CASE STUDY

Making a Smooth Operation Even Smoother: Smith & Nephew

When surgical device maker Smith & Nephew moved a critical manufacturing process in-house, Minitab helped them attain maximum efficiency while meeting stringent quality standards.

KEY FACTS

ORGANIZATION
Smith & Nephew

OVERVIEW
- Maker of advanced medical devices and healthcare products
- The UK's largest medical technology company
- Over 150 years of operating history
- Worldwide operations in 32 countries
- Annual sales of $3.8 billion

QUALITY CHALLENGE
Optimize a new in-house electropolishing process for a medical device used in knee replacement surgery.

PRODUCTS USED
Minitab® Statistical Software

RESULTS
- Used DOE to assess the impact of multiple factors
- Optimized new in-house process
- Minimized defects

Smith & Nephew develop advanced technologies that enable medical practitioners to provide effective treatment more quickly and economically. The company offers a wide range of innovative joint replacement systems for the knees, hips, and shoulders. With the help of its equipment, surgeons can perform minimally invasive procedures that decrease side effects, minimize pain, and speed recovery. Getting the best fit with the least amount of surgical trauma translates into increased efficiency, lower medical costs, and improved patient outcomes. To minimize the invasiveness and trauma of knee replacement surgery, the company developed the Tibial Sizing Trial Guide, a stainless steel device that helps a surgeon quickly and accurately determine the appropriate size of the implant for each patient during surgery. When the company decided to move a critical part of the manufacturing process for this device in-house, they needed to make sure their process would deliver both maximum efficiency and a finished product that exceeds the strict quality standards a surgical device demands. Quality engineer Prashanth Gopal and his project team used Minitab Statistical Software to help optimize the process and prove its effectiveness.

The Challenge

The surface finish, or luster, and corrosion resistance of the Tibial Guide are critical for its use in surgeries, and its dimensions must satisfy stringent specifications. Therefore, a key step in manufacturing this device is the electropolishing process. In this process, a metal object is immersed in a temperature-controlled electrolyte solution. As current passes through the metal and the solution, metal on the surface is oxidized and dissolved. The polishing process must not only remove burrs, create a smooth, shiny surface, and protect the device against corrosion, it also must minimize metal removal so that the dimensions of the device remain within specifications.

	Factors													
Run	2	3	4	5	6	7	8	9	10	11	12	13	14	15
4	Full	III												
8		Full	IV	III	III	III								
16			Full	V	IV	IV	IV	III	III	III	III	III	III	III
32				Full	VI	IV	IV	IV	IV	IV	IV	IV	IV	IV
64					Full	VII	V	IV	IV	IV	IV	IV	IV	IV
128						Full	VIII	VI	V	V	IV	IV	IV	IV

To help design your experiment, Minitab displays all the available designs and indicates the relationship between the number of factors, the number of runs, and the design resolution.

To reduce costs and improve quality control, Smith & Nephew decided to move their offshore electropolishing operations to their own facility. To make this move successful, they had to demonstrate that the in-house process met critical performance requirements. The project team identified four key factors that affected the electropolishing process:

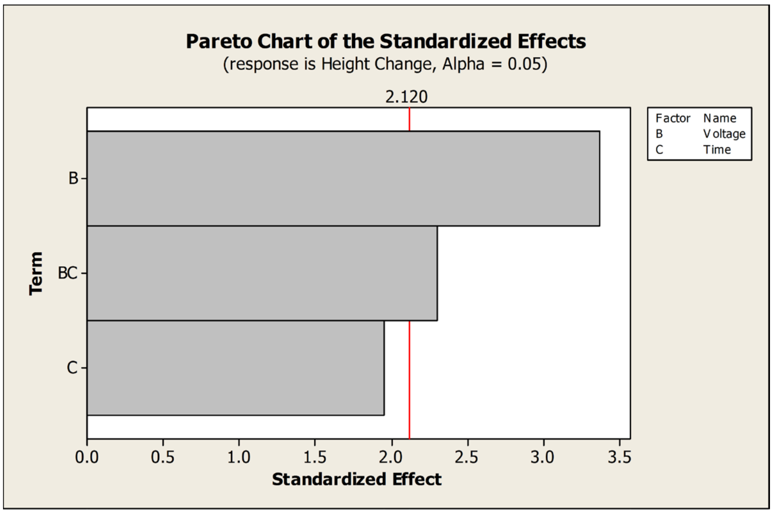
- Specific gravity of solution
- Voltage
- Cycle time
- Ambient temperature (noise variable)

They conducted preliminary tests to estimate the range of settings for each factor that would yield acceptable corrosion resistance and appearance. Now the team needed to design an experiment that allowed them to fully understand the effects of the three process variables, while also considering the noise variable, ambient temperature. They also needed to assess the interactions between the factors.

How Minitab Helped

Using Minitab's Design of Experiment (DOE) tools, Mr. Gopal quickly designed an efficient experiment to evaluate the electropolishing process and get answers to the team's questions. First, he used Minitab to create a design for their experiment based on the number of factors and the number of runs that they could feasibly perform, given their available resources.

The noise variable ambient temperature, which was controlled during the experiment, needed to be treated as a blocking factor. So he selected a full factorial design with three factors, two blocks for the low and high ambient temperature settings, and two replicates to increase the experiment's statistical power. He also added center points to the design to detect any curvature if it existed. The end result? A lean, efficient experiment that required only 20 runs, accounted for variation due to temperature, and allowed all interactions between the factors to be evaluated independently.

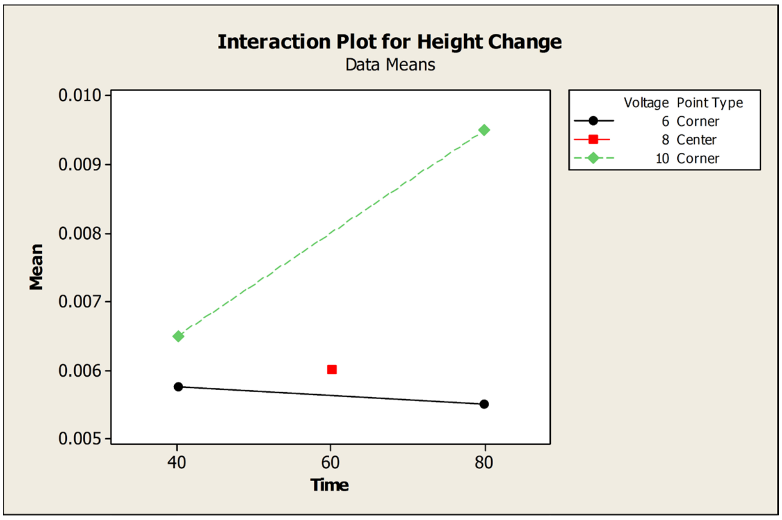


The Pareto chart allows users to clearly see main effects and interactions that cross over the red line and thus are statistically significant. This chart above shows that both voltage (B) and the interaction between voltage and time (BC) have significant p-values.

Results

Based on Minitab's DOE analysis results, the team found that ambient temperature, a potential source of unwanted variation that was difficult to control, had no statistically significant effect on dimensional change—which was good news. The specific gravity of the solution used also was not significant. However, voltage used in the electropolishing process (factor B below) did have a significant effect on how much the height of the device changed after polishing.

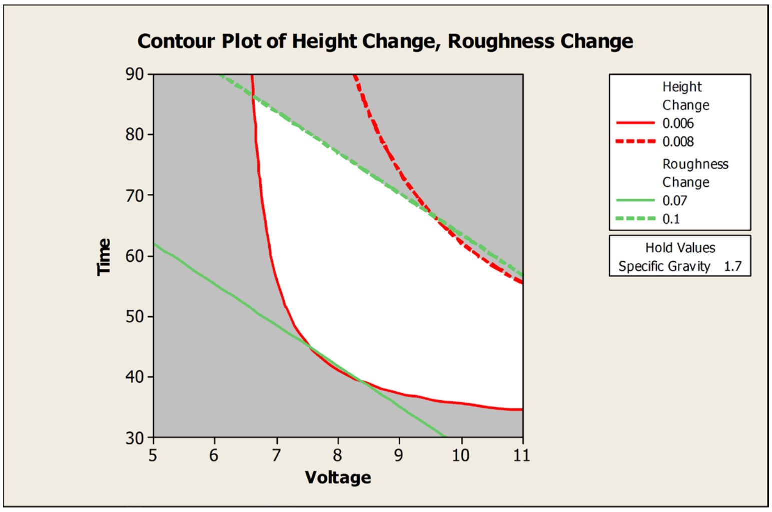
What's more, they found a statistically significant interaction between voltage (B) and cycle time (C). To explore the dynamics of this interaction and better understand how it related to changes in height, they used Minitab's interaction plot.



The interaction plot makes it easy to see and understand relationships between experimental factors.

The interaction plot made it easy to see and understand the relationship between these factors. When voltage was low (black line), the cycle time had little effect on the response. However, when voltage was high, a longer cycle time resulted in a much greater change in height. This interaction underscored the challenge of keeping height changes within an optimal range, while still ensuring that the device was adequately polished. To produce optimal results, the design settings would need to account for the push-pull relationship between removing enough material to smooth the surface, while not removing so much that the dimensions significantly changed.

To find those settings, the team used Minitab to create an overlaid contour plot from their experimental data. He specified lower and upper bounds for their two responses, height change and roughness change. Minitab then displayed contours for these bounds against voltage and cycle time on the plot's axes, highlighting the region where both responses were within bounds. This plot allowed the team to see the voltage and time settings that would produce optimal results.



The white space on the contour plot identifies the region of the design space that satisfies the criteria for all responses. Setting factors at any of the levels shown in the white area should yield responses that fall within the specified ranges.

Based on the results, Smith & Nephew determined that the electropolishing process produced results that were in specification when the voltage was between approximately 7 and 9 volts and the cycle time was between 50 and 70 seconds. Using these settings, they minimized defects, ensured that parts were all within specification limits, and successfully demonstrated a level of dependability that satisfied the regulatory guidelines for their product.

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