

Ask the Ethicist: When Patients Request Novel Treatments

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Q: *Several patients have asked about corneal cross-linking as a possible treatment option for keratoconus. I advised them that I do not perform this procedure and am not convinced by the current research that it is effective in slowing the progression of keratoconus or improving best-corrected vision. These patients did not meet the criteria for enrollment in the FDA-approved trials that were under way at the time of their inquiries, and thus I advised them that I would not provide them with a referral to another physician who performs this procedure. Several patients became upset with me and decided to pay large sums of money out of pocket to have the corneal cross-linking procedure performed. What are my obligations regarding referring patients to other ophthalmologists for procedures that are considered novel or experimental?*

A: The Academy's Code of Ethics addresses the ophthalmologist's obligations in situations such as this in Rule 4: *Other Opinions*. *The patient's request for additional opinion(s) shall be respected. Consultation(s) shall be obtained if required by the condition.*

Any novel treatment modality in clinical trials in the United States is by definition "under investigation" and therefore not considered standard therapy. While ophthalmologists should be aware of ongoing clinical trials and mention these to their patients when appropriate, they are by no means required to do so. In the situation described, the patients were not candidates for the FDA corneal cross-linking trial, and thus there is even less obligation to refer these patients to ophthalmologists performing this procedure.

If and when results of an FDA-approved trial are published in the peer-reviewed literature indicating that corneal cross-linking is a beneficial treatment modality for patients who meet certain inclusion criteria, you should mention this treatment option with eligible patients. If the patient expresses interest in having the procedure performed, you feel that he/she would benefit from the procedure and it falls within your scope of practice, you should offer to provide the treatment or refer the patient to another ophthalmologist who does.

In cases in which data are published in the peer-reviewed literature supporting the efficacy and safety of a new treatment option but you remain skeptical of the technology and/or critical of the published data, your reservations should be communicated to the patient.

For more information, visit www.aao.org/about and click "Ethics." To submit a question, contact the Ethics Committee staff at ethics@aao.org.