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STATISTICAL ANALYSIS USING THE AOFAS ANKLE-HINDFOOT SCORE TO ASSESS LONG-TERM OUTCOMES OF DISTAL TIBIA AND FIBULA METAPHYSEAL FRACTURES TREATMENT

СТАТИСТИЧНИЙ АНАЛІЗ ВІДДАЛЕНИХ РЕЗУЛЬТАТІВ МАЛОІНВАЗИВНОГО ОСТЕОСИНТЕЗУ ПЕРЕЛОМІВ ДИСТАЛЬНОГО МЕТАЕПІФІЗУ КІСТОК ГОМІЛКИ ЗА ШКАЛОЮ AOFAS ANKLE-HINDFOOT SCORE

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Abstract. *The relevance of clinical studies on the surgical treatment of fractures of the distal epimetaphysis of the tibia and fibula is beyond doubt, since the frequency of complications and unsatisfactory results reaches up to 30%. A study of long-term treatment results with a period after an injury of more than 5 years showed that only 35% of patients are satisfied with the results of treatment.* ***The purpose of the study*** *is to clinical substantiate the effectiveness of minimally invasive osteosynthesis of fractures of the distal epimetaphysis of the distal tibia by statistical analysis of long-term results on the AOFAS Ankle-Hindfoot Score in three clinical groups of patients. For the period from 2007 to 2017, 342 patients with fractures of the distal segment of the distal tibia were operated on, of which 265 patients were examined. The mean age of patients was 45.15±15.98 years (from 18 to 86 years). The first clinical group (experimental) included patients after minimally invasive osteosynthesis using K wire and screws using advanced technology (113 patients, 42.64% of the total group). patients after external osteosynthesis (36 patients, 13.58%) and patients after plate osteosynthesis (116 patients, 43.77%) were included in the third clinical group. Long-term effects were evaluated using the AOFAS Ankle-Hindfoot Score (100 Points Total) using parametric statistical analysis methods. Microsoft Office 2016 – Excel 2016 and BioStat 2007 (v. 5.9.8.5) are used. Our statistical analysis showed probably better results in the 1st clinical group. Accordingly, this was expressed in a significantly lower level of pain (lower than the Ankle-Hindfoot Scale by 17.7%), probably better functional activity of patients (only 10.84% lower than the Ankle-Hindfoot Scale) with a qualitative axial balance (only 3.8% lower than the Ankle-Hindfoot Score).*

Key words*: distal tibia fractures, pylon fractures, minimally invasive osteosynthesis, long-term outcomes, AOFAS Ankle-Hindfoot Score, statistical processing of indicators.*

Introduction.

The relevance of clinical studies on the surgical treatment of fractures of the distal epimetaphysis of the distal tibia, including the pylon, is beyond doubt, since the

frequency of complications and unsatisfactory results is up to 30% [1, 2, 4]. The main problems in the treatment of epimetaphyseal intra-articular fractures are the formation of contractures, deformities, osteoarthritis, lymphostasis [5, 6,8]. 72% of patients were treated with surgery and 38% with conservative methods.

At the present level, it is useful to study the long-term results of surgical treatment of fractures from the standpoint of evidence-based medicine (evidence-based medicine). This term, proposed in 1990 by Canadian scientists (Mack Master University, Toronto, Canada), defines an evidence-based branch of practical medicine that includes the search, comparison, summary and use of the evidence obtained in the interests of patients [5, 6]. The term "evidence-based medicine" for a significant category of people is hereafter Incomprehensible. It is often associated with forensic medical examination, establishing paternity, etc., or asked: "What is being proven here?". In the absence of sufficient control in the market of medical services, the introduction of the principle of evidence in medicine will protect the patient from an "experiment" on him, on the one hand, and a practicing doctor from groundless claims or unfounded lawsuits. The use of evidence-based medicine involves the use of exact sciences, in particular the use of parametric methods of statistical analysis [9, 10].

The purpose of the study is to clinical substantiate the effectiveness of minimally invasive osteosynthesis of fractures of the distal epimetaphysis of the distal tibia by statistical analysis of long-term results on the AOFAS Ankle-Hindfoot Scale in three clinical groups of patients.

Materials and methods. In the clinic of the Department of Traumatology and Orthopedics of Bukovyna State Medical University on the basis of the Emergency Hospital in Chernivtsi, 342 patients with fractures of the distal segment of the distal tibia were operated on in the period from 2007 to 2017. Of these, fractures of the distal metaepiphysis of the tibia/fibula (segment 43 according to the AO, Table 1 A) were observed in 105 victims, and fractures of the ankles (segment 44 according to the AO) were observed in 237 people. women – 136 (39.77%).

In the course of the work, we examined 265 patients. The average age of patients was 45.15±15.98 years (from 18 to 86 years). Among them: patients under 30 years

old – 52 people (19.62%), from 30 to 40 years old – 56 people (21.13%), from 40 to 50 years old – 52 people (19.62%), from 50 to 60 years old – 47 (17.74%), over 60 years old – 58 (21.8%). To **the first clinical group** included patients who underwent minimally invasive osteosynthesis using needles and screws (113 patients, 42.64% of the total group). The **second clinical group** included patients who underwent AZF osteosynthesis (36 patients, 13.58%) and the **third clinical group** included patients who underwent plate osteosynthesis (116 patients, 43.77%).

The assessment of long-term consequences was carried out with the determination of the following parameters on the **AOFAS Ankle-Hindfoot Scale** (100 Points Total): pain level (absent, mild, moderate, severe); activity restrictions (no restrictions, there are restrictions, the need for additional support, severe restrictions); the maximum distance that can be covered on foot (number of blocks from 1 to more than 6); walking on rough terrain, terrain (no difficulties, some difficulties on uneven terrain, significant difficulties on uneven terrain); changes in course (none, obvious, pronounced); sagittal movement (normal, moderate restriction, sharp restriction); movements in the back of the foot (normal, moderate restriction, sharp relaxation); stability in the ankle joint and back of the foot (stable, unstable); axial balance (good, satisfactory, unsatisfactory and total indicator in points (total 100 points).

After evaluating the long-term results of ankle surgery using the Ankle-Hindfoot Scale, we carried out a comprehensive statistical processing of the results obtained using parametric methods of statistical analysis. Microsoft Office 2016 – Excel 2016 and BioStat 2007 (v. 5.9.8.5) are used.

Results of the study and their discussion.

Comparison of the results of individual indicators and the sum of points as a whole revealed a statistically probable difference between individual indicators for clinical groups of operated patients (Table 1).

As can be seen from Table 1, patients in clinical group 1 had pain levels according to the Ankle-Hindfoot Scale at the lung level, while patients in group 2 were between moderate and mild levels. Also, patients of the 2nd clinical group have certain restrictions in everyday life, they can walk a much shorter distance on foot and move

more difficult over rough terrain. They have obvious changes in gait, a pronounced more moderate restriction of sagittal movements of the foot next to almost 50% restriction of its mobility in the posterior section. This leads to a decrease in stability in the ankle joint as a whole and the back of the foot with a violation of the axial balance by 11.60%. These changes are probably lower than those of patients in clinical group 1, respectively.

Table 1 Rates of Evaluation of Long-Term Outcomes of Ankle Surgery by Ankle-Hindfoot Scale for Long-Term Outcomes (x ± Sx)

	Group 1 (n=26)	*Group 2 (n=25)*	*Group 3 (n=23)*	*The entire sample (n=74)*
Pain level	32,92±1,469	26,25±2,630 p<0,05	32,61±1,436 p2<0,05	31,40±0,983
Activity restrictions	7,54±0,521	5,62±0,479 p<0,05	8,17±0,451 p2<0,01	7,67±0,316 p3<0,01
Maximum distance that can be walked	4,50±0,138	3,28±0,295 p<0,01	4,74±0,093 p2<0,001	4,51±0,090 p3<0,01
Walking on rough terrain, terrain	4,23±0,194	3,45±0,227 p<0,05	4,16±0,208 p2<0,05	4,28±0,145 p3<0,01
Changes in course	6,92±0,464	5,56±0,431 p<0,05	6,13±0,351	6,44±0,282
Sagittal movement	7,68±0,337	6,54±0,354 p<0,05	7,30±0,319	7,16±0,239
Movements in the back of the foot	5,82±0,289	4,65±0,397 p<0,05	5,03±0,263 p1<0,05	5,40±0,185
Stability in the ankle and back of the foot	7,89±0,115	6,45±0,245 p<0,001	7,65±0,347 p2<0,05	7,67±0,202 p3<0,01
Axial balance	9,62±0,157	8,54±0,377 p<0,05	9,13±0,161 p1<0,05	9,54±0,112 p3<0,05
Sum of points	84,00±2,956	73,15±3,547 p<0,05	86,87±2,870 p2<0,01	84,07±1,948 p3<0,05

p is the degree of probability of the difference in indicators between clinical groups 1 and 2

p1 is the degree of probability of the difference between clinical groups 1 and 3

p2 is the degree of probability of the difference in indicators between clinical groups 2 and 3

p3 is the degree of probability of the difference between group 2 and the entire sample

As for patients of the 3rd clinical group, they have probable changes mainly in the proportion of patients of the 2nd group, and most of the partial 1st clinical group. In particular, patients of the 3rd clinical group have almost similar indicators of the level of pain, the functionality of the operated ankle joint as a whole. However, there are probably lower indicators of the level of mobility in the posterior part of the foot and axial balance of the foot compared to patients in group 1. Compared to patients of the 2nd group in the 3rd clinical group, qualitatively better and probably higher indicators of activity, ability to move at a distance and on rough terrain with significantly better stability in the ankle joint and hindfoot next to the best indicators of both the axial balance of the operated foot and the total indicator as a whole. Similar probable differences were observed when comparing the indicators of long-term consequences in patients of the 2nd clinical group and the total sample of patients.

As shown in the table, there may be a certain correlation-regression relationship between the total indicator of the assessment of the condition of the ankle joint and the hindfoot according to the Ankle-Hindfoot Scale, between the individual indicators that were used to assess the long-term results of operations on this joint. The latter may indicate the influence of certain factors of the quality of life of patients after the operation on the total indicator, i.e. the quality of the surgical intervention as a whole.

Thus, when using various methods of surgical intervention on the ankle joint using spokes, plates and AZF, individual indicators in clinical group 1 are better than in groups 2 and 3, which was confirmed by a statistically probable difference between the corresponding indicators.

Therefore, for further assessment of the influence of individual indicators on the sum of points for assessing the long-term results of ankle surgery, a correlation analysis was carried out, and in the presence of positive correlation dependencies, the regression dependence of these pairs of indicators with each other was calculated (linear regression).

The results of the correlation analysis showed the following (Table 2).

A correlation analysis between individual indicators and the sum of points in the 1st clinical group showed a clear relationship between such indicators as pain level,

activity restriction, maximum distance traveled, the presence of gait changes, sagittal movements, movements in the hindfoot by the total indicator.

Table 2 Matrix of correlations of the impact of indicators evaluating the results of ankle surgery according to the Ankle-Hindfoot Scale on the sum of points (r)

	Group 1 (n=26)	*Group 2 (n=25)*	*Group 3 (n=23)*	*The entire sample (n= 74)*
	Sum of points			
Pain level	0,938 p<0,001	0,847 p<0,05	0,909 p<0,001	0,117
Activity restrictions	0,722 p<0,01	0,888 p<0,05	0,664 p<0,05	-0,533 p<0,001
Maximum distance that can be walked	0,736 p<0,01	0,874 p<0,05	0,575 p<0,05	-0,005
Walking on rough terrain, terrain	0,653 p<0,05	0,663	0,792 p<0,01	-0,094
Changes in course	0,738 p<0,01	0,616	0,652 p<0,05	-0,075
Sagittal movement	0,735 p<0,01	0,806 p<0,05	0,676 p<0,05	0,206
Movements in the back of the foot	0,691 p<0,05	0	0,613 p<0,05	-0,171
Stability in the ankle and back of the foot	0,528 p<0,05	0,755 p<0,05	0,647 p<0,05	0,020
Axial balance	0,766 p<0,01	0,813 p<0,05	0,651 p<0,05	-0,057
Terms of study of long-term results	0,837 p<0,01	0,540	0,635 p<0,05	-0,027

In particular, in this group of patients, the analysis showed a statistically probable relationship between the level of pain and the sum of points – r=0.938452 (p<0.001; n=26), which was expressed by the linear regression equation of the form x =-7.2671 + 0.4665 * y, where x is the sum of points; y is an indicator of the level of pain (Fig. 1).

In patients in clinical group 2, the indicators of the dependence of the level of pain and the sum of points were significantly lower and probably dependent - r=0.84733

($p<0.05$; $n=25$). This was expressed by linear regression equations of the type $x=-5.5308 + 0.4168 * y$, where x is the sum of points; y is an indicator of the level of pain (Fig. 2).

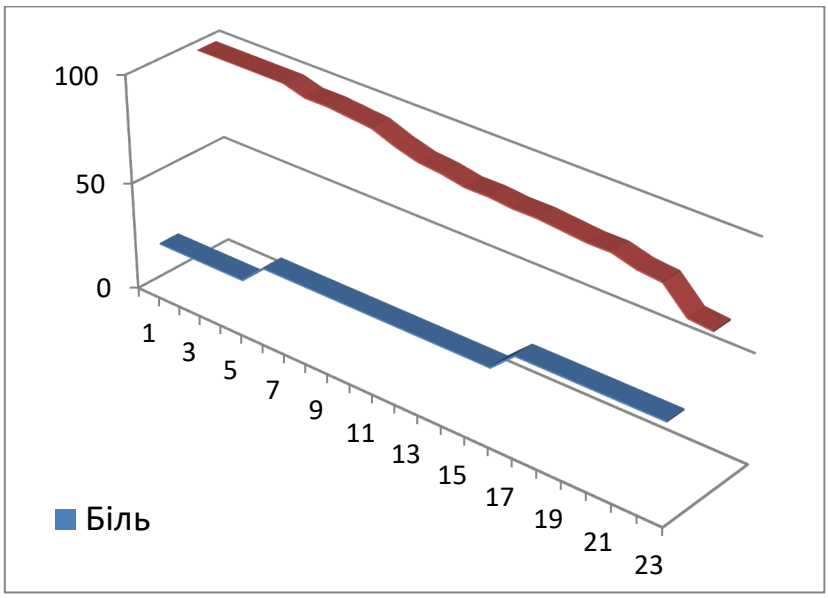

Fig. 1. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 1.

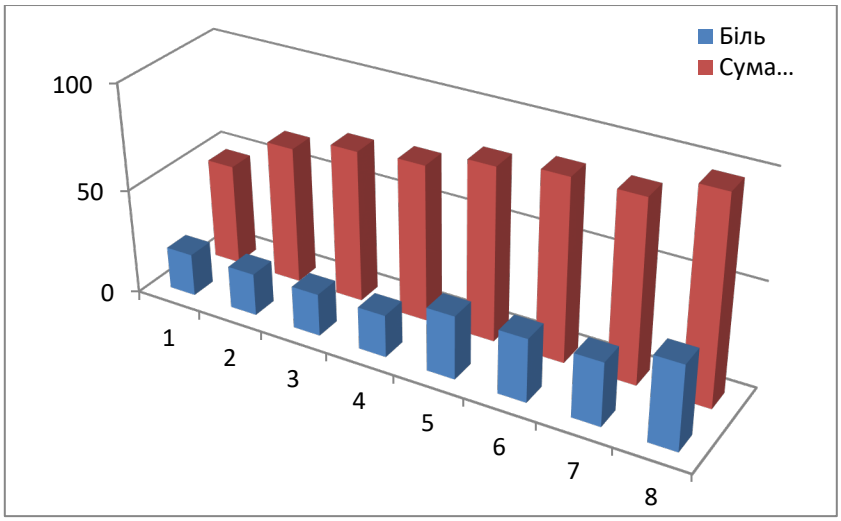

Fig. 2. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 2.

In patients in clinical group 3, the indicators of the dependence of the level of pain and the sum of points were also significantly lower and probably dependent - $r=0.909735$ ($p<0.001$; $n=23$), which was expressed by linear regression equations of type $x =- 6.9211 + 0.4550 * y$, where x is the sum of points; y is an indicator of the level of pain (Fig. 3).

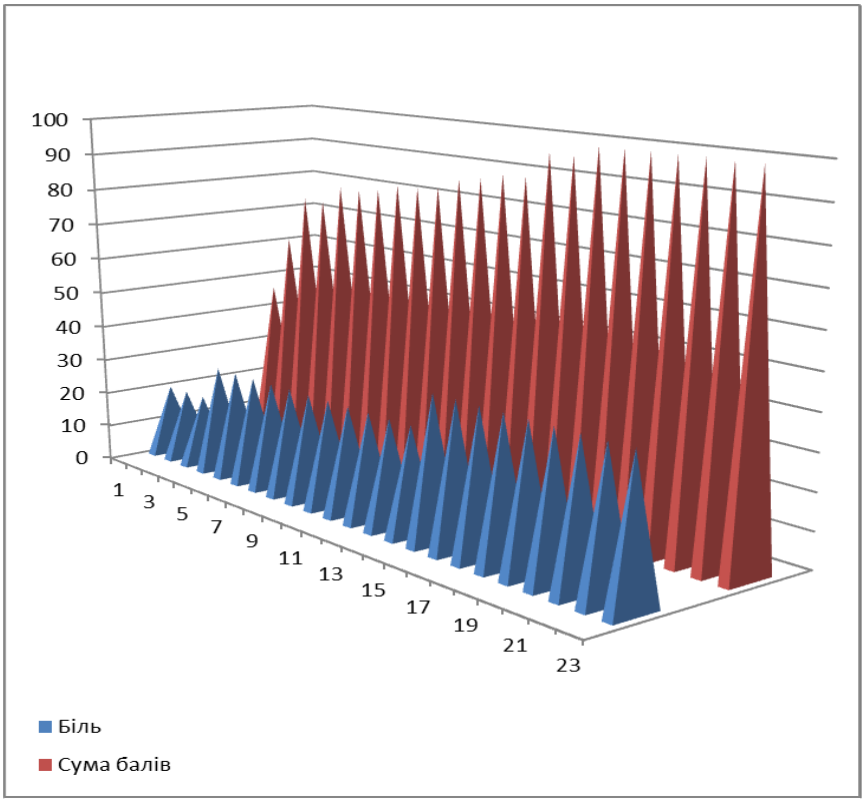

Fig. 3. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 3.

The next indicator that can significantly affect the total indicator of long-term results of ankle surgery is activity restriction with the need for additional support when walking. Thus, in 1 group of patients who underwent surgical intervention using needles, there was a probable correlation between these indicators ($r=0.722169$, $p<0.01$), which was expressed by the equation of linear regression of the view - $x = -3.1538 + 0.1273 * y$, where x is the sum of points; y is the activity limit (Fig. 4).

In group 2, a similar correlation relationship had a correlation index of $r=0.88792$ with a degree of probability of $p<0.05$, which was described by the linear regression equation - $x = -1.9808 + 0.1129 * y$, where x is the sum of points; y is the activity limit (Fig. 5).

The impact on the sum of points of indicators for assessing the long-term results of operations of such a component as the use of additional support also turned out to be probable in the 3rd group of patients – $r=0.663515$ ($p<0.05$), but significantly lower. The latter was described by a regression equation of the type - $x = -0.8976 + 0.1044 * y$ (Fig. 6).

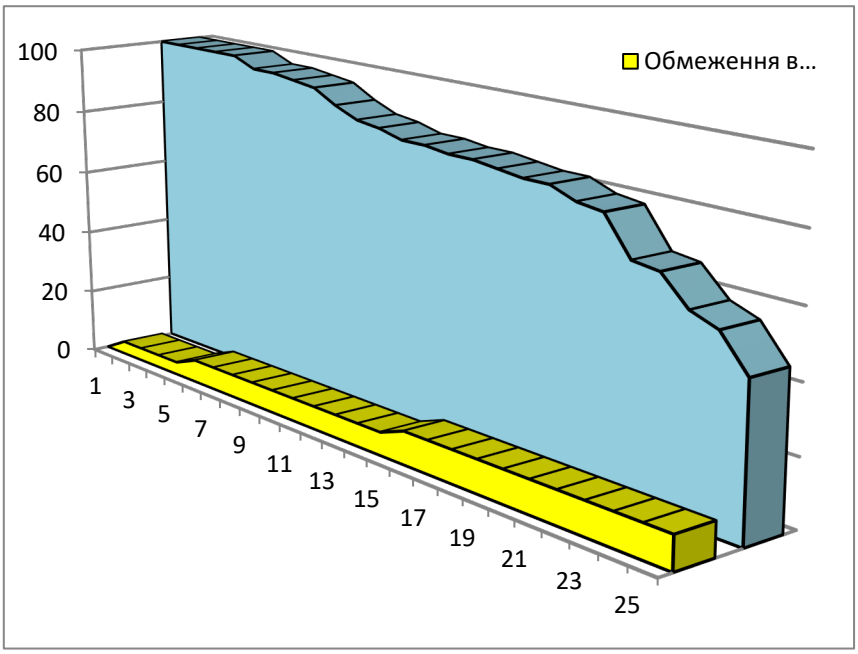

Fig. 4. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 1.

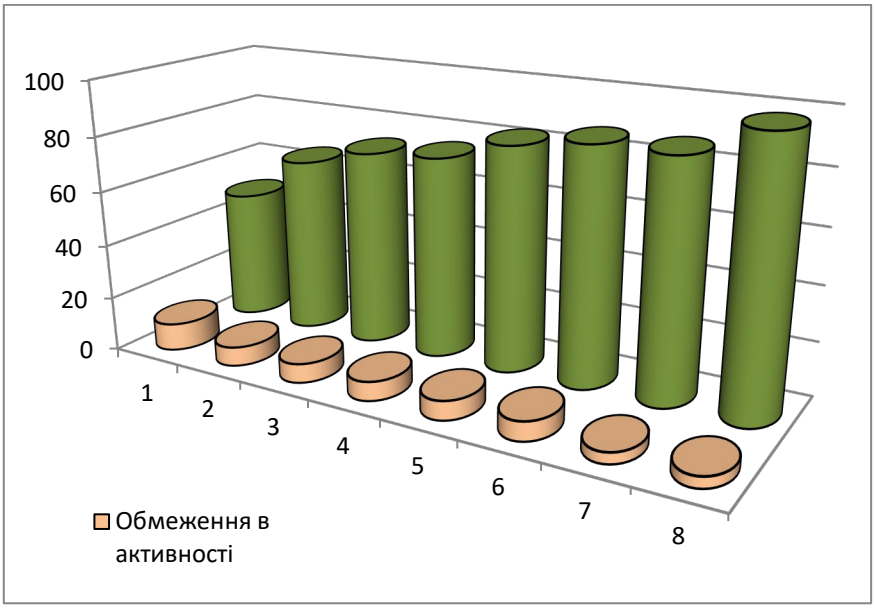

Fig. 5. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 2.

The next indicators that can significantly affect the amount of points and directly depend on the quality of the surgical intervention provided are the maximum distance that the patient can walk (number of blocks), walking on terrain, as well as changes in gait (from minor to significant). Our statistical processing showed that in the 1st group of patients, the studied above indicators affect the total indicator of the patient's condition quality when studying long-term results, although not significantly:

r=0.652548 (p<0.05), r=0.737782 (p<0.01) and r=0.734969 (p<0.01) for the dependence on distance, walking on the terrain and change in gait, respectively.

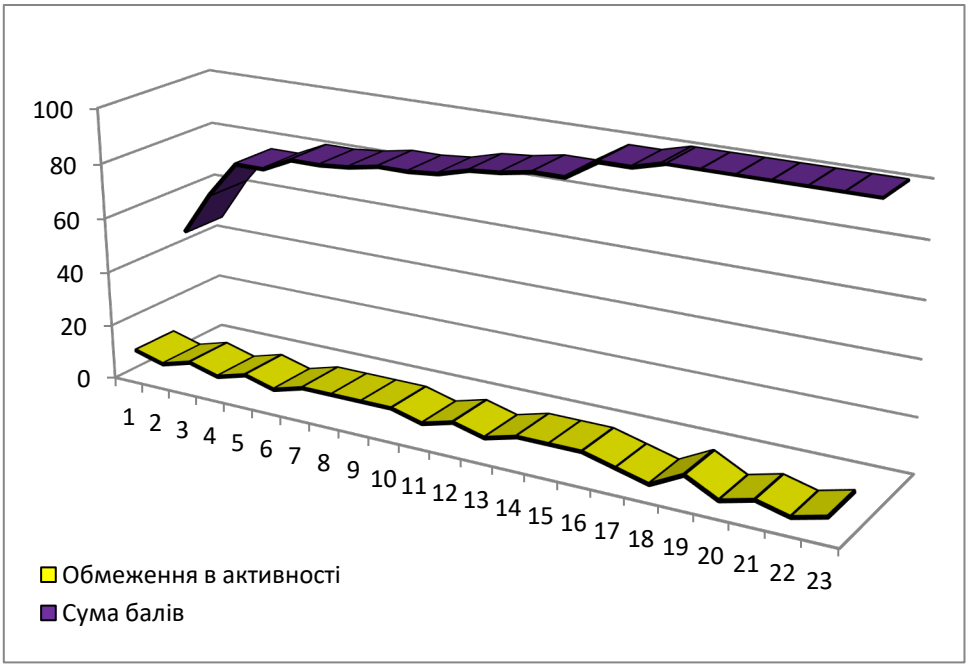

Fig. 6. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 3.

These correlation dependencies were described by the corresponding levels of linear regression: sum of points = 1.6014 + 0.0345 * maximum distance, sum of points = 0.6223 + 0.0430 * walking on terrain and sum of points =- 3.9233 + 0.1158 * changes in gait.

In the 2nd group of patients, after studying similar indicators with the use of surgery using AZF, similar indicators practically did not affect the total indicator of the patient's quality of life with the corresponding correlation coefficients: r=0.87427 (p<0.05), r=0.66309 and r=0.6159.

And accordingly, in the 3rd group of patients who underwent surgery on the ankle joint using plates, the same indicators also affected the total indicator, even with lower correlation coefficients: 0.575132 (p<0.05), 0.792127 (p<0.01) and 0.652435 (p<0.05), respectively.

Another important indicator that makes a qualitative contribution to the overall total indicator of the patient's condition is the ability to flex and extend the joint

(sagittal movements), which ensure the mobility of the patient as a whole. Thus, in the 1st group of patients, this indicator was probably correlated with the total with the correlation coefficient r=0.734969 (p<0.01) and the regression equation - the sum of points = 0.0375 + 0.0838 * sagittal movements (Fig. 7).

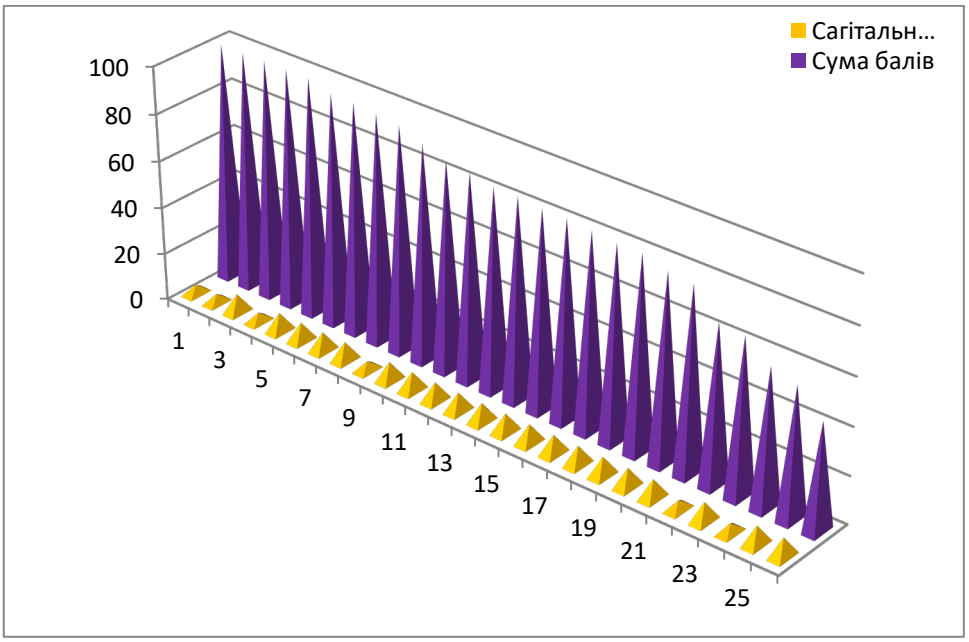

Fig. 7. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 1.

In group 2 of patients, the relationship between these two indicators was probably lower (r=0.80591, p<0.05) and was described by the corresponding linear regression equation of the form: x =- 0.5226 + 0.0987 * y, where x is the sum of points on the scale, y is sagittal mobility (Fig. 8).

In group 3, the flexion-extension index was also likely correlated with the sum of points on the Ankle-Hindfoot Scale (100 Points Total) with a significantly lower correlation coefficient than in the previous groups of patients (r=0.675548, p<0.05). This dependence was also expressed in the equation of linear regression of the type – sum of points =- 1.0671 + 0.0964 * sagittal movements (Fig. 9).

The following indicators that could affect the quality of the long-term consequences of the surgical interventions performed by us in different groups of patients were: movements in the back of the foot (presence or absence of restrictions), stability in the ankle joint and back of the foot (stable, unstable) and axial balance of

the foot (from good to unsatisfactory).

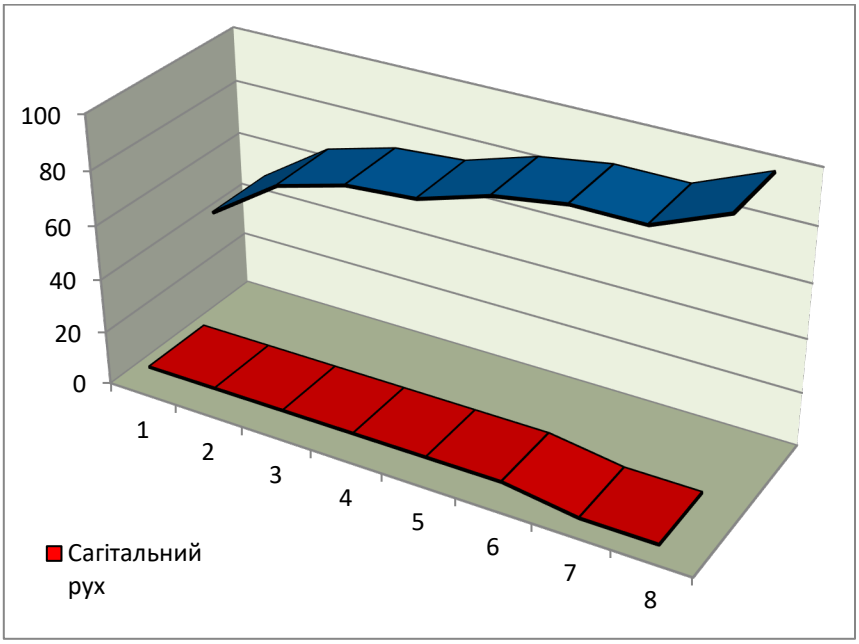

Fig. 8. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 2.

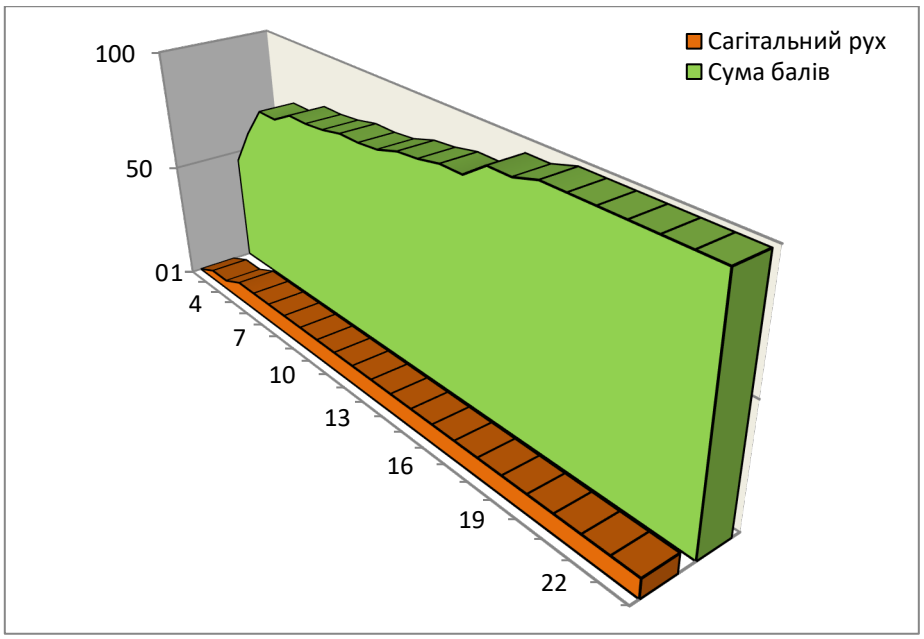

Fig. 9. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 3.

As evidenced by our data, in patients of the 1st clinical group using spokes during ankle surgery, the axial balance ($r=0.765907$, $p<0.01$) had the greatest impact on the total indicator of the above indicators. Significantly less - mobility in the back of the foot and stability in the ankle joint ($r=0.691151$, $p<0.05$ and $r=0.527724$, $p<0.05$,

respectively). At the same time, the relationship between the axial balance and the sum of points was expressed by the equation of linear regression of the form: the sum of points = 6.1844 + 0.0408 * axial balance (Fig. 10).

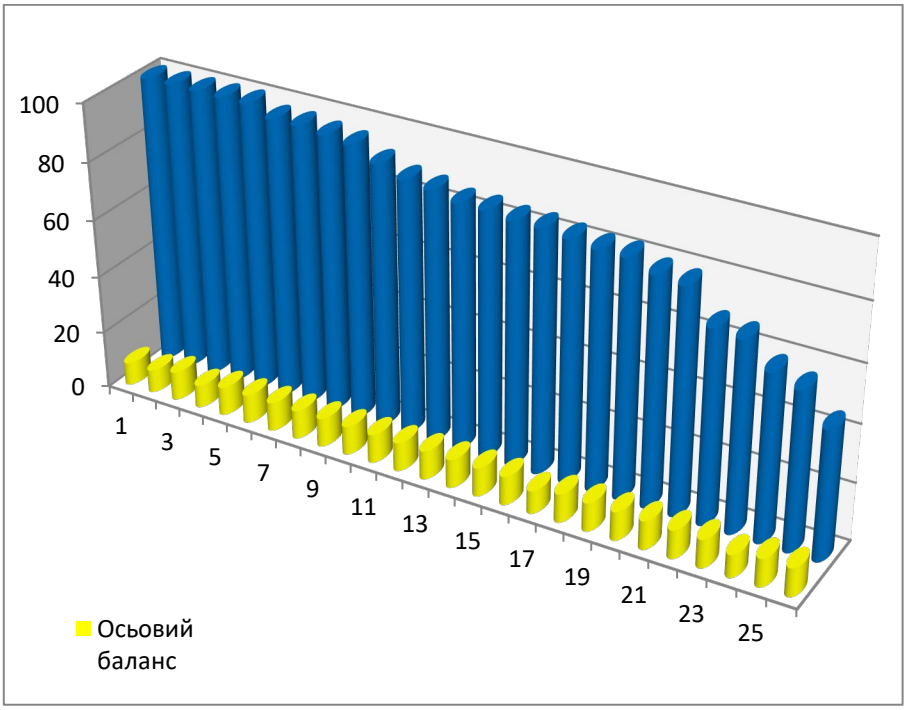

Fig. 10. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 1.

In patients of clinical group 2, similar indicators had a much smaller effect on the integral total index – r=0, r=0.75466 ($p<0.05$), r=0.81279 ($p<0.05$), respectively, for mobility in the back of the foot, stability in the ankle joint and posterior part of the foot and axial balance of the foot, respectively. The relationship between the axial balance and the sum of points was described by the equation of linear regression of the form - x = 4.6197 + 0.0574 * y, where x is the sum of points, y is the axial balance of the foot (Fig. 11).

And, accordingly, for patients of the 3rd clinical group, the dependence between the Ankle-Hindfoot Scale (100 Points Total) and movements in the back of the foot (presence or absence of restrictions), stability in the ankle joint and back of the foot (stable, unstable) and axial balance of the foot (from good to unsatisfactory) was expressed by correlation coefficients: r=0.613296 ($p<0.05$), r=0.647072 ($p<0.05$) and

r=0.651471 (p<0.05). In patients in this group, the dependence of the sum of points on the axial balance was expressed by the equation of linear regression with the corresponding expression - the sum of points = 6.4662 + 0.0367 * axial balance (Fig. 12).

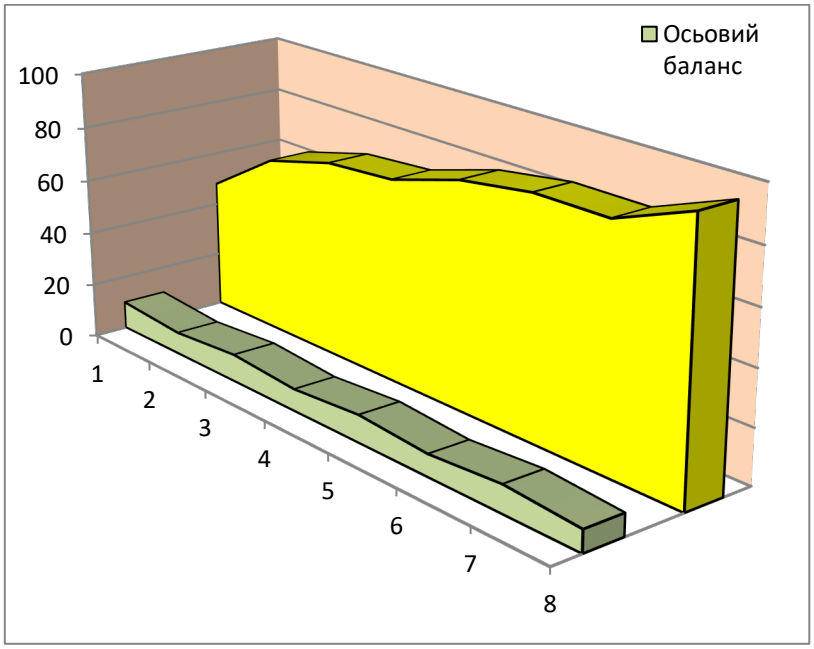

Fig. 11. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 2.

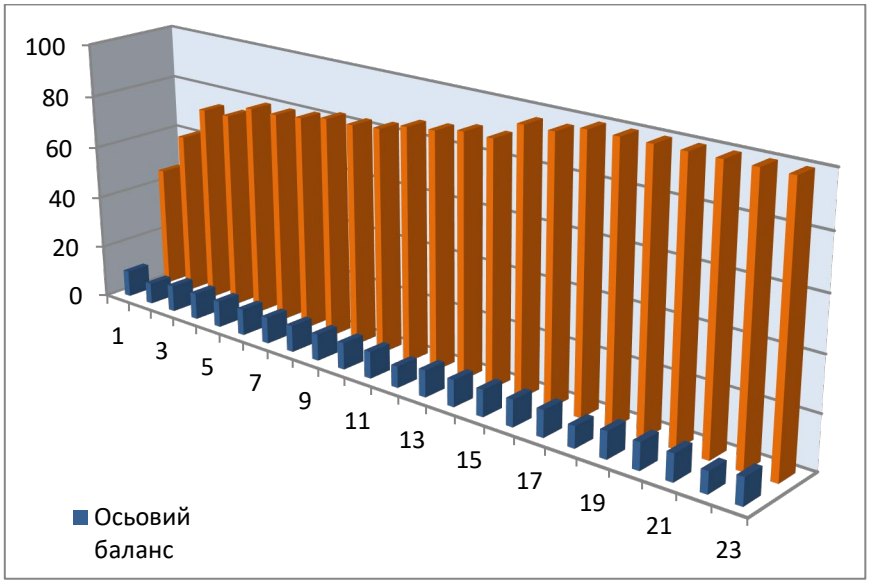

Fig. 12. Regression dependence of indicators for assessing the long-term results of ankle surgery in patients of group 3.

As can be seen from the obtained digital and statistical material, the most significant impact on the quality of the patient is exerted by the studied indicators on

the Ankle-Hindfoot Scale (100 Points Total) in patients of the 1st clinical group, who underwent surgery on the ankle joint using spokes. These patients have significantly higher mobility of both the joint itself and the ability to move over rough terrain, significantly lower pain levels 14-21 days after surgery, better stability of the joint itself and qualitatively better axial balance of the foot.

At the same time, slightly worse similar indicators were observed in patients of the 3rd clinical group and, accordingly, much worse in patients of the 2nd clinical group.

Conclusions.

1. Statistical analysis of the data obtained in patients of three groups regarding ankle surgery showed probably better results in the 1st clinical group. Accordingly, this was expressed in a significantly lower level of pain (lower than the Ankle-Hindfoot Scale by 17.7%), probably better functional activity of patients (only 10.84% lower than the Ankle-Hindfoot Scale) with a qualitative axial balance (only 3.8% lower than the Ankle-Hindfoot Scale).

2. Similar indicators in patients of the 2nd clinical group were significantly worse, both from the indicators of groups 1 and 3 operated by us. In particular, the level of pain in these patients was twice as pronounced (by 34.38%), the functional state of the ankle joint after surgery was lower than the Ankle-Hindfoot Scale by 28.90%, and, accordingly, the axial balance was reduced by 11.60%.

3. Patients of the 3rd clinical group had almost similar to group 1 individual indicators of the functioning of the ankle joint, but probably significantly lower indicators of axial balance (by 8.7%), as well as reduced mobility in the posterior part of the foot (by 16.17%).

4. The correlation-regression analysis of individual studied indicators of long-term consequences of the operated ankle joint and posterior part of the foot according to the Ankle-Hindfoot Scale of indicators showed a clear and probable correlation-regression relationship between the total indicator of patients' quality of life and individual components - pain level, activity restriction, ability to move, gait changes, axial balance. This was especially pronounced in patients of clinical group 1, slightly

lower in patients of group 3, and much worse, respectively, in patients of clinical group 2.

5. The contribution of these indicators to the total indicator according to our statistical analysis was distributed as follows (from 100% according to the Ankle-Hindfoot Scale): 1 clinical group – 87.12%, clinical group 2 – 70.34% and clinical group 3 – 84.92%.

Література / References:

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Анотація. *Актуальність клінічних досліджень присвячених хірургічному лікуванню переломів дистального епіметафіза кісток гомілки не викликає сумнівів, оскільки частота ускладнень та незадовільних результатів досягає 30%. Вивчення віддалених результатів лікування з термінами після травми понад 5 років показало, що тільки 35% хворих задоволені результатами лікування. Метою роботи є клінічне обґрунтування ефективності малоінвазивного остеосинтезу переломів дистального епіметафізу кісток гомілки шляхом статистичного аналізу показників віддалених результатів за шкалою AOFAS Ankle-Hindfoot Scale в трьох клінічних групах пацієнтів. За період з 2007 по 2017 роки прооперовано 342 пацієнти з переломами дистального сегменту кісток гомілки, з яких обстежено 265 пацієнтів. Середній вік пацієнтів складав 45,15±15,98 років (від 18 до 86 років). До І клінічної групи (дослідної) увійшли пацієнти, яким виконано малоінвазивний остеосинтез із використанням спиць та гвинтів за удосконаленою технологією (113 пацієнтів, 42,64% від загальної групи). До ІІ клінічної групи, увійшли пацієнти, яким виконано остеосинтез АЗФ (36 пацієнтів, 13,58%) та до ІІІ клінічної групи увійшли пацієнти, яким виконано остеосинтез пластинами (116 пацієнтів, 43,77%). Оцінювання віддалених наслідків проводилося за шкалою AOFAS Ankle-Hindfoot Scale (100 Points Total) із використанням параметричних методів статистичного аналізу. Використано програмне забезпечення Microsoft Office 2016 – Excel 2016 та програму для статистичної обробки даних BioStat 2007 (v. 5.9.8.5).*

Проведений нами статистичний аналіз показав вірогідно кращі результати у 1-ої клінічної групи. Відповідно це виражалося у суттєво нижчому рівні болю (нижче від показника шкали Ankle-Hindfoot Scale на 17,7%), вірогідно кращій функціональній активності пацієнтів (нижче від показника шкали Ankle-Hindfoot Scale лише на 10,84%) при якісному осьовому балансі (нижче від показника шкали Ankle-Hindfoot Score лише на 3,8%).

Ключові слова: *переломи дистальної гомілки, переломи пілона, малоінвазивний остеосинтез, мініінвазивний остеосинтез, віддалені результати, шкала Ankle-Hindfoot Score, статистична обробка показників.*