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# Analysis of Surgical Suture Production Process Control Using Statistical Process Control (SPC) Methods

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**Abstract.** The medical industry currently has very high-quality standards for medical products such as surgical sutures. PT XYZ, as a well-known manufacturer in this industry, faces challenges in reducing the level of surgical suture product defects. This research focuses on the surgical suture production process produced by PT XYZ. One strategy to gain a competitive advantage is to continuously improve the quality of its products. This condition must be supported by the implementation of quality control in the process so that it can run well to produce products that have high competitiveness. The aim of this research is to analyze whether the surgical suture production process is statistically controlled or not and to analyze whether the production process meets the specified design or not. The data used in this research are secondary data and primary data. Primary data was obtained through direct observation and interviews, while secondary data was obtained from the internet, literature and journals. This research uses statistical process control (SPC) as an analysis tool by creating X and R control charts and analyzing process capabilities. The research results show that the control of the surgical suture production process is a reliable process. This is an indication that the process is under control or is not experiencing deviations. The process capability ratio shows that the process is said to be feasible and does not need to be improved. The process capability index shows that the process accuracy is good, which means that the process does not need to be improved.

## 1 Introduction

The medical device manufacturing industry, such as PT.XYZ which produces surgical needles, is a strategic sector in supporting public health. In the era of globalization, this industry is also not immune from the impact of increasingly fierce competition due to the entry of similar products into the market [1]. Intense competition requires companies to continuously improve product quality as one of the strategies to win the competition.

Product quality is considered a key factor in consumer decisions. According to the American Society for Quality, quality is the overall features and characteristics of a

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product or service that are able to satisfy visible or hidden needs[2]. Quality excellence can be the main differentiator that makes consumers choose a company's products compared to its competitors.

The importance of quality control in the manufacture of medical devices, such as surgical needles, is reflected in the application of methods such as Statistical Quality Control (SQC) and Statistical Process Control (SPC) [3]. SQC and SPC provide an overview of process performance, both online and offline, to ensure that the production process is in a stable and predictable state at every stage.

Although quality control techniques are often considered as a consumption of large companies, PT.XYZ, as a medical device manufacturing company, must prioritize the implementation of quality control to maintain the quality of its products [4]. This is especially relevant in an industry that produces surgical needles that require high quality standards.

This study aims to (1) analyze the root causes of product defects; (2) analyze the deviations that occur against product non-conformity; and (3) propose a corrective action plan for the concept of implementing the production process, in the hope that these improvements can reduce the defect rate in surgical needle products produced by PT.XYZ.

## 2 Literature Review

In the context of the medical device manufacturing industry, PT. In this research, a quality control analysis model is used to optimize the surgical needle production process at PT. The selection of analytical tools is based on considerations of cost, time, product condition, and solutions that can be applied to the production process [5].

The use of control charts is central to quality control analysis. The control chart is divided into two maps, namely the average control map and the distance control map. The average control chart provides an overview of whether the production process is within predetermined control limits. This is useful for assessing the average conformity of products with company control standards. Meanwhile, the distance control map is used to evaluate the accuracy and precision of the process by finding the range of observation samples.

The concept of process capability is the main basis for this research. Process capability reflects the extent to which a process is able to meet design specifications established by engineering or consumer demand [6].

The research was carried out on Jl. Pulogadung No.23, RW.9, Jatinegara, Kec. Cakung, East Jakarta City, Special Capital Region of Jakarta 13930. The data used in this research includes primary data of qualitative and quantitative nature, obtained through direct observation in the field and interviews with business owners. In addition, secondary data was obtained from library materials relevant to research needs and other information sources obtained via the internet. By focusing on quality control analysis, this research is expected to provide in-depth insight regarding the efficiency and consistency of the surgical needle production process at PT.

### 3 Result

This control chart calculation uses yarn strength data taken during the pull tensile strength testing process, with the manual assistance of production operators. Thread strength testing for surgical needles is an important step in ensuring that the needle and thread are of suitable quality for use in surgical procedures and that stresses may occur during the surgical suture process without unwinding or breaking [7]. In the Pull Tensile Strength process, it is carried out by pulling the thread needle with a specification limit of  $\geq 20$  Newtons. When the Pull Tensile Strength stage is in progress, the inspection is carried out 100% thoroughly. This information collection was carried out between February and March 2023 (Table 1).

**Table 1.** Calculation of control charts  $\bar{X}$  and  $R$  on thread strength

No	Date	X1	X2	X3	X4	X5	X Bar	R
1	13-Feb	20.06	20.97	20.18	20.85	20.14	20.44	0.91
2	14-Feb	21.24	21.08	21.16	21.21	20.48	21.034	0.76
3	15-Feb	21.74	20.32	20.25	21.7	20.69	20.94	1.49
4	16-Feb	21.96	20.97	21.87	21.17	21.81	21.556	0.99
5	17-Feb	21.76	21.27	20.24	20.79	20.87	20.986	1.52
6	20-Feb	21.93	20.15	21.02	20.83	21.47	21.08	1.78
7	21-Feb	20.17	20.87	21.27	21.17	20.94	20.884	1.1
8	22-Feb	20.53	21.8	21.85	20.15	21.58	21.182	1.7
9	23-Feb	20.49	20.19	21.17	20.87	21.43	20.83	1.24
10	24-Feb	20.71	20.27	20.33	21.92	20.33	20.712	1.65
11	27-Feb	21.25	20.13	21.28	21.12	20.37	20.83	1.15
12	28-Feb	20.17	20.54	21.53	20.83	20.28	20.67	1.36
13	01-Mar	20.13	20.01	20.19	20.08	21.39	20.36	1.38
14	02-Mar	20.57	21.95	20.63	21.17	21.09	21.082	1.38
15	03-Mar	20.57	20.68	20.46	20.84	20.93	20.696	0.47
16	06-Mar	20.27	20.58	22.17	22.17	21.74	21.386	1.9
17	07-Mar	20.18	21.88	21.53	21.83	20.32	21.148	1.7
18	08-Mar	21.49	21.82	20.01	21.57	20.06	20.99	1.81
19	09-Mar	20.96	21.99	20.67	21.97	21.23	21.364	1.32
20	10-Mar	20.79	20.7	21.27	21.47	21.17	21.08	0.77
TOTAL							419.25	26.38
Mean							20.9625	1.319
Std. Dev							0.3949	

After successfully calculating the  $\bar{X}$  and  $R$  values, the next step is to carry out calculations to determine the control limits on the  $\bar{X}$  control chart and also calculate the control limits on the  $R$  control chart [8]. In this case, special calculations need to be

carried out to obtain the control limit values. This calculation process will produce important information in interpreting the results of the  $\bar{X}$  control chart and the R control chart. The following are the calculation steps required for each control limit on the two control charts.

Control Map  $\bar{X}$

$$CL = \bar{\bar{X}} = 20,963 \tag{1}$$

$$UCL = \bar{\bar{X}} + (A2 * \bar{R}) = 20,963 + (0,577 * 1,319) = 21,724 \tag{2}$$

$$LCL = \bar{\bar{X}} - (A2 * \bar{R}) = 20,963 - (0,577 * 1,319) = 20,201 \tag{3}$$

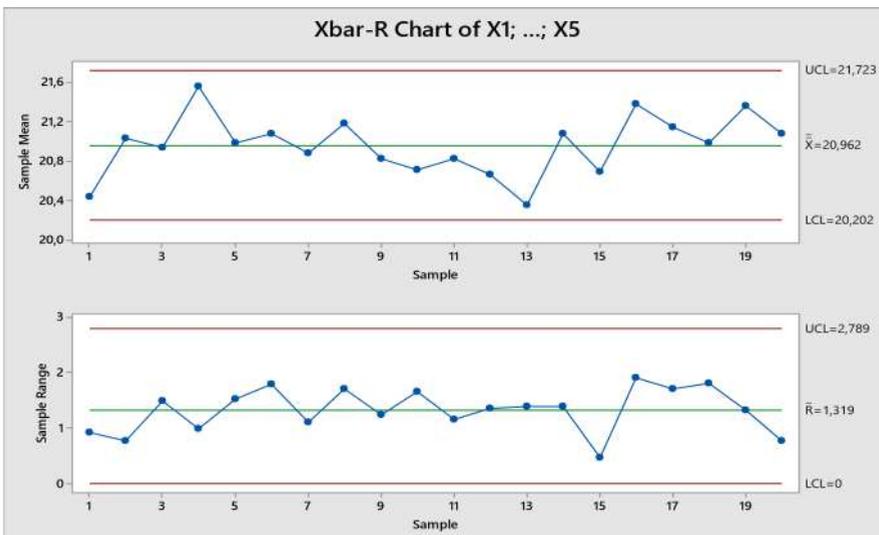
Control Map R

$$CL = \bar{R} = 1,319$$

$$UCL = (D4 * \bar{R}) = (2,114 * 1,319) = 2,788 \tag{4}$$

$$LCL = (D4 * \bar{R}) = (0 * 1,319) = 0 \tag{5}$$

Then, using Minitab software to create a control chart  $\bar{x}$  and R. From **Fig. 1**, it can be seen that all data points do not show any data that is outside the previously determined control limits. This indicates that the data distribution is currently in a controlled condition [9]. In other words, the distribution of this data is within predetermined control limits, indicating the stability of the process being observed.



**Fig. 1** Plot of Control Map Data  $\bar{x}$  and R

Data that has been maintained within control limits allows the next step, namely the calculation of the process capability index ( $C_p$ ), to be carried out. The purpose of this calculation is to evaluate whether the ongoing process meets the specified tolerance limits [10]. The results of the  $C_p$  calculation will provide insight into whether improvements to the process are needed or vice versa. The formula used in this calculation is as follows:

USL = 23  
 LSL = 19  
 s = 0,3949

$$CP = \frac{USL - LSL}{6s} = \frac{23 - 19}{6(0,3949)} = 1,69 \tag{6}$$

The calculation results of the capability index (Cp) reached 1.69, indicating that the process capability is at an adequate level. Having a Cp value that exceeds 1 is a positive indicator of the quality and consistency of the process. In the next stage, the Cpk index calculation will be carried out by calculating the CPU and CPL values first, using the following formula:

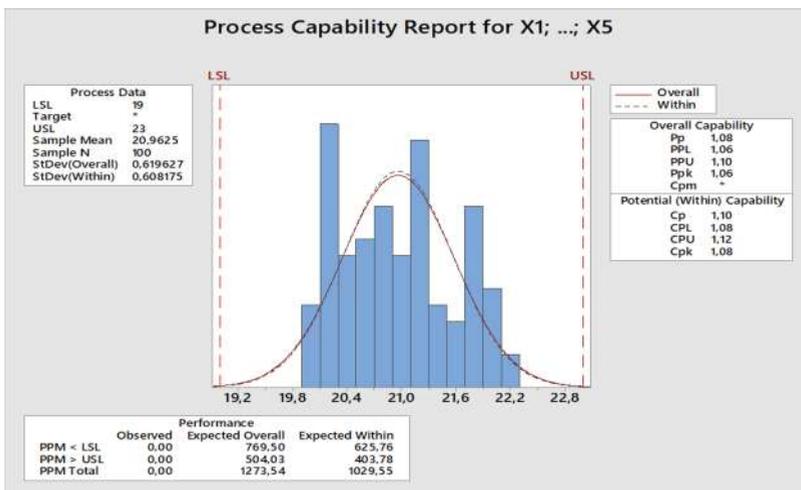
USL = 23  
 LSL = 19  
 S = 0,3949

$$CPU = \frac{USL - \bar{X}}{3s} = \frac{23 - 20,963}{3(0,3949)} = 1,72 \tag{7}$$

$$CPL = \frac{\bar{X} - LSL}{3s} = \frac{20,963 - 19}{3(0,3949)} = 1,66 \tag{8}$$

$$Cpk = \text{Min} \{CPU, CPL\} = \text{Min} (1,72; 1,66) = 1.6 \tag{9}$$

From the calculation results, the Cpk value is 1.66. Reviewing this value, which is also equivalent to the Cp value, indicates that the process is in balance, producing a product according to the specified specifications. Therefore, at this stage, there is no need for further remedial action. For a clearer picture, below is the Process Capability graph in **Fig. 2** which represents the process capability analysis of thread strength data in the Pull Tensile Strength process for surgical suture products.



**Fig. 2** Control chart process capability graph  $\bar{x}$  and R

## 4 Conclusion

Based on data processing and discussion above, the conclusions that can be drawn are: (1) Control of the surgical suture production process for improving quality at PT. XYZ already meets production process standards. This can be seen in the control chart graph shows where the points are within the control limits and the point fluctuates in order. This is an indication that the process is in a state controlled or not subject to deviation; (2) Ratio process capabilities  $C_p$  1,10, shows that the process is said to be feasible and there should be no need for corrective action even if the process is perfectly at center 80; (3) Index process capabilities  $C_{pk}$  1,08, indicates that the accuracy of the process is good. This means that the quality of the process does not need to be improved. For future research, seven tools that exist in management total quality control namely; check sheet, histogram, control chart, pareto diagram, cause and effect diagram, scatter diagrams, and process diagrams can be used.

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