INTERNATIONAL STANDARD

ISO 11979-3

Third edition
2012-12-01

Ophthalmic implants — Intraocular lenses —

Part 3:
Mechanical properties and test methods

Implants ophtalmiques — Lentilles intraoculaires —

Partie 3: Propriétés mécaniques et méthodes d'essai

Reference number
ISO 11979-3:2012(E)

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11979-3 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-3:2006), which has been technically revised in order to include relevant requirements and test methods for toric intraocular lenses and accommodating intraocular lenses.

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*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

Introduction

This part of ISO 11979 contains methods for which requirements are given and methods for which no requirements are formulated. The former are considered essential for the safety or performance of the intraocular lens, while the latter provide essential information to the ophthalmic surgeon or are used for other purposes.

A special purpose is the use of mechanical data to assess the need for clinical investigation of modifications of existing models as described in ISO 11979-7[7]. Because of the complexity of this analysis, detailed descriptions and examples have been given in ISO/TR 22979[8]. Due to the wide variety of intraocular lens designs already on the market, it has not been possible to devise test methods that are applicable to every design under all circumstances. It can be anticipated that new materials currently under development will result in drastically new designs that will require modified or other test methods. As with all standards, it is then up to the parties using the standard to modify or develop corresponding methods and give rationale and validation for them in a spirit that is consistent with this part of ISO 11979.

In cases where different tolerances have been given depending on material or design, they reflect an existing situation with well-established products.

Ophthalmic implants — Intraocular lenses —

Part 3: Mechanical properties and test methods

1 Scope

This part of ISO 11979 specifies requirements and test methods for certain mechanical properties of intraocular lenses (IOLs).

It is applicable to all types of IOLs intended for implantation in the anterior segment of the human eye, excluding corneal implants, provided that the test method is appropriate to the particular IOL design.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 apply.

4 Requirements

4.1 General

For all IOLs, the mechanical properties shall be determined at *in situ* conditions. The precise composition of the solution used shall be reported in all cases. Alternative test conditions, e.g. room temperature conditions, may be used if a justification to deviate from *in situ* is given. The alternative test conditions shall be specified in the test reports.

For each of the methods described below, tests shall be performed on a minimum of three IOL lots of medium dioptric power. If dioptric power affects the property tested, the lots shall comprise one each of low, medium and high dioptric powers. For toric intraocular lenses, half of each of these three lots shall contain intraocular lenses with the highest cylindrical power, and the other half shall contain intraocular lenses with the lowest cylindrical power. The minimum sample size for each test shall be 10 IOLs per lot. The lots shall be representative of IOLs being marketed. In all cases, the sampling criteria applied shall be reported. Means and standard deviations shall be reported for the pooled samples.

If, for certain designs and certain applications, a specific test method described in this part of ISO 11979 is not applicable, the IOL manufacturer can devise a corresponding test method and provide a validation and rationale for it.

For accommodating IOLs (AIOLs) the theoretical mechanism of action to change the power of the eye shall be described e.g. the change of curvature or the movement of lens elements under compression. The general factors determining this action shall be characterized and specified. Further mechanical testing over a range that includes the maximum and minimum limits of the theoretical mechanism of action shall be performed. If the dynamic response to the mechanism of action is time dependent, this time dependency shall be characterized.

4.2 Tolerances and dimensions

The tolerances for overall diameter, vault height and sagitta are given in Table 1.

Table 1 — Tolerances of overall diameter, vault height and sagitta

Test method	Overall diameter	Vault height	Sagitta
Anterior chamber IOLs	±0,20 mm	±0,15 mm	±0,25 mm
Multi piece posterior chamber IOLs	±0,30 mm	±0,35 mm	±0,45 mm
Other IOLs	±0,20 mm	±0,25 mm	±0,35 mm

The tolerance on the clear optic shall be ± 0,15 mm. The diameter of the clear optic shall be greater than 4,25 mm in any meridian. The tolerance on the dimensions of the body shall be ± 0,10 mm. For ellipsoid IOLs, the dimensions of the body shall be reported as (short axis) × (long axis).

The tolerance on the diameter of the positioning hole shall be nominal $\left(^{+0,05}_{0}\right)$ mm.

Dimensions for which tolerances are given above shall be specified in the manufacturer's design documentation. Some dimensions may vary with dioptric power, hence different specifications may apply to individual powers of an intraocular lens design.

4.3 Clearance analysis (anterior chamber lenses only)

An empirical analysis of anatomic placement shall be performed for anterior chamber lenses to evaluate the most proximate points with relation to the anatomical structures of the eye. The clearance of the anterior surface of the IOL optic in relation to the endothelial layer of the cornea shall be determined for the lens at its minimum recommended diameter in its compressed state. In addition the separation between the posterior surface of the IOL optic and the iris shall be determined. For phakic IOLs, the separation between the posterior surface of the IOL optic and the crystalline lens shall also be determined. These results shall be considered in the risk analysis. The theoretical eye model in Annex I can be used in the evaluation.

The manufacturer shall strive for a clearance of at least 1 mm under worst-case conditions, i.e. conditions which would result in the minimum amount of clearance.

4.4 Compression force

Using the method described in Annex A, the compression force shall be measured and reported as follows:

a) for IOLs intended for capsular bag placement, with the haptics compressed to a diameter of 10 mm;

b) for IOLs intended for sulcus placement, with the haptics compressed to a diameter of 11 mm;

c) for IOLs intended for both capsular bag and sulcus placement, with the haptics compressed to both a diameter of 10 mm and a diameter of 11 mm;

d) for anterior chamber IOLs, with the haptics compressed to the minimum and maximum intended compressed diameters recommended by the manufacturer in the product literature.

4.5 Axial displacement in compression

Using the method described in Annex B, the axial displacement in compression shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.4).

In addition, for anterior chamber IOLs, the vault height and the sagitta in the compressed state shall be given in the product literature as a function of dioptric power at the minimum and maximum intended compressed diameters, as specified in 4.4.

4.6 Optic decentration

Using the method described in Annex C, the optic decentration shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.4).

The sum of the arithmetic mean and two standard deviations of the optic decentration shall not exceed 10 % of the clear optic.

4.7 Optic tilt

Using the method described in Annex D, the optic tilt shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.4).

The sum of the arithmetic mean and two standard deviations of the optic tilt shall not exceed 5°.

4.8 Angle of contact

Using the method described in Annex E, the angle of contact shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.4).

NOTE The angle of contact is a measured approximation of the total haptic contact with the supporting ocular tissue.

4.9 Compression force decay

Using the method described in Annex F, the compression force decay shall be tested and reported at the same diameters that were used for the measurement of compression force (see 4.4).

The loops of IOLs are designed to exert some pressure on eye structures as a means of keeping the IOL in position and shall continue to do so for some time after implantation.

Results shall be reported as residual compression force after 24 h ± 2 h in compression at each required compressed diameter.

4.10 Dynamic fatigue durability

All loops shall be capable of withstanding, without breaking, 250 000 cycles of near-sinusoidal deformation of ± 0,25 mm around the compressed distance.

Using the method described in Annex G, fatigue testing shall be performed as follows:

a) for IOLs intended for capsular bag placement, at a compressed distance of 5,0 mm between the testing plate and the centre of the optic;

b) for IOLs intended for sulcus placement, at a compressed distance of 5,5 mm between the testing plate and the centre of the optic;

c) for IOLs intended for both capsular bag and sulcus placement, at a compressed distance of 5,0 mm between the testing plate and the centre of the optic;

d) for anterior chamber IOLs, at a distance between the testing plate and the centre of the optic, corresponding to half the maximum intended compressed diameter as recommended by the manufacturer in the product literature.

This test shall be carried out only for IOL designs in which the loop will be in a compressed state when implanted. The frequency shall be between 1 Hz and 10 Hz.

Higher frequencies can be used if it is verified that the loop follows the testing plate without lag at all times.

No loop tested shall break.

For IOLs designed to move axially under compression, additional testing shall be considered.

4.11 Surgical manipulation

The IOL manufacturer shall provide evidence that the loops of an IOL design are capable of withstanding surgical manipulations without failure. An appropriate test method and specification shall be established by the manufacturer to ensure that the device does not fail at typical deformations. A test method, useful for some designs with loops, is given in Annex H.

4.12 Surface and bulk homogeneity

The IOL shall be essentially free from defects, i.e. deviations from surface and bulk homogeneity that are not intended features of the design, including all kinds of surface defects such as scratches, digs, protrusions, cracks, roughness, etc., as well as bulk defects such as inclusions, bubbles, striae, discoloration, etc. The lens shall be inspected at 10 × magnification under optimal lighting conditions; any questionable or critical areas shall be viewed at higher magnification.

5 Recovery of properties following simulated surgical manipulation

The testing in this clause applies only to IOLs of which the optic is intended to be folded or compressed during implantation. Perform testing on 10 lenses of each of the dioptric powers with the smallest and largest cross-sectional dimensions. In practice this will typically be 10 lenses with the lowest and 10 lenses with the highest dioptric power. For toric intraocular lenses, half of each of these lens groups shall contain intraocular lenses with the highest cylindrical power, and the other half shall contain intraocular lenses with the lowest cylindrical power. Follow the instructions supplied by the manufacturer, using recommended lubricants and instrumentation. To determine the acceptable time during which the lens is allowed to be kept deformed prior to implantation, maintain the deformed state for a period of time. This time shall not be shorter than 3 min. Times in excess of 20 min need not be investigated. The time used shall be reported.

After release from the deformed state, allow the lens to relax at *in situ* conditions up to 24 h ± 2 h. The time used shall be reported. Subsequently:

a) measure dioptric power and image quality in accordance with ISO 11979-2;

b) measure overall diameter and sagitta in accordance with 4.2;

c) inspect for surface and bulk homogeneity in accordance with 4.12.

The results shall be reported and are acceptable if they remain within manufacturing specifications of the product.

6 Additions for accommodating IOLs (AIOLs)

6.1 Designs comprising multiple optical elements shall be evaluated on the alignment of the optics relative to each other in terms of centration. The effects of decentration on the optical performance of the AIOL shall be used to determine appropriate tolerances.

6.2 Designs comprising multiple optical elements shall be evaluated on the alignment of the optics relative to each other in terms of tilt. The effects of optic tilt on the optical performance of the AIOL shall be used to determine appropriate tolerances.

6.3 Using the principle described in 4.10, the theoretical motion of the AIOL in the eye shall be replicated for at least 1 million cycles. In addition to evaluating any damage of the AIOL after this treatment, the mechanical characteristics that determine the performance of the AIOL shall be assessed and shall not be found altered to an extent that can be clinically significant. Any other dynamic properties influencing the performance of the AIOL shall be evaluated. If the theoretical action does not include a radial compression of the haptic of 0,5 mm (±0,25 mm), the test in 4.10 shall be additionally performed.

6.4 If indicated by risk analysis and assessment, additional testing can be required to demonstrate the effect of aging on the continued functionality of the device. If the lens is meant to move or change shape, testing must elucidate the effect of ageing on movement or shape change (or other changes, such as refractive index).

6.5 Mechanical characteristics that affect the ability of an AIOL to function shall be demonstrated not to change to an extent that can be clinically significant following simulated surgical manipulation for implantation.

Annex A
(normative)

Measurement of compression force

A.1 Principle

The force exerted by the loops is measured when the IOL is confined to a prescribed diameter with the movement of the body being unrestricted.

A.2 Apparatus

A diagram of the apparatus is shown in Figures A.1 and A.2 and comprises the following.

A.2.1 **Two anvils**, with faces having a radius of 5,00 mm ± 0,02 mm or 5,50 mm ± 0,02 mm, as appropriate, constructed from a low-friction material to minimize loop rotational constraint, and aligned relatively with each other.

A.2.2 **Device**, capable of measuring force accurate to at least ± 0,1 mN.

A.3 Procedure

A.3.1 Carry out the testing with the IOL in the horizontal plane.

NOTE Testing in the vertical plane leads to asymmetrical distribution of force between the loops due to the mass of the IOL.

A.3.2 Set the anvils to a distance approximately equal to the overall dimension of the IOL and place the IOL between the anvils.

A.3.3 Locate the IOL in the uncompressed state so that the line of compression bisects the angle of contact in the compressed state or, in the case of IOLs where there are multiple contacts, so that the line of compression bisects the angle of contact of the extremes in the compressed state (see Figure A.3).

A.3.4 Close the anvils to the prescribed diameter.

A.3.5 Read the compression force after allowing between 10 s and 30 s for the IOL to stabilize.