

# Capability of CNC-Mori-Seiki ENDO HEAD

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**Abstract** — *Endo Head is a product suitable to perform hemiarthroplasty on any hip joint whose acetabular conditions are satisfactory. The Endo Head is a unipolar prosthesis made of CoCr alloy that consists of a Monobloc prosthetic femoral head articulated directly with the patient's acetabulum. Endo Head product at this moment is a product in a backorder status due to problems in the process in the machine area. Endo Head is performed in CNC machines and the project is based in the determination of real output of this CNC machines. Capability analysis will be performed to know if the process is capable. [1]*

**Key Terms** — *CNC, CoCr, Capability, Endo Head, Endo Head.*

## PROBLEM STATEMENT

This company is a manufacture industry that performs musculoskeletal products. One of the department of this industry is named HIPS and in one cell they manufacture the Endo products. The process in the cell of femoral Heads starts in the machining area. They are having different types of problems causing several interruptions. To determine the exact capacity in the process of machining for this product named Endo Femoral Heads, is the purpose of this project.

The Endo Femoral is a products currently backorder status in the market and it is extremely important to know our exact capacity of production to satisfy the need of costumers. At this moment, the machining operators are in a learning curve and the actually output are in a range of 6-10 units per shift of 8 hrs. The demand of the market is approximately 600 units per week and due to this circumstances the company is not accomplish with the requirements.



**Figure 1**  
**Femoral Head**

For that reason, is necessary to have the knowledge of the real output, to determine the capacity of machine and the requirement needed to achieve the actual goals.

## Research Description

This project will determinate the capacity of the CNC Mori-Seiki machine to produces Endo Femoral Heads. It important to identify the capacity of the Mori-Seiki to create a strategy to accomplish the demand of customers and reduce the actual backorders.

## Research Objectives

The project objective are to:

- Accomplish the demand goal of 60 units per shift.
- Develop a strategy to achieve the goal established.
- Identify process constraints.

## Research Contributions

- With the analysis of this project the company will benefit with an incremental profit and reduction in the backorders (1,200 units) that represent a total of \$360, 0000. The client will have a product in less time and the operators

will be able to have a fixed goal and a process in control.

## LITERATURE REVIEW

To identify if the process is capable or not capable, an analysis of the process in the CNC will be performed. A literature will help in the start and progress of the capability analysis. The results will conclude if the process can comply with the expectation of the business.

A capability study is one of the main tools of Six Sigma. It helps to understand what the process capability is and tells the probability that the process will produce defects. There are four main metrics used to define capability. These are Cp, Cpk, Pp, and Ppk. The two metrics starting with "C" measure short term capability. The other two starting with "P" measure long term performance. To remember easily, the "C" can be remembered as capability and the "P" can be remembered as performance. The capability study tells exactly how far the objectives are from the six sigma. It lets know if the process is centered and it also tells how much variability the process has compared to the specification limits or tolerance.

Cp (see equation 1) is the capability metric that tells how good our process variation is compared to the tolerance. It compares our process spread to the tolerance spread defined by the customer. The formula for calculating Cp is shown below: (USL = upper spec limit, LSL = lower spec limit, s = standard deviation):

$$C_p = \frac{|USL - LSL|}{6s} \quad (1)$$

Therefore always Cp is a good metric for judge internally how tight your process is, but it does not tell how well is conform to the customer's specifications.

When a capability study is performed using Cpk, it measures how well the process is centered as well as how much variation there is in it. To determine the probability of making defects, Cpk

should be used. This is also the metric that the customer will be interested in as it shows how well the process conforms to the specifications.

The formula for calculating Cpk is in equation 2.

$$C_{pk} = \text{Min}\left(\frac{\bar{X} - LSL}{3s}, \frac{USL - \bar{X}}{3s}\right) \quad (2)$$

Pp and Ppk, these capability study metrics are very similar to Cp and Cpk except that Pp and Ppk are the long term versions of Cp and Cpk. It is important to distinguish between Process Capability and Process Performance. Capability is assessed over a very short period of time and represents short term variation in the process. It does not consider the total variation, which would include the normal drifting and shifting of the process mean, as well as any changes in process spread.

Process Performance is assessed over a long period of time and includes the effects of shifting and drifting of the process mean and changes in the process spread. Process Performance is the more realistic assessment of the process. It is what can expect over the long term. Capability is the ideal situation. It is what would expect if all shifts and drifting could be eliminated.

Pp and Ppk calculation is the same as Cp and Cpk respectively. The difference is the method in which the standard deviation is calculated for Pp and Ppk. The formula for calculation the standard deviation for use with Pp and Ppk is given in Equation 3.

$$\sigma_{overall} = s = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}} \quad (3)$$

Another tool to perform calculation could be Minitab and Sigma XL these are two easy software to use and that can give you all the capability study metrics with just a few clicks.

The most important part of the concept of the capability study is to understand that:

- Cp is a measurement of how tight the process variability is compared to the specification tolerance. The higher of the Cp, the tighter of the process variability.
- Cpk is a measurement of how well the process is centered as well as how tight your process variability is. The higher the Cpk, the better process is and the less chance it has of creating defects.
- Pp and Ppk are the same as Cp and Cpk respectively, except that they show how the process performance is over the long term.

To analyze the process of CNC a Plan-Do-Study-Act (PDSA) will be performed. PDSA is another problem-solving approach many use to find and address root causes of problems. The method was originally proposed by Dr. Walter Shewhart (as PDCA, Plan-Do-Check-Act) in his book Economic Control of Quality of Manufactured Product (1931) and later espoused by W. Edwards Deming. Deming referred to the method as the Shewhart Cycle, but many, particularly after Deming achieved fame, refer to it as the Deming Cycle. See figure 2.

The method differs from the root cause analysis method described previously in that it is primarily a guide for identifying root causes through experimentation. This implies that the analysis of symptoms and theorizing of causes are done before the cycle actually starts, and then iterative experiments are performed to drill down to the root causes of the problem being addressed.

The more complete the appropriate knowledge, the better the improvements will be when the knowledge is applied to making changes. Any approach to improvement, therefore, must be based on building and applying knowledge. This view leads to a set of fundamental questions, the answers to which form the basis of improvement:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What changes can we make that will result in improvement?"



**Figure 2**  
**PDSA**

The PDSA approach follows these phases and steps:

- **Plan:** Define the change to be tested. Design the experiment to test the change.
- **Do:** Carry out the experimental plan. Collect data about the effectiveness of the change.
- **Study:** Analyze the data from the experiment. Summarize what was learned.
- **Act:** Determine what permanent changes are to be implemented. Determine what additional changes need to be tested.

Clearly, this approach has some advantages:

- It can yield results quickly if the experimenters are good at selecting solutions that will yield true improvement.
- It follows an experimental approach, which can yield a great deal of useful knowledge.
- It is widely accepted, particularly within health care and other organizations that typically rely on experimentation to determine beneficial changes.

One might also note some disadvantages:

- Results can be slow to come if the experimenters are not good at selecting solutions that will yield true improvement.
- Changes that do not succeed may not yield a lot of useful information.
- Experimentation, unless it is done in a laboratory setting, can be disruptive to the process and can be resource-intensive.
- Experimentation can be costly in many cases.

Based on these pros and cons, the project team should choose the methodology that best fits their work style and organization's needs.

## PROJECT METHODOLOGY

In order to meet the proposed objectives a study to determine if the process of CNC is capable or not capable a Process Capability will be performed with a structure of Plan Do Study Act.

Six Sigma is a set of techniques and tools for process improvement. Six Sigma seeks to improve the quality of process outputs by identifying and removing the causes of defects (errors) and minimizing variability in manufacturing and business processes. Six Sigma projects follow two project methodologies inspired by Deming's Plan-Do-Check-Act Cycle and DMAIC.

Plan Do Study Act is an iterative four-step management method used in business for the control and continuous improvement of processes and products. It is also known as the Deming circle/cycle/wheel, Shewhart cycle, control circle/cycle, or plan-do-study-act (PDSA).

**PLAN:** The first step is the plan, the objectives and processes necessary to deliver results will be developed in accordance with the expected output. By establishing output expectations, the completeness and accuracy of the specifications is also a part of the targeted improvement. When possible start on a small scale to test possible effects. Project Charter, Sipoc and VOC will be performed to define opportunities of the process, gather data to describe the process as they are currently worked and identify causes or problems.

**DO:** Implement the plan, execute the process and make the product. Collect data for charting and analysis in the following "CHECK" and "ACT" steps. A plan will be developed to make improvement.

**CHECK/STUDY:** Study the actual results and compare against the expected results to ascertain any differences. Look for deviation in implementation from the plan and also look for the

appropriateness and completeness of the plan to enable the execution, "Do". Charting data can make this much easier to see trends over several PDCA cycles and in order to convert the collected data into information. Collect information is the next step "ACT". Run Chart, Fishbone and Pareto will be performed to study the data.

**ACT:** If the CHECK shows that the PLAN that was implemented in DO is an improvement to the prior standard, then that becomes the new standard (baseline) for how the organization should ACT going forward. If the CHECK shows that the PLAN that was implemented in DO is not an improvement, then the existing standard will remain in place. In either case, if the CHECK showed something different than expected, then there is some more learning to be done and that will suggest potential future PDCA cycles. Note that some who teach PDCA assert that the ACT involves making adjustments or corrective actions but generally it would be counter to PDCA thinking to propose and decide upon alternative changes without using a proper PLAN phase, or to make them the new standard without going through DO and CHECK steps. Recommendation and photos of the process will be demonstrated in a comparison analysis before and after. A capability graph will be performed to identify if the process is capable or not. [2]

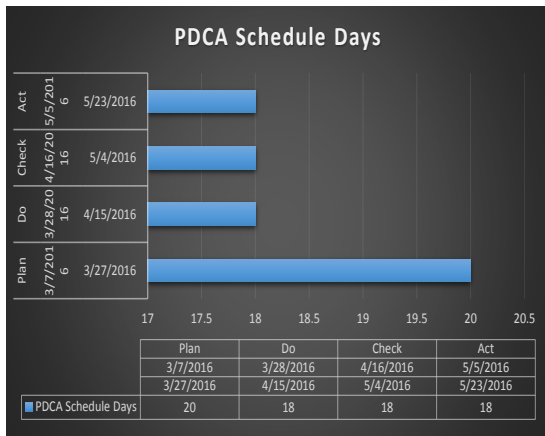
The Project Charter will help to provide a preliminary delineation of roles and responsibilities, outlines the project objectives, identifies the main stakeholders, and defines the authority of the project manager. It serves as a reference of authority for the future of the project.

**Table 1**  
**Project Charter**

<i>Problem Statement</i>
Reduce currently backorders of Endo Femoral and know our exact capacity of production to satisfy the need of costumers
<i>Goal</i>
Identify Output per shift to accomplish the 600 demand per week and Identify process constraints.
<i>Metrics Descriptions</i>
Capability of CNC

Table 1 proposes the schedule of the activities to complete the Project starting in March 2016 and finishing in May 2016 and the Project Charter.

The schedule is presented in a Gantt Chart that represent in a bar chart that the project schedule. Gantt charts illustrate the start and finish dates of the terminal elements and summary elements of a project. See figure 3.



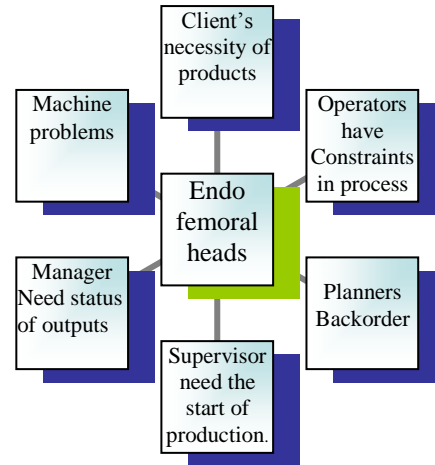
**Figure 3**  
**Proposed Project Schedule**

### VOICE OF CUSTOMERS

Voice of Customers is a term used in business and Information Technology to describe the in-depth process of capturing customer's expectations, preferences and aversions. Specifically, the Voice of the Customer is a market research technique that produces a detailed set of customer wants and needs, organized into a hierarchical structure, and then prioritized in terms of relative importance and satisfaction with current alternatives. Voice of the Customer studies typically consist of both qualitative and quantitative research steps. [3]

In the Voice of Customers (see figure 4) can appreciate that the clients need the products and if the company have femoral heads in backorder the team need to make a new strategy to make that the product of femoral head can achieve the goals established. The necessity of the operator after a One to One with the employees identified some constraints during the process. They are in a learning curve and the setup and problem with the machine like jaws, coolant and tools are the

principal causes to increase the lead time. Planners are affected because they need to established a real output to make a promise to client on when they going to make the delivery's.

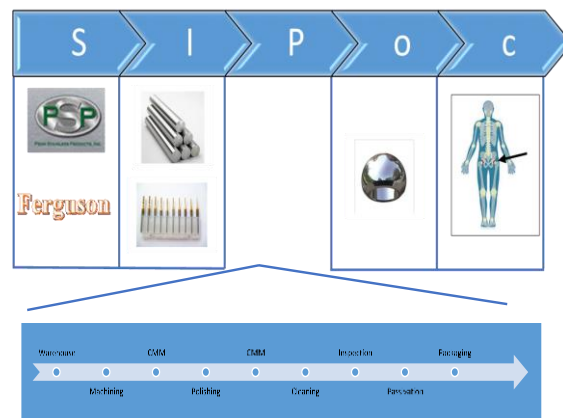


**Figure 4**  
**VOC**

From the outputs and with the help of supervisor and managers the team is going to minimize the setup time and help with a strategy to identify our capacity.

### SIPOC

To better understanding of the development of the Femoral Heads Product a SIPOC will be performed. A SIPOC diagram is a tool used by a team to identify all relevant elements of a process improvement project before work begins. [3] See figure 5.



**Figure 5**  
**SIPOC**

The company that sell the raw material to produce the femoral heads is Penn Products, Inc, they produce the bar of stainless steel. Another suppliers that are involved in the materials to perform the femoral heads are Ferguson. They give to us all the drill tools for the CNC machines and they are located in the same local of our company. The Input are the bar of different measure depending on the size of femoral head that will be performed. The process start in the warehouse, the group leader order the bar that the cell is going to manufacture in the CNC. Then pass through the process of Machining, CMM, Polisher, CMM, clean and Inspection, then pass for passivation, and then to the area of packaging. Our output is the Endo Femoral Head and our customer are the clients of hospital that have problem with the hip.

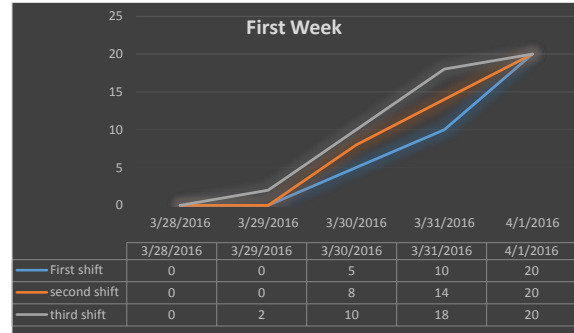


**Figure 6**  
CNC Machine

### RUN CHART

Run chart also known as a run-sequence plot is a graph that displays observed data in a time sequence. Often, the data displayed represent some aspect of the output or performance of a manufacturing or other business process. It is therefore a form of line chart.

To start with the capability analysis and identify constraints during the process we going to monitor the first week of production the starting is in April 4<sup>th</sup> ending in April 8<sup>th</sup>.

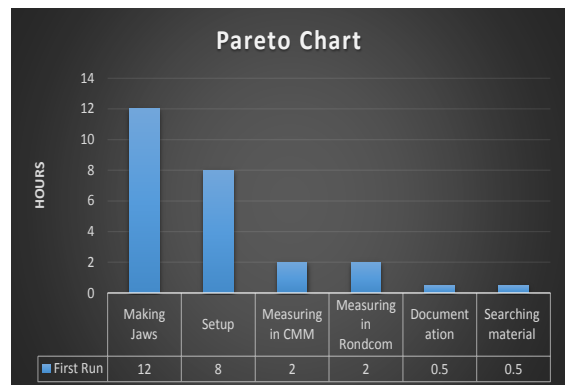


**Figure 7**  
Run Chart

In figure 7, the first week of production we can see that the learning curve is increasing day to day. The target to accomplish the demand is 40 pcs per shift and in the first week the higher output was 20 per shift. The first day the setup was the bottle neck in the process but was something that can happened when a new component is running. Another constraint in the process that is inside the time of setup is the development of jaws, because of the tool that secure the bar. The team observe that the operator walk to measure the unit in a CMM and lost 5 minutes of units and the machine stop running.

### PARETO CHART

The purpose of the Pareto chart is to highlight the most important among a (typically large) set of factors. In quality control, it often represents the most common sources of defects, the highest occurring type of defect, or the most frequent reasons for customer complaints, and so on.



**Figure 8**  
Pareto Chart



Figure #8 shows a Pareto chart in which the first major bottleneck in the process, performing Jaws. The Jaw is an important piece for the development of femoral head. If that jaws is develop in a bad mode the femoral isn't go to be in the correct size. The problem is the machine that we are using to make the Jaws. We need to find another alternative to perform Jaws and eliminated 12 hours of production waste. The second major waste is the setup time with 8 hours and this time is going to down as time passes because the first setup is always the greatest. Because it is the first time that we are setting programs and tools to the machine. We need to monitor our mix of units because that can be a factor that affect our output. We need to plan a schedule for the month with the planner's owners. There is a problem of measurements in both machine CMM and Rondcom, the operator needs to go to the machine and CNC machine stop the production in that time we going to put another support to eliminate that waste of time. We observed that the operator lost time when they not find some tool to create the shadow board to be performed.

### FISHBONE

Ishikawa diagrams also called fishbone diagrams, herringbone diagrams, cause-and-effect diagrams, or Fishikawa are causal diagrams created by Kaoru Ishikawa (1968) show the causes of a specific event. Common uses of the Ishikawa diagram are product design and quality defect prevention to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation.

In figure #9, the fishbone diagram for the femoral output constraints are see, the causes in this case of machine are the setup time and the making of jaws that are the most time of downtime causing a less production by 80 units. In the case of material when the process start, the operator is not prepare with all the instruments. In the people case, the operators is starting with the products in the Mori-seiki. In the process they are stopping the machine

to measure in Rondcom and CMM every five units and the problem is that they not have an assigned machine for this product.

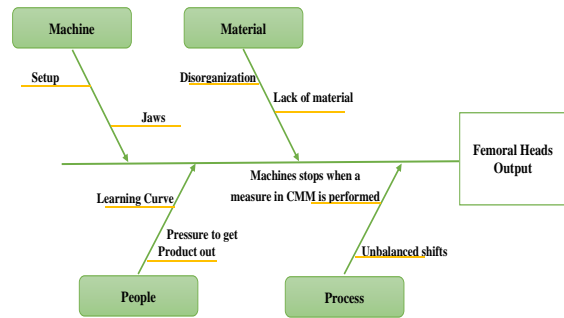


Figure 9  
Fishbone Diagram

### Plan Strategy

On the first week, the team started the production with three shift of 8 hours and 1 person in the Mori-seiki machine the same person make the measurements in CMM and Rondcom. The maximum output for that week was 20 units per shift. When we tried the same structure but with an additional shift on Saturday and Monday 4<sup>th</sup> and 5<sup>th</sup> shift we make 20 units per shift a total of 420 units per week. The other alternative was 2 shift of 12 hours but in this case with a Cell support to help to make the measures in the Rondcom and CMM. In this strategy the output increase to 60 units per shift with a total of 600 units per week. To eliminate the backorders a weekend plan for three months will be performed.

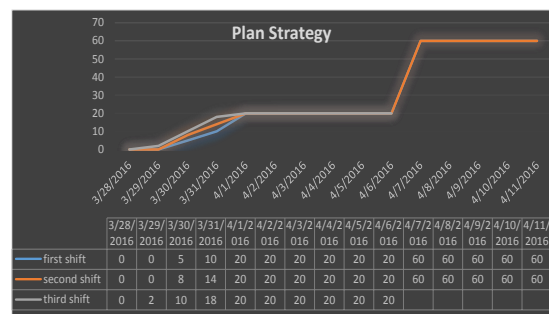


Figure 10  
Shift Plan Strategy Chart

### CONCLUSION

1. The team change the organization of shift to run in Mori-seiki, consist in two shift of 12

hours with 2 people working in the machine, 1 is going to make the measurement in Rondcom and CMM and the other is going to be in the machine. They going to take the break in different hours to eliminate the time of machine stops.



**Figure 11**  
**CMM and Rondcom**

- The team buy jaws to eliminate the 12 hours of downtime time, increasing instantly 48 units in production of 12 hours.



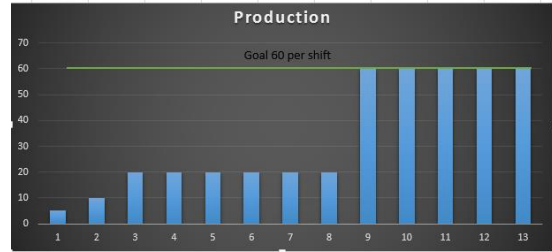
**Figure 12**  
**Jaws**

- In figure 13 shows tool box created to eliminate 30 minute per shift of downtime searching material. Additional 5'S creating shadow board in the cabinets.



**Figure 13**  
**Tool Box and Shadow Board**

- Negotiation with the planner to run only the product of Endo in the CNC Mori-seiki, one size per week to eliminate the most possible setup and the changed of coolant. Every setup have an initial downtime of 8 hours.



**Figure 14**  
**Goal per Shift**

- The goal of this project was complete 60 units per shift and after pass changed in strategy, the team identified that the most precise strategy was set 2 shift of 12 hours to make the goal of 600 units per week, but we are making more units during the weekend due to backorders then we only need to make 120 units per day. The capacity of the output of the machine after improvements was set to 60 units per shift.

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