MEDICAL PACKAGING ADHESIVE

RELEVANT JMP PLATFORMS AND STATISTICAL TECHNIQUES

Graph Builder : Comparative Dotplots and Boxplots.

Distribution : Histograms; Summary Statistics; One-Sample Inference for Population Mean and Standard Deviation/Variance; Process Capability Analysis

Fit Y by X : Two-Sample Inference comparing Population Means and Standard Deviations/Variances.

PROBLEM STATEMENT

Engineers in a product development team for a manufacturer of medical equipment packaging is evaluating the performance of two different formulations of adhesive that's used to seal the packaging.

An important characteristic is that the adhesive is strong enough to withstand the usual sterilization and handling rigors while not so strong that it is difficult for a medical practitioner to open up easily (Figures 1A and 1B).

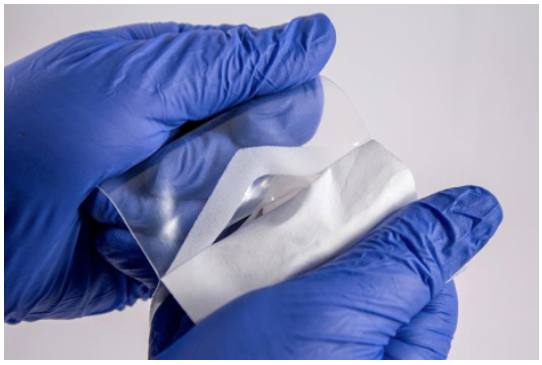

Figure 1A

Figure 1B

The engineers produce a sample of n=50 pouches sealed with each of these two new adhesive formulations (A and B). The Peel Strength on each specimen is measured using a device known as a 'Universal Testing Machine' (Figure 2).

Figure 2.
Image of Universal Testing Machine grips from Instron®.
https://www.instron.com

The tester records the force (in Newtons) being applied across a range of peel displacement. The average force across a defined range of peel displacements is used as a single data value summarizing a test. Figure 3 shows this for 3 specimens.

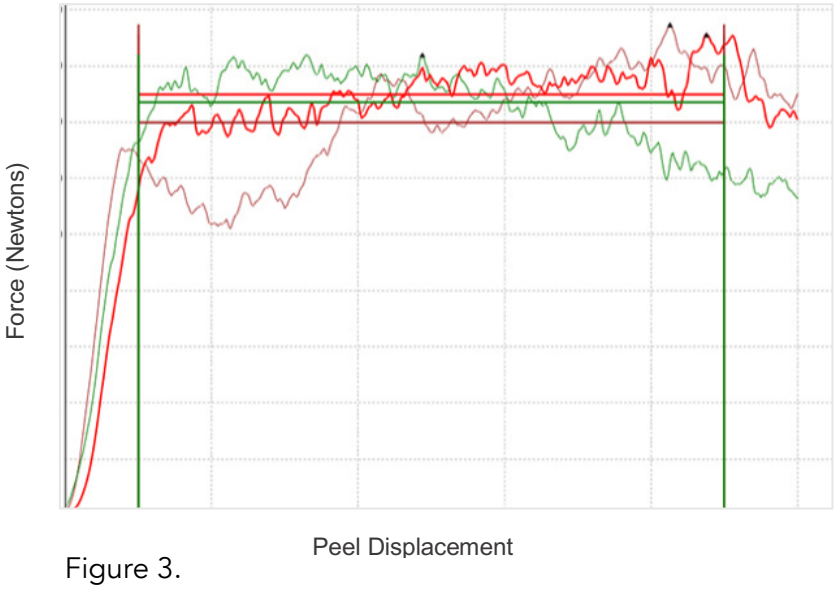

Figure 3.
Image of data produced by Universal Testing Machine from Instron®.
https://www.instron.com

The specifications for the adhesion is an average peel strength (μ) of 11.0 N, along with +/- 3 standard deviations (σ) < 1.5 N (i.e., σ < 0.5 N).

DATA MEDICAL_PACKAGING_ADHESIVE.JMP

Peel Strength A	Average Force (in N) to separate material using Adhesive Formulation A.
Peel Strength B	Average Force (in N) to separate material using Adhesive Formulation B.

EXCERCISES

1. Produce univariate graphical and numerical summaries of the peel strength of the two adhesive formulatons. Summarize, in a few brief sentences, the performance of each adhesive using these graphical and numerical summaries.
2. Perform the following statistical analyses.
   a. Conduct a hypothesis test for each formulation to determine if there statistical evidence indicating the average peel strength is different than 11.0 N. Summarize the results.
   b. Examine the 95% Confidence Intervals for the mean peel strength for each formulation. Provide an interpretation of these interval estimates?
   c. Perform analyses to evaluate if the Normal Distribution is a reasonable model to use for these variables (i.e., an assumption for the analyses above).
      Is the Normal Distribution a reasonable model use? If not, are there any substantial concerns you have with the interpretations reached in the analyses above?
   d. Conduct a hypothesis test to determine if there is statistical evidence to conclude the variation in peel strength for each formulation is < 0.5 N. different? Provide a practical interpretation of the results.
3. Perform the following comparison analyses.
   Note: This requires a new data table with the two peel strength columns stacked into one, and a second column indicating the formulation.
   a. Create a graph comparing the peel strength for each formulation. Add reference lines for the target of 11.0 N, along with +/- 1.5 N. Provide an interpretation.
   b. Conduct a statistical test to determine if the average peel strength between the two formulations are not equal. Provide a practical interpret of the results?
   c. Conduct a statistical test to determine if the variation in peel strength between the two formulations are not equal. Provide a practical interpret of the results.

4. Perform a capability analysis using the target of 11.0 N and lower and upper specification limits of 9.5 and 12.5 N.
    a. Provide estimates of the propotion of packages that will be outside of the specification limits for each formulation.
    b. Explain how each of these formulations would need to improve in order for them to perform better to specification?
5. Construct a 95% confidence / 99% coverge Tolerance Interval providing estimates of the low and high peel strength values that would capture 99% of a population of packages produced with these formulations. Provide a practical interpretation.