Research of Anterior Cervical System using different materials

Isabel Lugo Vélez
Dr. Héctor J. Cruzado
Master of Engineering Management
Polytechnic University of Puerto Rico

Abstract *- With the continuous worldwide demand for anterior cervical systems, Medtronic Spinal Division decided to makes changes in the manufacturing process in order to meet this demand. The company decided to introduce some new products. Therefore, various prototypes were developed to accomplish the US Food and Drug Administration (FDA) requirements and the market. All the prototypes were evaluated in order to give the company more alternatives to match the specific customer needs with the best technology and engineering management techniques in the industry. In this paper, the PEEK and TTN implants were compared. PEEK resulted to be the best choice.*

Key words*: anterior cervical system, engineering management, DMAIC, PEEK, Titanium*

Introduction

Medtronic Spinal, located in Humacao, Puerto Rico, is a medical device company dedicated to the manufacturing of screws, mini-plates, and other no-performance medical devices. The purpose of this paper is to understand the process of manufacturing a new product using poly-ether-ether-ketone (PEEK) material versus Titanium (TTN), the requirements needed for the manufacturing a new product, and management techniques used in one Medtronic Company Plant.

The objectives are to evaluate the engineering management tools implemented, analyze the project cost, determine the risk during the development and the manufacturing process, identify opportunities for improvement, and analyze the Timeline.

In this paper, the DMAIC method (Define, Measure, Analyze, Improve, and Control) is applied to evaluate the complete project. DMAIC method is used for the evaluation of actual and planned manufacturing process, risk assessment, project cost, and Timeline [1]. This document is intended to investigate the implemented procedures, analyze the findings or results, and propose recommendations to improve the new product manufacturing process.

Literature Review of Anterior Cervical Discectomy and Fusion: Comparison of Titanium and PEEK Cages

Cabraja et al [2] mentioned that design, shape, size, surface architecture of cage as well as bone density, endplate preparation and applied distraction during surgery need to be considered. Also, the authors included a sample taken during 2002 to 2007 of 154 patients that underwent single-level ACDF, and 44 patients that received a TTN and 42 patients a PEEK cage

The results during the authors study was 93.2% TTN and 88.1% PEEK arthrodesis were found. The cage subsidence was identified in 20.5% TTN and 14.3% of the PEEK group. A significant segmental lordotic correction was achieved by both cage-types.

The authors concluded that TTN and poly-PEEK are the most common materials used in the manufacturing implants market. Nonetheless, comparing the two materials they found that PEEK is a better material than TNN. The latter studies showed the PEEK-implants being superior in maintaining cervical interspace height and achieving radiographic fusion. Also, PEEK cage is cheaper than TTN. Therefore, after surgery, TTN and PEEK devices include a protocol for physical rest for six weeks and then physical therapy.

Define

Anterior Cervical System can be manufactured using two (2) different materials. Both materials have different physical and chemical properties. Based on that, in this paper the properties and processes to manufacturing both materials are analyzed to identify the best choice.

Measure

Some tools used to measure the properties and the manufacturing process were the flowchart, baseline, project cost, and risks for both materials. During the project, data was collected, some field visits was performed, and other essential information were collected to proceed with the analysis of the data.

Analyze

Two medical techniques for Anterior Cervical System are known in medical surgery procedures. These are discectomy and spinal fusion. Discectomy is the surgical removal of herniated disc material that presses on a nerve root or the spinal cord. Spinal fusion, also known as spondylodesis or spondylosyndesis, is a surgical technique used to join two or more vertebrae.

The common raw materials used are titanium, cobalt chrome, and poly-ether-ether-ketone (PEEK). All the raw materials are approved by US Food and Drug Administration (FDA). The federal codes that applied to medical devices are 21 CFR Part 11 Electronic Records; Electronic Signatures, Parts 210 & 211 cGMP in Manufacturing, Processing, Packing, or Holding of Drug and Finished Pharmaceuticals, and Part 820 Quality System Regulation.

In the following paragraphs, the metal and PEEK processes, and the timeline are described to understand the properties and requirements of the actual manufacturing process.

Metal Process Flowchart

The process to manufacture the metals includes but is not limited to machine completion, product verification, cleaning, deburring, and anodizing (Figure 1). Deburring is the process of removing any particles or residual material after machine complete and first cleaning process. Anodizyng is an electrochemical process that converts the metal surface into a decorative, corrosion resistant, anodic oxide finish. Moreover, anodyzing color coding of components and devices greatly reduces errors in assembly (Figure 2). In medical applications, color coding for size allows instant recognition of needed parts when time and accuracy are critical. Orthopedic implants, medical instruments and device components can be coded with standardized or specialty colors to increase efficiency during anterior cervical surgery.

Finally, the product passes to kit preparation, assembly, sterile package, labeling, final inspection and boxing, shipping and receiving, and then is transferred to finish goods. Commonly, the manufacturing process for metals and plastics has different requirements, validation process and equipment and tools. The company typically uses Tornos, Ultrasonic Cleaners and Atlas Vac Heat Sealer (Table 1). All the employees receive training before using the machine, when exists a new manufacturing deviation or new approved modification.

PEEK Process Flowchart

The process which is considered the more adequate in Anterior Cervical System surgeries is PEEK implants. Therefore, the PEEK process is describe to understand the implications and why is considered more adequate. PEEK process involves in the process flow the machine completion, first cleaning, deburring, and second cleaning. Then, the product passes to the kit preparation, assembly, sterile packaging, and labeling, final inspection, receiving and shipping.

In the industry, the medical apparatus is classified under Anterior Cervical Discectomy and Fusion (ACDF). There are many types of medical devices in the industry but all-in-one use is the most used. Therefore, Anterior Cervical Discectomy and Fusion (ACDF) used an all-in-one, stand-alone system for one level ACDF procedures. All-in-one refers to the fact that this system contains everything needed to perform an ACDF. Moreover, cervical stand-alone implants are interbody devices with integrated screws fixation (Figure 3). The devices are indicated for ACDF procedures from the C2-C3 to the C7-T1 disc.

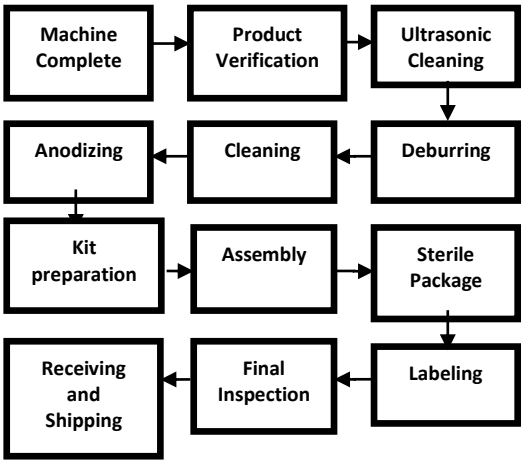

Figure 1

Manufacturing screw process

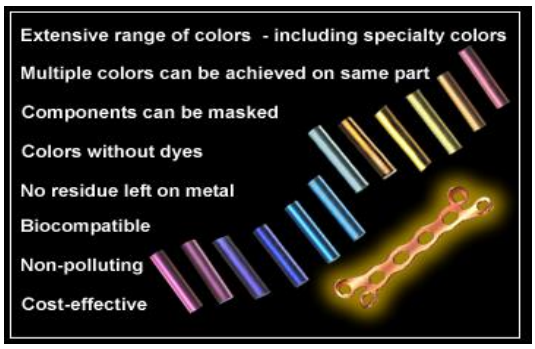

Figure 2

Typical Validated Color Titanium Anodyzing

Table 1

Typical Equipment for screws manufacturing

Process Steps	Equipment Tool
Machine Complete	Tornos Machine
Product Verification	N/A
Cleaning	Crest 4NT-1224-12 Ultrasonic Cleaner
Deburring	Microscope
Anodizing	Anodize Tanks
Kit Prep	Computer
Laser	Laser Etch Equipment
Product ID	Computer (vision system)
Screw Inspection	Caliper
	Micrometer
Sterile Cleaning	Ultrasonic Cleaner
Sterile Packaging	Atlas Vac Heat Sealer
Labeling	Label Printer
Final Inspect and Boxing	Kalfass Shrink-Wrap System
Sterilization	Gamma Sterilizer

Figure 3

Example of a stand-alone device, Medtronic's Peek Prevail Device.

In general, patient candidates have cervical disc disease with radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation. A cervical stand-alone device is an alternative to a traditional anterior cervical plate with interbody.

The Anterior Cervical System new product comprised of a No-Profile Implant (Figure 4), and related instruments. The No-Profile Implant is made of PEEK and is implemented with two Titanium screws. The medical device is compounded by two Titanium screws, a No-P PEEK Implant, a locking cap and a washer.

The advantage and disadvantage could be found in the design, material, and cost. The density of the material is a critical element to be considered when an apparatus is selected. Other implications in the manufacturing process are evaluated and analyzed to comply with the good manufacturing practices.

Figure 4

Anterior Cervical System, No-Profile Implant – Ideal ACDF option when surgeon wants to offer an implant contained entirely in disc space.

Timeline

Any process requires a typical or ideal planning before starting the execution of any activity. The Timeline is a good tool to define and tracking the progress of the activities contemplated in a project. To develop an adequate Timeline, it is needed to include the activities, milestones, resources pool, and start and finish dates, duration, the percentage completion, and then create a baseline. The baseline represents the original plan.

A typical manufacturing process for a new product that includes screws or PEEK parts, takes an average period of ten months. Based on that, the case study is compared with a period of ten months project. Considering this, the case study selected started the third quarter of 2013. The manufacturing date is February 2014, the expecting end date is May 2014 with a launch quantity of 7000 units in August 2014.

It is important in the development of the new product the qualification of the equipment, facilities, and the process. In this case, the facilities have been qualified previously. The new equipment and the new process require to be validated following the company's Master Validation Plan. Therefore, any new procedure requires an assessment, the review of the standard operation procedures, develop, review and approve validation documents, monitoring,

laboratory testing and more. This study includes six (6) weeks for microbiology samples and reports, but not failures are considered during sampling.

During the development of this project the following high level activities were completed:

1. Planning
2. Process Flowchart
3. Project Cost

The following activities are part of the original schedule, but require more time to be evaluated and compared with a ten months plan.

1. Validation
2. Manufacturing
3. Shipping

A critical path is defined like a series of task that, if delayed, will push out the planned end date of a project. In this case study, the critical path was the project cost document. The project cost is a confidential document managed by high level managers. This document is not a public document. With the project cost, a forecast analysis will be tabulated and then compared with the actual cost. In this analysis, a correlation of cost was analyzed to objectively have an idea of the production cost.

Result

In this section, the materials properties and characteristics, the actual and planned project cost and the Timeline are described and are compared mutually. It is important to be analyzed and understand the results to select the best material, and maintaining the project cost without lost and a proper timeline.

Metal versus PEEK Process

PEEK was compared to steel, bronze and aluminum, (see Table 2). During the development of this project was found that the metal and PEEK are materials with different densities and composition. PEEK is also more useful in medical applications. PEEK has low coefficient of friction, which doesn't allow heat to build up, reducing downtime and speeding time-sensitive procedures. For example, medical devices which require repeated sterilization, PEEK tubing can withstand 3000+ autoclave sterilization cycles. Moreover, PEEK maintains high mechanical strength, resists stress cracking, and hydrolytic stability in hot water, steam, solvents, and chemicals. Therefore, PEEK is considered a better product in biocompatibility, mechanical strength, and resistant to stress cracking.

The equipment to machining the parts is completely different. Both materials require separate process flowcharts, and validation procedures. For metal process is commonly used the process shown in Figure 1. For PEEK process are required machine completion, deburring, dimensional inspection, product verification, and cleaning. Then, it continues in kit preparation, assembly, sterile packaging, labeling, final inspection and boxing, shipping and receiving.

Baseline versus Actual Timeline

The actual project duration to manufacturing a new product is ten months. All activities were completed at 100% during this period (August, September, and October 2013). The milestones identified during this quarter are listed in the Table 3.

During the development of the baseline, the company found that the resource allocation was over allocated in the schedule. The company decided to create a new Resource Pool with the corresponding load. This tools help to define and redesign the scorecard. Actually, the resource pool was redistributed with different tasks to avoid over allocation. Based on that, Medtronic Spinal probably needs to consider increasing the labor force.

Table 2

2005 data provided by Zeus Industrial Products, Inc.

PEEK comparison to metals		
Steel	Bronze	Aluminum
PEEK has cheaper manufacturing cost	PEEK has a better mechanical properties	PEEK has cheaper manufacturing cost
PEEK has fewer leachable	PEEK is harder	PEEK is better
PEEK has better dry wear properties	PEEK has better wear & friction	PEEK has a better wear & friction
PEEK has better chemical resistance	PEEK has better chemical resistance	PEEK has better chemical resistance
PEEK has 83% Lower Density	PEEK has 85% Lower Density	PEEK has 50% Lower Density
PEEK has less "memory" / chemical absorption & release	PEEK has low outgassing	

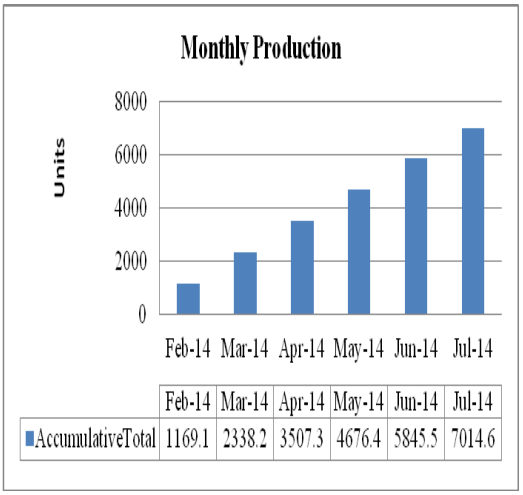

Figure 5

Accumulative Total per one operating machine

Another finding was the new product amount was 7000 units. The machine performed only 67% of the require orders. An estimate of 90 parts per day could be manufactured. The manufacturing beginning time is February 2014. Figure 5 shows the Monthly Production using one machine. If the company wants to complete the project in ten months, an additional machine should be considered to achieve the 7000 units.

Table 3

Milestones

Activities
1. Original Schedule
2. Project Cost Document
3. Risk Assessment
4. Process Flowchart a. Design b. Review c. Approval
5. Planning a. Define Milestones b. Define Critical Path
6. Review and Recommendations to Risk Assessment
7. Implementation Plan
8. Validation
9. Manufacturing
10. Shipping

During the period of 2010 the market of spinal surgery devices was dominated by Medtronic sales (Figure 6). For example, a typical Medtronic Sofamor Danek has a sales price of $1,119, while Depuy Spine has one of $987, and Stryker has one of $1,304 (Figure 7). Warren et al [3] mentioned that a total cost of common surgery procedure with ACDF is about $16,162. This cost includes hospital ($11,747), surgeon ($3,107), anesthesia ($597), and neuromonitoring ($710).

In the annual report for the United States Securities and Exchange Commission, Form 10-K, Medtronic reported for 2010 Fiscal Year (FY) a total net sale of $3,500 million of spinal products, and $11, 892 millions in other products. In 2012, the total net sale was $3,267 million for spinal products, and $12,917 million in other product.

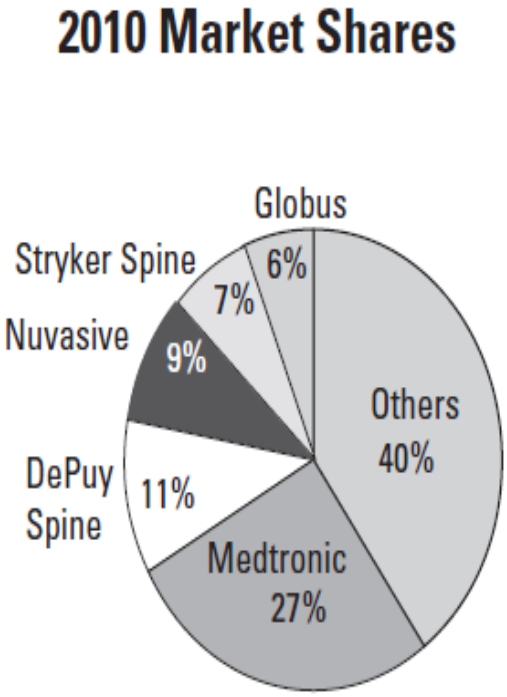

Figure 6

2010 Market Shares
[Source: Orthopedic Network News Report]

Medtronic Spinal is expecting an increase in the annual sales with the new products to be incorporated in the market. If the sale price of one ACDF is near $1,119.00 (US Dollars), and 7000 units are manufactured, the expected total sale is $7,833,000.00. The manufacturing production of our new product represents less than 1% of the annual sales reported in FY 12 (new product total sales divided by total net sales for FY 12).

Any production request depends on the markets demand. Based on that, the company has to create a plan to achieve the market of over 60 million of patients. The company strategy need to be done base on market demand, new products

manufacturing capacity and deliverables, finance, and other high level corporate decisions.

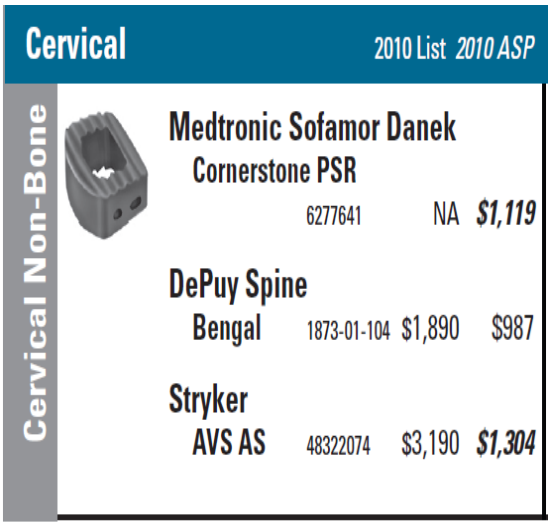

Figure 7

Cervical Non-Bone Device Price
[Source: Orthopedic Network News Report

Research Findings

During this project it was found that Medtronic Spinal Division in Puerto Rico is implementing a Project Management Team division dedicated only to project management. In the past, the Engineering Team was performing multitasks including but not limited on validation, manufacturing, and project management activities.

Presently, this Company is growing rapidly and constantly more transfer products are received from other companies and new products are developed. Furthermore, the Company product demand is growing and the Company is considering buying more machines. If more operating machines are required, more employees are needed.

In August, the new Project Management Team implemented the MS Project software, but the software was used individually without the links required to communicate the entire project in a Master Plan. The schedules were developed without a common Company or business terms. A general template was not implemented totally in the team.

A resource pool was not developed nor properly implemented. Based on the total quantity of projects and products deliverables, the employees are over-allocated in some specific activities. The Company has two production shifts, and activates the thirds shift only when exits special deliveries.

In September, the company has an estimated monthly loss of about 4000 pieces of different products that is considered scrap. This represents a yearly impact cost.

Conclusions

Traditional treatment for the 65 million Americans who suffer from lower back pain includes implanting metal or plastic spacers between vertebrae. This represents a great demand of products. The competition between the major companies is very strong. New strategies are addressed to develop more quality product in a short time period. Any project require a proper analysis of the manufacturing process, cost, and the requirements to achieve a quality product with the best management techniques. In this study it was demonstrated that PEEK continue to be the leader in the implant markets.

In this study, the major findings are the manufacturing process was redesigned, the activities or tasks in the schedule was completely modified with a proper logic and terms, the resource pool was implemented with the best management practices, the project cost did not suffer any impact in the project implementation phase, and it is projected not impact at the end of the process. The risk assessment identified the risks during the project life. The managers were notified about the risks and an action plan was determined.

It is highly recommended to continue reengineering the Project Management Office. Therefore, additional training in management, especially DMAIC, is recommended to be expanded to the managers and employees.

To avoid any risk before the product launch, an additional machine is required to be installed before February 2014. Also, more employees in the development of the project need to be hired.

The project schedule should be continued adjusted and should be followed as the plan. The critical path need to be monitored to avoid any impact in the project Timeline.

Maintaining writing reports, and continuous meetings are the best way to keep communication with all the managers and employees.

During this study some prototypes were developed in the company. There were some difficulties machining some small parts. The machine and program are under software modifications to pass the inspection process. The possible scrap during the machining of the material is not considered in this study. The cost of this new product scrap need to be evaluated to verify the impact in cost.

There are potential risks associated with the use of the implants. These are disassembly, bending, and/or breakage of any or all of the components, pressure on the skin from the device

which could cause skin penetration, irritation, and/or pain, tissue or nerve damage and scar formation. It is important to study and analysis researches about doctor prescriptions, protocol for physical rest followed and then physical therapy recommended after a surgery procedures. The customer complaint needs to be analyzed to determine the cause of these implants post operatives situations.

Also, another interesting research to be followed is silicon nitride versus titanium or PEEK [4]. According to Amedica researches, they found that silicon nitrides is less vulnerable to bacterial colonization than PEEK and titanium. This material has a positive surface charge, nanostructure and hydrophilic nature that can rapid adhere fibronectin, vitronectic and laminin proteins which can decrease susceptibility to bacteria and increase osteointegration.

References

[1] George, M., Rowland, D., Price, M., and Maxey, J. (2005) Lean Six Sigma Pocket Toolbox, McGraw-Hill

[2] Cabraja M., Oezdemir S., Koeppen D., and Kroppenstedt S. (2012). Anterior cervical discectomy and fusion: comparison of titanium and polyetheretherketone cages. PMC US National Library of Medicine National Institutes of Health

[3] Warren, D, Hoelscher, C., Ricart-Hoffiz, P., Bendo, J., and Goldstein, G. (2011). Cost-utility analysis of anterior cervical discectomy and fusion versus cervical disc arthroplasty. Evidence Based Spine Care J

[4] Biloine, Y., (2012). Silicon Nitride vs. Titanium or PEEK. Orthopedic This Week Inc.