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# A STUDY ON IMMEDIATE AND LONG-TERM EFFECTS OF A NOVEL MINERAL-VITAMIN COMPLEX FOR STRENGTHENING THE NAIL PLATE

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**ABSTRACT** — We conducted a randomized, blind, comparative, placebo-controlled, parallel study of a biologically active food supplement designed to normalize the condition of the nail plate. The paper presents the results of studying the effectiveness of this vitamin and mineral complex. It was experimentally established that a course intake of the study drug improves the appearance of the nail plate, the effect is observed in 93% of all studied cases. In respondents who used the drug, an increase in the strength of the nail plate was confirmed. It was found that a six-week course of daily intake of the product in recommended doses fully provides the nail plate with all necessary vitamins and minerals. There were no side effects during the observation period.

**KEYWORDS** — vitamins, mineral-vitamin complex, nail plate, strength.

## INTRODUCTION

Today there are many different options for the health and appearance of nails, from traditional home recipes to professional salon procedures. The condition of the nails primarily depends on what kind of internal recharge they have, and only then on external factors [1].

Features of the structure, area and thickness of the nail depend on many factors: hormonal activity of the body, structural features of the terminal phalanx of the fingers, age, gender, and even on the profession. If the thickness of the nails is formed genetically, then their health largely depends on nutrition [2, 3]. Unfortunately, modern reality is such that, due to circumstances, a person cannot get the necessary amount of nutrients. To compensate for the deficiency of these nutrients, mineral and vitamin complexes are being developed [4].

The aim of the work was to study the effect of the use of mineral-vitamin complex on the strength of the nail plate.

The study was conducted on the basis of the Department of Pharmaceutical Technology with the course of medical biotechnology of the Pyatigorsk Medical and Pharmaceutical Institute, a branch of the Volgograd State Medical University.

## OBJECTS AND RESEARCH METHODS

The object of the study was a biologically active food supplement, the certificate of state registration No.RU.77.99.88.003.E.000498.02.18 dated 02.02.2018; the approval of the Federal Research Center of Nutrition, Biotechnology and Food Safety (Moscow, Russia) No. 529 / E-1109 / b-17 dated 28.12.2017.

The vitamin-mineral complex under study is recommended as a biologically active food supplement - an additional source of vitamins: A, D3, E, B1, B2, B3, B5, B6 and minerals: zinc, iron, calcium. It promotes healthy development and growth of the nail plate.

The study included 60 volunteers aged 18 to 60 years (mean age  $25.58 \pm 3.1$  years) who attended a beauty salon. The volunteers were divided into 2 clinical groups: the main (1<sup>st</sup> group) and control (2<sup>nd</sup> group), 30 people each (4 men and 26 women), comparable in age and condition of the nail plate. The main complaints were: rough, opaque nail plate, fragility and splitting of the nail. Slow nail growth ( $<0.7$  mm in 2 weeks) was verified in 9 and 9 volunteers, respectively (30%). The disturbed relief of the nail plate was revealed in 33.33% and 36.36%, respectively. According to the oral survey, 60% of volunteers used gel nail polishes for a long time (more than 1 year). Some of the subjects (43.33% and 40%, respectively) had white spots and grooves on their nails, indicating a lack of zinc [5].

Volunteers received the supplement in a randomized, double-blind, comparative, placebo-controlled and parallel study. The duration of the study was 6 weeks. The supplementation was prescribed in the dose of one pill twice a day with food. In the control group, volunteers took one placebo pill twice a day with food. In the next 4 weeks of observation (7–10 weeks), long-term results were studied without intake of the supplementation.

Table 1. Composition of the mineral and vitamin complex

Active (functional) matrix			
Nº	Name	Content in one tablet, mg	% of the recommended daily intake
1	Vitamin B1 (as thiamine hydrochloride)	1,5	207
2	Vitamin B2 (riboflavin)	2,0	250
3	Vitamin B3 (nicotinamide)	20,0	222
4	Vitamin B5 (as calcium pantothenate)	5,0	167
5	Vitamin B6 (pyridoxine)	2,0	200
6	Vitamin A (as retinol acetate)	0,9	225
7	Vitamin E (as alpha-tocopherol)	15,0	200
8	Vitamin D3 (as Cholecalciferol)	0,005	200
9	Calcium	400,0	80
10	Iron	10,0	121–143
11	Zinc	6,0	133–167
Excipients			
Nº	Name	Content in one tablet, g	Content in a daily dose, g
1	microcrystalline cellulose	0,4619	0,9238
2	magnesium stearate	0,016	0,032
3	polyvinylpyrrolidone	0,0111	0,0222
4	hydroxypropyl methylcellulose	0,0267	0,0534
5	polyethylene glycol	0,00896	0,01792
6	iron oxide yellow	0,0028	0,0056
7	titanium dioxide	0,00896	0,01792
8	iron oxide red	0,00058	0,00116

## RESEARCH METHODS

In the laboratory, the condition of the nail plate of the little finger of the left hand was recorded every two weeks in all the volunteers participating in the study. The outgrowing part of the nail plate was removed by the specialists of the beauty salon with the appropriate processing of the cut edge. The cut part of the nail was tested for tensile strength using a Pharmaceutical tester PJ-3. The procedure for determining the strength of the cut nail was carried out during the day, in order to avoid the loss of moisture and, accordingly, elasticity.

Statistical data processing was carried out by methods of variation statistics using parametric criteria. Continuous numerical values were expressed as mean values and their standard deviation ( $\bar{X} \pm \sigma$ ) [6, 7].

## RESULTS AND DISCUSSION

At the initial stage of the research, the strength of the nail plate was determined. The initial measurement of the strength of the nail plate varied from 0.2 N/m<sup>2</sup> to 0.51 N/m<sup>2</sup>, which is associated with the individual characteristics of the body (age, diet, professional activity, etc.). The study was carried out in the spring.

The first two weeks of taking the drug showed the following results. In the main group, the strength of the nail plate increased only in 41% of cases, in 7% of cases it remained unchanged, in 52% of cases, the strength continued to decrease. In the placebo group, only in 20% of cases, the strength of the nail plate increased, in 10% it remained unchanged. In 70% of cases, the strength continued to decline. On average, both groups showed a seasonal decrease in strength (Fig. 1, 2).

After next two weeks of receiving the drug, due to the accumulation of the drug, the clinical picture has changed a little in the main group. Already in 62% of cases, the strength of the nail plate increased compared to the previous period, in 1% it remained unchanged, in 37% of cases the strength slightly decreased. On average, the group showed a tendency to increase the strength of the nail plate. In the placebo group, the strength of the nail plate slightly increased in 70% of cases, it remained unchanged in 7%, and the strength continued to decrease in 23% of cases. Thus, on average, there was a slight increase in strength across the group.

Over the next two weeks of observation (5–6 weeks) in 90% of cases in the main group, the strength of the nail plate increased compared to the previous period whereas 7% remained unchanged. A decrease in strength was noted only in 3%. In the main group, the trend towards an increase in the strength of the nail plate persisted, as a positive growth rate of 0.22 was confirmed. In the control group, in 13% of cases, the strength of the nail plate slightly increased compared to the previous period, in 3% it remained unchanged, in 74% of cases, the strength continued to decrease. In this group, there was a decrease in density compared to the previous two weeks, respectively, the growth rate of the indicator was -0.01.

Within 7–8 weeks of observation already without taking the product in the main group in 86% of cases, the strength of the nail plate increased compared to the previous period, a slight decrease in strength was noted only 14%. In the placebo group, in 75% of cases, the strength of the nail plate slightly increased compared to the previous period, in 25% of cases, the strength continued to decrease.

In the next two weeks of observation (9–10 weeks) in the main group in 79% of cases, the strength

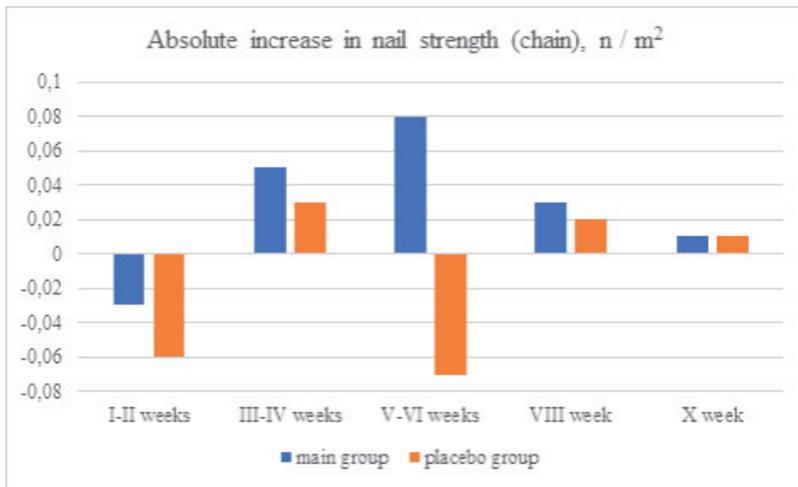


Fig. 1. Chain strength gain of the nail plate

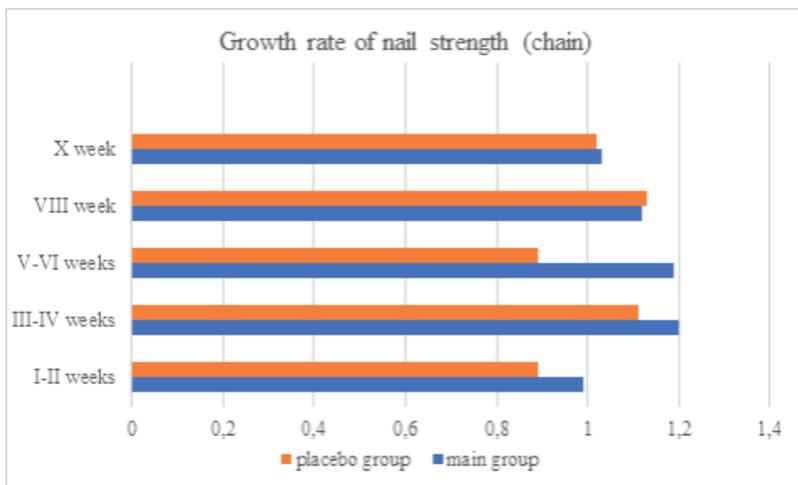


Fig. 2. The chain growth rate of the strength of the nail plate

of the nail plate increased in comparison with the previous period, it was noted in 21%. The average absolute increase in the indicator was  $0.01 \pm 0.001$  n/m<sup>2</sup>. Average coefficient of change in strength (growth) was  $1.05 \pm 0.002$ . On average in the group, there was a moderate trend towards an increase in the strength of the nail plate, as evidenced by a positive growth rate of 0.20.

In the placebo group, in 62% of cases, the strength of the nail plate slightly increased compared to the previous period, in 2% it remained unchanged, and in 36% of cases, the strength continued to decrease. The average absolute increase in the indicator is negative and amounts to  $0.01$  N/m<sup>2</sup>  $\pm 0.001$ . Average coefficient of change (growth) of strength was  $1.03 \pm 0.002$ . On average, the group showed a tendency towards a decrease in density compared to the previous two weeks, respectively, the rate of growth of the indicator was  $-0.11$ .

Taking the strength of the nail plate as a basis for comparison at the time of the beginning of the experiment, we obtained the following average basic characteristics for the groups (Table 2).

The given values indicate that in the main group there is an increase in the strength of the nail plate, the average strength of the plate increased by  $37 \pm 0.2\%$ , there is a clear tendency to an increase in strength (the growth rate of nail strength is  $0.5 > 0$ ). In the control group, the average strength of the nail plate decreased by an average of  $9\% \pm 0.8$  and there is a tendency to further decrease ( $-0.01 < 0$ ).

## CONCLUSION

In a subjective assessment carried out by a questionnaire-survey method, the study participants before the start of therapy were not satisfied with the appearance and condition of their nails, the effectiveness of previously conducted measures to improve their appearance.

**Table 2.** Average values of the basic characteristics of the time series for the first indicator

Groups	Absolute increase in nail strength	Growth rate of nail strength	The rate of increase of strength of the nail
Main group	0,13±0,001	1,37±0,001	0,50±0,003
Control group	-0,05 ±0,001	0,91 ±0,001	-0,01 ±0,003

The results of a randomized, blind, comparative, placebo-controlled and parallel studies have confirmed the ability of the drug to increase the strength of the nail plate.

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