Basis of Measuring Equipment Suitability in Quality Control

As a result of technical progress as well as new demands on the manufactured product and the production process, contact lens manufacturers are often faced with the task of selecting the most suitable measuring equipment. Irrespective of the many technical possibilities available, with all measuring equipment used in the production of contact lenses must be possible to demonstrate that they are fit-for-purpose under production conditions. For this the factors affecting the entire testing procedure and their impact must be fully understood. While a good theoretical understanding is certainly helpful here, in all cases an experimental evaluation of the testing procedure is indispensable.

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With the investigation and selection of new kinds of measuring equipment, it is thus not enough simply to choose a measuring device on the basis of the manufacturer's technical data sheet. The accuracy claimed by the equipment supplier can, unfortunately, often not be achieved in practice. The reason for this is clear: with the accuracies indicated, the supplier inevitably cannot take into account any uncertainties resulting from the operating conditions, the inspection process in the lab, the user himself or the product to be inspected. Thus the question is how can the quality-related characteristics be assured with the necessary precision and accuracy so that the required production tolerances are assured? Based on the example of a measuring instrument used to examine the central rear contact lens surface radius, the following contribution shows one way in which this proof can be provided.

MEASURING PRINCIPLE

Over the past 15 years, in contact lens manufacturing, automated measuring procedures based on digital image processing (e.g. using wavefront sensors or Moiré deflectometers) have been increasingly used to measure the rear surface radii. These processes are based on different operating principles. As a rule they not only make possible the measurement of central curvature radii but also measurement of the axis orientation, determination of surface deviations as well as the visual inspection of lathe grooves, scratches, etc.

For this study, the SHSOphthalmic autoROC from Optocraft was evaluated.

This system can be used for measuring spheric, toric and weakly aspheric samples which may be both convex and concave. It essentially returns the radius of curvature and the surface deviation of a sphere. Based on this, extended evaluation steps like a Zernike decomposition or a pass-fail analysis can be performed. A vision camera returns an image of the sample to enable assessment of surface defects, e.g. lathe grooves or scratches. Radii are measurable from about 4.5 to 12.5 mm with up to 2 mm radial difference of the meridians of toric samples.

The automated measurement procedure is wavefront guided and receives its input data from a Shack-Hartmann wavefront sensor. The radius of curvature of the sample is obtained by moving the sample to the cat's eye position and the confocal position of an illuminating microscope lens. Typically a measurement is performed in about 10 to 15 seconds. To reduce handling errors, different access modes provide the required level of complexity for a production or an R&D environment. A database interface can be used to read the nominal values via a bar-code reader and to store the measurement results.

AIMS WHEN CHOOSING SUITABLE MEASURING EQUIPMENT

The choice of a suitable measuring device does not only concern its accuracy and precision. The aims can be roughly divided into application-specific, process-specific and economic considerations. They are all of great importance when choosing a measuring system. In the following, however, the main emphasis will be on the assessment of the application aims (precision, resolution, accuracy, etc.).

TERMS

SYSTEMATIC ERRORS

Systematic errors are caused by the way the measurements are set up. They also reoccur when the measurement is repeated. The amount and sign of these errors remain constant over time. Thus these errors can be eliminated by recalibrating the measuring instrument.

RANDOM ERRORS

Here we are dealing with unavoidable, fortuitous errors. They do not remain constant over time, i.e. measured values vary around a mean value. The causes may be temporary or spatially occurring random external factors or internal factors (such as interference). Assertions about these errors can be made based on statistical analysis of the measurement data.

REPEATABILITY

The same observer carries out measurements according to a fixed measuring procedure repeated at short intervals on the same object and under the same test conditions. This results in the standard deviation under repeat conditions (i.e. the repeat precision).

REPEAT CONDITIONS

Different observers carry out measurements according to a fixed measuring procedure repeated at short intervals on the same object and under different test conditions[1] at different times. This results in the standard deviation under repeat conditions.

MEASURING EQUIPMENT CAPABILITY

The measuring instrument capability has the goal of determining the systematic and random deviations of a measuring system using a standard. They are described with the aid of the two standard properties c_g and c_{gk} using the variables c_{gko} and c_{gku}:

$$c_g = \frac{0{,}2\,T}{6\,s_g}$$

$$c_{gko} = \frac{(x_m + 0{,}1 \cdot T) - \overline{x_g}}{3\,s_g}$$

$$c_{gku} = \frac{\overline{x_g} - (x_m - 0{,}1 \cdot T)}{3\,s_g}$$

$$c_{gk} = MIN\left(c_{gku};\ c_{gko}\right)$$

where

X_m is the characteristic value of the standard

x_g is the mean value

s_g is the standard deviation

T is the given tolerance value

A measuring instrument is deemed suitable when the calculated properties $C_g \geq 1.33$ and $C_{gk} \geq 1.33$. There is no uniform definition for the calculation of the values Cg and C_{gk}. These differ according to company standards. The equation used here is based on the BOSCH guideline [8].

REPEATABILITY AND REPRODUCIBILITY (R&R)

Repeatability and reproducible precision are mainly used to determine the influence of the user. In order to calculate these characteristics, measured values from different operators must be available. Thus R&R provides an estimated composite value for the repeatability and reproducibility of a measuring system. For a measuring instrument to be classified as suitable, the following conditions must be satisfied [4]:

For a new measuring system	%R&R ≤ 20%
For a measuring system in use	%R&R ≤ 30%

DEFINING A SUITABLE PROCEDURE

For proof of suitability, reliable determination of the repeatability and reproducible precision is of key importance. It needs to be determined based on the testing property affecting quality, in this case the central rear surface radius. No guideline exists which specifies how determination of the suitability of the measuring instrument used in contact lens or inter ocular lens (IOL) production is to be carried out. One possibility, for example, is the use of measurement system analysis (MSA) [7]. The reasons in favor of using MSA for this application are as follows:

- This is a recognized method used in many different fields.
- MSA is a process-referred method, which considers also requirements before and during the use phase.
- It is multi-stage process which takes account of all the uncertainties in the testing process.

ASSESSMENT OF THE RESOLUTION

Before an analysis of the measuring instrument can take place, its resolution needs to be assessed:
According to [1], DIN 1319-1: 1995-01
"Smallest distinguishable difference between two indications of an indicating device."
Resolution is the ability of a measuring instrument to recognize a reproducible difference between two measured values. The evaluation of the resolution must be performed with all of the indicating measuring devices. At Hecht Contactlinsen GmbH with regard to resolution the following condition applies:

$$\text{Resolution} = \frac{\text{Scale graduation value}}{\text{Tolerance}} \leq 5\%$$

EXAMPLE:

Scale graduation value = 0.0001 mm
Tolerance = 0.005 mm

Resolution = 0.0001 mm / 0.005 mm = 0.02 = 2%
→ Measuring instrument is suitable

If no resolution is achieved under 5%, the procedure described below will not be used. Once the measuring instrument has been deemed to be suitable with regard to resolution, proof of suitability can be carried out.

SIMPLE PROOF OF SUITABILITY USING A STANDARD

A simple proof of suitability is used to assess the manufacturer's details, particularly in the case of new measuring systems or after modification of existing ones. To do this, the systematic measurement deviations and the standard deviations are determined under repeatable conditions. Subsequently the values cg (measuring instruments suitability) and c_{gk} (critical measuring instrument suitability) are determined, based on the previously mentioned limit values. The aim of the investigation is thus to determine – based on the suitability values c_g and c_{gk} –whether a measuring system using a standard is suitable for the intended purpose under the given operating conditions.
The investigation is hereby carried out under "repeatable conditions":
"Conditions under which individual measured values of the same particular measurements can be taken repeatedly, independently of each other, in such a way that the systematic deviation for each measured value remains the same."
DIN 1319-1

For this, according to DIN, at least the following conditions must be fulfilled:
- The same observer
- The same measuring procedure
- The same measuring instruments
- The same special measuring variable

STRICTER PROOF OF SUITABILITY FOR PRODUCTION PARTS

With this proof the aim is to determine, based on the variable %R&R, whether a measuring instruments is suitable, taking into account all the parameters of a particular measurement task. For this the Equipment Variation (EV) and the Appraiser Variation (AV) are determined. While the equipment variation shows the influence of the measuring instrument on the reliability of the measurements, the appraiser variation shows the influence of the person performing them. Values of %R&R ≤ 20% for new measuring systems and %R&R ≤ 30% for systems already in use respectively apply here as limit values for suitability.
The use of this procedure only makes sense, however, after prior proof of suitability using the procedure with a standard, as described above.

Here conditions differ under which the measurements are carried out:
- Measurements are made according to a clearly defined testing method or procedure
(testing instructions).
- The test is carried out on production parts.
- Where the influence of the measuring process cannot be distinguished from the actions of the appraiser, then this influence is to be investigated [8]. Thus the investigation should be carried out by at least two appraisers.
- The test may be carried out on different test equipment, i.e. on devices of the same type.
- The test should be carried out on several different testing devices at different locations.

After the investigations described above have been carried out and the suitability of the measuring instrument could be proved, this is followed by release approval for the production process.

RESULTS

The study of measuring instrument suitability for the surface testing device SHSInspect Ophthalmic autoROC (see figure) proves its suitability both in the simpler and in the stricter suitability test. The following values were determined:

Measuring instruments suitability:

$c_g = 2.67$ and $c_{gk} = 1.53$

And for the stricter suitability test:

%R&R = 16.1%

In addition, practical experience shows that, with the stricter suitability test, only very few measuring processes achieve the value of %R&R < 10%. The overall tolerance range was based here in each case on ±0.020 mm, i.e. T=0.040 mm as the allowance for the tolerance value of the rear surface radii. The radius of curvature lay in the range of approx. 8mm.

However, the results for measuring instrument suitability are, in this shortened form without a more detailed discussion, only of limited significance. Therefore a more detailed analysis will be provided in a subsequent article.

CONCLUSION AND OUTLOOK

As mentioned at the beginning, unfortunately the measuring system supplier can only offer certain "reference points" concerning accuracy and precision. As a rule he has little or no knowledge of the following important considerations:

- The surrounding conditions in which the measuring equipment is to be used (temperature, humidity, lighting, amount of dirt, vibrations, etc.).
- The conditions (Standard Operating Procedures) under which the measurements of the quality-related parameters are carried out by the manufacturer.
- The setup of the process and the stage within the process at which the measuring equipment is to be used.
- Part-specific characteristics of the series parts, i.e. the peculiarities of the objects to be measured. In the case of contact lenses this means e.g. design irregularities (shape, surface), material properties or the inherent stability of the contact lens material.
- The criteria defined for assessing the suitability of a contact lens measuring system by the manufacturer.
- The operators (parallaxes, constitution, qualification, carefulness, motivation, etc.).

In order to judge the test procedure under realistic conditions, these influences and their impact must be known.
For the contact lens manufacturer to be able to measure the required properties with the desired accuracy, good and close cooperation with the supplier is not only desirable but absolutely essential.
Already when choosing a measuring instrument, a detailed technical specification needs to be drawn up by the contact lens manufacturer, containing the intended operating site and including the points mentioned above.
Detailed consideration of the simpler and stricter proof of suitability will be dealt with in a subsequent article. It will also discuss the justification for multi-stage processes, their significance and possible improvements. ■

References

[1] DIN 1319-1
Grundlagen der Messtechnik – Teil 1 Grundbegriffe, Beuth-Verlag

[2] DIN Taschenbuch 355
Statistik, Genauigkeit von Messungen, Ringversuche, Beuth-Verlag
ISBN 3-410-15752-2

[3] Edgar Dietrich, Alfred Schulze (2007)
Eignungsnachweis von Prüfprozessen, 3rd Revised & Expanded Edition,
Carl Hanser Verlag München,
ISBN-10: 3-446-40732-4

[4] General Motors Co. – GM Powertrain(July 2004), SP-Q-EMS-Global 10.6,
Evaluation of Measurement Systems Specification,
Detroit/Rüsselsheim

[5] Horst Rinne/Hans-Joachim Mittag (1989)
Statistische Methoden der Qualitätssicherung,
Carl Hanser Verlag München,
ISBN 3-446-15503-1

[6] Hans-Jochen Bartsch
Taschenbuch mathematischer Formeln,
7th to 11th Edition,
Verlag Harry Deutsch, Thun & Frankfurt-am-Main,
ISBN 3-87144-7749

[7] A.I.A.G. – Chrysler Corp., Ford Motor Co., General Motors Corp.(2002)
Measurement System Analysis, Reference Manual, 3rdEdition, Michigan, USA

[8] BOSCH Heft 10: "Fähigkeit von Mess- und Prüfprozessen"

[9] Duncan A. J (1986) Quality Control and Industrial Statistics,
Irwin Professional Publishing; 5 Sub. Edition
ISBN 978-0256035353

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