MAKING A QUALITY LENS

Through the years we all have a tendency to take for granted the lenses we use, regardless of the material from which they are made. Compared to lenses of old that contained bubbles, stria and generally uneven surfaces, the quality we expect today is much different. In fact, the lenses of today have such excellent quality that we seldom think about those defects during the course of daily business.

This discussion includes a discussion of glass lenses that are currently made today and note the differences in manufacture from glass versus plastic lenses.

The greatest percentage of time will be spent on CR-39 lenses, since they represent the lenses which enjoy the largest volume of manufacture today in the United States.

Polycarbonate lenses will also be discussed. Polycarbonate is on the increase in usage and its important to understand differences between polycarbonate lenses and other lens materials.

Then we’ll discuss quality as it relates to the CR-39 lens and process.

GMP stands for “Good Manufacturing Practices” and has been created by the FDA to help control the manufacture of first, second and third class medical devices.

What happens when the lens leaves the factory and goes on to be surfaced at the laboratory will also be discussed as well as “after manufacturing” quality to see how the lens is treated before it reaches you.

Glass:

A simple definition of glass is a fused mixture of silica, usually in the form of natural sand, and two or more component glasses, such as soda, lime, or potash. There are single component glasses, such as silica glass and there are even two component glasses, such as sodium silicates. Glass is generally transparent or translucent and is brittle and when heated becomes soft and ductile finally melting.

An important concept is that the glass is not crystalline and when cooled to room temperature may seem hard, but in fact, has an extremely high viscosity and is actually still liquid.

It is not certain the exact date that glass was discovered. In 1857 Pliny wrote the following: “The story is, that a ship, laden with nitre, was moored upon (the river Belus). The merchants, while preparing their repast upon the seashore; finding no stones at hand for supporting their caldrons, employed for the purpose some lumps of nitre which they had taken from the vessel. Upon its being subjected to the action of fire in combination with sand of the seashore, they beheld transparent streams flowing forth of a liquid hitherto unknown. This, it is said, was the origin of glass.” This supposedly took place in Phoenice in Syria.
According to another historian, the earliest glaze known is that on stone beads during the Badarian age in Egypt, about 12,000 B.C. This glass was green in color and was used as a basis for making small figures. However, the more one reads about the origin of glass the more confusing it becomes due to the disagreement of historians on who and when it was discovered. We'll leave the controversy to the history buffs and take a look at production of the Crown glass of today.

Silicate sand is heated to between 2400 and 2600 degrees Fahrenheit. That together with other additives, such as soda ash, become molten and flows down this trough where it is snipped off in specific lengths. Each length that's snipped is a specific gram weight dependent upon the mold blank size it is to become.

Each piece drops into a mold and the red hot glass bank is die pressed in a hydraulic machine to form the shape appropriate.

The glass blank must cool slowly and this is accomplished through a series of gas burners which allow it to cool more slowly that it might otherwise.

From this point of the process the glass blank is annealed which is a process of heating the glass blank, and then cooling it very slowly over a period of four hours or more. This is necessary to remove the stress in the blank from the molding process.

Since the glass blank is unfinished on both sides, it must have at least one of its surfaces finished at the factory before being released as a semi-finished blank, or have two surfaces finished if it is to be a finished blank. What is shown here is something called the process where the blanks are positioned on a block using a derivative of pitch to secure the blank while it is generated to the proper surface and then polished.

If the blank is to be finished on both sides, the rear surface is generated and then polished in a multiple spindle system typical of a manufacturing process.

**Polycarbonate:**

Since polycarbonate is used for a variety of tasks in everyday life, it is supplied in a variety of colors.

Several chemical companies produce on optical quality polycarbonate material which actually looks like tiny ice crystals. One of these companies is Mobay Chemical Company in Pennsylvania. Another is Dow Chemical and G.E. in Pittsfield, MA, where Lexan is produced. These are actually small pieces of pre-formed polycarbonate material. The material is heated to a temperature of about 600 degrees Fahrenheit to make it less viscous and easier to form into particular shapes.
The piece of equipment used to shape it and heat it, is a large hydraulic press called an injection molding machine. The lenses are formed in this press in batches, which are called “shots”, between two to eight lenses each. The molds used to produce this product are made of polished steel and are cooled to bring the temperature down to solidify the molten plastic once the lenses have been formed to shape.

Once removed the lenses are inspected and cut from the “sprue” or “lens tree” as it is most often termed, prior to the next operation. This is the solidified river of material from the press to the mold.

Polycarbonate material is so soft that it must be immediately coated before even a Lensmeter inspection can be accomplished. Again, once the lens has reached the laboratory and has been surfaced, the rear surface must be coated immediately at the optical laboratory.

**Hard Resin:**

The incoming monomer is first mixed with a catalyst which will allow it to chemically form into a solid material. The monomer is then filtered and then degassed before it is used to fill the lens molds or “cells.” Once the cells have been filed they are placed in an oven to be cured and then disassembled and inspected.

In most instances the liquid monomer arrives in 55 gallon drums before it is mixed with the initiator or catalyst which is I.P.P (Isopropyle Peroxide Pardonte). Other additives can be included at this time, such as a UV inhibitor.

Air must be removed at this point of the process and the monomer must be kept cold. This is important so that the monomer doesn’t begin to solidify before it gets into the mold.

Almost a separate science, that of making gaskets from rubber, is taking place parallel to this operation. Important in gasket procedures is the ability of the gasket to remain flexible, yet hold its shape during the process. We’ll discuss this in more detail later.

Glass molds are produced using glass grinding and polishing equipment.

All of these different items meet in the production department where the molds and gaskets are assembled, filled with the monomer and put through a curing process to solidity and harden the lens. After the mold is disassembled, the lens goes through a series of quality control inspections which we’ll discuss in detail later.

And then finally, the lenses are packaged and readied for shipping and distribution. Now that we’ve taken a quick walk through what we’ll be discussing, let’s begin with the monomer.
Details:

While each manufacturer may have differences, the following example will be used.

Every morning a specific quantity of monomer is drawn and then mixed in a mixing house outside of the main plant. It is done outside due to the flammability of I.P.P when warm. I.P.P. must remain at sub zero temperatures prior to mixing. This is done through the use of deep freeze storage containers. Once this is completed, the monomer is degassed centrifugally to remove the air content, filtered and then finally poured into these holding drums.

The drums are then stored in the refrigerator to keep them cool until they are used during the course of the day.

Molds are generally made of glass and surfaced in the same way we would surface the average lens. The difference in this case is that the rear surface of this mold has been finished so that it will properly form the front surface of the CR-39 lens. We will assume that this particular mold has been surfaced and polished and has an acceptable surface on the inside. The outside surface that has been left is in a “rough ground” form.

If we desired to create a mold to produce a straight top bifocal CR-39 lens, then we would add several steps to this glass processing procedure.

One additional curve is ground and polished into the mold. The curve that’s ground, is steeper or a higher curve than the rest of the mold, as it is to be the add power. For example, if the lens we were to cast from this mold were to be a +2 add, then this additional minus curve would be about two diopters stronger than the surrounding curve of the mold.

A second piece of glass which closely resembles one half of a finished lens is ground and polished to fit the concave curve in the mold.

The second piece of glass is assembled to the mold. The two pieces will become hot enough to just melt together without changing form.

Once the fusion has been completed, more than half of the original concave spot curve has disappeared, as it is now one piece of glass.

At this point, the mold is ready to be regenerated, ground and polished.

Once this is done, the mold will appear as the reverse image of the lens it will eventually produce.

While the cast lens would look like this, it is really only part of the story. To have a successful casting, a cell must be formed with yet one additional mold to form the inside curve and a gasket to contain the liquid monomer. We’ll discuss this in a little more detail later in the program.
Perhaps the most rigorous inspection of all is done on the finished mold this is due to the fact that it will cast hundreds of lenses and if there were a flaw on the mold, each of the lenses would contain that flaw, as they are the mirror image of the mold. The inspector depicted here is using a powerful loupe to view the mold and assure that there are no cosmetic flaws, which could produce a reject lens.

The mold is then further inspected where measurements are taken as to the placement and exact size of the straight top bifocal in it. Since there are hundreds of molds of this same variety in use, each must conform to a rigorous engineering specification and quality specification because these molds will be intermixed, but must produce the identical lens.

Reflected monochromatic light further helps to establish that the edge around the bifocal is flawless.

Cosmetic and mechanical as well as visible inspections of the mold have been discussed. There are other inspections, of course, for sphere curve, cylinder curve, axis and add curve, etc., all of which are done on each and every mold. But the mold must be sealed against a gasket to form the final cell from which the lens will come, which is the next stop.

Gaskets are injection molded.

Although this seems quite simple, gasket tolerances must be watched very carefully as there are different gaskets produced, dependent on: size of the final lens; whether they are finished lenses or semi-finished lenses; various curves; thickness and of course, cylinder lenses.

Just one of the many tolerances found in gasket manufacture, is the “flexibility” or “ductility” of the gasket. Durometer test is completed where the ductility can be accurately measured. It is also recorded as part of the quality function.

The gasket can now be used as part of the mold assembly. The concave mold is shown on the left, the convex mold is shown on the right and the spring clip which is used to hold the two molds against the gasket, is shown below. The resulting lens of hard resin is shown to the right.

The actual assembly procedure takes place in a reasonably clean environment with an inspection light, so that the mold can be inspected for lint or dust prior to this assembly. Clean dry air is used to blow particles from the mold assembly.

A spring clip is snapped into position holding the molds firmly in place on the gasket. While this seems quite simple, it must be remembered that the amount of pressure exerted by the spring clip must not squeeze the gasket so much as to deform it and change the center thickness or edge thickness of the resulting lens, but enough so that no leakage can occur. This is why the Durometer test on the gaskets flexibility, is a vital part of the quality procedure in producing the lens.
The cell assemblies are pushed onto a needle and filled. This is done manually or automatically.

Once filled, the cells are then loaded into an oven where they will stay for the duration of the curing process over the course of a number of hours. Once cured, the newly formed CR-39 lens is firmly attached to both molds of the cell and force must be used to pry them apart to obtain the new finished lens.

The finished lens is inspected at this point for cosmetic flaws or chips that may have occurred due to a damaged mold. At this point in the operation, both molds are still available and can be rerouted for repair if the damage seen in the lens was caused by either of the two molds. This is Mold Traceability and is extremely important to reduce the number of repeated rejects caused by one damaged mold in the system.

The new lens is now ready for mechanical inspection. The lensmeter or Humphrey lens analyzer is utilized to verify sphere and cylinder power of the lens. Center thickness is then checked against specifications.

Final cosmetic inspection then takes place before the lens can go on to the next operation. Each lens is judged upon standards that have been previously set and are maintained in the quality control laboratory.

Operators are tested regularly against these standards as we will see later on.

In some manufacturing processes, the lenses are put into the oven for a post cure which help rid the lens of any moisture within the surface.

At this point, if the lens is to remain uncoated, it moves on to packaging. If, however, the lens is to be coated, it follows a different path.

The lenses are mounted on specially made hangers.

The hangers are then placed by an operator into an ultrasonic cleaner which must be used just prior to the coating process.

It is a multi stage cleaning operation which completely scour the lens and then dries it just prior to the coating operation.

Both the ultrasonic cleaning and the coating must be done in a clean environment. The coating machine is high technology equipment which controls its own environment, including the air filtration, temperature and humidity within.

The lenses are dipped into the coating solution for a predetermined time.
Once the cycle has been completed the lenses are removed by an operator and then placed in an oven or an ultraviolet chamber for curing.

Once again, the quality becomes an important issue for the coated lens as well. A complete inspection, as has been described previously, is once again done on a coated product to assure the same excellent quality.

Since abrasion resistance is an extremely important point, certain tests are conducted to verify that each batch of coated lenses maintains the same high standards of abrasion resistance.

This is a shaker attached to the Bayer abrasion tester. After a period of time in this shaker, the lens is removed and measured on a Hazemeter. The hazemeter establishes the amount of haze on the lens against the standard. Obviously if there was more haze than standard allows, then something in the batch may have been amiss and the lenses must be considered defective.

One abrasion test is good but two tests are better.

In a separate part of the plant a packaging operation is underway. Labeling is produced which contains all of the lens information as well as the bar code used for inventory purposes. Most important is the date of manufacture which helps the manufacturer trace lenses, which could be returned for a defect undetected by the quality function. While it is most unlikely that this will occur, traceability is very important in the manufacturing process.

In the warehouse or distribution center, the variety of lenses produced are maintained both in cartons and singularly along the edge of the packaging conveyor. There are over 8,000 different types of lenses in the typical warehouse. When an order is received the stock person picks each lens individually and packages it into that customer’s box for shipment that day.

Shipping time has been improved greatly through the use of the bar code system that was mentioned earlier. Through the use of this system, customers can place orders up to their closing time and then their computer feeds the Silor computer, which generates a picking list during the wee hours of the morning when everyone else is sleeping.

Quality Assurance:

Throughout this process is a system of checks and double checks to assure that the final product is one of excellence where quality is concerned.

Important is the concept of quality. Quality cannot be inspected into a lens but must be built into the lens. Quality assurance checks are reporting mechanisms which give feed back to each operator who are responsible for the prevention of the defective lenses. In the final analysis, everyone from the operator to the C.E.O. of the company is responsible for quality.
The monomer is checked on a daily basis in the laboratory to assure that the chemicals are within the tolerances specified. But even after this, it must be checked again once the lens is produced.

Actual dying or tinting is also done as a verification of consistency between lenses of a particular batch.

Each of the lenses is then measured for transmittance.

The amount of transmittance is specified for this test and the lens cannot exhibit transmittance higher or lower than this amount within a given tolerance or the batch is rejected.

Perhaps one of the most important tests is that of the drop-ball test which is done on a batch basis. The factory does this as a matter of course on both its uncoated and coated lenses to comply with the waiver to FDA drop-ball law. This waiver provided that as long as the manufacturer drop-balled a statistical number of lenses from each batch of lenses, then the optical laboratory and the professional would not have to drop-ball these lenses and the law would still be satisfied.

It was felt at that time the 5/8” ball which you see here, might damage a plastic lens surface, so that it would not be usable by the wearer. It’s important to note that this waiver only applies to those lenses which have been batch tested by the factory and have not been altered since that time other than normal edging or surfacing. Anyone purchasing the lens, who then coats the lens, cannot qualify under the manufacturer’s waiver and must again drop-ball that lens since it’s composition has been changed significantly.

The cosmetic inspection of the lens by an inspector is a subjective process. For this reason training is a continual need to insure that the inspector stays within the subjective tolerances set forth.

Most manufacturers have included the audit function which helps to guarantee product quality or quality assurance. Audits are done on all lens products, gaskets, monomer and molds. In addition an audit is also done on the packaged product after it leaves the manufacturing floor. This is to assure that the packaging label matches the product inside the envelope.

But testing is only one way to assure that quality stays within good processing guidelines. Quality Assurance or QA is a random statistical inspection of products to assure that they are within specifications. It is really a feed back process to manufacturing and engineering.

SPC or Statistical Process Control is very similar, except that this is a feed back of the process rather than the product to assure that the process stays with control.
GMP stands for “Good Manufacturing Practice” and while this sounds like Quality Assurance. GMP was set up by the FDA and is really a government manufacturing policing program for the wearer.

This is a voluntary function for lens manufacturers since lenses are a Class I medical device. Class II and Class III medical devices also are audited by the FDA. These would include things such as contact lenses and intraocular lens implants.

An FDA inspector actually arrives on the premises every 18 months to do the quality assurance function against previously set standards.

As an example, on instruments, such as this Humphrey lens analyzer, there are systematic inspections for the equipment to assure that it is accurate by GMP guidelines. The equipment must be then labeled with the inspection date and the inspector that passed that particular piece of equipment. This is later checked by the FDA requirements.

At this point, the factory has done the best job possible in producing a quality lens. In the event, however, that something still slips by, there is yet another process to help control even this small percentage of reject lenses.

A report which is generated by those quality people in the plant who receive customer returned lenses. For every lens returned, a quality audit inspector carefully re-inspects the lens that had been returned. The code number on the lens box will assist the inspector in tracing any defects found back to the batch from which it was manufactured.

**After Manufacturing:**

Lots of things happen after the lens leaves the plant, most important of which is laboratory processing.

In the laboratory, the lens undergoes layout for surfacing, surfacing layout for edging, edging, tinting, and coating. There is far more involved in laboratory processing than we could cover in the time remaining. It should be pointed out however, that a good laboratory is very much involved in assuring good quality to the customer.

Another extremely important area for the laboratory is good coating techniques on the pack surface of the lens, if they are involved in coating at all.

A coating system first involves the cleaning of the lens.

Once the lens has been completely cleaned and dried, it then is coated using the same technique. The lens is dropped down over a fountain of coating material and spun at a specific RPM to achieve the proper thickness. Rear surfaces thickness is extremely important in regards to the resulting strength of the lens. The thickness is controlled by a number of factors including temperature, viscosity and
RPM of the spin process. It is important, then, to control and inspect regularly those things which can affect the final quality of the lens.

Each batch of lenses must then leave the coating area to be cured in an oven or a UV light source. Here again, cure time, temperature and air cleanliness and humidity should be monitored in accordance with the coating manufacturer’s specifications.

Once this has been completed, the lens must be drop-balled before leaving the laboratory in order to comply with FDA impact resistance requirements. While this normally does not have to be done on standard CR-39 lenses, it must be carried out on all lenses which have been coated in an area other than the factory as the coating does effect the strength of the lens.

The quality procedures outlined here today are the very tools that help manufacturers provide a consistency and excellence so that you may remain confident that lenses dispensed to your customers and patients will be free of defects which ultimately reduces customer or patient complaints.