My PSM Biostatistics internship at Aspen Surgical

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Purpose and Background

Aspen Surgical is a medical device company based in Caledonia Michigan. The product portfolio is focused on operating room safety with other products including skin marking pens and scalpels. The parent company is Hill Rom which is a leading worldwide manufacturer and provider of medical technologies and related services for the health care industry, including patient support systems, safe mobility and handling solutions, non-invasive therapeutic products for a variety of acute and chronic medical conditions, medical equipment rentals, surgical products and information technology solutions. Hill-Rom's comprehensive product and service offerings are used by health care providers across the health care continuum and around the world in hospitals, extended care facilities and home care settings to enhance the safety and quality of patient care.

Objectives

The goals of my internship were to apply statistical techniques and act as a consultant to new product engineering, manufacturing engineering and quality control. From class work at GVSU I was able to perform statistical analysis including the use of regression, t-tests, ANOVA and chi-squared. By working for such a diverse group I was also able to learn and perform capability studies, tolerance analysis, Gauge R & R studies, and design an experiment including screening, steepest ascent and optimization.

Experience: Regression

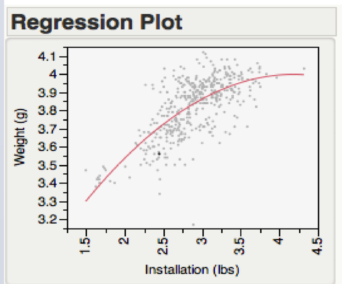
Background

- A product was received that needed to be sorted for a defect. The functional testing to ensure acceptable product was destructive. Because of this a different method was needed to be able to discriminate product.
- Parts were evaluated for a correlation between a weight, which would allow efficient sorting, and an installation force (that is a functional requirement).

Objectives

- A model was constructed using the force as a predictor and weight as a response.
- Using the acceptable parts a tolerance interval for the weight will be reported to allow for sorting of product.

Results



Tolerance Intervals

Proportion	Lower TI	Upper TI	1-Alpha
0.900	3.571567	4.086739	0.950

Conclusion

- The weight of the light handles is shown to have a moderate positive correlation with the installation force based on the R2 value of 0.50. The lack of fit p-value of 0.9948 further illustrates that the model accurately predicts weight.
- A tolerance interval was calculated using light handles that had removal and installation forces greater than two pounds (90% of the population with a 95% confidence) 3.57g to 4.09.

Experience: Process Optimization

Background

- As a corrective action for a customer complaint that involved a sharp vestige on the tip of a pen cap breaking the sterile barrier during a surgery; parameters to minimize this defect during the molding process were needed for operators.
- Current production on this molding tool were six cavities out of thirty two due to this defect. Optimizing this process to have the greatest quantity of acceptable parts was also crucial for rate in this work center.

Objectives

- An iterative design approach was used beginning with a screening design to identify which of the original eleven factors had the largest effect on the molding process.
- The design was augmented to further explore the significance of factors after the initial screening.
- The design was then optimized to determine the settings that would produce the greatest quantity of acceptable caps.

Results

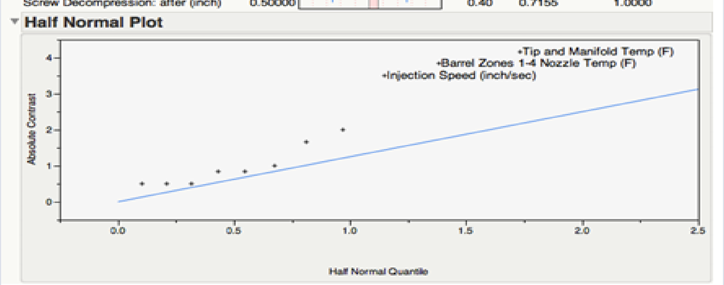
Screen Design Results

Screening for Number of cavities passed

Contrasts

Term	Contrast	Lenth t-Ratio	Individual p-Value	Simultaneous p-Value
Tip and Manifold Temp (F)	4.16667	3.33	0.0173*	0.1186
Barrel Zones 1-4 Nozzle Temp (F)	-3.83333	-3.07	0.0224*	0.1519
Injection Speed (inch/sec)	-3.50000	-2.80	0.0278*	0.1883
B-Side Coolant (F)	2.00000	1.60	0.1183	0.6447
A-Side Coolant (F)	-1.66667	-1.33	0.1777	0.8240
Cooling Time (sec)	-1.00000	-0.80	0.3809	0.9996
Screw Decompression before (inch)	-0.83333	-0.67	0.4846	1.0000
Pack & Hold Time (sec)	-0.83333	-0.67	0.5508	1.0000
Back Pressure (psi)	-0.50000	-0.40	0.7155	1.0000
Pack & Hold Pressure	0.50000	0.40	0.7155	1.0000
Screw Decompression: after (inch)	0.50000	0.40	0.7155	1.0000

Half Normal Plot



Second stage general linear model

Term	Estimate	Std Error	ChiSquare	Prob>ChiSq
Intercept	46.976142	9.8753493	15.56111	<.0001*
Injection Speed	-9.89811	4.4069496	4.5418038	0.0331*
Cooling Time (sec)(3,6)	-2.907371	0.9230208	8.169232	0.0042*
Barrel Zones 1-4 Nozzle Temp (F)	-29.96513	11.718093	5.7251248	0.0167*
Tip and Manifold Temp (F)(475,525)	3.3809097	0.9275347	10.394004	0.0013*
Cooling Time (sec)*Tip and Manifold Temp (F)	2.096025	0.9330824	4.5429801	0.0331*

Conclusion

- The initial screening design identified three significant effects. Tip and Manifold Temp (p-value 0.0179), Barrel Zones Nozzle Temp (p-value 0.0215) and injection speed (p-value 0.0261).
- The original design was augmented and all main effects and interactions were evaluated (significant factors and p-values are shown above).
- A method of steepest ascent was used to move the design space and further investigate the optimum settings. The caps were evaluated and all runs had 100% passing parts. New limits were set for molding parameters based on these results.

Experience: Gauge R &R

Background

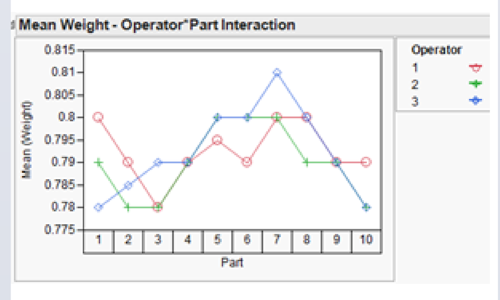
- Ink weights are monitored during the production of markers to ensure the correct amount of solution is being injected into reservoirs
- Inspectors were measuring the reservoirs on a scale that was in a different area then the manufacturing line.
- It was requested that the operators of the manufacturing line take the measurements instead of the inspectors to make the process more efficient. To do this a different scale would have to be used on the pen line.

Objectives

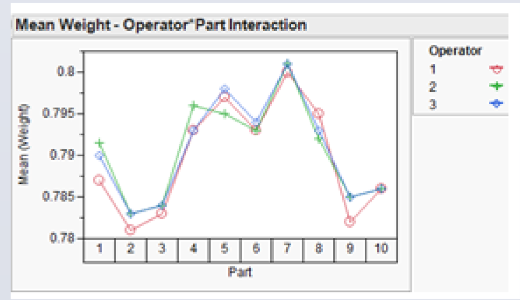
- Have three operators weigh reservoirs in a designed experiment to evaluate the repeatability, reproducibility and part to part variation.
- Execute the experiment on the two different scales in the two different environments both on the pen line and in the separate room off line.

Results

Scale 1



Scale 2



Scale 1 – Variance Components for Gauge R&R

Component	Var Component	% of Total
Gauge R&R	0.00002732	51.56
Repeatability	0.00001652	31.18
Reproducibility	0.00001079	20.38
Part-to-Part	0.00002566	48.44

Scale 2 – Variance Components for Gauge R&R

Component	Var Component	% of Total
Gauge R&R	0.00000190	4.77
Repeatability	0.00000078	1.96
Reproducibility	0.00000112	2.82
Part-to-Part	0.00003788	95.23

Conclusion

- A random effects model was used to evaluate the variation attributed to operator, the operator part interaction and the part.
- Scale 1, the scale used on the operating line, was found to have an unacceptable amount of variation within the measurement system (51.56% of the total variation).
- Scale 2, the scale used off the operating line, was found to have an acceptable amount of variation with the measurement system (4.77% of the total variation).
- It was recommended that controls, such as a vibration resistant table, be implemented and the study would be repeated on the production on line scale.

Experience: Additional Projects

Blade Sharpness Base line to Three Year Comparison [*ANOVA*]

- The sharpness of blades were evaluated between initial (base line) and three years aged to ensure there was no degradation of the functionality of the product.

Transparent Dressing [*Capability*]

- During a category line extension additional information regarding capability of the manufacturing process of the product was needed to complete a validation.

Molding 24 Hour Hold Study [*Repeated Measure ANOVA*]

- This study demonstrated that a 24 hour hold on molded components was not necessary. By removing the hold production is allowed to use parts immediately after production. A repeated measure ANOVA model was needed to evaluate a specific cavity within the study that was out of specification. The variance was described between cavities and during the measurement; when time was fit in the model it was found to be a poor predictor.

Challenges

Acting as the statistical subject matter expert on project teams I researched techniques and construct recommendations independently. Also during my time at Aspen I was challenged to find solutions to unique problems using statistical tools.

Impact

During my internship experience I was able to apply statistical tools while collaborating with other professionals, which proved to be an integral part of my career development. I communicated my recommendations and findings to a wide audience. Also, I was able to transition from knowledge of a technique to effectively applying it. Being able to explain my methodology and recommendations was key to my growth as a professional.

Acknowledgements

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