Impact of Smart Incoming Inspection System on the Production, in a Medical Device Manufacturing MSME

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1 Introduction

Quality-related issues and challenges are critical to be addressed during manufacturing [1]. Quality control in manufacturing plays a significant role in finding defective parts and processes and assuring quality outcome throughout the intended life cycle of the product. It is a vital part in the Quality Management System (QMS) which dictates the requirements of quality assurance as a regulation and standard [2]. Hence, to integrate the quality system, organizations need to follow the standards recommended by regulatory agencies and government bodies. The standards are so important that if not followed, it might affect the life of the consumer (e.g. medical devices, automotive parts, aerospace parts).

Quality assurance is defined in ISO 9000–2000 as "part of quality management focused on providing confidence that quality requirements are fulfilled" [3]. The term quality control refers to the activities or tools that are used to provide this assurance. Quality-related in-process inspection/verification is an essential part of quality control in manufacturing. Inspection in manufacturing includes measuring, examining, testing or gauging one or more characteristics of a product or process and comparing the results with specified requirements to determine whether the requirements are met for each characteristic [4]. To perform inspection activities, accurate measuring instruments are needed. Normally, this instrument is purchased; however, it may be necessary to design and build it in cooperation with process design [5]. Using human for 100% inspection requires considerable manpower that significantly increases costs and the time for inspection [6]. Even though the recent advancements in manufacturing systems have been characterized by precision of

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work through automation [7]. It is very difficult to automate any manufacturing system due to budget constraints, space constrains or lack of skilled labour [2].

The issues and challenges are mostly encountered in the MSMEs. The Indian MSMEs are the main contributors of the Indian economy, especially in medical devices, 65% of the indigenous manufacturers are categorized under MSME in India. There are 750–800 domestic medical device manufacturers in India, with an average investment of $2.3–2.7 million and an average turnover of $6.2–6.9 million and contribute 30% or (USD 1.1 billion) to the Indian medical devices market [8]. Even with this huge contribution the MSMEs struggle to compete with the global market. There are various reasons for the enterprises like lack of manpower, lack of resources, time, regulatory challenges, cost etc.

This research started in a focus to identify the challenges faced during the implementation of QMS for the certification of medical devices in Indian MSMEs. During understanding of the quality control activities of a local orthotic footwear manufacturer, it was found the inspection of the raw materials was not being performed. This was mainly due to the unaffordability of the state-of-the-art inspection setup. Therefore, a bespoke smart incoming inspection system was developed which uses off-the-shelf cameras and image processing techniques to capture image, analyse the defects and show the defects on the UI. The testing of the developed system for various light condition and for different colours of the raw materials was established earlier [9]. Brewer et al. [10] rightly said that reduction of waste, production cycle time, other non-value-added time or inventory is the purpose of a new technology, not the introduction of the technology itself.

The performance of the system was analysed using the six sigma DMAIC methodology. Statistical analysis of the final inspection data before and after introducing the smart incoming inspection system showed a significant change in the rejection rates. The impact on production was indicated by improvement in the FPY.

2 Literature

Quality means freedom from deficiencies and features of products which meet customer needs and thereby provide customer satisfaction [1]. Freedom from deficiencies is freedom from errors that require doing work over again (rework). Quality-related research has been an interesting topic among researchers for decades. Various researchers have worked on the rejection rates using different quality control methods. Most notable is by using six sigma methodology using DMAIC (Define-Measure-Analyse-Improve-Control) approach.

Gijo and Scaria [11] discuss the implementation of six sigma methodology in reducing rejection and rework in a honing process in an automobile part manufacturing company, where six sigma implementation in a manufacturing process for improving quality resulted in reduction of rejection and rework, thus improving the first pass yield from 88 to 100%. At one of the Indian small-scale unit, to improve rejection/rework rate in manufacturing products by pressure die casting process,

quality was improved from 3.1σ to 3.7σ by reducing the rejection rate from 15.50% to 4.47% which is 71.2% improvement [12]. By making modification in the design of tool, viz., jig, the process sigma level is improved from 1.5 to 4.15, while the reworking rate in the manufacturing of track shoe was decreased to almost zero; this resulted into no delay in delivery and improved customer satisfaction [13]. To reduce the rejection rates, some jigs and fixtures were designed which in turn reduced the setup time and adjustments for a pump casing manufacturing using the DMAIC methodology [14]. Also, the smart manufacturing (referred to as Industry 4.0 also) has the major contribution on QMS, using smart factories, cyber-physical systems (CPS), Internet of Things (IoT), etc. [15].

3 Methodology

To understand the quality-related issues associated with QMS, a local medical device manufacturing micro-enterprise was selected. The company produces a low-risk orthotic footwear used to cure medical conditions like calcaneal spurs, corns, heel cracks, heel pain, etc. by providing customized footwear with medial arch for flat feet, cushioned heel for heel pain, scooped insoles or offloading for ulcers, crow shoes and ankle shoes for specific foot disorders, outsole modifications for differential height, soft packed insole for corns and so on.

The footwear consists of different materials in both upper and sole parts. The bottom sole part is divided into three parts, namely, bottom sole, midsole and insole. The bottom sole is made of 10-mm-thick rubber material. The midsole is a 10 mm Ethylene–Vinyl Acetate (EVA) foam material. The insole is also a 2 mm EVA foam material. The insole is the part which directly encounters the human foot. Therefore, the raw material of the insole is considered for the inline inspection just before it gets assembled with the midsole.

To ***Define*** the problem—during the production process, the rejections are made if the defects are encountered (see Fig. 1). These rejected parts are then scrapped and considered as waste. Figure 2 shows the percentage of the insole rejections, where close to 64% are because of the rejections of insoles with defect. This is the ***Measure***

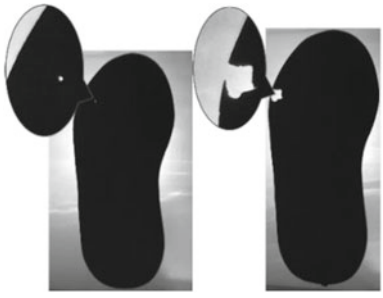

Fig. 1 Defects encountered

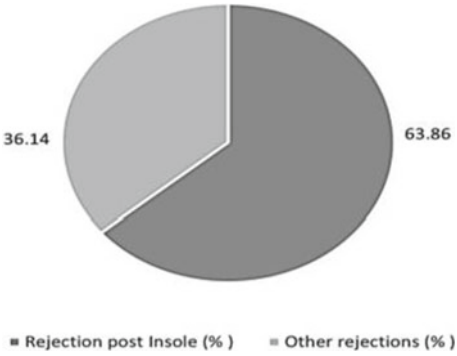

Fig. 2 % Rejections post insole cutting

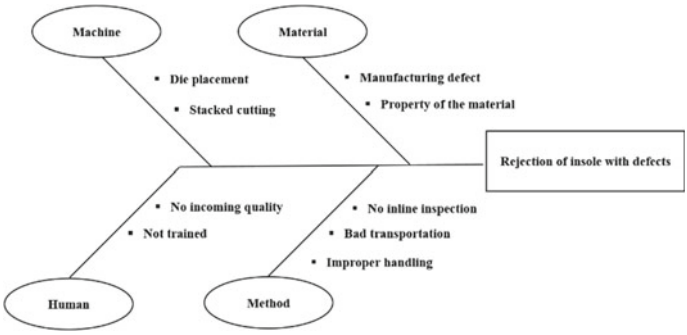

Fig. 3 Cause-and-effect diagram for the rejections of the insole

of the problem. To ***Analyse*** the problem, a cause-and-effect diagram is constructed (see Fig. 3) for the rejection of insoles with defects.

4 Experimentation

To avoid the wastage of resources like material, time and manpower, a smart incoming inspection system is proposed to introduce in the incoming stage of the raw materials to the production line (see Fig. 4). This incoming quality control stage will not only serve as a quality assurance but also a necessary inclusion to comply with the quality management system of the organization.

The design of the smart inspection system, identification of the defects and testing for various light settings were performed successfully. It has been proved the defects of at least 1 mm of size are identified within a range of 3100 lx to 3250 lx with both surface and bottom light settings [9].

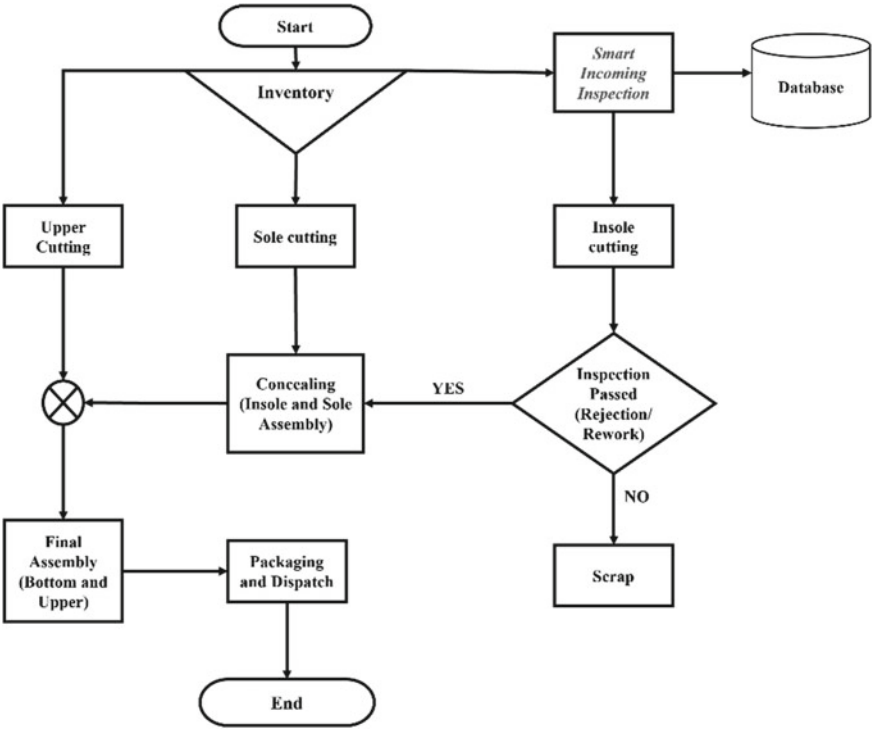

Fig. 4 Production line with the smart incoming inspection included in the insole cutting line

The raw materials were investigated using the system and labelling was done on the defects as highlighting. This helped the worker at the cutting station to notice the defective sheets. The barcode was used as the identification method which helped in registering the number of defects identified in each sheet during the smart inspection. The cutting operation was then performed by altering the stacking procedure of the sheets, which prevented the defective areas of the sheet being included in the cut-out insole pieces. The batch of cut sheets into insole was then moved to the concealing area where it was then glued with the midsole using a special adhesive. Prior to this stage is the inspection of cut insole and most of the rejection takes place here.

The program was designed to capture the defects in two forms. One is capturing the image of the defective area and storing it in local as well as cloud database and another to store the coordinate values of the defects. The latter will also have the information of the sheet, viz, dimensions, colour and unique ID (Barcode). The inspection was carried out for a batch of black and brown colour EVA sheets which was issued by the inventory for production. These sheets are examined for any defects but the data on rejection at the concealing process was collected for 4 weeks before the experiment was conducted.

To establish statistical significance for the two test groups, the experiment was based on rejecting the null hypothesis. (H0: $\sigma_1{}^2 = \sigma_2{}^2$). The hypothesis testing is by accepting alternate hypothesis (Ha: $\sigma_1{}^2 \neq \sigma_2{}^2$).

5 Results

To test the hypothesis, the data of rejection rate at the pre-concealing stage over the span of 5 weeks were collected N = 15 with $M = 1.609$ and $SD = 1.282$. Similarly, the data was collected at this stage for another 2 weeks, but for those raw materials which had undergone smart incoming inspection N = 7 with $M = 0.421$ and $SD = 0.630$. The introduction of incoming inspection enabled the production supervisor to record the defective areas in the raw material sheets. The recorded data were then statistically analysed to check for the significance and reject the null hypothesis (H_0: $\sigma_1{}^2 = \sigma_2{}^2$). An *F*-test (see Table 1) was performed to test the homogeneity of the variances of two populations with $\alpha = 0.05$ as criterion for significance $F\ (6,14) = 4.14$, $p = 0.045$. This test is a one-tailed test as to reject null hypothesis and shows the two-sample means are not equal, i.e. alternative hypothesis (Ha: $\sigma_1{}^2 \neq \sigma_2{}^2$). The independent sample *t*-test (see Table 2) was conducted to show the significance since the sample sizes were not the same, $t\ (20) = 2.911$, $p = 0.0086$. As the significance value α is greater than the value obtained by *t*-test, the null hypothesis can be rejected. There is enough evidence to establish the means of two samples are different and to claim the alternate hypothesis. Thus, it is evident the rejection rates after introducing incoming inspection are significant than the rejection rate without the inspection.

Figure 5 shows the rejection rates (RR_o) without inspection and rejection rates post inspection (RR_i) and the standard error mean of 0.33 and 0.23, respectively.

The ***Improve*** of the DMAIC is addressed by analysing the results after the statistical testing. The inspection of raw materials not only reduced the rejection rate but also improved the First Pass Yield (FPY) from an average of 97.65–99.52% contributing up to increase in 1.88%. As the production initiated post incoming

Table 1 F-test two-sample for variances of rejection rates with and without the smart incoming inspection

	Rejection rate (RRo)	Rejection rate (RRi)
Mean	1.609	0.421
Variance	$\sigma_1{}^2 = 1.645$	$\sigma_2{}^2 = 0.397$
Observations	15	7
df	14	6
F	4.14	
P(F < = f) one-tail	**0.045**	
F Critical one-tail	3.956	

Table 2 t-test: two-sample assuming unequal variances of rejection rates due to the unequal sample sizes

	Rejection rate (RRo)	Rejection rate (RRi)
Mean	1.609	0.421
Variance	$\sigma_1^2 = 1.645$	$\sigma_2^2 = 0.397$
Observations	15	7
df	20	
t Stat	2.9108	
P(T <= t) one-tail	0.0043	
t Critical one-tail	1.7247	
P(T <= t) two-tail	**0.0086**	
t Critical two-tail	2.0859	

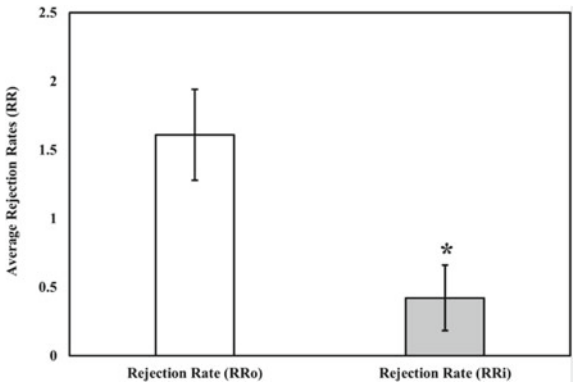

Fig. 5 Average rejection rates without and with inspection

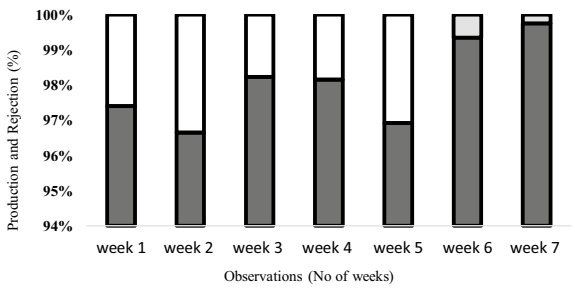

Fig. 6 Average weekly First Pass Yield (FPY) tracked over the weeks of the study. Weeks 1–5 are without smart inspection system while weeks 6 and 7 were after introduction of smart inspection system

inspection, the rejections on week 6 and week 7 are comparatively low which contributed on the overall FPY (see Fig. 6).

The ***Control*** is shown using a control chart (Fig. 7) with mean of $\mu = 1.231$ and an upper control limit (UCL) of $\mu + 3\sigma = 4.943$. The number of rejections which was closer to the UCL can be seen to be under control and equalizes to zero as the number of days go by with the inclusion of smart incoming inspection system to

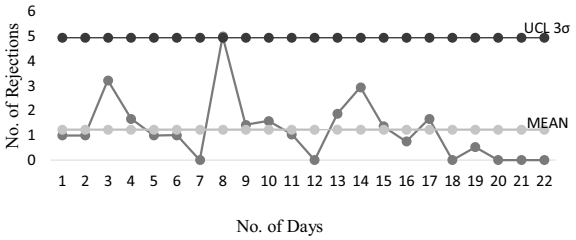

Fig. 7 Control chart for the number of rejections shown across the number of days. Number of rejections reduced from day 16 once the smart incoming inspection was introduced. (the lower control line is assumed 0, since rejections cannot go negative)

the production line. Since the mean is very close to zero the lower control line is assumed to be zero as the number of defects cannot become negative.

6 Conclusions

The quality-related challenges in a medical device manufacturing MSME were the adoption of state-of-the-art inspection system. A bespoke smart incoming inspection system was proposed and developed. It was tested for its performance in live production line of partnering MSME. The six sigma DMAIC methodology was adopted for the quality control. The incoming raw materials were tested, and inspection data was analysed using statistical process control method for the rejection rates before and after introducing incoming inspection stage and smart incoming inspection system in the production line. The analysis resulted in more than threefold decrease in rejections and improvement in FPY by 1.88%.

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