Six Sigma Methodology & Mechanical Design for Atrial Fibrillation Ablation Component Inspection

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Kellogg Honors College Capstone Project

Abstract

Heart disease is the leading cause of death in the United States and worldwide, even in the midst of the COVID-19 pandemic; a large subset of that includes atrial fibrillation ("afib"), i.e., cardiac arrythmia or irregular beating of the heart. Biosense Webster, Inc. is the industry leader in producing catheters to diagnose and treat afib. A currently-unreleased product utilizes electrode rings on the catheter tip to perform such mapping. Due to the critical function performed by these rings, each must be inspected individually. This a time-consuming, tedious, and expensive process. The goal of this project is to 1) analyze the time and costs of the current process; 2) design an inspection fixture to significantly improve and cost-reduce the process; and 3) measure, analyze, and demonstrate the overall process improvement. Such measurement and analysis will implement the Six Sigma methodology, a process improvement strategy common throughout quality control engineering in industry. The fixture 3D design process will consider the constraints of the required accuracy and precision of the part specifications, the manufacturability of the fixture, and the inspection equipment and processes.

1) Define Phase

The unreleased catheter is used to map and diagnose the interior of the heart. It does so by using small cylindrical electrode rings on the tip of the catheter, which are nearly the size of a grain of rice. A not-to-scale representation of these rings is depicted below (Figure 1).

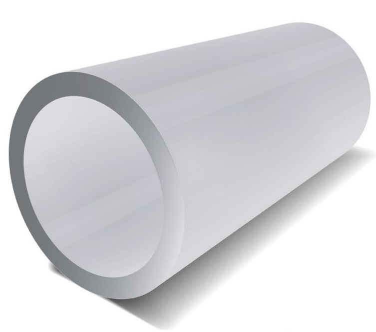

Figure 1: Representation of catheter rings

The criticality of this component necessitates 100% inspection of each individual ring. The length, outer diameter, and thickness dimensions must be inspected. This is a significant use of time and resources when done in-house, and a significant cost when outsourced. A process improvement will potentially result in major cost reductions and efficiency gains. This situation is laid out in the SIPOC (Supplier, Inputs, Process, Outputs, Customers) chart below.

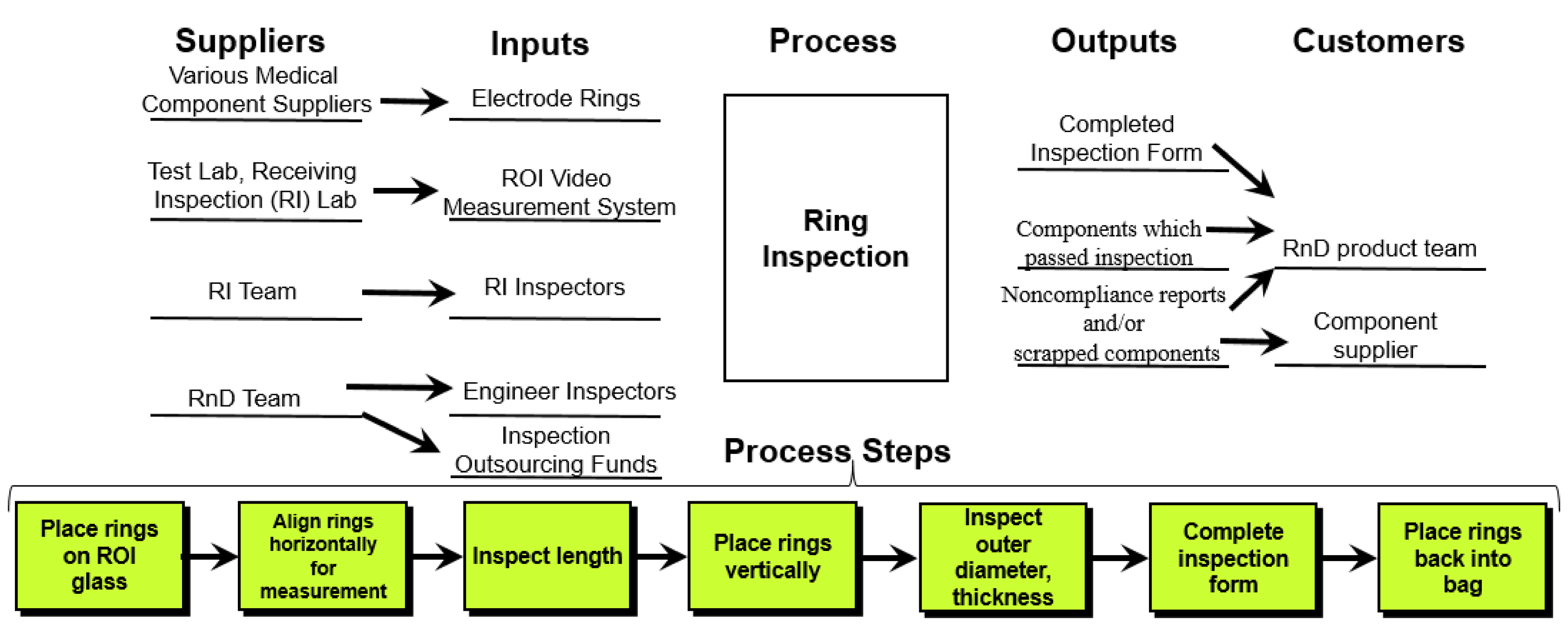

Figure 2: Ring Inspection SIPOC

The left side of the SIPOC makes clear that various teams are contributing limited resources to conduct inspection of the rings. The ROI Video Measurement System must be used for extended lengths of time, preventing use of this resource by other teams. Additionally, during these times, the members of both the product's Research and Development team and the Receiving Inspection (RI) team which are performing the inspections are occupied and thus cannot perform other critical functions of their roles. For example, the entire company depends upon the RI team to inspect components before they can be used; any time and equipment freed as a result of improving this process will result in process improvements company-wide. Outsourced inspections also require a monetary cost from the R&D team.

The SIPOC also delineates the current inspection process. Each step represents a time cost, and potentially a material cost as well: given the tiny dimensions of these components, they are easily lost – a possibility which increases with each step in the process.

Time costs are the most prevalent cost for all parties and steps represented in this inspection process. Therefore the objective of this project will be to implement a time improvement. From the outset, it was the recommendation of the product's lead engineer that the focus of the project be the design of an inspection fixture to make the inspection simpler and faster.

2, 3) Measure & Analyze Phases

Having defined the issue, the next step was to analyze the current process. This was done using a time study of current inspections. In order to achieve the necessary precision in the time study data and thus have a clear picture of the current process, a sufficient sample size needed to be used. This size was determined using the formula n=(2s/d)^2, where n is number of samples, s is the standard deviation, and d is the precision (+/- __ minutes). After collecting a few sample data points the standard deviation was determined to be about 2.5 minutes. These sample data points also showed an inspection time ranging between 14 and 20 minutes. Initially a precision of +/- 1 minute was desired, however due to time constraints it was determined that a precision of +/-1.5 minutes would be acceptable. Thus, the required sample size was n = (2*2.4/1.5)^2 = 11.11 samples.

An engineer from the product's R&D team who regularly performed the inspections volunteered to conduct the time study inspections using her regular set of tools. This was done to closely represent the actual current inspection process. Each sample of the study consisted of over 100 parts, which is a common inspection lot size for these components. Measuring the entire inspection process even 11 times would require quite an extensive amount of time, which due to the engineer's other duties was determined to be impossible. Therefore only the component setup time was to be measured, as this would be the area of time improvement if an inspection fixture was used. In all transparency, the engineer had already designed a very simple fixture for performing the length inspections. The engineer's design avoided steps in earlier iterations that required manually grasping of the part. The main feature of this fixture was the series of long grooves which were similar in width and depth to the diameter of the rings; not so close that the rings bottomed out in them, but rather settled to rest somewhat atop them when the fixture was agitated, allowing for the length inspection.

Minitab Statistical Software version 17 was used to analyze the data and generate results. Those results are displayed below in Table 1. The mean duration for inspection of about 100 rings was found to be 14.818 minutes with the current process. The duration of the length inspection was drastically shorter than that of the OD, t inspection: 0.909 minutes versus 0.636 (seven times greater). This was due to the use of the pre-existing inspection fixture designed by the inspecting engineer. Due to the advantages of this design proven from the time study, the designs used for the length inspection fixture for this project drew significant inspiration for this pre-existing fixture and the design focus was narrowed even further to the outer diameter and thickness measurements.

Also of note is that the desired sample size precision was exceeded.

Variable	Total Count	Mean	SE Mean	St. Dev.	Minimum	Median
OD, t Duration	11	13.636	0.636	2.111	12.0000	13.0000
L Duration	11	1.0909	0.0909	0.3015	1.0000	1.0000
Total Duration	11	14.818	0.658	2.183	13.0000	14.0000

Table 1: Time Study Statistical Analysis

These results bolstered the suggestion of the lead engineer that the inspection process step with the most potential for improvement was the Outer Diameter dimension inspection.

4) Improve Phase & Mechanical Design

The inspection fixture would need to function for both the length inspection as well as the outer diameter and thickness inspection. For the length inspection, it would need to quickly stabilize all the rings and align them horizontally. The next design requirement was a quick and simple transition from this mode of inspection to the outer diameter and thickness inspection. This inspection requires the rings to stand up exactly vertically. Finally, the fixture would need to accommodate the fact that the light source on the ROI video measurement system is supplied from beneath the inspection stage.

An iterative design process was used, in which design improvements were made, a new 3D model was printed and assessed, and the cycle repeated. The most current iteration is presented below in Figures 4-6.

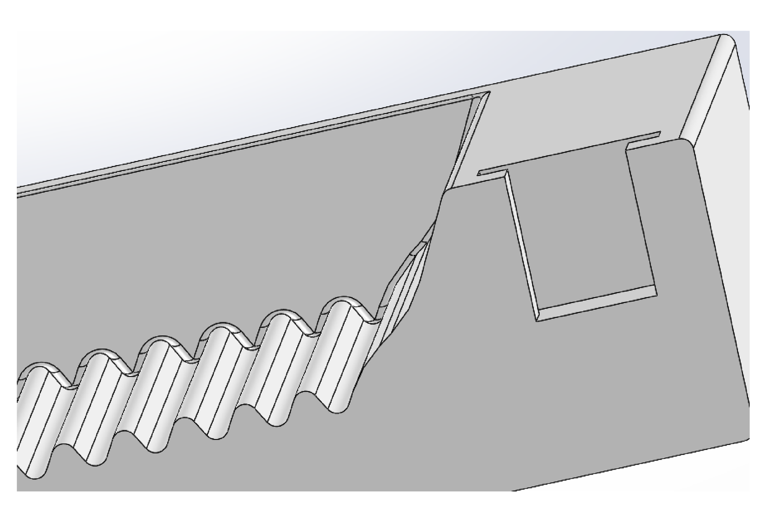

Figure 3: Fixture, Length Component

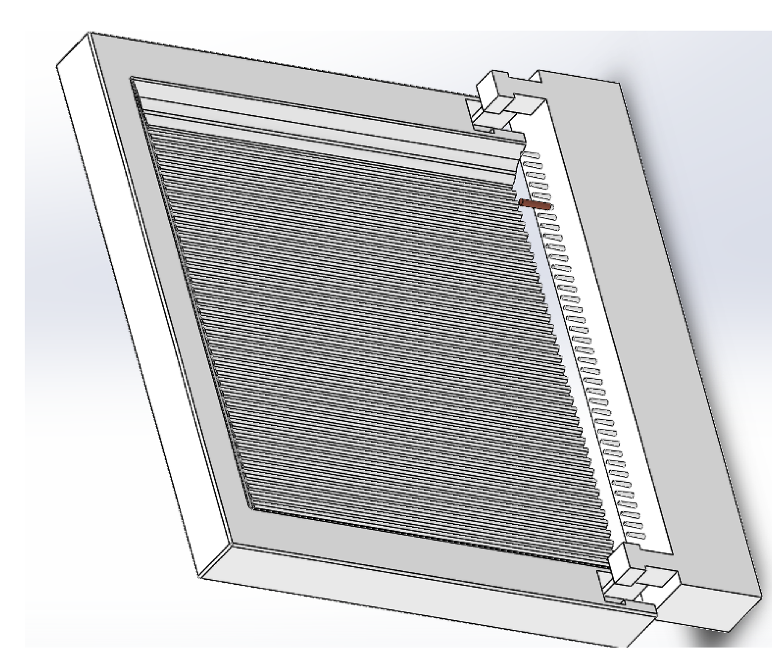

Figure 4: Nearly-Assembled Fixture

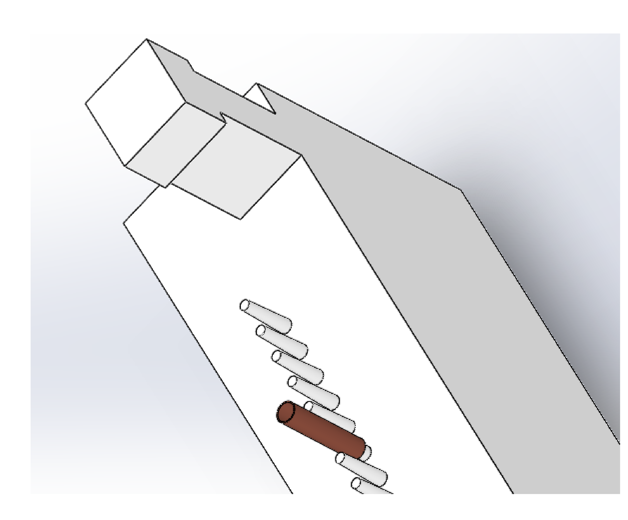

Figure 5: Fixture, OD+t Component

Figure 5 depicts the assembled inspection fixture, which consists of two components: the length inspection component and the outer diameter and thickness inspection component. Both pieces are currently being printed with translucent resin in order to allow light from the ROI system to pass through for component inspection. This requirement may soon become obsolete, or at least less critical, if other vision systems currently undergoing validation are validated for inspection of this component.

The length inspection component (Figure 4), which as mentioned previously drew on the pre-existing design of the inspecting engineer, is essentially a bed of grooves surrounded on three sides by walls. The rings are dumped into the bed, and with gentle shaking are deposited into the grooves. Given the size of the rings, many rings can be deposited and quickly sorted; most recently 100 rings have been sorted in a matter of seconds. By aligning all the rings in the same horizontal direction and stabilizing them in the grooves, the fixture allows for quick measurement of the lengths of the rings. This became the preferred design when this project's initial design failed after several modifications.

The trickier component to design, and which required several more iterations, was the outer diameter and thickness inspection component (Figure 6). This component slides into the length components slots once the length dimension has been inspected, aligning the spikes with the ridges and concentrically with the rings. With a gentle tapping of the length fixture and possibly a tool such as tweezers moving the rings, the rings are moved onto the spikes. If the material is changed to a metal, hypothetically the rings will slide onto the spikes much more smoothly. The OD+t component is then raised vertically and rotated ninety degrees to allow the rings to stand vertically, allowing the outer diameter and thickness to be measured with the ROI system. With the current number of spikes, thirty-seven rings can be inspected at a time. The rings can then be removed into their container.

5) Next Steps & Control Phase

Due to the coronavirus pandemic, access to the worksite was very limited, including long periods of time when any on-site work was prohibited. Further, once regular activities did begin to resume, the need to make up for lost time resulted in stricter allocation of resources (time, equipment, etc.) For this reason, the intent of the project has not yet been fully realized and more work needs to be done. This work will continue through the end of the academic year and potentially beyond that.

The current fixture design has not yet been printed or tested, and will likely require improvement in several areas. It will ultimately need to be tested using the ROI video measurement system to ensure sufficient light can pass through the material to inspect the components. It may also be tested with newer vision systems which are not yet validated, which may prove to be more compatible with this fixture. Other improvements to the design are being considered, including adding a magnetic locking feature to keep the components securely mated.

Once a working fixture has been finalized, the process must be re-measured using the new fixture and any other process improvements to demonstrate benefit. This will take the form of more time studies of an equal or greater sample size. The time savings will be translated into dollar saving. When considering employee pay rates, freeing up of the measurement system for other projects, and reduction in lost components among other factors, an optimistic projection puts these dollar savings at a minimum in the tens of thousands, and potentially into the hundreds of thousands.

Finally, to complete the Six Sigma process, the Control phase must be addressed. Tools being considered for this phase are Documentation/Operational Instructions as well as training on these documents.

Special Thanks

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