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Preoperative refraction, age and optical zone as predictors of optical and visual quality after advanced surface ablation in high myopic patients: a cross-sectional study

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Title: Preoperative refraction, age and optical zone as predictors of optical and visual quality after advanced surface ablation in high myopic patients: a cross-sectional study

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ABSTRACT

Objective: To investigate the factors associated with optical and visual quality of advanced surface ablation (ASA) in high myopia.

Design: A cross-sectional study of high myopic eyes treated with LASEK/epi-LASIK.

Setting: Eye and ENT Hospital of Fudan University in Shanghai

Methods: One hundred thirty-eight high myopic eyes (138 patients) (myopia -6 D or more) were examined more than 12 months after LASEK or Epi-LASIK with advanced surface ablation on the MEL 80 excimer laser (Zeiss AG, Jena, Germany). Refraction, higher-order aberrations (HOAs) and contrast sensitivity before and after surgery were evaluated. Factors including preoperative refraction, age, gender, central corneal thickness, pupil size, optical diameter, ablation depth, and flap creation method were analyzed for association with postoperative high order aberration, contrast and glare sensitivities, and different analytic diameters.

Results: HOAs increased significantly postoperatively (P<0.05), with the most significant change found in Z(4,0). At a 5-mm analysis diameter, increased coma was associated with age; increased spherical aberration difference was associated with age, optical zone diameter, and method of epithelial flap creation. At a 3-mm analysis diameter, none of the factors contributed to changes in HOAs. Higher preoperative refractive error was associated with

decreased contrast and glare sensitivity at each spatial frequency.

Conclusion: A larger optical zone diameter design is recommended to achieve better visual quality in advanced surface ablation for high myopia correction. Age and preoperative refraction may help predict postoperative visual quality.

Article summary

Strengths and limitations of this study

(1) This present study further analyzes the visual quality of high myopic patients (-6D or more), while previous investigations on visual quality were focused on low and moderate myopia.

(2) All cases were performed by a single experienced surgeon, removing any confounding effects from inter-surgeon variability or training level.

(3) Participants in this study were recruited only from Shanghai, which may lead to limited external validity.

(4) The contrast sensitivity measurement range was limited in this study, and should be expanded to a larger range of frequencies in future studies.

Introduction

Corneal refractive surgeries have rapidly evolved in the past 30 years. In 2003, the term "advanced surface ablation" was coined to reflect the improvements in surface ablation from the early days of photorefractive keratectomy (PRK). Today's advanced surface ablation procedures include numerous techniques, including laser epithelial keratomileusis (LASEK) and epipolis laser in-situ keratomileusis (epi-LASIK).

Visual quality following refractive surgery is a major concern, especially for high myopia patients. Pupil size, initial refractive error, optical zone size, decentration, and residual refractive error are the main factors affecting visual quality after corneal ablation procedures.[1-3] Improved ablation methods such as Q-optimized algorithms may decrease the chances of postoperative visual quality problems in both high myopia patients and hyperopic patients.[4, 5] Despite abundant literature on visual quality after corneal refractive surgery[6-8], a multivariate analysis of high myopia, studying preoperative patient data, ablation profile, and visual quality in advance surface ablation has not been conducted. Patients' preoperative data and corneal ablation measurements (optical diameter and ablation depth) have previously been reported—however, do these factors also play important roles in postoperative visual quality in high myopia? And which factors are most significantly related to postoperative visual quality? Furthermore, it is unknown whether the epithelium flap creation method plays a role in postoperative visual quality. Thus, the current study aims to investigate the significant factors influencing visual quality in advanced surface ablations in high myopia.

Materials and Methods

Study design

A cross-sectional study was performed to assess the factors influencing advanced surface ablation for the treatment of high myopia with more than one year follow up (average 1.32±0.21y, range 1~1.6y). From patients' surgical records, we collected preoperative refraction, pupil size, central corneal thickness, patient age and gender, methods of epithelial flap creation, optical zone diameter, and ablation depth. All surgical procedures were performed at the Eye and ENT Hospital of Fudan University, and informed consents were acquired prior to the study. The study followed the tenets of the Declaration of Helsinki and was approved by the ethics committee of the Eye and ENT Hospital of Fudan University (No. YYJG2007-03).

Patient selection

This study included high myopic patients (-6 D or more with up to -3 D of astigmatism) who had chosen to undergo surface ablation over intraocular lens implantation. Participants underwent the procedure at the same surgical session.

Measurements

Preoperative examinations included uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), non-cycloplegic manifest refraction, intraocular pressure, corneal topography, corneal pachymetry, contrast sensitivity, wavefront aberrations, slit-lamp examination, and dilated fundus examination. Before the preoperative examination, contact lenses were discontinued for at least 3 weeks in rigid lens wearers and for at least 1 week in soft contact lens wearers.

Pre- and post-operative higher order aberrations (HOAs) were measured with a Hartmann-Shack aberrometer (WASCA, Carl Zeiss Meditec, Jena, Germany) in scotopic conditions after 10 minutes of dark adaptation. Data were calculated within both 5mm and 3mm analysis diameters. Contrast sensitivity was measured with a Contrast Glare tester CGT-1000 (Takagi Seiko Corp, Toyama, Japan). The CGT-1000 uses 6 types of ring-like targets with 12 levels of contrast for measurement. The target sizes are of 6.3°, 4°, 2.5°, 1.6°, 1.0°, and 0.7° visual angles, which correspond to 6 through 12 cycles/degree (cpd) in spatial frequencies. BCVA was measured first under mesopic conditions, and then under photopic conditions.

Surgical technique

LASEK treatments began with 20% alcohol-assisted epithelial removal, followed by standard excimer laser ablation with a Mel-80 excimer laser (Software version: 3.6, Carl Zeiss Meditec AG, Jena, Germany; Tissue Saving Ablation (TSA) profiles; standard nomogram). As the patient focused on a fixation light, the excimer laser energy was delivered to the cornea centered on the optical axis. The epithelium was repositioned after laser ablation, and a bandage contact lens applied.

During Epi-LASIK, the rotational epi-LASIK microkeratome (KM-5000D, Wuxi Kangming Medical Device Corp, Wuxi, China) was used to create the epithelial sheet.[9] The remainder of the procedure closely mirrored the LASEK procedure.

Mitomycin C was not used in either LASEK or epi-LASIK cases. Bandage contact lenses were removed when epithelialization was complete (usually between postoperative day 3 and 7).

Statistical analysis

One eye of each patient was randomly chosen for analysis. Statistical analysis was performed using SAS software (version 9.2). Continuous variables are expressed as the mean ±SD. A normality test and homogeneity test of variance were performed before analysis. Logarithmic transformation was used for variables with skewed distributions. T-test, repeated measures analysis of variance (ANOVA), multivariate linear regression, and multivariate logistic regression were performed in the influencing factors analysis. The chi-squared test and row mean scores difference test was used for analysis of qualitative data. The chi-squared test and one-way ordinal data for mean difference test were used for qualitative data represented in frequencies. The

95% confidence intervals are shown with upper and lower limits. *P* values less than 0.05 were considered statistically significant.

Results

Patient Characteristics

A total of 138 eyes of 138 consecutive high myopic patients were included (68 females, 70 males). Patient age at the time of refractive surgery was 31.1±9.0 years (range, 19 to 52). The spherical equivalent refraction refractive error was -11.78±1.89 D (range, -8.25 to -17.00). The preoperative central corneal thickness was 513.1±24.1μm (range, 452 to 613). The preoperative mesopic pupil size was 6.04±0.83 mm (range, 5.2 to 7.0). The ablation zone was 5.72±0.23 mm (range, 5.0 to 6.25). The ablation depth was 139.9±15.6 μm (range, 108 to 177).

Wavefront aberration

Mean postoperative root-mean-square (RMS) wavefront aberration values were significantly greater than those obtained preoperatively under both 5mm and 3mm analysis diameters (all P<0.05). Coma-like, spherical-like aberrations and spherical aberration all increased significantly under the analysis diameters of 5 mm and 3 mm (all P<0.05), with greater values observed in the 5 mm analysis diameter. (Table 1)

Results of multivariate analysis of wavefront aberrations with 5 mm analysis diameter are presented in table 2. Smaller optical zone (β(coefficient value)=-1.17, *P*=0.037) and younger age (β=-0.07, *P*<0.001) were found to be associated with higher RMS values of HOAs. Age (β=-0.06, *P*=0.002) and male gender (β=-0.08, *P*=0.028) were associated with higher coma-like aberrations. Smaller optical zone (β=-0.38, *P*<0.001), method of epithelial flap creation (β=-0.07, *P*=0.01), and younger age (β=-0.06, *P*<0.001) were associated with increased spherical-like aberration. Although smaller optical zone and younger age were associated with the increase in spherical-like aberrations and decrease in spherical aberration, respectively, under 3mm of analysis diameter, the coefficient of determination values were very small (all r^2<0.1)

Table 1. Mean higher order aberrations before and 1 year after surgery (Mean ± SD, μm)

	HOAs	coma-like	spherical-like	spherical aberration
5 mm analysis diameter				
Preoperative	0.19 ± 0.11	0.154±0.098	0.092±0.063	-0.024±0.187
Postoperative	0.11 ± 0.07	0.334±0.131	0.393±0.136	-0.862±0.321
P value	<0.001	<0.001	<0.001	<0.001
3 mm analysis diameter				
Preoperative	0.55 ± 0.13	0.077±0.062	0.059±0.043	0.069±0.090
Postoperative	0.14 ± 0.04	0.110±0.042	0.073±0.024	-0.131±0.061
P value	0.001	<0.001	0.012	<0.001

HOAs: high order aberrations

Table 2. Multivariate analysis of higher order aberrations (meaningful coefficient value)

	5 mm pupil diameter				3 mm pupil diameter			
	HOAS	CLA	SLA	SA	HOAS	CLA	SLA	SA
Age								
β value	-0.072***	-0.057**	-0.055***	0.084*				
Gender								
β value		-0.079*						0.066**
Methods								
β value			-0.074*					
Optical diameter								
β value	-1.167*		-0.376***	0.729***			-0.061*	
Ablation depth								
β value				-0.005*				

HOAS= higher order aberrations CLA = coma-like aberration SLA = spherical-like aberration

SA = spherical aberration β value = coefficient value *P < 0.05, **P <0.01, ***P <0.001

Contrast sensitivity

The contrast sensitivity (CS) results are summarized in table 3. CS was significantly lower at all spatial frequencies under mesopic conditions and at all spatial frequencies except 6.3° and 4.0° visual targets under photopic conditions, at 1-year postoperative follow-up.

Three factors, including preoperative refraction, age and optical diameter, were found to be related to the change in contrast sensitivity. At 4.0°, 2.5°, 1.6°, and 1.0° visual targets, preoperative refractive error was associated with decreased contrast sensitivity (all P<0.05). Under mesopic conditions, a smaller optical zone was associated with decreased contrast sensitivity at the 6.3° visual target (β=-0.02, P=0.018), and younger age was associated with decreased contrast sensitivity at the 0.7° visual target (β=-0.03, P=0.044); however, the values of the coefficients of determination were too small to confirm these relationships in both cases (r^2<0.1). In the multivariate analysis of contrast sensitivity under photopic conditions (Table 4), higher preoperative refractive error was associated with decreased contrast sensitivity values at 4.0°(β=-0.003, *P*=0.001), 2.5°(β=-0.005, *P*<0.001), 1.6°(β=-0.007, *P*<0.001), and 1.0°(β=-0.01, *P*=0.011) visual targets.

Table 3. Contrast sensitivity before and after surgery (log unit)

	Target Size (°)					
	6.3	4.0	2.5	1.6	1.0	0.7
In mesopic condition						
Preoperative	1.696±0.218	1.676±0.241	1.532±0.228	1.289±0.230	1.003±0.256	0.712±0.281
Postoperative	1.542±0.194	1.514±0.211	1.353±0.240	1.114±0.238	0.849±0.261	0.576±0.206
P value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
In photopic condition						
Preoperative	1.510±0.246	1.499±0.280	1.331±0.278	1.124±0.265	0.854±0.259	0.635±0.197
Postoperative	1.455±0.247	1.447±0.243	1.269±0.253	1.035±0.248	0.786±0.243	0.548±0.206
P value	0.02	0.03	0.01	<0.001	0.006	0.004

Table 4. Multivariate analysis of contrast sensitivity（meaningful coefficient value）

	Mesopic						Photopic					
	6.3	4.0	2.5	1.6	1.0	0.7	6.3	4.0	2.5	1.6	1.0	0.7
Refraction												
β value		-0.003***	-0.005***	-0.007***	-0.010*		-0.004**	-0.005**	-0.007**	-0.010**		
CCT												
β value									0.0005*			
Age												
β value						-0.028*						
optical diameter												
β value	-0.015*											

CCT = central corneal thickness

β value = coefficient value   *P < 0.05, **P <0.01, ***P <0.001

Slit lamp examination

At 1-year post-operative follow-up, 96.38%(133/138) of eyes were clear and 3.62% (5/138) had trace haze. None of the eyes in the study developed corneal haze worse than grade 1, and haze did not affect the visual acuity in any of the operated eyes.

Discussion

Laser refractive surgery increases ocular aberrations in mild, moderate, and high myopia.[7, 10-13] HOA changes after laser ablations are one of the main factors affecting the visual quality after refractive operations.[12, 13]

Spherical-like aberrations can be described as decreased retinal image quality with a mesopic pupil diameter. It is greater when light enters the pupil from the periphery, and is not found at the pupil center. For a large pupil, the effects of aberration are increased approximately 10 to 20-fold.[10, 11, 14] In previous studies, Alarcón and colleagues[1] found that retinal image quality was affected by pupil size only when the pupil size was larger than the optical zone. The research of Kyoung Yul Seo et al.[8] and Endl et al.[15] also indicated that wavefront aberrations after refractive surgery with a larger ablation zone are less pronounced and closer to physiological level than those with a regular ablation zone. Consistent with previous studies[10, 15], we also found that a smaller optical zone is associated with greater changes in HOAs. One explanation for these similar results is that light passes through the area connecting the ablation zone and the transition zone under a smaller optical zone and larger pupil diameter, which increases the aberration and reduces the contrast of the retinal image. All of the above may be the causes of glare and halo encountered at night in patients with smaller ablation zones and larger pupil diameters. It is clear that a larger optical zone design prevents a significant increase in HOAs, which would in turn decrease visual quality.

In the present study, younger high myopia patients were more likely to experience an increase in postoperative HOAs. This correlation has never been reported in previous studies, and may be related to the corneal wound healing process after surgery. Previous studies showed that corneal wound healing was critical to the success of topography-guided or wavefront-guided excimer laser ablation to optimize visual performance.[16, 17] Moreno-Barriuso et al.'s study[12] reported that the presence of stromal opacities induced by the corneal wound healing process after refractive surgery caused a loss of corneal transparency and an increase of scattering. In addition, histological studies suggested that individual variation in the wound healing process was a major factor affecting refractive surgery outcomes. It is possible that proliferation of corneal stromal cells in young people is more active, which results in elevated degrees of tissue repair. Consequently, younger patients undergoing surface ablation procedures should be informed of the possibility of visual disturbances after surgery, and should receive close follow-up postoperatively.

Contrast sensitivity is another important indicator of visual quality. Previous studies revealed that in eyes undergoing PRK, contrast sensitivity was reduced at the early postoperative stage but gradually returned to preoperative levels after approximately 6 to 12 months.[18, 19] A study by Ghaith and colleagues[20] showed that PRK significantly reduced contrast sensitivity and induced glare at all spatial frequencies at 1 month postoperatively. These effects seemed to persist over time at lower spatial frequencies, but there was a trend toward recovery at higher spatial frequencies at 6 months. Contrary to their reports, our investigation revealed that contrast sensitivity under both lighting and dim conditions was worse with higher preoperative refractive errors for long-term observation. In particular, the decrease in contrast sensitivity under mesopic conditions was greater than that under photopic conditions. Interestingly, preoperative refractive error was significantly associated with decreased contrast sensitivity values in both photopic and mesopic conditions. One explanation may be that in high myopes, the change in postoperative corneal asphericity resulting in light scattering from the tips of the radial scars and irregular astigmatism in or near the central clear zone may lead to a significant drop in contrast sensitivity function (CSF) at medium to high spatial frequencies.[2] The present study also reveals that surgical factors, including the method of epithelial flap creation, optical zone, and ablation depth, did not affect postoperative contrast sensitivity under either lighting condition. This may be because all selected cases had myopia of -6.00 D or more; the effect of high myopia correction on contrast sensitivity could be a completely distinct relationship. Therefore, further research is needed to verify the association between these surgical factors and contrast sensitivity in patients with differing levels of refractive error.

Increasing HOAs and decreasing contrast sensitivity are associated with poor visual quality in high myopic patients. In our study, the method of epithelial flap creation had no effect on the HOAs or contrast sensitivity under mesopic and photopic conditions. The most significant factor was the ablation procedure. The relationship between age and higher order aberrations require further study and confirmation. Nonetheless, our results identified the significance of surgical and patient factors on postoperative visual quality; these findings are clinically important for providers and patients alike in choosing the optimal procedure and predicting visual quality outcomes.

A limitation of the study is that the participants were recruited from Shanghai only for the sake of patients' convenience, which might lead to limited external validity. In addition, although the influence of corneal refractive surgery on postoperative contrast sensitivity of high myopia patients is mostly concentrated in the middle frequency band, a larger range of target frequencies should be evaluated in the future for a more comprehensive assessment.

In conclusion, for high myopia patients, a larger optical zone diameter design is recommended to achieve better postoperative visual quality in advanced surface ablation. Patient age and preoperative refraction may also predict postoperative visual quality.

Author contributions:

Concept and design (J.Z. and Y.X.); analysis and interpretation (J.Z. and M.L.); writing the article (J.Z. and Y.X.); critical revision of the article (M.K. and X.Z.); final approval of the article (J.Z., Y.X., M.L., M.K. and X.Z.); data collection (J.Z. and Y.X.); provision of materials, patients or resources (Y.X); statistical expertise (M.L.) and literature research (Y.X.). All authors have reviewed the manuscript.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	3-4
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3-4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7,8,9,10
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7,8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8,9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8,9
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7,8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9,10
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7,10
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	10-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12,14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	14-17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	3-4
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3-4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7,8,9,10
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7,8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8,9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8,9
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7,8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9,10
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7,10
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	10-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12,14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	14-17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.