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# Taguchi method application in the pilot production phase-a case study

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**Abstract**

This work comes at the product and process development stage in a medical device company, namely the bone substitute. The production of bone substitutes has high regulatory requirements, also the consumer of these products has high-quality requirements. In the pilot production phase, a quality problem was detected in the bone substitute blocks. The work presented was developed in a real context requiring an understanding of the production process and the product. Through a multidisciplinary analysis allowed to direct the problem to the impregnation process. The study of the impregnation process was developed according to the DOE through the Taguchi method. For the experiment, six factors and one interaction allocated in an L8 array were identified. Results obtained show that the process variability is clearly superior to the effect of the studied factors. For future work, the removal of non-significant factors is recommended, adding new factors not included in the study.



*Keywords:* Design of Experiments (DOE); Taguchi Method; Pilot Production Phase; Medical Devices.

## 1. Introduction

This paper presents the work done at a medical device company, in a context of structural and strategic changes. The company, after decades of distributing medical devices in the field of orthopedics, is moving towards the production of medical devices, more specifically, bone substitutes. This project takes place at the stage of product development and the production process, prior to the production and commercialization of the product. For reasons of confidentiality, the information presented is restricted to what is essential.

The medical device industry and particularly the production of bone substitutes, is under high legislative and normative control, being essential high levels of product quality. The application of design of experiments (DOE) techniques in the early stages of the process product development can help to understand the production process behavior and to achieve high levels of product and process robustness in competitive time and experimentation costs.

The Taguchi method is a DOE method applied in quality engineering and, although it has been developed for applications in an industrial context, it is currently applied to several scientific areas.

The bone substitute must have a rectangular geometric shape and uniform porosity. In the early stages of the product and process development, pilot productions showed that there was a "void" inside the bone substitute, constituting a product quality problem. The analysis of the production process revealed that this problem was associated with the impregnation process. Through this paper, we present the study of the impregnation process and the respective results obtained, in the context that the company did not have any data on the performance of the impregnation process.


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## 2. Taguchi method

Design of Experiments (DOE), is a method that tests a set of planned changes to the input variables of a process to identify its impact on the process response [1].

The Taguchi method consists of a method of designing fractional factorial experiments. That is, only a part of the possible combinations is performed. Genichi Taguchi proposed the execution of a part of the possible combinations through the application of orthogonal arrays (OA), thus defining the combinations to be applied in the execution of the experiment [2].

The execution of experiments in the industry with many factors and high costs, make the complete factorial planning impractical. Taguchi developed fractional factorial experiments with an orthogonal arrangement that allow a smaller number of experiments to be carried out for a certain number of factors [2].

The application of the Taguchi method allows parameterizing the quality of a product or process with the use of experience planning. This method is part of the offline quality method. That is, the effort to improve quality is developed before production, in the testing phase [2].

The application of an OA is preceded by an analysis of the problem under study. In this phase, the problem under study is defined objectively, the response and quality characteristic. The determination of the factors involved in the problem under study can be carried out through the constitution of a multidisciplinary team using tools such as brainstorming and the Ishikawa diagram [2].

The definition of factors is an important step, as the selection or omission of factors in the study can lead to wrong or inaccurate conclusions. The factors selected for carrying out the experiment must have a high influence on the response and be controllable in an industrial environment [2].

The study levels for the selected factors is recommended to be two in an initial phase, feasible in an industrial environment and close to the current values [3].

Taguchi proposed the use of fractional factorial experiments through the application of standard orthogonal arrays. These standardized arrays allow the application for different number of factors and trials. An OA is classified as orthogonal when it is verified that each column is statistically independent, in the scope of experimentation in general arrays with two or three levels are used for all factors. The most common matrices for factors with two levels are L8, L12 and L16. For matrices of three levels, matrices L9 and L27 are often used. Despite its less frequent use, it is possible to use orthogonal matrices whose factors have different levels. For example, matrix L36 allows the study of 23 factors, two of which 11 with the assignment of 2 levels and 12 factors with the assignment of 3 levels [4].

To achieve the robustness of a product, quality must be planned from the product design phase and continue in the production and manufacturing phases [5].

The Taguchi method emerges with the objective of improving the quality of products and processes, through experimentation with reduced cost and time. This method is applied in many areas of knowledge, such as medicine, chemistry, pharmacology, engineering of manufacturing processes, engineering of materials, marketing and there is even reference to the application of this method to optimization techniques.

In the area of medicine, Lopes et al. (2016) [6], presented an investigation that applies the Taguchi method to determine the optimal parameters in the drilling of bone tissue using the Taguchi method. In this investigation the objective is to study the effect of the variation of the rotation speed and the diameter of the drill on the increase of temperatures in the bone tissue, during the drilling process. The performance of the tests was based on the Taguchi method, to obtain the optimal combination of drilling parameters. An L9 orthogonal array was used and the signal-to-noise ratio was analyzed, as well as the Pareto ratio to obtain the effect and interaction of each parameter in the process.

Within the scope of medical devices Bonow et al. [7], applied the Taguchi method for the analysis of constructive parameters in the operation of mechanized infusion equipment. In this work, the pressure reached in the linear peristaltic pump was studied, it did not meet the criteria for the release of the product to the market. The effects of the parameters, springs, press material, distance between fingers and press, metal plate and lever were checked, using an L8 array and studied the effects of the parameters on the operation of the equipment.

The determination of parameters of medical device production processes such as the process parameters of a Tyvek sealer is studied by Terán et al. [8]. In this paper, the authors study the effects of sealing parameters on Tyvek bags. The Taguchi method is applied through L9 arrays for controllable factors and noise factors. Controllable factors were temperature, pressure and speed. The noise factors were the wall thickness and the height of the bag in order to reduce the variation in the rupture values resulting from the variation in the material.

The studies referred to in this chapter present a common approach. They all start with the research question, research problem or objective. They identify and define the quality characteristic under study, the controllable factors and the respective levels. At this stage, it is possible to define the orthogonal array and plan the experiment. After conducting the experiment, the results are treated with the use of statistical methods such as ANOVA, and the signal-to-noise (S/N) study is carried out. To a large extent, the confirmation experiment is carried out to evaluate the response provided by the method [9][10].

## 3. Methodology

This chapter presents the problem under study and the development and the application of the DOE in this context. For the treatment of results, the tools Excel and Minitab 18 were used. The production raw materials used are referenced only with the function performed in the product, the quantities and concentration of are omitted for reasons of confidentiality.

### 3.1. Product description

A bone substitute is all material of human, animal, vegetable or synthetic origin, intended for implantation in man with the prospect of rebuilding bone capital, to strengthen a bone structure or to fill in a loss of bone substance traumatic or orthopedic origin (Gutierres et al., 2005). β-TCP is a bioceramic material used as a bone substitute with characteristics such as, good compatibility, osteoconductivity, biodegradation and mechanical resistance (Narayan, 2009). Clinically, different shapes and sizes are used according to the application. Figure 1 shows the variety of sizes, blocks and granules, of bone substitutes for different clinical applications.

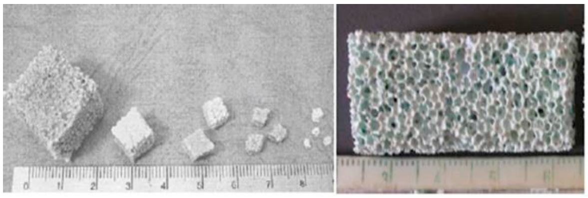

Fig. 1. Different sizes of bone substitutes.

These ceramics are porous and with interconnected pores, this characteristic is essential for the process of reabsorption of the substitute in the body. The pore distribution is between 300 to 1250μm. The rate of resorption can thus be controlled in this way. The characteristics of bioceramic such as β-TCP are defined according to ISO 13779: 2018.

### 3.2. Production process description

The production of bone substitute blocks requires several operations up to the final product. The necessary raw materials are β-TCP, deflocculant, binder, water and organic vehicle (polyurethane foam). A recipe was developed for these raw materials, according to the characteristics of porosity and mechanical resistance defined in ISO 13779.

The production process for β-TCP bioceramics is divided into the following operations:

- Suspension of β-TCP - in this phase of the process, the suspension containing the reagents in the established quantities is prepared. To produce the bone substitute, β-TCP bioceramic, water, ligand and deflocculant are used.
- Mixing and homogenization - the suspension is mixed and homogenized, ensuring a homogeneous distribution of the solids in the water. This process is carried out with the use of mechanical stirring (mill), and zirconia balls inside the mixing containers.
- Impregnation - this operation consists of the replication of polymeric foam (polyurethane foam). That is, the β-TCP suspension is introduced into the foam using mechanical agitation (mill) and compression of the foam through zirconia balls. After mixing and homogenization, polyurethane foam zirconia balls are added to the same container and mechanical agitation is activated.
- Drying - in this phase, the polymeric foam is impregnated with the suspension. Drying aims to eliminate the water present inside the impregnated blocks. This process takes place in a greenhouse.
- Sintering - is a thermal process in which the polyurethane foam is burned at a temperature of 400 ° C, when the temperature of 600 ° C is reached, the burning of organic volatiles begins. Another important step in the thermal process occurs around 1150 ° C causing rheological changes in β-TCP. In this process, the burning of the polyurethane foam allows the β-TCP to acquire the shape and porosity of the foam, serving as a mold for the final shape of the product.
- Disinfection and packaging - to disinfect the product for double sleeve packaging.
- Sterilization - the use of this product requires sterilization. Sterilization is performed by electron beam (gamma rays).

### 3.3. Problem description

After developing the product and production process, pilot productions for bone substitute blocks with different dimensions started. Several laboratory analyzes were started to verify the legal and normative requirements of the product, and the results showed a significative level of empty spaces in the larger blocks (Figure 2).

To analyze the detected problem, a multidisciplinary team composed by experts from product quality, design and development and production was formed and concluded that the production phase in which the void formation occurred inside the block was the impregnation phase. That is, in the impregnation operation, the suspension of β–TCP is introduced into the polyurethane foam and if this operation fails, areas inside the blocks are formed with only polyurethane foam. In the next operation, the impregnated foams are placed in the oven for the heat removal of the water impregnated in the block, followed by the sintering operation in a thermal cycle, allowing the burning (disappearance) of all the polyurethane foam. After sintering, the blocks are formed only of β–TCP that take the shape of polyurethane foam and in areas of foam whose suspension did not impregnate after the foam burns, empty areas are formed.

Fig. 2. Empty spaces in the larger blocks.

### 3.4. Design of the experiment

After determining the phase of the production process where the problem occurred, a cause-effect diagram (or Ishikawa) was developed to study the impregnation process, which identified the following parameters in this process:

- Material
  - -Density of PU foam
  - -β–TCP particle size
  - -Hardness of PU foam
- Method
  - -Mass of grinding balls
  - -PU foam and β –TCP ratio
  - -Size (volume) of the impregnation container
  - -Concentration of solids in the suspension
- Machine (Roll Mill)
  - -Impregnation time
  - -Rotation speed
  - -Maintenance
- Environment
  - -Temperature
  - -Humidity
  - -Suspension temperature

Once the potential influential parameters were identified through the Ishikawa diagram, the team selected the following influential parameters to be included in the study:

- PU foam and β-TCP ratio
- Concentration of solids in the suspension
- Impregnation time
- Impregnation mill speed
- Size of the impregnation container
- Ball compression mass

The response variable of the quality characteristic under study can be classified as a continuous variable, of the higher-is-better type. This response variable corresponds to the mass of the block after sintering. However, the mass of the sintered block does not allow to evaluate the distribution of the β-TCP suspension in the PU foam. Thus, in order to overcome this limitation, the void area in the blocks was also defined as a response variable. To assess the existence of voids in the blocks, destructive tests of the blocks were carried out, determining the width and length of the voids. This analysis is also a continuous variable, but of the lower-is-better type. For both response variables, an individual study is carried out. The response variables under study are not the optimal approach for assessing the distribution of pores within the bone substitute block. For a more precise assessment it would be necessary to utilize computer micro tomography. However, for financial reasons it was not possible to use this technique.

The control-variable information was developed as shown in Table 1.

The selection of the orthogonal array is determined by the total degrees of freedom, indicating which is the smallest possible array. The total degrees of freedom are seven which corresponds to a L8 orthogonal array (two-level eight trials array), presented in Table 2.

Table 1. Control variables

| Factors (units) and interactions | Level 1 | Level 2 |
|---|---|---|
| A- PU foam and β –TCP ratio (g:g) | 1:27 | 1:28 |
| B- Concentration of solids in the suspension (%) | 67% | 68% |
| C- AxB interaction | | |
| D- Impregnation time (min) | 10 | 15 |
| E- Impregnation mill speed (rpm) | 100 | 150 |
| F- Size of the impregnation container (ml) | 500 | 1000 |
| G- Ball compression mass (g) | 2M | 3M |

Table 2. L8 orthogonal matrix-assignment of factors and interactions

| | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| | Column | | | | | | |
| Trial no. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 2 | 1 | 1 | 1 | 2 | 2 | 2 | 2 |
| 3 | 1 | 2 | 2 | 1 | 1 | 2 | 2 |
| 4 | 1 | 2 | 2 | 2 | 2 | 1 | 1 |
| 5 | 2 | 1 | 2 | 1 | 2 | 1 | 2 |
| 6 | 2 | 1 | 2 | 2 | 1 | 2 | 1 |
| 7 | 2 | 2 | 1 | 1 | 2 | 2 | 1 |
| 8 | 2 | 2 | 1 | 2 | 1 | 1 | 2 |

To carry out the 8 tests planned in the L8 array, only one replica was defined due to the high cost of raw materials. The sequence in which the experiments were carried out was randomly defined and for each test 6 units (blocks) are processed because it corresponds to the minimum units of a production lot.

### 3.5. Experimental results

The experimentation results for the response variable mass (M) of the block is presented in Table 3.

Table 3. Experimentation results for the response variable mass of the block

| Trial no. | M1 | M2 | M3 | M4 | M5 | M6 |
|---|---|---|---|---|---|---|
| 1 | 12,76 | 10,24 | 10,58 | 12,69 | 12,97 | 12,24 |
| 2 | 12,98 | 12,95 | 13,32 | 11,58 | 12,87 | 11,35 |
| 3 | 11,75 | 11,47 | 12,15 | 12,92 | 13,02 | 11,78 |
| 4 | 11,34 | 13,54 | 13,10 | 12,17 | 12,58 | 11,45 |
| 5 | 11,98 | 11,71 | 11,55 | 13,14 | 12,55 | 12,21 |
| 6 | 11,94 | 12,13 | 12,20 | 12,75 | 12,64 | 12,06 |
| 7 | 11,12 | 12,76 | 12,24 | 11,99 | 12,62 | 12,32 |
| 8 | 11,46 | 11,93 | 12,13 | 11,83 | 12,18 | 12,23 |

The experimentation results for the response variable void area (A) of the block is presented in Table 4.

Table 4. Experimentation results for the response variable void area of the block

| Trial no. | A1 | A2 | A3 | A4 | A5 | A6 |
|---|---|---|---|---|---|---|
| 1 | 40,56 | 17,28 | 0,00 | 20,65 | 24,08 | 0,00 |
| 2 | 0,00 | 0,00 | 32,25 | 0,00 | 0,00 | 0,00 |
| 3 | 18,70 | 0,00 | 0,00 | 33,14 | 79,23 | 20,80 |
| 4 | 0,00 | 19,45 | 34,75 | 0,00 | 0,00 | 0,00 |
| 5 | 49,83 | 0,00 | 0,00 | 72,23 | 52,06 | 21,61 |
| 6 | 31,50 | 27,26 | 26,46 | 0,00 | 0,00 | 32,88 |
| 7 | 0,00 | 0,00 | 47,96 | 60,88 | 73,18 | 44,28 |
| 8 | 36,54 | 16,12 | 0,00 | 18,72 | 0,00 | 7,48 |

### 3.6. Analysis of experimental results

The experimentation results are analyzed according to the Taguchi method, using the graphic analysis of the main effect of each factor complemented with the analysis of variance. In this phase, the analysis of variance (ANOVA) was developed in two phases. In the first phase, the results of the experimentation are analyzed, treating the repetitions of the trials as replications. In the second phase, the Signal-to-Noise is analyzed using the pooling of the factors. Given the absence of previous studies on the impregnation process, a 90% confidence level was defined for the analysis of the experimentation results.

- Mass (M) response

In order to identify the influential factors in the variation around the mass (M) average, according to the higher-is-better quality characteristic, the difference in the response of each level in all factors (Table 5) and graphical representation (Figure 3) of the levels for the factors and interactions under study were determined.

The speed of impregnation of the roller mill (E) is the factor that presents the biggest difference between levels 1 and 2 and, consequently, with the first position in the ranking of influential factors, followed in the ranking by the size of the impregnation container (F), the time of impregnation (D) and the AB interaction (C). The remaining factors, PU/β-TCP foam ratio (A),concentration of solids in the suspension (B) and ball compression mass (G) show very low differences between levels 1 and 2, indicating that the variation in levels does not show much influence on the responses obtained.

Table 5. Analysis for the mass average response

| | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| | Column | | | | | | |
| Level. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 1 | 12,24 | 12,22 | 12,14 | 12,12 | 12,09 | 12,11 | 12,18 |
| 2 | 12,15 | 12,17 | 12,26 | 12,28 | 12,31 | 12,29 | 12,21 |
| Difference | 0,09 | 0,05 | 0,12 | 0,16 | 0,22 | 0,18 | 0,03 |
| Ranking | 5 | 6 | 4 | 3 | 1 | 2 | 7 |

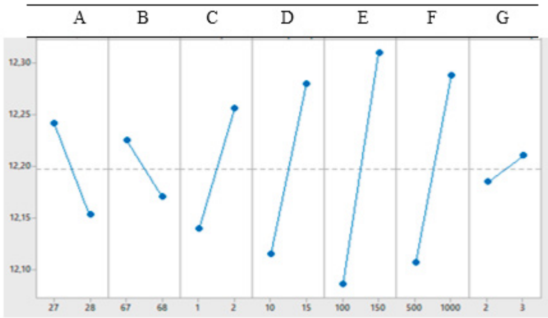


Fig. 3. Plot analysis for the mass average response.

Despite the execution of the experiment with only one replica, the 6 samples collected in each trial were treated as replicates for the analysis of variance. ANOVA results are presented in Table 6.

Table 6. ANOVA analysis for the mass response

| Factors and interactions | DF | SS | V | F | % Contribution |
|---|---|---|---|---|---|
| A- PU foam and β –TCP ratio | 1 | 0,095 | 0,095 | 0,18 | 0,42 |
| B- Concentration of solids in the suspension | 1 | 0,036 | 0,036 | 0,07 | 0,16 |
| C- AxB interaction | 1 | 0,162 | 0,162 | 0,31 | 0,72 |
| D- Impregnation time | 1 | 0,335 | 0,335 | 0,62 | 1,44 |
| E- Impregnation mill speed | 1 | 0,601 | 0,601 | 1,15 | 2,67 |
| F- Size of the impregnation container | 1 | 0,394 | 0,394 | 0,75 | 1,75 |
| G- Ball compression mass | 1 | 0,008 | 0,008 | 0,01 | 0,03 |
| Err | 40 | 20,918 | 0,5230 | | 92,81 |
| Total | 47 | 22,54 | | | 100,00 |

$F_{(0,10;1;40)}=2,835$

The experimental results show that the variation within trial, with a 92,81% contribution, is much higher than the variation between trials, with a contribution of 7,19%. These results indicate that there are significant factors that were not considered in the study.

- Void area (V) response

Void area (V) average response of each level in all factors are presented in Table 7 and the respective graphical representation in Figure 5.

The impregnation time (D) is the factor that presents the biggest difference between levels 1 and 2, followed in the ranking hierarchy by the PU/β-TCP foam ratio (A), the size of the impregnation container (F) and the AB interaction (C). The remaining factors (concentration of solids in the suspension (B), impregnation mill speed (E) and ball compression mass (G)) variation in levels does not have significative influence in the responses obtained.

Table 7. Analysis for the void area average response

| | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| | Column | | | | | | |
| Level. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 1 | 14,20 | 18,69 | 18,33 | 28,19 | 18,81 | 17,98 | 20,88 |
| 2 | 25,79 | 21,30 | 21,66 | 11,81 | 21,19 | 22,02 | 19,11 |
| Difference | 11,59 | 2,61 | 3,33 | 16,38 | 2,38 | 4,05 | 1,77 |
| Ranking | 2 | 5 | 4 | 1 | 6 | 3 | 7 |

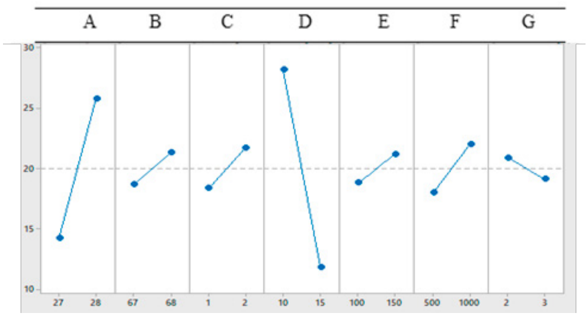


Fig. 4. Plot analysis for the void area average response.

ANOVA results are presented in Table 6 ($F_{(0,10;1;40)}$=2,835)

Table 8. ANOVA analysis for the void area response

| Factors and interactions | DF | SS | V | F | % Contribution |
|---|---|---|---|---|---|
| A- PU foam and β – TCP ratio | 1 | 1611,42 | 1611,42 | 3,41 | 6,64 |
| B- Concentration of solids in the suspension | 1 | 81,33 | 81,33 | 0,17 | 0,34 |
| C- AxB interaction | 1 | 133,62 | 133,62 | 0,28 | 0,55 |
| D- Impregnation time | 1 | 3220,30 | 3220,30 | 6,81 | 13,27 |
| E- Impregnation mill speed | 1 | 68,00 | 68,00 | 0,14 | 0,28 |
| F- Size of the impregnation container | 1 | 196,43 | 196,43 | 0,42 | 0,81 |
| G- Ball compression mass | 1 | 37,38 | 37,38 | 0,08 | 0,15 |
| Err | 40 | 18915,6 | 472,89 | | 77,96 |
| Total | 47 | 24264,0 | | | 100,00 |

The ANOVA results (Table 8) show that PU/β-TCP ratio and the impregnation time are statistically significant ($F_{(0,10;1;40)}$=2,835). The variation within trial, with a 77,96% contribution, is clearly higher than the variation between trials, with a contribution of 22,04% and indicate again that there are significant factors that were not considered in the study.

## 4. Conclusions and future work

The main objective of this work was the determination of the root causes of the "empty" quality problem.

The application of the Taguchi method allowed to develop in a structured way the evaluation of the process parameters, which constituted the first study of the performance of the process after its implementation.

The selection of the factors under study was developed by a multidisciplinary team using quality tools, cause-effect diagram (Ishikawa) and brainstorming.

In accordance with the Taguchi method, tests developed and performed using the orthogonal arrays, were planned and executed, allowing the analysis of mass and area responses. After collecting the results for the responses, graphic analyses of the effects of factors and analysis of variance were developed.

For the mass response of the block, the graphic analysis allowed to identify the factors of impregnation speed, size of the impregnation container, time of impregnation and PU/β-TCP ratio interaction with concentration of solids in the suspension as factors with bigger impact. The analysis of variance for all observations indicates that the error contribution is very high and none of the factors under study is significant. That is, the results obtained are not justified by the factors selected for the study, indicating the possibility of the existence of factors with influence on the impregnation process that was not included in the study.

For the void area response, the graphical analysis identifies the factors, PU/β-TCP ratio, impregnation time, size of the impregnation container and PU/β-TCP ratio interaction with concentration of solids in the suspension, as the bigger impact factors. The evaluation of the results through the analysis of variance for the obtained responses it was verified that the factors impregnation time and PU/β-TCP foam ratio are significant.

This work makes evident the contribution of the studied factors, avoiding the empirical analyzes carried out until the moment of the study, on the contribution of the factors to the impregnation process.

For future work it is recommended to remove non-significant factors, adding new factors not included in the study. The selection of candidates for new factors for the study requires an extensive analysis of all the identifiable factors for the process under study. New experiment designs should include replicating experiments making the important effects of factors more evident.

In addition to the experimental study, the R&R study for the measurement system was developed and confirmed its capacity.

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