With hundreds of millions of people choosing contacts for either visual or aesthetic reasons, and millions more having surgery to solve vision problems associated with aging, there is a growing need for high-volume manufacturing process control for ophthalmic products. Proper process control will improve yield and comfort for the wearers as well as ensure quality manufacturing. This application note discusses the manufacture and production of various contact lenses and intraocular implantable lenses (IOLs) and how properly deployed metrology, using advanced 3D optical microscopes provide a high return on investment to manufacturers in this space.

**Spherical, Bifocal, Specialized Contact Lenses and Intraocular Implantable Lenses**

A contact lens is a device worn in the eye primarily to correct poor vision. The thin plastic film floats on a film of tears directly over the cornea of the eye ball. The spherical contact lens was the original contact lens design and was targeted for the younger consumer. Its spherical design shape made it the perfect solution for near-sightedness and the person on the go that didn’t want the hassle of wearing glasses.

With the dynamics of an aging population came the design of bifocal contacts and intraocular implanted lenses (IOLs), which are now the fastest growing segments of the ophthalmic lens industry. This change is being driven by the 40+ age group due to two issues. The first is presbyopia, which is believed to be a gradual hardening of the lens of the eye that limits the ability to focus on near objects. Among the first signs of presbyopia are difficulty seeing in dim light, problems focusing on small objects, and difficulty reading fine print. The second condition is cataracts, which is a clouding of the natural lens of the eye ball. Since both cataracts and presbyopia are age related, they often occur together later in life. Typically a person that wore contact lenses younger in life for nearsightedness who has now developed presbyopia, would now require bifocal contact lenses for correction for near and far sightedness.

Bifocal lenses can be designed in several different ways. Figure 1 shows the three main designs. The translating or alternating design is very similar to bifocal glasses, with distance on the top and near power on the bottom. The eye needs to alternate between the top and bottom of the contact lens to see properly. The other two designs are simultaneous designs, which require your eye to look
to keep the lens in place within the eye. Early IOLs were mono-focal, meaning they offered vision correction for only near or far sightedness. Similar to bifocal contacts, multifocal IOLs have now been developed to correct for multiple distances.

Another condition of the eye that isn’t age dependent is known as keratoconus, which affects around one person in a thousand. This is a degenerative disorder of the eye in which changes within the cornea cause it to thin, change shape, and bulge out of a normal gradual curve. Keratoconus can cause substantial distortion of vision with multiple images, streaking, and sensitivity to light as common effects.

In the early stages of keratoconus, soft contact lenses can suffice to correct for the mild astigmatism. A soft lens has a tendency to conform to the conical shape of the cornea, thus diminishing its efficacy. The patient then can move to rigid contact lenses, which give more cornea support by allowing tears to fill the gap between the irregular corneal surface and the smooth regular inner surface of the lens. As the condition worsens and before surgery is considered, hybrid lenses have been developed, which are hard in the center and encompassed by a soft outer skirt. The transition between the hard inner core and the soft outer skirt needs to be smooth and defect free to prevent any eye or eyelid discomfort.
Many older consumers also need correction for astigmatism, where the ocular system needs one power of correction in one axis and another power of correction in another axis. Toric lenses that correct for astigmatism generally have two powers orthogonal to each other, and the corrective lens must be held static to maintain the proper angular orientation between the two powers. Two different methods for maintaining angular stabilization for a contact lens are a double-slab-off and prism ballast, both of which use gravity and blinking to hold the lens in place. IOL Toric contact lenses also require that the lens does not rotate.

There are additional variations of lenses that block certain wavelengths of lights, correct for aberrations, improve contrast and adjust light, to name a few. There is even development going on to incorporate Heads-up Displays (HUDs) into contact lens, which will help to further grow the contact industry.

**Lens Manufacturing and Master Pins**

The market is being driven toward contact lenses and IOLs that contain both surface structures at the nanometer level and aspheric designs with spherical and cylindrical shapes in differing axes. Although all contact lenses’ raw material is made from a form of plastic polymer, there are several different ways to manufacture the lens, with each method yielding slightly different results and different selling costs. Typically the two main ways of making the lens is by cutting it on a lathe, or by molding the lens into the proper shape by forming or injection (casting).

Cast molding is the primary manufacturing method used for producing the more complex lens designs. This method utilizes front and back curve molds that typically are molded from a “master pin” tool that is machined using a diamond blade. This master pin contains the nanometer-level structures that must be accurately replicated on the lens. Different master pins are used to create the front and back curve molds. The front and back curve molds are assembled in mold inserts. A polymer is injected into the mold and thermally cured. The lenses are then hydrated where they absorb 20% to 70% water by mass.

The master pins wear out after producing a number of molds, so contact lens manufacturing plants often must build new ones. Before each master pin can be used to make production molds, it must first be tested by building a trial mold that is used to produce a limited pilot run of lenses. The lenses are then tested to see if they provide the right prescription. In most cases the first batch of lenses does not produce the right prescription, so the pin must be re-engineered and re-machined, new molds must be produced, and finally a new batch of lenses must be molded and tested. In a typical lens manufacturing plant, it can easily take two to six iterations of this process to produce lenses that meet the prescription. Even after the lenses pass the test, problems later develop in many of the pins that require the pin to be re-worked causing additional production time loss.

**Comfort and Serialization on Contacts**

Obviously the major functionality of the contact lenses and IOLs is to improve the wearer’s vision. While modern contact lenses are designed to be very comfortable for most people, it is not uncommon to experience some discomfort. In fact, about half of the former contact users
report that they stopped wearing their lenses because they were uncomfortable. This irritation could be caused by the wrong prescription size for the eyeball, improper care for lenses, worn out lenses, dry eyes or even allergens and dust.

From the manufacturer’s point of view, it is worth great effort to prevent eye irritation before the contacts reach the consumer base. There are many process steps through the various different types of lens manufacturing. Many involve lapping, trimming, and polishing of the lens to eliminate any potential for protrusion, pits, and edge burrs that could potentially cause eye irritation.

**Advantages of 3D Optical Microscopy Measurements**

Bruker’s 3D optical microscopes utilize white light interferometry, also known as optical profiling, to accurately measure 3D surface roughness and profiles of the samples under test. In an optical profiler, light approaching the sample is split and directed partly at the sample and partly at a high-quality reference surface. The light reflected from these two surfaces is then recombined. When the sample is near focus, the light interacts to form a pattern of bright and dark lines, or fringes, that track the surface shape. The microscope is scanned vertically with respect to the surface so that each point of the test surface passes through focus. The location of the maximum contrast in the bright and dark lines indicates the best focus position for each pixel and a
An advantage of the 3D optical microscope is that a complete 3D surface measurement provides a much more holistic representation of the lens surface than is produced via 2D stylus. This can greatly reduce the need for additional iterations and rework for IOL pin generation, or optical tooling for contact lens manufacture. There are no step height measurement limitations applicable for ophthalmic manufacture, so 3D optical microscopes can be used to measure all types of lenses. For example, on IOLs, Bruker’s 3D optical microscopes can perform fast, non-contact characterization of the transition between the hard inner core and the soft outer skirt to ensure it is smooth and defect free.

In Bruker’s latest generation of instruments, the ContourGT® family of 3D optical microscopes, 64-bit software and multicore processing provide a faster and more intuitive software workflow while facilitating a higher rate of data collection. A patented illumination source provides increased light throughput speeding up measurement time while simultaneously providing enhanced data collection.

### Measurement Automation Techniques and Analysis

Bruker has added automation capabilities to their 3D Microscopes to speed the ability to measure large surfaces that don’t fit into the field of view of one image. One enhancement is the ability to stitch multiple images together. This allows the ability to make approximately 1000 images and stitch them together into one complete image.
Along with the stitching option, spiral stitching is an option where you can start at the apex of a lens and traverse down and around the lens until you reach the bottom. To ease setup, there is a lens stitch option where you enter the lens radius and sign.

In addition to these features, there is a “Return Scanner to Top” option, which starts the next measurement where the last measurement started. This allows the measurement to step up and/or down the lens as needed. Along with that is an Autoscan option, which stops the scan once the software sees that all or part of the data within that image was captured. This allows the very long scan ranges needed at the stepper edge slopes, but automatically stops the scan as soon as a full image is acquired.

In addition to the advanced automation, Bruker’s 3D optical microscopes all incorporate software with advanced analysis and data-logging capabilities. Not only does it automatically calculate all types of surface parameters with surface defect detection, it has a complete line of form removal and analyses for radius of curvature, volume, step, and Zernike coefficients for ease of data analysis.

**Conclusion**

The ophthalmic manufacturing world is faced with a rapidly growing demand for vision products over the next several years that will challenge manufacturers to lower production costs to remain successful. To help manufacturers keep pace with the rise in production volume and corresponding metrology needs, Bruker has tailored its 3D optical microscopes to provide versatile, rapid, non-contact surface finish and form measurements in a wide variety of ophthalmic research laboratory and production floor applications, from volume production of IOL pins and molds to lens surface analyses and optical tooling for contact lenses. Bruker’s 3D microscopes have the ability to give surface finish information that can detect burrs, pits, voids, and smooth transitions that other inspection tools cannot provide without significant time costs, or potential damage to the surface due to contact nature of the measurement.

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