Ophthalmic implants — Intraocular lenses —

Part 2: Optical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —
Partie 2: Propriétés optiques et méthodes d’essai
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This second edition cancels and replaces the first edition (ISO 11979-2:1999), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11979-2:1999/Cor.1:2003.

ISO 11979 consists of the following parts, under the general title Ophthalmic implants — Intraocular lenses:

— Part 1: Vocabulary
— Part 2: Optical properties and test methods
— Part 3: Mechanical properties and test methods
— Part 4: Labelling and information
— Part 5: Biocompatibility
— Part 6: Shelf-life and transport stability testing
— Part 7: Clinical investigations
— Part 8: Fundamental requirements
— Part 9: Multifocal intraocular lenses
— Part 10: Phakic intraocular lenses
Introduction

This part of ISO 11979 initially addressed monofocal IOLs and now has been revised to include the requirements and test methods for spherical monofocal, aspheric monofocal, toric, multifocal, and accommodative IOLs. This part of ISO 11979 contains several test methods for which associated requirements are given and one test method for which no requirement is formulated. The former are directly connected to the optical functions of intraocular lenses. The latter, the test for spectral transmittance, has been provided for information about UV transmission and in specific situations, e.g. when using laser light sources for diagnosis and treatment.

For the original spherical monofocal IOLs, extensive interlaboratory testing was carried out before setting the limits specified. During this testing some basic problems were encountered as described in Reference [1]. The accuracy in the determination of dioptric power has an error that is not negligible in relation to the half dioptre steps in which intraocular lenses are commonly labelled. The dioptric power tolerances take this fact into account. Hence the limits set may lead to some overlap into the next labelled power, especially for high dioptre lenses. Reference [1] gives further discussion on this subject.

The majority of lenses hitherto implanted were qualified using the method described in Annex B or Annex C (model eye 1). The method in Annex B is limited in its applicability, however. The limits for the more general method in Annex C have been set in terms of MTF in a model eye, following two approaches. The first is by correlation to the method and limit in Annex B. Further discussion can be found in Reference [2]. The second is set as a percentage of what is calculated as theoretical maximum for the design, with the rationale that a minimum level of manufacturing accuracy be guaranteed. For common PMMA lenses, these two limits correspond well with each other. For lenses made of materials with lower refractive index, or with certain shape factors, or for extreme power lenses in general, the latter limit is lower than the former. However, such lenses are already in use, indicating clinical acceptance. The question of which is the absolute lowest limit that is compatible with good vision arises. No definite answer can be found, but following clinical data presented to the working group, an absolute lower limit has been set for the calculation method.