Demonstrating Change (Data Shift)

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Edwards

Why Demonstrate Change?

- Demonstrate to the FDA (and yourself) that a product problem has been improved
- Evaluate a new piece of equipment to ensure it is better than the existing
- Grounds for change in process, materials, etc. (favorable)
- Determine if changes to the facilities have a positive affect on its environment.

How to Show Change?

A myriad of tools are available to demonstrate a change has been effective or to evaluate if a change has occurred causing a negative impact.

If Changes Are Known

Standard statistical techniques can be utilized to document the difference between populations.

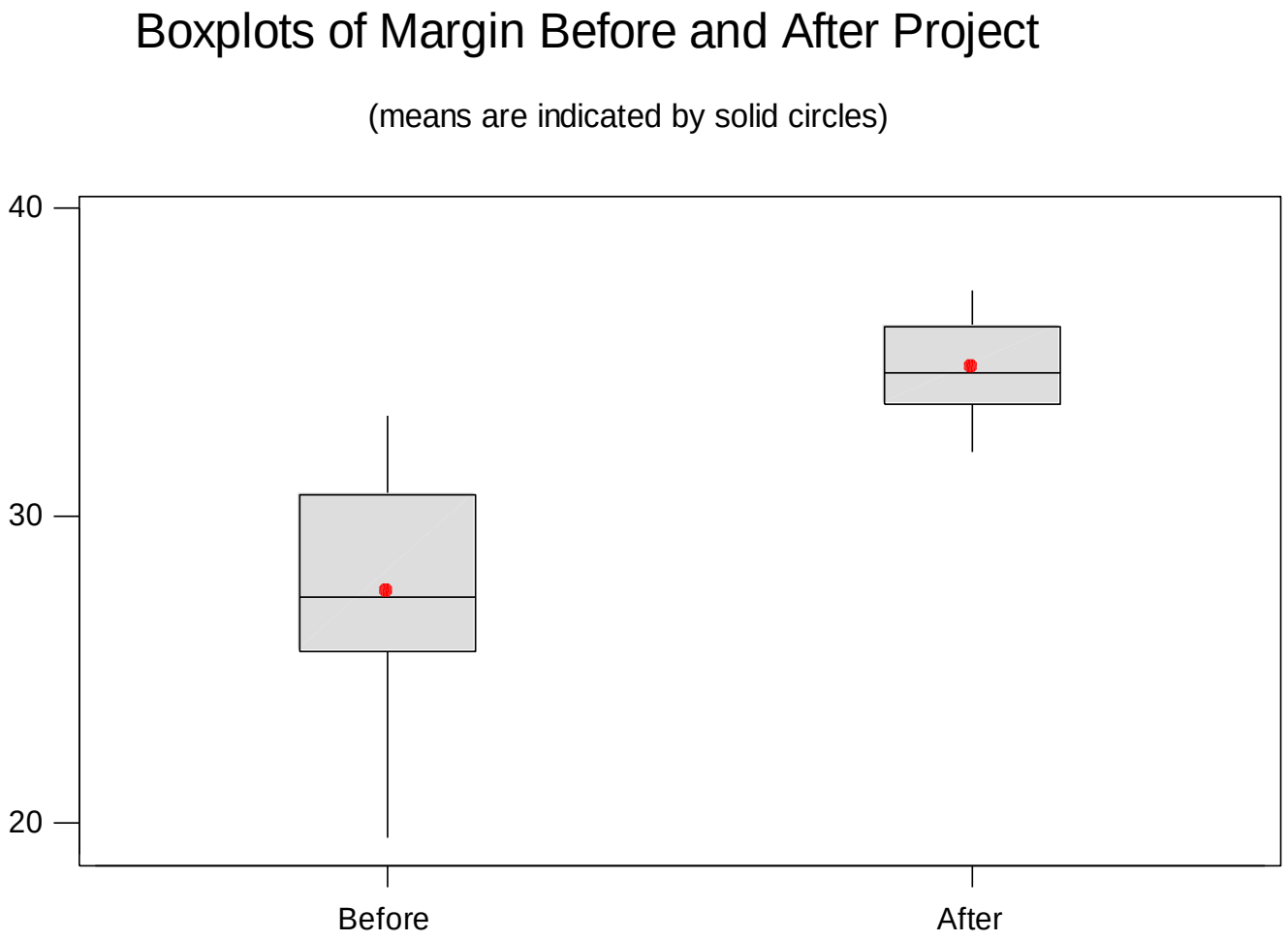
Hypothesis Test	Purpose
t-test	Compare two group averages
Paired *t*-test	Compare two group averages when data is paired
ANOVA (Analysis of Variance)	Compare two or more group averages
Test of Homogeneity of Variance	Compare two or more group variances
Chi-Square test	Compare two or more group proportions
1-Proportion test	Compare one proportion to a Prescribed boundary
2-Proportion test	Compare two group proportions

If Changes Are Known

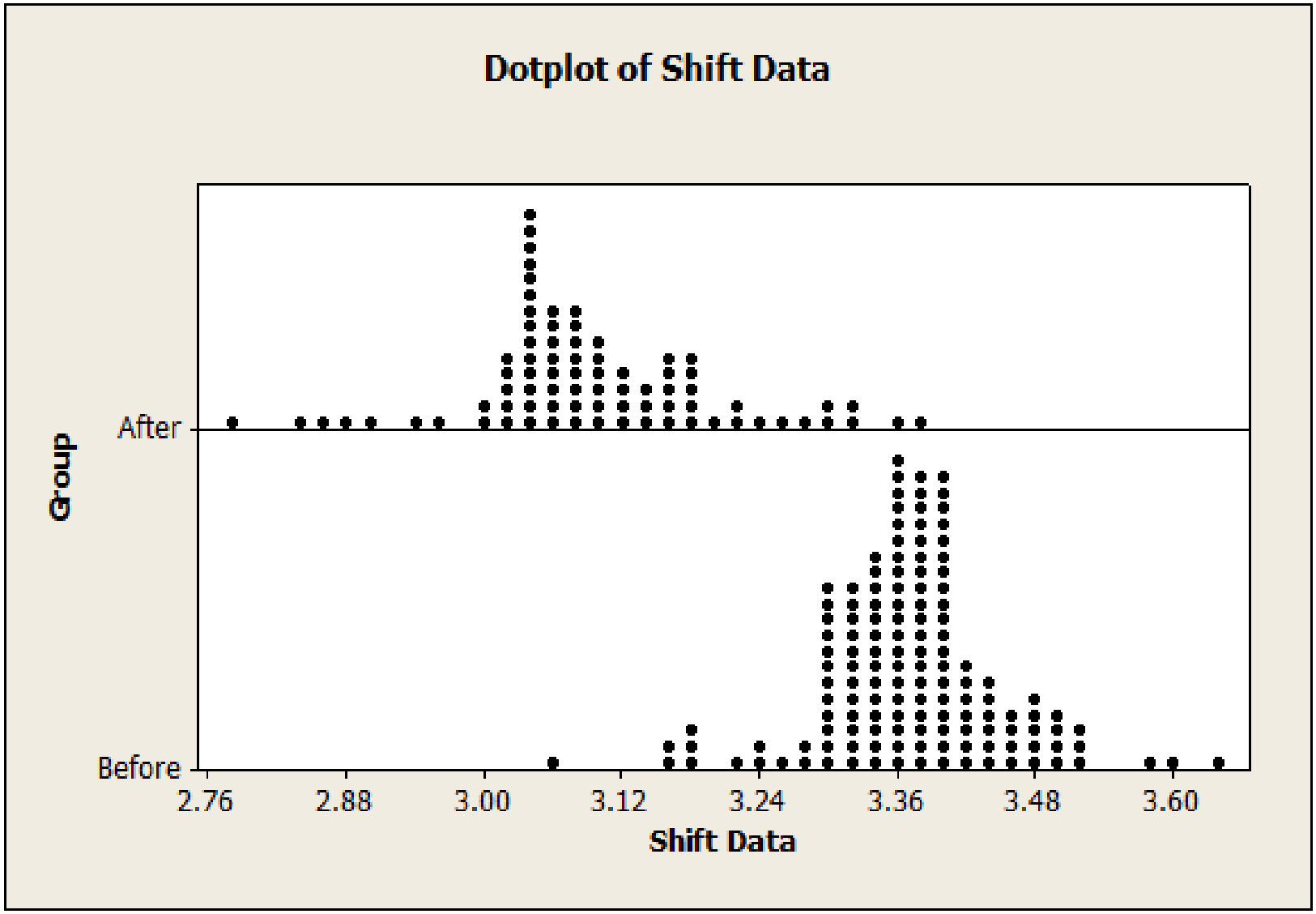
- Box Plots
- Dot Plots
- Time Series Plot
- Multi-Vari Charts
- Capability Comparisons
- Shewart Control Charts
- Time-weighted Charts (EWMA or CUSUM)

These Graphical Representations are better in visualizing the shift for all interested parties.

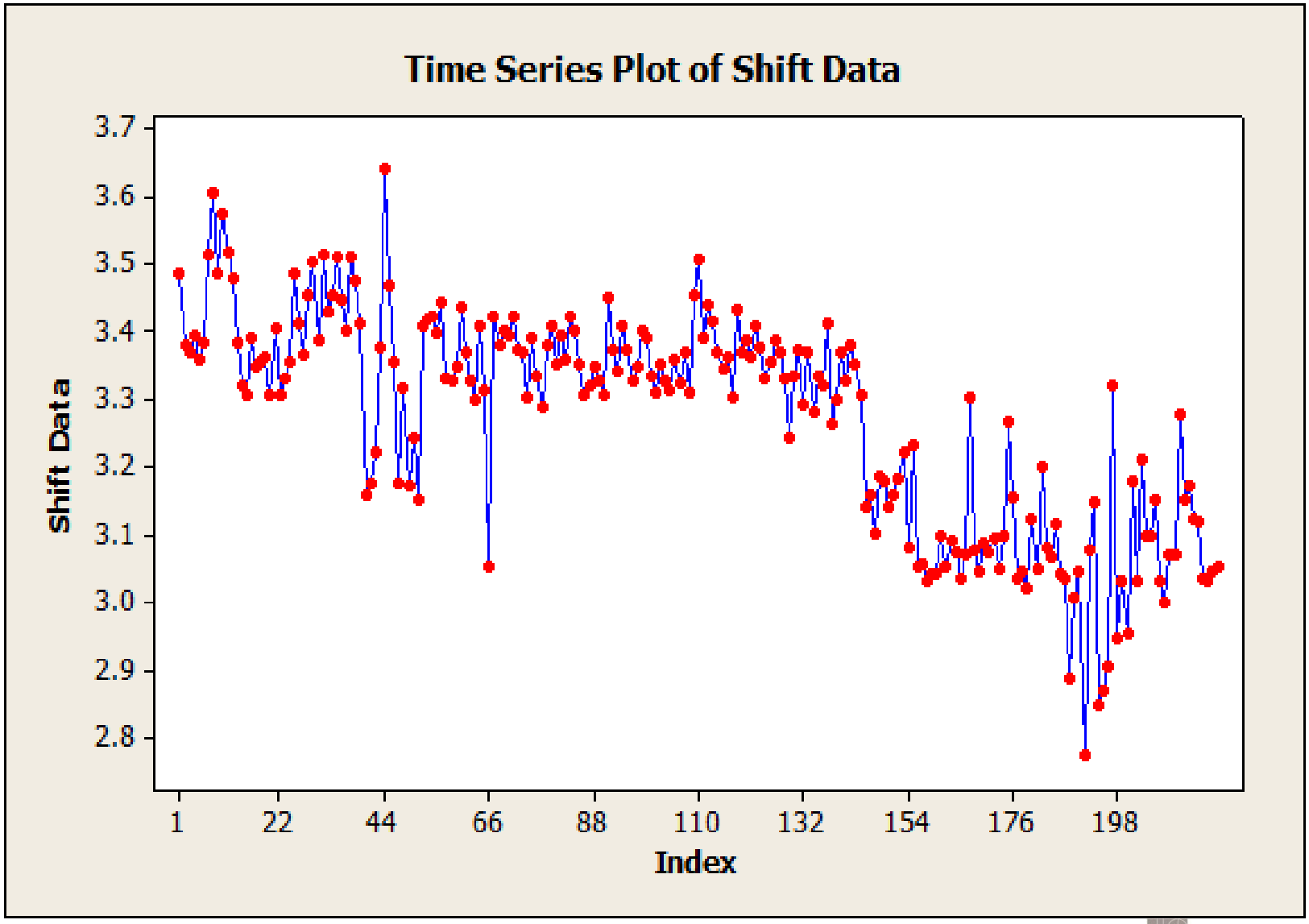
Boxplot Showing Data Shift



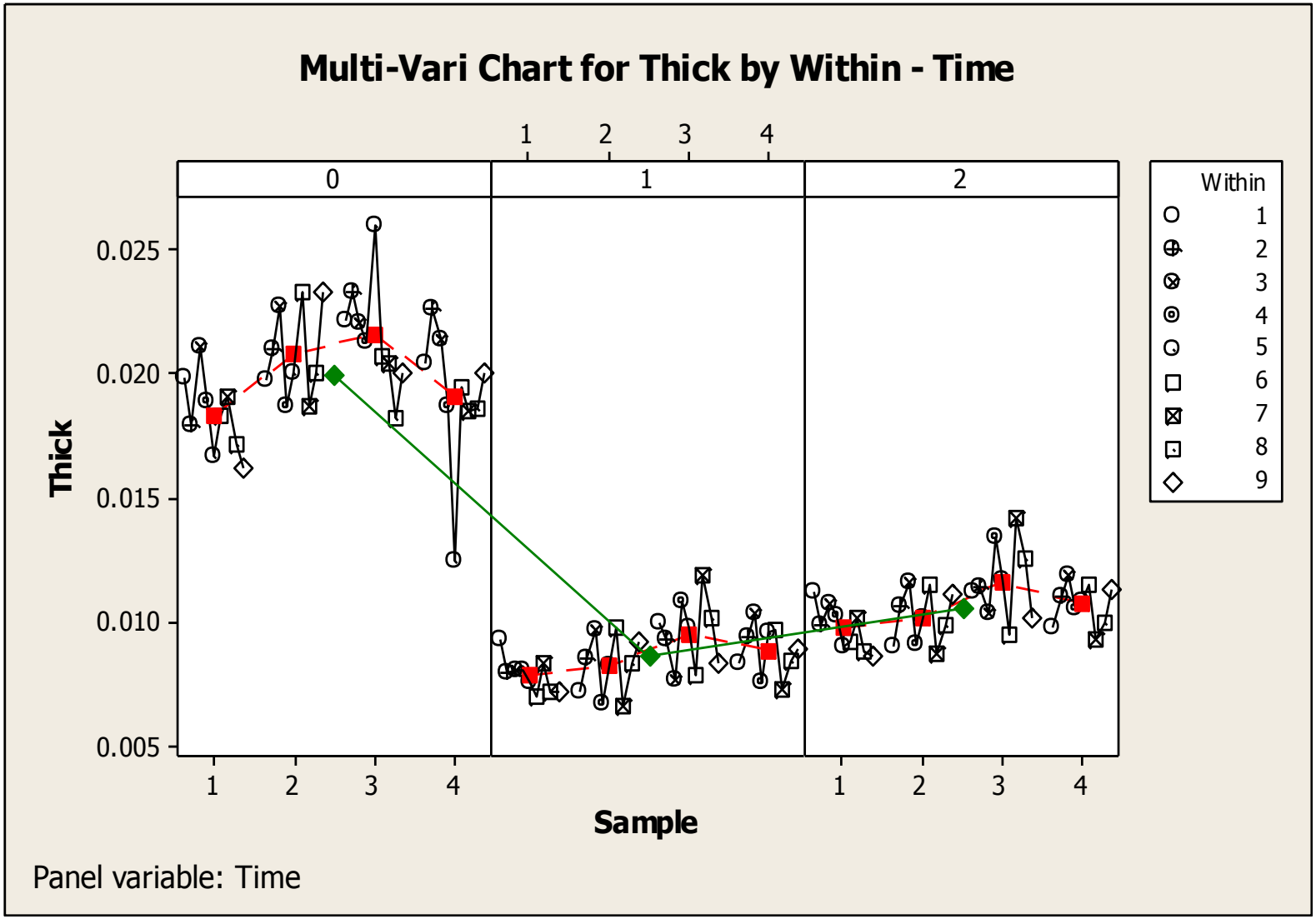
Dotplot Showing Data Shift



Time Series Plot Showing Data Shift

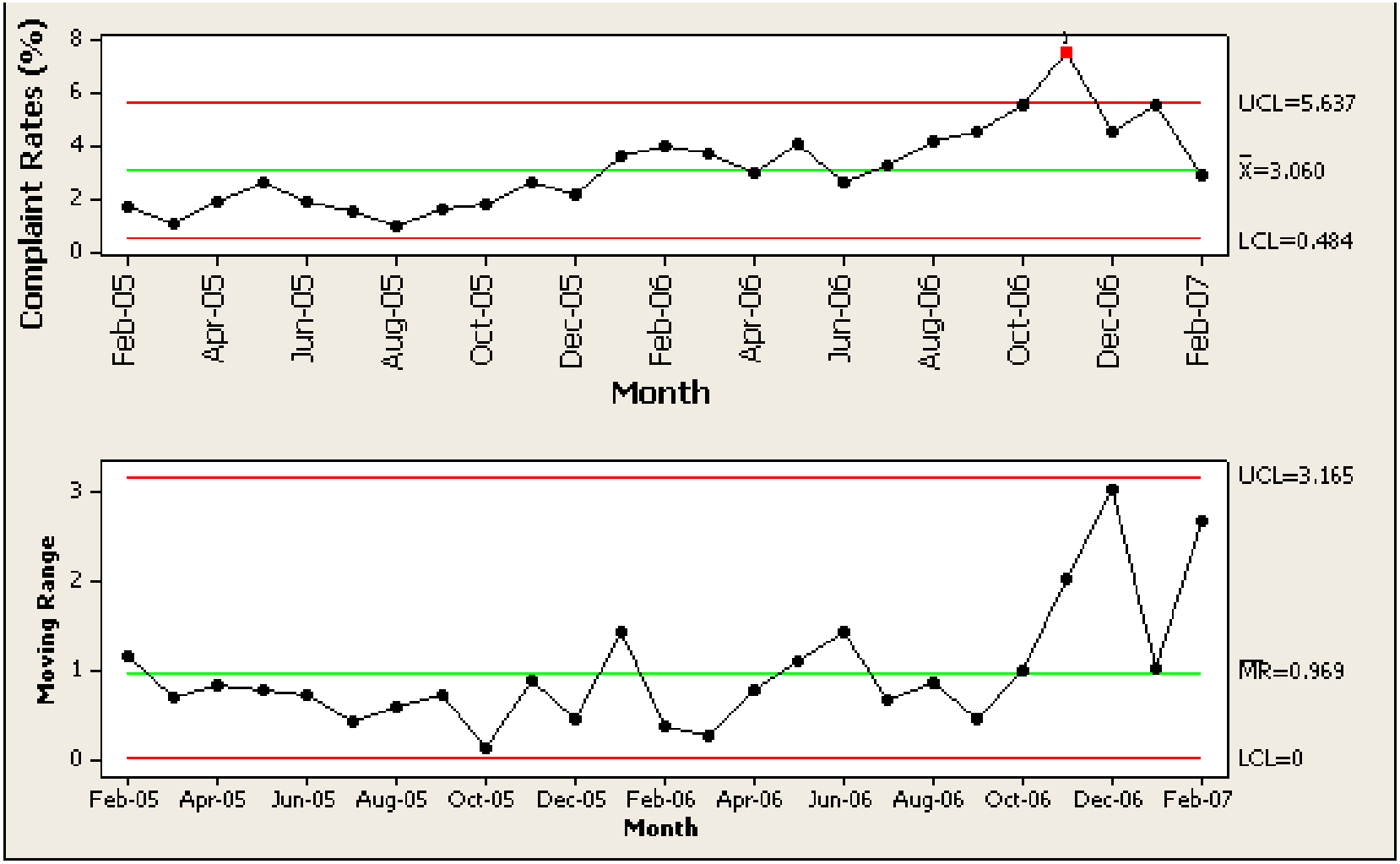


Multi- Vari Chart Example

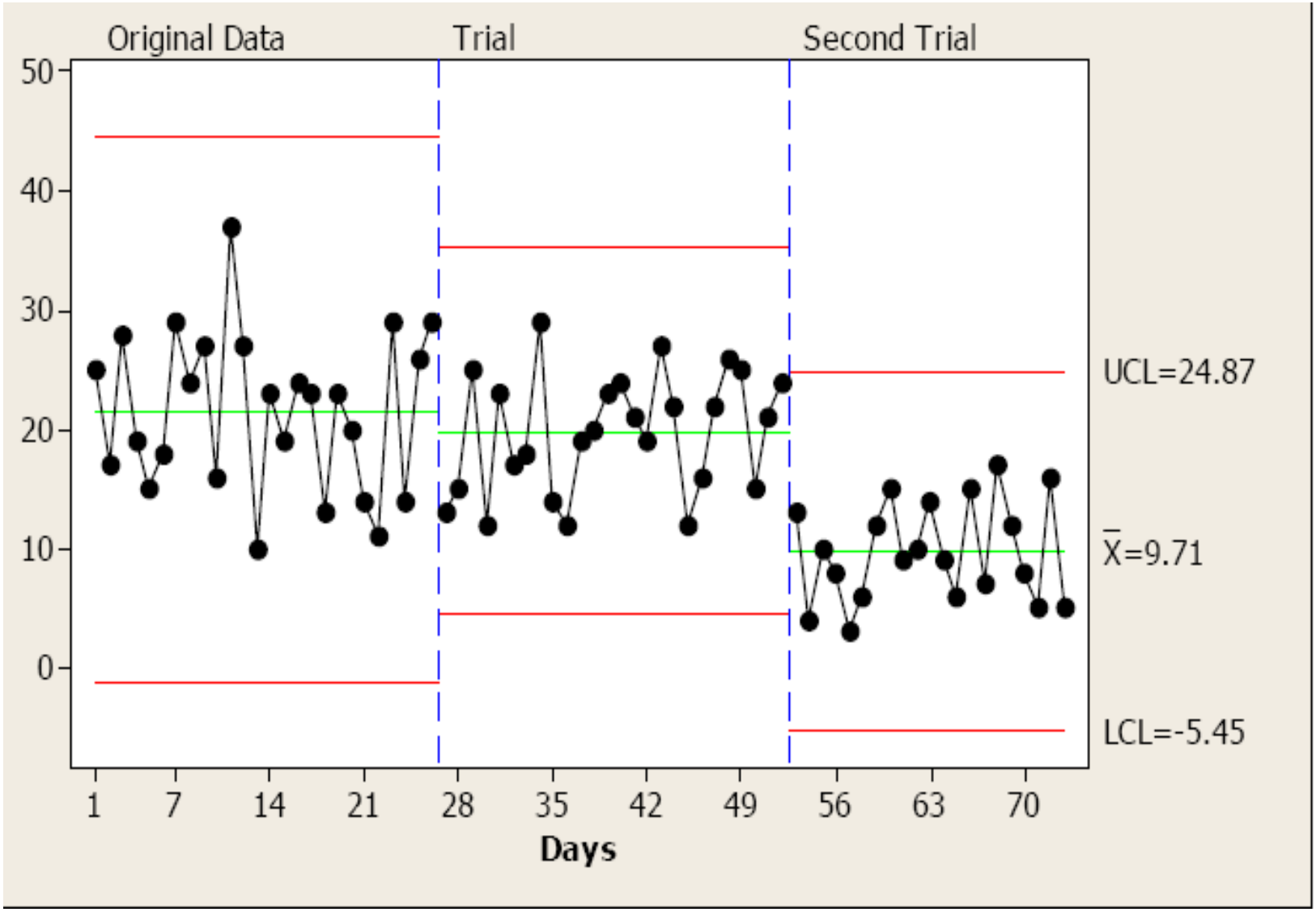


Shewart Control Chart Example

Complaint Rates

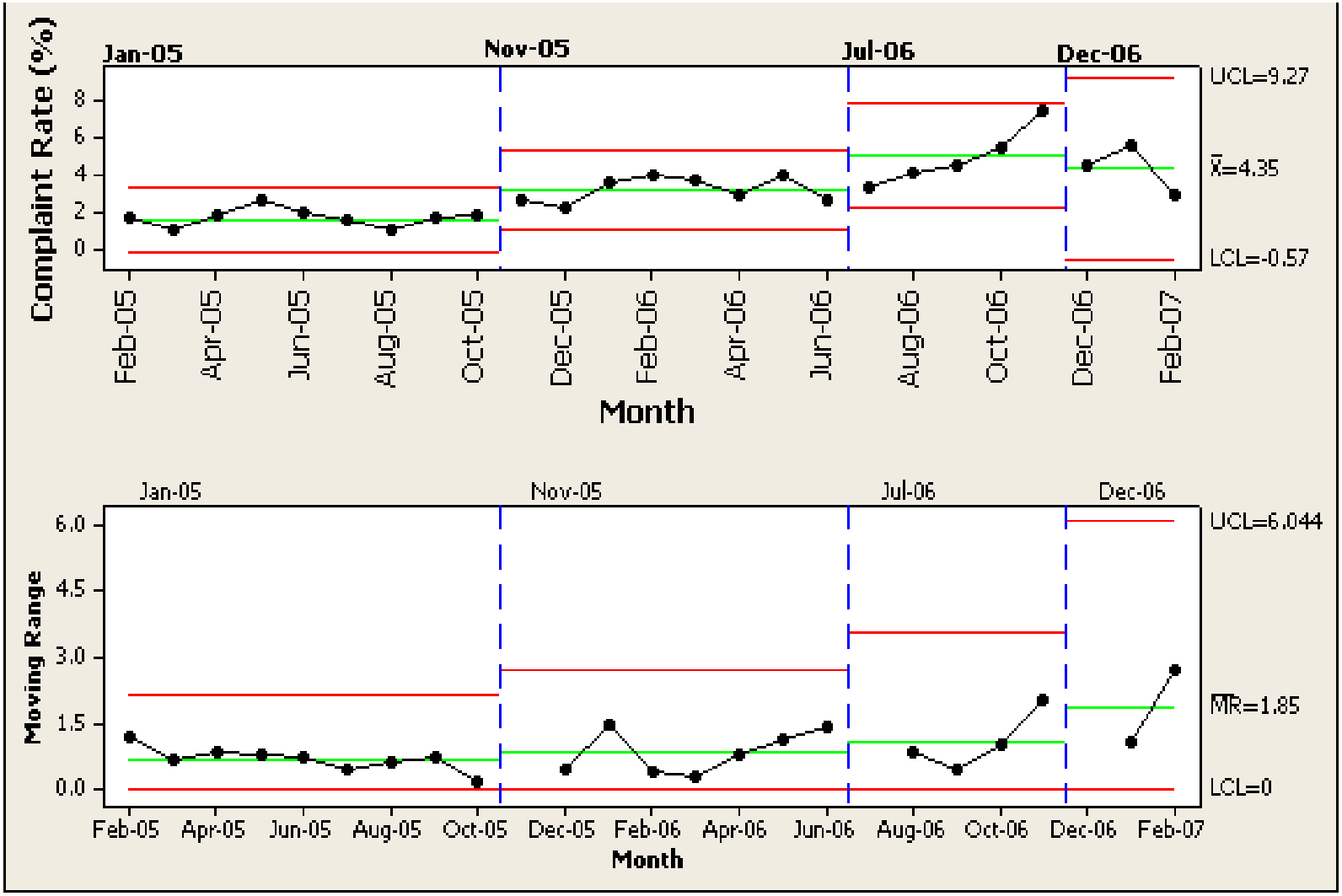


Shewart Control Chart – Showing Phases



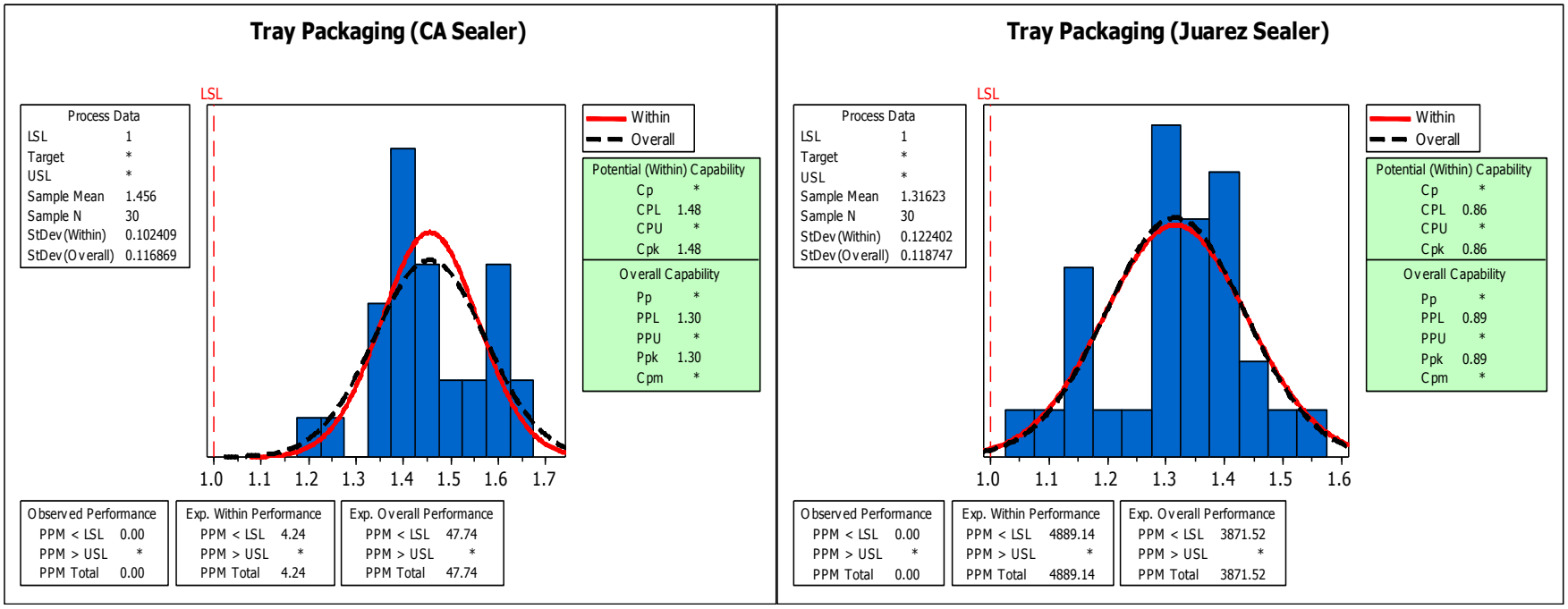
Shewart Chart Example

Complaint Rates



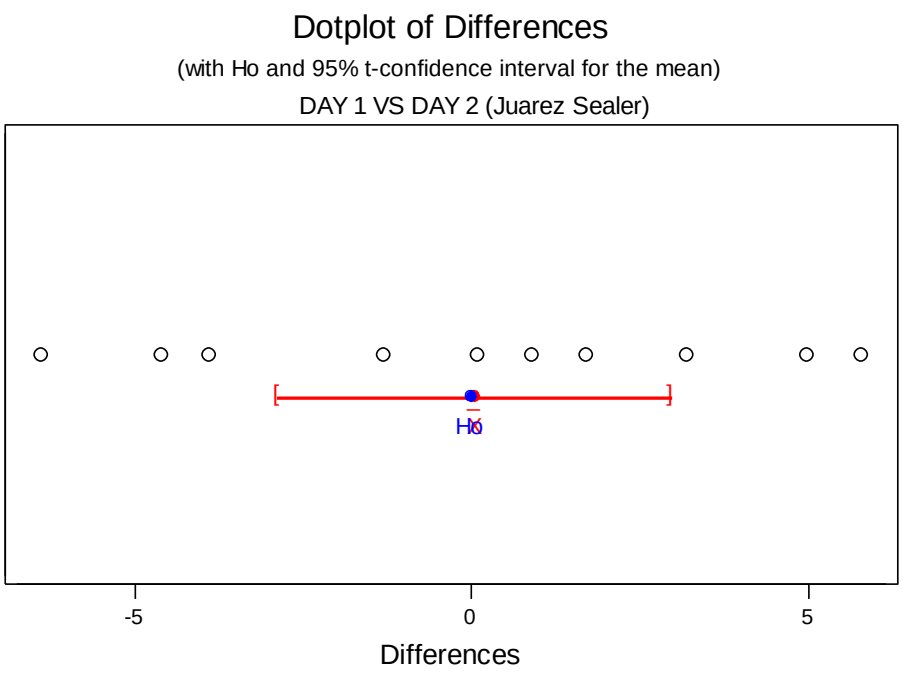
Combinations of Numeric and Graph

A powerful way of showing change can be the combination of both numeric (stat analysis) and graphical representation of the data.

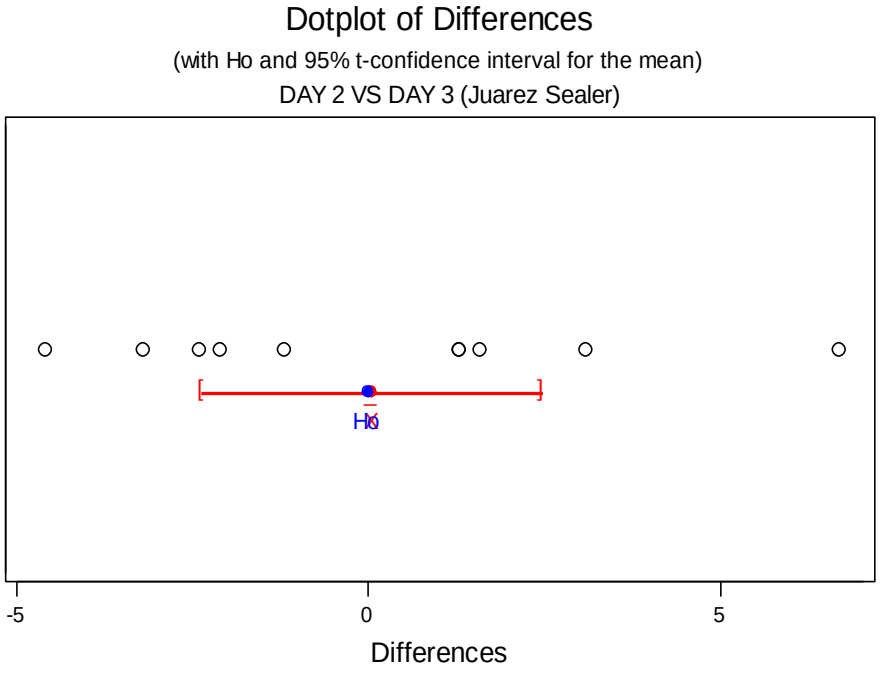


Graphing a Change

Sometimes presenting both the numeric data along with a chart does not add to the discussion, but rather takes away from it.



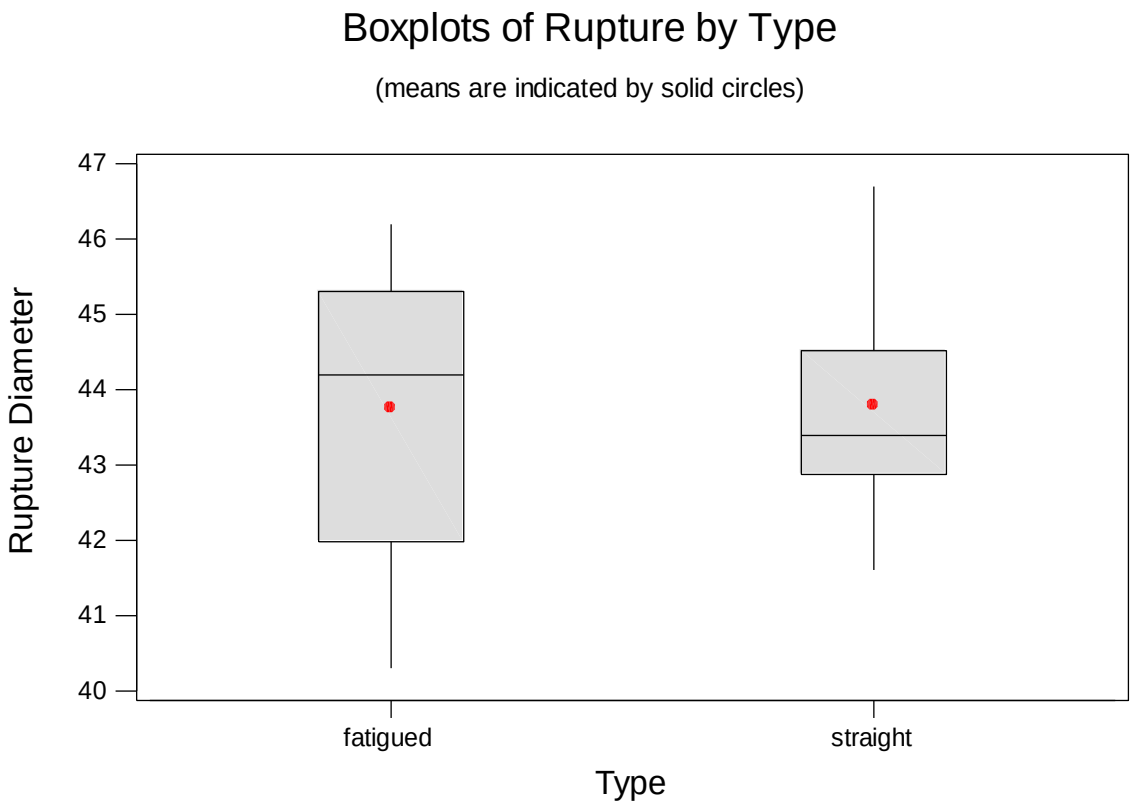
p-value = 0.970



p-value = 0.964

Another Simple Combination

Does fatigue affect mean rupture diameter?

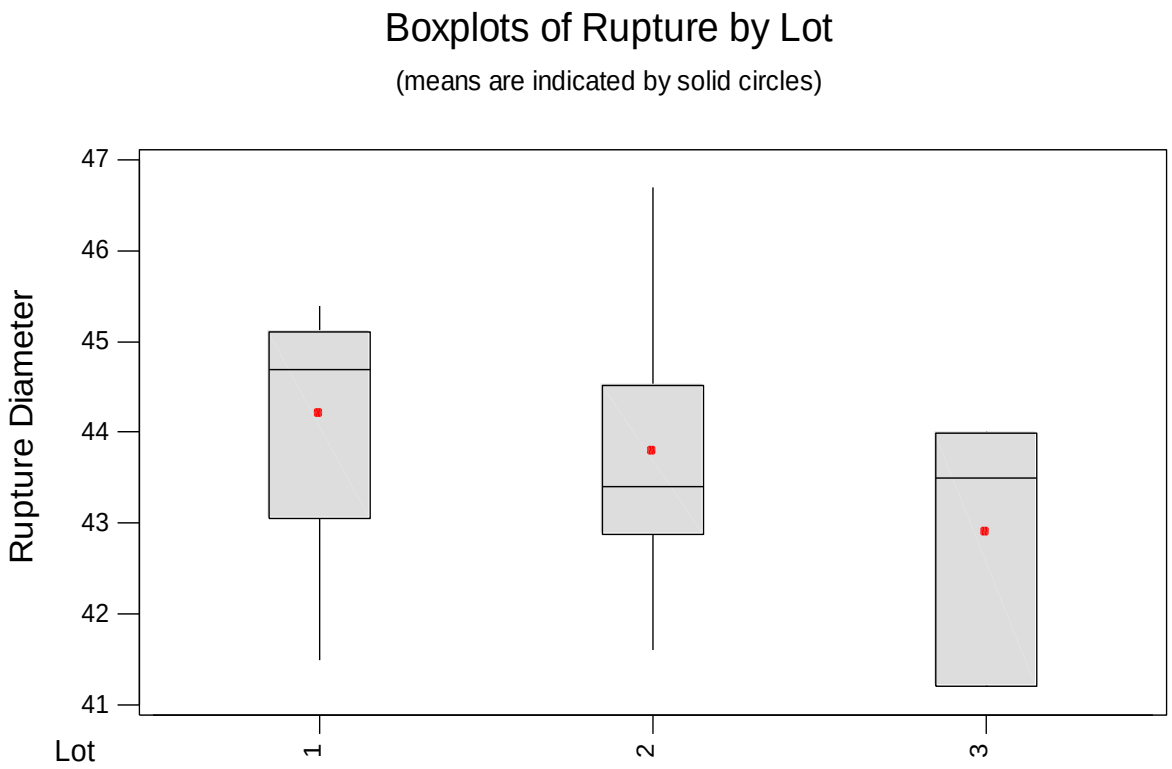


t-test: p=0.96 F-Test p=0.605 Levene's Test p=0.382 ⇒

NO. No statistically significant difference in mean rupture diameter pre and post fatigue…….

Boxplots with Statistical Analysis

Do balloon lots affect mean rupture diameter?



ANOVA: p=0.55 $\Rightarrow$

NO. No statistically significant difference in mean rupture diameter across raw material balloon lots

Determining If A Data Shift Has Occurred

Edwards

If Changes Are Unknown

- Quite often we do not know of any intentional changes to a process, but must be aware of shifts when they occur. The various control chart methodologies are most important for monitoring a process and determining shifts in data.
- Shewart Control Charts (X-Bar & R, I & MR, p, etc.) are helpful when we want to detect large shifts in data. In "Introduction to Statistical Quality Control" Montgomery states that these are effective for a magnitude of 1.5σ to 2σ shift or larger. There are alternatives for detecting smaller shifts!

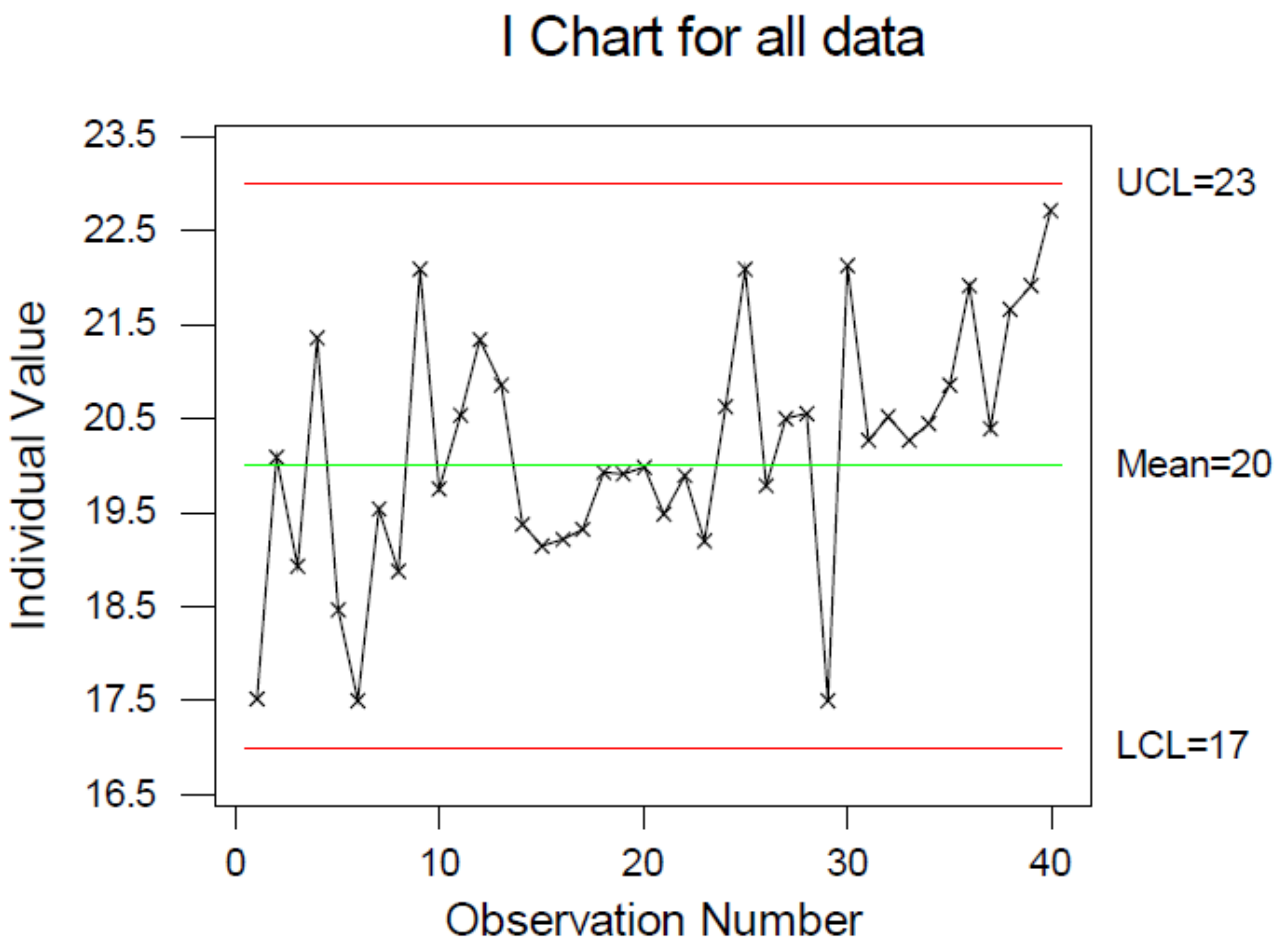
EWMA Charts

The EWMA (Exponentially-Weighted Moving Average) chart weights moving average values according to time. The more recent the value, the greater the weight assigned to that value and, in effect, the greater the emphasis given to that value.

The EWMA chart is sensitive to small shifts in the process mean, but does not match the ability of Shewhart-style charts (like the X-Bar and R or the X-Bar and s charts) to detect large shifts.

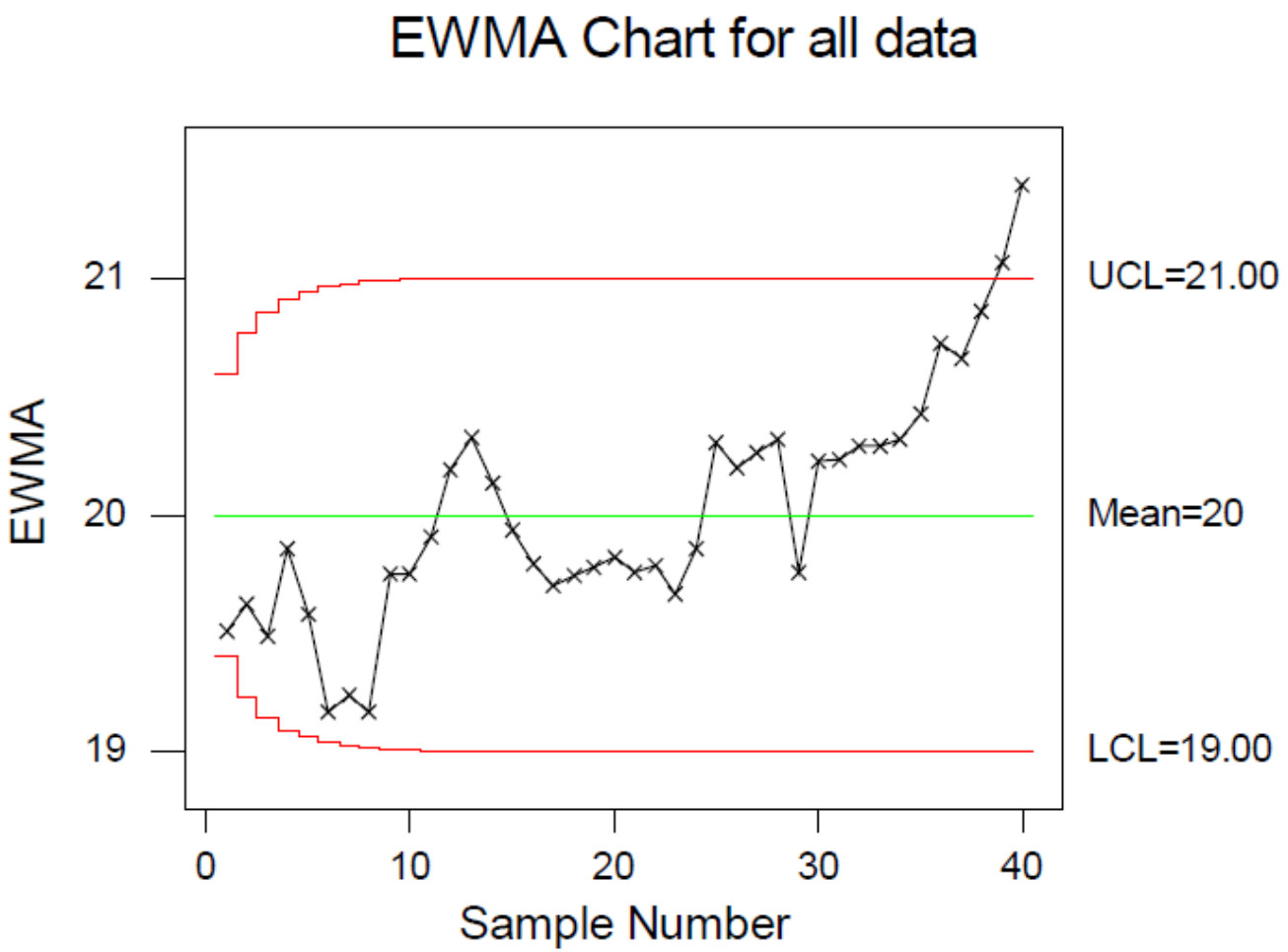
EWMA Charts

First let's look at a data set using an Individual Chart



EWMA Charts

Now same data as an EWMA Chart

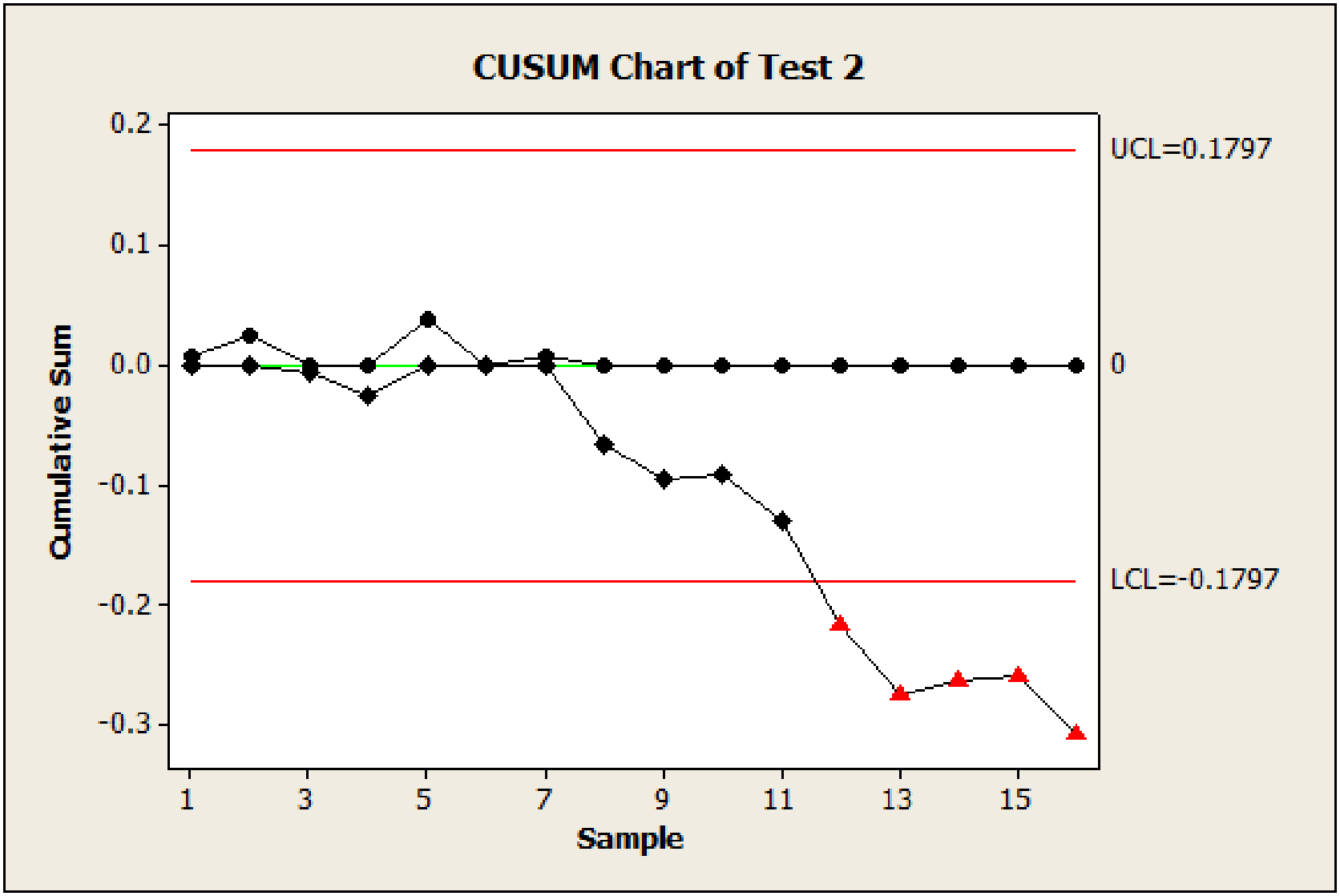


CUSUM Charts

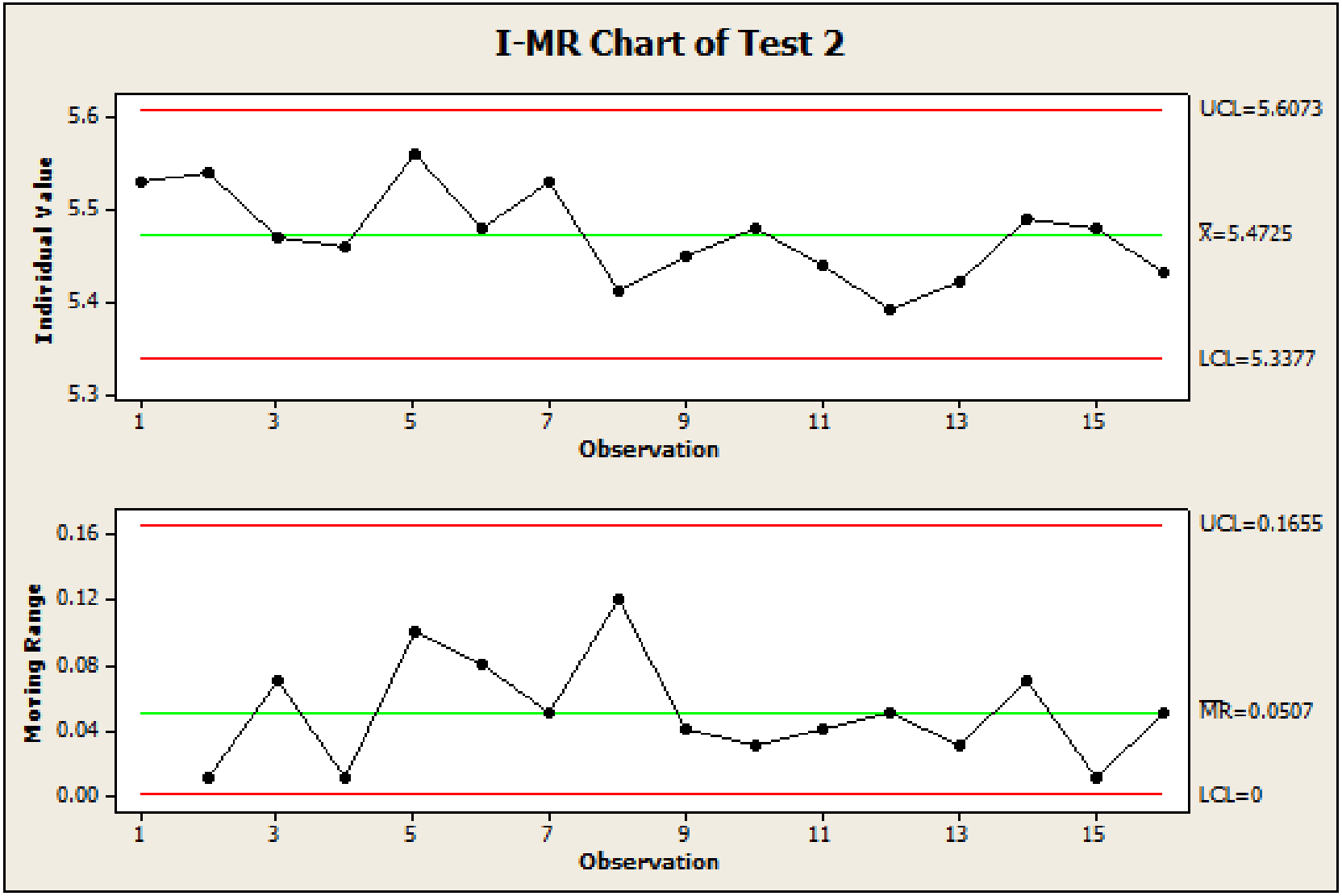
Another useful chart to detect small shifts is the CUSUM or Cumulative-Sum Control Chart. As described by Douglas C. Montgomery " The cusum chart directly incorporates in the sequence of sample values by plotting the cumulative sums of the deviations of the sample values from a target value."

The CUSUM Chart uses average moving range, median moving range, or Square root of MSSD for its control limits for subgroup size of 1. It uses R bar, S bar, or Pooled Standard Deviation for subgroup sizes greater than 1.

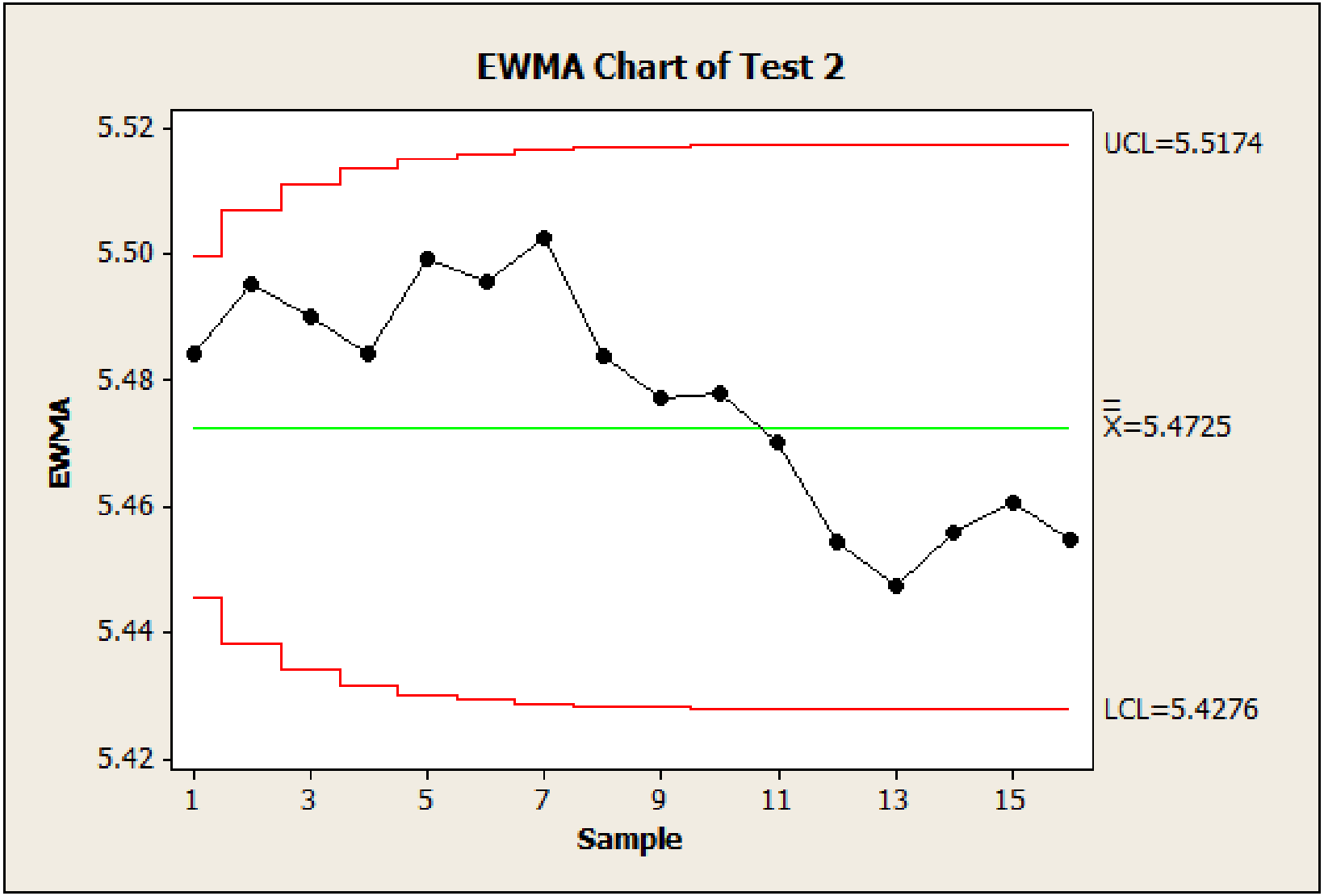
CUSUM Charts



Individual-Moving Range of Same Data

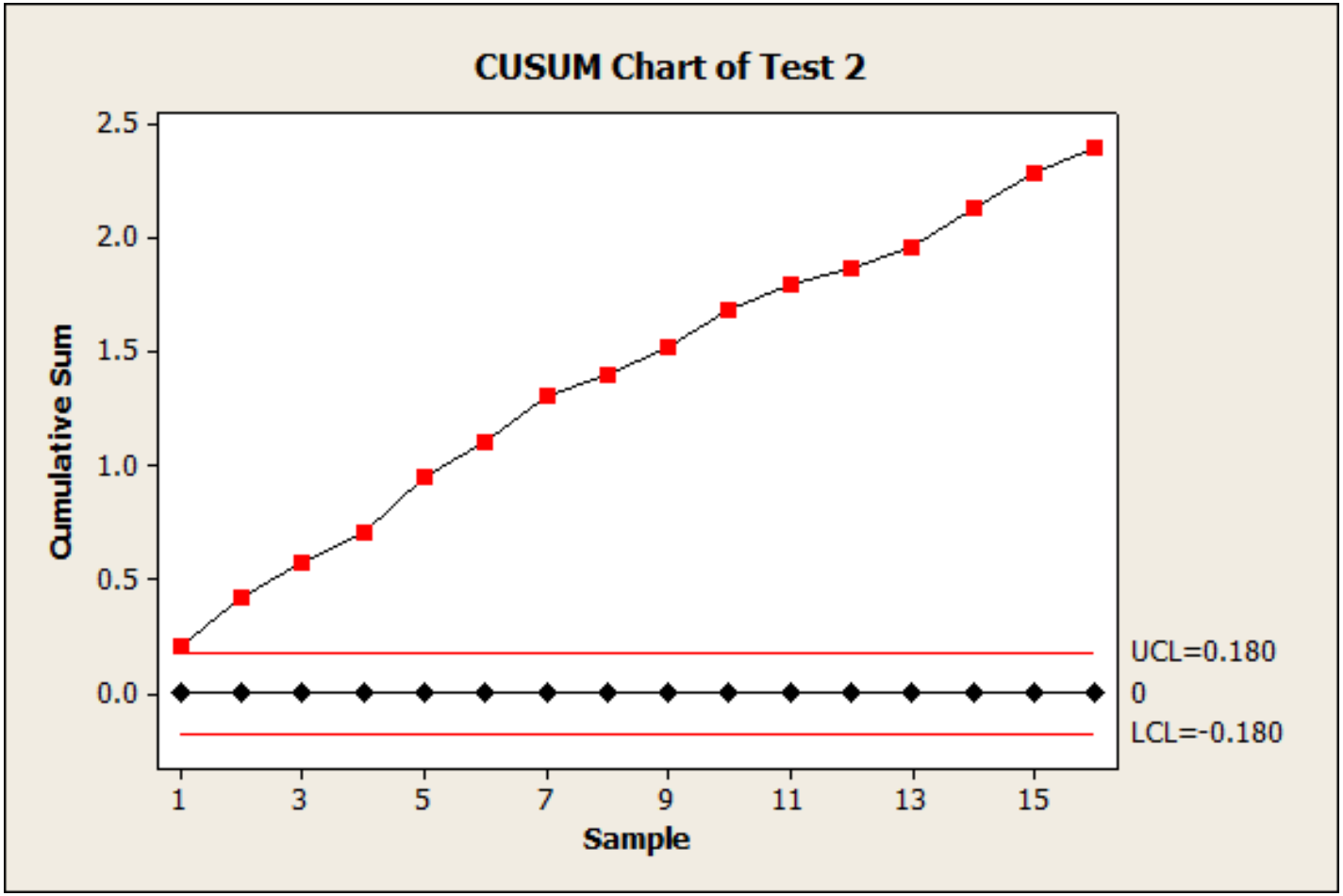


EWMA Chart with Same Data



Note About CUSUM Charts

Remember it's based on a target value!! If we change our target from 3.5 to 3.3 this is what happens.

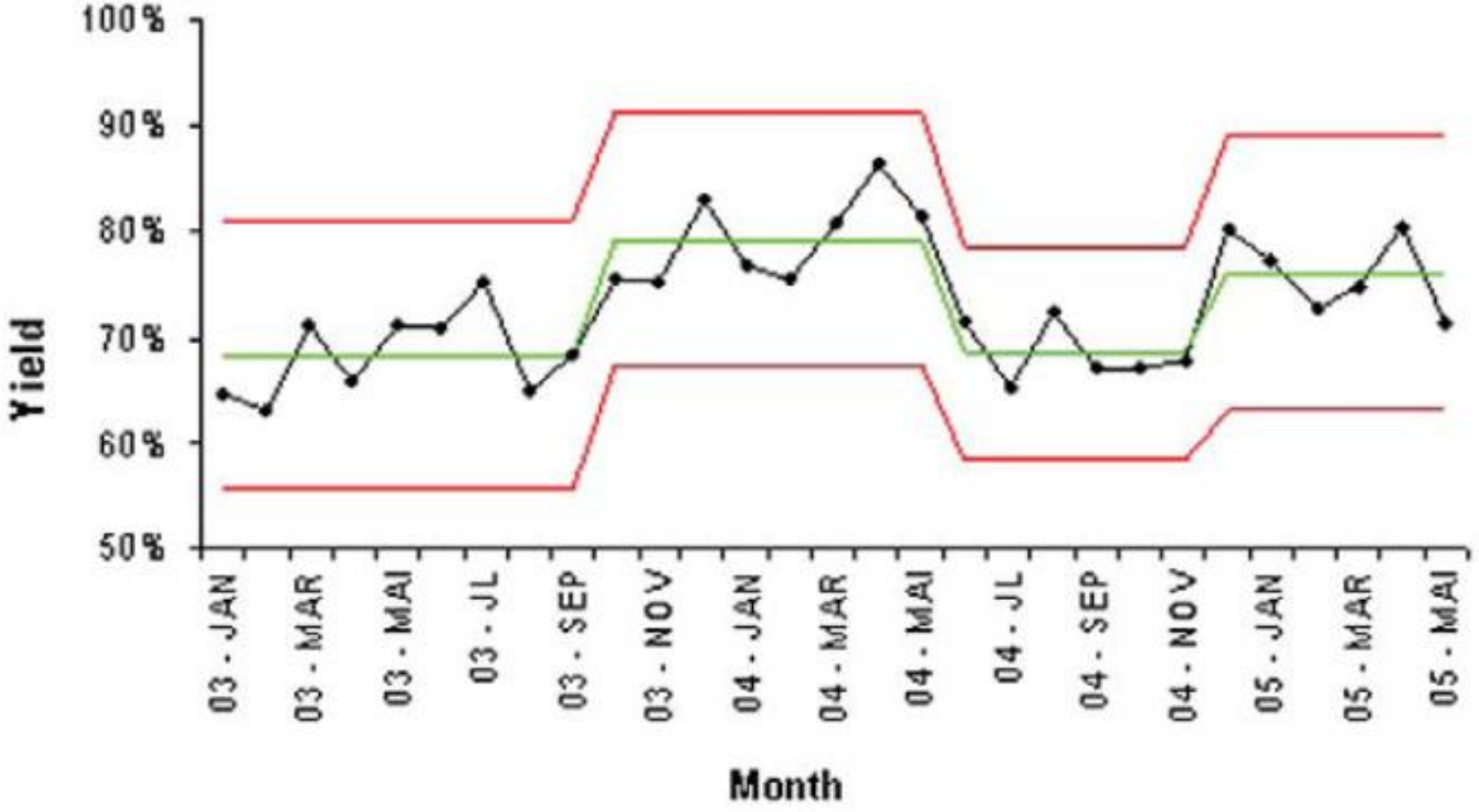


Change Point Analysis

From Dr. Wayne Taylor:
"A change-point analysis is performed on a series of time ordered data in order to detect whether any changes have occurred. It determines the number of changes and estimates the time of each change. It further provides confidence levels for each change and confidence intervals for the time of each change."

The two techniques used during change-point analysis are bootstrapping and CUSUM Charts. These cumulative sums are the sums of differences between the average and the values. At the end the sums will equal zero, but it is the trends that are of interest in this analysis.

Change Point Analysis



Thanks!

Thank You for Your Time and Attention !