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KAIZEN WORKSHOP: PRODUCTION PROCESS IMPROVEMENTS FOR A MEDICAL COMPONENTS MAQUILADORA

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KEYWORDS: Kaizen, Maquiladora, Metrics, Improvement.

ABSTRACT
The maquiladora industry has become the most important economic sector in the region of Sonora, with exponential growth and major surges in the automotive, electronic, and medical device industries in recent years. These are in constant evolution due to scientific and technological advances, which require manpower that can provide quality. The project, which consists of the analysis of workstation, due to an increase in customer complaint indicators and products to be reworked, was developed in Empalme, Sonora, at a medical maquiladora company. To deal with this situation, the objective was set to improve production process indicators through the implementation of continuous improvement tools. The Kaizen, or continuous improvement methodology, proposed by Masaaki Imai in 1980, in which the participation of all levels is of vital importance. The methodology places emphasis the changes to achieving continuous improvement. The above produces a significant improvement in scrap, RMA, and PPM metrics, reaching values of 20, 10, and 21,000, respectively, thus contributing with a quality operation and product.

Resumen: La industria maquiladora se ha convertido en el sector económico más importante en la región de Sonora, con un crecimiento exponencial con el paso de los años. Siendo la industria Automotriz, electrónica y de dispositivos médicos las que han tenido un auge importante en los últimos años. Estas se encuentran en constante evolución debido a los avances científicos y tecnológicos, las cuales necesitan de mano de obra que pueda proporcionar calidad. En Empalme Sonora se localiza una maquiladora de giro médico, lugar del desarrolló del proyecto, el cual consiste en el análisis de una estación de trabajo, debido al incremento en los indicadores de quejas de clientes y productos para re-trabajar. Para poder hacer frente a tal situación se planteó el objetivo de mejorar los indicadores del proceso de producción mediante la implementación de herramientas de mejora. La metodología empleada es la de mejora continua Kaizen propuesta por Masaaki Imai en 1980 la cual hace énfasis en la participación de todos los niveles y en los cambios para lograr la mejora continua. Al aplicarla se produjo una mejora significativa en los métricos de Scrap, RMA y PPM ubicándolos en 20%, 10% y 1300 respectivamente contribuyendo así con la calidad de la operación y del producto.

Palabras clave: Kaizen, Maquiladora, Indicadores, Mejora.

INTRODUCTION
In México, the exchange of goods and services is a core activity, mainly due to massive production volumes, low costs, trade agreements, and the quality with which they are produced in the maquiladoras (Martínez, 2013). These entities have focused on ecological and labor issues (salaries, working conditions) and on the development of technologies that offer a better quality of life (Salazar and Carrillo, 2010), thus promoting accelerated growth in the manufacturing of medical, surgical, and dental devices, among others, and placing the country among the main exporters of medical devices in the world (ProMéxico, 2015).

The company under study is in the medical device processing business, has three business units, and is distributed into manufacturing cells. Each cell processes different part numbers, divided into families of products, whose activities include X-rays, electrical tests, soldering, and inspection, among others. The quality area is in charge of evaluating these products based on customer specifications, of approving the unit by shipping it to the shipping area or else filing a rework order, or failing that, labeling it as scrap.

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All cells generate scrap in different ways and in different quantities. Every month, aspects relating to production, hours worked, scrap, productivity, and customer complaints are scored. All this information is registered digitally and is published as indicators so that all staff can be aware of the status of the process. When revising the number of customer complaints, the cell with the greatest number of non-conformities was identified, thus being cataloged as an area of opportunity. When exploring the relationship between the non-conformities in the aforementioned cell with the 12 products that it produces, A shows 84 calls to attention, with the remaining showing 20 or less (see Figure 1A). For its part, the indicator Parts per million (PPM) in the same cell shows an average of 33,000 which reflects a risk situation in terms of quality, given that a goal of 1,300 per product is considered (see Figure 1B).

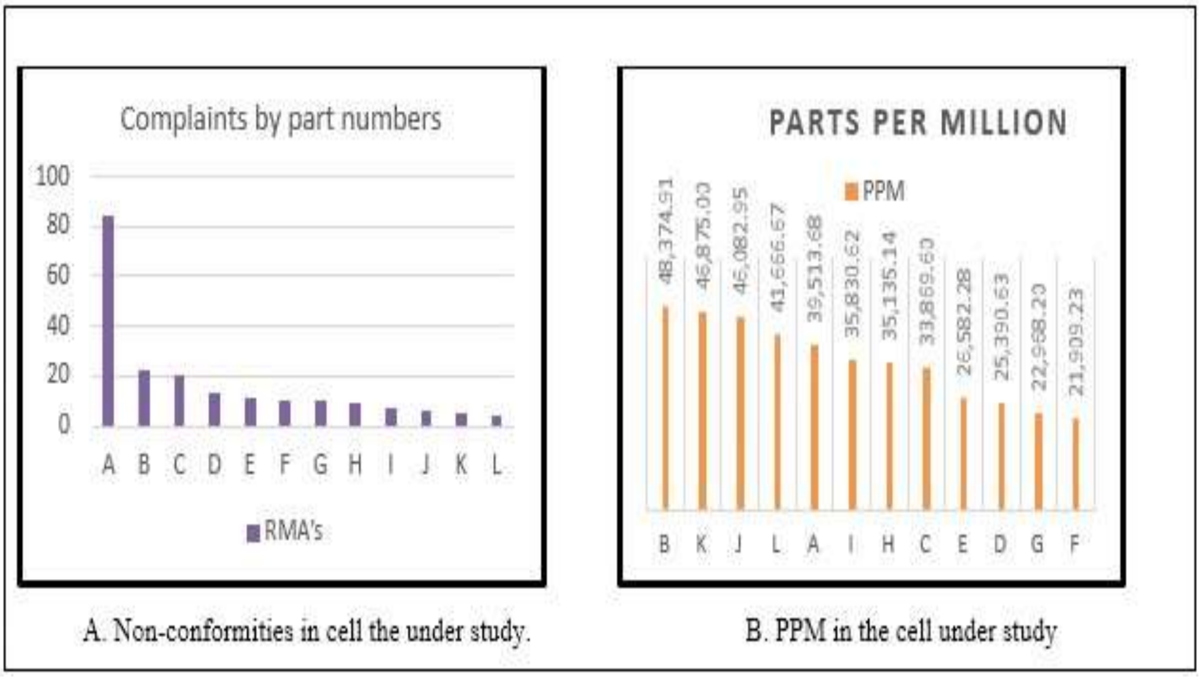

Figure 1. Operational indicators from the cell under study.

The preparation of a type of linear transducer requires the following steps: place tape on the cable set, affix the cover, prepare the kit, maneuver the panel, solder, prepare the ends, carry out electrical tests, and inspect the finished product. Once this is done, the product is taken to the shipping area to be sent to the customer. When a non-conforming product reaches the customer, a warning called an RMA is filed, which is a Return Merchandise Authorization, making the company liable for a refund, repair, or replacement. This indicator has been increasing lately, causing customer dissatisfaction. In light of this situation, the company poses the following question: What actions should the maquiladora company implement to achieve improved quality indicators in the cell under study?

OBJECTIVE

To implement actions that allow improving the main production process indicators in a medical maquiladora company.

DESCRIPTION OF THE METHOD

The methods proposed by Gutiérrez (2009), Socconini (2008), and Cerecer (2016) — all related to continuous improvement and complemented with some features from (Jackson, 2013) — were used to develop this project,. The steps were: Plan the improvement process: in this phase, reference is made to the place, the period of time, the reasons, the goals, and other aspects of the project using the 5W +1H tool; obtain and analyze data: here, data of interest were gathered, stratifying them by means of Pareto charts; determine the causes of the problem: this is

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achieved through the use of the Ishikawa diagram; develop solutions: here, a list of improvement actions was generated to counteract the root causes of the identified problems, which required a Kaizen event; verify the impact of the improvement: as a final step, a comparative table was made of the indicators before and after implementation.

RESULTS

For a clearer vision of the problem as well as an improvement plan, the 5W+1H method was applied, in which each participant responded to the questions. The results are shown in Table 1.

Table 1. Planning the improvement process through 5W+1H

Questions 5W+1H	*Why is this necessary? What is going to be done? When should it be done? Who is most qualified to do it? Where should it be done? How should it be done? How will it be validated?*
WHY?	To improve customer complaint, PPM, and Scrap indicators.
WHAT?	Analyze the data, identifying the origin of the defects to determine the root cause, until improvement actions are generated.
WHO?	The persons involved are: the Operational staff, the Quality Engineer, the Quality technician, the Process engineer, and the Manufacturing engineer.
HOW?	A Kaizen event will be carried out, closely following a methodological structure and responding to the problem raised in a timely manner.
WHERE?	In the cell under study
WHEN?	The problem will be dealt with immediately and the validation process will take place two months later by reviewing indicators with respect to their goals.

Source: Prepared by the authors, 2017.

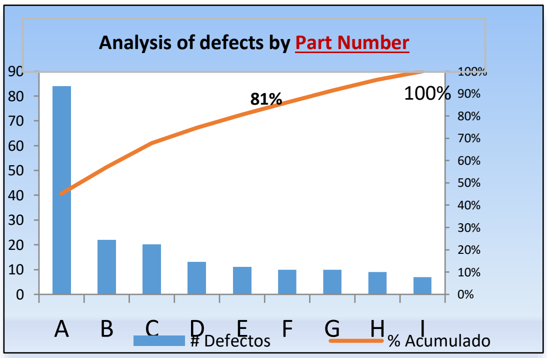
A particularly notable aspect in the above table is the interest in improving customer complaint, PPM, and Scrap indicators, through a Kaizen event involving all staff related to the cell under study, as this is one of the main conditions for guaranteed success. Once the improvement plan was established, an analysis was carried out on the defects by part number, by work station, and by type, which will be used to determine the causes of the problem (see Table). 2).

Table 2. Definition of the problem and the causal analysis (Kaizen).

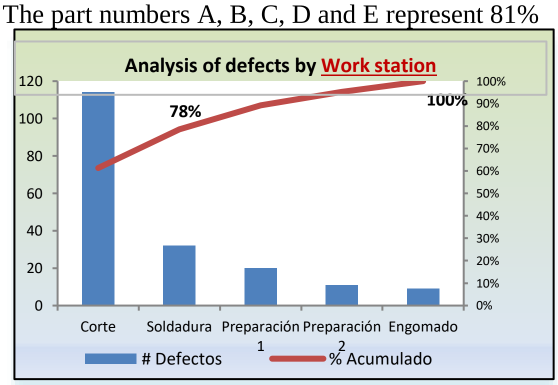
KAIZEN Improvements

Chain/Area:	Line:	Date:	#Kaizen
Impact on:	☐Security ☐Quality	☐Productivity ☐Cost	

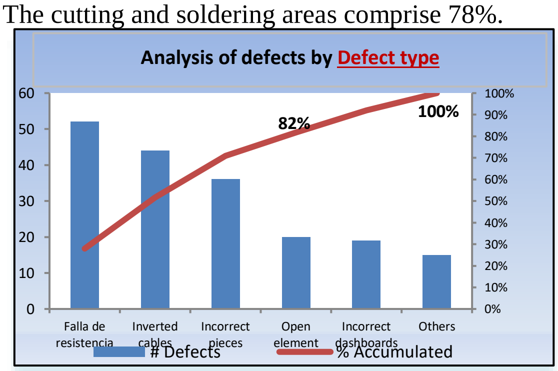
A. DEFINITION OF THE PROBLEM



The part numbers A, B, C, D and E represent 81%

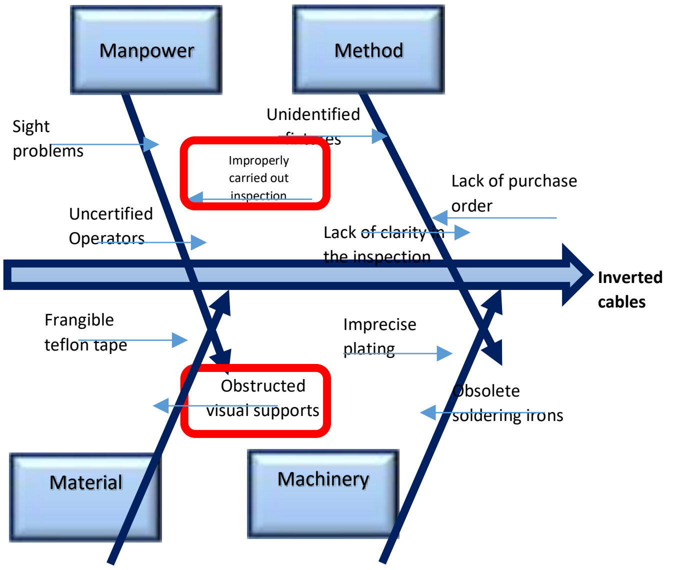


The cutting and soldering areas comprise 78%.



Resistor failure, inverted cables, incorrect pieces, and open element amount to 82%.

B. CAUSAL ANALYSIS



Main defects	Root causes
Resistor failure.	➢ Process omission ➢ Laser power variance ➢ Lack of process inspections
Inverted cables.	➢ Improper inspection ➢ Obstructed visual support
Incorrect Flex and Handle.	➢ Lack of detail in visual inspection ➢ Similar handles ➢ Similar flexes ➢ Mixed components
Open element.	➢ Lack of operator ability ➢ Unclear assembly instructions ➢ Improper global bend and cut ➢ Not following assembly instructions carefully

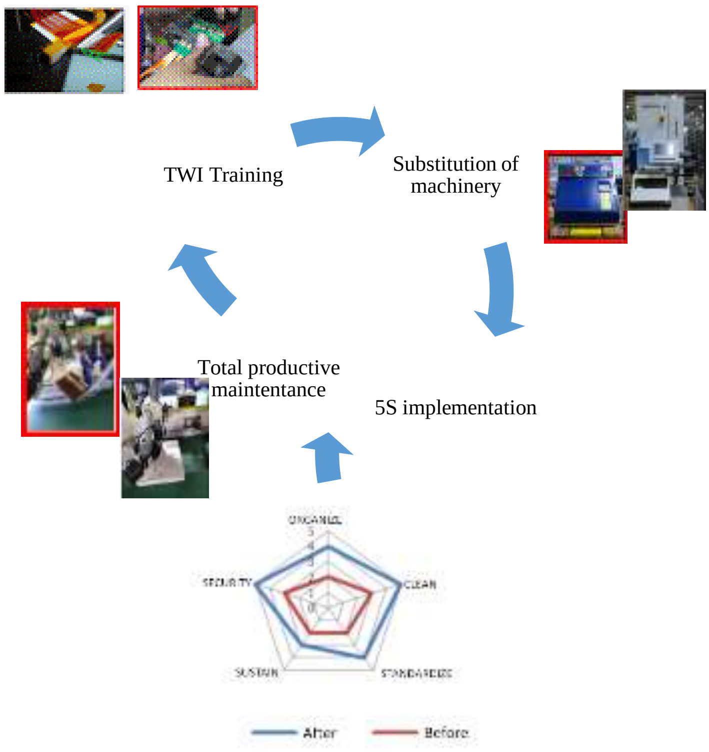
The above table registers the main defects (section A) and the main causes for each defect and the root causes (section B) in two sections, using the causal analysis as a sample for one of these. It was thus determined through the 80-20 rule that: the majority of the defects occur at the cutting and soldering stations; the part numbers involved are A, B, C, D, and E; and the most frequent types are resistor failure, inverted cables, incorrect pieces, and an open element. Once the causal analysis was carried out for each defect mentioned, a table was created at the end of section B with the root causes identified, chief among them being process omission and improper bend inspection and operation, among others.

As a next step, the root causes were grouped according to origin (method, manpower, machinery, material) to brainstorm actions to undertake in order to improve the indicators, such as the implementation of a 5S program, TWI training, the implementation of total productive maintenance, and the substitution of machinery (see Table 3).

Table 3. Improvement actions

C. IMPROVEMENT ACTIONS

Problems: Resistor failure, Inverted cables, Incorrect Flex and Handle, and Open elements	
Root causes.	Actions
MANPOWER ➢ Process omission ➢ Improper inspection ➢ Lack of operator ability ➢ Not following assembly instructions carefully	➢ Training in the process and importance of quality control.
METHOD OF OPERATION ➢ Lack of process inspection ➢ Lack of details in visual inspection. ➢ Unclear assembly instructions. ➢ Obstructed visual support	➢ Assignment of the assembly method. ➢ Updating the assembly and quality instructions
MATERIAL ➢ Similar handles ➢ Similar flexes ➢ Mixed components	➢ 5S Implementation program
MACHINERY ➢ Improper global bend and cut ➢ Obsolete machine. ➢ Variation in laser power.	➢ Preventive maintenance ➢ Assignment of a new machine.



The training sessions, based on TWI, were carried out once the instructions were updated. The training focused on detecting defects during the assembly process, updating processes, and establishing the quality circles. As regards the 5 S program, each step arising from this philosophy was implemented in a timely manner, achieving increased evaluation scores. As part of the standardization, visual supports were designed to easily distinguish flexes from handles, so as not to confuse these, and staff were instructed to continue following the organization's methods to avoid this problem. Preventive maintenance led to the preparation of a registry to clearly establish the target dates for same and to give follow-up. Changes to machinery changes were carried out in due time and manner under the terms set by the production area, so as not to interrupt flow. To validate the results, the indicators were compared before and after the improvements were implemented, obtaining the following:

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Table 4. Validation of the results

Indicator	Previous state	Current state	Goal
Scrap	28%	20%	20%
RMAs	13%	10%	10%
PPM	34,746	21,000	1,300

The scrap index was reduced, as were the RMA indicators (customer complaints), meeting the proposed goal; however, while it is true that the PPMs show a reduction of nearly 50%, it was concluded that the goal was not met, although there was indeed a significant reduction. To finalize the Kaizen event, the results were made known through management, recognizing the efforts and achievements of the work team, which, if the indicators continue to be monitored, will allow responding in a timely manner, bringing with it long-term benefits.

CONCLUSIONS

By implementing concrete actions, an improvement was achieved in the main production process indicators of the medical maquiladora company under study: scrap (from 28 to 20%), RMA (from 13 to 10%), and PPM (from 34746 to 21,000). As part of the Kaizen method, it was necessary to implement a 5S + 1 program, achieving an increased score in each aspect, with security and housekeeping showing the maximum values.

The acquisition of a new laser machine reduced the number of resistor failure defects, and consequently, those related to scrap, as noted above; however, this change was only in one part of the process, leaving two more machines to be changed. Successful TWI training is rightly added to the above, which, together with maintenance, helped to avoid shipping defective products and the resulting customer complaints (RMAs).

Special emphasis should be placed on quality inspection instructions, as inspectors follow these to the letter; an incorrect quantity number, sub-assembly, color, or name, can generate huge problems for the organization. Likewise, the creation of a software program for reporting findings in inspections, instructions, processes, and products, among others, is recommended, so that these can be reported in real time to all area members and ultimately to follow up on Kaizen events in other areas of the company.

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