Ultrasonic Welding Process Improvement for the Scrap Reduction of a Medical Device

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Abstract *— A medical device company in Puerto Rico aims to improve an Ultrasonic Welding Process of a high-volume bone shredding medical device. The current process yield is 93% and must be at least 95% to meet the manufacturing site Key Performance Indicators. Six Sigma methodology was used as the improvement project framework. Tools such as Process Failure Mode and Effect Analysis, Cause and Effect Analysis and Tool Life Studies were used to evaluate the root cause of the underperforming yield. The root cause for the incomplete and over-welding defects was confirmed to be wear in the ultrasonic welding holding fixture which allowed parts to vibrate during welding. Improvements to reduce wear to the fixture were implemented. Process yield monitoring after the implementation of changes consistently show an increase in yield of over 95% and a cost avoidance of over $12,000 dollars a month.*

Key Terms *— Polymer Chemistry, Six Sigma Methodology, Tool Life, Ultrasonic welding*

INTRODUCTION

A company that manufactures medical devices in Puerto Rico is presenting high scrap rates in the Ultrasonic Welding Process of a high-volume bone shredding medical device. During the assembly of the medical device a shredding disk is assembled between two injection molded plastic parts that serve as a housing. These two molded plastic parts are joined together through an ultrasonic welding process.

During the ultrasonic welding process, defects such as incomplete weld and over-welding in some parts of the weld area are being detected by the in-process inspection. These defects do not allow the shredding disk to rotate inside the housing as is the intended function of the device. Therefore, these units are scrapped resulting in an average process yield of 93%. The minimum process yield to meet the manufacturing site Key Performance Indicator (KPI) for yield is 95%.

The objective of this project is to reduce the scrap rate in the ultrasonic welding process due to incomplete and over-welding defects and achieve a yield of at least 95% to meet the site KPI.

LITERATURE REVIEW

Polymers are widely used in the medical device industry due to their versatility to be shaped into different forms, their varying strengths, and their ability to be processes through different manufacturing methods to achieve a desired outcome or design. Polymers can be classified in two major categories according to their reaction when exposed to thermal conditions. Thermoplastics can be heated repeatedly and impermanently by softening through heat and hardening through cooling. Thermosets on the other hand are heated and cured irreversibly. Once cured, the polymer is cross-linked, and shaping cannot be redone. If reheated the material may decompose or break [1].

There are several methods employed to join plastic parts such as electromagnetic welding, thermal welding, friction welding, microwave welding, resistance welding, infrared welding, hot gas welding, laser welding, vibration welding, spin welding, etc. [2]. Each method has its advantages and disadvantages.

One of the most effective and widely used methods in high volume manufacturing is ultrasonic welding. Ultrasonic welding works through high-frequency vibrations applied to polymer pieces that are held together in a fixed shaped nest or fixture. A sonotrode or horn, which is connected to a transducer, produces low amplitude vibrations which creates friction and heat that melts and welds parts in seconds. This makes ultrasonic welding one of the fastest welding methods for thermoplastics [3]. The main components in an ultrasonic welding equipment are the power supply, transducer, booster, horn and a nest or fixture that ensures parts are held tightly and securely during welding [4]. Fixture design, part energy director design and process parameters such as weld time, hold time and static force are important to ensure adequate energy dissipation through parts and achieve a uniform strong weld in thermoplastics [5].

ANALYSIS PROJECT PHASE

Various tools were used to determine and confirm the root cause for the underperforming yield in the ultrasonic welding process. Based on the findings, solutions were proposed and implemented.

Cause and Effect Analysis

A Cause-and-Effect Analysis was used as one of the tools to identify all the potential causes of the problem. Different elements such as the equipment, ultrasonic welding process, procedures, components and operators, as shown in Figure 1, were evaluated. The ultrasonic welding process is automated and only requires the operators to load parts into the fixture. The fixture is designed to be Poke-Yoke, which means that parts can only fit in one direction. Due to the nature of this process, most contributing factors were narrowed down to equipment, process and materials (components and equipment component materials).

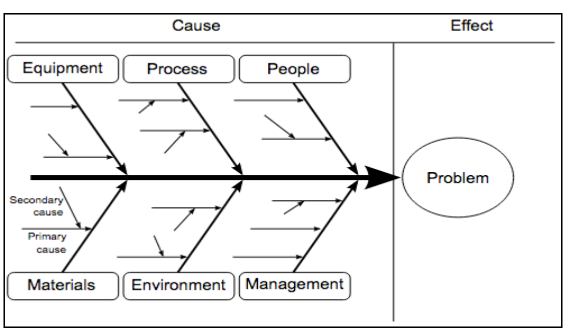

Figure 1
Cause and Effect Diagram

Process Failure Mode and Effect Analysis

The Process Failure Mode and Effect for the process was also evaluated to identify potential causes for the defect of incomplete welding and over-welding. The main failure modes for these defects pointed to any cause that would promote undesired or uneven vibration of parts beyond the vibration applied by the pressure and frequency of the ultrasonic welding equipment. Some of the listed causes were: misalignment of the equipment stack (transducer, horn, fixtures), wear and tear of part holding components and uneven components. Alignment verification of the welder stack was performed and found to be within parameters.

The main pin centering fixture was assessed and found to be made of Delrin. Although Delrin is a tough thermoplastic (acetal homopolymer - engineering resin) with strong mechanical properties and high temperature resistance [6] it is being used in a high-volume process against stainless steel parts. The fixture was inspected as per print and found to be out of specification. Wear on the main pin centering fixture was identified as one of the potential and main contributing factors for the underperforming yield.

Additionally, top and bottom housing components were inspected for dimensions beyond the Critical to Quality (critical to performance) that are routinely inspected as part of incoming inspection. During inspection it was observed that some parts presented a slight warpage condition that could be contributing to the observed defects as per the PFMEA. Warpage condition on parts was identified as an additional potential and main contributing factor for the underperforming yield.

PROPOSED AND IMPLEMENTED SOLUTIONS

Based on the investigation and findings obtained during the Analysis Phase, two solutions were proposed. Solution #1 consisted of re-designing the pin centering fixture which holds the parts together during the welding operation. Re-design was proposed to change the material from the acetal homopolymer Delrin to a high wear resistant metal like tungsten carbide to withstand the metal-to-metal friction of the stainless-steel disk. Since the fixture was already designed and only consisted of a material change, the engineering hours invested into fixture design were negligible. An external machine shop quoted $1,000 to manufacture the fixture with a lead time of two weeks. Implementation of the new fixture can be performed in one day through an unscheduled preventive maintenance event if necessary.

Solution #2 consisted of addressing the warpage on parts through and optimized injection molding process. For this, Scientific Injection Molding and Process Characterization had to be performed to determine preliminary process parameters. The time investment of having to generate a change control, document protocols for Operational Qualification and Process Qualification, schedule machine time to perform multiple runs and close reports for these runs made Solution #2 more burdensome to implement than Solution #1. However, preliminary process parameters were determined as a risk mitigation plan in case implementation of Solution #1 did not yield the desired results.

Therefore, Solution #1 was pursued and implemented. Fixture design as shown in Figure 2, Figure 3 and Figure 4 was sent to a machine shop approved supplier for machining.

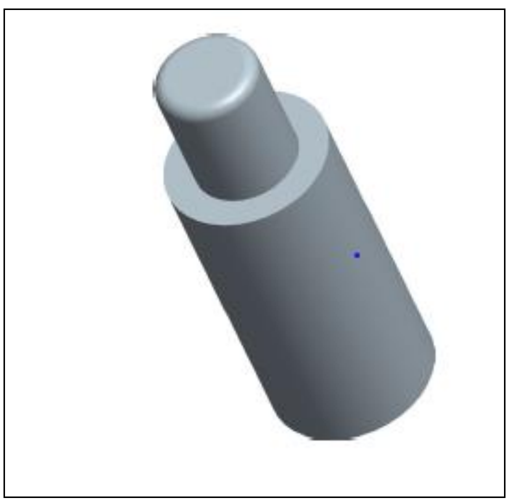

Figure 2
Centering Fixture Support Pin

Figure 3
Centering Fixture Support Base

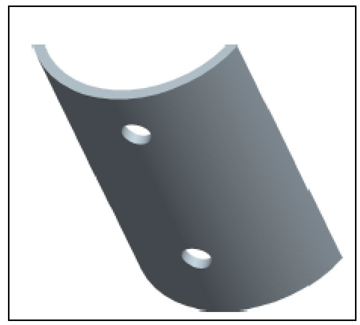

Figure 4
Centering Fixture Front Plate

RESULTS AND CONCLUSION

The new centering fixture, as shown in Figure 5, was received and implemented in the ultrasonic welding process as a preventive maintenance event during a planned plant shut down in December 2020. After the change implementation the monitoring phase began. The ultrasonic process yield is being monitored for a period of three (3) months on a weekly basis.

Figure 5
Tungsten-Carbide Centering Fixture

As can it be observed in Figure 6, yield has been consistently reported to be higher than 95% since the change was implemented. If this trend continues it can be concluded that the wear on the centering fixture was the main contributing factor and root cause of the underperforming yield. Moreover, the improvement project can be considered successful and effective at meeting the objectives to reach the KPI goal of at least 95% and providing a cost avoidance of over $12,000 monthly.

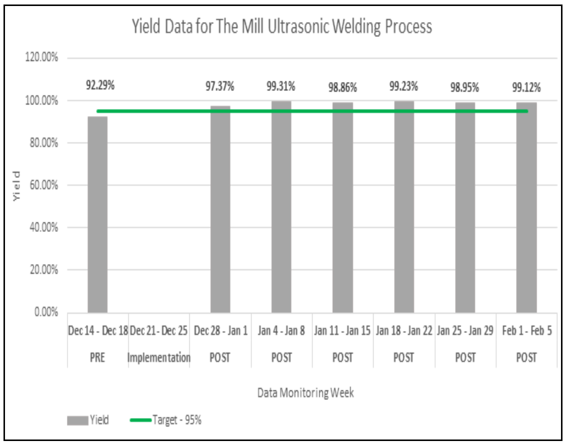

Figure 6
Yield Data Pre and Post Change Implementation

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