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Lean Manufacturing Implementation in a Protective Mask Production Process: A Case of Study in Quito

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Introduction

Face masks have been important to the personal protection against the COVID-19 pandemic, in different fields such as academic, industrial, and others., The dominant factors in mask performance are currently being investigated, including the thickness and filling rate of melt-blown fibers for a filtering layer (Shi et al., 2021). Masks are manufactured with nonwoven materials, such as spunbond (S) and melt-blown (M), which are most often utilized in composite form, in spunbond - melt-blown - spunbond type structures designated as SMS fabric (Hutten, 2015).

The fast spread of COVID-19 is driven by a major route of person-to-person transmission via viral saliva droplets (> 10 μm) and aerosols (<10 μm), which infected people release into the air when they breathe, talk, cough, or sneeze. Viral aerosols less than 5 μm in diameter are critically dangerous, as they remain suspended in the air for long periods and can reach the lower respiratory tract of a susceptible host (Kutter et al., 2018). Wearing a protective mask is fundamental to avoid propagation of the virus, as Leung et al. (2020) demonstrated when stating protective mask use reduced viral transmission from 30 % of positive cases to 0 %, at droplet diameters less than 5 µm and from 40 % of positive cases to 0 % in aerosols with droplet diameters above 5 µm. Drewnick et al. (2021) indicated that surgical masks and KN95 have a higher than 80 % for small particles, between 30 to 250 nm, compared to handcrafted masks, which only efficiently filter large particles from 0.5 to 10 µm.

The efficiency of the masks is due to the unique, single-step melt-blown process to obtain fibrous nonwoven membranes from polymeric resins, with an average fiber diameter from 1 to 10 µm (Hassan et al., 2013). However, by modifying the processing parameters, it has been possible to obtain fibers up to 36 nm (Soltani and Macosko, 2018). Masks are already part of people's daily, but by reusing them after 3 days, their filtration efficiency decreases rapidly, approximately 12%, and by continuing to reuse them for another four days, the mask filtration efficiency drops drastically to 55% (Wu et al., 2021).

Sterilization as a method of mask reuse is carried out with vaporized hydrogen peroxide (VHP) and it is the only method currently approved by the U.S.A. Food and Drug Administration (FDA). By applying VHP, the level of hydrogen peroxide decreased to 0.6 ppm, below the safe limit of 1 ppm for 2 hours after treatment, and became undetectable after 3 hours. Nevertheless, the VHP treatment has several limitations, including the cost of the technology, degradation of the elastic bands, and organic waste deactivation of the hydrogen peroxide. Due to the decrease in filtration efficiency over time and the challenge of reuse, it is necessary to change the mask at least in 3 days and at most in 7 days (Ju et al., 2021).

The World Health Organization (OMS) recommends the use of masks in public and private spaces, leading to an increase in demand and greater production by specialized companies in mask manufacturing. The case study is a company in the city of Quito, where the production of surgical masks tripled. Before the pandemic, the annual production was 9'000 000 units and now the annual production is 27'000 000 units. KN95 masks were recently introduced with an annual production of 2'880 000 units. This information coincides with Ardusso et al. (2021), indicating that the monthly mask production in the Colombian plastic industry increased from 2 to 10 million surgical masks and 60,000 to 100,000 units for N95 masks, affirming the trend in South America to increase mask production. Considering the current demand as well as the production, it is necessary to implement the Lean Manufacturing (LM) methodology in the company that manufactures the masks. Bhadu et al. (2022) state that the main objective of LM is to implement a philosophy of continuous improvement that allows companies to reduce costs, improve processes, and eliminate waste to achieve customer satisfaction and maintain profit margins.

There are direct benefits of lean tools in the textile industry, as Demirci and Gündüz (2020) demonstrated, by combining the techniques of value stream mapping (VSM) with the time measurement method for universal system analysis. By eliminating non-value-added activities and standardizing the movements, it was observed that the production time reduced at a rate of 56 %, and also the duration of non-value-added activities improved by 57 %. By applying the VSM tool in a Peruvian textile company, it managed to reduce the rework by a defect from 13.12 to 4.23 %, decreased the processes that were delayed from 18.49 to 9.61 %, and increased the productivity index of the cutting area from 0.38 to 1.16 (Alanya et al., 2020). Guleria et al. (2021) applied LM to the production of filter media and obtained a reduction in the rejection of the final product from 12 to 4%. Likewise, in the finishing and dyeing of textiles, a reduction of up to 8.14% in reprocesses has also been achieved (Romero-Sánchez et al., 2019).

The objective of the present study is to improve the melt-blown area of a company dedicated to protective mask manufacturing by implementing the Lean Manufacturing methodology. It is important to mention that this area started operations in October-November 2020 and the line is not adequately balanced to work with synergy with the subsequent areas. The document is divided as follows: Methodology describes the activities in the field data collection process. The Results present the calculated values and the presentation of comparative Figures. Finally, Conclusions synthesize the information in an objective way for the evaluation of the fulfillment of the proposed objective.

Materials and Methods

The methods to be used are mainly exploratory and descriptive, based on the collection and analysis of data from the melt-blown area, through written and/or digital documents containing specialized bibliography, and interviews with people involved in the production process of the masks. It also includes applied research, understood as an efficient alternative response to the current pandemic need and the industrial situation of health and biosafety.

Approach and Variables

In an approach based on the lean manufacturing philosophy, any use of resources or actions that do not generate value for the customer is considered waste and should be eliminated. This means that with Lean, only what the customer asks for is produced (Tissir et al., 2020). Therefore, the variables considered are two, production and enterprise. The indicators for production are Operating times and the reduction of waste. For the company variable, they are Quality and competitiveness. The results of the documentary and bibliographic research will contribute to the necessary data for the thematic development and its consequent theoretical-practical inferences that allow obtaining the necessary conclusions.

Collection of information

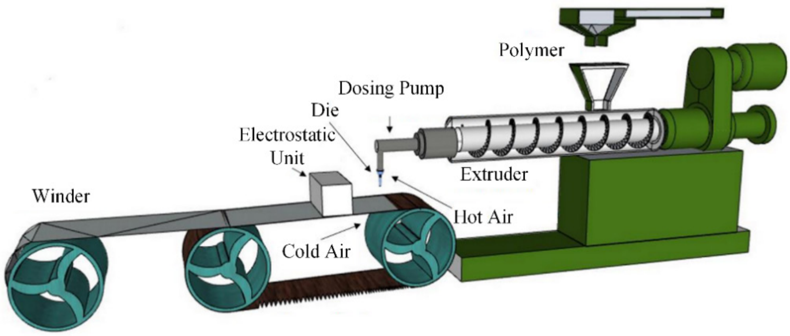
For health research, it is common to use the Odds Ratio (OR) as a way of expressing the possibility of the occurrence of an event of interest or the presence of exposure (Cerda et al., 2013). A systematic review and meta-analysis of a total of 5178 eligible articles in databases and references from different countries showed that the use of a facemask is associated with a significant reduction in the risk of COVID-19 infection (OR = 0.38; 95 % CI: 0.21-0.69) (Li et al., 2021). This means that the chance of occurrence of infection is 38 % with a confidence interval of 95 %. The results show a concordance with the previous findings of Leung et al. (2020) on the reduction of infection when wearing a facemask. The different types of masks and their effectiveness in protection against the SARS-CoV-2 virus vary depending on the material, although fabric masks are more comfortable and economical in the long term, the person who wears them ends up being just as exposed, since their filtration efficiency for particles smaller than 0.3 µm is 0%. Nonwoven fiber masks have a higher filtration efficiency, ranging from 60 to 95%, with KN95 having the highest efficiency; a more detailed summary is presented in Table 1.

Table 1
Comparison between the different masks (Das et al., 2021)

Type of mask	Material	Efficiency	Purpose	Reusable
Fabric	Common textiles, generally cotton, and polyester	0 % on particles smaller than 0.3 µm	Dust particles, viruses, and bacteria.	Yes
Surgical	Nonwoven fabric	60 to 80 % on particles smaller than 0.3 µm	Dust particles, pollen, viruses, and bacteria.	No
KN95	Non-woven polypropylene fabric	80 to 95 % on particles smaller than 0.3 µm	Dust particles, pollen, virus, and bacteria aerosols	No

Melt-blown fusion is a simple, one-step process from a polymer resin. The melt-blown configuration generally consists of an extruder, metering pump, melt-blown die assembly, and drum manifold (Sarbatly et al., 2021), as shown in Fig 1.

Figure. 1
Melt-blown fiber production process



Current situation

The company's production is 27'360 000 surgical masks and 2'880 000 KN95, resulting in a total of 30'240 000 units produced. For this production volume, Table 2 summarizes the operating conditions of the melt-blown area, which are: two 12-hour shifts, approximately 44 rolls per week, with a 14 % waste rate, and 2-day cleaning of the equipment.

Table 2
Melt-blown Production Summary

Parameter	Operation
Working Day	Double shift from Monday to Friday from 7:30 a.m. to 7:30 p.m. and from 7:30 p.m. to 7:30 a.m.
Quantity	0.5 rolls per hour of melt-blown fiber
Weight	31.3 kg per roll
Waste	4.5 kg per roll
Cleaning	Friday in the first shift 7:30 am to 7:30 pm

In the production process, the characterization of the raw material is carried out in an accredited laboratory to know the state of the raw material and the local environmental conditions. The production process starts with the mixing of polypropylene pellets with a fluidity index of 1500 (PP HSD 1500) and electret masterbatch pellets (PP ZJ101) in a proportion of 97 and 3 %, respectively. The mixing takes approximately 15 minutes and the start-up process takes 2 hours, because of the heating of the zones until they reach 270 ˚C; from then on, the machinery works until the last day. At the end of the process, we wait for the parts to lower their temperature to 65 ˚C for their disassembly and transfer to the washing area.

The cleaning is done in 2 stages, the first stage is physical and starts with the disassembly of the mold when it has cooled down and a manual cleaning of the mold orifices. The chemical stage consists of placing the mold in an oven at 480 ˚C for calcination of the polypropylene (PP) and subsequently washing it with a sodium hydroxide solution for 4 hours in an ultrasound. Finally, the residues are marketed to plastic industries. The storage of both raw materials and the final product is at room temperature, however, this environment is not controlled, since it depends on the environmental conditions of the surroundings, which change throughout the day, varying the temperature and relative humidity.

Operating Conditions

A batch statistical hypothesis test is performed to know if the densities obtained experimentally contain the true value of the population mean, and if they are within or outside a confidence interval; the proposed interval is 90 %. The free software *R Studio* is used for statistical analysis. The significance level is 0.1, since the sample is less than 30, the *t student* statistical test is used and the decision rule is: if the calculated *t* is less than the critical *t*, the null hypothesis is accepted. Hence, the null hypothesis states H0 = μ, while the alternative hypothesis is H1 $\neq \mu$. The equation (1) utilized for the *t*-student statistic is presented below:

$$t = \frac{\bar{x}-\mu}{s/\sqrt{n}} \tag{1}$$

Where $\bar{x}$ is the average of the obtained data, μ is the population, s is the standard deviation, and n is the total amount of data. To control the output quality of the product, it should be understood that the phenomenon that governs the production process is the melting of polypropylene. Therefore, operating pressure and temperature ranges should be established as a function of the initial density and environmental conditions, and with the Spencer-Gilmore equation, it is possible to approximate the operating conditions based on pressure and temperature. The general equation (2) is then presented:

$$(P+\pi)(V\text{-}W) = R'T \tag{2}$$

Where π, W, and R’ are constants, in the case of PP the values are 3080 atm, 0.70 cm/g, and 2, respectively. Then, the modified equation would be the following (Foster et al., 1966):

$$(P+3080)(V\text{-}0.7) = 2T \tag{3}$$

Equation 2 describes the behavior of polypropylene in the liquid state, whose means is above the melting temperature of the polymer. The pressure (*P*) is the ratio of the operating pressure to the atmospheric pressure, the units required are atmospheres. The specific volume (*V*) is an intensive property necessary in order not to depend on the amount of raw material to be used in the process, and the temperature (*T*) is absolute. For a better prediction of the behavior of the material, it will be operated under the same conditions of the flow index, which are a temperature of 230 ˚C and an operating pressure of 0.34 bar (5 psi), then the absolute pressure is

1.34 atm. With these conditions the specific volume of the molten polypropylene is calculated, clearing from equation (3) resulting in equation (4):

$$V = \frac{2T}{P + 3080} + 0.7 \quad (4)$$

The result of the specific volume is 1.0265 cm^3/g, this value is the one to be obtained in the production process. Now, the suggested operating pressure is 5 psi based on 1 atm of atmospheric pressure. In Quito, the atmospheric pressure is lower, it is 0.71 atm, therefore, a new operating pressure must be found with the new conditions. The absolute pressure (P_{abs}) is obtained by adding the atmospheric pressure (P_{atm}) to the gauge pressure (P_{gauge}), as shown in equation (5):

$$P_{abs} = P_{atm} + P_{gauge} \quad (5)$$

The absolute pressure is 1.34 atm and the atmospheric pressure in Quito is 0.71 atm, clearing the gauge pressure gives 0.63 atm, for instance, 9.26 psi, then the gauge pressure in the process must be increased to 9 psi. The operating temperature must be changed to obtain the flow rate condition. Currently it is 225 ± 5 ˚C, when the operating temperature must be increased to 230 ± 5 ˚C. The variation of ± 5 ˚C is based on the pro-average temperature changes recorded in Quito. In addition, the process during the transformation of the raw material is subject to high temperatures and the presence of oxygen, it is there where damage occurs at the molecular level that degrades the material, thus causing non-uniformity in the grammage of the fabric, from here derives the presence of crystals, brittle fabric and low tensile strength of the fabric.

Problems can occur if the material is kept at the processing temperature for an excessive amount of time, for instance, during a machine stop. These problems reduce when using thermoplastic solid binding resins, polyamides, polyethylene, EVA, PVC, and thermosets, such as phenolic resins (Pintea and Manea, 2019), since they favor the bonding, transformation, and finishing of the melt-blown fabric. The international standard for nonwovens is ISO 9073 with its 18 sections, in Ecuadorian legislation, is INEN NTE-ISO 9073. However, this standard is an identical translation of the same international standard with its 18 sections. The quality control in the fabric is the grammage that must be in a range of 20 to 30 g/m^3 (gsm) for use in masks. Currently, this range is met, ensuring air filtration and retention of external agents within the fiber mesh of the melt blown.

Results

Quality Control of Raw Materials

One of the initial findings in the raw material was that the physical characteristics of virgin polypropylene and electret masterbatch are not constant, so currently the physical characterization of the flow index is performed in specialized laboratories. In addition, at the time of receipt of the raw material, there is no documented support for the specific conditions of the received batch of PP. The proposal to improve the reception of raw materials is to have parameters and acceptance ranges. Table 3 shows the polypropylene parameters, in addition to requesting the Certificate of Analysis (COA) from the supplier.

Table 3

PP quality parameters

Property	Test	Conditions	Units	Values
Density	ISO 1183	23 °C	g/cm³	0.9125 ± 0.0018
Flow Index	ISO 1183	230 °C / 2.16 kg	g per 10 min	1500 ± 100
Melting Point	DSC	---	°C	155 - 175
Ash Content	ISO 3451	850 °C / 60 min	%	≤ 0.03
Volatile Components	ISO 787	105 °C	%	≤ 0.03
Water Amount	---	105 °C / 2 hours	%	≤ 0.05

Note: DSC is Differential Scanning Calorimetry

At the beginning of the process, it is important to know the value of the density of the polypropylene to adjust the melting temperature ranges. The density measurement does not require specialized equipment so it was possible to do it *in situ*. The density of the 4 different batches of raw material that were acquired together with the melt-blown machinery in October 2020 was characterized. The procedure to obtain this measurement is described in the ISO-1183 tests (ISO, 2019), and the results are presented in Table 4.

Table 4

The density of the raw material

Description	Batch 01 [g/mL]	Batch 02 [g/mL]	Batch 03 [g/mL]	Batch 04 [g/mL]
Virgin polypropylene	0.9106	0.9122	0.9142	0.9127
	0.9104	0.9127	0.9144	0.9132
	0.9101	0.9121	0.9147	0.9124
Partial Average	0.9104	0.9123	0.9144	0.9128
Global Average	0.9124			

For the critical t is necessary the degrees of freedom (d_f), which is calculated as n - 1. The results for each of the batches are presented in Table

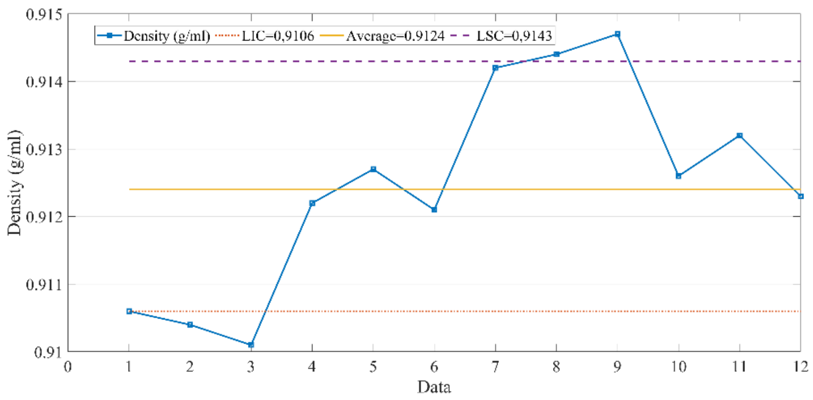
5. Batches 01 and 03 do not enter the confidence interval, Batch 01 for being below, and Batch 03 for being above the confidence interval. Now with the quality control chart made in IBM SPSS, the average and distribution of the values obtained for the densities are presented, as well as the upper control limit (*UCL*) and lower control limit (*LCL*).

Table 5
Results of hypothesis testing by batch

Parameters	Batch 01	Batch 02	Batch 03	Batch 04
$\bar{x}$	0.9125	0.9125	0.9125	0.9125
μ	0.9104	0.9123	0.9144	0.9128
s	0.002517	0.000321	0.000252	0.000404
n	3	3	3	3
t-calculated	-14.6826	-0.8980	13.3061	1.1429
df	2	2	2	2
t-critical	± 2.91999	± 2.91999	± 2.91999	± 2.91999
Decision	H_0 Rejected	H_0 Accepted	H_0 Rejected	H_0 Accepted

Figure 2 shows values outside the upper and lower control limits, of which points 1, 2, and 3 belong to Batch 01 and points 8 and 9 belong to Batch 03. With these two statistical and graphical evidences, there could be no production of the melt-blown fabric with these batches.

Figure 2
Distribution of raw data



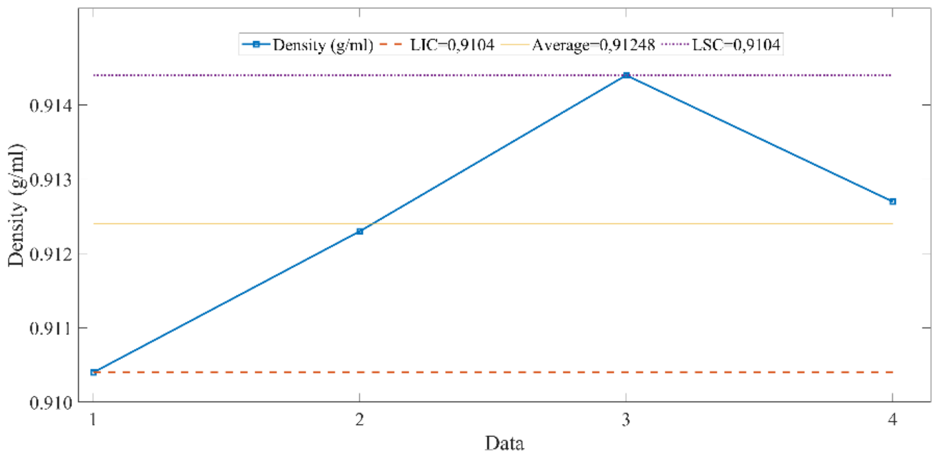
However, it is not economically feasible to discard two lots of purchased raw material, so by mixing the four lots in equal proportions the result is already within the proposed confidence interval of 0.1, as presented in Table 6.

Table 6
Results of global hypothesis tests

Parameters	Results
μ	0.9125
$\bar{x}$	0.9124
s	0.00165
n	4
t-calculated	-0.0303
d_f	3
t-critical	± 2.3534
Decision	H_0 accepted

With these results, the new range of acceptance of the product is defined as the upper control limit (*UCL*) a maximum density of 0.9144 g/ml, and the lower control limit (*LCL*) a minimum density of 0.9104 g/ml. It can be seen in Figure 3 that there is still a tendency for two Batches to be at the extremes of the required density. However, they enter the confidence interval since the average value is close to the mean of the density required for operation.

Figure 3
Distribution of new data

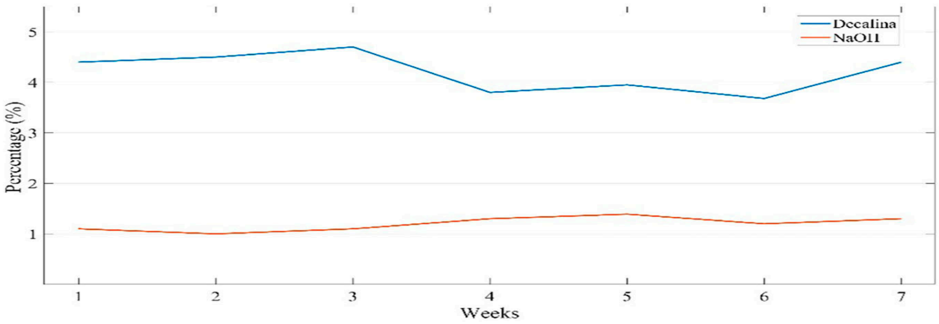


The density of each Batch of raw material to be used must be within the significance level of 0.1 since the melting temperature implies providing enough energy for the chains to move as a whole.Polypropylene, being a semi-crystalline material, is composed of both amorphous zones, branched structures, and crystalline or compact zones linear structures. Consequently, the energy to break the bonds in the compact zones is higher (Kar'kova et al., 2019), with this in mind the proportionality between density and melting temperature can be established, as directly proportional to the linear crystallinity and inversely proportional to branched structures.

Another finding in the raw material was the storage conditions of the polypropylene, currently, the bags are covered inside the facilities. Nevertheless, they still do not have control over environmental variations such as light, humidity, and temperature. The raw material is susceptible to degradation when exposed to heat and UV radiation, causing a network of fine cracks and the longer the exposure time the more severe the internal damage of the raw material (Pathak et al., 2021), this damage at the molecular level causes non-uniformity in the weight of the fabric. The proposal for improvement is to adapt a space to control the storage conditions, in which there are temperature and humidity records; the use of a thermo-hygrometer can help for this purpose. Concerning exposure to UV radiation, simply providing physical protection from sunlight and artificial light is sufficient to ensure the quality of the raw material.

The cleaning of the molds of the current 2-stage procedure should be maintained but the change should be made in the washing solution, from sodium hydroxide to decalin, decahydronaphthalene, which is a bicyclic hydrocarbon and is used as an organic solvent (Troughton, 2008). The amount of dissolved polypropylene, as a solute, in the final washing solution differs between sodium hydroxide and decalin, where each week the parts to be washed were separated between decalin and sodium hydroxide, obtaining an average percentage by weight of solute in sodium hydroxide of 1.15 %, while in decalin it is 4.18 % as shown in Figure 4. The percentage of solute in decalin is four times higher than that contained in sodium hydroxide, therefore, it turns out that the solute is completely dissolved in decalin and partially in sodium hydroxide. Hence. the utilization of the organic solvent causes an improvement in the washing stage with a decrease in the working time.

Figure 4
Percentage of solute



Final indicators

The stages that give the production rate are the conditions of the raw material, as well as the control in the process, besides the cleaning of the equipment should be as short and effective as possible. With these results, the following improvements in production time are obtained. The start of production is given by the preparation of the raw material and the heating of the melting and blowing zones. Table 7 presents the optimizations, showing that the start of the process is reduced by 55.56 % since with the initial characterization the machinery is programed and the trial-and-error process is eliminated. Now, with the range of temperatures and operating pressure, unexpected or unscheduled downtime is reduced by 62.50%.

Table 7
Optimization of production times

Process	Then [hours]	Now [hours]	Optimized [%]
Process Startup	2.25	1	55.56
Daily Contingencies	2	0.75	62.50
Weekly Cleaning	8	5	37.50

Scheduled downtime for cleaning is reduced by 3 hours, being 37.50 %, this is due to the change from an aqueous cleaning solution to an organic solvent exclusive for polypropylene. With the change from sodium hydroxide solution to decalin, only one hour would be needed for the dismountable parts to be immersed in the ultrasound. The solid waste of finished product decreases due to the optimization of both the daily contingencies, less raw material expense at the start of the process and stabilization. The reduction was 1.42 kg/roll, representinga 31.56 % for the initial waste of 4.50 kg/roll. Each roll weighs an average of 31.30 kg, as presented in Table 2, and with the present optimization, the waste was reduced from 14.38 to 9.84 %. The optimizations are summarized in Figure 5, wherein in each process there is an improvement in both, time and amount of waste.

Figure 5
Overall results

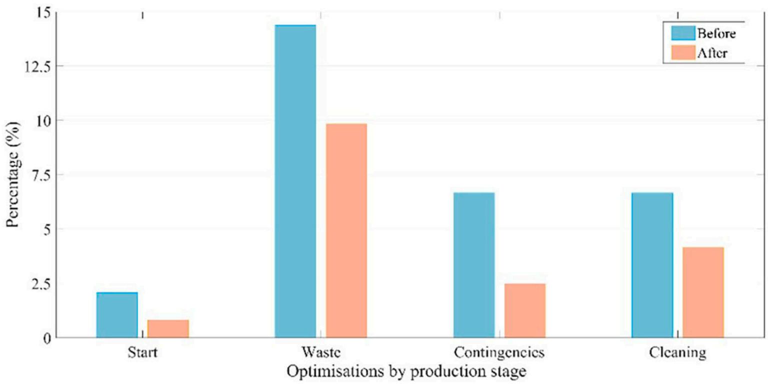
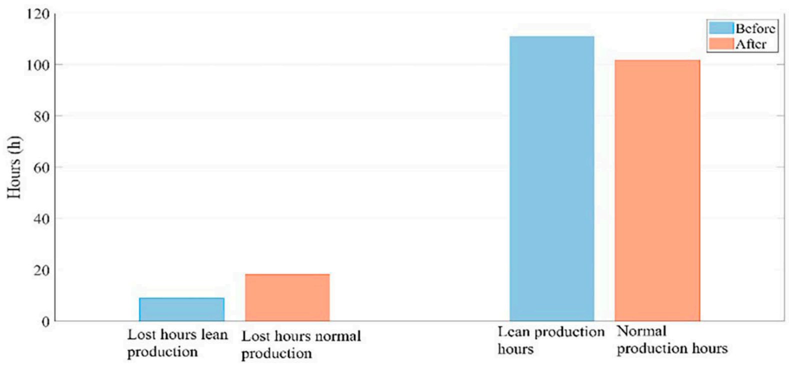


Figure 6 presents the values in hours of normal production and the new production applying Lean Manufacturing. With the reduction of 50.68 % of the times in the different production stages, there was a reduction from 18.25 to 9 hours, which caused the net production of melt-blown rolls to increase from 101.75 to 111 hours, representing an increase of 9.09 % concerning the normal production hours. The implications for the organization of these improvements range from increased stock for sales to supply the demand for masks and/or a reduction in working hours to optimize resources.

Figure 6
Melt-blown production



Currently, in the melt-blown area, there are two technical operators and due to the unforeseen events of the machinery, it is necessary to be aware of the production. By the standardization of the process, it is possible to train an operator, and thus optimize the human and economic resources of the company.

Table 8 shows the economic optimization focused on human resources salaries. The net saving is USD. 400 per month, i.e., a savings of 33.33 %. This saving, together with compliance with international standards, not only guarantees the quality of filtration but also improves competitiveness by presenting better masks to the market, as well as the possibility of exporting and being a local supplier of raw material with melt-blown fabric.

Table 8
Economic optimization

Status	People	Position	Salary [USD]	Total Monthly Cost [USD]	Optimization [%]
Then	2	Technical	600	1200	33.33
Now	2	Operator	400	800	

Conclusions

Regarding the concept of Lean manufacturing, which is the identification of waste and its elimination or reduction through the continuous improvement of the process, wastes of time, resources, and products were determined. The reason is the lack of acceptance parameters of raw materials and standardized parameters of finished products. Therefore, by identifying waste, the melt-blown area for the production of face masks was improved by characterizing raw materials, technical controls, and specification of operating conditions.

The production depends on the raw material and the working conditions, especially in the area of raw materials; the physical characteristics of polypropylene are not constant between batches., For this reason, only 2 Batches of the 4 existing ones could be used for the production of the melt-blown fabric, however, a combination between the four Batches was achieved, guaranteeing the adequate characteristics for the production. The data presented show the relationship between the working conditions and the environmental conditions. In Quito, with an atmospheric pressure of 0.71 atm, the working pressure increases from 5 psi to 9.26 psi, an equivalent total pressure of 1.34 atm. With this new working condition, the flow rate necessary to obtain a melt-blown fabric with constant characteristics is ensured.

With the described changes, process start-up times improved by 55.56

%, unexpected events were reduced by 62.50 %, and cleaning was optimized by 37.50 % of the total washing time. In addition, product waste is reduced by 4.54 % and the savings in economic resources is USD 400 per month. The optimization of economic resources should be the subject of further investigations, focusing on the cost of raw materials, production, and finished product, based on current and future market demand.

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