Spinal Cord Stimulator Glassed Feedthrough Improvement Using DMADV Methodology

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Abstract *– Chronic pain is an illness that affects more than 1.5 billion humans worldwide and can affect daily activities leading up to disability and despair. The goal of treating chronic pain is to reduce pain and improve function so that a person can resume day-to-day activities. The neurological device supplied by a private medical device company is a spinal cord stimulator therapy which masks pain signals before they reach the brain and produces relief to the patient. This investigation will analyze the manufacturing operation optimization using a Six Sigma framework to investigate ways to generate more revenue from a commercially released medical device.*

Key Terms *— Chronic Pain, DMADV, Food and Drug Administration, Neurological, Spinal Cord Stimulator.*

PROJECT STATEMENT

Medical device companies worldwide work effortlessly every day to provide patients the best available technologies to treat thousands of conditions. In order for these companies to continue to invest in innovations and ways to improve their product, revenue from their market products needs to be obtained. A top ranked medical device company is currently focused on providing customers with the best quality products and continuing their research to promote reliability and consumer trust in their products. One of these products is spinal cord stimulator product. This device is currently one of the best-selling devices for chronic pain relief marketed worldwide. Recently, this private medical device company as any other company feels the need to make a fair profit on current operations to meet obligations, sustain growth, and reach goals. Through this research and with the use of known manufacturing methodologies, an improvement in the neurological device will provide a substantial financial saving in raw material as well as manufacturing labor for increased revenue of the company.

Research Description

The primary focus of this investigation is to improve a currently marketed medical device from the spinal cord stimulation category supplied by a private company. This improvement consists of substitution of titanium raw material to glass in the feedthrough assembly used to manufacture the neurological device. The DMADV methodology will be used through this investigation to identify processes that are impacted by this change, determine design improvements, and mitigate any risks associated.

Research Objectives

The main objective will allow a pathway for the higher profits from the neurological device as well as a higher efficiency during the manufacturing operation in the private medical device facility. A general improvement in the product's performance, reliability and quality will achieving company interests and allowing sustainability and growth for the company.

Research Contributions

This study will address ways to create a higher revenue from a released medical device. This product improvement will not only allow the company to increase profits but will also allow the private medical device company to reconsider the device's cost making it more affordable to the 1.5 billion consumers who suffer from chronic pain. Equally, this investigation allows the company more capital to continue investing ways to improve

released products as well as invest in new technologies for future products.

LITERATURE REVIEW

Chronic pain is often defined as any pain lasting more than 12 weeks. Whereas acute pain is a normal sensation that alerts us to possible injury, chronic pain is very different. Chronic pain persists, often for months or even longer.

Chronic pain may arise from an initial injury, such as a back sprain, or there may be an ongoing cause, such as illness. However, there may also be no clear cause. Other health problems, such as fatigue, sleep disturbance, decreased appetite, and mood changes, often accompany chronic pain. Chronic pain may limit a person's movements, which can reduce flexibility, strength, and stamina. This difficulty in carrying out important and enjoyable activities can lead to disability and despair.[1]

Figure 1
Chronic Pain by the Numbers

Pain is a very personal and subjective experience. There is no test that can measure and locate pain with precision. So, health professionals rely on the patient's own description of the type, timing, and location of pain. Since chronic pain may occur in a variety of locations in the body and for many different reasons, patients and their health professionals need to work together to identify the causes and symptoms of that pain and how it can be relieved.

The goal of treatment with chronic pain is to reduce pain and improve function, so the person can resume day-to-day activities. Patients and their healthcare providers have several options for the treatment of pain. Some are more effective than others. Whatever the treatment plan, it is important to remember that chronic pain usually cannot be cured, but it can be managed.

One of the most innovative technologies used to treat chronic pain is spinal cord stimulation therapy. This therapy masks pain signals before they reach the brain. A small device, similar to a pacemaker, delivers electrical pulses to the spinal cord. It helps people better manage their chronic pain and reduce their use of opioid medications. It may be an option if you suffer chronic back, leg or arm pain and have not found relief with other therapies.

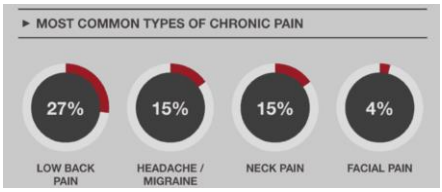

Figure 2
Most Common Types of Chronic Pain

A spinal cord stimulator (SCS) device is surgically placed under your skin and sends a mild electric current to your spinal cord. Thin wires carry current from a pulse generator to the nerve fibers of the spinal cord. When turned on, the SCS stimulates the nerves in the area where your pain is felt. Pain is reduced because the electrical pulses modify and mask the pain signal from reaching your brain. [2]

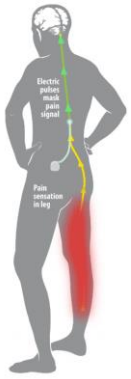

Figure 3
Stimulation Diagram (Illustrative purposes only)

Stimulation does not eliminate the source of pain. It simply changes the way the brain perceives it. As a result, the amount of pain relief varies for each person. The goal for SCS is a 50 to 70%

reduction in pain. However, even a small amount of pain reduction can be significant if it helps you perform daily activities and reduces the amount of pain medication you take. Stimulation does not work for everyone. If unsuccessful, the implant can be removed and does not damage the spinal cord or nerves.

The device to be assessed during this investigation is one of the leading SPC products in the market and produced by a private medical device company. This implantable neurostimulator is powered by proprietary Overdrive™ battery technology. It is designed to overcome limitations with current SCS systems and is optimized for the increased energy demands of High Dose (HD) therapy. The platform uses a tablet with wireless programming and a neurostimulator that can record patient activity around the clock. Snapshot™ reporting allows physicians to objectively monitor a patient's progress. Additional full-body MRI technologies are also part of the platform.

The implantable neurostimulation system is indicated for spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs – including unilateral or bilateral pain associated with the following conditions:

- Failed Back Syndrome (FBS)
- Radicular pain syndrome or herniated disk
- Post laminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Peripheral causalgia
- Epidural fibrosis

Some of the key features and characteristics of the spinal cord stimulation device include:

- Smallest fully implantable spinal cord neurostimulator.
- Improved battery performance with minimal capacity fade (<5%).
- Designed for patient comfort and more flexible placement during the implant.
- Unrivaled battery chemistry performance.
- >95% battery capacity retained at 9 years, independent of therapy parameters or recharge preferences.

These improvements within this investigation will account for a substantial financial saving in raw material as well as manufacturing labor. Through this investigation and following the methodology established in the next section, the feasibility for this project will be determined. Based on the findings and analysis performed, the project will be carried out and findings will be presented.

METHODOLOGY

This project will apply the DMADV methodology which is a Six Sigma framework for implementing new strategies in a current process. The DMADV approach also known as DFSS varies, of course, according to whether the design is of a product or of a process. This approach is especially useful when implementing new strategies and initiatives because of its basis in data, early identification of success and thorough analysis. It might also vary according to the type of product. [3] The DMADV model is usually a five-step process:

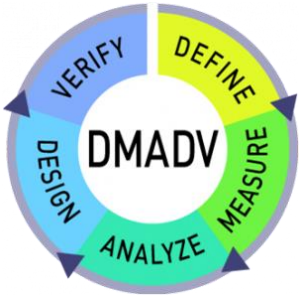

Figure 4
DMADV 5 Step Process

- *Define.* A clear definition of the project is established during this step, and every strategy and goal must be aligned with the expectations of the company and the customers.
- *Measure.* Next comes measuring the factors that are critical to quality, or CTQs. Steps taken should include: defining requirements and market segments, identifying the critical

design parameters, reassessing risk and assessing the production process capability and product capability. Once the values for these factors are known, then an effective approach can be taken to start the production process. It is important here to determine which metrics are critical to the stakeholder and to translate the customer requirements into clear project goals.

- *Analyze.* Actions taken during this phase will include: developing design alternatives, identifying the optimal combination of requirements to achieve value within constraints, developing conceptual designs, evaluating then selecting the best components, then developing the best possible design. It is during this stage that an estimate of the total life cycle cost of the design is determined.
- *Design.* Develop the process to meet the customer requirements. This stage includes both a detailed and high-level design for the selected alternative. The elements of the design are prioritized and from there a high-level design is developed. Once this step is complete, a more detailed model will be prototyped to identify where errors may occur and to make necessary modifications.
- *Verify*. In the final phase, the team validates that the design is acceptable to all stakeholders. Several pilot and production runs will be necessary to ensure that the quality is the highest possible. Here, expectations will be confirmed, deployment will be expanded, and all lessons learned will be documented. The Verify step also includes a plan to transition the product or service to a routine operation and to ensure that this change is sustainable.

For any DMADV project, there may be more emphasis on certain components of the approach over others, though the goal remains the same: to address an identified issue and produce desired results in a way that can be maintained through normal operations.

Our investigation will propose a new technology in the existing market of the spinal cord stimulation device. This improvement will be implemented following the DMADV methodology. The DMADV will help understand the critical factors that need to be assessed in order for the improvement to be successful.

RESULTS AND DISCUSSION

As an initiative to reduce the manufacturing cost and increase revenue of this spinal cord stimulation device, a plan to analyze achievable improvements within the device was developed. After identification of a possible improvement area within the device, this investigation applies the DMADV Six Sigma Methodology to determine feasibility of the project. Based on the findings and analysis performed, the project will be carried out and findings will be presented.

Define Phase

Reducing the cost of manufacturing the spinal cord stimulator for the private medical device company is defined as the main focus of this project. After analyzing the current manufacturing process, the device's Connector Module Assembly was identified as the target for innovation and improvement. The proposed improvement consists of eliminating components from the existing Connector Module Assembly while also exchanging an existing material.

The goal of this re-design is to decrease costs of raw material and remove components considered waste that add burden to the cost of production of this device. Keeping this in mind and top priority, a target of a two (2) million increase in revenue was established for the project to be successful.

Measure Phase

The manufacturing process for the spinal cord stimulation device is divided into two main processes. The first is known as the Connector Assembly Module and the second is the Complete Device Assembly (CDA). Based on analysis of

both processes, the project focused on the Connector Module Assembly portion of the device. The following diagram will illustrate the Process Flow Chart for the Connector Module Assembly portion being assessed:

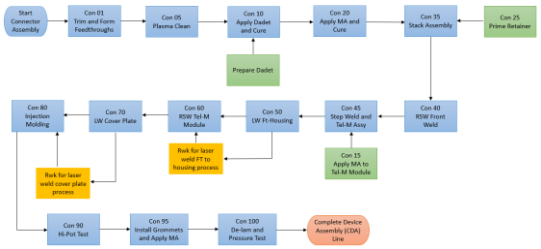

Figure 5
Connector Module Assembly Process Flow Diagram [4]

A cost evaluation was performed on the aforementioned manufacturing processes to document and understand expenses related to these processes. Evaluation determined a total of $261.96 was the cost to build each Connector Module Assembly. This cost includes the Labor, Burden, and Material (LBM) costs within each manufactured device. For the intend of this evaluation, the project will be based on the assumption of selling 40,000 neurological devices. This meaning that current manufacturing process costs a total of approximately $11,678,000 to produce the desired number of devices. This amount is baseline to achieve established $2M improvement on product revenue.

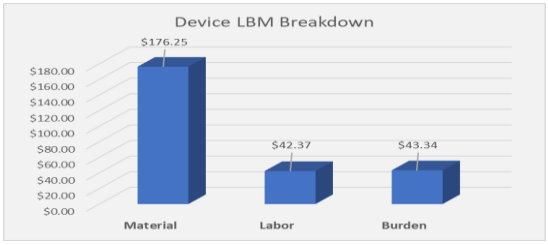

Figure 6
Device LBM Breakdown

Analyze Phase

A modification to the manufacturing process for the production of the neurological device is difficult to achieve since any minor change could impact the quality of the finished product. This change needs to be presented to the Food and Drug Administration Agency (FDA) for approval prior to implementing in the facility. The modification also needs to have an impact on the cost of the device for it to be considered successful.

After carefully evaluating each process of the Connector Module Assembly individually and collectively, it was found that the mayor source of increasing the cost of the device was the materials needed for manufacturing. Applying the 80/20 Six Sigma Pareto Principle [5] it was noted that 20% of the contributing factors, in this case raw materials, were accounting for nearly 80% of the device's manufacturing costs. Therefore, team members should seek to address the problem with the greatest impact on profitability or ability to achieve the project's objective. It was decided that their effort will be focused in ways of reducing unnecessary materials or lowering cost with one equally effective.

Figure 7
Pareto Chart for Costs

The team identified the feedthrough portion of the device as the one adding the most waste and burden to the device. Parts within the feedthrough were adding no value to the effectiveness of the therapy and a re-design of this Connector Module Assembly component was begun to eliminate waste and replace materials while reducing costs.

Design Phase

The proposed improvement on the Connector Module Assembly consists of eliminating components while also exchanging an existing material. One of the main components in the Connector Module Assembly is the feedthrough

assembly. This feedthrough assembly is currently composed of the Electronic Module Assembly (EMA), Solder Wire, Solder Preform, Capacitor, Array Plate, Ground Pin, and Feedthrough.

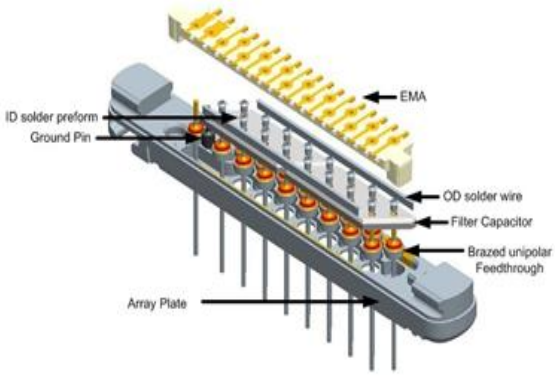

Figure 8
Existing Feedthrough Assembly

A re-designed model is presented where Capacitor, Preforms, and Solder Wires are removed from the design. Also, there is a major change in the feedthrough ferrule to be used in the devices since the new ferrule will be made out of glass as opposed to existing one made out of titanium.

Verify Phase

The proposed design from the previous phase cannot be implemented until validation that the design is appropriate and fully functional. One of the mayor verifications that needs to be completed is that the current manufacturing process flow is not impacted by any modifications done on the device. All of these processes have undergone rigorous validation cycles to confirm efficient and functional processes for the manufacturing of the spinal cord stimulation device. Also, there is the fact that this device is already in the market and any change needs to be presented to the FDA for approval prior to being marketed.

A full process assessment was performed to identify Connector Module Assembly processes impacted by this re-design and what type of validation requirements need to be completed for the it to be approved. Refer to the following table for processes requiring additional validation activities after assessment:

Table 1
Process Assessment Results

Process	Impact Description	Validation Activity
Trim and Form Feedthroughs	Evaluation of damage on new glass material	•Process Characterization
Apply Dadet and Cure	Inpsection on feedthroughs	•Test Method Validation
Stack Assembly	Internal Component Volume	•Process Characterization
RSW Front Weld	Evaluation of damage on new glass material	•Process Characterization
LW Cover Plate	Evaluation of damage on new glass material	•Process Characterization
Rework for Laser Weld Cover Plate	Evaluation of damage on new glass material	•Process Characterization
Injection Molding	Completely filled with LSR	•Process Characterization

Following the completion of required validation activities, a confirmation run was performed to verify that during a normal manufacturing cycle no problems are encountered, and desired product is achieved. All documentation is delivered to the FDA for the re-design approval and clearance to commercially market the device.

The re-design of the feedthrough assembly in the Connector Module allowed the company to reduce LBM costs from $261.96 per connector to $190.00. This lowers the manufacturing cost, taking into consideration the established 40,000 units to be produced, to a total of $7.6M.

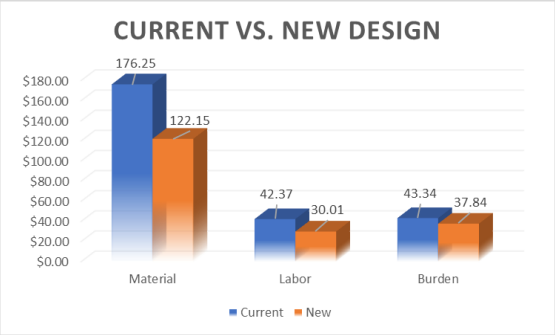

Figure 9
Device LBM Breakdown Comparison

CONCLUSION

After completing the improvement of the Connector Module Assembly for the spinal cord stimulator while applying the DMADV Six Sigma Methodology, it was determined that an improvement was feasible for the existing device where revenue could be gained. With the help of the engineering and design team, the implementation of this project will be completed once receiving confirmation from the FDA to commercially produce the device. The objective of this investigation was achieved by reaching and exceeding the target goal of a $2M revenue increase.

Figure 10
Summarized Project Benefits

This approach will also serve as guideline for future projects from the same product family within the medical device manufacturing facility. This project is another demonstration of how Lean Six Sigma methodologies can be applied for existing products in the manufacturing industry.

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