Complete Summary

GUIDELINE TITLE

Laser refractive surgery.

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Laser refractive surgery. Singapore: Singapore Ministry of Health; 2001 Jul. 27 p. (MOH clinical practice guidelines; no. 4/2001). [32 references]

COMPLETE SUMMARY CONTENT

SCOPE
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SCOPE

DISEASE/CONDITION(S)

Myopia

GUIDELINE CATEGORY

Evaluation
Risk Assessment
Treatment

CLINICAL SPECIALTY

Ophthalmology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To identify appropriate inclusion and exclusion criteria for patients undergoing laser refractive surgery
- To provide parameters for the effective and safe practice of laser refractive surgery
- To identify training and certification requirements for ophthalmologists who want to incorporate laser refractive surgery into their clinical practice

TARGET POPULATION

Adults 18 years or older with a cycloplegic refraction of $\geq$ -1.0D and stable refractive error

INTERVENTIONS AND PRACTICES CONSIDERED

Patient Selection and Diagnostic/Preoperative Investigations

1. Appropriate patient selection for surgery based on patient age, ocular refraction, and possible contraindications to surgery.
2. Complete patient history, including medical history and drug allergies.
3. Measurement of unaided and best corrected distance and near visual acuity with Snellen or LogMAR charts.
4. Complete ocular examination including slit lamp biomicroscopy and dilated binocular indirect ophthalmoscopic examination of the retina.
5. Measurement of intraocular pressures by tonometry.
6. Measurement of refractive status with manifest and cycloplegic refraction.
7. Keratometry to document preoperative astigmatism.
8. Computerised videokeratography (corneal topography) to detect irregular astigmatism and keratoconus.
9. Central corneal pachymetry (for laser in situ keratomileusis [LASIK] only).
10. Measurement of pupil size in mesopic/scotopic conditions to allow appropriate counseling of potential night vision problems to patients with large pupils in dim lighting (optional).
11. Contrast sensitivity measurements (optional).
12. Endothelial cell counts preoperatively and postoperatively (for laser in situ keratomileusis only; optional).
13. Obtaining full informed patient consent for surgery.

Choice of Surgery Based on Ophthalmologist's Technical Experience and Appropriateness for Patient

1. Photorefractive keratectomy (PRK).
2. Laser in situ keratomileusis (LASIK).

Repeat Surgery for Undercorrection or Regression

MAJOR OUTCOMES CONSIDERED

- Unaided visual acuity
- Predictability (percentage of eyes within +/- 1.0D of the intended correction)
- Incidence of operative and post-operative adverse reactions or complications
- Loss of $\geq$2 Snellen lines of best spectacle corrected visual acuity

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level Ia: Evidence obtained from meta-analysis of randomised controlled trials.

Level Ib: Evidence obtained from at least one randomised controlled trial.

Level IIa: Evidence obtained from at least one well-designed controlled study without randomisation.

Level IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

Level III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Grade A (evidence levels Ia, Ib): Requires at least one randomized controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

Grade B (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality.

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is rated based on the level of the evidence and the grades of recommendation. Definitions of the grades of the recommendations (A, B, C, Good Practice Points) and level of the evidence (Level I-Level IV) are presented at the end of the Major Recommendations field.

C - Appropriate patients for laser refractive surgery should be at least 18 years old, with a cycloplegic refraction of $\geq$ -1.0D, and a stable refractive error. (Grade C, Level IV) (Note: See the original guideline for list of absolute and relative ocular and systemic contraindications to laser refractive surgery.)

C - A comprehensive medical and ophthalmic history, complete ocular examination including visual acuity, slit lamp biomicroscopy, dilated retinal examination, determination of refractive status, tonometry, keratometry and

corneal topography should be performed on all patients undergoing laser refractive surgery. (Grade C, Level IV)

C - A full informed consent for laser refractive surgery must be obtained from each patient prior to surgery. (Grade C, Level IV)

C - Sequential surgery between the two eyes of a patient is preferred over bilateral simultaneous surgery. (Grade C, Level IV)

A - The choice between photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) for the correction of a refractive error should be made based on the ophthalmologist's technical expertise, the equipment available and the patient's refractive error. The patient should also be informed of the choices available for laser refractive surgery and advised as to which of the 2 procedures would be appropriate. (Grade A, Level Ib)

B - There should be an interval of at least 3 months after the initial surgery for laser in situ keratomileusis and 6 months after the initial surgery for photorefractive keratectomy, before a repeat operation is carried out for undercorrection and regression after laser refractive surgery. (Grade B, Level IIb)

C - An Institutional Review Board should determine the training requirements and certify the competence and currency of ophthalmologists who practice laser refractive surgery. (Grade C, Level IV)

Grades of Recommendation

Grade A (evidence levels Ia, Ib): Requires at least one randomized controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

Grade B (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality.

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

Levels of Evidence

Level Ia: Evidence obtained from meta-analysis of randomised controlled trials.

Level Ib: Evidence obtained from at least one randomised controlled trial.

Level IIa: Evidence obtained from at least one well-designed controlled study without randomisation.

Level IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

Level III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Approximately one-fourth of the world's population and 44% of Singaporeans are myopic. Myopia appears to affect the Chinese race more than other racial groups and there is a progressively higher prevalence of myopia in those with more years of formal education. Myopia of even low degrees can cause significant deterioration of visual acuity. In the modern society, where many tasks are visually demanding, myopia may even result in economic or social disadvantage. The introduction of the excimer laser has allowed the cornea to be reshaped to correct refractive errors with sub-micron precision and accuracy. Selective removal of tissue from the anterior cornea results in a change of anterior corneal curvature, thereby correcting myopia with good efficacy, predictability, and safety.

POTENTIAL HARMS

- Commonly experienced visual effects after surgery, (temporary or permanent) include, blurred vision, starburst effects, haloes, and anisometropia
- Serious complications (infrequent or uncommon) include corneal vascularization, infective keratitis, corneal perforation, corneal scarring, epithelial healing problems, irregular astigmatism, endophthalmitis, cataract, retinal detachment, glaucoma, partial or total loss of vision, and complications requiring additional treatment and/or surgery
- Possibility of loss of best corrected visual acuity, over- or under-correction, presbyopia, ptosis, diplopia, and difficulties fitting contact lenses post-operatively
- Postoperative pain and discomfort

- Possibility of disqualification or inability to participate in certain vocations after surgery
- Possibility of inability to drive a vehicle or function in dark conditions due to night vision problems after surgery

Subgroups Most Likely to Be Harmed:

The incidence of corneal scarring appears to be correlated with increasing degrees of attempted myopic correction. The results of photorefractive keratectomy for high myopia have tended to be less impressive, with a higher incidence of corneal scarring leading to loss of best corrected visual acuity, regression as well as poorer predictability.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines do not cover the use of photorefractive keratectomy and laser in situ keratomileusis for the correction of hyperopia and hyperopic astigmatism. Neither does it cover other new and evolving refractive surgical procedures, such as the intrastromal corneal ring, phakic intraocular lenses or intrastromal photoablation with nanosecond yttrium-aluminum-garnet (YAG) lasers.

These guidelines are not intended to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances and patterns of care evolve.

The contents of the guideline document are guidelines to clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care. Each physician is ultimately responsible for the management of his/her unique patient in the light of the clinical data presented by the patient and the diagnostic and treatment options available.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The main outcome measures for laser refractive surgery include:

- Unaided visual acuity: percentage of eyes seeing 6/12 or 6/6 and better
- Predictability: percentage of eyes within +/- 1D of the intended correction
- Safety:
    - Percentage of eyes with loss of greater than or equal to 2 Snellen lines of best spectacle corrected visual acuity
    - Incidence of operative and postoperative adverse reactions or complications

See the original guideline document for the table of expected outcomes after photorefractive keratectomy and laser in situ keratomileusis (at 6 months follow-up).

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Laser refractive surgery. Singapore: Singapore Ministry of Health; 2001 Jul. 27 p. (MOH clinical practice guidelines; no. 4/2001). [32 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jul

GUIDELINE DEVELOPER(S)

National Committee on Ophthalmology (Singapore) - National Government Agency [Non-U.S.]
National Medical Research Council (Singapore Ministry of Health) - National Government Agency [Non-U.S.]
Singapore Ministry of Health - National Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

These guidelines on laser refractive surgery were drawn up by a workgroup appointed by the National Committee on Ophthalmology.

SOURCE(S) OF FUNDING

Singapore Ministry of Health

GUIDELINE COMMITTEE

National Committee on Ophthalmology Workgroup on Laser Refractive Surgery

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Singapore Ministry of Health Web site.

Print copies: Available from the Singapore Ministry of Health, College of Medicine Building, Mezzanine Floor 16 College Rd, Singapore 169854.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on October 25, 2001. The information was verified by the guideline developer on November 16, 2001.

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Date Modified: 5/10/2004