Results of the full-factor experiments of prophylactic footwear construction recommended for patients with insular diabetes

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\textbf{Abstract.} The article covers the results of full-factor experiments of prophylactic footwear recommended for patients with diabetes. Comparative effects results of production determined the optimal parameters of prophylactic footwear are given. The article evaluates the use of orthopedic shoes in patients with diabetes mellitus with a foot ulcer or a minor previous one. Special prophylactic footwear with inner insole have been studied and applied and have been proven to relieve toenail pain in diabetes, thereby reducing the maximum pressure of the toe. The analysis of the dependence graphs obtained on the basis of analytical solutions of the regression equations obtained as a result of the conducted experiments and full factorial experiments is given.

\textbf{1. Introduction}

Timely selected prophylactic footwear prevent foot gangrene and reduce the risk of disability. Therefore, it is important to study the physiological and biomechanical characteristics of foot pathology in diabetic patients, the method of designing the optimal design of prophylactic footwear based on medical and technical requirements \cite{1}.

An effective prophylactic footwear includes an inner insole; each zone of the insole has a certain stiffness and is made of elastic EVA material. The insole zones are selected based on the actual pressure of the patient’s foot zones. To prevent pressure on the inflamed part of the patient’s foot, we suggest a load-bearing portion of the insole based on the deformation of the foot surface. In this case, the toes are protected from any inflammation, even at amputation \cite{2}.

Effectiveness of prophylactic footwear for patients with insular diabetes is determined by the degree to which it prevents the appearance and development of trophic wounds and the extent to which pre-existing changes in the foot are prevented. The main parameters for evaluating the effectiveness of prophylactic footwear are: reduction of tissue area in the pre-wound condition; reducing the number of foci of trophic wounds when wearing individually manufactured prophylactic footwear only depending on the condition of the foot, petrography (measuring the distribution of pressure on the sole of the foot in a footwear) of the feet.

Special prophylactic footwear with inner insole have been studied and applied and have been proven to relieve toenail pain in diabetes, thereby reducing the maximum pressure of the toe.

The basis for the creation of modern techniques and technologies is to conduct experiments on new developments and determine their optimal technological performance based on the results obtained. Mathematical and statistical methods are used in the planning of operations to increase the efficiency of
operations. In practice, these methods reduce the time to solve the set tasks, reduce the cost of practice and improve the quality of the results obtained [3].

2. Materials and methods

Conducting full-factor experiments this is one of the most common methods is the full-factor experiment method. When practicing this method, all the input factors determined are varied, the output factors are obtained, and their reliability is checked based on mathematical-statistical methods [4,5].

It is possible to vary the factors infinitely during the practice period, but it is sufficient to change the factors to two, three, or five levels to obtain clear practice results [6,7].

The experimental data were processed according to the program “regression analysis” developed in the laboratory of experimental planning of Bukhara Engineering-Technological Institute. Cochrane criterion was used to assess the homogeneity of the variance, Student criterion was used to assess the value of the regression coefficients and the Fisher criterion was used to assess the adequacy of the regression models [8, 9].

Thus, if the tattoo is given to cotton pieces with geometric dimensions \(100 \leq h \leq 125 \text{mm}\) at an angle of \(\alpha \geq 10^\circ\), they will change the trajectory of motion by touching the top wall, and the above-mentioned defects in the work of the machine will appear.

Factors influencing the technological performance of prophylactic footwear for patients with insular diabetes are the thickness of the special insole of the footwear (mm), the ratio of the specific insole surface (%), weight (kg) of patients with diabetes, so we define these indicators as undesirable factors (table 1).

| Table 1. Levels of variation of experimental factors. |
|------------------------------------------------------|
| Name of the factor | Coded icon | The real value of the factor | | Change interval |
|---------------------|------------|-----------------------------|---|----------------|
| Thickness of the insole (mm) | \(x_1\) | 5 | 10 | 15 | 5 |
| Ratio of insole surface (%) | \(x_2\) | 20 | 30 | 40 | 10 |
| Patient weight (kg) | \(x_3\) | 70 | 90 | 110 | 20 |

First, we substantiate the accepted values of these input factors:

- \(x_1\) is the thickness of the insole (mm). Patients with insular diabetes are provided with a special insole design designed for prophylactic footwear to provide the required load to the required pain points of the foot. In the construction of the insole, special attention was paid to its thickness, because it is the thickness of the inner insole and the material chosen for the insole that has the ability to absorb wounds when walking. Therefore, in order to study the optimal dimensions of a special insole made for prophylactic footwear, experiments used pad thicknesses ranging from 5 mm to 15 mm.

- \(x_2\) is the ratio of the surface of the insole. In studies, the essence of a special inner insole construction designed for prophylactic footwear of patients is that the rhombus elements, which have different hardness properties, are connected to each other. Depending on the painful zones of the patient's foot claw, rhomboid elements that are less pronounced in the corresponding zones of the insole are selected. Based on these studies, it is possible to vary the ratio of insole surface to 20% to 40%.

- \(x_3\) Weight (kg) of a patient with diabetes. Scientific research has been conducted mainly in middleweight patients. The results of experimental tests of patients with a lightweight of 70 kg to a maximum weight of 110 kg were obtained. On this basis, the deformation of the proposed
 prophylactic footwear special insole depending on the patient's weight was studied. The weight of patient varied from 70 kg to 110 kg were taken as input factor in the study.

As output factors, we determine the overall average deformation index of the special footwear insole for patients with insular diabetes. “Equatorial Footwear” LLC, “Gijduvon Poyabzali” PE footwear factories produced prophylactic footwear and special insole in practice, and conducted experiments on patients listed in the Republican specialized scientific-practical medical center of endocrinology named after Academician E.H. Turakulov.

The arithmetic mean of the output factors \( \bar{Y} \) was determined and the variance of the results \( S_i^2 \{ Y \} \) was calculated (table 2).

\[
\bar{Y} = \frac{Y_{i1} + Y_{i2} + Y_{i3}}{3}
\]

(1)

\[
S_i^2 \{ Y \} = \frac{\sum_{i=1}^{3} (Y_i - \bar{Y})^2}{m-1}
\]

(2)

Where \( m \) is the number of repetitions of the experiments under the same conditions.

| No. | \( x_1 \) | \( x_2 \) | \( x_3 \) | \( Y_1 \) | \( Y_2 \) | \( Y_3 \) | \( \bar{Y} \) | \( S_i^2 \{ Y \} \) |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| 1   | 0   | 0   | 0   | 4.5 | 4.6 | 4.8 | 4.63 | 0.02333 |
| 2   | 1   | 0   | 0   | 5.0 | 5.2 | 4.9 | 5.03 | 0.02333 |
| 3   | 0   | 1   | 0   | 5.4 | 5.6 | 5.5 | 5.50 | 0.01000 |
| 4   | 0   | 0   | 1   | 6.8 | 6.85| 6.75| 6.80 | 0.00250 |
| 5   | 0   | 0   | 0   | 5.6 | 5.8 | 5.5 | 5.63 | 0.02333 |
| 6   | 1   | 0   | 0   | 7.2 | 7.0 | 7.3 | 7.17 | 0.02333 |
| 7   | 0   | 0   | 1   | 7.6 | 7.5 | 7.2 | 7.43 | 0.04333 |
| 8   | 1   | 1   | 0   | 8.2 | 8.4 | 8.0 | 8.20 | 0.04000 |
| Total | | | | 6.300 | | | 0.18917 |

We check the homogeneity of the variance values using the Cochrane criterion. The value of the Cochrane criterion is determined by the following formula:

\[
G_s = \frac{S_i^2 \{ Y \}_{\text{max}}}{\sum_{i=1}^{N} S_i^2 \{ Y \}} = \frac{0.04333}{0.18917} = 0.229
\]

(3)

Where: \( G_s \) is the calculated value of the Cochrane criterion, \( S_i^2 \{ Y \} \) is the largest variance value of the test results, \( \sum_{i=1}^{N} S_i^2 \{ Y \} \) is the sum of the variance values.

The calculated value of the Cochrane criterion is compared with the value selected from the table. In this case, the condition \( G_s < G_{\text{tab}} \) must be met.

When there is a tabular value of the Cochrane criterion is \( P_D = 0.95 \).

\[
G_{\text{tab}} = \{ f_1 = N = 8, \ f_2 = m-1 = 3-1 = 2 \} = 0.5137
\]

(4)
Therefore, in our case the variances are homogeneous. Because the set condition $0.229 < 0.5137$ was met. Once these conditions are met, the regression coefficients are calculated and the regression equation is constructed. The regression equation is as follows [10, 11]:

$$ Y = b_0 + b_1 x_1 + b_2 x_2 + b_3 x_3 + b_{12} x_1 x_2 + b_{13} x_1 x_3 + b_{23} x_2 x_3 + b_{123} x_1 x_2 x_3 $$

(5)

Regression coefficients are calculated using the following formula:

$$ b_0 = \frac{1}{N} \sum_{i=1}^{N} \bar{Y}_i $$

(6)

Where: $N$ is number of experiments.

$$ b_j = \frac{1}{N} \sum_{i=1}^{N} x_{ij} \bar{Y}_i \quad \text{and} \quad b_{ij} = \frac{1}{N} \sum_{i=1}^{N} x_{ij} \bar{Y}_i $$

(7)

Where: $i$ is order of tests; $j$ is order of factors.

$$ b_0 = 6.3, \quad b_1 = 0.5, \quad b_2 = 0.68, \quad b_3 = 0.81, \quad b_{12} = 0.017, \quad b_{13} = 0.075, \quad b_{23} = 0.025, \quad b_{123} = -0.21. $$

Based on the calculations, the regression equation is as follows:

$$ Y = 6.3 + 0.5 x_1 + 0.68 x_2 + 0.81 x_3 + 0.017 x_1 x_2 + 0.075 x_1 x_3 + 0.025 x_2 x_3 - 0.21 x_1 x_2 x_3 $$

(8)

The significance of the regression coefficients was examined by calculating the calculated value of Student criterion:

$$ t_R = \frac{|b_j|}{S(b_j)}; \quad S^2(b_j) = \frac{S^2(\bar{Y})}{N} $$

(9)

Where: $S^2(Y)$ is series variance, it is determined by the following expression:

$$ S_m^2(Y) = \frac{1}{N \cdot m} \sum_{i=1}^{N} S_i^2(\bar{Y}) $$

(10)

Where: $S_m^2(\bar{Y})$ is recovery variance, which is defined by the following expression:

$$ S_m^2(\bar{Y}) = \frac{1}{N \cdot m} \sum_{i=1}^{N} S_i^2(Y) = \frac{1}{3 \cdot 8} \cdot 0.18917 = 0.0079 $$

$$ S^2(b_j) = \frac{S^2(Y)}{N} = \frac{1}{8} \cdot 0.0079 = 0.00098, \quad S(b_j) = \sqrt{0.00098} = 0.0313 $$

The calculated values of the Student criterion were calculated for the determined regression coefficients.

Where: $t_R(b_0) = 201.3, \quad t_R(b_1) = 15.9, \quad t_R(b_2) = 21.77, \quad t_R(b_3) = 25.75, \quad t_R(b_{12}) = 0.53 \quad t_R(b_{13}) = 2.39 \quad t_R(b_{23}) = 0.79 \quad t_R(b_{123}) = 6.63.$

The calculated value of the student criterion was compared with the value selected from the table. In this case, the following condition must be met.

$$ t_\alpha > t_{ab}; \quad t_{ab} = [P = 0.95; f_2 = 16] = 2.12 $$
If a given condition is met, the calculated regression coefficients are considered significant, but if the condition is not met, this regression coefficient is considered insignificant and is excluded from subsequent calculations. Based on the results of the calculations, since the values of $b_{12}$ and $b_{13}$ are smaller than the values selected from the table, and the subsequent calculation of the coefficients $b_{12}$ and $b_{13}$ is excluded as insignificant.

Thus, because of our calculations, the coefficients $b_0$, $b_1$, $b_2$, $b_3$, $b_{23}$ and $b_{123}$ are found to be significant, and subsequent calculations are continued with these coefficients. In this case, the regression equation is as follows:

$$Y = 6.3 + 0.5x_1 + 0.68x_2 + 0.81x_3 + 0.075x_1x_3 - 0.21x_1^2x_3$$

The resulting regression equation was tested for adequacy based on the Fisher criterion [5]. The calculated value of the Fisher criterion was determined from the following expression:

$$F_R = \frac{S_{ad}^2(Y)}{S^2(Y)}$$

(12)

Where, when $N - M > 0$, $S_{ad}^2(Y)$ is adequacy variance; $M$ is the number of significant coefficients.

$$S_{ad}^2(Y) = \frac{1}{N - (k + 1)} \cdot \sum_{i=1}^{N} (\bar{Y}_i - Y_{Ri})^2$$

(13)

The calculation results are presented in Table 3.

| No. | $\bar{Y}_i$ | $Y_{Ri}$ | $\bar{Y}_i - Y_{Ri}$ | $(\bar{Y}_i - Y_{Ri})^2$ |
|-----|-------------|----------|----------------------|------------------------|
| 1   | 4.63        | 4.595    | 0.035                | 0.001225               |
| 2   | 5.03        | 5.025    | 0.005                | 0.000025               |
| 3   | 5.50        | 5.535    | -0.035               | 0.001225               |
| 4   | 6.80        | 6.805    | -0.005               | 0.000025               |
| 5   | 5.63        | 5.645    | -0.015               | 0.000225               |
| 6   | 7.17        | 7.215    | -0.045               | 0.002025               |
| 7   | 7.43        | 7.425    | 0.005                | 0.000025               |
| 8   | 8.20        | 8.155    | 0.045                | 0.002025               |
| Total|             |          | 0.01                 | 0.0068                 |

Hence, the model is inadequate because Fisher criterion is $F_R < F_p$, i.e., it adequately represents the change in the deformation index of a particular footwear insole in the process.

The tabular value of the Fisher criterion from a special table:

$$F_R [P_D = 0.95; f = 8 \cdot (3 - 1) = 16; \ S_{ad}^2 = 4] = 5.85$$

Table 3. The results of calculating the output factor using the regression equation are shown in the table.
The regression coefficients in the regression equation play an important role in characterizing the output factor.

The higher the value of the regression coefficient before the input factor, the higher the effect of this factor on the outgoing factor. Conversely, if the value of the coefficient is small, the effect is small. The signs in front of the coefficients indicate how they will be affected. That is, if (+) is positive, it has a positive effect on the value of the output factor, and if (-) is negative, it has a negative effect.

3. Results and discussion

3.1. Analysis of regression equations and results

In order to clarify the research, the numerical solution of the equation was solved in Excel and the graphs of the relationship of the parameters were obtained (figure 1, 2). Figure 1 shows a graph of the thickness of the insole as a function of its overall mean deformation. The first line on the graph is at the minimum values of $x_2$ and $x_3$, the second and third lines are at intermediate values, and the fourth line is at maximum values.

![Figure 1. Graph of the thickness of the insole depending on the overall average deformation of the insole.](image)

where: 1. $X_2 = 20\%$, $X_3 = 70\ kg$; 2. $X_2 = 30\%$, $X_3 = 90\ kg$; 3. $X_2 = 40\%$, $X_3 = 110\ kg$.

The graphical analysis showed that the total average deformation of the pile from increasing the pile thickness from 5 mm to 15 mm, i.e. the minimum values of $x_2$ and $x_3$ are $x_2 = 20\%$, from $x_5 = 70\ kg$ to 4.52 mm to 4.95 mm, in the intermediate values $x_2 = 30\%$, $x_3 = 90\ kg$, an increase of 5.3 mm to 6 mm was observed. At maximum values $x_2 = 40\%$ and at $x_3 = 110\ kg$ we can see an increase from 6.3 mm to 6.95 mm.

Figure 1 shows a graph of the relationship between the surface area of the insole and the overall average deformation of the insole.
where: 1- $X_1 = 5 \text{mm}$, $X_3 = 70 \text{kg}$; 2- $X_1 = 10 \text{mm}$, $X_3 = 90 \text{kg}$; 3- $X_1 = 15 \text{mm}$, $X_3 = 110 \text{kg}$.

In this case, when the ratio of the surface of the shell increases from 20% to 40%, the total average deformation of the shell is at the minimum values of $x_1$ and $x_3$, i.e. $x_1 = 5 \text{ mm}$, $x_3 = 70 \text{ kg}$ from 4.55 mm to 6.2 mm, at intermediate values $x_1 = 10 \text{ mm}$, $x_3 = 90 \text{ kg}$ appears to vary from 4.95 mm to 6.51 mm, $x_1 = 15 \text{ mm}$ and $x_3 = 80 \text{ kg}$ from 5.2 mm to 6.95 mm.

4. Conclusions
Analysis of the dependence graphs obtained based on analytical solutions of regression equations obtained as a result of experiments and full-factor experiments shows that the optimal parameters of prophylactic footwear special insole used in patients with diabetes were selected as follows: insole thickness 15 mm, insole surface ratio 35 – 40 % and when the average weight of the patients is 70 – 80 kg, we can see that the average total deformation of the insole in the new construction, which is recommended, is 6.6 – 6.95 mm. Production test results are given.

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