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Richard K. Parrish, II, MD, Editor-in-Chief
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**Methods:** The first paragraph of the Methods section should describe all the specifics of the study design (see glossary of study designs below) and information about human informed consent or animal care. State whether the IRB approval was prospective (before the study began) or retrospective and indicate precisely what the IRB approved. Name of IRB that approved the research or provide a statement and rationale as to why the named IRB waived approval. Indicate proper informed consent for the treatment and/or participation in the research, and confirm compliance with HIPAA, Clinical Trials registration (number and location of the registration), Investigational New Drug (IND) or Investigational Device Exemption (IDE) (provide number), and Institutional Animal Care and Use Committee guidelines. If the IRB waived the need for approval of this research or study, then indicate adherence to the Declaration of Helsinki and all federal or state laws in your country. Authors cannot make the decision as to whether IRB approval is needed; your IRB should make that decision and provide a waiver if they feel it does not require IRB approval.

Methods section should also include setting (multicenter, institutional, or clinical practice); patients and study population (including patient numbers, selection procedures, inclusion/exclusion criteria, randomization, and masking); intervention or observation procedure; and main outcome measure(s). Previously published procedures should be identified by reference only unless they are uncommon to AJO readers. Provide sufficient detail to enable others to duplicate the research. Use standard chemical or nonproprietary pharmaceutical nomenclature. Identify in parentheses specific sources by brand name, company, city, state, and/or country.

**Results:** Describe outcomes and measurements in an objective sequence with a minimum of discussion. Tables and figures should be cited in text in sequence. Data should be accompanied by confidence intervals (usually at the 95% interval) and exact \( P \) values or other indications of statistical significance.

**Discussion:** Elucidate (but do not reiterate) the results, identify any statistically or clinically significant limitations or qualifications of the study, provide responses to other and contradictory literature, and state the conclusions that are directly supported by the data. Excessive generalization and undue speculation should be avoided. Give equal emphasis to positive and negative findings, state whether and what additional study is required, and conclude with the clinical applications or implications supported by the study. The conclusions should be incorporated into the end of the discussion.

Authors should avoid statements of economic benefits and costs unless their manuscript includes economic data and analyses. Avoid claiming priority (first publication) of the content unless you provide the literature search protocol used. Do not allude to work that has not been completed.

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APPENDIX
Appendixes should be used sparingly, but they are appropriate to provide survey forms, list the members of a study group, or complex formulas and information. Please note that Supplemental Material for the AJO website may be provided for Full-Length Articles and Perspectives at the time of acceptance.

Abstract
Provide a structured abstract of 250 words or less with the following five headings:

Purpose: State the principal question or objective of the study and the major hypothesis tested, if any.

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Conclusions: State the conclusions directly supported by the data and describe the clinical applications. Avoid over-generalizations. Give equal emphasis to positive and negative findings, and note specific additional study required.

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When multiple-panel figures are submitted, refer to each panel from Top left to Top right, then Bottom left to Bottom right.

**Example.** FIGURE 1. Patient 3 with staphylococcal corneal abscess. A. The patient's cornea is shown preoperatively with the abscess located superior to the visual axis, B. 3 days postoperatively with the corneal transplant well centered and clear, and C. 4 months postoperatively with a crystal clear cornea. D. The patient, 1 year postoperatively, shows smooth corneal surface with all sutures removed.

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Tables take up substantial space in the print journal and should be limited in number. The information in the text and tables should not be duplicative.

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These principles describe the relationship of PhRMA member companies with others involved in clinical research and set forth the rules companies have volunteered to follow in order to protect the safety of research participants wherever the companies conduct clinical trials. In the principles, the PhRMA companies commit to the timely communication of all meaningful results of clinical trials, whether those results are positive or negative. The principles further state that the results should be communicated in an objective, accurate, balanced, and complete manner.

I. access AJO ACCESS TO SCIENTIFIC DATA

Thorough peer review by the AJO may require that organizations that sponsor research provide access to data and analyses that are not provided in a submitted manuscript, and sometimes such access is needed after publication as well. The opportunity also exists to post this information on the AJO website as Supplemental Material in association with the published manuscript.

J. microb REPORTING NEW MICROBIAL ORGANISMS IN OPHTHALMIC INFECTIONS

The AJO is interested in confirming that certain organisms participate in ocular disease. The text must provide adequate laboratory information that can substantiate the microbial identification. This requires that any unusual pathogen be confirmed by two different methods or at two independent laboratories. The journal Cornea initiated this confirmatory policy (Wilhelmus KR. New corneal infections: preventing a crisis of identity. Cornea 2003;22:95-96).

K. cancer CANCER CLASSIFICATION SCHEME

Authors should use the American Joint Commission on Cancer classification scheme when describing patients with ophthalmic malignancies; see American Joint Committee on Cancer.ACC Cancer Staging Manual, Seventh Edition, Springer, New York.

L. ocular OCULAR TRAUMA TERMINOLOGY


M. regis CLINICAL TRIALS REGISTRATION

The AJO requires that human clinical trials are registered before enrollment in order for the results to be published in the AJO. See Arch Ophthalmol 2005:123:1263-1264 for complete statement. Phase III trials should be registered as well as many phase II trials. Most phase I trials do not need to be registered. The Methods section should contain a statement about where the registration information is available to the public. Satisfactory public databases include the National Institute of Health maintained site at http://www.clinicaltrials.gov (for either NIH or non-NIH sponsored studies) or the International Standard Randomized Controlled Trials at http://www.controlled-trials.com.

N. refractive surgery STANDARDIZED GRAPHS AND TERMS FOR REFRACTIVE SURGERY RESULTS


Forms
A. flow CONSORT STATEMENT
B. idphoto CONSENT FORM FOR IDENTIFIABLE PHOTOGRAPHS

Glossary of study designs

Randomized Clinical Trial: A human trial involving at least one experimental treatment group and one control treatment group, concurrent enrollment, and follow-up of the experimental and control groups with assignment to experimental and control groups by a randomization process. Persons responsible for treatment and subjects are not able to influence the treatment assignment, and assignment remains unknown to the staff and subjects until eligibility has been determined.

Nonrandomized Clinical Trial: A human trial involving at least one experimental treatment group and one control group, concurrent enrollment, and follow-up of the treatment and control groups. Assignment to experimental control groups is by a process other than randomization.
**Interventional Case Series**: Three or more cases, which may or may not be consecutive, that describe the outcome of an intervention without a control group for comparison.

**Cohort Study**: A longitudinal observational study that includes subjects with identifying characteristics and involves measurements or observations on more than one occasion.

**Case-control Study**: An observational, and usually retrospective, study of subjects with identifying characteristics and a disease or abnormality (cases) for comparison to subjects with similar characteristics, but without the disease or abnormality (controls). Comparison proceeds from effect to cause and generally yields odds ratio (usually an approximation of relative risk).

**Cross-sectional Study**: An observational study that identifies subjects with and without the disease or abnormality being studied at the same time. Study yields prevalence data and may or may not be population based.

**Observational Case Series**: Three or more cases in which natural history of the disease or abnormality is described. Cases may be collected and studied retrospectively or prospectively over any time frame.

**Experimental Study**: Animal or laboratory research describing observations, surgical or medical interventions, testing, or devices. Experimental studies are generally prospective and utilize a protocol in which controls are included.

**Meta-analysis of Literature**: Analysis of literature using statistical methods to integrate and summarize several studies.

**AUTHOR INQUIRIES**
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