Improvement of Contact Lens Field Complaint Rate Using the DMAIC Approach

Emil A. Pietri
Manufacturing Engineering
José A. Pesante, Ph.D.
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— Contact lenses are susceptible to a defect call "tearing". This is common but seldom condition detected in the field by the customer. The manufacturing process of a contact lens is a very precise method of combining an injection molding processes with a chemically bonded monomer. The liquid monomer is automatically placed between two half's of plastic injected molds then forming the lens ,subsequent process of curing ,de-molding , hydration and packaging would form the final product for sale. The purpose of this study is to demonstrate that the application of the 6 sigma DMAIC approach to problem solving would provide a methodical and enriched conclusion to the root cause determination of contact lens "tearing" thus reducing the defect rate, subsequently customer complaints.*

Key Terms *— Define, Measure, Analyze, Control.*

SITUATION SUMMARY

- The complaints are spread over the entire spectrum of "Proclear" TM products. Occasionally, field complaints are mentioned regarding similar failures of 2 or 3 lenses in the same pack of 6 lenses (see Figure 1), for assembly configuration reference of a lens.
- The complaints have been particularly difficult to investigate due to lack of consistent complaint documentation and few returned samples of damaged lenses. The number of formal complaints has been historically lower than what would be expected given the level of this problem as conveyed by our sales force.
- The investigation focused specifically on potential causes for the incidence of "tearing" (See Figure 2) in "Proclear" lenses. Using the 6 Sigma approach to problem solving.

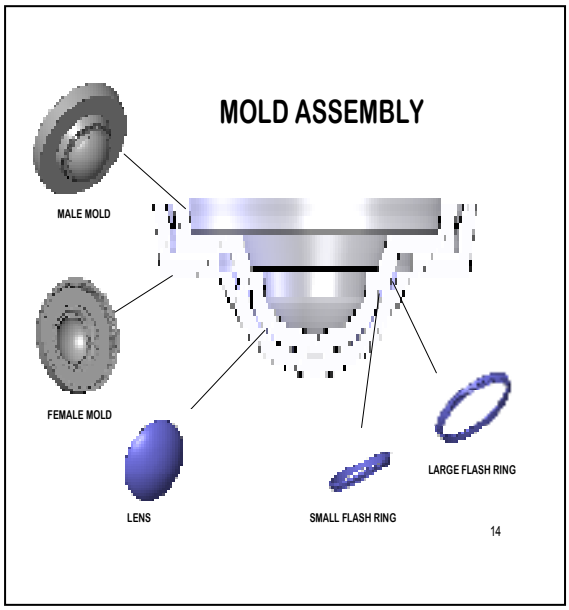

Figure 1
Contact Lens Assembly

Figure 2
Contact Lens Tear

Key "Proclear" Material Findings

- There is no evidence that product aging is a possible cause for the torn and split defects seen on "Proclear" products in the market.
- The study confirmed that "Omafilcon Proclear" material is significantly weaker than the material used as control for the study (Ocufilcon). Previous studies going back as far as 2001 had also shown "Proclear" Material to be weaker when compared with other CVI materials as well as competitor lenses.
- Tensile strength analysis indicates a difference between the material formulation utilized for most "Proclear" products and the slightly different material formulation utilized for "Proclear" Daily Disposable lenses, with the Daily Disposable material being stronger.
- Tear test show that lens strength is significantly affected by induced splits to the material. The force required to break a good strip of a lens versus a strip with a 2mm split is on average 7 times higher (average for materials tested).

PHASE I - DEFINE

The Define phase determines the initiation of a project, customer requirements and key process outputs variables. To define this process a "team charter" is created (See Figure 3 above).

The key elements of the Charter are as follows:

- Process: the process in which the opportunity exist.
- Problem description: describes the problem to solved.
- Objective: what improvement is targeted.
- Metrics: quantifies the project success.
- Business results: improvement in business performance.
- Program scope: what part of the business is considered.
- Team Members: name and roles of the team.
- Benefit to external customers: who are the final customers or who will benefit from the project.
- Schedule: key milestones and dates.

Element	Description	Team Charter
Process:	The process in which the opportunity exists.	All Proclear Omafilcon contact Lens manufacturing at Norfolk Plants.
Problem Description:	Describe the problem that needs to be solved, or the opportunity to be addressed.	High Noise-Complaints are being received from sales force in that contact lenses are tearing- before use and in use.
Objective:	What improvement is targeted?	• Standardize with automation De-molding operation. • Material improvement with in monomer tint. Reduce handling.
Metrics:	What are the measurements that quantify program progress and success? *What is the best the process is expected to produce?	Name of Metric: CPM's; Baseline: 100; Goal: 25; Entitlement*: 3.4 to 50; Units of Measure: CPM's
Business Results:	What is the improvement in business performance? Please list any other improvements on a separate sheet as needed.	Cost Reduction; Cost Avoidance; WIP/ Inventory Reduction; Cash Flow; Labor Savings; Inc. Sales: X
Program Scope:	Which parts of our business processes will be considered? Which customer segments, organizations, geographies, and timeframe?	Included: Proclear Omafilcon lens Product. Norfolk Facility Excluded
Team Members:	Names and roles of team members	Emil Pietri Project Leader Brian Charlton Dan Earnhardt - Engineering Joe Calcagno - Manufacturing Klaus Hummel - Manufacturing Tom Barrett - Engineering
Benefit to External Customers:	Who are the final customers, what are their most critical requirements/measurements, and what benefits do we expect to deliver to them?	External customer the user will experience a improvement in lens tearing by the beginning of March 09.
Schedule:	Give the key milestones and dates.	Key Project Dates: Project Start: May 08 Define Complete: June 08 Measure Complete: July 08 Analyze Complete: September 08 Improve Complete: April 09 Control Complete: May 09

Figure 3
Project Charter

PHASE II - MEASURE

The measure phase concentrates in four mayor aspects, understanding the process by developing a comprehensive process map (See Figure 4), process input variables and process output variables are evaluated using a cause and effect matrix, this tool decides the most important inputs sorted and included in the failure mode and effect analysis table (See Figure 5).

Preliminary conclusions and examined results from the C&E and the FMEA guided the team to start the data mining process at the de molding process, cure process, and hydration process.

After the lens is made it passes thru a cure oven process and then is de-molded by semi automatic, automatic or manual machine (The GT 100's de- molders) these processes introduced extreme variation form machine to machine, shift to shift and perhaps product to product.

The Key Outcomes from the Measure Phase were geared to be focused in different areas such as:

- Brain Storm Section Using the 5 M's to determine areas where to focus assigning resources adequately and finalizing plan activities.
- Compare manufacturing processes of sphere product vs. a-sphere product that could explain differences in outgoing quality results.
- Investigate other areas of the manufacturing process that might result in subtle surface defects being induced.
- Verify detection capability of current vision aided inspection system technology to detect surface splits on dry/wet lenses.

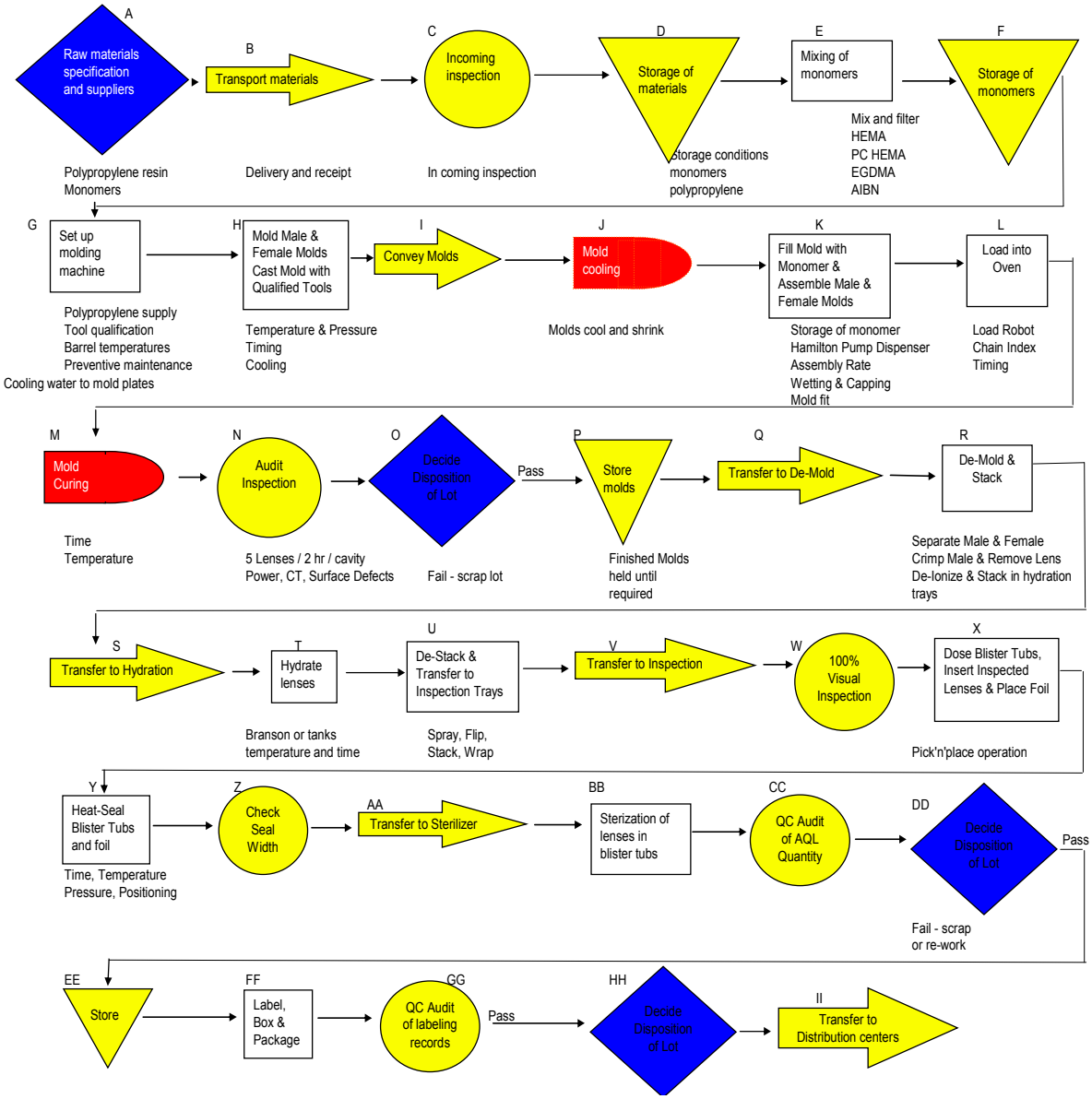

Figure 4
Process Map

The team selected what key process input variables were more important in respect to the customer requirements in this case the Key processes outputs variables KPOV's and input them into the FMEA (See Figure 5). This is the First Part of the FMEA-selection to start working and analyzing data from the RPM's higher than 90. The result of the FMEA analysis is summarized in (Figure 6 below) the "Pareto Chart".

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN
What is the process step	What is the Key Process Input?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the Key Input to go wrong?	How often does cause or FM	What are the existing controls and procedures (inspection and test) that prevent eith the cause or the Failure Mode? Should include an SOP number.	How well can you detect cause or	
De-molding	de-mold - crimpers	Jaw design	damage lense	8	design	10	none	10	800
De-molding	Mold fits	Fit too tight	damage lense	8	mold shrinkage	9	none	10	720
De-molding	Mold fits	Fit too loose	damage lense	8	mold shrinkage	9	none	10	720
De-molding	handling in blister transfer - swabs	Operator handling / pressure	damage lense	8	Human variability	9	none	10	720
De-molding	Heating of molds	Variation of temperature	damage lense	8	Incorrect temperatures	9	none	10	720
De-molding	GT 100 vs semi-automatic vs manual proc	Different processes	damaged lenses	8	Equipment and human variability	10	SOP for machine set up	9	720
De-molding	de-molding press punch profile design	curved / flat / uneven / diameter too small	damage lense	8	deformation of mold in pressing	9	none	10	720

Figure 5
FMEA (Extract)

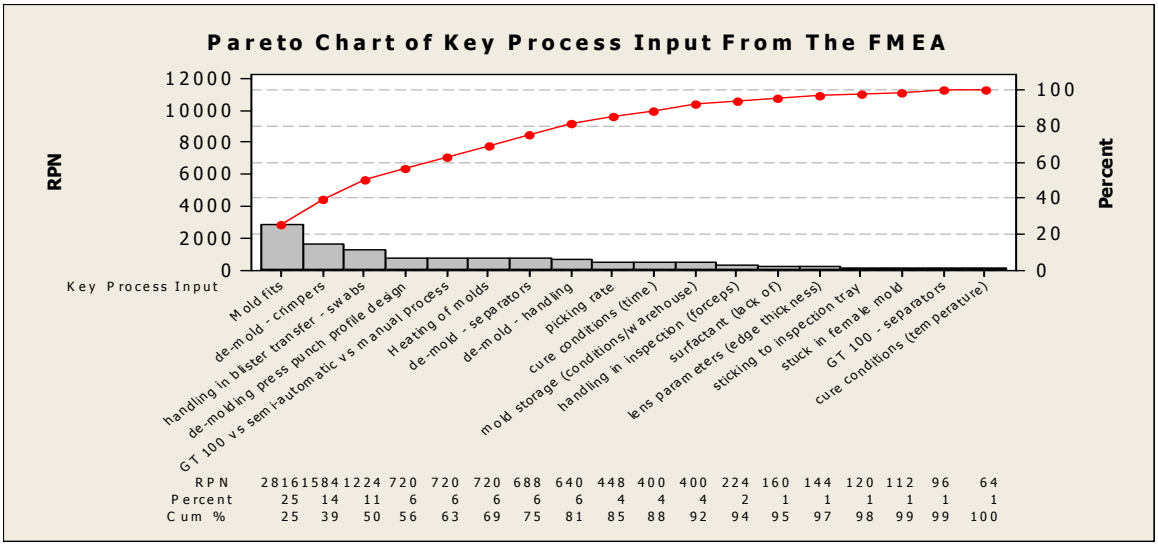

Figure 6
Pareto Chart from the FMEA

PHASE III - ANALYSIS

The group started the process of data mining and analysis where conclusion were drawn; some of techniques utilized were Box plots, analysis of variance, and comparison by shift and by de-molding equipment (See Figures 7, 8).

Several Key findings:

- Thinner Lens Edge suffers greater vulnerability to "lens tear".
- A significant interaction exists between Norfolk Cast Mold Line 2 a-sphere Lens (70-micron Lens edge thickness). (See Figure 7).
- Tear Rates and De-Mold GT100 #2. This interaction is not exhibited to this degree on other Lines or Lens Types (See Figure 8).

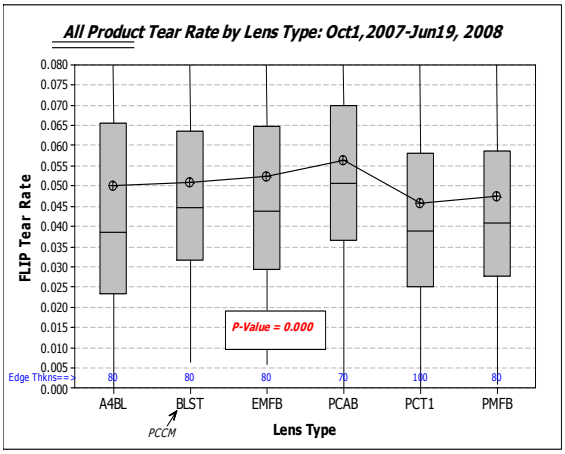

Figure 7
Box Plot Difference Lens Type vs. Edge Thickness

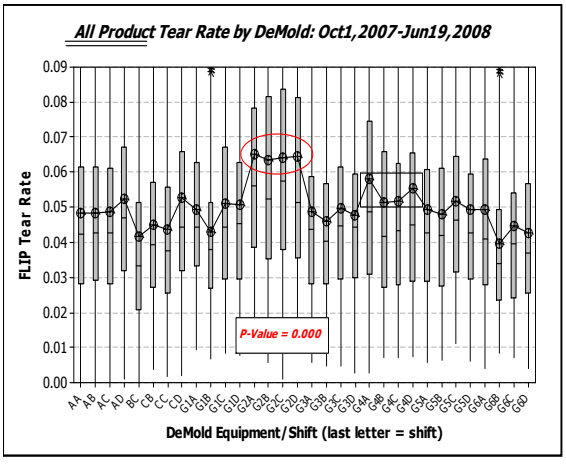

Figure 8
Box Plot Difference in De-molding Equipment

There was no evidence of differences in detection capabilities at quality audits visual inspection and sampling. The following graphs suggest that there is difference between shifts in picking and placing lenses very manual operation damage to lens could happen here.

Key observations were:

- Handling and picking lenses for inspection is causing more "tearing" in different shifts (See Figure 9).
- Detection inspection audit is not different (See Figure 10).

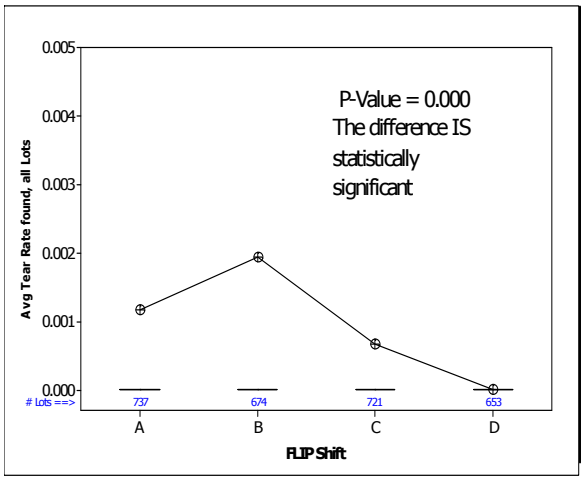

Figure 9
Plot difference in manual pick and place inspection

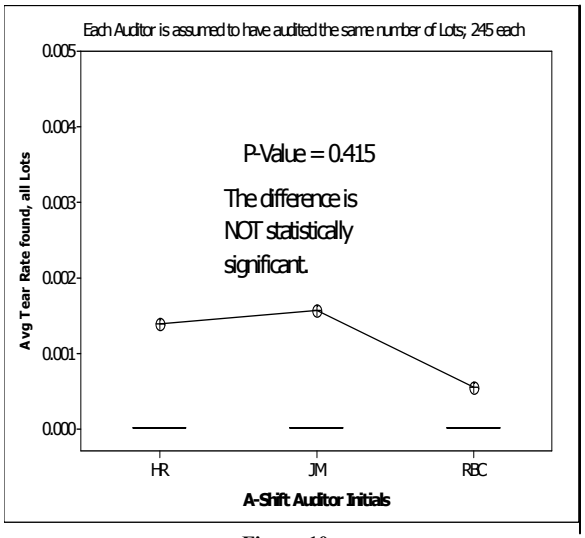

Figure 10
Plot no Difference in Auditors

Further studies revealed that cast mold line 2 in a combination with de mold equipment GT 100 4 line had a significant different in tear rate (See Figure 11). There was also observed the GT 100 line 4 was higher in tear rates by shift specially shift # 4 (See Figure 12 & 13).

Key observations:

- Cast mold line 2 had a high "tear" rate when compared with de molder # 4 so focus on reducing variation in cast mold vs. de-molder 4 is imperative.
- De-mold line GT100 # 4 in combination with shift D. Shift D appears to be manipulating de-mold equipment and set ups.

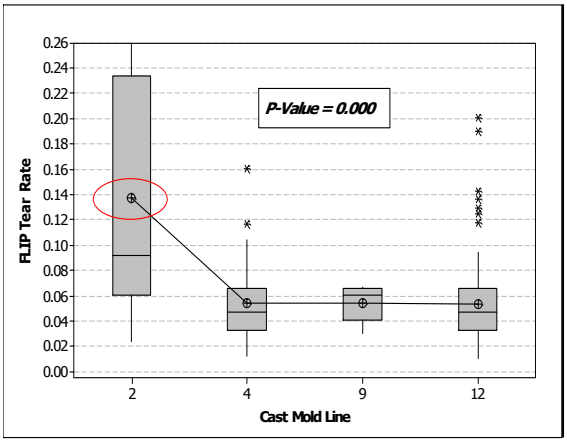

Figure 11
Box Plot Difference Line 2 & De-molding Equipment

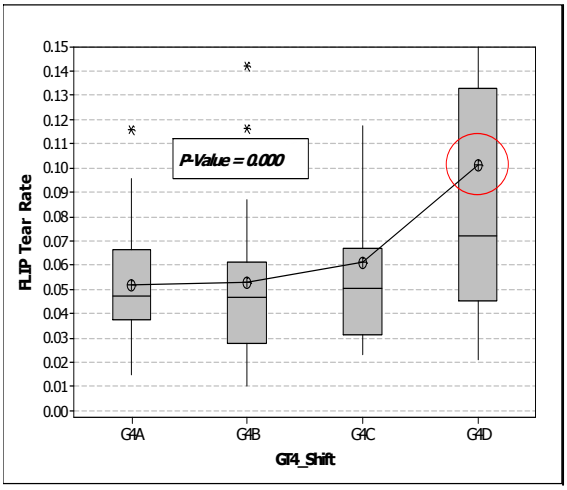

Figure 12
Box Plot Difference De-molding Equipment vs. Shift

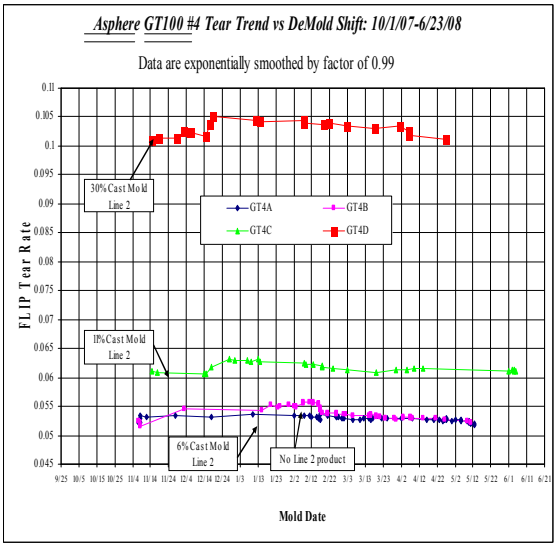

Figure 13
Box Plot Difference De-molding Equipment vs. Shift

Thinner Lens Edge suffers greater vulnerability to "tear" mechanisms. A significant interaction exists between Norfolk Cast Mold Line 2 a-sphere Lens (70-micron Lens edge thickness) Tear Rates and De-Mold GT100 #4.

PHASE VI - IMPROVEMENT

In Phase VI several improvements were examined and implemented to reduce the incidence of In-process lens tears, chip edges. After determining that the critical to quality causes to be lens material strength, handling post cast molding & poor inspection detection the team projects were configured concurrently.

- The system called the "**Low Volume Automation**" to reduce lens handling by operators and aided with automated visual inspection system - cameras.
- The introduction of a **new monomer** initiator "**Perkadox**" strengthen the lens to avoid potential tearing when handling by patient.
- The introduction of an **air gauge system** aided in the identification of "mold fit" the mold fit is an important part of the cast molding process as it determines the gap between the female mold and the male mold when together, when fit is not monitored properly and corrected at

set up the mold too loose may cause excessive monomer material thus permitting that at the de mold process lenses can be ruptured as it pulls.

The Air Gauge System: The nearly-vertical portion of the critical diameter region in the Male and Female Molds is that region where seal-off occurs, to set the trapped Monomer volume and to form the Lens edge. This region is typically about 80 microns beyond a "transition edge."
(See Figure 13 & 14).

This fit-region is short (20-250 microns) and is elliptical in shape an average "Mold-Fit" (Female Dia. – Male Dia.) is the same, regardless of Mold-to-Mold relative orientation, but "At-Gate" and Off-Gate" fits vary considerably, depending on relative orientation.

Precise measure of both the At-Gate and Off-Gate diameters, to the "micron-level," is required in order to control these fits.

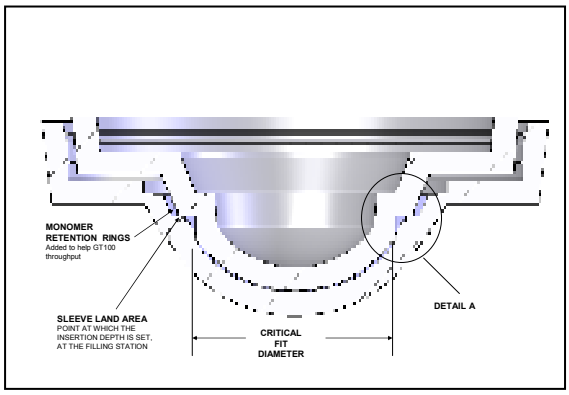

Figure 13
Mold Fit Regions

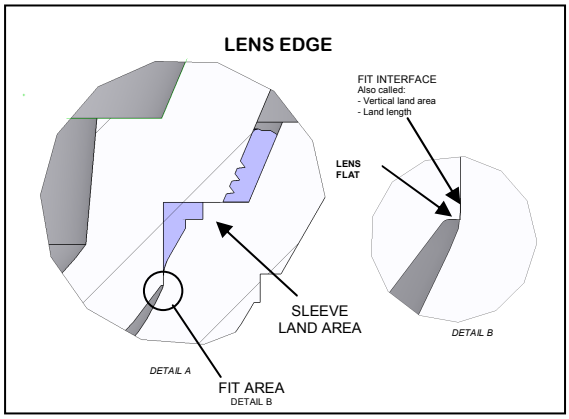

Figure 14
Mold Fit Regions-lens Edge

It is important to note that the mold fit is important to the lens cast molding manufacturing stage, with this measurement process the technician can measure exactly what is the circumference of the mold and make minute adjustments to the injection molding process this will avoid potential problems.(See Figure 14).

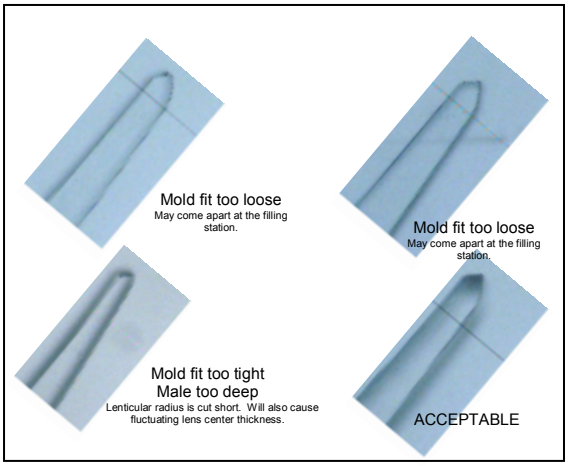

Figure 14
Cross Section of Lens with Irregular Mold Fits

The Air Gauge explanation: The mold is placed on top of the air gage. The critical fit diameter is positioned exactly at the nozzle exit. Nitrogen is supplied through the gage head. Because of the small gap between the mold and the gage head, the escape of nitrogen is restricted. The restriction causes back pressure and this back pressure is measured in volts. The voltage measurement is used to calculate a precise mold diameter. (See Figure 15).

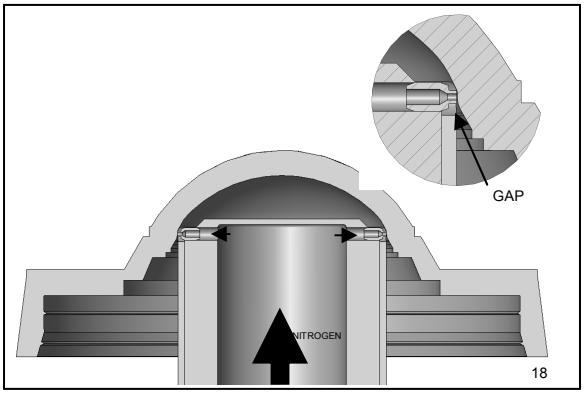

Figure 15

Cross section of Air Gauge

The use of the Air gauge provides the technician an accurate measurement, this helps the early detection of fit too loose or too tight which in turn would potentially cause variation in the process, this variation of fit will yield product susceptible to tearing or chip edges. As evidenced the higher the mold loosens the more propensity of the product to be tearing at de-molding stations, the tighter to mold fit the thinner the edge, more susceptible to tearing as it weakens the area of edge contact. (See Figure 16).

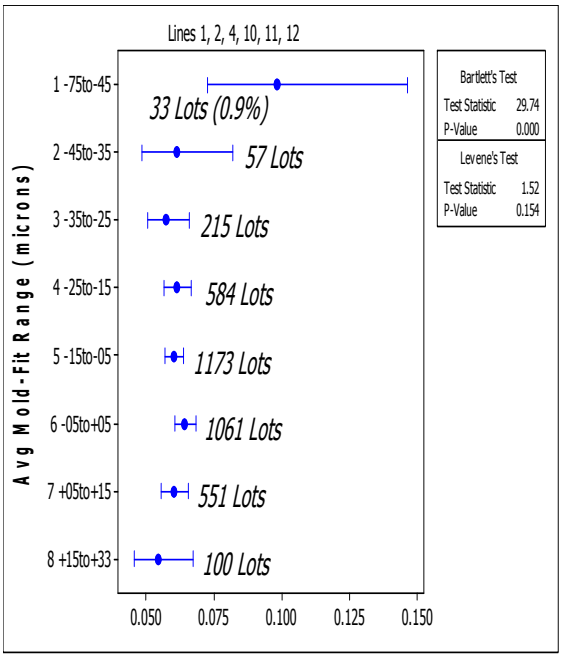

Figure 16
Tear & Edge Defect Rate Variance by Mold Fit Measurement

Key Highlight: The air gauge has the capability to identify precisely de gap between female and male molds fit, as observed in the data graph (Figure 16).

The new developed monomer formulation: The implementation of a new "Perkadox" Initiator appears to have more strength (See Figure 17), all "Proclear" product required FDA submissions to the 510K as supplements, approval granted in les than 180 days, sites were FDA inspected after the submissions. The formulation already used in other products has more stability when stressed, it is also a pre requisite for non extract process, meaning that the lens will not have to undergo the process of external tint addition and lens hydration, the formulation tint will be part of the monomer preparation and will flow with cast molding process, hydration will occur in blister sealed with saline water.

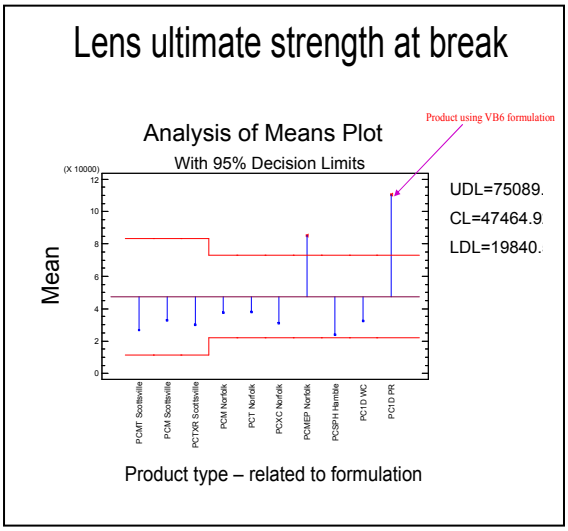

Figure 17
Brake test results new "perkadox" formulation

The Low Volume Automation System: The LVA system provides a long range of capabilities that enhances several issues with the lens performance pertaining to tears and split edges. The system is design to automatically handle lenses after the molding where we believe most defects occur as discovered in the FMEA de-molding stage. The system provides two automatic camera inspections that will replace the use of human eye; this will be done to 100% of lenses as if done in regular wet lens inspection by an individual.

In addition, with the use of the new monomer "perkadox" lenses will now be hydrated in the blister it does not have to pass thru the tedious process of bath hydration as exhibited in the process map, this will also eliminate lens handling and picking the lens manually. (This is called the extract process). The system was fully implemented on September 2008 with exceptional results improving internal yields pertaining "lens tearing"

and improving-reducing confirmed customer complaints in the field.

Key component of the system:

- (AIS) Automatic inspection system and lens handling system. (See Figures 19 & 20).

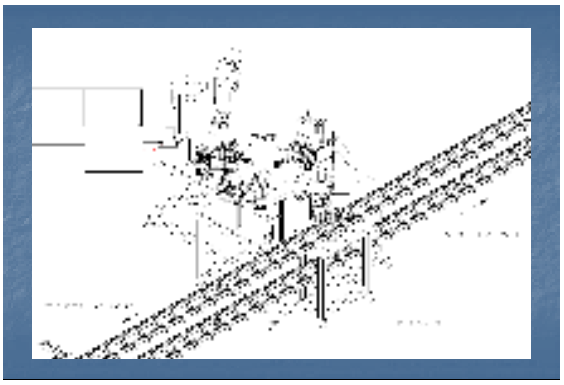

Figure 19
AIS Rotary Table

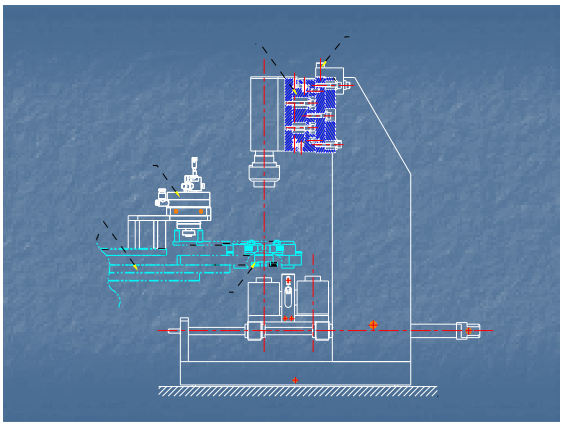

Figure 20
Rotary Table AIS Vision System

PHASE V - CONTROL

In this phase two mayor standard operating procedure were implemented, the generation of visual standards (see Figure 21) for objective classification of tears and other defectives and the development of a new procedure to trigger corrective actions at in-process and customer complaints. These two controls were generated as result of an analysis of the complaints and the feedback from the field representatives.

The success and control was going to monitored on a monthly basis by the means of complaints per million by product platform.

Condition	Size (mm) Actual	17.5 X	10X	Description
Embedded Particles	0.34	6	3.4	Any foreign matter that cannot be removed which is embedded in the lens matrix.
Attached to surface Particles	0.11	2	1.14	Any particle attached to the lens surface that cannot be removed by cleaning. Reject if exceeds size or more than three.
Flash				Excess lens material protruding from the edge.
Bubbles	0.11	2	1.14	Enclosed void in the matrix of the lens. Exception: None in OZ. Reject if exceeds size or more than three.
Edge Splits	0.29	5	2.86	Split from edge of lens extending inwards Exception: for ProClear lenses no edge splits are allowed. Reject if exceeds size or more than three, except for daily disposable non ProClear lenses.
Edge Chip (depth or width)	0.17	3	1.71	The lens circumference is incomplete, due to 1 or more indentations that exceed the image of the edge inwards (i.e. V or U shaped chips). Reject if exceeds size or more than three.
Rough Edge (length)	1.14	20	11.43	Lens has an irregularly shaped edge which is not smooth. Irregularity does not exceed the image of the edge inwards.
Surface Split	Reject All			Sharp dark line which appears more obvious when lens is stretched

Figure 21
Acceptance standard

Trigger for Corrective Actions: The purpose was to define the requirements to detect and identify product or process data trends, qualitatively or quantitatively, the following diagram shows the process as to when to rise a CAPA (see Figure 22).

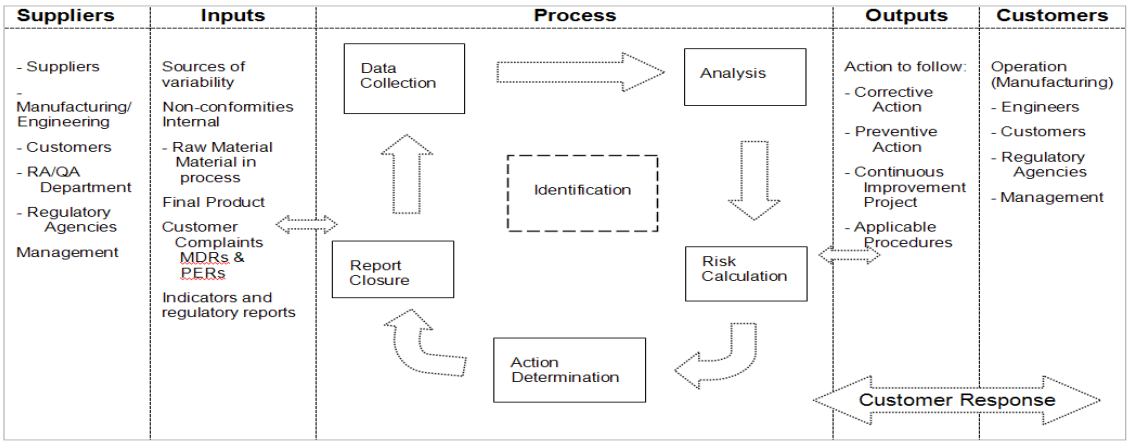

Figure 22
CAPA generation Process

Results of the project: The following indicators provided congruent data that the project was successfully implemented:

- Part II of the FMEA-RPN's was reduced in the critical key input variables from the process (See Figure 23).

RPN	Actions Recommended	Resp.	Actions Taken	SEV	OCC	DET	RPN
800	**Standarize design** low detection, damaged lenses are detected	Tom B	Develop an gauge that can control "air gauge"	8	10	1	80
720	Study of mold fit ve lens tear reate	Dan E	Develop an gauge that can control "air gauge"	8	9	1	72
720	Study of mold fit ve lens tear reate	Dan E	Develop an gauge that can control "air gauge"	8	9	1	72
720	Study tear rates manual process vs auto process	Klaus	Develop an Automated system for Handlig & inspecting lens	8	9	2	144
720	Check on temp and make sure they work all the time.	Tom B	Develop an Automated system for Handlig & inspecting lens	8	9	2	144

Figure 23
Part II FMEA (extract)

Conclusion: The optimization project to reduce the amount of complaints prove to be a success, with improvements the market is expanding to Asia and growing because of the recent excellent quality of the "Proclear" product noticed in the field.

The "6 Sigma-DMAIC" process methods gave the team the know how to determine the Key process input variables that made an effect in the process for "Tears, Chipped Edge or Split"[1].

The goal was to achieve less than 3.4 complaints per million for tears –split edges by February 2009 as stated in the charter.

REFERENCES

[1] Breyfogle F,W, "*Implementing Six Sigma*" second edition, 2003, published by John Wiley & Sons, Inc. New Jersey.