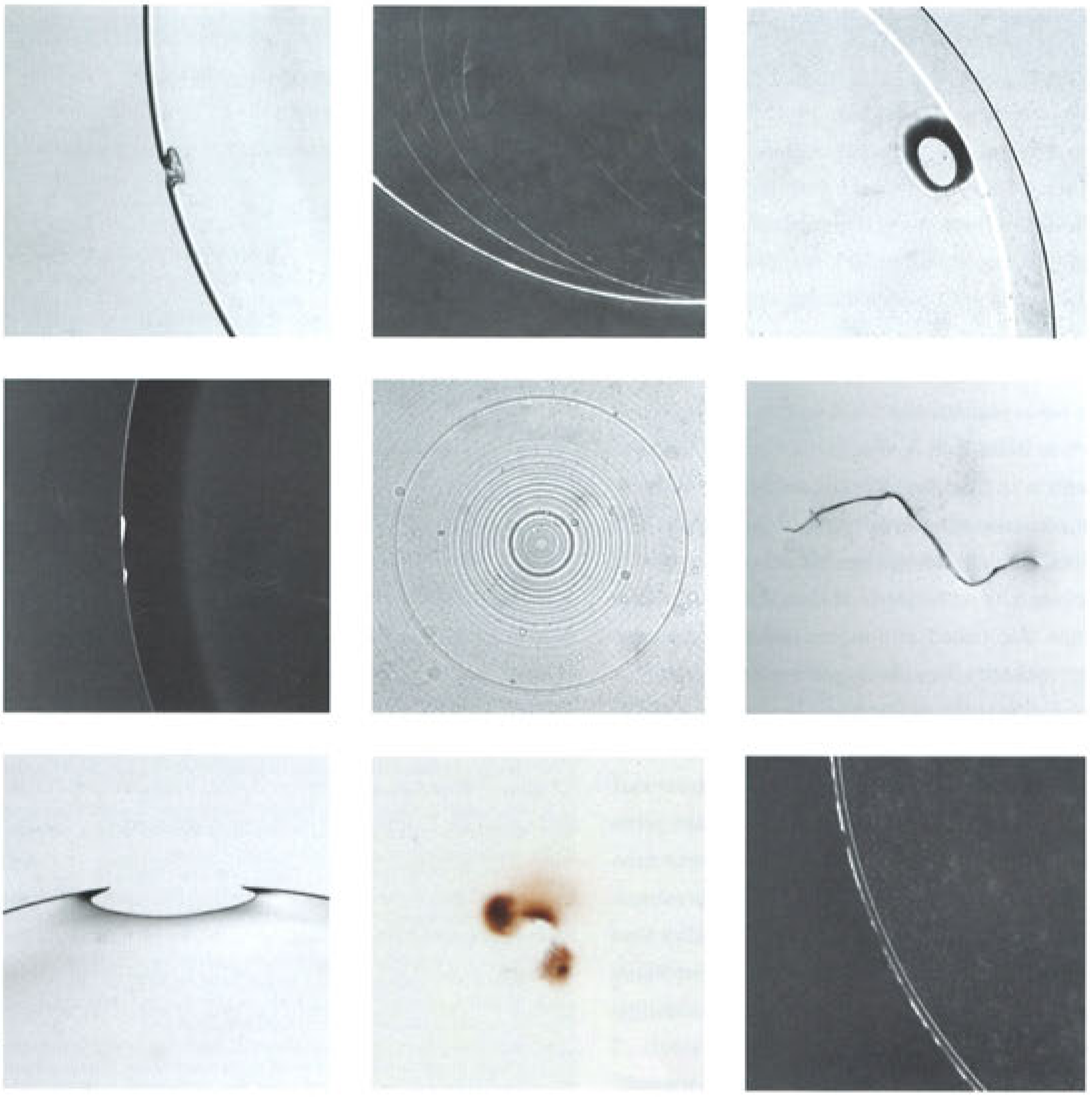


Examples of defects visualized in different views

The (r)evolution of soft contact lens testing

Today's soft contact lenses have little in common with the early examples of the Hema spherical devices first created by Professor Otto Whictele, other than their intended purpose, to provide safe, comfortable and satisfactory vision to the individual that is wearing them.

By Steve Newman and Johannes Pfund

The humble Hema contact lens has been reinvented and refined over the years to the point that today's lenses can now accommodate almost any optical or ocular anomaly. This development has involved the creation of sophisticated materials and designs that can provide an eye care practitioner and patient with choices that were unheard of in Professor Whicterle's day. Materials that mimic naturally occurring components of the tears and can provide hyper levels of oxygen to the cornea are now the norm, rather than the exception.

Lens designs are becoming more and more comprehensive and can now provide patients with unparalled quality of comfort and vision; difficult types of corrections that used to be treated only with RGP lenses are now routinely corrected; severe astigmatism, presbyopia, keratoconic management etc. are all candidate conditions to be treated by soft lenses today. This level of design sophistication has been driven, in part, by improvements in the equipment used to measure and analyze the eye and its various ocular shortcomings. The use of such equipment and the acquisition of critical knowledge related to the eye has allowed lens designers to create lenses that can relate to the eye's physiological and optical requirements, however severe they may be.

The introduction of daily disposable soft contact lenses raised the bar even further, in as much as the eye's natural adaptive abilities were rendered null and void. The practice of wearing a contact lens over a period of a week or a month allowed lens manufacturers a little latitude in parameter consistency as the patient can adapt to small variances in key parameters over the

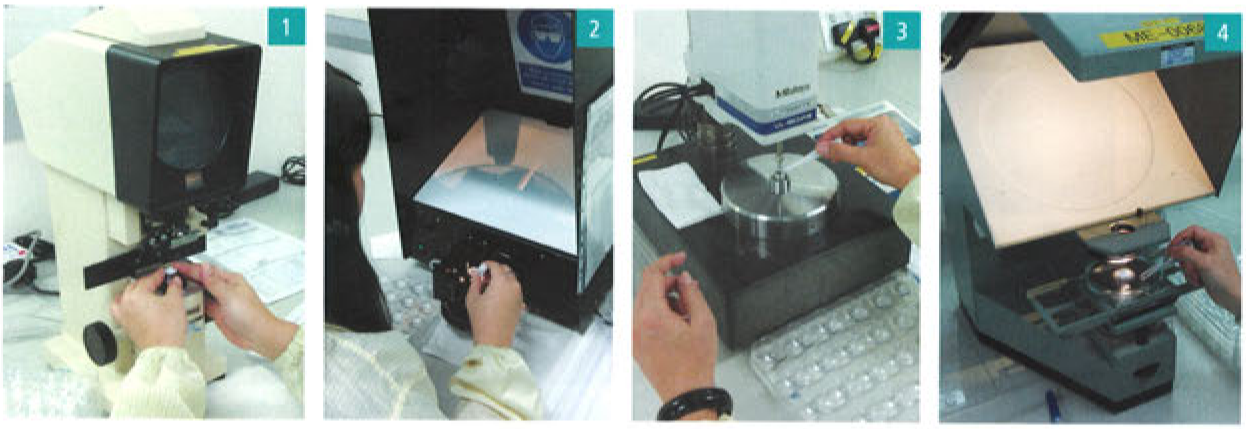


Fig. 1-4: Soft contact lens testing

wearing period. Replacing the lens on a daily basis however places a greater onus on ensuring that the lens feels and behaves exactly the same as the lens that preceded it. Companies that produce daily disposable contact lenses constantly strive to improve their processes and material consistencies to achieve this aim. Vast amounts of capital are spent in developing manufacturing systems that will deliver lenses at mind boggling volumes, low unit costs and yet maintain higher levels of quality then ever seen in this industry.

In order to validate these sophisticated designs and high volume products an appropriate inspection system is required.

To date, such a level of inspection has been lagging behind the ever changing design and manufacturing landscape. Even the current ISO standards concerning lens parameter acceptance criteria and the methodologies described therein do not address all available lens designs and it is largely up to the manufacturers to define the parameters and accuracy of those products.

Thus, there is an opportunity to improve the monitoring and management of relevant manufacturing processes via more accurate and comprehensive inspection techniques, both of the products in general and particularly in quality control and the ultimate level of assurance that the company will be able to provide for its products. In this article a selection of traditional test equipment are described and a brief discussion of the current status quo will be provided.

The SHSOphthalmic omniSpect will be introduced as a novel approach to SCL testing. We believe that such a system can improve processes in industry and institutes.

SOFT CONTACT LENS TESTING SO FAR

There are a number of key parameters that have to be routinely tested in soft contact lenses (figures 1 to 5):

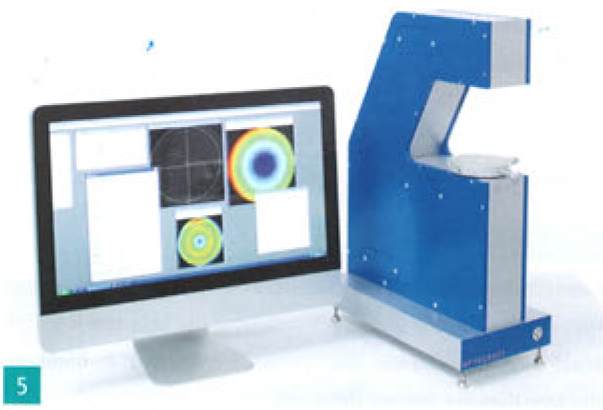
- optical function (conformance to prescription and quality)
- parameters (geometry)
- product integrity (imperfections)

OPTICAL FUNCTION

The optical function of the SCL is related to achieving optimal visual acuity for a given correction, whether that correction be spherical, astigmatic or something more complex. The more common lenses can address both spherical and astigmatic requirements in a number of materials, ranging from low to high water contents to silicone hydrogel. Such material diversity can result in varying measurement conditions due to differences in refractive indices, modulus and the like. Contact lens behavior can vary quite dramatically due to such factors and can influence final parameter or quality interpretation as a result. Certain designs will include the use of mild levels of asphericity in an attempt to improve visual acuity via the neutralization of certain aberrations present in the human eye. Other designs may employ the use of stronger or more complex levels of asphericity to achieve pseudo accommodation for the presbyopic eye, or to control the growth of the young eye in order to manage myopia.

POWER

Traditional soft contact lens power measurement utilizes manual refractometers (focimeters) that can generally only measure spherical and toric power and axis. They are based upon the principle of lens neutralization and are not suitable for analyzing aspherical lens forms. Many of these devices have a rather coarse numeric output and depend on the operator's expertise and experience in achieving accurate and consistent results.



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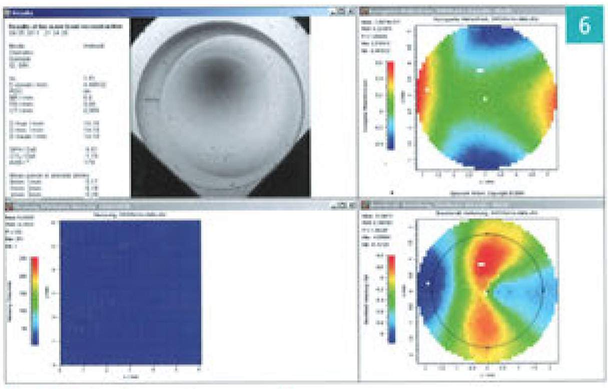

Fig. 6: Typical output screen of a power mapper

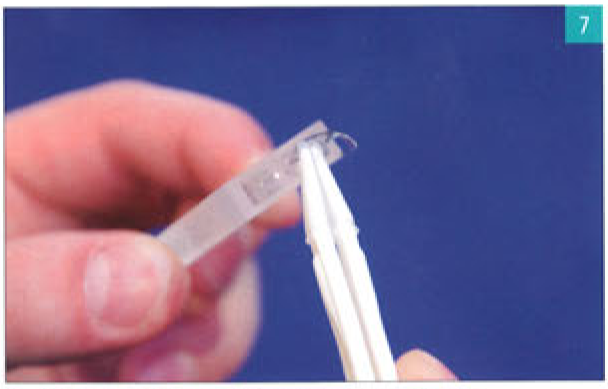

Fig. 7: Traditional plano wet cell for power mappers

Newer versions may include digital measurement and output and thus provide a somewhat higher accuracy and higher repeatability. All of these systems however rely on the soft lens being dabbed or dried to a certain extent prior to measurement to remove surface water from the lens. If this were not done, the focimeter would not be able to resolve the contact lens image and therefore not be able to determine a power or focus quality level. Both the lens dabbing procedure and the actual positioning of the lens onto the focimeter require a high level of skill to ensure accuracy and consistency.

POWER MAP

For aspheric and multifocal lenses, various instruments have been developed that can measure the local power distribution across the optical zone. Such instruments include those that utilize Shack-Hartmann sensors or Fringe projection techniques. See the screenshot of a typical output of the graphical user interface (figure7). These lens mapping systems use special plano cuvettes to measure the hydrated lenses in liquid (figure 8). There is a challenge to load the lens in the plano cuvette without affecting it's shape and thus affect the measured result and/or quality of the lens under test. The act of positioning a lens in such a cuvette is also time consuming and not particularly suited to high volume inspection processes.

GEOMETRY

Geometric testing includes at least three different parameters:

- diameter of the lens (diameter)
- concave radius of the lens or sagittal depth over a given chord (BCOR)
- thickness of the lens at its center (CT)

DIAMETER

Lens diameter is commonly measured by using instrumentation that projects both a magnified image of the lens and a length scale onto a screen and thus allows the operator to compare the lens directly against the scale.

BCOR

The base radius (BCOR) of the lens is tested by various means. In one form the total height of the lens vertex (SAG) is measured and the center thickness and the lens diameter are used in order to calculate an equivalent base radius using a spherical model. Another technique is to probe the position of the inner lens vertex (i.e., the vertex of the concave surface) with a pin that has its origin on a chord of a known length (upon which the concave surface of the lens is resting) and to measure the axial point where the lens shows movement induced by the pin. Both techniques require skilled operators and provide a limited level of measurement sensitivity.

CT

For CT measurement, low force touching probes, ultrasonic devices and other types of sensors are used as stand-alone devices. Again this adds another device in the process whereupon the lens has to be inserted and aligned properly.

IMPERFECTIONS

There are many different types of imperfections that can be created during the manufacturing process, such as edge defects, surface defects, bubbles, etc. and they must be identified and evaluated to a standard of quality.

The level of quality to which the manufacturer will grade its lens imperfections can have a significant impact on lens comfort, handling, in eye performance etc. Due to the variety in both type and severity of such imperfections some have to be measured qualitatively and some quantitatively.

Today, imperfections are generally tested via manual instruments or by way of automated process (automated inspection systems are often custom built for a particular customer and are not readily available for all types of product or processes).

A standard testing process in QC foresees that an operator uses a projection device with large magnification (e.g., in the range of 10x to 20x) in order to observe, identify and judge a lens to a quality standard that is adopted by the company.

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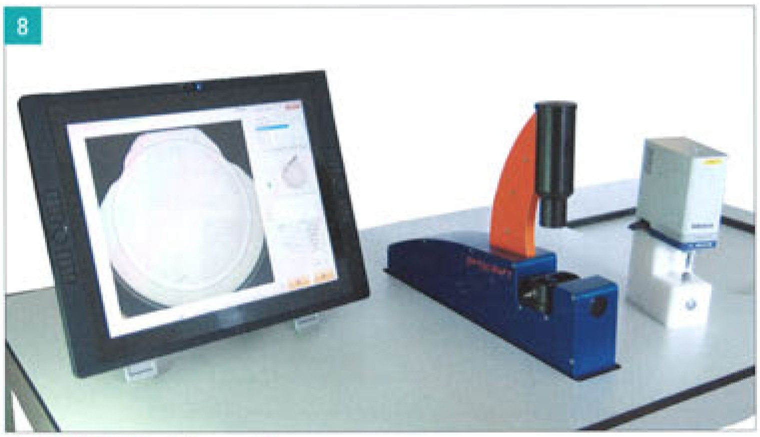

Fig. 8: SHSOphthalmic omniSpect

9

Fig. 9: Working screen of the SHSOphthalmic omniSpect

ISO standards provide a minimum guideline in terms of magnification to be used and grading that can be adopted. This does not preclude companies from adopting standards that are higher than those provided by ISO.

WHAT MUST BE IMPROVED?

Common standard operating procedures (SOPs) for contact lens inspection often call for the use of different instruments that need to be operated manually. This has several implications. Firstly, the lenses are handled multiple times in both air and saline and as such can be damaged or may be prone to inaccuracies due to parameter changes caused by physical or environmental effects. Secondly, the lens must be tracked between instruments and techniques and a record of inspection must be maintained manually. This can lead to time loss, inefficiencies in procedure and inaccurate QC outcomes due to human error. Due to the independent nature and output of each instrument and the overall complexity of the combined inspection process, the inspection operators who are carrying out this exercise must be well trained and experienced, particularly if they involved in the sampling of high volume lenses for the purposes of batch release (the quality acceptance of a large LOT of lenses, based upon a quality sampling plan). The fate of hundreds of thousands of lenses can rest on the shoulders of a few individual operators. Inspection accuracy and consistency both individually and between operators must be optimal if accurate QC results are to be obtained. This becomes a significant area of human investment for large contact lens manufacturers and requires both time and careful staff management.

The current QC processes can be time consuming and, depending on the size of the manufacturer, can pose a significant cost to the organization. A typical manual cycle for a comprehensive QC of a soft contact lens may extend to three till five minutes. The ideal modern testing equipment should be able to accomplish the requisite measurements and analytical processes with a high level of sensitivity, accuracy, consistency and objectivity. Such a system would assist companies in developing and validating more sophisticated lens designs whilst providing better levels of quality assurance for their customers.

THE FUTURE OF SCL TESTING

The concept of the SHSOphthalmic omniSpect (figure 9) was an attempt to provide a step change to the current level of contact lens inspection processes by creating a sophisticated inspection station that would be able to assess any type of contact lens, irrespective of design complexity, and yet be intuitive and simple to use. It had to be able to address both qualitative and quantitative analysis via a singular process, provide objectivity to the act of inspection and be significantly faster than the current processes. It also had to address ergonomic, training and data management concerns and would be designed from the ground up for its purpose.

Whilst the brain of this system is all-new software that provides a unique ergonomic workflow and intuitive interface, the heart of the SHSOphthalmic omniSpect is a unique semi-open top cuvette with extended functionality and superior lens handling properties.

ERGONOMIC SOFTWARE

The complete testing process is controlled by the software. There are different levels of control and complexity provided to allow full customization to match the intended inspection mode (figure 10). These include administration, R&D and production modes and within each of these, particular tasks can be initiated.

Production mode for example, allows for essential data input such as LOT number and nominal power and a single button step by step procedure to take the operator through the inspection routine. The operator will have a single touch screen available that shows all relevant data as defined by the administrator. Operator ID can be input via a variety of secure means, including

Fig. 10: Multi-functional open wet cell

biometric. The procedure consists of up to five single steps via an intuitive and prompted workflow. This is accomplished with a single start button on the screen and a minimum of operator to lens interaction and handling. All data-communication is running in the background without need for input by the operator. The tolerance values for the lens under test are read from the acceptance table (customizable input) and all measurement and qualification results throughout the process are stored in the result table. A link to customer data bases can be provided for retention of all recorded inspection data. All human influence in recording such inspection information can be avoided effectively by retention and management of inspection data. At the conclusion of a sample based inspection LOT or a testing cycle for an individual lens a report can be printed for signature by the operator.

Operator training and qualification is greatly simplified as the software comprises a player mode that can be used for cycling measurements with well-defined results. For example, the appearance of different types of imperfections and the measurement of their size can be demonstrated and trained easily. Such imperfections can be classified simply and assigned to objective overlay pass/fail criteria. The operator no longer passes judgment on the imperfection, having only to identify its type. Even identification activity can be precluded from their role if required, particularly in the cases of critical imperfections such as rust. Running the system in this mode the software will automatically identify and judge such imperfections. Also an objective qualification of the training and operating results can be achieved by comparing the results of the individual operator with the reference data and for calculating statistical process control (SPC) numbers.

In addition to the process oriented features, SHSOphthalmic omniSpect provides a sophisticated measurement performance. Its high sensitivity level reveals features and imperfections in soft lenses that have tended to be hidden by measurement noise and inter operator variability so far.

MULTIFUNCTIONAL WET-CELL

The wet-cell in which the lens is inspected is a key area of concern in any inspection system as it controls both the positioning and stability of the lens during a critical testing phase. It must also be optically inert and must not influence the overall result to any degree.

The wet cell designed for the SHSOphthalmic omniSpect, is a sophisticated, optically inert unit that maintains the lens in a vibration and temperature controlled environment, whilst still allowing the operator freedom to manipulate the lens if required. It has high optical quality and includes different optical access paths for various measurement functions (compare the picture in figure 10, that shows a plano wet-cell commonly used for lens mappers). This type of wet cell design, in combination with the intuitive and simple software has dramatically improved both inter operator variability and inspection times. A complete measurement cycle can be completed in less than one minute including loading and unloading of the lens under test.

CONCLUSION

A thorough analysis of the shortcomings of the traditional quality control process of soft contact lenses has led to a concept for a completely new system that will help to improve the performance of the quality control process. The system described in this article will provide a simple, faster and more consistent inspection process and will enable new possibilities for design and production of soft contact lenses in future.

The instrument described in this article is a result of a joint development project between Optocraft GmbH (Germany) and Menicon Singapore Ptd Ltd. (Singapore). Special thanks to Mr. Hiro Oyama (Menicon), Dr. Juergen Lamprecht (Optocraft) and Mr. Maik Lano (Optocraft).

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Dr. Johannes Pfund is co-founder and managing partner of Optocraft. He obtained his PhD in physics at the University of Erlangen-Nuremberg. His expertise covers the range from wavefront sensing, interferometry, optical test systems for optical industry, laser industry, astronomy and ophthalmology. Today he is focussing on strategic planning and market development.