Measurement system analysis based on the example of the radius and surface inspection measuring instruments SHSOphthalmic autoROC

In a previous article, the basic theoretical considerations of measurement system analysis (MSA) were described in great detail [10]. In this article, the practical implications will be discussed, based on the measurement system SHSOphthalmic autoROC (from Optocraft GmbH, Erlangen, Germany) which is capable of determining the radius of curvature of spheric, toric or weak aspheric samples. Moreover, it is also able to measure surface deviations and to inspect surface quality. By Stefan Muckenhirn

**MSA FOR A ROC MEASUREMENT SYSTEM**

The results shown below for the SHSOphthalmic autoROC measuring system were determined at Hecht Contactlinsen GmbH, whereby a procedure was used based on the BOSCH guideline [8]. This system was used for measuring the rear surface radii of contact lenses at different stages of manufacture. Measurement of the radii during production was performed in the state (see figure 1).

**THE SIMPLE SUITABILITY TEST (PART 1)**

**PREPARING FOR THE INVESTIGATION**

The aim of the investigation was to assess the manufacturer’s data. To carry out the ‘simple suitability test’ a master standard was used. The standard was supplied with an inspection certificate which documented the accuracy of the standard. This standard was kept for at least 24 hours in the area where it was to be used to let it acclimatize. The standard is of spherical geometry with a radius in the typical application range.

The measuring system was set up according to the manufacturer’s guidelines and made ready for use. The standards and the contact surfaces of the measuring system were cleaned. After starting the measuring system, this was followed by a 30-minute warm-up phase.

**CARRYING OUT THE MEASUREMENTS**

After the warm-up phase, the operator carried out 50 measurements. The measurements were performed one after the other without pause. To do this the standard was placed in the measuring system before each measurement and removed again afterwards. The measurement was carried out according to a fixed procedure (standard operation procedure). The radii measured were documented for subsequent evaluation.
CALCULATION OF THE SUITABILITY INDICES

After measuring the standard, the calculation and evaluation of the following characteristic values was performed. The following data was used to calculate the suitability indices:

- \( n = 50 \)  
  Number of measurements carried out
- \( X_m = 8.125 \text{mm} \)  
  Set value (Normal)
- \( T = 0.04 \text{mm} \) (equiv. \( ±0.02 \text{mm} \))  
  Default for the tolerance value of the rear surface radii

Before it was possible to start with the calculation of the suitability values, the following consideration was taken into account: The suitability values \( c_g \) and \( c_{gk} \) can only be reliably estimated if the measured values are normally distributed. If the measured values are distributed differently, the suitability of the measuring instrument will either be over- or underestimated. Thus, in all cases, the measured values should be checked for normal distribution. Once this has been shown to be the case, then in the next step the arithmetic mean value and the standard deviation can be determined:

**Determined mean value**

\[
X_g = \frac{1}{n} \sum_{i=1}^{n} x_i = 8.1267 \text{mm}
\]

**Determined standard deviation**

\[
s_g = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} (x_i - X_g)^2} = 0.0005 \text{mm}
\]

Based on these the suitability indices can be calculated.

Measuring instrument suitability \( c_g \)

\[
c_g = \frac{0.2 \cdot T}{6 \cdot s_g} = \frac{0.2 \cdot 0.04}{6 \cdot 0.0005} = 2.67
\]

Critical measuring instrument suitability \( c_{gk} \)

\[
c_{gk} = (X_m + 0.1 \cdot T - X_g) = \frac{8.125 + 0.1 \cdot 0.04 - 8.1267}{3 \cdot 0.0005} = 1.53
\]
\[
c_{gk} = \frac{X_g - (X_m - 0.1 \cdot T)}{3 \cdot 0.0005} = \frac{8.1267 - (8.125 + 0.1 \cdot 0.04)}{3 \cdot 0.0005} = 3.8
\]
\[
c_{gk} = \text{MIN}(c_{gk}; c_{gk})
\]

Thus it follows:

\( c_{gk} = 1.53 \)

INFERENCE REGARDING SUITABILITY

The measuring instrument is suitable when the following demands are met:

\( c_{gk} \geq 1.33 \)
\( c_g \geq 1.33 \)

In the example described, this applies both for the measuring instrument suitability \( c_g \) as well as for the critical measuring instrument suitability \( c_{gk} \). Thus, the preconditions for the subsequent suitability test under stricter suitability conditions were fulfilled.

THE STRICTER SUITABILITY TEST (PART 2)

Test samples were deliberately chosen for the stricter suitability test. In comparison to the simple suitability test, this procedure is considerably more complicated. One aim is to gain a good impression of the reliability of the measured results over the whole range of the process. Thus, the rear surface of the contact lens to be tested needs to be representative of the whole range of the process.

PREPARING FOR THE MEASUREMENTS

In preparation for the investigation, the samples were first made under real production conditions. The material to be used was first stored for 24 hours in the production area before manufacturing the rear surfaces. For the stricter suitability test at Hecht Contactlinsen GmbH, samples with a spherical geometry and radii of curvature in the whole supply range are made in a ‘usual’ material (not PMMA).

As with the simple suitability test (part 1) here, too, the measuring system was set up and rated according to the manufacturer’s guidelines. After starting the measuring system, this was followed by a 30-minute warm-up phase. The aim of the investigation was to access the characteristic value %R&R. This indicates, taking account of...
all process parameters, whether the measuring instruments is suitable for a measuring task. Here it is important under what conditions the measurements are carried out:

- Measurements are performed according to a fixed inspection method/procedure (testing instructions)
- The test in each case is carried out on 10 (n=10) specimen samples
- Three repeat measurements are carried out
- The test is carried out by two operators (k=2)
- The test may be carried out on different test equipment.
- The test should be carried out (where possible) at different locations.

CARRYING OUT THE MEASUREMENTS

The individual operators carry out the measurements on the different test specimens. The results of the measurements are made up of the true value together with the systematic and random errors. When carrying out the test, it is important to take the following points into account:

1. The parts were chosen so they come from the whole manufacturing range.
2. They were measured in random order; the operator measures all the parts one after the other.
3. In order to be able to assess the differences between the individual operators, no other operator is present during the measurements.

EVALUATION OF THE RESULTS

The following tables show the results of a series of measurements which were carried out. In this investigation the total of ten production parts (n=10) were measured three times each (r=3) by two operators (k=2).

For evaluating the results, various methods have proved their worth in practice. Since these methods differ, they also lead to differences in the R&R value calculated. Thus it is always important to specify which method was used. The following results were calculated using the average and range method (ARM).

For k=2 operators, r=3 repeat measurements and n=10 production parts, this resulted in the K-factor K1=0.587 [7].

For k =2 operators, the K-factor K2=0.7072 [7]. Thus it follows:

The determination of the repeat and comparable precision (R&R) can now be calculated as follows:

\[
AV = \sqrt{10 \cdot \left(0.0012\text{mm} \cdot 0.707\right)^2 - \frac{0.0007\text{mm}^2}{30}} = 0.0081\text{mm}
\]

The operator variation (EV) is determined by

\[
EV = R \cdot K_1
\]

where

\[
R = \frac{\sum_{k=1}^{2} \sum_{i=1}^{n} R_{k,i}}{k \cdot n}
\]

For k=2 operators, r=3 repeat measurements and n=10 production parts, this resulted in the K-factor K1=0.587 [7].

\[
EV = R \cdot K_1 = 0.0012\text{mm} \cdot 0.587 = 0.0007\text{mm}
\]

When calculating the appraiser variation (AV), the following must be taken into account:

For \( R \cdot K_1 \leq \frac{EV^2}{n \cdot r} \) to be fulfilled, the result of the square root must be zero or negative. In this case the influence of the operator is so small with respect to repeatability that it can be ignored.

For k=2 operators, the K-factor K2=0.7072 [7]. Thus it follows:

\[
AV = \sqrt{(0.0012\text{mm} \cdot 0.707)^2 - \frac{(0.0007\text{mm})^2}{30}} = 0.0081\text{mm}
\]
The measurement of a quality-related parameter such as, for example, the rear surface radius of a contact lens comprises a variety of factors all of which may influence the result of the measurement. To obtain a realistic assessment of the accuracy and precision, the following factors need to be taken into account:

- Resolution
- Operator
- Object to be measured
- Method/Testing instructions
- Surroundings

Frequently only the first three points above are considered. However, particularly in the case of complex measuring tasks for example, the surroundings often have a significant effect on the results. Whatever the case to assess the suitability of a measuring system the values of the resolution, repeatability and reproducibility should always be taken into account.

### For and Against a Multi-Stage Process

The simple suitability test (part 1) assesses the systematic measurement deviation and the repeat precision under ‘idealized’ conditions: With repeated measurement of the rear surface radius the existing conditions remain unchanged. Thus, results determined under these conditions always represent the ‘ideal case’.

Since the ‘stricter’ process (part 2) represents the more comprehensive procedure and takes a larger number of parameters into account, it would be easy to think one could do without the first process. But in reality it is still very important. Because it is through this process that the traceability to national and international standards can be established and divergences determined based on systematic measurement deviations. A further reason lies in the simplicity of this process (part 1). Even though it is carried out under idealized conditions (i.e. with measurements only being made on one reference part by one operator/appraiser), one very quickly gets an initial impression. If the simple procedure immediately shows that the measuring system is not suitable, it is not necessary to proceed with any further investigations using the stricter process. Thus, at an early stage in the proof of suitability it is possible to initiate improvements and corrective measures.

### Significance of the Results

The method presented here for testing the suitability of inspection processes is just one possible variant. As previously mentioned, the way of calculating the suitability values cg and cgk may vary (depending on the manufacturer’s guideline). Also, when evaluating the measured values according to the stricter process, different methods may be used. Here, for example, the Average and Range Method (ARM) has been used. The same applies to the decision about which reference value (reference figure = RF) to use for calculating the repeat and comparable precision. Furthermore, each manufacturer can decide in-house which tolerances to use for his own standard.

### NOTES:

The K-factors are determined from the so-called d2-table according to Duncan [9]. All the guidelines known to us are based on this table (see references).

### Inferences Regarding Suitability

Up to now, only defined characteristic values exist which were calculated with the aid of the measured value. To make a statement about the suitability of the measuring process, these results must be compared with a reference value (RF'). In our case, for this we use the tolerance T specified in the testing instructions. The advantage here lies in the fact that the tolerance is generally specified as a fixed value. A measuring instrument is suitable, when the following conditions are satisfied:

- $\%R&R \leq 20\%$ for new measuring systems
- $\%R&R \leq 30\%$ for measuring systems in use

The first condition is based on the GMPT Guideline [4]. The calculation is based on the following equation and leads for the parameter $\%R&R$ to the following results:

$$\%R&R = \frac{6 \cdot R&R}{T} \cdot 100\% = \frac{6 \cdot 0.0011\text{mm}}{0.04\text{mm}} = 16.1\%$$

Here, T expresses the total tolerance range, i.e. at T=±0.020mm the total tolerance range T=0.040mm. Practical experience shows that only the most important measuring processes reach values for $\%R&R < 10\%$.

### Conclusion

A common and widely used method today for proving the suitability of measuring pro cesses consists in investigating the measuring instrument suitability. However, as there is no standardized procedure for doing this, a variety of different methods are used in practice. The measurement system analysis (MSA) variant described here has proved a reliable way of determining the measuring instrument suitability at Hecht Contactlinsen GmbH.

### Appropriate Procedure

The measurement of a quality-related parameter such as, for example, the rear surface radius of a contact lens comprises a variety of factors all of which may influence the result of the measurement. To obtain a realistic assessment of the...
The results presented here are thus not ‘generally applicable’. This may lead one to ask the question what is the purpose of all this effort. However, the principal aim of suitability testing is to ensure that the measuring results within one company are reproducible and comparable. Irrespective of any individual differences between the methods for calculating the suitability parameters, the procedure leads to a concrete statement about whether specific tolerances can be met under production conditions.

CORRECTING SYSTEMATIC ERRORS

When assessing measuring instrument suitability (simple suitability test), the procedure presented here only uses one single standard. Due to the natural limitation of a measuring system this leads to systematic errors which may vary in size over the full measuring range. In order to compensate for these systematic errors, before the investigation of the measuring instrument suitability and the use in production, the device needs to be calibrated and the linearity assessed.

LIMITATIONS OF THE PROCEDURE

The experimental values shown here confirm the suitability of the measuring system presented, based on the given tolerance limits for spherical and rotationally symmetrical geometries. On this basis, however, it is not possible to make any assertions regarding the accuracy and precision under the following conditions:

- Unpolished surfaces
- Toric surfaces
- Aspherical or multi-curved surfaces
- Combinations of the above conditions

Based on current experience with the use of measuring technology at Hecht Contactlinsen GmbH no appreciable impairment of the results is to be expected. However, with toric surfaces it should be taken into account that, where appropriate, tolerances concerning the differences in radii could be defined. In this case, when calculating the characteristic values, the spread of both measured values (in the surface and in the steep meridians) should be taken into account in the error calculation.

CLOSE COOPERATION

As already described in the previous article, unfortunately the supplier of the measuring system can only give ‘points of reference’ concerning accuracy and precision. To be able to assess the testing process under realistic conditions it is necessary to know the influencing factors as well as their effects.

For the contact lens manufacturer to be able to measure the required parameters with the appropriate accuracy, close cooperation with the supplier in our opinion is not only desirable but absolutely essential. Already when choosing the measuring instrument, the contact lens manufacturer should define a specification in which amongst other things the intended site where the equipment is to be used is described in detail, taking into account the points mentioned.

OUTLOOK

The importance and use of highly specialized measuring equipment has increased in significance over the past few years; not only in the field of contact lens manufacture. When determining the radii not only do the automatic measuring instruments available today provide precise measurements in seconds but also additional information about surface and shape deviations. Depending on the system used it may also be possible to inspect the surface for scratches, fissures or turning marks. The accuracy and precision is usually sufficient for use in contact lens manufacture.

In the meantime, the topics of ‘suitability investigation’ or ‘testing process suitability’ have become increasingly important. For example, EN ISO 13485 not only requires that measuring equipment is regularly calibrated and verified,
but in addition that, the measuring process be planned and implemented in such a way, that the conformity of the product can be demonstrated. These properties can only be adequately determined if the implemented testing procedure is assured. While none of the guidelines used by contact lens manufacturers specify how the suitability of a testing procedure is to be proven, nonetheless suitability investigations need to be presented in order to obtain QS approval certification. Independent of this, such investigations always provide the following: a meaningful statement about how accurately quality-related parameters and realistic production conditions can be determined. Thus, the wish remains, combined with the request to the appropriate standardization bodies, to define suitable tolerances based on what is technically possible under comparable conditions.

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