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DEFECT REPAIR EFFORTS IN BONE PLATE PRODUCT QUALITY CONTROL USING SIX SIGMA (CASE STUDY: PT ABC)

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Abstract

This study aims to identify and reduce Bone Plate product defects at PT Risa Implantama, a domestic orthopedic and traumatology implant manufacturer. Using Six Sigma methodology, this research applies the DMAIC (Define, Measure, Analyze, Improve, and Control) stages to analyze Bone Plate production data from January to December 2023. The analysis results show that the most dominant defect is in the hole diameter with a total of 114 defects. The resulting DPMO (Defects Per Million Opportunities) value is 7474, with an average sigma level of 3,94. Proposed improvements include improving raw material quality control, operator training, and routine machine maintenance to improve product quality and approach the Sigma level 6 target.

Keywords: Six Sigma, DMAIC, Quality Control, Bone Plate Products, Orthopedic

INTRODUCTION

Industrial developments in this era of globalization have made competition between companies increasingly tight, especially in the manufacturing industry (Simachev et al., 2021). Companies are competing to determine the right strategy to attract consumers and meet consumer demand. Many factors can influence consumer purchasing decisions, one of which is the quality of the product produced (Haitao, 2022). Product quality is a combination of properties and characteristics that determine the extent to which the product can meet the prerequisites of customer needs (Javaid et al., 2021). Improving product quality is one of the right strategies to win this tight market competition by minimizing defects in the products produced (Garvin, 1988).

Medical devices are one of the manufacturing industries where up to now the use of domestic products is still inferior to imported products. The problem faced by the domestic medical equipment industry is the low level of consumer trust in domestic products (Prasetya et al., 2022). Data in the Indonesia Medical Devices Report shows that the number of imports of medical device products in Indonesia is 90%, while the national medical device market is growing by 12% each year, which is expected by domestic producers to participate in competing in this market (Fadliyah and Nurwahyuni, 2022). One of the medical devices that already exist in Indonesia is orthopedic and traumatology implants. Orthopedic and traumatology implants are components that connect bones resulting from fractured injuries (Zhang et al., 2023). Orthopedic implants are divided into two categories, namely temporary (plates and bolts) and permanent (hips, backs, knees, etc.) (Wiranegara, Fauzi, and Virdhian, 2020).

PT. Risa Implantama is a domestic manufacturer that focuses on the production of Orthopedic and Traumatology Implants. PT. Risa Implantama has experienced many developments both in terms of technology and management. In the production process, PT Risa Imlantama often experiences defects in the production of Bone Plates. With a reject percentage of 2.22%, the sigma value in January 2023 was 3.93, whereas the company wanted to set a sigma value of at least 4 or the equivalent of United States companies. Therefore, quality control is needed to increase the sigma value from 3.94 to 4 to reduce the

defect. Apart from that, quality control is also needed to provide improvement solutions (Attaqwa, Saputra, and Khamal, 2021).

In overcoming existing problems in the company, quality control is needed using one of the quality controls tools, namely Six Sigma. Six Sigma is a comprehensive and flexible system for achieving, maintaining, and maximizing business success (Elfanda, 2021). Six Sigma is the right tool to achieve zero defects because it is a vision of improving quality towards 3.4 failures in a million opportunities for every product or service transaction (Psarommatis et al., 2020).

REVIEW OF LITERATURE

Product defects are highly avoided by the company. Several companies try various methods to reduce or even eliminate product defects. Numerous studies have been conducted to address this issue, including the use of seven tools, new seven tools, Lean Sigma, and Six Sigma. Seven Tools is one of the tools in quality control that uses a continuous seven-tool approach to control the quality or standard of a product (Fatimah and Wahyuni, 2023). The New Seven Tools add several other tools to the Seven Tools to solve more complex problems (Ginting and Fattah, 2020). Meanwhile, Lean Sigma is a method that combines Lean and Six Sigma to improve efficiency and quality in a process, thereby creating a faster, more efficient, and higher-quality process (Stojanović and Milovanović, 2020).

Six sigma comes from the Greek letter $\boldsymbol{\sigma}$ which is used as a form of standard deviation or standard deviation. Six Sigma is a structured methodology that aims to improve processes by focusing on reducing product defects through a statistical approach and intensive use of problem-solving tools, thereby increasing operational efficiency and adding company value (Untoro and Iftadi, 2020). The focus of Six Sigma is on reducing cycle time, reducing the number of defective products, and obtaining customer satisfaction. The greater the sigma value obtained, the greater the sample diversity. Six Sigma as a measurement system uses Defects Per Million Opportunities (DPMO) as a measurement. DPMO is a good measure of the quality of a product or process because DPMO directly correlates with defects, costs, and wasted time. By using the DPMO conversion table, we will easily find out the sigma and DPMO levels (Pardiyono and Indrayani, 2020).

The basic principle of Six Sigma is to improve products by making process improvements to create perfect products. This method aims for long-term performance through improving quality to reduce the number of defects to achieve zero defects at a process capacity equal to or greater than 6 sigma level with a standard deviation of 99.99997% of the desired target value so that deviations or product defects are possible is only 3.4 defects out of 1 million possibilities (Shahabuddin, 2008). The application of Six Sigma is expected to satisfy customers, increase company profits or reduce production costs, and add value to the company and its business (Purba et al., 2021).

Six Sigma is a method for finding the best improvement solutions for existing problems using the stages of the DMAIC process. The DMAIC stages start from the process of defining (identification), measuring (measurement), analyzing (analysis), improving (improvement), and controlling (control) used to make continuous improvements or improvements to achieve the Six Sigma target (Patel and Chudgar, 2020).

RESEARCH METHOD

The method used in this study is quantitative research. The first stage carried out in this study is a literature review to obtain a theoretical basis used in the study. The next stage is a preliminary study to determine the problems that occur at the research location. After the preliminary stage, the next step is to determine the research objectives and identify variables. Data collection can be done through interviews with the Quality Control of PT Risa Implantama to determine the causes of the types of defects that occur in the bone plate produced and document studies to obtain production data. This research began in May 2023 and continued until the data needed for this study was complete.

Data processing and analysis techniques were carried out using the Six Sigma with DMAIC. Six Sigma is a structured methodology that aims to improve processes by focusing on reducing product defects through a statistical approach and intensive use of problem-solving tools The analysis in this study produces recommendations for improvements to overcome quality control problems in Bone Plate product defects.

RESULTS AND DISCUSSION

In this study, the data used are data on the amount of production and data on the type and amount of Bone Plate product defects in the period January 2023 to December 2023. There are 3 types of defects in Bone Plate products, namely thickness, length, and diameter (Kovac et al., 2023).

Table 1
Total Production Data and Defect Type Data of Bone Plate Products Period of January 2023 to December 2023

Month	Production Amount (Pcs)	Number of Defects of Each Type (Pcs)		
		Thickness	Length	Diameter Hole
January	669	5	2	8
February	1.023	8	4	12
March	984	7	5	10
April	336	2	1	5
May	930	6	3	11
June	767	5	3	8
July	615	5	2	6
August	930	9	3	9
September	791	4	1	12
October	1.055	9	3	13
November	833	6	3	10
December	808	5	2	10

From the data above, further data processing is carried out into histograms and Pareto diagrams as shown below.

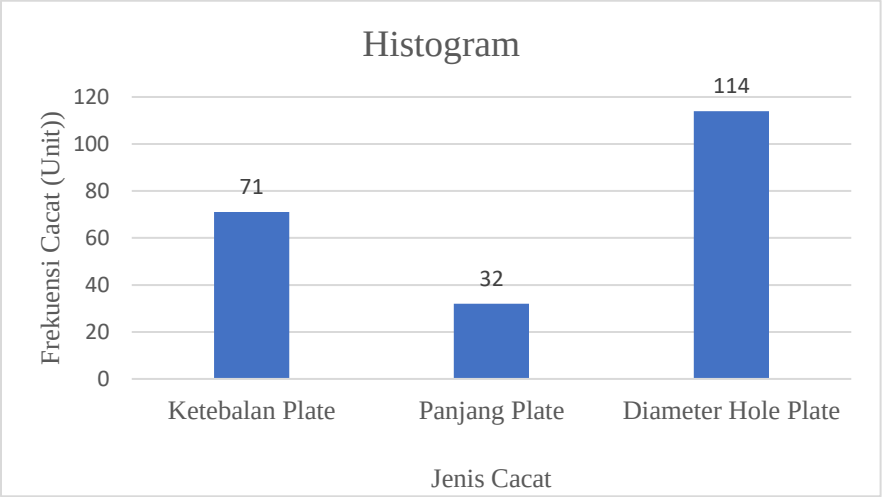

Figure 1
Histogram

Based on this figure, it is known that the current defect in the Bone Plate production process is dominated by the defect of diameter hole with a total amount of 114 pieces followed by plate thickness and plate length with defect frequency values of 71 and 32, respectively.

Calculating DPO, DPMO, and Sigma Level Values

$$\text{DPO} = \frac{number\ of\ defects}{number\ of\ units\ x\ CTQ}$$
$$= \frac{15}{669\ x\ 3}$$
$$= 0{,}007474$$
$$\text{DPMO} = \frac{number\ of\ defects}{number\ of\ units\ x\ CTQ} \text{ x } 1.000.000$$
$$= \frac{15}{669\ x\ 3} \text{ x } 1.000.000$$
$$= 7.474$$

Based on the above calculations, it is known that in January 2023 there were 15 units of defects from the total production of 669 units. The characteristics (CTQ) are 3 types of defects so the chance of failure that occurs in one million products is 7,474 units. Based on the results of the calculation of DPO, and DPMO, and with the help of the sigma table in Appendix 5, the calculation of the sigma level value can be determined and then interpolated. The calculations are:

$$\frac{(X-X1)}{(X2-X1)} = \frac{(Y-Y1)}{(Y2-Y1)}$$
$$\frac{(X-3{,}93)}{(3{,}94-3{,}93)} = \frac{(7.474-7.549)}{(7.344-7.549)} = 3{,}94$$

Description :

X = Calculated sigma value
X1 = Upper limit value of sigma table
X2 = Lower limit value of sigma table
Y = Calculated DPMO Value
Y1 = Upper limit value of DPMO table
Y2 = Lower limit value of DPMO table

So, for a DPMO value of 7,474, a sigma value of 3.94 is obtained. These sigma values are still below the company's standard, which requires a minimum sigma value of 4. Therefore, improvement measures are needed to raise the sigma value.

Proposed Improvements

From the table above, it can be seen that the proposed improvements for each factor are as follows:

Table 2
Proposed Improvements

Factor	Proposed Improvements
Material	Checking raw materials regularly
Methods	Periodically check the production process at each workstation
Human	Conduct training at least once every 3 months
Machine	Create a machine maintenance interval schedule and perform regular and periodic machine checks and autonomous maintenance
Environment	Checking the room temperature regularly

In the calculation of DPMO values and sigma levels, it is obtained that the average DPMO during the period January 2023 - December 2023 is 7421.42 with an average sigma value of 3.94. From this average, it is necessary to analyze the causes of failure at the analysis stage and provide suggestions for improvement at the improvement stage because the average value of the sigma level is still less than 6.

At the analysis stage, analyze and determine the root cause of the problem from CTQ using a cause and effect diagram. The causes of defects include, among others, poor quality of raw materials that can affect the final result of the hole of the bone plate product produced, the absence of inspection in the middle of the production process, lack of supervision during production, and operators who are less competent in supervising or running the production process, inappropriate machine calibration, and fluctuating temperature changes (Hossain, Tipper, and Wei, 2019).

The next stage is the improvement stage using the 5W + 1H technique. for the suggested improvements, namely checking raw materials regularly and using the first material that comes (FIFO), checking the production process regularly at each workstation,

conducting training at least once every 3 months, making a machine maintenance interval schedule, and checking machines regularly and periodically, and checking room temperature regularly.

The last stage of Six Sigma is the control stage. At this stage, the company has a process control system both in controlling specification standards and to control work instructions so that each process can be controlled, out specs that occur can be reduced by the company and the target of Six Sigma quality improvement can be achieved. However, in this study, because the improvement stage is only limited to proposed improvements and does not carry out implementation, the control stage is not carried out.

CONCLUSION

Based on the research conducted, it was found that the company's current sigma value has an average of 3.94. This value can be considered insufficient compared to the company's standard, which requires a minimum sigma value of 4. Suggested improvements to increase the company's sigma value include: enhancements in material factors that can be realized by performing regular inspections of materials before they enter the process. Methodological improvements can be made by implementing consistent control measures at every process within each workstation. To address human factors, regular training sessions should be held every three months. Machine-related issues can be managed through both periodic and self-directed maintenance. Lastly, environmental factors can be improved by routinely checking the temperature at workstations.

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