China; +886 (0)3 3196200; ccyi@cgmh.org.tw), IRB No.: 201801039B0

Study design
Retrospective observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Involutional lower eyelid entropion

Interventions
Every outpatient receiving the modified Quickert procedure is arranged regular follow-ups at the outpatient clinic at the time of pre-op, 1 week and 2 months after surgery, and then when needed according to the patient's other chronic eye diseases.

Intervention Type
Procedure/Surgery

Primary outcome measure
Success rate: successful surgery was defined as a normal eyelid position at rest, and inability to induce entropion by provocative test. Success rate was measured using external eye photography and provocative test performed in clinic, measured at follow-up after 2 months, and also after 12 months for patients when needed due to their other ocular diseases

Secondary outcome measures
Measured at follow-up after 2 months, and also after 12 months for patients when needed due to their other ocular diseases:
1. Recurrence rate: recurrence defined as either the majority of eyelashes remained in contact with the globe or persistent irritation/keratitis in the presence of residual in-turned eyelashes
2. Overcorrection rate: overcorrection defined as ectropion and conjunctiva inside out
3. Complication rate: complication defined as formation of symblepharon, wound infection or wound dehiscence during the follow-up period

Overall study start date
04/07/2018

Completion date
03/01/2019

Eligibility

Key inclusion criteria
1. Patients aged > 55 years
2. Involutional lower eyelid entropion confirmed by the presenting of trichiasis, eyelid laxity, vertical laxity, and abundant of orbicularis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Total final enrolment
97

Key exclusion criteria
1. Patients with concurrent eyelid pathologies such as malignant tumor, cicatricial entropion caused by trauma, infection or inflammatory, spastic entropion caused by essential blepharospasm, hemifacial spasm-involutional entropion
2. Post-operative follow-up period of < 2 months
3. Aged < 55 years at the time of surgery
4. Patients with any history of previous surgery for involutional entropion

Date of first enrolment
01/01/2012

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
Taiwan

Study participating centre

Chang Gung Memorial Hospital
Department of Ophthalmology
6, Sec, West, Chia Pu Road, Pu Zih City
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Sponsor information

Organisation
Chiayi Chang Gung Memorial Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.cgmh.org.tw/branch/branch_jia.htm

ROR
https://ror.org/04gy6pv35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chiayi Chang Gung Memorial Hospital

Alternative Name(s)
Chia-Yi Chang-Gong Memorial Hospital, Chang Gung Memorial Hospital, Chia-Yi

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
Taiwan

Results and Publications

Publication and dissemination plan
Planned publication in an ophthamology or plastic surgery journal

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		29/04/2020	18/05/2020	No	No