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Comparison of dry eye syndrome and corneal sensation after femtosecond- and microkeratome-assisted LASIK

Submission date 28/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/03/2011	**Overall study status** Completed	
Last Edited 11/04/2014	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Comparison of dry eye syndrome and corneal sensation after femtosecond- and microkeratome-assisted LASIK: a single-centre, prospective, comparative, non-randomised study

Acronym
LASIK:Laser in situ keratomileusis

Study objectives

The corneal flap of LASIK can be created by using a mechanical microkeratome or a femtosecond laser. The flap-related complications by mechanical microkeratomes occur in as many as 5% of cases and occasionally result in delayed visual recovery or permanent vision loss. The femtosecond laser is a safe and effective alternative to mechanical microkeratomes. It may provide greater safety, better reproducibility and predictability of flap diameter and thickness and more precise control of hinge size and location. However, the effects of different flap-creating methods by femtosecond or mechanical microkeratome on post-LASIK dry eye parameters have rarely been reported. In this study, we used both subjective questionnaire and objective parameters to analyse the effects of the two methods for creating corneal flaps on dry eye syndrome after LASIK surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted to the Institutional Review Board at Chang Gung Memorial Hospital on 2/25/2011. Registered number:99-2939A3 -Approval pending as of 04/03/2011

Primary study design
Interventional

Study design
Single-centre prospective comparative non-randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nearsightedness (myopia)

Interventions
In femtosecond (FS) group, the 60 KHz IntraLase femtosecond laser (Abbott Medical Optics, Inc.) was preprogrammed for each procedure with a planned flap diameter of 9.0 millimeter (mm), flap thickness of 110 µm, hinge angle of 70 degrees, raster energy of 2.0 microjoule (µJ) and side-cut energy of 3.0 µJ. In mechanical microkeratome (MK) group, the flap was created using the Moria M2 microkeratome (Moria) with a 110 µm plate depth and 9.0 mm diameter suction head. Laser ablation was performed using the Visx S4 (Abbott Medical Optics, Inc.) laser using an optical zone of 6.5 mm under topical anesthesia with the intended unablated corneal thickness more than 250ìm. Postoperatively, all patients were given Tobradex® (tobramycin and dexamethasone) ophthalmic solution (Pred Forte®) and ciprofloxacin ophthalmic solution (Ciloxan®) to use 4 times a day for 1 week. Patients were also directed to use artificial tears (Systane®, Alcon) 4 times a day for 1 week and then as needed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Corneal Sensation:
Corneal sensitivity was measured with a Cochet-Bonnet esthesiometer (Luneau Ophtalmologie, Chartres Cedex, France) (Macri A and Pflugfelder SC, 2000) consisting of a 60.0 mm adjustable nylon monofilament. The filament is soft when fully extended and becomes firm when retracted into the handpiece, creating a pressure gradient that ranges from 11 to 200 milligram(mg)/mm2. Patients were asked to look straight ahead and to indicate when the top of nylon filament was felt to touch the cornea. The measurement was started at 60.0 mm and the length of the filament was decreased by 5.0 mm increments to increase its rigidity. The corneal sensitivity was defined as the length of the filament that produced a first positive response. The higher the number obtained, the more sensitive the cornea.

Key secondary outcome(s)
1. Schirmers Basic Tear Secretion Test
Five minutes after installing a drop of proparacaine 1% into the conjunctival sac and drying the fornix, a sterile standardised Schirmer Tear Test Strip (Alcon Laboratories) was placed in both inferior fornices at the junction of the lateral and middle third for another 5 minutes. The strip wetting was measured and recorded in millimeters.
2. Tear Breakup Time
The fluorescein tear breakup time was evaluated 2 minutes after the inferotemporal bulbar conjunctiva was touched with a sodium fluorescein strip (Fluor-I-strip; Bausch & Lomb Pharmaceuticals Inc, Tampa, Florida). All patients were instructed to blink and the pre-corneal tear film was examined under blue-light illumination with a slit lamp. The time interval (seconds) from the last blink to the first area of breakup was recorded. Three separate readings were taken for each eye and the results were averaged.
3. Ocular Surface Staining
The conjunctival and corneal staining measurements were graded from 0 (none) to 3 (severe) based on the amount of staining. The cornea evaluated by fluorescein strips was divided into the central cornea, the superior, inferior, nasal, and temporal quadrants. Rose bengal staining was graded for cornea and each quadrants of superior, inferior, nasal, and temporal conjunctiva. The range of staining scores was from 0 to 15.
4. Ocular Surface Disease Index
The Ocular Surface Disease Index (OSDI) was developed by the Outcomes Research Group (Allergan) and consists of a 12-item questionnaire designed to assess the symptoms of ocular irritation consistent with dry-eye disease and their impact on vision-related functioning. The questions are divided into 3 categories including vision-related function, ocular symptoms and environmental triggers. The grading of the OSDI is from 0 to 4, where 0 indicates none of the time; 1, some of the time; 2, half of the time; 3, most of the time; and 4, all of the time. The total OSDI score was calculated on the basis of the following formula: (sum of scores for all questions answered) x 25 / (total number of questions answered) (Schiffman RM, et al. 2000). The results are numerical from 0 to 100, where the higher scores represent a greater disability.

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Patients of both sexes with low to moderate myopia (< -6.00 diopetrs, D) with or without astigmatism up to 3.00 D after informed consent
2. A minimum age of 18 and younger than 35 years, a normal ophthalmic examination except for

refractive error and a stable refraction
3. A minimum calculated residual corneal stromal bed thickness greater than 250 µm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients with keratoconus, severe dry eyes, herpetic eye diseases or other cornal diseases
2. Patients with active collagen vascular disease, autoimmune disorders
3. Pregnant or breast feeding
4. Patients with severe abnormal curvature of the cornea (more than 47D / less than 38-41D)
5. Patients with acute or subacute uveitis
6. Patients with unrealistic expectations

Date of first enrolment
01/03/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Taiwan

Study participating centre
4F, No. 405, Chang Gung I Hu Hsin Tsun, Kwei Shan Township
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Sponsor information

Organisation
Chang Gung Memorial Hospital (Taiwan)

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nobel Laser Eye Center (Taiwan)

Funder Name
Chang Gung Memorial Hospital (Taiwan)

Results and Publications

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	01/10/2013		Yes	No