Statistics for Product Development

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Abstract

Analyzing a product's performance during development is essential to making informed design decisions, yet many engineers are uncomfortable using statistics. This shouldn't be the case: statistical tools can be invaluable for recognizing patterns in experimental data, and therefore offer a means of improving the quality and consistency of design decisions. Here, DCA's current use of statistics is evaluated relative to the medical industry as a whole. Experiment design, analysis, and presentation tools are suggested that would enhance DCA's testing process. These tools are evaluated against the realities of DCA's work by considering how they might be implemented in DCA's experimental procedures.

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Notation & Glossary

Attribute A measurable property of a *unit*.

Block A set of *units* thought to share some common *attribute* that influences their *response*.

Event A set of *outcomes*.

Experiment[1] The controlled collection of data.

Experiment[2] Physically realizing an outcome of the system under study.

Factors *Treatments* that are discrete. For example, lubricated/unlubricated.

Outcome A possible result of a *trial*.

Probability A method for quantifying uncertainty, or a value representing the uncertainty of an event.

Response The measured performance of a *unit*.

Treatment A modification applied to a *unit*.

Unit A single test specimen - in the context of product testing, this is likely to be a prototype build of the product.

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Declaration

I confirm that the work presented here is wholly my own and has been generated as a result of my own thought and study. Where I have consulted the work of others it is mentioned, and where my work was part of a group effort my contribution is made clear. Where the work of another is quoted, the source is given.

1 Introduction

DCA Design International is a 150-person product design consultancy based in Warwick. Their work is oriented towards the mechanical design of medical and consumer products. Much of what they develop is hand-held items such as insulin injector pens or deoderant cans. DCA's competitors are [DCA's COMPETITORS AND THEIR CAPABILITIES].

DCA employs about sixty mechanical engineers. These engineers are assigned to projects in response to workload and required expertise. From initial concept generation through physical product testing, they are responsible for a broad range of mechanical engineering activities.

DCA's substantial investment in engineering distinguishes it from other product design consultancies, many of which do not have the capabilities to handle a product's technical development [REFERENCE]. This investment is manifest not only in the number of DCA's mechanical engineers, but also their ownership of four test labs. Together these labs are equipped with axial and torsional load stands, mass balances, and a coordinate measuring machine [IMAGE?]. This equipment is used by DCA's mechanical engineers to either:

- Investigate a product's behaviour
- Verify that a product will meet market standards

Investigative tests seek to understand and measure the influence of design alterations. These alterations could be prospective features in the final product, or they may be to exaggerate the behaviour of the current design. An example of the latter would be to machine the components to their tolerance extremes in order to check whether their mechanism still functions correctly. They are especially useful during the late phases of a product's development when minor improvements in performance are sought through incremental design alterations. They are also used to discriminate between contending conceptual designs in early to mid-phase work.

Verification tests are run to ensure a product meets the standards enforced by the authorities regulating a product's destination market. Examples of these tests are:

- ISO tests
- FDA tests
- Chinese equivalent?

This report focuses on how DCA's engineers currently apply and could apply statistics to their lab investigations. No doubt there exist other activities within DCA where statistical methods would be useful - such as human factors or operations research - but in this report those possibilities are only mentioned in passing. Hopefully it is the case that the methods suggest themselves as useful beyond the application used to contextualize them.

Before discussing the role of statistics in DCA's lab work, it's necessary to clarify what "statistics" refers to and what it's relevance is to mechanical engineering. In this report, statistics is the systematic approach to the collection, analysis, and presentation of data. Some statistical methods are justified via probability theory, which is a logically consistent way to describe uncertainty. Other techniques are pragmatic, such as visualizing data in a way that is not misleading, or appropriately defining an experiment's scope. The defining characteristic of statistical methods is that they seek to make the best use of the information and resources available.

Statistics is most useful if it's applied before, during, and after an experiment. This is because it encourages forethought about what exactly needs to be known, what factors might create uncertainty during analysis, and how these factors can be mitigated within the experiment itself. Statistical tools have been designed around a process consisting of four steps:

- Design an experiment to capture the desired information.

- Execute said experiment in a controlled fashion.
- Analyze the resulting dataset.
- Present and document the analyses' results.

"experiment" refers exclusively to the data generation procedure of the second step, whereas "statistical process" denotes the combination of all four steps. The statistical process can be applied at various levels: for example, an investigation can be thought of as an experiment consisting of several sub-experiments.

Experiment design is usually on an ad-hoc basis and will usually apply simple but effective techniques such as blocking or factorial structures. DCA's engineers are aware of the important factors to control during an experiment, and may in some cases iterate upon an experiment's set-up until they are satisfied that the data is not being corrupted by nuisance factors. Certain documents must be kept for all experiments run - this means that raw data files, scans of handwritten observations, a table of the components used, and an Excel report summarizing the experiment's results must be produced and stored.

Some experiments have specific protocols and prescribed analysis procedures. Other, more novel, experiments do not have a documented procedure and will usually have a spontaneously formatted report, since there is no general template. To the best of my knowledge, there are no internal guidelines regarding how data should be visualized, or how analytical results should be verified. Broadly speaking, an analysis will typically consist of

- Line charts of raw data
- Summary statistics by group or unit, sometimes charted in a scatter plot
- Summary of derived results from graphical inspection of the data

For the better-documented tests, hypothesis tests may also be run.

In summary, this report analyzes how DCA currently uses and could use statistics in its lab investigations. Section X1 explains their investigatory framework and how statistics is currently applied within it. In Section X2 approach is then compared to the SOMETHING industry as a whole. This is followed by Section X3, in which statistical methods are suggested that DCA's engineers and clients may find relevant. These methods are introduced conceptually, then tools (i.e. software and tangibles) for implementing them showcased. The report concludes with an evaluation of how actionable these suggestions are, and a suggestions for further work.

This report compares various statistical methods, not alternative methods for technical product development.

2 Overview of DCA's Use of Statistics in Lab Investigations

The flow chart shown in Figure **??** depicts the structure of DCA's lab investigations. Table **??** summarizes the activities associated with each node in the chart.

Lab investigations are used to reduce uncertainty about the behaviour of a product or process. By collecting data, DCA's engineers aim to become better informed. This allows them to make design decisions that are both more effective and justified than they might be otherwise. In this Section, we'll refer to the item being tested as a unit, and

2.1 Experiment Design

Good experimental design makes it vastly easier to unambiguously interpret the results of an experiment. The essentials of good design are

- Controlling variation of units
- Structured application of treatments
- Designing according to an objective

Topics covered:

- Block design
- Factorial design
- Sample sizing

2.2 Experiment Control

2.3 Analysis

Topics covered:

- Regression
- Uncertainty
- Post-hoc arguments
- Fourier analysis

2.4 Presentation & Visualization

Topics covered:

- Structuring data
- Visualization

2.5 Summary

3 Overview of the Medical Industry's Use of Statistics

3.1 Experiment Design

3.2 Analysis

3.2.1 Exploratory Analysis

3.2.2 Descriptive Analysis

3.2.3 Inferential Analysis

3.3 Presentation & Visualization

3.4 Summary

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4.1 Design of Experiments

4.1.1 Blocking

4.1.2 Factorial designs

4.1.3 Taguchi

4.1.4 Strategies for handling limited sample sizes

4.2 Analysis

4.2.1 Sumary Statistics

- Estimate the effects of discrete and continuous factors on a unit's response - even if they interact or have a nonlinear influence.
- Identify differences between units that aren't immediately apparent from raw data
- Measure how well our understanding of a product lines up with its reality

4.2.3 Bayesian Inference

4.2.4 Markov Chain Simulation

4.3 Presentation & Visualization

4.3.1 The Psychology of a Plot

4.3.2 Scatter plots

4.3.3 Histograms

4.3.4 Box plots

4.3.5 Separation Plots

http://mdwardlab.com/sites/default/files/GreenhillWardSacks.pdf

4.4 Software

- Excel
- Matlab
- R
- Python
- Minitab

5 Conclusions & Recommendations

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