Using JMP® to Improve Manufacturing Yield for Medical Devices Via Sequential Experimental Design

Chad Naegeli, Incisive Surgical, Plymouth, MN 55447

Introduction

The INSORB® |2030 subcuticular skin stapler approximates, closes, and fastens tissue using a penetrator to create an opening for u-shaped absorbable staples. The staples are placed below the skin and hold the incision during normal healing. The stapler competes against metal skin staplers and suture.

A new production assembly machine was implemented that checks the functionality of every stapler for proper staple feeding by loading an extra staple and actuating a test-fire. The test-fire determines whether or not the stapler is rejected or accepted.

Historically, the yield for this process is near 98.5%. The goal is to increase the yield beyond 99% using sequential experimentation.

Methods

The current output for the production machine test-fire is either pass for no staple "push" or fail for a staple "push". A staple "push" occurs when the staple does not feed properly into the penetrator.

Staple Test-Fire	Pass / Fail	Score
No Push	Pass	3
Light Push	Fail	2
Medium Push	Fail	1
Heavy Push	Fail	0

This output was converted from a binary output to a continuous output by grading each test-fire with a numeric score from 0 to 3, and averaging the result of all staple test-fires. For each staple test-fire the optimal score is 3, and the least desirable is 0. Each stapler has 30 staples, so the score will be the average of all the 30 staple test-fires. The scoring system was developed to lower the required sample size.

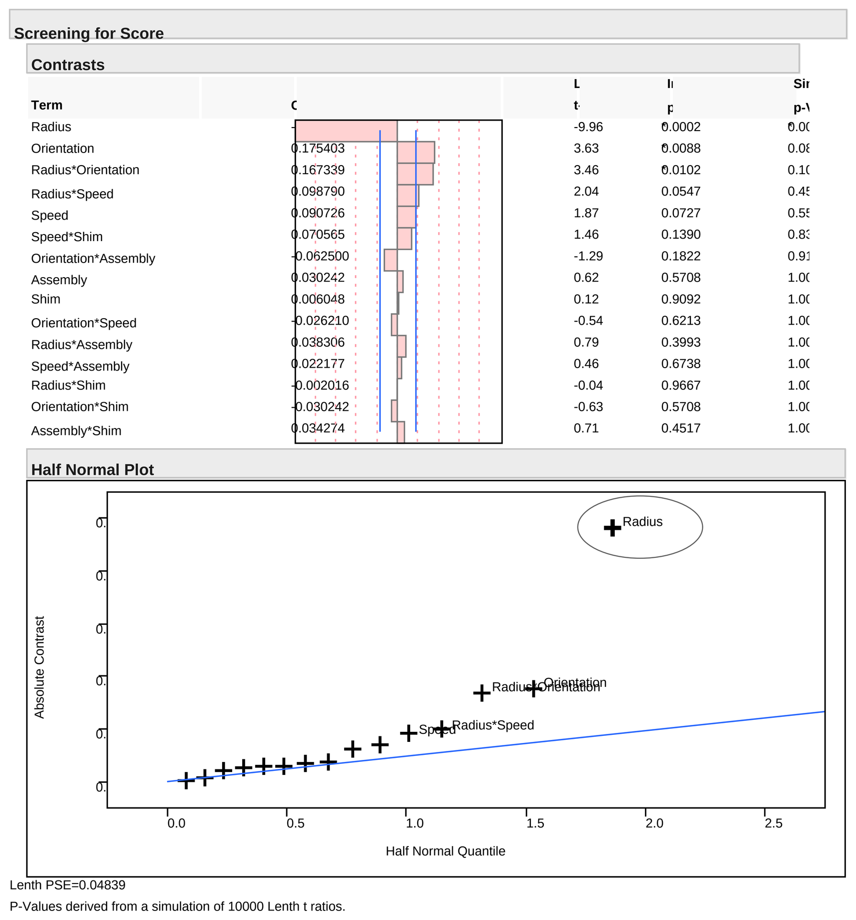
To improve the yields of the staple test-fire process, a list of possible factors was developed and ranked. The five most promising factors for improving the test-fire yields were explored first.

DOE #1

The top five factors were funneled into a 16-run (resolution V) fractional factorial design of experiments which allows estimation of main factors and all second order interactions with the staple test-fire score as the output. Since many of the factor settings were improvements over the existing design, the rate of pushing would be too low to detect without a large sample size. To create staple pushes the penetrators were intentionally damaged, but with not too much damage to cause all the staples to push during the test-fire.

Factor	Levels	
Shim	No	Yes
Assembly	Low	High
Radius	S	XL
Orientation	Standard	Inverted
Speed	Slow	Fast

- The screening platform was used to find the active factors.
- The simultaneous p-value column was sorted by ascending value.



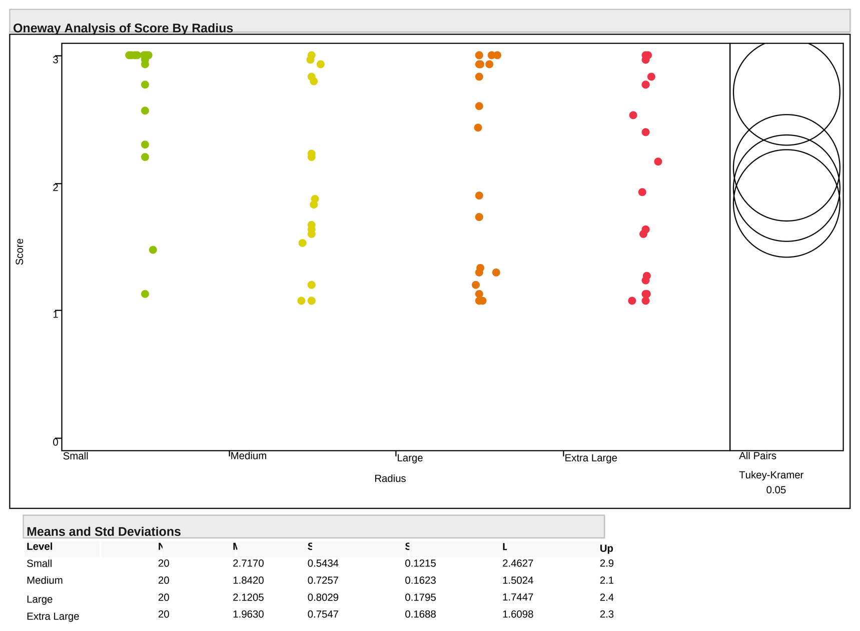
- Radius is the top active factor, and clearly a visible signal from the noise on the half normal plot. The small radius (S) resulted in the highest score.

DOE #2

Since DOE #1 indicated the radius was an active factor, the experiment was repeated with only this factor. However, DOE #2 used four different radius sizes instead of only two radius sizes. The remaining four factors tested in DOE #1 were held constant. By testing the radius in four different sizes, tolerance limits could be established for the radius dimension. The sample size was increased to 20 runs for each radius size, or 80 runs total.

Factor	Levels			
Shim	No			
Assembly	Low			
Radius	S	M	L	XL
Orientation	Standard			
Speed	Medium			

- The one way platform was used to find differences between the different radiuses.



- The 95% confidence intervals for small radius (S) are clearly different from the other radius sizes (M, L, and XL).
- The small radius average score was 2.72, but there were two scores below 2.00. In contrast, the other radius sizes had 10 or more scores below 2.00.

Conclusions

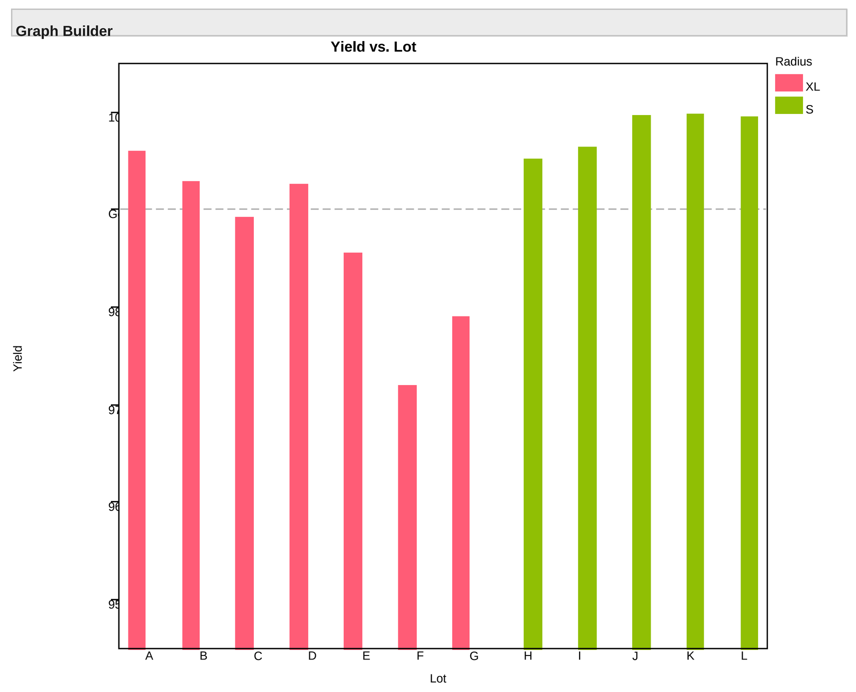
Since the two previous experiments used intentionally damaged penetrators, a verification run was conducted to ensure the results were valid for non-damaged penetrators. 30 staplers using each radius size were assembled and test-fired in a similar manner as before.

Radius	Sample Size	Yield
Small (S)	900	100.00%
Medium (M)	900	100.00%
Large (L)	900	98.11%
Extra Large (XL)	900	99.67%

- The small radius and medium radius had a yield of 100%. The large radius was just above 98%, and the extra large radius was near 100%.
- The small radius was implemented due to the robust performance with both damaged and un-damaged penetrators.

Post-Production

The data below shows yield over the last several production lots after implementing the small radius. The red bars are staplers with extra large radiuses, and the green bars are staplers with the small radius.



- The average yield increased from 98.5% to 99.8% and is above the 99% project goal. This promising trend will continue to be monitored over time.