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DOI: <http://dx.doi.org/10.15674/0030-5987202515-12>**Remote infrared thermography in the system of comprehensive diagnostics of the health of military personnel before surgical intervention****O. O. Kostrub¹, O. I. Shukalo¹, V. I. Dunaievskiy²,
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A complete and informative diagnosis of the general health of military personnel before surgical intervention is of great importance for its successful implementation. A simple and affordable diagnostic method of radiological diagnostics is the method of remote infrared thermography. Conducting a comprehensive thermographic examination of military personnel before surgical intervention allows for the treatment of those pathological conditions that were detected during the thermographic examination. Objective. To show the possibility and evaluate the diagnostic informativeness remote infrared thermography in the system of comprehensive diagnostic monitoring of the health of military personnel before surgical intervention; to obtain thermographic visualizations of detected pathological changes associated with participation in combat operations. Methods. The work used a domestic thermograph with a temperature sensitivity of 0.07 °C and a ThermoCAM thermograph E 300 FLIR SYSTEM. Observation and control of thermal fields were carried out in the ranges of 3÷5 μm and 8÷14 μm. The examination was carried out during inpatient and outpatient treatment. Results. Received thermographic visualizations detected pathologies: disorders functions breathing; thermal asymmetries zones projections lung because of COVID-19; complications after firearm injury — pneumothorax; zones hyperthermia temporal bones due to contusion; vascular pattern disorders in the thyroid gland; functional and chronic disorders organs gastrointestinal and urological pathologies; degenerative-dystrophic musculoskeletal changes The oscillographic distributions of temperature patterns of the detected pathological conditions, which characterize the severity of traumatic and degenerative-dystrophic changes, were studied. Conclusions. In the presented work for the first time obtained and the results of a comprehensive thermographic health check-up military personnel after a long stay in the combat zone and before operational Remote infrared thermography, as one of the methods of radiological diagnostics, allows for a comprehensive examination of a significant number of military personnel in a short period of time and to identify pathological changes that require additional examination by narrowly specialized specialists.

Повноцінна й інформативна діагностика загального стану здоров'я військовослужбовців перед хірургічним втручанням має велике значення для його успішного проведення. Простим і доступним діагностичним методом променевої діагностики є спосіб дистанційної інфрачервоної термографії. Мета. Показати можливість та оцінити діагностичну інформативність дистанційної інфрачервоної термографії в системі комплексного діагностичного контролю за станом здоров'я військовослужбовців перед оперативним втручанням; отримати термографічні візуалізації виявлених патологічних змін, пов'язаних з участю в бойових діях. Методи. Застосовано вітчизняний термограф із температурною чутливістю 0,07 °C і термограф ThermoCAM E300 FLIR SYSTEM. Спостереження та контроль теплових полів здійснювались у діапазонах 3÷5 та 8÷14 мкм. Обстеження проводилось під час стаціонарного й амбулаторного лікування. Результати. Отримані термографічні візуалізації виявлених патологій: порушення функцій дихання; термоасиметрії зони проєкції легень після перенесеного COVID-19; ускладнення після вогнепального поранення — пневмоторакс; зони гіпертермії скроневих кісток унаслідок контузії; порушення судинного рисунку в щитоподібній залозі; функціональні та хронічні розлади органів шлунково-кишкового тракту й урологічні патології; дегенеративно-дистрофічні зміни опорно-рухового апарата. Висновки. Наведено вперше отримані результати комплексного термографічного обстеження стану здоров'я військовослужбовців після тривалого перебування в зоні бойових дій та перед оперативним втручанням. Дистанційна інфрачервона термографія, як один із методів променевої діагностики, дозволяє комплексно обстежити значну кількість військових за короткий період часу та виявити патологічні зміни, які потребують додаткового обстеження вузькопрофільними спеціалістами. Ключові слова. Інфрачервона термографія, градієнт, температура, військовослужбовці, осцилографічний термозріз.

Keywords. Infrared thermography, gradient, temperature, military personnel, oscillographic thermal image

Introduction

Non-invasive research methods in clinical diagnostic medicine with the maximum informative content of examination results allows detecting diseases at an early stage, which is the key to successful treatment.

Such non-invasive diagnostic methods of modern radiology include computer thermal diagnostics, which is based on highly sensitive spectral fixation of infrared radiation of the affected anatomical structure with the possibility of further digital processing of the obtained information on thermal radiation of organs and tissues of the human body [1, 2].

To verify the diagnosis in the shortest possible time or determine the need for its verification using other clinical methods, as well as monitor the course of the disease over a long period of time and evaluate the effectiveness of the treatment process.

Modern thermal imaging systems use multi-element matrix photodetectors in the so-called «instantaneous look» mode. The formation of a thermal image is created by projecting the study area using a lens onto the matrix photodetector, electronically reading information from the photodetector matrix element by element, and presenting the thermograms on the PC display screen.

The thermograph provides the ability to perform measurements in any part of the skin surface (SS) of a biological object (BO) in the ranges of $3\div 5\text{ }\mu\text{m}$ and $8\div 14\text{ }\mu\text{m}$. The ability to visualize the studied BO with qualitatively new characteristics (temperature sensitivity, image contrast) allows significantly expanding the scope of application of remote infrared thermography (RIT) in medical practice. Intensive work is underway to improve the software and hardware [3, 4].

The RIT method does not compete with other diagnostic methods. It occupies its own special niche as a diagnostic and preventive method, which is associated with analytical and radiological diagnostics. RIT contributes to reducing the duration of primary diagnostics, predicting treatment tactics and timely establishing the necessary nature and volume of medical care.

It should be noted that temperature is a universal reflection of the vital activity of the body. A change in temperature distribution is a potential signal of the development of a pathological process, which can manifest itself in one of three thermographic signs: the existence of anomalous zones of hypo- or hyperthermia, a violation of the normal thermotopographic pattern, as well as a change in the tempera-

ture gradient in the area under study. Inflammatory processes cause a change in the gradient between the affected area and surrounding tissues: in chronic inflammatory processes $0.7\text{ }^{\circ}\text{C}$, in acute $1.0\text{--}1.5\text{ }^{\circ}\text{C}$, in purulent-destructive $1.5\text{--}2.0\text{ }^{\circ}\text{C}$. Analysis of thermograms includes their qualitative and quantitative assessment. Qualitative assessment is the visualization of the thermal picture on the surface of the BO (distribution of «hot» and «cold» areas). The quantitative assessment includes the so-called temperature gradient — the difference between the temperature of the studied area and the neighboring area, which makes it possible to take into account the localization of the exposed area, the degree of its vascularization and the severity of the pathological process. In addition to changes in the temperature gradient, thermograms during inflammatory processes register zones of thermal asymmetry, which in shape, size and location correspond to the most pathological changes.

The presence of pathological changes in internal organs leads to temperature anomalies and is projected onto the skin due to tissue thermal conductivity, capillary convection, and convection through large vessels. In addition, local changes in tissue temperature often appear before structural changes that can be detected by other instrumental methods.

Thus, thermography makes it possible to identify the relationship between the severity of clinical manifestations of a potential disease and the temperature of the respiratory tract.

In conditions of military operations, it is impossible to ensure the conduct of high-quality diagnostic measures to determine the health status of military personnel, especially those who have been wounded and injured. RIT is a mobile diagnostic complex that allows you to obtain information about damaged areas and the scope of surgical intervention.

To diagnose the health of military personnel, complex laboratory and instrumental diagnostic methods are used, such as: radiography (RF); computed tomography (CT); ultrasound diagnostics (USD); magnetic resonance imaging (MRI) and others.

Each of the above diagnostic methods has its own advantages and disadvantages. Significant radiation exposure to the subject, which requires a certain period of time before the next examination, significant cost and insufficient informativeness, especially in the early stages of the development of the pathological process, necessitated the use of the RIT method.

The current level of development of thermal imaging technology allows for the reliable diagnosis of a wide range of diseases, which is reflected in the works of domestic and foreign clinicians [2, 5–11].

The undeniable advantages of this method in medicine are: remote and non-invasive nature of the study, the possibility of repeated use both during comprehensive diagnostic examinations and during treatment for the purpose of monitoring and correcting therapeutic measures.

Objective: to perform a comprehensive examination of the health of military personnel using the method of remote infrared thermography before surgical intervention; to obtain thermograms of pathological changes associated with participation in combat operations; to analyze oscillographic temperature patterns of the thermal field.

Material and methods

The work used a domestic thermograph with a temperature sensitivity of 0.07 °C developed by the V. Ye. Lashkaryov Institute of Semiconductor Physics of the NAS of Ukraine with a cooled matrix photodetector and a basic test program for the TherrmoVisio thermal imaging system, as well as the ThermoCAM E300 FLIR SYSTEM thermograph. Observation and control of thermal fields was carried out in the ranges of 3÷5 µm and 8÷14 µm. The implementation of program codes was carried out in the Delphi programming language in the Borland Delphi 7 development environment.

When formatting the results of thermographic studies (personal thermographic patient card), the program uses the properties of a Microsoft Word document to create a template and inserts them into the appropriate field of the text editor, and also adds a set of special commands necessary for working with infrared (IR) images (the ability to insert a text comment, a patient photo card, his IR image, the required thermal profile, a results table, etc.) and various research tools. The diagnostic information obtained in this way can be stored as an electronic card in the Basic IR Photo template for further operational analysis, observation and prediction of the dynamics of the functional state.

The examination was conducted during inpatient and outpatient treatment. The age of the patients ranged from 25 to 58 years, the weight of the patients ranged from 55 kg to 80 kg depending on age, the number of examined persons was 66. No special division of patients into groups was carried out.

Before the thermographic examination, the patients did not undergo thermal procedures, they did not take medications that affect blood circulation and metabolic processes, and they were also subject to adaptation to the temperature conditions of the thermography room.

The study was conducted in accordance with the principles of bioethics set forth in the Declaration of Helsinki «Ethical Principles for Medical Research Involving Human Subjects» and the «Universal Declaration on Bioethics and Human Rights» (UNESCO).

Thermogram processing and further actions to format the results of thermographic studies were performed using the TherrmoVisio program, which was improved by the authors and allows obtaining thermographic images with removed background noise and imperfect pixels, and simplifying the obtaining of oscillographic thermal sections in the real temperature value [12, 13].

Results

The paper presents the results of a comprehensive thermographic examination of military personnel before surgical intervention on knee joints, which they received in the combat zone.

Being in difficult field conditions and not being able to contact medical specialists in a timely manner regarding diseases, military personnel experience exacerbation of both chronic and acquired pathologies. The combination of gunshot wounds with other types of diseases such as: traumatic injuries of the musculoskeletal system, inflammatory processes of the ENT organs and respiratory organs, frostbite and hypothermia in winter require multidisciplinary diagnostic methods. The RIT method allows you to effectively get an idea of the prevalence and nature of diseases with the possibility of photofixation and ensuring dynamic monitoring of pathological processes.

The inflammatory process in the maxillary and frontal cavities, which leads to impaired respiratory function, is the most common pathological condition. One of the causes of this pathology is a congenital or acquired deviation of the nasal septum.

Fig. 1, a shows thermographic visualization — impaired respiratory function on the left (the air flow inhaled through the right nasal cavity is isolated, through the left — absent). The pathological condition revealed is a deviation of the nasal septum and an inflammatory process in the maxillary sinuses. The temperature gradient on the left is: ΔT °C = +1.42 °C, on the right — +0.83 °C.

The thyroid gland (TH) has significant vascularization and is located directly under the thyroid gland, making it an easily accessible organ for thermographic examination [11]. Thermographic visualization of pathological changes and oscillographic temperature distribution in the projection zone of the thyroid gland on the right are shown in

Fig. 1, b, c. The hyperthermic area is characterized by a temperature gradient of $+1.48\text{ }^{\circ}\text{C}$, which is a diagnostic signal for a detailed examination of the thyroid gland.

A thermographic examination of a serviceman was performed during the rehabilitation period after a gunshot wound to the left lung and a complication — left-sided pneumothorax (shown by arrow 1, Fig. 1, d). The temperature gradient between the selected and adjacent areas (arrows 1 and 2, respectively) is: $\Delta T^{\circ}1-2 = +1.52\text{ }^{\circ}\text{C}$, which indicates the presence of pathological changes in the lungs.

Thermography, as part of the differential diagnosis of diseases of the bronchopulmonary system, allows you to identify areas of local hyperthermia and thermal asymmetry of the posterior projection of the lungs [14, 15].

It should be noted that thermographic imaging of lung thermal fields in patients after COVID-19 differs from thermographic imaging of the lungs after bacterial or viral pneumonia not associated with COVID-19.

Fig. 1, e, f shows a thermogram of the posterior projection of the lungs (history of COVID-19) and an oscillographic thermal section relative to the line. The temperature gradient in the projection zone of the left lung is $+1.74\text{ }^{\circ}\text{C}$; in the right lung zone — $+1.87\text{ }^{\circ}\text{C}$.

One of the characteristic signs of COVID-associated pneumonia is the symptom of “ground glass” — areas of reduced transparency of the lung parenchyma, which have a low density, against the background of “ground glass” vessels and bronchi are differentiated, which are distinguished by a denser structure [15, 16]. Parenchymal consolidation (consolidation) is an area of often irregular shape, which exceeds the density of the “ground glass” zone, due to which vessels and bronchi are not visualized. Consolidation is also due to the accumulation of exudate in the alveolar spaces, which is characteristic of bacterial pneumonia, which affects the nature of infrared radiation from lung tissue.

A dangerous health condition is contusion [17], which is thermographically visualized as hyperthermia of the temporal part (Fig. 2, a, c). The temperature gradient in the hyperthermia zone on the left (arrow 1) has a maximum value of $+3.03\text{ }^{\circ}\text{C}$ and $+2.96\text{ }^{\circ}\text{C}$ (arrow 3 — intact zone). The serviceman received a bullet wound in the area shown by arrow 2 in Fig. 2, a. The temperature distribution oscillogram (b) is made relative to the line ((a), bullet wound zone), on which the appearance of separate zones with temperature maxima is observed (zones 1,

2 are highlighted in Fig. 2, b). After the temperature drop, we observe a sharply pronounced zone (3) with a maximum temperature corresponding to the area of the bullet wound; the thermogram of the temporal part on the right with the oscillographic temperature distribution (c, d — respectively) is also shown.

Gastrointestinal disorders (GI) appear as various combinations of chronic or recurrent symptoms, which often indicate the result of the interaction of psychosocial factors and changes in the physiology of the stomach, gallbladder, intestine in field conditions. The appearance of pathological changes in the organs of the digestive system leads to changes in the temperature indicators of the abdominal cavity.

Fig. 3, a shows the projection zone of the pancreas, performed by the ThermoCAM E300 FLIR SYSTEM thermograph. Temperature fluctuations in the visualization zone of the pancreas (along the line in Fig. 3, a) are in the range from $32.7\text{ }^{\circ}\text{C}$ to $34.2\text{ }^{\circ}\text{C}$.

The use of the RIT method for detecting urological pathology complements the comprehensive diagnostic base. As an example, Fig. 3, b shows thermographic visualization of hypothermia areas in the kidney projection zone. This nature of thermographic visualization indicates the presence of urolithiasis, which is confirmed in the anamnesis. The temperature gradient of the left kidney projection zone is: — $1.3\text{ }^{\circ}\text{C}$, on the right: — $1.8\text{ }^{\circ}\text{C}$.

Significant physical exertion leads to exacerbation of degenerative-dystrophic changes, discogenic pathologies of the spine in military personnel. RIT provides an opportunity to promptly and objectively assess the severity of the identified pathologies. Thus, in Fig. 4, a, a hyperthermia area in the lumbosacral region is presented (arrow 1, a; arrow 2 — intact zone) and oscillographic distribution (b) relative to the line; the temperature gradient is: $\Delta T\ 2-1 = +1.87\text{ }^{\circ}\text{C}$, which indicates an exacerbation of the identified pathology and significant pain syndrome.

The presented thermogram (Fig. 4, c) and oscillographic temperature distribution (Fig. 4, d) visualize Thermotopography of the lower limb with temperature changes characteristic of a vascular disorder — varicose veins (VV). VV of the left lower limb is represented by uneven saccular dilation of the veins, accompanied by valve insufficiency and impaired blood flow.

The presence of VVD imposes restrictions on the ability to perform heavy physical exertion. According to the authors, circulatory disorders serve as a prerequisite for the occurrence of functional and degenerative changes in the knee joints, which was also reflected in the works of other researchers [18–21].

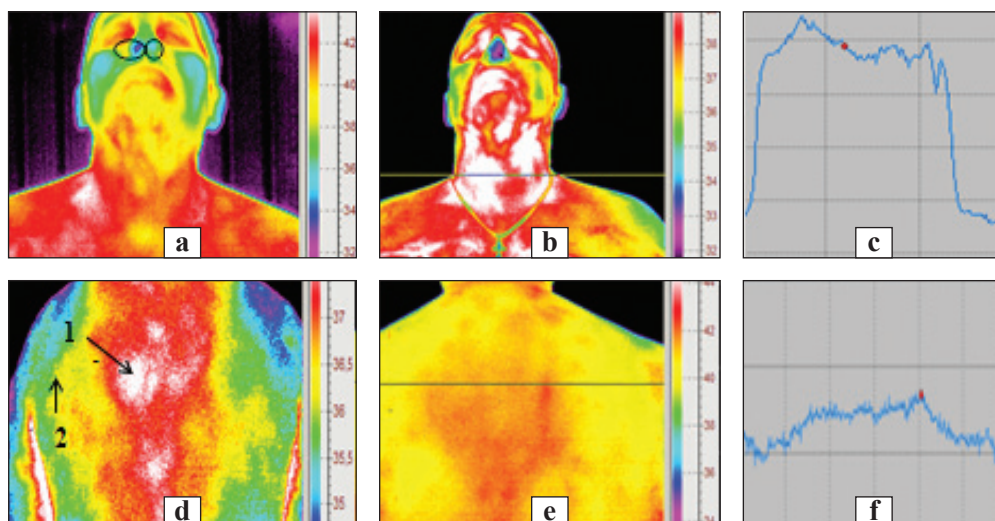


Fig. 1. Impaired respiratory function on the left (a); hyperthermia of the right lobe of the thyroid gland (b) and temperature distribution oscillogram relative to the line (c); hyperthermia of the posterior projection of the lungs, pneumothorax (d); hyperthermia of the posterior projection of the lungs after COVID-19 (e) and temperature distribution oscillogram (f) relative to the line

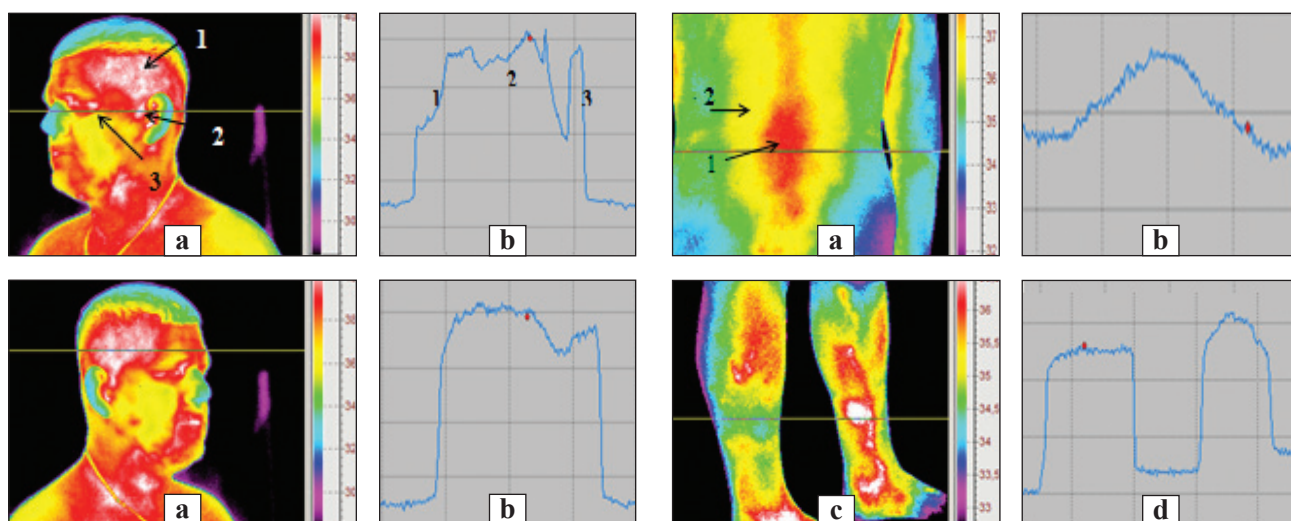


Fig. 2. Hyperthermia of the temporal regions (a, c) due to concussion, (arrow 2 – site of bullet wound); oscillographic distribution of temperature (b, d) relative to the lines

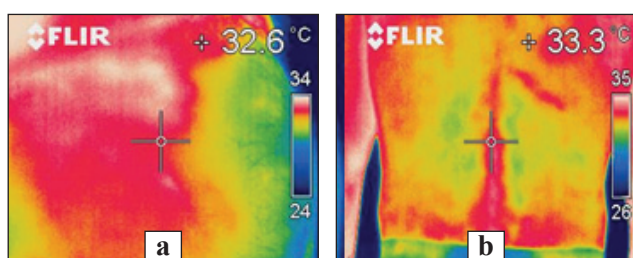


Fig. 3. Hyperthermia of the projection zone of the pancreas (a); hypothermia of the projection zone of the kidneys (b)

Orthopedic pathology of the knee joints occupies a leading position in terms of frequency of occurrence among degenerative-dystrophic diseases of the musculoskeletal system in military personnel. An important aspect of the problem is the timely diagnosis of the disease using simple and affordable methods of radiological diagnostics.

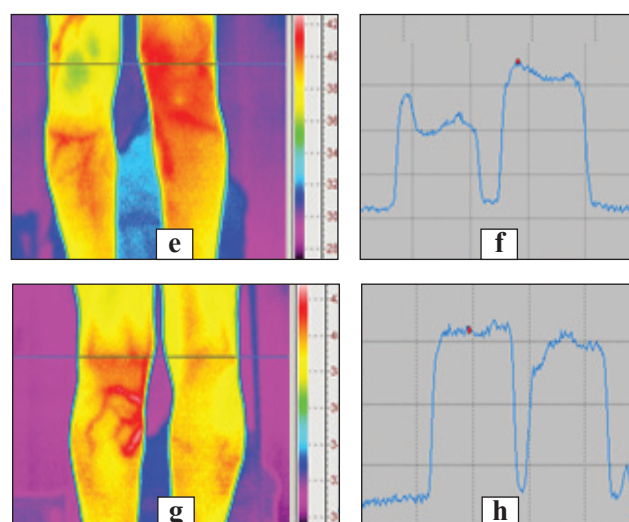


Fig. 4. Hyperthermia of the lumbosacral region (a) and oscillographic distribution (b) relative to the line; HRV of the lower extremities (c) and oscillographic distribution (d) relative to the line; hyperthermia of the left knee joint after anterior cruciate ligament reconstruction, partial resection of the medial meniscus: anterior (e) and posterior (g) projections; oscillographic distribution (f, h) relative to the lines

Thermographic visualization of knee joints with various manifestations of lesions allows you to reliably and informatively enrich the comprehensive diagnostics of the musculoskeletal system, provide an assessment of the effectiveness of treatment and safely monitor it [12, 22–24].

Fig. 4, e, shows thermographic visualization of the left knee joint after surgical treatment — anterior cruciate ligament reconstruction, partial resection of the medial meniscus. The condition after surgery and the presence of implants leads to changes in temperature patterns, presented in oscillographic temperature distributions (Fig. 4, e, g).

Discussion

In connection with military operations, interest in the use of RIT, which is aimed at identifying and timely treating diseases in military personnel, has significantly increased.

The authors of the work [25–26] investigated the diagnostic capabilities of spectral infrared thermography in the treatment of gunshot wounds of soft tissues. The issue of the use of RIT in obliterating diseases of the lower extremities is the subject of the work of the author [18]. The use of the thermal imaging control technique for monitoring the dynamics of thermal fields on the SS in the case of short-term cryosurgical treatment of soft tissue pathology with quasi-point the authors' work [27] is devoted to the cryoapplicator. The feasibility of using thermal imaging studies in medicine to obtain thermal radiation from the CB's SS is described in [3]. Visualized thermal radiation makes it possible to assess the state of both peripheral blood circulation and obtain information about deep processes in the body.

The authors of [28] used the thermographic method to assess the condition of military personnel before and after surgical intervention due to gunshot wounds, which allows for timely detection of complications and taking prompt medical measures to prevent postoperative complications.

In the presented work, the results of a comprehensive thermographic examination of the health status of military personnel before surgical intervention are obtained for the first time. Oscillographic distributions of temperature patterns of detected pathological conditions are presented separately, which characterize the severity of traumatic and degenerative-dystrophic changes. Thermographic visualizations of detected pathologies were obtained: respiratory function disorders; hyperthermia of the lung projection zone after COVID-19 and complications due to gunshot wound — pneumothorax; hyper-

thermia of the temporal parts after contusion; pathological processes in the thyroid gland; functional and chronic disorders of the gastrointestinal tract and urological pathologies; degenerative-dystrophic changes in the musculoskeletal system. A comprehensive understanding of the health status of military personnel will be the key to successful surgical intervention and will contribute to a speedy recovery.

Conclusions

Preservation of the health of military personnel is a top priority for ensuring the combat readiness of military units. The use of existing radiation diagnostic methods in field conditions and in conditions of front-line deployment of military personnel is a problematic issue due to the use of complex equipment and limited capabilities for conducting diagnostic actions.

First performed comprehensive thermographic examination of military personnel before surgical intervention: obtained thermographic visualizations and oscillographic temperature distributions of such pathological conditions as contusion, bullet wound, residual phenomena in the bronchopulmonary system due to COVID-19, exacerbation of chronic diseases of the pancreas and urinary system, traumatic injuries of the musculoskeletal system, etc.

Remote infrared thermography, as one of the methods of radiation diagnostics, in the system of comprehensive diagnostic measures additionally provides doctors of almost all specialties with important information about the presence and severity of detected pathologies before surgical intervention.

Given the ease of use, mobility, significant informativeness and efficiency, it is advisable to introduce the method of remote infrared thermography into the system of comprehensive diagnostic measures at various stages of providing medical care to military personnel.

Conflict of interest. The authors declare no conflict of interest.

Prospects for further research. Prospects for further research include the use of the remote infrared thermography method in the postoperative period to determine the course of wound regeneration, as well as monitoring the health of servicemen after identified pathological conditions during thermographic examination and appropriate treatment. Special attention will be paid to the study of the state of health of servicemen after mine-explosive injuries, complications after diseases of the bronchopulmonary system, neuropathy. Actual and promising work on expanding the information base of thermographic visualizations of identified pathological conditions, which can be used by doctors of almost all specialties in medical practice.

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ДИСТАНЦІЙНА ІНФРАЧЕРВОНА ТЕРМОГРАФІЯ В СИСТЕМІ КОМПЛЕКСНОЇ ДІАГНОСТИКИ СТАНУ ЗДОРОВ'Я ВІЙСЬКОВОСЛУЖБОВЦІВ ПЕРЕД ОПЕРАТИВНИМ ВТРУЧАННЯМ

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Ankle arthrodesis after combat related injuries

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Combat related injuries of the ankle joint (AJ) are often accompanied by severe changes in the musculoskeletal system, which require arthrodesis of the damaged joints in the final stage of treatment. Objective. To analyze the results of AJ arthrodesis in patients after combat related injuries, to highlight aspects of the use of different fixation methods. Methods. AJ arthrodesis was performed in 21 patients with the consequences of severe combat related injuries of the posterior part of the foot. An intramedullary locked rod (18 patients), screws (2 patients) and an Ilizarov-type external fixation device (EFD) were used for fixation in one patient. The results were assessed no earlier than 6 months after the start of loading using the AOFAS (posterior part), SMFA (short musculoskeletal functional assessment) and EQ-5D-5L (mobility, self-care, usual activity, pain, anxiety, VAS) scales and questionnaires. Results: In the specified terms, the results were traced in 21 patients. A differential approach was used in choosing the method of fixation of the AJ. A significant increase in function was obtained according to the AOFAS, SMFA and EQ-5D-5L scales ($p < 0.001$). Conclusions. AJ arthrodesis in patients with the consequences of severe combat related injuries allows to restore the resistance of the limb and is the final stage of treatment of these patients.

Бойові поранення нижньої кінцівки, в тому числі ділянки над'яtkово-гомількового суглоба (НГС), є найчастішими на полі бою й зазвичай супроводжуються тяжкими змінами опорно-рухової системи. Ортопедичні реконструктивні втручання є фінальним етапом лікування уражень цієї ділянки і направлені на виконання артродезу через тяжкі внутрішньосуглобові ушкодження НГС, що супроводжуються післятравматичним остеоартрозом із вираженим больовим синдромом. Мета. Проаналізувати результати артродезу НГС у хворих після вогнепальних поранень, висвітлити аспекти застосування різних способів фіксації. Методи. Проведений артродез НГС у 21 пацієнта з наслідками тяжких вогнепальних поранень заднього відділу стопи. Вік постраждалих становив $(38,1 \pm 10,9)$ року, жінок було 2, чоловіків — 19. Застосували для фіксації інтрамедулярний блокований стрижень (18 осіб), гвинти (2) та в одного — апарат зовнішньої фіксації (АЗФ) типу Ілізарова. Методика артродезу НГС передбачала виконання двох доступів: латерального та медіального, останній здійснювали за необхідності. Результати оцінювали не раніше 6 міс. після початку навантаження за шкалами та опитувальниками AOFAS (задній відділ), SMFA (short musculoskeletal functional assessment) та EQ-5D-5L (мобільність, самообслуговування, звичайна активність, біль, тривога, VAS). Результати. У зазначені терміни результати оцінювали у 21 пацієнта. Застосовували диференційний підхід у виборі метода фіксації НГС. Незадовільний результат отримано в 1 випадку, відповідно до AOFAS, але згідно з шкалами SMFA та якості життя EQ-5D-5L відмічено суттєве покращення показників самообслуговування пацієнта через 6 міс. Зафіксовано достовірний приріст функції за шкалами AOFAS, SMFA та EQ-5D-5L ($p < 0,001$). Висновки. Артродез НГС у осіб із наслідками тяжких поранень дозволяє відновлювати опороздатність кінцівки та є фінальним етапом лікування цих пацієнтів. Ключові слова. Вогнепальне поранення, над'яtkово-гомільковий суглоб, артродез, опороздатність кінцівки.

Keywords. Combat related injuries, ankle joint, arthrodesis, resistance of the limb

Introduction

Today's combat injury is a severe injury due to the high kinetic energy of projectiles and the use of a wide range of means of destruction. All gunshot wounds can be divided into bullet and mine-explosive (mine-explosive trauma, MET) with high, medium and low energy of impact on the human body, which depends on many factors. In MET, damage occurs both because of direct contact with an explosive device and as a result of injury by elements (fragments, shrapnel, etc.). Severe injury can also occur without direct contact with the projectile (device), i. e. as a result of the action of the blast wave on protective elements and their direct traumatic effect (for example, an explosion in a car without the penetration of fragments into the interior) [1].

Lower limb injuries are the most common on the battlefield [2–4]. At the same time, gunshot wounds to the lower leg and foot occur in 26 % of cases, with bullet wounds prevailing over explosive trauma [5].

Injuries to the talocrural joint (TCJ) have their own characteristics due to the small volume of soft tissues around the bone and joint, which, for example, in 80 % of cases of gunshot wounds leads to bone fractures with a predominance of intra-articular injuries and trauma to the vascular and neurovascular trunks [6]. A corresponding problem of injuries to the TCJ is the issue of preserving the lower limb or performing primary amputation. We were unable to track the frequency of TCJ injuries separately in the literature [5, 7, 8].

Orthopedic reconstructive interventions are the final stage of treatment of lesions in this area and are aimed at performing arthrodesis due to severe intra-articular injuries of the TCJ, accompanied by post-traumatic osteoarthritis with severe pain syndrome [9]. External fixation devices (EFDs), particularly those using ring supports of the Ilizarov type, are commonly employed for the fixation of the TCJ after gunshot wounds. This method is associated with microbial contamination of the tissues. The possibility of using other fixation methods and the frequency of complications during their use are unclear. The terms of union of the TCJ area when using different fixation methods are observed on average after 8–12 weeks [11], and bone union occurs in 69–77 % of cases [12], which may require repeated surgical interventions.

Purpose: to analyze the results of arthrodesis of the talocrural joint in patients after gunshot

wounds, to highlight aspects of the use of different fixation methods.

Material and methods

The results of the treatment of 21 patients with the consequences of severe injuries of the TCJ area, who were hospitalized in the clinic at the State Institution “National Institute of Traumatology and Orthopedics of the National Academy of Medical Sciences of Ukraine”, Kyiv from 2014 to 2024, are presented. The study was approved by the Bioethics Commission of the State Institution “ITO of the National Academy of Medical Sciences of Ukraine” (protocol No. 2 dated 07.02.2025). The study was conducted in compliance with the requirements and provisions of the Helsinki Declaration on Human Rights (2000), including the revision of EC-GCP, the Constitution and Fundamentals of Ukrainian Legislation on Health Care (1992), and all ethical standards for conducting clinical trials. All patients signed informed consent.

Most patients (18 subjects, 86%) were injured after the start of the full-scale invasion of the Russian Federation on 24 February 2022. Among them, 2 (9.5 %) were civilians. The age of the patients was (38.1 ± 10.9) years, there were 2 women, and 19 men.

The patients received treatment at the evacuation stages in accordance with the rules for providing medical care to the wounded. At the time of hospitalization, they had no wounds or clinical signs of infection.

The study did not include patients with consequences of minor injuries to the TCJ area and those who required high amputation of the lower limb.

Arthrodesis of the TCJ was performed with screw fixation, intramedullary locking rod, and external fixation device. The function of the lower limb was assessed before and after surgical treatment using the AOFAS scale (TCJ segment and hindfoot (HF)), SMFA (Short musculoskeletal function assessment) and EQ-5D-5L quality of life questionnaire. The data were entered into Excel spreadsheets, and the significance of the difference in means was calculated using a paired two-sample t-test. The results were evaluated no earlier than 6 months after the start of loading the limb after surgery.

Additionally, the type of injury (mine-explosive or bullet), the degree of tissue damage according to the Gustilo-Anderson classification, the time from the moment of injury to reconstructive surgery, the number of previous operations, the presence of an infectious process at the previous stages of treatment or after the performed reconstructive surgery were analyzed.

Results

Severe cases of gunshot wounds of the TCJ are characterized by significant disintegration of the anatomy of this area (Fig. 1), the supporting function in this case is achieved by arthrodesis of the damaged joints.

The technique of arthrodesis of the TCJ involved performing two approaches: lateral and medial, the latter was performed if necessary. A feature of the approaches after TCJ injuries is the presence of post-traumatic scars, which can be quite large in area, different in localization, and depends on the nature of the injury, methods of treatment and closure of soft tissue defects. In our study, lateral access to the TCJ was not possible in 2 injured patients (10 % of cases), so the main one was medial, due to significant cicatricial changes of the lateral surface of the TCJ. Resection of the lateral bone was mandatory, which could later be used for plastic surgery of bone defects; in 2 patients it was not performed due to damage to this bone. Next, sparing resection of the articular ends of the TCJ of the tibia and talus was performed in such a plane that it was possible to set the foot at 90° to the axis of the lower leg and in a neutral position of the posterior part of the foot to the supporting surface.

We mostly used intramedullary locking rod (ILR) for fixation (18 out of 21 cases), due to existing bone defects in the wound area, complex disintegration of anatomical structures (not only the TCJ, but also the entire posterior part of the foot) with significant changes in the subtalar joint. In 6 patients (29 % of cases), a significant defect of the tibia or talus in the TCJ area was diagnosed, but bone defect replacement was used in 4 (19 % of cases). In 2 with existing defects, stability of fixation was achieved by using intramedullary rod fixation without bone autoplasty.

In 2 patients, screws were installed for fixation of the TCJ (without fixing the subtalar joint), since the patients had a rapid development of post-traumatic osteoarthritis of the TCJ after injury, but there were no avascular changes in either the talus or degenerative changes in the subtalar joint. In 1 person, a rod EFD on Ilizarov-type ring supports was used for fixation due to the manifestation of clinical signs of infection during hospitalization and preparation for surgical intervention. EFD fixation was in the stabilization version without further correction of fragments, since the plane of resection of the articular surfaces provided for the installation of the foot at an angle of 90° to the tibia with tight contact of the surfaces. In the case of ILR fixation, dosed loading of the limb was started 4–5 weeks after dynamization of the fixator, in the case of screws — after 8 weeks, and in the case of EFD — after 12 weeks, when signs of union were noted. The presence of a defect and bone autoplasty during surgery did not affect the timing of the start of dosed loading with ILR fixation.

Most patients had the consequences of mine-explosive trauma with shrapnel wounds (Table 1), which is a result of modern wars with the use of explosive shells. In our study, there were no consequences of bullet wounds, but this is more of an exception than a rule, since bullet wounds of the talocrural joint usually occur on the battlefield [3].

Severe injuries of the TCJ were observed in METs that occurred in the event of a car explosion without the penetration of fragments, as well as during injury by a “petal” type mine. It should be noted that the latter variant of injury did not lead to amputation of the lower limb if the servicemen used footwear with the appropriate class of protection against such mines.



Fig. 1. Radiographic images and clinical presentation of patient G. exhibiting the sequelae of shrapnel injury to the TCJ and the posterior part of the foot

Among the features of gunshot wounds are injury to soft tissues, tendons, vessels and nerves, primary contamination of wounds with microorganisms, which requires appropriate tactics with staged surgical interventions. In our study, the number of previous operations ranged from 1 to 8, on average (4.7 ± 2.6). All of them were aimed at bone stabilization, infection prevention, staged necrotectomies and secondary closure of the tissue defect. Accordingly, the time from injury to reconstructive intervention took on average (10.8 ± 6.9) months (from 1 to 30 months). During reconstruction, 11 out of 21 patients (52 %) had an equinus foot position, which did not allow full loading of the limb and sufficient assessment of the possibility of its single-bearing loading.

We obtained good anatomical and functional results, taking into account the indicators of the AOFAS scales (segment for TCJ and HF) and SMFA, as well as the data of the EQ-5D-5L quality of life questionnaire (Table 2 and 3), with a significant increase in function 6 months after the start of limb loading after surgery.

Infectious complications in the postoperative period were observed in 2 patients (9.5%). In one case, after drainage of the pathological focus and targeted antibiotic therapy, the infectious process was stopped, the wound healed with secondary tension. In another patient, after 6 months of observation and union at the site of TCJ resection, the metal fixator was removed, and the infectious process was transferred to the remission stage (Fig. 2).

Table 1

Distribution of patients by nature of injury, type of TCJ injury according to the Gustilo-Anderson classification, number of previous surgical interventions, and history of clinical infection

No.	Type of injury	G-A	Time to arthrodesis of the TCJ, months	Number of previous interventions	History of clinical infection
1	MET (fragments)	II	9	6	—
2	MET (fragments)	II	10	3	—
3	MET (fragments)	III-A	9	5	—
4	MET (fragments)	II	13	1	—
5	MET (mine)	III-A	30	1	—
6	MET (fragments)	II	4	7	—
7	MET (fragments)	II	8	3	—
8	MET (fragments)	II	10	5	—
9	MET (fragments)	II	5	4	—
10	MET (fragments)	III-A	9	8	yes
11	MET (fragments)	II	11	8	—
12	MET (mine)	III-A	2	7	—
13	MET (mine)	—	1	4	—
14	MET (fragments)	II	12	5	—
15	MET (fragments)	III-A	24	7	—
16	MET (car bomb)	—	10	1	—
17	MET (fragments)	III-A	8	8	yes
18	MET (fragments)	III-A	10	7	—
19	MET (car bomb)	II	21	1	—
20	MET (fragments)	II	11	6	—
21	MET (fragments)	III-A	8	5	yes

Table 2

Average lower limb function scores according to the AOFAS and SMFA scales before and after surgical treatment with comparison of the difference in means

Scale	Before intervention (n = 21)	After intervention (n = 21)	p (at $\alpha = 0.05$)
AOFAS	24.6 ± 16.3	79.8 ± 10.5	$p < 0.001$
SMFA	126.5 ± 19.4	46.7 ± 14.5	$p < 0.001$

Clinical example

A 36-year-old patient G., military serviceman. In the anti-terroristic operation zone (2015) as a result of an MET (stepped on an anti-personnel mine with his left foot), the left foot was amputated and open comminuted fractures of the right TCJ (Gustilo-Anderson IIIA) bones and toes of the foot occurred. Staged treatment, final amputation of the left lower limb at the level of the proximal third of the tibia, successful prosthetic repair. Open injuries of the right lower limb were healed, the fusion of the right TCJ fracture did not occur, due to the use of the leg, a varus deformity was formed, and deforming arthrosis significantly progressed. Full loading of the limb is impossible. He was hospitalized and examined in the clinic of the State Institution “National Institute of Traumatology and Orthopedics of the National Academy of Medical Sciences of Ukraine”. Resection arthrodesis of the TCJ with intramedullary fixation with a blocked retrograde tibial rod in a dynamic blocking variant was performed. The postoperative period was uneventful, after 1.5 months the patient began to bear weight in the “Chobit” orthosis, after another month — without restrictions. Examination after 6 months: walks without additional support, full weight-bearing on the right lower limb (Fig. 3).

Discussion

Intra-articular gunshot fractures of the TCJ are characterized by pronounced post-traumatic changes, which are accompanied by the development of osteoarthritis and require reconstructive interventions aimed at immobilizing the joint with the foot in a functionally advantageous position [9, 13]. This improves the function of the limb, despite the lack of complete recovery.

In our study, an unsatisfactory result was obtained in 1 case, according to AOFAS, but according to the SMFA and EQ-5D-5L quality of life scales, asig-nificant increase in patient self-care indicators was noted 6 months after the start of loading the limb, while the patient's function recovery is still ongoing. Therefore, we also used patient-oriented scales in the assessment of results. If we consider only the AO-FAS scale, then the number of good, positive and negative results in our study coincides with the observations of recent years by foreign specialists [9, 13].

We excluded from the analysis patients requiring high lower limb amputation (HLA) based on the sum of the signs and the absence of prospects for recon-structive and restorative treatment. Despite the possible reluctance of the patient and doctors to perform HLA, the results of reconstructive interventions in

Table 3

Average values of EQ-5D-5L before and after surgical treatment
with comparison of the difference in means

EQ-5D-5L	Before intervention (n = 21)	After intervention (n = 21)	p (at $\alpha = 0,05$)
Mobility	3.9 ± 0.8	2.1 ± 0.5	$p < 0.001$
Self-care	2.9 ± 1.1	1.5 ± 0.6	$p < 0.001$
Routine activity	3.8 ± 0.9	2.2 ± 0.6	$p < 0.001$
Pain	3.8 ± 0.9	2.1 ± 0.6	$p < 0.001$
Anxiety/depression	2.6 ± 0.9	1.4 ± 0.5	$p < 0.001$
VAS	53.4 ± 14.8	81 ± 6.0	$p < 0.001$



Fig. 2. Radiographic images and clinical presentation of patient G. exhibiting the condition after reconstructive and restorative treatment and removal of the metal fixator

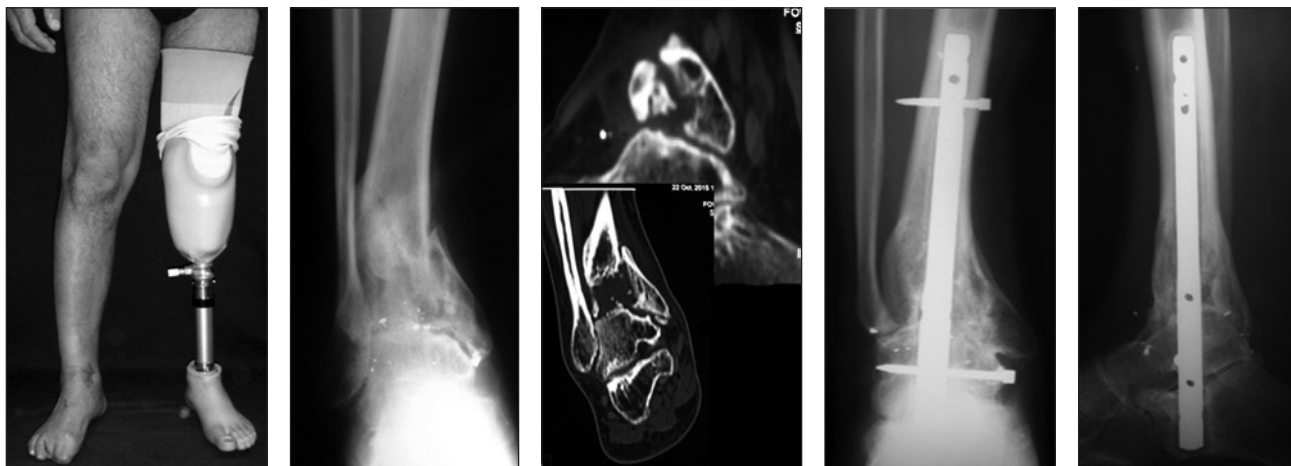


Fig. 3. Radiographic images, computer scans and clinical presentation of patient G. before and after reconstructive and restorative treatment on the right lower limb

such cases, even in the case of achieving wound healing and bone consolidation, do not provide a significant increase in limb function, which is confirmed by relevant studies [10, 14, 15].

Depending on the type of TCJ injury, the main ones are mine-explosive (fragmentation, direct contact with mines and in the case of a car explosion) and bullet wounds. The former are more common in the case of combat operations in open and rural areas [3], which may explain the absence of consequences of bullet wounds in our study.

An additional problem in patients is the development of equinus foot posture, which makes it impossible to load the entire surface after injury. Prevention of the development of such posture at the stages of treatment in several cases allows avoiding orthopedic surgical interventions, since the destruction of cartilage from injury can spontaneously lead to ankylosing of the joint. If the limb is fixed after removal of the EFD in an orthosis or plaster cast, the desired angle of 90° can be obtained to achieve resistance of the limb and avoid further surgical interventions.

During the treatment of patients with the consequences of gunshot wounds to the area of the TCJ, we applied a differential approach to choosing a fixation method, which was aimed at achieving resistance with maximum preservation of limb function. This approach is similar to the approach to treating the consequences of traumatic injuries to the TCJ [11].

For the treatment of post-traumatic changes in the joints that developed because of gunshot wounds, many authors consider it advisable to use only EFD of various modifications [6, 9, 10, 13]. Despite the contamination of tissues with microorganisms

during the wound, the use of internal fixation is possible, it does not cause more complications, compared to other methods [16, 17]. The use of ILR in cases of existing bone defects in these patients provides reliable fixation and allows for early rehabilitation and loading of the limb. This is especially important considering the time from the moment of injury to the performance of TCJ arthrodesis (Table 1), since the prolonged absence of loading of the limb negatively affects the restoration of its functionality. Post-operative complications with internal fixation in our study were in 2 cases, while removal of the fixator was performed in one wounded patient, which did not affect the overall result, since bone union was achieved.

Such complications and their number do not go beyond the known data during the treatment of patients with consequences of open fractures using various fixation methods [12], therefore, we believe that ILR is not contraindicated and can be used in patients with consequences of gunshot wounds with fixation of the TCJ. Bek et al. [9], who used EFD for fixation of the TCJ, indicate the presence of previous operations in patients with consequences of gunshot wounds of the hindfoot, which preceded the arthrodesis of the TCJ. These interventions were aimed at arthrodesis of the joints adjacent to the TCJ, damaged during the injury. In our study, the use of ILR allowed us to solve the issue of simultaneous stabilization of the TCJ and the subtalar joint in cases where there was damage to both the talus and calcaneus, which was 2/3 of the cases of gunshot wound consequences, which makes the use of ILR even more appropriate in patients with the consequences of gunshot wounds of the TCJ.

In cases without avascular changes in the talus or severe degenerative changes in the subtalar joint, it is absolutely reasonable to block only the TCJ (fixation with screws or a combination of screws and a plate). It is important to maintain maximum mobility of the posterior part of the foot, and the mobility of the subtalar and transverse metatarsal joints provide 30 % of the amplitude of movements of the ankle joint, allowing to preserve a significant share of human motor activity.

In the presence of clinical signs of infection, we used the TCJ area for fixation of the EFD on Ilizarov-type ring supports. Undoubtedly, EFD is an acceptable option in case of existing infectious processes in the surgical area.

At the same time, the possible choice of types of EFD is quite wide and allows to perform a number of tasks during the treatment of patients with similar issues. In our observation, we waited for the signs of bone union before starting the load in this patient due to pronounced osteoporotic changes in the bones of the foot and fears of the development of osteolysis around the rods, but the use of EFD gives an opportunity to start early load on the operated limb [18], which is relevant during the treatment of this category of patients, as mentioned above.

Conclusions

The final stage of treatment of the consequences of severe gunshot wounds of the TCJ area with the prospect of restoring the function of the limb is the arthrodesis of this joint. Severe disintegration of its anatomy, as well as the subtalar joint, in combination with existing bone defects, makes the option of fixation using ILR a priority during surgical intervention. Rapid rehabilitation of these patients is very important, since the treatment period after injury is extended in time and negatively affects the restoration of the function of the injured limb. At the same time, a differential approach should be applied to fix the TCJ in such patients to achieve the maximum possible functional result.

Conflict of interest. The authors declare the absence of a conflict of interest.

Prospects for further research. In-depth study of the long-term consequences of injuries and the results of treatment of these patients.

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of literary sources; Kharchyk V. S. — patient selection, medical documentation processing, data summarization in Excel table.

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ANKLE ARTHRODESIS AFTER COMBAT RELATED INJURIES

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Our experience in using modified bioactive ceramics for the reconstruction of critical post-traumatic bone defects

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According to statistical data from the National Military Medical Clinical Center for the period from February to May 2022, bone defects in gunshot fractures accounted for 76 % of cases, with defects exceeding 6 cm — classified as critical — found in 28 % of cases. Currently, the "gold standard" for reconstructing critical bone defects is the induced membrane technique, also known as the two-stage Masquelet technique. The most promising substitute for autologous bone is considered to be biphasic bioactive ceramics. In this study, we aimed to evaluate the feasibility of reconstructing critical bone defects resulting from combat trauma using a modified bioactive ceramic-autograft mixture during the second stage of the Masquelet technique, combined with additive manufacturing technologies. The study included a sample of 36 patients with critical bone defects who underwent reconstruction using the Masquelet technique. During the second stage, the defect was filled with a mixture of calcium phosphate ceramics (CPC) and autologous cancellous bone. We analyzed the treatment outcomes of patients with critical bone defects caused by combat-related injuries over the past 2.5 years who received treatment at the Dobrobut Medical Center. The evaluation criteria included pain levels, range of motion, axial load capacity, functional recovery (work capacity), and radiological signs of callus formation, deformities, graft migration, or remodeling. After 12 months of follow-up: Complete functional recovery (clinically and in range of motion) was achieved in 28 (78 %) patients. Partial functional recovery was observed in 7 (17 %) patients. Significant functional impairment requiring additional surgical interventions occurred in 1 (5 %) patient. Conclusions. Based on our experience, the use of a CPC-autograft mixture in the two-stage reconstruction of critical diaphyseal bone defects provides positive treatment outcomes in most clinical cases. The integration of 3D modeling and biodegradable materials enhances the range of possibilities for performing bone grafting procedures and simplifies technical challenges in reconstructive surgery.

За даними статистичного відділу Військово-медичного клінічного центру Північного регіону за період лютий–травень 2022 року кісткові дефекти в разі вогнепальних переломів склали 76 %, із них понад 6 см (критичні) — у 28 %. На сьогодні статусу «золотого стандарту» в реконструкції кісткових дефектів критичного розміру набуває методика індукованої мембрани або двоетапна техніка за Masquelet. Найбільш перспективним замінником аутокістки вважають двофазну біоактивну кераміку. У дослідженні оцінювали можливості реконструкції критичних кісткових дефектів після бойової травми на другому етапі методики Masquelet сумішшю модифікованої біоактивної кераміки й аутоспонгіози, зі застосуванням адитивних технологій. Опрацьовано вибірку з 36 пацієнтів, котрим за критичних розмірів кісткових дефектів послуговувалися методикою Masquelet. На 2-му етапі проводили пластику дефекту з використанням суміші КФК та аутоспонгіози. Проаналізовано результати лікування постраждалих після ВПК із критичними розмірами дефектів кісток кінцівок за останні 2,5 роки, які отримували лікування в «МЦ Добробут». За критеріїв оцінювання обрали показники болю, обсяг рухів, осьове навантаження і відновлення функції (працездатності), рентген ознаки мозолеутворення, деформацій або міграції чи перебудови трансплантата. За 12 міс. повне відновлення функції кінцівки клінічно та за обсягом рухів було в 18 (78 %), часткове відновлення функції у 4 (17 %), у 1 (5 %) пацієнта значні порушення, які потребували подальших оперативних втручань. Висновки. Використання суміші КФК і аутоспонгіози за 2-етапного заміщення критичних діафізарних кісткових дефектів дає здебільшого позитивні результати лікування. 3D-моделювання та застосування біодеградуючих матеріалів розширює діапазон можливостей для проведення кістковопластичних маніпуляцій. Ключові слова. Критичні розміри кісткових дефектів, методика Masquelet, кістково-пластичні маніпуляції, кістковопластична суміш, біоактивна кераміка, адитивні технології.

Keywords. Critical bone defects, Masquelet technique, bone grafting, bioactive ceramics, additive technologies, bone reconstruction

Introduction

The use of modern means of killing manpower in most armies, in particular during the war in Ukraine, has led to a significant increase in the severity of combat trauma to the limbs, increased the frequency and volume of multiple and combined injuries [1, 6]. Gunshot bone fractures (GBF) are quite complex in terms of biomechanics and pathophysiological reactions of traumatic disease, mainly due to the loss of the regenerative potential of bone tissue and the formation of significant bone defects. Thus, according to literature sources, primary bone defects in GBF are recorded in 7.1% of victims, of which 79.3 % have damage to long bones over 3 cm [1, 5, 6]. Among explosive injuries, limb injuries account for 56.3–70.1 % of cases [4, 6]. According to the statistical department of the Military Medical Clinical Center of the Northern Region, for the period February–May 2022 bone defects in the case of gunshot fractures were 76 %, of which more than 6 cm — in 28 %. Injuries of the extremities received on the battlefield, in addition to large fragmentary bone defects, are distinguished by the development of infection from the very moment of injury, which significantly complicates the use of traditional methods of their treatment.

The use of the “gold standard” — bone autoplasty, is effective in eliminating segmental defects < 5 cm in size [1, 2]. For defects > 5 cm, autograft is impractical due to the large volume of bone that must be moved to the area of injury, which most often leads to necrotization of a significant part of it [2, 10].

Today, the status of the “gold standard” in the reconstruction of bone defects of critical size is acquired by the induced membrane technique or the two-stage technique according to Masquelet. This method can be used with limited resources in the harsh conditions of surgical departments on the front line or improvised field hospitals. Unlike microvascularized bone grafting or bone transport procedures, the technique is limited by the availability of osteoinductive biomaterial and has positive results when using autologous bone [1, 10].

Thus, it is generally accepted that the best result is obtained with cancellous autoplasty [2, 10, 12]. However, traumatologists face the issue of the lack of a sufficient volume of autospongiosis (considering the critical sizes of defects). The second problem in the case of plastic surgery of critical bone defects with autospongiosis is the frequent presence of loci of aseptic necrosis [2, 10]. To solve these problems,

allogeneic bone grafts and alloplastic materials are increasingly used: bioceramics, bioglass, etc. [2, 5]. The ideal ratio between autogenous, allogeneic and alloplastic biomaterials is still a subject of controversy. In general, 70 % of autogenous bone and 30% of volume expanders are considered optimal [1, 2, 10, 12]. In his articles, Masquelet noted that the most promising substitute for autologous bone is a two-phase bioactive ceramic, which is a combination of hydroxyapatite (20%) and β -tricalcium phosphate (80 %). This substitute has a micro- and macroporous structure and proven osteogenic properties [10, 15].

The increase in the number of cases of critical bone defects, a large number of complications after GBF and a high percentage of disability require error analysis, development and improvement of the algorithm of actions, optimization of the approach to their treatment. The existence of a significant number of techniques and materials for plastic defects requires a thorough study of the effectiveness of operations depending on such factors as the localization of the defect, mechanical stability, the presence of concomitant complications, circulatory disorders, and the ability of the body to reparative osteogenesis [2, 4].

Purpose: to evaluate the possibilities of reconstructing critical bone defects after combat trauma in the second stage of the Masquelet technique with a mixture of modified bioactive ceramics and autospongiosa using additive technologies.

Material and methods

During the period 2022–2024, more than 110 patients with tubular bone defects were observed in the clinic “MC Dobrobut”, 63 of whom had critical defects. It is considered that critical defects cannot heal physiologically and require surgical manipulation for fusion. By size, they are generally considered to be defects larger than 2 cm with 50% loss of bone circumference [1, 2].

In our study, we selected a sample of 36 patients who received the Masquelet technique for treating critical bone defects and used a mixture of calcium phosphate ceramics (CPC) and autospongiosis in the second stage for defect plasticity. The study was approved by the Bioethics Commission of the private higher education institution “Academy Dobrobut” (protocol No. 1 dated 03.02.2025). Informed consent was obtained from all patients.

The treatment of patients with bone defects of the femur (7 cases (19 %), humerus (14 people (40 %), tibia (9 (24 %)) and forearm bones (6 (17 %))

resulting from combat injuries, without septic manifestations at the time of bone-plastic manipulations, was analyzed.

The results of treatment of patients after GBF with critical sizes of limb bone defects over the past 2.5 years, who underwent reconstruction using a mixture of silicon-doped CPC (SdCPC) and autospongiosis and involving additive technologies of 3D modeling and printing, were studied.

The average age of the patients was (28 ± 3) years (from 19 to 54), the treatment period of patients was from 3.5 to 16 months (on average 7.3). The vast majority were men — 34 (94 %), women — 2 (6 %).

Plasticity of bone defects was carried out in two stages using PMMA spacers (polymethylmethacrylate with gentamicin) in the first stage according to the Masquelet method. In patients with severe GBF, this method is chosen to prevent possible local infectious complications and temporarily fill the cavity of the bone defect in order to form a bed for future plasticity. In the first stage, a membrane saturated with antibiotics and growth factors is induced around the PMMA spacer-filled defect. In the second stage, plasticity of defects was carried out and during this period the stability of bone fragments was maintained, which allows for early rehabilitation [10, 12].

The timing of osteoplastic manipulations varied greatly, which is due, in our opinion, to a large number of influencing factors, namely: the quality and timing of primary surgical wound treatment (PST) and secondary wound treatment (SST), which were most often performed in different clinics, the degree of wound contamination, the extent of trophic disorders and the level of the patients' immune system. Therefore, when assessing the timing of the 2nd stage of the Masquelet technique, we chose not the recommended 2–3 months after the first [10, 16], when the process of induced membrane formation is considered to be the most active, but a period of at least 1–2 months after normalization of general clinical indicators of inflammatory processes in the blood and after 2 negative results of microbiological tests from the site of the bone defect.

Replacement of bone damage was mostly performed simultaneously with the replacement of the metal fixation method with a mixture of SdCPC in combination with autospongiosis. To fill cavity defects of critical sizes of the diaphyseal part of the bone, preference was given to the use of a mixture of granules of modified nanostructured two-phase bioactive ceramics and autospongiosa tissue, which made it possible to achieve

the following goals: increasing the volume of plastic material, providing osteoinductive properties to bioactive ceramics, compliance with the terms of replacing plastic bioceramic material with bone tissue with the terms of limb consolidation. As a plastic biomaterial for implantation into the cavity of the induced membrane, porous granules of SdCPC, 3–4 mm in size, were used. It consisted of three biocompatible phases: 65 wt. % hydroxyapatite (HAP), 30 wt. % β -tricalcium phosphate (β -TCP), 5 wt. % α -tricalcium phosphate (α -TCP). Due to different crystal structures, the three phases of the biomaterial have different solubility. During contact with the physiological environment, a small amount of the more soluble α -TCP phase dissolves faster, increasing the nanoporosity of the biomaterial. The more resistant to dissolution phase of the HAP provides a framework that, gradually resorbing, keeps the shape of the lost bone fragment. Silicon alloying contributes to the creation of a nanostructure (Fig. 1), which gives osteoinductive properties to the biomaterial; in addition, silicon is an important element of connective and bone tissue, accelerates the healing of injured bones, activates stem cells, and gives osteoinductive properties to synthetic materials [3, 11, 13].

In order to maintain the shape of the plastic material and the possibility of impaction, polymer and titanium meshes were used as a frame for the plastic area and frame meshes made of biodegradable polylactide material. In 4 cases, additive technologies were used — 3D-modeled and printed on a 3D printer volumetric forms of plastic material similar to the bone defect, which had a relationship with metal fixators.

To analyze the degree of concomitant traumatic injuries and contamination of soft tissues during gunshot wounds, the R. B. Gustillo classification of open fractures was used, in order to identify the severity of bone tissue damage — the AO classification, which in most cases of observation in our clinic included type C for metaphyseal and diaphyseal GBFs, as well as group C3 for limb joints. Vascular and neurological lesions in GBFs were assessed according to the AO classification of open fractures.

All patients underwent bacteriological culture of wounds and bone defect sites for flora and antibiotic sensitivity determination during hospitalization and surgery.

Patients were clinically and radiologically monitored after 1 and 3 months, in the absence of complications. Treatment results were analyzed at 6, 12 and 18 months from the time of plastic surgery on bones.

The outcome of surgical treatment was assessed using our own modified 100-point scale, which, according to the principles of the Harris and Rowe scale, takes into account 4 criteria: pain syndrome, clinical picture of functional recovery, radiographic images and the presence or absence of infectious and trophic complications (Table).

Results

The method of temporary filling of wounds with a PMMA cement spacer with gentamicin was used in 36 patients with bone defects and the risk of local manifestations of septic inflammation.

In the absence of septic manifestations in the lesion area and normalization of general clinical analysis indicators, the second stage of planned bone plasticity of defects was performed, taking into account the size and localization of the injury, the state of soft tissue damage and limb trophism (Fig. 2).

For critical bone defects, using the Masquelet technique in segments with one bone (shoulder, thigh) intramedullary blocked osteosynthesis with

additional fixation with a bone metal fixator (plate) or two plates was mainly chosen. In segments with 2 bones (forearm, tibia) during fixation of bone fragments of one bone, bone metal fixators — plates were mainly used.

At the 2nd stage of replacing the PMMA spacer with a bone-plastic mixture, in some cases, a titanium mesh was additionally used in 17 patients, a biopolymer mesh in 6 patients, a frame mesh made of biodegradable material hollowed out in the shape of the defect using a 3D printer in 2 patients (Fig. 3).

In 9 patients, no additional materials were used to form the plastic mixture, mostly those who were operated on in 2022–2023. The plastic material was placed in a cavity that was formed and limited only by the induced membrane, but from experience, this led to partial migration of the plastic material into the surrounding soft tissues, or during the plastic surgery it was not possible to impact the mixture accordingly to give it greater physiological density.

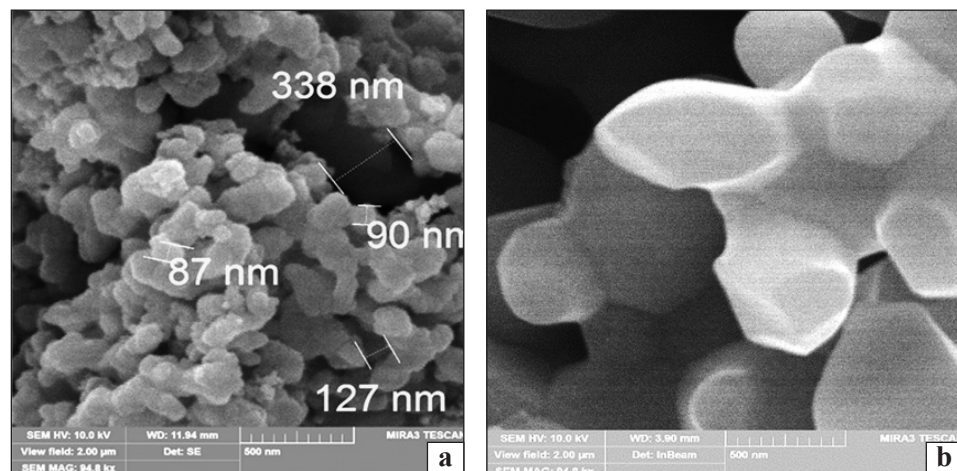


Fig. 1. Microstructure of nanostructured bioactive ceramics modified with silicon (a) and conventional porous two-phase bioactive ceramics (b), same magnification

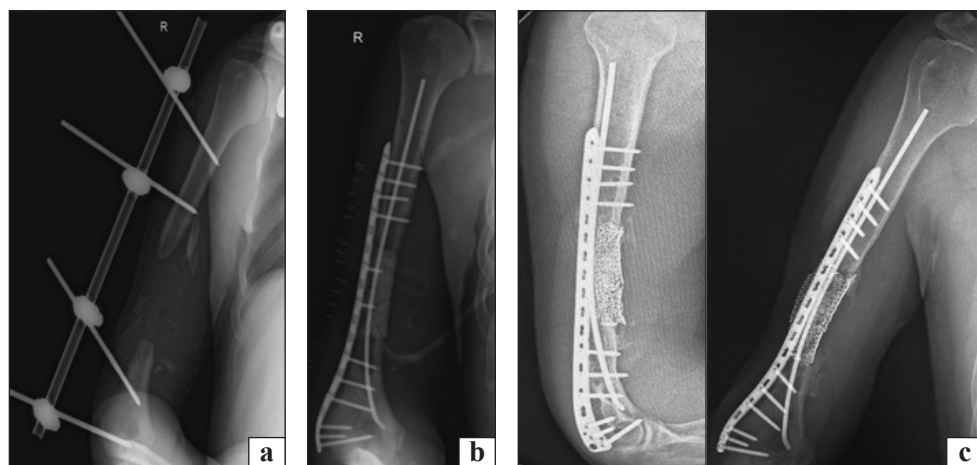


Fig. 2. Combined two-stage bone grafting according to the Masquelet method (radiographs after necrosectomy in the EFD (a) and the 1st stage (conversion of metal osteosynthesis and filling of the defect with a PMMA spacer) (b) and the 2nd with TEN metal fixation with a bone plate and titanium mesh, fixing mixture of autospungiosa and SdCPC (c))

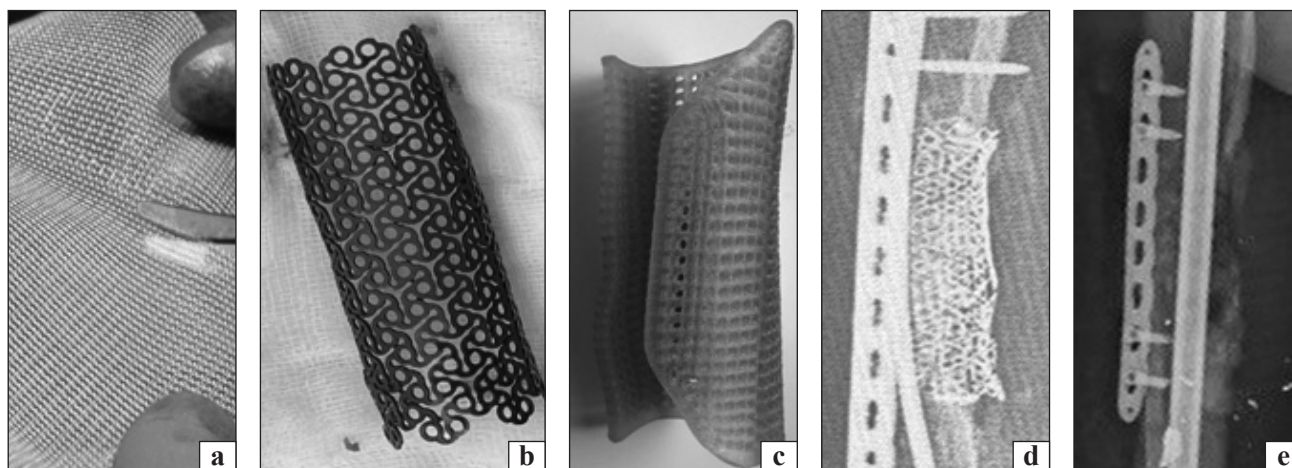


Fig. 3. Examples of using different types of meshes to form a mixture of autospongiosa and SdCPC (biopolymer mesh (a), titanium modeled mesh (b), 3D-modeled biodegradable mesh (c)), examples of the appearance of meshes on X-ray control (radio-contrast titanium (d) and non-radio-contrast biopolymer (e))

Table

Modified 100-point scale for evaluating surgical outcomes

Criteria	Result			Scoring criteria
	excellent	satisfactory	unsatisfactory	
P a i n s y n d r o m e according to the VAS scale	up to 2 points	up to 5 points	more than 5 points	25–21 — no pain; 20–11 — pain during movements; 0–10 — pain at rest
Clinical assessment: range of motion in adjacent joints, axial loading (restoration of function)	Limitation to 20 % of range of motion in adjacent joints; axial loading is complete; full recovery of working capacity	Limitation to 50 % of range of motion; axial loading to 40–50 % of body weight (walking with a cane); partial recovery of working capacity, socialization	Limitation of more than 50 % of range of motion; axial loading to 50 % of body weight (walking with crutches, wheelchair use); absence or slight recovery of limb function that limits socialization	25–21 — full recovery of working capacity, range of motion and axial loading; 20–15 — partial recovery of working capacity, socialization, limitation of the range of motion in adjacent joints to 20–30%, partial limitation of load; 0–14 — limitation of movement, load, socialization
X-ray sign	Presence of signs of callus formation and osseointegration and reconstruction of the graft; absence of signs of migration or deformation of metal fixators and graft	Weak manifestations of signs of callus formation; absence of osteointegration and reconstruction of the graft; presence of minor signs of migration or deformation of metal fixators and graft, which do not require corrective treatment	Absence of signs of callus formation and osseointegration and reconstruction of the graft; presence of signs of migration or deformation of metal fixators and graft, which require corrective treatment	25–21 — presence of signs of periosteal callus formation and osseointegration and reconstruction of the graft; 20–11 — absence of signs of consolidation, presence of minor deformation or migration of metal fixators and graft; 0–10 — absence of signs of consolidation, presence of significant deformation or migration of metal fixators
Presence of complica- tions	Absence of infectious or local trophic complications	Local infectious or trophic complications that are eliminated by conservative treatment or local surgical manipulations	Infectious or trophic complications that require further intervention	25 — absence of complications; 20–11 — local minor infectious or trophic complications; 0–10 — infectious or trophic complications that require further intervention
Total number of points	75–100	50–75	less than 50	—

In 2 cases, for the need for early axial loading during the replacement of a critical defect of the femur, additive technologies were used, which consisted of 3D design, modeling and manufacturing of SdCPC products, which were used as a plastic material to replace the bone defect at the 2nd stage of treatment (Fig. 4).

Patients were monitored after 1 and 3 months, pain syndrome was assessed using the visual analog scale (VAS), the volume of movements in adjacent joints and X-ray signs of stability of metal fixators and the absence of deformations or migrations from the side of the grafts. The results of treatment were studied in 6 months in all 36 subjects, in 12 months in 23, and in 18 months in 17 patients, they differ for those with injuries of the upper and lower extremities.

Most patients with critical defects of the upper extremities during the 6-month control showed excellent clinical results, and with lower limb injuries — satisfactory, which corresponds to the average terms of consolidation of bone injuries of this localization and restoration of working capacity. When analyzing the results of treatment in the 12-month period after plastic manipulations, excellent indicators with full restoration of limb function were obtained in 18 (78 %) patients, satisfactory — in 4 (17 %) subjects, in 1 (5 %) the result was unsatisfactory, which required further surgical interventions. As an example, we present the data of a patient with a critical defect of the humerus, who underwent treatment and recovered within 6 months after plastic manipulations (Fig. 5). The average pain syndrome index in the control period of 6 and 12 months on the VAS scale in patients with an excellent treatment result was 1.6 points, in the group with a satisfactory — 2.4 points, in a person with an unsatisfactory result — 4.1. Radiographic assessment of consolidation was performed according to 3 criteria: bone callus formation, signs of graft consolidation and remodeling. All 36 patients had signs of bone callus formation at 3, 6 and 12 months, and with regard to the degree of graft consolidation and structural consolidation, assessment of significant signs can be performed at longer periods of time (18, 24 months and more), which requires further observation.

Complications in the postoperative period in the form of local septic inflammatory processes were in 7 patients, in 5 cases they were of the nature of local manifestations in the area of postoperative scars and were leveled after surgical and antiseptic manipulations.

In 2 cases there was a need for secondary surgical treatment using pulse lavage, washing and VAC systems.

Discussion

Recently, the number of studies on combat trauma of the limbs, especially GBF with a bone tissue defect, has been increasing. It damages all components of the limb architecture, namely: skin, soft tissues, bone, vascular and nerve elements, which requires a quick and accurate assessment with the selection of treatment methods to optimize functional results.

Due to early replacement of tissue defects, it is possible to achieve a significant reduction in the risk of infectious complications, preservation of the viability of bone fragments, tendons, articular cartilage, vessels and nerves, as well as optimization of the course of reparative processes, and as a result, better results of healing and restoration of limb function [1, 6, 7].

Despite the large number of literary sources on this topic, today there is no generally accepted algorithm of actions, clear criteria for tactics, timing of manipulations, choice of plastic materials and methods of stabilizing fragments have not been defined.

Own experience of using a mixture of autospungiosa and SdCPC in combination with stable submerged osteosynthesis (performed in two stages by the method of conversion from external to submerged) makes it possible to obtain a positive result in most clinical cases of treatment of critical post-traumatic diaphyseal bone defects.

The use of such modern technologies as 3D-modeling using CT of the bone defect of patients, together with the possibility of using bioactive bioresorbable materials, simplifies the technical difficulties that arise during reconstructive and restorative operations.

Thus, the use of 3D-grids made of biodegradable plastic helps to form and maintain the required volume of plastic mixture to fill a critical bone defect of the required shape. And the manufacture of a 3D-model of an implant from SdCPC provides the opportunity not only to use plastic material according to the shape and size of the defect, but also greater interfragmentary stability and can, by correcting the density of the material, adjust the terms of biodegradation in accordance with the physiological terms of bone remodeling. Taking into account the longer terms of remodeling of the bone-plastic mixture, as compared with the average term of union

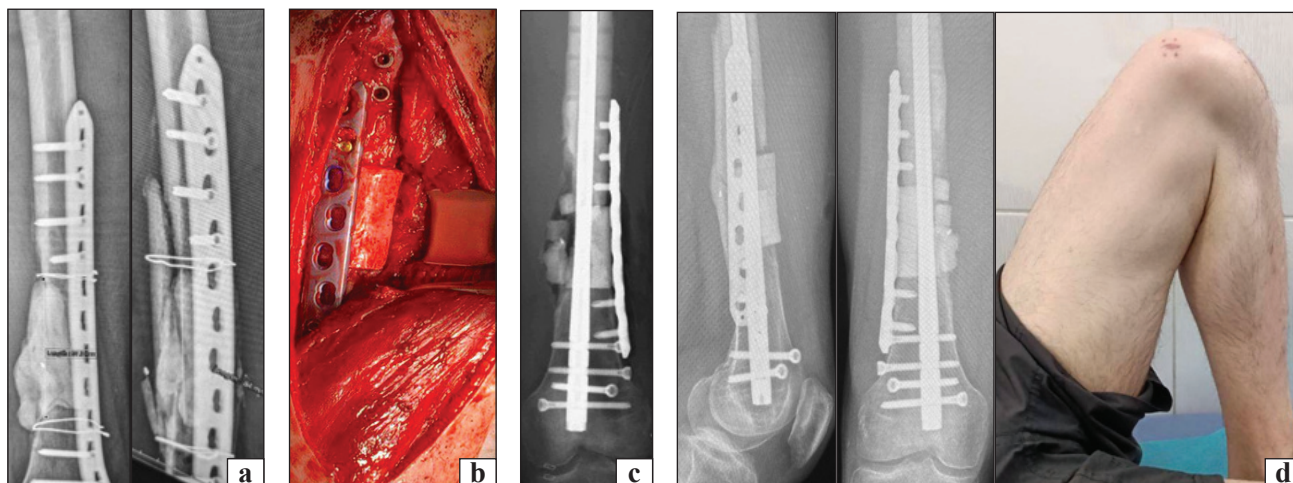


Fig. 4. Example of using 3D modeling in the conditions of using SdCPC products. X-ray of a patient with a defect of the femoral shaft after MOS with a plate and replacement of the defect with a PMMA spacer (a), during the operation, replacement of the defect with a 3D-modeled SdCPC implant (b), in the postoperative period, X-ray control on the day after surgery (c) and after 4 months, photo of the operated limb after restoration of function (d)

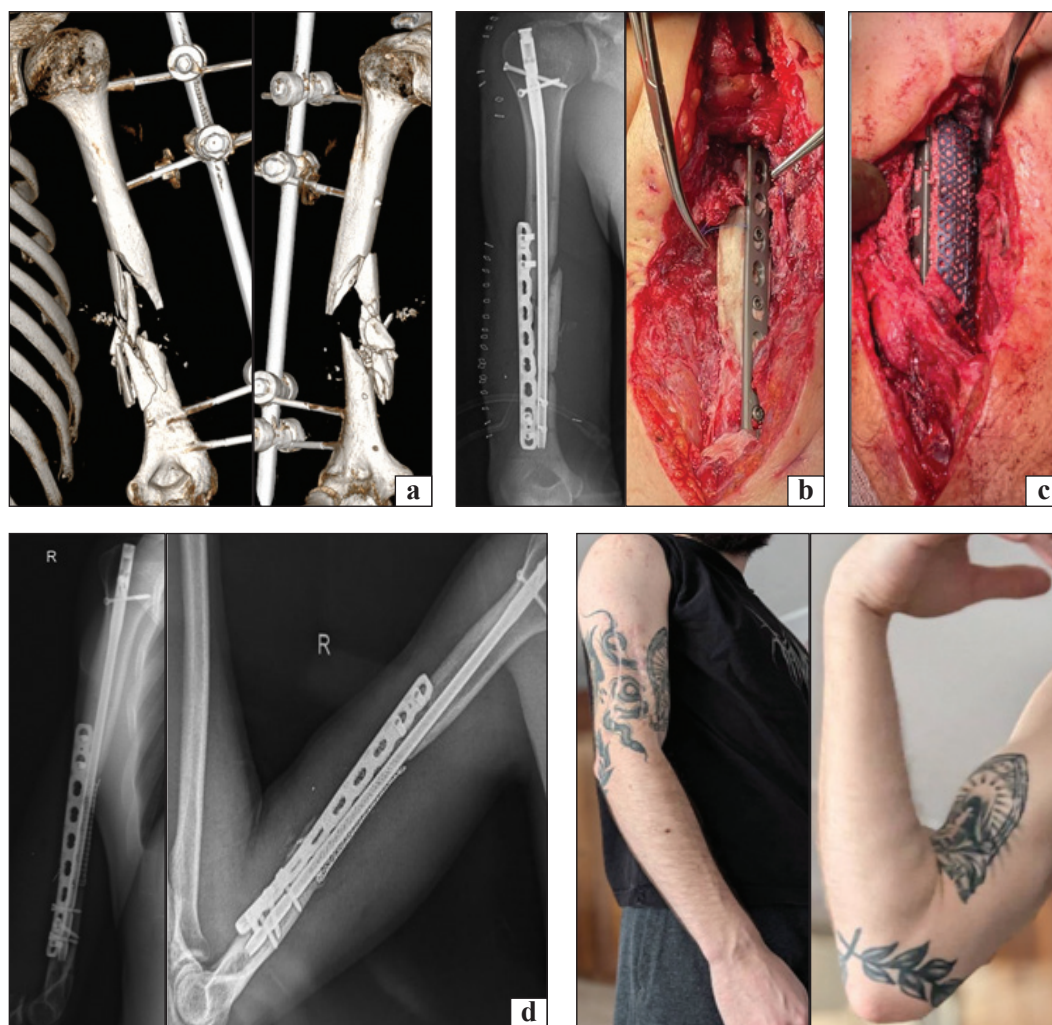


Fig. 5. An example of treatment of a patient using the Masquelet technique with a critical defect of the humeral diaphysis on CT (a), after conversion of external metal osteosynthesis to submerged at the 1st stage with replacement of the defect with a PMMA spacer (b) and at the 2nd stage — plastic surgery of the defect with a mixture of autospungiosa and SdCPC using a titanium mesh on intraoperative photos (c) and X-ray control after surgery (d) and a photo of the treatment result with the volume of movements and restoration of function and working capacity after 6 months (e)

of fractures of this localization, longer observations in the distant period (24 and 36 months) are required for their evaluation.

Conclusions

After analyzing the treatment results, we believe that the use of a mixture of SdCPC and autospungiosa during two-stage replacement of critical diaphyseal bone defects has a positive effect in most clinical cases.

Rational in the treatment of wounded from the military-industrial complex and critical bone defects is the combination of modern orthopedic and traumatological techniques and the latest technologies. 3D modeling and the use of biodegradable materials expand the range of possibilities of the doctor for performing bone plastic manipulations.

The recommended tactics of choosing techniques and materials for replacing post-traumatic critical bone defects due to combat injury in combination with stable metal osteosynthesis made it possible to obtain positive treatment results in more than 90 % of patients, which indicates the possibility of its use in traumatological practice.

Conflict of interest. The authors declare the absence of a conflict of interest.

Prospects for further research. The use of modern additive technologies in conjunction with the possibility of using bioactive bioresorbable materials simplifies the technical difficulties that arise during reconstructive and restorative operations. However, the assessment of radiological signs of bone callus formation and bioresorption and remodeling of the graft can be traced back to periods longer than 12 months (namely, 18, 24 and more), which requires further observation, which is planned for subsequent periods with the study of long-term treatment results.

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Authors' contribution. Shmagoy V. L. — conducted clinical studies, did scientific and statistical processing of materials; Yurzhenko M. V. — performed practical work with additive technologies, wrote the article; Ulyanchych N. V., Kolomiets V. V., Firstov S. O. — selected and provided CPC, provided scientific and technical information.

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OUR EXPERIENCE IN USING MODIFIED BIOACTIVE CERAMICS FOR THE RECONSTRUCTION OF CRITICAL POST-TRAUMATIC BONE DEFECTS

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The effect of CO₂ therapy and its combinations on inflammatory activity and immune status: an experimental study

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Osteoarthritis (OA) is a chronic degenerative disease characterized by cartilage destruction, inflammation, and autoimmune processes. The limited effectiveness of current therapies has generated interest in alternative approaches, such as carboxytherapy, which possesses anti-inflammatory and regenerative properties. Objective. To evaluate the effects of carboxytherapy (CO₂) in mono- and combination therapy on a carrageenan-induced model of inflammation in rats by assessing leukocyte differential counts and integral indices. Methods. The study was conducted on 56 white rats divided into 7 groups (n = 8): control (intact and carrageenan-induced), mono- and combination therapy with CO₂ in conjunction with diclofenac or chondroitin. Changes in the leukocyte differential counts and integral indices (NMR, NLR, LSI, LI, IIR) were evaluated. Results. CO₂ monotherapy (Group V) reduced the NMR (Neutrophil-to-Monocyte Ratio) by 25.4 % (15.60 ± 2.95 vs. 20.92 ± 8.89 in Group II, $p < 0.001$). The Leukocyte Index (LI) increased by 82.2 % (1.471 ± 0.155 vs. 1.791 ± 0.191 , $p = 0.001$). The combination of CO₂ with diclofenac (Group VI) reduced NMR by 68.3 % (6.61 ± 2.72 , $p < 0.001$) and increased LI by 103.1 % (3.637 ± 0.770 , $p < 0.001$). CO₂ combined with chondroitin (Group VII) reduced the NLR (Neutrophil-to-Lymphocyte Ratio) by 48.6 % (0.290 ± 0.0938 , $p < 0.001$) and increased LI by 121.7 % (3.847 ± 1.421 , $p < 0.001$). In Groups VI and VII, there was a significant decrease in band neutrophils (by 79.2 % and 75.0 %, respectively) and an increase in lymphocytes (by 72.2 % and 70.9 %, $p < 0.001$). Conclusions. Carboxytherapy modulates the inflammatory response and enhances the immune response. The best results were observed with combined CO₂ therapy with diclofenac or chondroitin, confirming their potential in reducing inflammation and stimulating regeneration.

Остеоартрит (ОА) — хронічне дегенеративне захворювання суглобів, патогенез якого пов'язаний із запаленням і дисфункцією імунної системи. У свою чергу, карбокситерапія (CO₂) є перспективним методом лікування остеоартриту завдяки своїм протизапальним і регенеративним властивостям. Мета. Оцінити вплив карбокситерапії як монотерапії та в комбінації з диклофенаком натрію та хондроїтину сульфатом на показники лейкоцитарної формули, інтегральні індекси запалення й імунної відповіді у щурів із карагеніновою моделлю запалення. Методи. Дослідження проведено на 56 білих щурів, поділених на 7 груп (n = 8). Для моделювання запалення використовували карагенін. Групи отримували CO₂ (0,5 мл), диклофенак натрію (4–8 мг/кг), хондроїтину сульфат (3 мг/кг) або їх комбінації. Аналіз лейкоцитарної формули проводили за стандартною методикою; розраховували інтегральні індекси лейкограми (ІСНМ, ІСЛМ, ІСНЛ, ІЗЛ, ЛІ). Дані обробляли за допомогою дисперсійного аналізу ($p < 0,05$). Результати. Монотерапія CO₂ знизила ІСНМ на 25,4 % ($p < 0,001$) та ІСНЛ на 46,9 % ($p < 0,001$), тоді як комбіноване застосування CO₂ із диклофенаком натрію зменшило ІСНМ на 68,3 % ($p < 0,001$) і підвищило ЛІ на 103,1 % ($p < 0,001$). CO₂ із хондроїтину сульфатом знизив ІСНМ на 45,5 % ($p = 0,026$), а ЛІ зріс на 121,7 % ($p < 0,001$). Частка лімфоцитів у групі CO₂ + диклофенак натрію збільшилася на 42,9 % ($p < 0,001$), що вказує на активацію адаптивного імунітету. Висновки. Карбокситерапія ефективно модулює запальні процеси, знижуючи нейтрофільну активність і посилюючи адаптивну імунну відповідь. Комбінація CO₂ із диклофенаком натрію або хондроїтину сульфатом демонструє синергічний ефект, що дозволяє зменшити дози традиційних препаратів і мінімізувати побічні ефекти. Отримані результати підтверджують перспективність використання CO₂-терапії у лікуванні остеоартриту. Ключові слова. Карбокситерапія, вуглекислий газ, запалення, нейтрофіли, лімфоцити, диклофенак натрію, хондроїтину сульфат, карагенінова модель

Key words. Carboxytherapy, carbon dioxide, inflammation, neutrophils, lymphocytes, diclofenac, chondroitin sulfate, carrageenan model

Introduction

Osteoarthritis (OA) is a long-term degenerative joint disease, with its pathogenesis remaining incompletely understood. It is characterized by cartilage destruction, osteophyte formation, and inflammatory processes [1]. OA was previously considered a disease caused mainly by mechanical wear of the joints. However, modern studies emphasize the significant role of the immune system in its development. Infiltration of immune cells into the joint, production of inflammatory mediators, and autoimmune processes indicate that OA has an immunological nature [2].

The release of pro-inflammatory mediators (cytokines, adipokines, growth factors) has been proven to determine inflammatory reactions in joint tissues, which are accompanied by loss of their structure and function [3].

Studies have shown that changes in hematological parameters, in particular leukocyte (neutrophil, lymphocyte, monocyte) and platelet levels, as well as erythrocyte distribution width and acute phase protein content, can reflect the degree of systemic inflammatory response in OA [4, 5]. On this basis, it has been proposed to use different ratios of blood cellular elements, neutrophil to lymphocyte (NLR) or monocyte to lymphocyte (MLR), as markers that correlate with the course of OA [6]. The study of hematological parameters is a convenient, minimally invasive and economically available method for detecting systemic inflammation in osteoarthritis [4].

Modern treatment of OA mainly includes chondroprotectors, nonsteroidal anti-inflammatory drugs (NSAIDs), and in case of progression, arthroplasty [7]. Recently, more and more attention has been paid to the use of natural substances that block molecules involved in the progression of inflammation and cartilage destruction [8]. Modern therapy is increasingly focused on a comprehensive approach, supplemented by alternative treatment methods [7].

One of the promising areas in the treatment of OA is carboxytherapy, a method based on the introduction of carbon dioxide (CO₂). This approach attracts attention due to the anti-inflammatory and regenerative properties of CO₂ [9]. The mechanism of action includes improving microcirculation, stimulating tissue metabolism and activating regenerative processes [10]. The introduction of CO₂ promotes vasodilation, improves oxygen transport to tissues and the removal of metabolic products [11, 12].

It is assumed that CO₂ may have an anti-inflammatory effect, modulating the immune response and promoting the recovery of damaged tissues [13, 14].

However, the mechanisms of action of CO₂ during the treatment of OA remain poorly understood.

Purpose: to evaluate the effect of carboxytherapy both as monotherapy and in combination with traditional anti-inflammatory drugs (diclofenac sodium and chondroitin sulfate) on leukocyte formula and integral intoxication indices in case of carrageenan inflammation in rats.

The study aims to determine whether carboxytherapy is able to modulate inflammatory processes and promote tissue regeneration, as well as to investigate its ability to enhance the anti-inflammatory effect of traditional drugs. We assume that combination therapy will contribute to a more effective immune response, reduce inflammatory activity and trigger recovery processes, which may become the basis for the development of new therapeutic approaches in the treatment of osteoarthritis.

Material and methods

The study, conducted at the vivarium of Poltava State Medical University, was approved by the ethical committees of Poltava State University (protocol No. 225 dated 21.03.2024) and Uzhhorod National University (protocol No. 9/2 dated 07.06.2023). All procedures complied with the main provisions of the Council of Europe Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, as well as Directive 2010/63/EU of the European Parliament and of the Council of the EU.

This fragment is part of the initiative research topic of the Department of Pharmacology, Clinical Pharmacology and Pharmacy of Poltava State Medical University “Pharmacological study of biologically active substances and drugs for the development and optimization of indications for their use in medical practice” (state registration number 0120U103921), as well as the research topic of the Department of General Surgery of the State Higher Educational Institution “Uzhhorod National University” “Monitoring of traumatic disease against the background of chronic stress” (state registration number 0124U002167).

The study used 56 white rats ($n = 56$), weighing 285–315 g, of which 34 (60.7 %) were females. The animals were kept in standard vivarium conditions at a temperature of $(22 \pm 2) ^\circ\text{C}$, relative humidity $(55 \pm 5) \%$ and a 12-hour light regime. They had free access to water and standard food. The animals were randomized and divided into 7 groups of 8 rats each ($n = 8$): group I — intact control (saline); group II — control pathology (carrageenan 1 %,

0.1 ml); group III — control pathology + diclofenac sodium (8 mg/kg, intraperitoneally); group IV — control pathology + chondroitin sulfate (3 mg/kg, intraperitoneally); group V — control pathology + carbon dioxide (CO₂, 0.5 ml, p/s); group VI — control pathology + diclofenac sodium (4 mg/kg) + CO₂ (0.5 ml); group VII — control pathology + chondroitin sulfate (3 mg/kg) + CO₂ (0.5 ml).

To simulate acute inflammation, a carrageenan model was used in rats. Animals were injected subplantarily with a 1 % solution of carrageenan in a volume of 0.1 ml. Diclofenac sodium in doses of 8 and 4 mg/kg, and chondroitin sulfate in a dose of 3 mg/kg, were administered intraperitoneally one hour before the carrageenan test. Subcutaneous administration of CO₂ was performed using an INDAP Insuf apparatus (Czech Republic) using a BD Mikrolance 3.30 G ½ 0.3 × 13 mm needle in a dose of 0.5 ml per animal one hour before the administration of carrageenan. The intact control group was administered saline in an equivalent volume.

Six hours after the administration of carrageenan, the rats were euthanized under thiopental anesthesia (50 mg/kg), and blood was collected from the heart until it stopped. The blood was fixed in test tubes with a layer of 2-substituted salt of ethylenediaminetetraacetic acid. For cytological examination, blood smears were prepared, fixed and stained according to the standard Romanovsky-Giemza method. Their analysis was performed using a light microscope with an immersion system (lens ×100, eyepiece ×10). The number of leukocytes of different types in the field of view per 100 cells (cells/μl) was counted.

To identify the intensity of the inflammatory process and the general state of the immune system, the following integral leukocyte indices were calculated: INMR (neutrophil-monocyte ratio = neutrophils/monocytes); ILMR (lymphocyte-monocyte ratio = lymphocytes/monocytes); INLR (neutrophil-lymphocyte ratio = (rod-nucleated neutrophils + segmented neutrophils)/lymphocytes); ILS (leukocyte shift index = (eosinophils + basophils + segmented neutrophils + rod-nucleated neutrophils) / (lymphocytes + monocytes)); LI (leukocyte index = lymphocytes/neutrophils); IIR (immuno-resistancy index) = (lymphocytes + eosinophils)/monocytes [15, 16].

Digital data were processed using Jamovi 2.3.21 version. Results are presented as mean values ± standard deviation. The Shapiro-Wilk test was used to check normality. Group comparisons were performed using Welch's t-test or Tukey's test for normal distribution, and for non-normal distributions,

the Kruskal-Wallis test with Bonferroni correction. Results were considered statistically significant at $p < 0.05$.

Results

Analysis of the results (Tables 1 and 2) demonstrates the modulating effect of CO₂ on the hemogram, which is manifested in changes in both individual leukocyte indices and integral indices.

The tables show relative indicators. The values are presented in percentages per 100 cells, and “< 0.01” indicates a level that does not exceed the detection limit of the analysis method. Statistical analysis was performed using one-way analysis of variance followed by Tukey's a posteriori test. Statistically significant difference *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$ compared to the control pathology group (carrageenan).

In order to find new effective methods for the treatment of inflammatory diseases, a study was conducted to study the anti-inflammatory activity of combined therapy of traditional drugs using CO₂ and to analyze changes in the leukocyte formula and immune indices, which allowed to identify the mechanisms of the positive effect of CO₂ during its use as part of both mono- and complex therapy with traditional drugs. The results obtained may contribute to the development of new approaches to the treatment of osteoarthritis and other diseases associated with inflammatory processes. In group II (carrageenan), an increase in the level of neutrophils was observed: rod-shaped by 12.0 %, segmented by 24.4 %, and the proportion of lymphocytes decreased by 30.1 % compared to intact animals ($p < 0.05$). The INMR increased almost threefold (by 190.9 %, $p < 0.001$), the INLR by 97.2 % ($p < 0.001$), and the ILS by 118.5 % ($p < 0.001$), which indicates the activation of the acute phase of inflammation.

In group III (diclofenac), a decrease in neutrophil activity was observed: rod-shaped neutrophils decreased by 62.8 %, segmented neutrophils by 24.6 %, while the proportion of lymphocytes increased by 31.9 % ($p < 0.001$). The INMR decreased by 28.6 % ($p < 0.001$), the INLR by 47.3 % ($p < 0.001$), and the ILS by 43.9 % ($p < 0.001$), which indicates a decrease in the intensity of inflammation and the activation of adaptive immunity.

Group IV (chondroitin sulfate) had the highest level of segmented neutrophils, which increased by 52.9 % ($p < 0.001$), while lymphocytes decreased by 23.3% ($p < 0.001$) compared to group II. INMR and INLR remained at high levels, indicating an in-

creased neutrophilic response characteristic of acute inflammation.

In group V (CO₂ monotherapy), there was a decrease in the INMR by 25.4 % ($p < 0.001$), the INLR by 46.9 % ($p < 0.001$), and the ILS by 43.5 % ($p = 0.015$), which indicates a decrease in neutrophil activity.

The combination of CO₂ with diclofenac sodium (group VI) provided a decrease in the INMR by

68.3 % ($p < 0.001$), the INLR by 49.3 % ($p < 0.001$), and the ILS by 51.9 % ($p < 0.001$). LI increased by 103.1 % ($p < 0.001$), and the proportion of lymphocytes by 42.9 % ($p < 0.001$), which confirms the activation of adaptive immunity.

In group VII (CO₂ + chondroitin sulfate), the INMR decreased by 45.5 % ($p = 0.026$), the INLR by 48.6 % ($p = 0.014$), and the ILS by 49.1 % ($p < 0.001$). The LI increased by 121.7 % ($p < 0.001$),

Table 1

Effect of carboxytherapy on leukocyte formula in carrageenan inflammation in rats ($M \pm SD$, $n = 8$)

Animal group	Changed, %	Rods, %	Segmented, %	Eosinophils, %	Monocytes, %	Basophils, %	Lymphocytes, %
Intact	not detected (< 0.01) ± 0	not detected (< 0.01) ± 0	21.60 ± 3.543	2.13 ± 0.641	3.13 ± 0.991	not detected (< 0.01) ± 0	73.00 ± 3.550
II	12.00 ± 0.586	4.38 ± 0.916	24.40 ± 3.623	6.00 ± 1.069	1.75 ± 1.035	0.125 ± 0.354	51.00 ± 2.730
III	5.25 ± 1.035	$1.63 \pm 0.518^{***}$	$18.40 \pm 1.408^{**}$	5.38 ± 1.923	1.50 ± 0.535	0.125 ± 0.354	$67.30 \pm 1.040^{***}$
IV	3.75 ± 1.282	3.50 ± 0.756	$37.30 \pm 3.732^{***}$	$14.00 \pm 2.507^{***}$	3 ± 0.756	not detected (< 0.01) ± 0	$39.10 \pm 2.170^{***}$
V	3.00 ± 1.195	$2.75 \pm 1.165^{**}$	$33.00 \pm 0.926^{***}$	6.50 ± 1.309	2.38 ± 0.518	not detected (< 0.01) ± 0	52.40 ± 3.160
VI	not detected (< 0.01) ± 0	$2.50 \pm 1.309^{***}$	$18.30 \pm 2.765^{**}$	$3.38 \pm 0.518^*$	3 ± 1.069	not detected (< 0.01) ± 0	$72.90 \pm 2.590^{***}$
VII	0.50 ± 0.535	$3.00 \pm 0.756^*$	$17.60 \pm 5.097^{**}$	4.25 ± 1.488	2.50 ± 1.604	not detected (< 0.01) ± 0	$72.40 \pm 4.720^{***}$
Probable intergroup differences	$\chi^2 = 51.20$ $p < 0.001$	$\chi^2 = 37.90$ $p < 0.001$	$F = 118.00$ $p < 0.001$	$F = 38.40$ $p < 0.001$	$F = 5.23$ $P = 0.002$	$\chi^2 = 5.09$ $p = 0.532$	$F = 224.00$ $p < 0.001$
Normality Test (Shapiro-Wilk)	$W = 0.836$ $p < 0.001$	$W = 0.955$ $p = 0.036$	$W = 0.988$ $p = 0.862$	$W = 0.968$ $p = 0.149$	$W = 0.982$ $p = 0.589$	$W = 0.382$ $p < 0.001$	$W = 0.991$ $p = 0.953$

Notes: * — $p < 0.05$; ** — $p < 0.01$; *** — $p < 0.001$.

Table 2

Effect of carboxytherapy on integral immune response indices in carrageenan inflammation in rats ($M \pm SD$,

Animal group	INMR	ILMR	INLR	ILS	LI	IIR
Intact	7.19 ± 2.31	25.4 ± 7.75	0.286 ± 0.0603	0.303 ± 0.0651	3.623 ± 0.738	26.1 ± 7.97
II	20.92 ± 8.89	38.3 ± 17.90	0.564 ± 0.0660	0.662 ± 0.0486	1.791 ± 0.191	43.0 ± 20.24
III	14.94 ± 5.27	50.5 ± 18.20	$0.297 \pm 0.0220^{***}$	$0.371 \pm 0.0279^{***}$	$3.376 \pm 0.246^{***}$	54.9 ± 20.75
IV	14.53 ± 4.78	13.8 ± 3.79	$1.048 \pm 0.1502^{***}$	1.306 ± 0.1472	0.970 ± 0.124	18.7 ± 4.81
V	15.60 ± 2.95	23.0 ± 5.08	$0.686 \pm 0.0738^*$	0.776 ± 0.0835	1.471 ± 0.155	25.9 ± 5.67
VI	$6.61 \pm 2.72^{***}$	22.7 ± 5.86	$0.286 \pm 0.0641^{***}$	$0.318 \pm 0.0587^{***}$	$3.637 \pm 0.770^{***}$	23.7 ± 6.04
VII	$11.47 \pm 8.69^*$	37.1 ± 22.89	$0.290 \pm 0.0938^{***}$	$0.337 \pm 0.0843^{***}$	$3.847 \pm 1.421^{***}$	39.0 ± 23.44
Probable intergroup differences	$F = 11.40$ $p < 0.001$	$F = 9.32$ $\chi^2 = 25.7$ $p < 0.001$	$\chi^2 = 44.1$ $p < 0.001$	$F = 101.00$ $p < 0.001$	$\chi^2 = 44.1$ $p < 0.001$	$F = 5.63$ $p = 0.001$
Normality Test (Shapiro-Wilk)	$W = 0.983$ $p = 0.594$	$W = 0.963$ $p = 0.086$	$W = 0.942$ $p = 0.010$	$W = 0.985$ $p = 0.687$	$W = 0.917$ $p < 0.001$	$W = 0.973$ $p = 0.244$

Notes: * — $p < 0.05$; *** — $p < 0.001$.

and the proportion of lymphocytes increased by 42.0 % ($p < 0.001$), which indicates a decrease in inflammation and activation of the immune response.

Comparison of groups III (diclofenac sodium) and VI (diclofenac sodium + CO₂) showed that the combined therapy significantly enhances the anti-inflammatory effect. The INMR in group VI decreased by 55.8 % compared to group III ($p < 0.001$), the INLR by 3.7 % ($p < 0.001$), and the ILS by 14.3 % ($p < 0.001$). The LI increased by 7.7 % ($p < 0.05$), and the proportion of lymphocytes increased by 8.3 % ($p < 0.001$). These results indicate a synergistic effect of CO₂ with diclofenac, which reduces neutrophil activity and enhances the adaptive immune response.

Comparison of groups IV (chondroitin sulfate) and VII (chondroitin sulfate + CO₂) demonstrates a similar trend. The INMR in group VII decreased by 21.1 % compared to group IV ($p < 0.05$), the INLR by 72.3 % ($p < 0.001$), and the ILS by 25.8 % ($p < 0.001$). The LI increased by 194.2 % ($p < 0.001$), and the proportion of lymphocytes increased by 85.2 % ($p < 0.001$). These changes confirm that the addition of CO₂ to chondroitin enhances the anti-inflammatory effect and significantly activates the adaptive immune response.

The results obtained emphasize that CO₂ is important both in monotherapy and in combination with anti-inflammatory drugs, enhancing their effect and contributing to the reduction of inflammatory activity.

Discussion

Our studies confirm that carboxytherapy (CO₂) is a promising method in modulating inflammatory and regenerative processes. The observation also showed that the combined use of CO₂ with diclofenac sodium or chondroitin sulfate is more effective in reducing inflammatory activity and enhancing the adaptive immune response than the use of each component separately. The greatest effect was demonstrated under the conditions of combined therapy of CO₂ with diclofenac, where a decrease in the INMR index by 68.3 % ($p < 0.001$) and an increase in LI by 103.1 % ($p < 0.001$) was observed compared to the pathology group. In the "CO₂ + chondroitin sulfate" group, the INMR decreased by 45.5 % ($p = 0.026$), and the LI increased by 121.7 % ($p < 0.001$). It is important that CO₂ enhances the anti-inflammatory effect of traditional drugs, allowing to reduce their dosage by 2 times and, thus, to reduce the risk of side effects. A similar synergistic effect of CO₂ was also observed in clinical studies involving patients with post-traumatic and postoperative lesions [9]. The mechanisms

of action of CO₂ include a decrease in the activity of NF- κ B and MAPK, which suppresses the expression of pro-inflammatory cytokines [17, 18]. In addition, hypercapnic acidosis inhibits ERK1/2, contributing to a decrease in the inflammatory response, which confirms the role of CO₂ in the modulation of cellular metabolism [19].

CO₂ is actively studied and used in many areas of medicine, as it helps to accelerate fracture healing and increase bone strength by stimulating microcirculation, tissue oxygenation, as well as reducing the levels of pro-inflammatory cytokines (HIF-1 α , IL-1 β , IL-6) and increasing the expression of factors that produce regeneration (VEGF, TGF- β) [20]. A study by P. Chou et al. demonstrated that the use of a decellularized matrix treated with supercritical CO₂ in combination with stem cells significantly improves tissue regeneration and reduces inflammation. This confirms the potential of CO₂ in stimulating reparative processes [21]. In the treatment of muscle injuries, the use of CO₂ paste helps to increase the expression of MyoD and myogenin, reduce the levels of IL-1 β , IL-6 and TGF- β , and accelerate muscle regeneration through the induction of the Bohr effect [22]. In addition, the use of CO₂ stimulates angiogenesis by regulating the expression of VEGF and TGF- β , which in turn improves the repair and regeneration of damaged tissues [23, 24]. Thus, the available data demonstrate the broad therapeutic potential of the use of carbon dioxide due to its ability to modulate key molecular and cellular processes that underlie reparative mechanisms in the body. The use of carboxytherapy in orthopedics is becoming increasingly relevant due to its ability to modulate inflammatory and regenerative processes. Osteoarthritis and other degenerative joint diseases are often accompanied by chronic inflammation, impaired blood circulation and progressive damage to cartilage tissue. Since neutrophils play a central role in the pathophysiology of osteoarthritis, the modulating effect of CO₂ on their activity through the effect on pH and inhibition of NF- κ B opens up new perspectives for therapeutic intervention [25]. In addition, CO₂ enhances the anti-inflammatory effect of traditional drugs, allowing to reduce their dosage and reduce the risk of side effects. Thus, the use of carboxytherapy in orthopedics is of great importance for the individualized and effective treatment of osteoarthritis and other degenerative joint diseases.

Conclusions

Carboxytherapy demonstrated a significant anti-inflammatory effect in the carrageenan model of inflammation. The use of CO₂ as monotherapy

reduced the neutrophil-monocyte ratio index by 25.4 % ($p < 0.001$), the neutrophil-lymphocyte index by 46.9 % ($p < 0.001$), and the leukocyte shift index by 43.5 % ($p = 0.015$), indicating a decrease in neutrophil activity.

The combination of CO₂ with diclofenac reduced the neutrophil-monocyte ratio index by 68.3 % ($p < 0.001$) and the neutrophil-lymphocyte ratio index by 49.3 % ($p < 0.001$), while increasing the leukocyte index by 103.1 % ($p < 0.001$). The combination of CO₂ with chondroitin also demonstrated a positive effect: a decrease in the neutrophil-monocyte ratio index by 45.5 % ($p = 0.026$), the neutrophil-lymphocyte index by 48.6 % ($p = 0.014$) and an increase in the leukocyte index by 121.7 % ($p < 0.001$). These results indicate an increase in the anti-inflammatory effect of traditional drugs due to the addition of CO₂.

The use of CO₂ contributed to an increase in the proportion of lymphocytes by 42.9 % ($p < 0.001$) in the CO₂ + diclofenac sodium group and by 42.0 % ($p < 0.001$) in the CO₂ + chondroitin sulfate group, which indicates the activation of the adaptive immune response.

The results obtained in the carrageenan model of inflammation in animals confirm the promising potential of combined use of carboxytherapy with diclofenac or chondroitin for modulating inflammatory processes. Given the effectiveness of reducing neutrophil activity, improving integral indices and stimulating the adaptive immune response, further clinical studies are appropriate.

The prospective use of such combined therapy can provide a more targeted correction of the inflammatory process in patients with degenerative joint diseases, in particular osteoarthritis of the knee and hip joints. This will allow reducing the dosage of traditional anti-inflammatory drugs, minimizing side effects and enhancing regenerative processes in the affected tissues.

Conflict of interest. The author declares the absence of a conflict of interest.

Prospects for further research. A preclinical study is planned on a model of monoiodoacetate-induced osteoarthritis (MIA-OA) to assess the effectiveness of carboxytherapy both as monotherapy and in combination with diclofenac or chondroitin. The study will assess the impact of combined CO₂ use on the main mechanisms of inflammation in the joints, in particular: analysis of the expression of key pro-inflammatory cytokines (IL-1 β , IL-6, TNF- α) to determine the anti-inflammatory effect of combined carboxytherapy and its potential ability to reduce the level of chronic inflammation in joint tissues and assessment of the level of transforming growth factor β (TGF- β), in order to determine the impact of CO₂ and its combinations on the stimulation of cartilage tissue regeneration.

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THE EFFECT OF CO₂ THERAPY AND ITS COMBINATIONS ON INFLAMMATORY ACTIVITY AND IMMUNE STATUS: AN EXPERIMENTAL STUDY

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Analysis of postoperative complications in the surgical treatment of proximal humeral fractures in patients with decreased mineral bone density

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Objective. To conduct a comparative retrospective analysis of the impact of postoperative complications on functional outcomes following different surgical treatment methods for proximal humeral fractures of AO/OTA types 11-B and 11-C in patients over 45 years old with decreased bone mineral density. **Methods.** The study analyzed the surgical treatment outcomes and postoperative complications in 102 patients aged (61.1 ± 8.1) years, who were divided into three groups based on the treatment method: (1) open reduction and internal fixation (ORIF) using a PHILOS plate ($n = 50$); (2) ORIF with a PHILOS plate combined with 3D-printed PLA implants ($n = 44$); (3) primary reverse total shoulder arthroplasty (RTSA) using a newly developed total reverse endoprosthesis ($n = 8$). Functional outcomes in patients with complications were assessed using the Constant-Murley Score at 3, 6, and 12 months postoperatively and analyzed based on individual preoperative parameters and treatment methods. **Results.** A total of 30 postoperative complications were recorded, the most common being superficial infection (7.8 % of the total population), secondary displacement (6.9 %), varus malalignment of fragments (6.9 %), and avascular necrosis of the humeral head (3.9 %). The highest number of complications was observed in Group (1), with 19 patients affected, accounting for 38 %. For all complications except avascular necrosis, a significant improvement in functional outcomes was observed between 3 and 12 months postoperatively. The mean Constant-Murley Score in patients with complications at 12 months postoperatively was (78.7 ± 8.5) . **Conclusions** A retrospective analysis of postoperative complications following different surgical treatment methods established that, compared to other options, reverse total shoulder arthroplasty (RTSA) is a modern and optimal surgical treatment option for proximal humeral fractures of AO/OTA types 11-B or 11-C in the context of severe bone mineral density reduction, particularly in elderly patients.

Мета. Провести порівняльний ретроспективний аналіз впливу післяопераційних ускладнень на функціональні результати за різних методик хірургічного лікування переломів проксимального відділу плечової кістки типів АО/ОТА 11-В, 11-С у пацієнтів старших за 45 років із зниженням мінеральної щільності кісткової тканини. **Методи.** Вивчено результати хірургічного втручання та післяопераційні ускладнення в 102 осіб віком $(61,1 \pm 8,1)$ року, які за методом лікування розділені на 3 групи: (1) відкрита репозиція та накістковий металоостеосинтез пластиною PHILOS ($n = 50$); (2) відкрита репозиція та накістковий металоостеосинтез пластиною PHILOS із використанням 3D-імплантів PLA ($n = 44$); (3) первинне RTSA розробленим тотальним реверсивним ендопротезом ($n = 8$). Функціональні результати пацієнтів із ускладненнями оцінювали за системою Constant-Murley Score через 3, 6, 12 міс. після хірургічного втручання й аналізували залежно від індивідуальних передопераційних показників і методики лікування. **Результати.** Усього зафіксовано 30 випадків післяопераційних ускладнень, з яких найпоширенішими були поверхнева інфекція (7,8 % від загальної популяції), вторинне зміщення (6,9 %), варусне зміщення відламків (6,9 %), аваскулярний некроз головки плечової кістки (3,9 %). Найбільша кількість ускладнень зафіксована в (1) групі — 19 осіб (38 %). Для всіх видів ускладнень, окрім аваскулярного некрозу, встановлено достовірне покращення функціональних результатів у терміни з 3 до 12 міс. Середній бал Constant-Murley Score в осіб з ускладненнями через 12 міс. після втручання становив $(78,7 \pm 8,5)$. **Висновки.** Ретроспективний аналіз післяопераційних ускладнень за різних методик хірургічного лікування довів, що RTSA є сучасним і оптимальним варіантом операції проксимальних переломів плечової кістки АО/ОТА 11-В або 11-С на фоні вираженого зниження мінеральної щільності кісткової тканини, особливо в пацієнтів похилого віку. **Ключові слова.** Перелом проксимального відділу плечової кістки, реверсивна тотальна артропластика плечового суглоба, RTSA, ускладнення, Constant-Murley Score, мінеральна щільність кісткової тканини, функціональне оцінювання

Keywords. Proximal humerus fracture, reverse total shoulder arthroplasty, RTSA, complications, Constant-Murley Score, reduced bone mineral density, functional assessment

Introduction

Fractures of the proximal humerus (FPH) are the second most common upper extremity traumas and account for 40 to 82 % of all injuries, and 5–7 % of musculoskeletal ones [1, 2]. In recent times, particularly in developed nations, shoulder injuries have been increasingly recognized not only as a medical concern but also as a source of substantial economic loss. These injuries and the resultant pain significantly decrease the quality of life, often leading to a considerable number of hospital stay days on average. For example, among the working population, up to 30 % of patients report daily pain in the shoulder joint within a year after the injury [3, 4]. Impaired function of the upper extremity, in particular the shoulder, creates critical limitations in professional and daily activities, leads to deterioration of health due to reduced activity, reduced income and overall quality of life. Therefore, a significant proportion of complications and repeated interventions in the case of surgical treatment of shoulder injuries is becoming a real challenge for the healthcare system in the world [3, 4]. Mostly, FPHs are observed in patients over 50 years of age secondary to a decrease in bone mineral density, which complicates the choice of the optimal treatment method to ensure stable fixation and early mobilization of movements [5–8]. Unlike most two-fragmentary FPHs, when it is possible to obtain good functional results during conservative treatment, in the case of unstable 3- and 4-fragmentary FPHs (AO/OTA 11-B, 11-C), which are most common in the age group over 50 years, positive results can be achieved only with the help of surgical intervention [9, 10].

Recently, in the treatment of FPH fractures in patients with reduced bone mineral density, there has been an increase in the use of reversible total shoulder arthroplasty (RTSA), compared with open reduction and internal fixation (ORIF) and hemiarthroplasty (HA) [11–14]. Due to the biomechanically proven principles of operation and design features of reversible RTSA endoprotheses, functional outcomes as assessed by the Constant-Murley Score have been significantly improved, as they provide a relatively better impact on health-related quality of life than other treatment methods [15]. However, overall, the rate of complications and reoperations for shoulder injuries remains high, and the analysis of complications and functional outcomes in people with FPH fractures is relevant. Thus, according to a French study, patients with shoulder pain lost 1.8 to 8.1 years of work during a 9-year follow-up period, and the decrease in quality of life may persist

even after retirement [4]. The literature highlights concerns regarding the insufficient quality of studies and the lack of data on the relative proportion and distribution by type of complications associated with the surgical treatment of FPH [16]. The indicators are mostly obtained from meta-analyses or information summarized by different clinics and even countries, which makes it difficult to predict the effectiveness of surgical treatment of FPH fractures and the dynamics of functional results acceptable to the patient or the need for repeated interventions.

Purpose: to conduct a comparative retrospective analysis of the impact of postoperative complications on functional results with different methods of surgical treatment of fractures of the proximal humerus of types AO/OTA 11-B, 11-C in patients older than 45 years with reduced bone mineral density.

Material and methods

The study materials were reviewed and approved by the Bioethics Committee at the State Establishment “Professor M. I. Sytenko Institute of Spine and Joint Pathology of the National Academy of Medical Sciences of Ukraine” (protocol No. 191 dated 22.04.2019, No. 229 dated 20.02.2023). All patients involved in the study were familiarized with the plan of surgical interventions and signed an informed consent.

The study involved an assessment of anatomical and functional results of surgical treatment of 102 patients (mean age 61.1 ± 8.1 ; range 45–78 years) with reduced bone mineral density and three- and 4-fragmentary fractures of the lumbar spine of types 11-B, 11-C according to the AO/OTA classification, as well as postoperative complications recorded in this population. The severity of bone mineral density loss was determined by radiographs of the humerus in the anteroposterior projection with the calculation of the cortical index (CI). According to the treatment method, patients were divided into groups as follows:

- I — open reduction, bone-on-bone metal osteosynthesis with a PHILOS plate, period 2009–2022 ($n = 50$);

- II — open reduction and bone-on-bone metal osteosynthesis with a PHILOS plate using 3D PLA implants were applied, period 2015–2022 ($n = 44$);

- III — primary RTSA was performed with a developed total reversible endoprosthesis, the indication for which in all cases was fractures of the AO/OTA 11-B or 11-C type secondary to a pronounced decrease in bone mineral density; period 2015–2023 ($n = 8$).

The detailed procedure for performing the operations, as well as the examinations in the pre- and postoperative periods, has been described in a previous study [17]. The functional results of the treatment itself were assessed using the Constant-Murley Score system 3, 6, and 12 months after surgery, and patients with complications were analyzed depending on individual preoperative indicators and treatment methods.

In the statistical analysis, categorical variables were presented as percentages, demographic data as means and ranges, and quantitative estimates were presented as sample means and standard deviations (SD), expressed as ($M \pm SD$). To visualize the comparison of sample values, graphs with SD markers were constructed. When studying the differences in mean values, ANOVA and Tukey's test with a significance level of $p < 0.01$ were used.

Results

According to the results of the treatment of 102 patients, 30 cases of postoperative complications were recorded. Their distribution by type and treatment group (Table 1) showed a higher number of complications in group I both in absolute value and in proportion.

In group I, 4 patients (2 women, 2 men) were diagnosed with avascular necrosis of the humeral head due to an unfavorable ORIF outcome (no signs of consolidation, migration of the metal structure), so the structure was removed and RTSA was performed 6 to 12 months after the primary surgical intervention; in 6 patients, a secondary displacement of the greater tubercle up to 10–15 mm was detected a month after the operation; in 2 patients, varus migration of the head occurred without significant impairment of the function of the shoulder joint; in one patient, complete destabilization of the metal structure occurred, which led to its removal 3 months after installation.

In group II, in the postoperative period, in one patient, a perforation of the humeral head fragment occurred with a screw 6 weeks after the operation, and it was removed under C-Arm control through a skin puncture under local anesthesia; in one patient, 3 months after surgery, secondary displacement of the lesser tubercle up to 8–10 mm occurred; in 5 patients, varus displacement of the humeral head up to 5 mm was diagnosed, but this did not lead to perforation with screws. Signs of avascular necrosis of the humeral head were not recorded in patients of group II.

Table 1

Distribution of postoperative complications by type and treatment group

Complication	Group		
	I (n = 50)	II (n = 44)	III (n = 8)
Superficial infection	5	2	1
Secondary displacement	6	1	—
Varus displacement of fragments	2	5	—
Avascular necrosis of the humeral head	4	—	—
Perforation of the fragment of the humeral head with a screw	1	1	—
Destabilization of the metal structure	1	—	—
Dislocation of the endoprosthesis	—	—	1
Total	19	9	2

In group III, one case of superficial infection and one dislocation of the endoprosthesis were recorded among patients.

In all cases, superficial infection was eliminated by antibacterial local and systemic therapy.

Determination of the directions of further analysis implied consideration of the demographic and preoperative indicators of the patients (Table 2). Within the age range of patients 45–78 years, the division into age subgroups was carried out with a 10-year grouping interval, namely 45–54, 55–64 and 65–78 years; the last subgroup was expanded to 78 years, since in total there were only 6 subjects over 75 years of age and their allocation to a separate age subgroup was inappropriate.

There were no differences in mean age, sex ratios and side of injury between subgroups of patients with and without complications. Among patients in the age subgroups 55–64 and 65–78 years, complications were recorded on average twice as often as in patients aged 45–54 years. In the subgroup of patients with complications, the proportion of type 11-C fractures was higher, compared to patients without complications.

During the analysis of bone mineral density indicators for patients without complications, the cortical index was (0.386 ± 0.020) , with complications (0.374 ± 0.025) , and among patients who had a CI within $0.38 \div 0.40$, the proportion of complications was 20.2 %, in the case of $CI \leq 0.36$ it was as high as 53.6 %.

When comparing the functional results of patients on the CMS scale within each individual observation time (3, 6 and 12 months after the intervention), no significant difference was obtained between

Table 2

Patient demographics and preoperative characteristics (N = 102)

Indicator	Patient		Category	Person	
	with complications	without complications		with complications	without complications
Number (proportion)	30 (29.4 %)	72 (70.6 %)			
Age, years	63.2 ± 7.6	60.3 ± 8.2			
Sex, number (proportion): female/male	23 (76.7 %) / 7 (23.3 %)	55 (76.4 %) / 17 (23.6 %)	Вікова група, кількість (частка): 45–54 років (n = 19) 55–64 років (n = 44) 65–78 років (n = 39)	3 (15.8 %)	16 (84.2 %)
	22 (73.3 %) / 8 (26.7 %)	56 (77.8 %) / 16 (22.2 %)		13 (29.5 %)	31 (70.5 %)
				14 (35.9 %)	25 (64.1 %)
Side of injury, number (proportion): right/left	22 (73.3 %) / 8 (26.7 %)	56 (77.8 %) / 16 (22.2 %)	Методика лікування, кількість (частка): І група (n = 50) ІІ група (n = 44) ІІІ група (n = 8)		
Type of fracture according to AO/ OTA, number (proportion): 11-B / 11-C	17 (56.7 %) / 13 (43.3 %)	54 (75.0 %) / 18 (25.0 %)		19 (38.0 %)	31 (62.0 %)
				9 (20.5 %)	35 (79.5 %)
				2 (25.0 %)	6 (75.0 %)

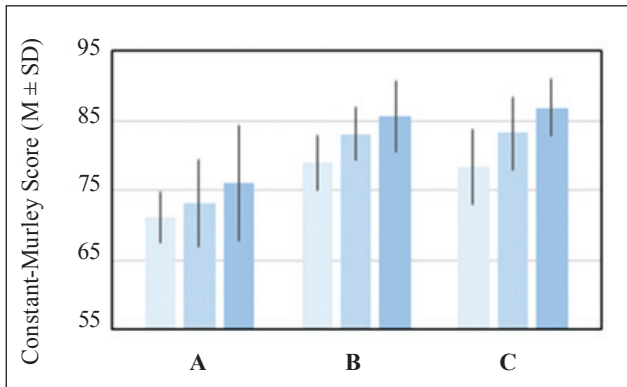


Fig. 1. Functional outcomes of patients with and without complications; X-axis — comparison subgroups: A — complications excluding superficial infection (n = 22), B — superficial infection (n = 8), C — without complications (n = 72). Values for different terms after intervention (months) are indicated by different colors: light blue — 3, blue — 6, blue — 12

the indicators of patients with superficial infection (n = 8) and people without complications: at the same time, the average values in these subgroups had significant ($p = 0.005 < 0.01$) positive changes from 3 to 12 months of observation (Fig. 1). Given that patients with superficial infection achieved a functional outcome at the level of those without complications, their data were not taken into account in further study of postoperative complications.

For the following study, three subgroups of common complications were selected in sufficient numbers for comparative analysis: secondary displacement (n = 7), varus displacement of fragments (n = 7), and avascular necrosis of the humeral head (n = 4). Since in the general population the proportion of complications varies for different types of fractures and values of bone mineral density indicators, a more detailed examination of the individual pre-

operative indicators of patients was carried out for the selected subgroups, which revealed different proportions of AO/OTA 11-B and 11-C fractures, as well as the average CI values for these subgroups (Table 3): varus displacement of fragments was observed mainly after type 11-B fractures, secondary displacement after 11-C, avascular necrosis of the humeral head in the case of 11-C with CI values ≤ 0.36 .

For subgroups of patients with the three most common postoperative complications in this study, the dynamics of the Constant-Murley Score scale was also analyzed 3, 6, and 12 months after the intervention (Table 3). A significant improvement in functional outcomes was found in patients with secondary displacement from 3 to 6 months ($p = 0.001 < 0.01$), and for those with varus displacement of fragments from 3 to 12 months after the injury ($p = 0.003 < 0.01$). In patients with avascular necrosis of the humeral head, the Constant-Murley Score deteriorated from (72.5 ± 2.9) in 3 months to (62.5 ± 2.9) in 6 months after the intervention.

Discussion

The demographics of the patients who participated in the study, and in particular the subgroups with complications, correspond to the known global trends in the prevalence of FPH fractures mainly in the age category of people over 50 years [2] and the average European indicators of a 2–3 times higher rate of such fractures among women [1, 6, 7].

The overall rate of complications in the study population was 29.4 %, the highest value by treatment group — 38 % in group I. Systematic reviews and study reports of recent years contain conflicting values and assessments of the rate of postoperative com-

Table 3

Preoperative indicators and functional outcomes of patients by type of complications

Indicator	Secondary displacement (n = 7)	Varus displacement of fragments (n = 7)	Avascular necrosis of the humeral head (n = 4)
Proportion in the general population	6.9 %	6.9 %	3.9 %
Age, years	58.8 ± 9.5	67.9 ± 4.2	66.3 ± 8.2
Cortical index	0.380 ± 0.020	0.366 ± 0.018	0.358 ± 0.005
Number (proportion) of AO/OTA fractures 11-B / 11-C	2 (28.6 %) / 5 (71.4 %)	6 (85.7 %) / 1 (14.3 %)	1 (25 %) / 3 (75 %)
Constant-Murley Score in – 3 months;	70.9 ± 2.3* **	70.0 ± 5.0*	72.5 ± 2.9* **
– 6 months;	75.7 ± 1.9**	75.0 ± 5.0	62.5 ± 2.9**
– 12 months after intervention	77.1 ± 3.9*	81.4 ± 6.3*	62.5 ± 2.9*

Note. Different numbers of * indicate values that are significantly different from each other within the same column of the table according to the results of comparison using the Tukey test.

plications with different methods of surgical treatment of FPH fractures.

In [18], it was reported that, in 173 patients over 60 years of age, ORIF for the treatment of FPH had a complication rate of 44 % and a reoperation rate of 11 %; the failure rate was 39 % for 3-fragment fractures and 45 % for 4-fragment fractures. The average complication rate after shoulder surgery was 42.6 % [1]. According to [19], the overall complication rate after RTSA was 12.1 %, with dislocation being the most common (2.5 %). It was also noted that compared to patients after ORIF or hemiarthroplasty, older or female patients who underwent RSA had a higher Charlson comorbidity index. Patients who underwent ORIF had a higher incidence of both complications (23.03 % vs. 18.62 %) and reoperations (20.3 % vs. 10.3 %) than patients who underwent RSA [12]. After revision shoulder arthroplasty, complications occurred in 34 % of cases, with 20 % requiring reoperation [20].

The proportion of patients with avascular necrosis reported in these studies, 3.9 %, is consistent with the results of other investigators (4 %) [1].

Thus, the overall proportion of complications and the percentage of their individual types found in this study are generally within the ranges of postoperative complication estimates reported in the literature for similar types of surgical procedures.

The mean CMS in the subgroup of patients with complications is lower than in the remaining patients (Fig. 1), but the results 12 months after surgery, except for those with avascular necrosis, are satisfactory. The average CMS score for patients with complications after 12 months was (78.7 ± 8.5). This suggests an effective selection of treatment method and management of complications, aligning with cur-

rent RTSA practices as the complication rate is lower than the group average.

Analysis of negative ORIF results in patients of group I, where porous PLA implants could be used, allowed us to propose a differentiated approach to the choice of surgical treatment for people with AO/OTA 11-B, 11-C type FPH fractures, according to which in case of CI = 0.4–0.5, ORIF is considered appropriate and necessary; under CI < 0.4, ORIF is possible, with the mandatory use of 3D-porous polylactide implants as a reinforcing material; for AO/OTA 11-C type; CI < 0.4, in case of technical impossibility of stable ORIF, primary reversible total hip arthroplasty is necessary [17].

The initial use of RTSA in cases of AO/OTA 11-B, 11-C type AO/OTA fractures and in conditions where ORIF was technically impossible allowed for positive results in 75 % of cases 6 to 12 months after surgery with an average CMS score in the subgroup (81.2 ± 6.4) with restoration of shoulder joint function in the absence of signs of instability of the endoprosthesis components [17]. However, a limitation of this study is the relatively small number of both the total number of people with RTSA and the number of patients with complications among them, which makes it impossible to conduct a quantitative analysis to identify the main risk factors for postoperative complications during this treatment method. The recommendations of the European Society of Trauma and Emergency Surgery (ESTES) for FPH in the elderly indicate that the risk factors for failure in the case of HA are age, sex, the presence of comminuted tubercles, avulsion fractures, and decreased bone mineral density. There is a clear trend towards reverse shoulder arthroplasty, especially in people over 75 years of age, while RTSA, especially secondary to

other surgical interventions, provides good clinical results with a low number of revisions [21]. This technique is considered the gold standard for the treatment of 3- and 4-part displaced fractures in the elderly [16].

The information provided [15] proves that conservative therapy and RTSA are associated with a lower risk of need for re-intervention. At the same time, a number of authors believe that due to the complexity of the RTSA technique, the surgeon should have a complete design of the fracture characteristics, available surgical options and possible complications that may occur, as this will increase safety and ensure satisfactory clinical results [1]. According to the observations of Tagliero et al. [20], among patients with negative consequences of RTSA, 12 % had persistent dislocations, and 10 % had radiological signs of loosening of the endoprosthesis stem. Analysis of the results of RTSA, including the assessment of previous conservative or surgical treatment of FPH, type of fracture, type of reversible endoprosthesis, type of prosthesis or osteosynthesis of the tubercles, proved the lack of statistical significance of factors affecting the risk of endoprosthesis dislocation [20]. Younger age and diabetes mellitus at RTSA significantly increased the risk of reoperation ($p = 0.013$ and $p = 0.037$, respectively). The authors noted a trend towards an increased risk of reoperation in patients who had failed ORIF in FPH at the first stage (hazard ratio = 2.95), but without reaching statistical significance [20]. When comparing the two groups (total 125 people, ORIF in 66 (52.8 %), RTSA in 59 (41.2 %), both groups had comparable Charlson indices) it was shown that the overall complication rate was 37.8 for ORIF and 22.0 % for RTSA, with revision rates of 12.1 % and 5.1 %, respectively [22]. Multivariate analysis did not show significant differences between the two types of surgery ($P = 0.500$), but age was an independent significant factor in overall complications ($P = 0.018$) [22]. Risk factors for serious complications after ORIF were low bone mineral density, varus impression FPH, posteromedial fracture line with a distance between fragments greater than 8 mm, diaphyseal displacement > 4 mm, and multifragmentary tubercle fractures. For RTSA, more complications were observed in patients with a higher Charlson index, diabetes mellitus, and tubercle fractures, although the authors emphasize that the Neer classification system was not predictive in either group [22].

It should be noted that for each surgical technique for the treatment of FPH, the incidence of complications has been decreasing in recent years [13]. This is

due to the improvement of biomechanical characteristics and implant design for both ORIF and RTSA, combined with the accumulation of experience of surgeons [23]. An important factor is the abandonment of hemiarthroplasty and the preference for RTSA in FPH, especially in patients over 65 [14].

Thus, the choice of RTSA compared to other surgical options is a modern and optimal way to treat proximal humeral fractures AO/OTA 11-B or 11-C against the background of a pronounced decrease in bone mineral density, especially in elderly patients.

However, evidence-based recommendations are still lacking [21]. In patients with AO/OTA 11-B, 11-C FPH, RTSA is a reliable surgical treatment option with predictable functional outcomes and few revisions [21]. Hemiarthroplasty is appropriate if fixation and healing of the tubercles are achievable. Unfortunately, this is not the case in most fractures. Risk factors for failure include age, sex, comminuted tubercle fractures, avulsion fractures, and low bone mineral density [21].

So, can RTSA be considered the gold standard for the treatment of proximal humeral fractures in the elderly when ORIF is not technically feasible and conservative treatment fails to relieve pain and restore upper limb function? The answer is currently unknown. The literature suggests mostly low-quality studies, which requires further work to achieve a complete understanding of this important issue.

Conclusions

Retrospective analysis of postoperative complications with different surgical methods of treating proximal humeral fractures of types AO/OTA 11-B, 11-C in patients over 45 with reduced bone mineral density revealed a higher proportion of complications in patients who underwent open reduction and bone-on-bone metal osteosynthesis with the PHILOS plate (38% of the group).

Comparative analysis of functional outcomes with complications established that patients with superficial infection did not differ from those without complications in terms of the dynamics of functional changes during the observation period ($p = 0.005 < 0.01$); patients with secondary and varus displacement of fragments had a significant improvement in functional outcomes in the period from 3 to 12 months ($p = 0.001 < 0.01$; $p = 0.003 < 0.01$, respectively).

Avascular necrosis of the humeral head in this population was recorded only in patients who underwent open reduction and bone-on-bone metal osteosynthesis with the PHILOS plate, mainly after type 11-C

fractures with CI values ≤ 0.36 . In them, CMS indicators deteriorated from (72.5 ± 2.9) in 3 months to (62.5 ± 2.9) in 6 months after the intervention.

RTSA, compared with other techniques, is a modern and optimal option for surgical treatment of proximal humeral fractures AO/OTA 11-B or 11-C against the background of a pronounced decrease in bone mineral density, especially in elderly patients.

Conflict of interest. The authors declare no conflict of interest.

Prospects for further research. In the future, studies with a more detailed analysis of the results of reverse arthroplasty of the shoulder joint using individually printed on a 3D laser printer from porous titanium endoprosthesis components are of interest.

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ANALYSIS OF POSTOPERATIVE COMPLICATIONS IN THE SURGICAL TREATMENT OF PROXIMAL HUMERAL FRACTURES IN PATIENTS WITH DECREASED MINERAL BONE DENSITY

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The impact of preoperative volume overload on hemodynamic parameters during shoulder arthroscopy

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Objective. To investigate the influence of preoperative volemic loading on changes in hemodynamic parameters due to positioning of anesthetized patients in the beach chair position. **Methods.** A prospective randomized single-center study included 140 patients. Group I ($n = 70$) — patients who underwent preoperative loading in a volume of 12 ml/kg before changing the body position. Group II ($n = 70$) — patients who did not undergo preoperative loading. After induction with propofol/fentanyl in standard doses and orotracheal intubation, the patient was transferred from the supine position to the BCP. Non-invasive systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate were determined using a Mediana YM6000 monitor. The first measurement of SBP, DBP, and MAP was performed immediately after positioning the patient supine, the second after induction, the third 5 minutes after positioning in the NSP, and subsequently blood pressure measurements were performed every 5 minutes, heart rate, and SpO_2 continuously. In the postoperative period, the following criteria were evaluated: frequency of nausea/vomiting, frequency of orthostatic collapse within 48 hours, average heart rate within 6 hours. **Results.** Induction of general anesthesia caused comparable changes in hemodynamics in patients of the studied groups without significant differences between groups. When changing the body position in the BCP, hemodynamic changes had significant differences between groups. Only 7.1 % of the subjects in group I had nausea and vomiting in the early postoperative period, while in group II 21.4 % of patients had nausea and vomiting. The development of tachycardia was noted during the first 6 hours after surgery in patients in group II (95.0 ± 5.8), compared with group I (70.3 ± 6.5) ($p < 0.001$). The development of orthostatic collapse was observed more often in patients in group II and amounted to 14.3 % vs. 10.0 % of the subjects in group I. **Conclusions.** Preoperative infusion loading does not significantly affect hemodynamic reactions that occur during induction of general anesthesia in young patients ASA I-II. Preoperative infusion loading during operations in a BCP significantly reduces the number of early postoperative complications: postoperative nausea and vomiting, orthostatic collapse and the development of tachycardia.

Мета. Дослідити вплив передопераційного волемічного навантаження на зміни показників гемодинаміки внаслідок позиціонування анестезованих хворих у напівсидячому положенні (НСП). **Методи.** Проспективне рандомізоване одноцентрове дослідження включало 140 пацієнтів. Група I ($n = 70$) — хворі, яким проводилось передопераційне навантаження в обсязі 12 мл/кг перед змінням положення тіла. Група II ($n = 70$) — особи, без передопераційного навантаження. Після проведення індукції пропофол/фентаніл у стандартних дозах та оротрахеальної інтубації пацієнт переводився з положення лежачи до НСП. Перше вимірювання систолічного артеріального тиску (СiАТ), діастолічного артеріального тиску (ДiАТ) та середнього артеріального тиску (САТ) виконувалось одразу після позиціонування хворого лежачи на спині, друге — після індукції, третє — через 5 хв після позиціонування в НСП та надалі вимірювання артеріального тиску здійснювали кожні 5 хв, частоту серцевих скорочень (ЧСС) та сатурацію периферичної крові (SpO_2) постійно. У післяопераційному періоді оцінювали: частоту нудоти/блювання та розвитку ортостатичного колапсу протягом 48 год, середню ЧСС протягом 6 год. **Результати.** Індукція загальної анестезії викликала співставні зміни гемодинаміки в пацієнтів досліджуваних груп без достовірної різниці між групами. Артеріальний тиск також достовірно відрізнявся в пацієнтів I та II груп. У 7,1 % досліджених у I групі спостерігалось нудота та блювання в ранньому післяопераційному періоді проти II групи 21,4 % хворих. Розвиток тахікардії протягом перших 6 год після операції в пацієнтів II групи склав ($95,0 \pm 5,8$), проти ($70,3 \pm 6,5$) ($p < 0,001$), а ортостатичний колапс у II групі був 14,3 проти 10,0 %. **Висновки.** Передопераційне інфузійне навантаження дозволяє мінімізувати постуральні зміни гемодинаміки під час операцій в напівсидячому положенні. Воно достовірно не впливає на реакції гемодинаміки, які виникають під час індукції загальної анестезії в молодих пацієнтів. За умов операції в напівсидячому положенні достовірно зменшуються кількість ранніх післяопераційних ускладнень: нудота та блювання, ортостатичний колапс, розвиток тахікардії. **Ключові слова.** Напівсидяче положення, загальна анестезія, інфузійна терапія, артроскопія

Keywords. Semi-sitting position, general anesthesia, infusion therapy, arthroscopy

Introduction

The change in the patient's body position from the supine to the semi-sitting position (SSP) initiates physiological changes to adapt the cardiovascular system. In particular, this adaptation is impaired during general anesthesia due to the effects of anesthetics on sympathetic activity and dysregulation of the baroreceptor system. However, this is associated with significant hemodynamic instability, which leads to an increased risk of cerebral hypoperfusion [1]. Cerebral perfusion pressure decreases by approximately 15 % in the sitting position in non-anesthetized patients and drops significantly under anesthesia due to vasodilation and impaired venous return, resulting in hemodynamic instability, impaired oxygen delivery with possible subsequent organ dysfunction. Conversely, fluid overload leads to multisystem effects, including interstitial edema with effects on gas exchange, renal function, and the gastrointestinal system [2]. Perioperative hypotension is not necessarily indicative of an intravascular fluid deficit, but rather a result of general anesthesia causing a weakening of vascular tone [3]. A decrease in cardiac index by 24 % during the transfer of patients to the SSP occurs due to the transfer of 14 % of blood volume from the intra- to the extra-thoracic space [4]. At the time of changing the body position, the hemodynamic problem becomes greater due to caudal accumulation of blood, and, in turn, a decrease in preload [5]. The effect of infusion loading before transferring an anesthetized patient to the SSP remains uncertain. Traditionally, infusion preload has been used to prevent intraoperative hypotension caused by spinal anesthesia, but this issue still remains controversial [6]. New data are emerging on the positive effect of infusion preload on hemodynamic stability in patients with SSP [7], so this issue requires further investigation.

Purpose: to investigate the influence of preoperative volemic load on changes in hemodynamic parameters due to positioning of anesthetized patients in a semi-sitting position.

Material and methods

The study was performed at the State Establishment "Professor M. I. Sytenko Institute of Spine and Joint Pathology of the NAMS of Ukraine". It was approved by the local Bioethics Committee (protocol No. 231 dated 20.05.2023) of the relevant institution in accordance with the rules of ICH GCP, the Helsinki Declaration of Human Rights of 2002, the Council of Europe Convention on Human Rights and Biomedicine approved in 1977, as well as the current legislation of Ukraine. Informed consent was obtained from

all patients included in the study. The prospective randomized study included 140 patients, divided into 2 groups: I ($n = 70$) individuals who underwent preoperative loading in the amount of 12 ml/kg before changing the body position; II ($n = 70$) without preoperative loading. The average age of patients in group I was (42.4 ± 10.7), in group II (41.1 ± 13.3) years. Patients with cardiac arrhythmia, angina pectoris, respiratory, renal or hepatic failure were excluded from the study.

According to the American Society of Anesthesiologists (ASA) scale, all subjects were classified as Class I and II. Patients in Group I received a volume load of 12 ml/kg 30 min before surgery. The qualitative composition of the infusion therapy consisted of balanced crystalloid solutions. Patients in Group II did not receive a preliminary volume load before the intervention. Before induction, patients were administered pantoprazole 40 mg, diazepam 10 mg. Induction was provided with propofol 1 % 2 mg/kg, fentanyl solution 0.2 mg, muscle relaxation was provided with suxamethonium solution 1 mg/kg, and subsequently atracurium besylate 0.3 mg/kg. General anesthesia was maintained with propofol 1 % 5–7 mg/kg/h, and fentanyl solution was used for anesthesia. After orotracheal intubation and transfer of the patients to mechanical ventilation, their position was changed to the SSP.

Peripheral blood saturation (SpO_2), non-invasive systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), heart rate (HR) were determined with a Mediana YM6000 monitor. The first measurement of SpO_2 , SBP, DBP was performed immediately after positioning the patients lying on their back, the second one after induction, the third one 5 min after positioning in the SSP, subsequently blood pressure control was performed every 5 min, heart rate and SpO_2 constantly.

In the postoperative period, the following criteria were studied: the frequency of nausea/vomiting and the development of orthostatic collapse within 48 h, average heart rate within 6 h.

The groups were comparable in age and duration of surgery (Table 1).

Statistical analysis. The obtained data were analyzed using the IBM SPSS 9.0 software. The normal distribution of the samples was checked using the Kolmogorov-Smirnov test. The mean and standard deviation were determined. Differences between groups of indicators were assessed using the Student's t-test.

Results

Analysis of changes in hemodynamics depending on preoperative volume load

The primary hemodynamic indicators did not differ statistically between the groups (Table 2). Similarly, induction of general anesthesia caused comparable changes in hemodynamics in patients of the studied groups without a significant difference between them. In the case of a change in body position before SSP, hemodynamics had significant differences between the groups. The most significant were recorded in terms of heart rate (beats/min): (95.0 ± 5.8) in patients of group II compared to (70.34 ± 6.52) in group I ($p < 0.001$). Blood pressure also significantly differed in patients of groups I and II (mm Hg): Systolic blood pressure (103.9 ± 7.8) vs. (95.9 ± 5.9), respectively ($p < 0.001$); Diastolic blood pressure (63.3 ± 7.2) vs. (57.5 ± 5.0) ($p < 0.001$) and MBP (76.8 ± 7.2) vs. (69.6 ± 5.4) ($p < 0.001$). Considering that SSP support provides autoregulation of cerebral circulation, the study did not allow even a short-term decrease to 65 mm Hg.

Analysis of postoperative complications

The criteria for the adequacy of intraoperative volemic status and hemodynamic stability can be considered the frequency of postoperative complications: tachycardia in the postoperative period, vomiting and orthostatic collapse in the first 48 hours after the intervention. Our observation data showed that patients of the studied groups had a significant difference in these indicators. Thus, only in 7.1 % of cases in group I nausea and vomiting were recorded in the early postoperative period, while

in group II in 21.4 %. The development of tachycardia was noted during the first 6 hours after surgery in patients of group II (95.0 ± 5.8), in group I (70.3 ± 6.5) beats/min ($p < 0.001$), and orthostatic collapse was observed more often in patients of group II and amounted to 14.3 versus 10.0 % of the studied in group I (Table 3).

Discussion

Significant cardiovascular changes can occur when patients are placed in the upright position. Mean blood pressure, central venous pressure, and arterial partial pressure of oxygen (PaO_2) decrease, while the alveolar-arterial oxygen gradient ($\text{PAO}_2 - \text{PaO}_2$), pulmonary vascular resistance, and total peripheral resistance increase. Under nonanesthetic conditions, these effects are compensated for by an increase in systemic vascular resistance of 50–80 %. However, this autonomic response is blocked by the vasodilatory effects of anesthetics, which further increase and impair cardiac output. Blood pressure remains unchanged or increases in nonanesthetic patients in the sitting position but decreases under anesthesia.

In the supine position, the blood pressure measured in the arm and that providing brain perfusion are essentially the same, but if the patient is in an upright position in a chair, it is lower in the brain than in the heart or arm. The difference in blood pressure will be equal to the hydrostatic pressure gradient between the heart/arm and the brain.

A study of 23,073 patients found that if the arm systolic blood pressure is 65 mm Hg and the distance to the external auditory canal (which is the base of the brain) is 30 cm above the heart, the pressure at the level of the cerebral cortex is 42 mm Hg (Figure). That is, when changing the body position in anesthetized persons in the SSP, each centimeter of verticalization leads to a decrease in blood pressure by 0.77 mm Hg [8].

Table 1
General characteristics of the examined patients

Patient group	Age of patients, years	Duration of surgical intervention, min
I (n = 70)	42.4 ± 10.7	126.0 ± 25.4
II (n = 70)	41.1 ± 13.3	129.1 ± 25.2

Table 2
Hemodynamic variations observed in patients of the study groups

Patient group	Hemodynamics indicators											
	primary				after induction				after positioning			
	SBP (mm Hg)	DBP (mm Hg)	MBP (mm Hg)	HR (b/min)	SBP (mm Hg)	DBP (mm Hg)	MBP (mm Hg)	HR (b/min)	SBP (mm Hg)	DBP (mm Hg)	MBP (mm Hg)	HR (b/min)
I (n = 70)	141.5 ± 20.6	86.2 ± 12.6	104.7 ± 14.1	80.8 ± 11.5	104.6 ± 14.9	67.4 ± 7.9	79.8 ± 9.0	72.5 ± 10.5	103.9 ± 7.8	63.3 ± 7.2	76.8 ± 7.2	70.3 ± 6.5
II (n = 70)	145.5 ± 17.8	88.8 ± 14.8	104.0 ± 12.7	83.5 ± 9.4	104.0 ± 12.7	65.6 ± 9.2	78.4 ± 9.9	77.8 ± 10.4	$95.9 \pm 5.9^*$	$57.5 \pm 5.0^*$	$69.6 \pm 5.4^*$	$95.0 \pm 5.8^*$

Note. * — $p < 0.001$, comparing groups I and II.

**Presence of complications
in early post-operative period**

Patient group	Average heart rate in the first 6 hours after surgery, beats/min	Nausea and vomiting within 48 hours, patients	Orthostatic collapse within 48 hours, patients
I (n = 70)	70.3 ± 6.5	5	7
II (n = 70)	95.0 ± 5.8 *	15	10

Note. * — $p < 0.001$, comparing groups I and II.

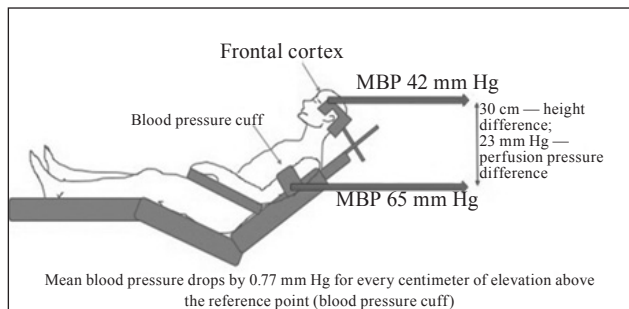


Figure. Comparison of MBP at shoulder and head level when changing body position in SSP (according to Rodney A. Gabriel)

A. Jesudoss et al. compared SSP and middle cerebral artery blood flow velocity and found that the semi-sitting position under general anesthesia resulted in an average decrease in SSP of 24.8 % and in middle cerebral artery blood flow velocity of 28.0 % [9]. Lee et al. noted that postural hemodynamic responses during transfer to the SSP were observed in patients with elevated baseline blood pressure [10].

Current guidelines recommend maintaining systolic blood pressure at a level of at least 70 mm Hg [11]. The issue of hemodynamic correction in the SSP remains controversial. In their studies, Soo Y Cho et al. found that the use of vasopressin solution before transferring the patient to the SSP helps reduce episodes of hypotension associated with verticalization [12], but correction of low intraoperative values of systolic blood pressure with vasoconstrictors alone does not guarantee good organ perfusion. Gokduman et al. performed fluid loading (crystalloid and colloidal solutions) in a volume of 10 ml/kg of ideal body weight 30 min before surgery before positioning, which contributed to a decrease in the frequency of episodes of postoperative nausea and vomiting [7]. The results obtained by the authors are comparable with our data. Other methods of preventing cerebral hypoperfusion in SSP include preventing hyperventilation and using high compression stockings [11]. Maintaining normovolemia may be more beneficial than using vasoconstriction to increase SSP to pre-

serve cerebral perfusion; therefore, increasing intravascular volume may be more effective in protecting patients from possible hypoperfusion [13].

Conclusions

A preoperative infusion load of 12 ml/kg minimizes postural changes in hemodynamics during operations in the semi-sitting position.

Therefore, it does not significantly affect the hemodynamic responses that occur during induction of general anesthesia in young ASA I–II patients.

Preoperative infusion load during interventions in the semi-sitting position significantly reduces the number of early postoperative complications: nausea and vomiting, orthostatic collapse, and tachycardia.

Conflict of interest. The authors declare no conflict of interest.

Prospects for further research. Research on changes in hemodynamics and cerebral perfusion in the perioperative period during body position changes in anesthetized patients is relevant.

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Authors' contribution. Lyzogub K. I. — concept and design, analysis of the obtained data; Lyzogub M. V. — analysis of the obtained data, text editing, processing of materials.

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THE IMPACT OF PREOPERATIVE VOLUME OVERLOAD ON HEMODYNAMIC PARAMETERS DURING SHOULDER ARTHROSCOPY

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Ukrainian-language validated scales Forgotten Joint Score-12 for patients after hip and knee arthroplasty

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The Forgotten Joint Score-12 (FJS-12) is an important tool for assessing the effectiveness of treatment of patients after large joint arthroplasty. Its main advantage is its sensitivity to the patient's subjective perception of the artificial joint, which makes it extremely useful for assessing the level of comfort after surgery. Objective. To perform an official translation of the Forgotten Joint Score-12 scale into Ukrainian, to conduct its adaptation and validation among patients who have undergone knee or hip arthroplasty. The translation was carried out within the framework of official cooperation with Forgotten Joint Scores (BGGK GmbH, Switzerland) in accordance with international standards Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures. Results. The pilot testing was conducted among 20 patients and was aimed at identifying the clarity of the questions, ease of completion and time required to complete the survey. That is why this scale allows to assess the degree of awareness of the presence of a joint implant in everyday life, is an important addition to existing methods of studying the results of treatment. Conclusions. Due to its unique approach, the FJS-12 allows for a more accurate assessment of the results of arthroplasty, which contributes to the improvement of surgical techniques, optimisation of rehabilitation programmes and improvement of the level of medical care. Its Ukrainian-language version is now available for use in clinical practice and scientific research in our country, which will contribute to a more objective assessment of the effectiveness of treatment of patients after total arthroplasty. This also opens up new opportunities for international cooperation, as it allows Ukrainian researchers to use unified assessment methods and compare their results with those of their colleagues.

Шкала Forgotten Joint Score-12 (FJS-12) є важливим інструментом для оцінки ефективності лікування пацієнтів після ендопротезування великих суглобів. Її головна перевага полягає в чутливості до суб'єктивного сприйняття штучного суглоба самим пацієнтом, що робить її надзвичайно корисною для оцінювання рівня комфорту після операції. Мета. Виконати офіційний переклад шкали Forgotten Joint Score-12 на українську мову, провести її адаптацію та валідацію серед пацієнтів, яким виконали ендопротезування колінного або кульшового суглобів. Переклад здійснювався в межах офіційного співробітництва з Forgotten Joint Scores (BGGK GmbH, Switzerland) відповідно до міжнародних стандартів Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures. Результати. Пілотне тестування проводилося серед 20 пацієнтів, було спрямоване на виявлення зрозумілості запитань, зручності заповнення та часу, необхідного для проходження опитування. Саме тому ця шкала дозволяє оцінити ступінь усвідомлення наявності суглобового імплантата в повсякденному житті, є важливим доповненням до існуючих методів вивчення результатів лікування. Висновки. Завдяки своєму унікальному підходу FJS-12 дозволяє проводити більш точну оцінку результатів ендопротезування, що сприяє вдосконаленню хірургічних методик, оптимізації програм реабілітації та підвищенню рівня медичної допомоги. Її українськомовна версія наразі доступна для використання в клінічній практиці та наукових дослідженнях нашої країни, що сприятиме більшій об'єктивності оцінки ефективності лікування пацієнтів після тотального ендопротезування. Це також відкриває нові можливості для міжнародного співробітництва, оскільки дозволяє українським дослідникам використовувати уніфіковані методики оцінювання та порівнювати свої результати з даними колег. Ключові слова. Тотальне ендопротезування кульшового суглоба, тотальне ендопротезування колінного суглоба, Forgotten Joint Score-12, FJS-12.

Keywords. Total hip arthroplasty, total knee arthroplasty, Forgotten Joint Score-12, FJS-12

Introduction

Total hip and knee arthroplasty is an effective treatment for patients with severe osteoarthritis or other degenerative joint diseases. This surgical procedure can significantly improve the quality of life of patients, reduce pain, and restore joint function. Assessment of arthroplasty outcomes using traditional scales such as the Harris Hip Score (HHS) [1], Knee Society Score (KSS) [2], Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [3] focuses primarily on objective parameters: pain, physical function, range of motion, and risk of complications. In contrast, the HHS and KSS scales rely solely on clinical evaluations conducted by physicians. Meanwhile, the WOMAC [3] and Oxford Hip and Knee Scores (OHS/OKS) [4, 5] incorporate patients' subjective experiences and perceptions into their assessments. However, it is the person who is at the center of attention in modern medicine, within which the quality of life and the patient's subjective perception of the results of treatment are considered an important indicator for determining the effectiveness of treatment. In this context, the Forgotten Joint Score-12 (FJS-12) [6] is a key tool for assessing the patient's ability to forget about the artificial joint in everyday life. The concept of the "forgotten joint" suggests that the more inconspicuous the joint becomes to the patient, the more successful the surgical treatment was [7]. The FJS-12 allows the assessment of not only physical functionality but also the patient's psychological comfort, making it an extremely sensitive indicator of the success of the treatment [8]. This scale was developed in 2007 by Professor Marcus S. Couste, an orthopedic surgeon specializing in joint replacement. The results of its validation were first published in 2012 in *The Journal of Arthroplasty* [7].

The Forgotten Joint Score-12 (FJS-12) scale has been tested for reliability and validity in patients after knee [9–12] or hip [11–13] arthroplasty. Due to its high sensitivity to assessing subjective comfort after total joint replacement, this scale has a minimal ceiling effect, unlike other patient-reported outcome measures (PROMs) [14]. A ceiling effect refers to the point at which the scale cannot detect improvement in a patient's condition after treatment. This is important for detecting small functional changes, especially among individuals with high activity levels.

The FJS-12 has been translated into several languages with promising results regarding validity and reliability for patients after knee [15–19] and hip [20,

21] arthroplasty, but a translation into Ukrainian has not yet been performed. This limits the possibilities for improving treatment due to the lack of feedback from the patient regarding his feeling of the artificial joint and the absence of this assessment in other used scales.

Purpose: To translate the Forgotten Joint Score-12 scale into Ukrainian and validate it for patients who have undergone knee or hip arthroplasty.

Material and methods

The study was approved by the Bioethics Commission of the State Establishment "Professor M. I. Sytenko Institute of Spine and Joint Pathology of the NAMS of Ukraine" (protocol No. 248 dated 10.02.2025). All patients signed an informed consent.

The work was carried out within the framework of a formal cooperation agreement with Forgotten Joint Scores (BGGK GmbH, Switzerland) [9], represented by the Chief Translation and Licensing Officer Dagmara Kulis. During the cooperation, we translated into Ukrainian and conducted linguistic validation of the English version of the FJS-12 scale for further use in the practice of Ukrainian doctors. This was carried out in the following sequence, in accordance with the requirements of the Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures [22]:

- double translation: the questionnaire was translated into Ukrainian by two independent experts;
- reconciliation: both translations were combined into one optimal version;
- back translation: two independent back translations of the Ukrainian version into English were created;
- verification: a team of translators and clinicians checked the text for compliance with the original;
- expert proofreading: the text was proofread by a professional linguist;
- pilot testing: testing was conducted with the participation of 20 patients after hip ($n = 10$) and knee ($n = 10$) joint replacement;
- finalization: all necessary corrections were made based on the testing results.

Results

The result of the collaborative work is the Ukrainian-language validated Forgotten Joint Score-12 scales for patients after knee or hip arthroplasty, shown in Fig. 1 and 2.

Questions for assessing the condition of the knee joint (Forgotten Joint Score-12)

Patient: _____ Date: _____

A joint is considered healthy if it functions without you noticing it. However, even the slightest problem can draw your attention to the joint. You start thinking about it, paying attention to your feelings. The following questions concern **how often you pay attention to your affected knee joint in everyday life**.

Please choose the answer that best reflects your feelings.

No.	Do you pay attention to your knee joint...	Never	Almost never	Rarely	Sometimes	Almost always
1.	... at night, when you are in bed?	☐	☐	☐	☐	☐
2.	... when you sit in a chair for an hour or more?	☐	☐	☐	☐	☐
3.	... when you walk for more than 15 minutes?	☐	☐	☐	☐	☐
4.	... when you take a bath/shower?	☐	☐	☐	☐	☐
5.	... when you drive/travel as a passenger in a car	☐	☐	☐	☐	☐
6.	... when you climb stairs?	☐	☐	☐	☐	☐
7.	... when you walk on uneven surfaces?	☐	☐	☐	☐	☐
8.	... when you get up from sitting on a low surface?	☐	☐	☐	☐	☐
9.	... when you stand for a long time?	☐	☐	☐	☐	☐
10.	... when you do housework or gardening?	☐	☐	☐	☐	☐
11.	... when you go for a walk/hike?	☐	☐	☐	☐	☐
12.	... when you play your favorite sport?	☐	☐	☐	☐	☐

Fig. 1. Forgotten Joint Score -12 scale for the knee joint

During the pilot testing, the purpose of the survey and the meaning of all questions were well understood by all patients without exception.

Scoring algorithm

Each of the 12 questions in the scale is scored from 0 to 4 points, where the patient's answer "Never" is equal to 0, and "Almost always" is equal to 4 points. Thus, the total score obtained ranges from 0 to 48 [7]. The resulting score is linearly transformed into a scale from 0 to 100 according to the formula:

$$\text{The final score} = 100 - ((\text{sum of all points} / \text{number of questions with answers}) \times 25). \quad (1)$$

For example, if the patient answered "Sometimes" (3 points) to all 12 questions, then the final score is 25.

$$\text{The final score} = 100 - ((36 / 12) \times 25) = 25. \quad (2)$$

A high score on the FJS-12 scale indicates a good result after treatment.

If the patient did not answer more than 4 questions, the total score is not used.

The FJS-12 scale for the hip joint (Fig. 1) is aimed at assessing the level of involvement of the operated limb in the patient's usual life after total hip arthroplasty. The main attention is paid to such aspects as the feeling of discomfort in the joint while sitting,

walking, climbing stairs, driving a car, standing for a long time or performing physical exercises.

The patient's responses are scored on a scale from "Never" to "Almost Always," which measures the level of awareness of the joint in various everyday situations. The total score is converted into a scale from 0 to 100 points, where 0 indicates maximum awareness (discomfort, limited movement), and 100 means complete "forgetfulness" of the joint. This approach allows us to assess not only the physical function, but also the patient's psychological comfort, in particular the ability to return to an active lifestyle.

The FJS-12 scale for the knee joint (Fig. 2) is aimed at assessing the functionality and sensation of the joint in patients after arthroplasty. It covers aspects such as the ability to climb and descend stairs, walk on uneven surfaces, do household chores, play sports, or stand for long periods of time.

Each response is scored in the same way as in the hip joint scale. Due to the high sensitivity of the scale, it is possible to accurately detect the patient's level of recovery, differentiating even the slightest changes in the condition of the joint. The FJS-12 for the knee joint is extremely useful for individuals seeking to restore physical activity, including sports.

Discussion

The FJS-12 scale can be used to assess the results of clinical studies aimed at improving the quality

Questions for assessing the condition of the hip joint (Forgotten Joint Score-12)

Patient: _____ Date: _____

A joint is considered healthy if it functions without you noticing it. However, even the slightest problem can draw your attention to the joint. You start thinking about it, paying attention to your feelings. The following questions concern **how often you pay attention to your affected hip joint in everyday life**.

Please choose the answer that best reflects your feelings.

№ 3/n	Do you pay attention to your hip joint...	Never	Almost never	Rarely	Sometimes	Almost always
1.	... at night, when you are in bed?	☐	☐	☐	☐	☐
2.	... when you sit in a chair for an hour or more?	☐	☐	☐	☐	☐
3.	... when you walk for more than 15 minutes?	☐	☐	☐	☐	☐
4.	... when you take a bath/shower?	☐	☐	☐	☐	☐
5.	... when you drive/travel as a passenger in a car	☐	☐	☐	☐	☐
6.	... when you climb stairs?	☐	☐	☐	☐	☐
7.	... when you walk on uneven surfaces?	☐	☐	☐	☐	☐
8.	... when you get up from sitting on a low surface?	☐	☐	☐	☐	☐
9.	... when you stand for a long time?	☐	☐	☐	☐	☐
10.	... when you do housework or gardening?	☐	☐	☐	☐	☐
11.	... when you go for a walk/hike?	☐	☐	☐	☐	☐
12.	... when you play your favorite sport?	☐	☐	☐	☐	☐

Fig. 2. Forgotten Joint Score -12 scale for the hip joint

of life of patients after joint replacement. The effectiveness and benefits of using the FJS-12 scale are based not only on the subjective experience of orthopedic surgeons but also have practical application in clinical studies. Behrend et al. [7], using the FJS-12 scale, showed the influence of the year of manufacture of hip joint endoprotheses on the outcome of patient treatment, indicating the possibility of using the FJS-12 for studies of different options for prostheses. This scale can be used to assess the results in studies of different durations. Thus, using the FJS-12, J. Manara et al. [23] revealed the advantages of using a robotic system during partial knee replacement over a 2-year follow-up period. The use of FJS-12 for long-term observation was evaluated in patients with total hip arthroplasty due to femoral head aseptic necrosis over a period of 10 years [24].

The internal consistency of the FJS-12, according to Cronbach's alpha, is high [14] and is 0.95 in the first publication [7], for the knee joint from 0.97 to 0.86 [11, 15, 25], demonstrating its reliability as a self-report instrument for patients. The construct validity of the FJS-12 is confirmed by the presence of strong correlations with WOMAC ($r = -0.75$) [7], and with OHS/OKS ($r = 0.79$ and $r = 0.75$, respectively) [11]. Moreover, the FJS-12 scale has a high sensitivity to detect minimal changes in the condition of patients after arthroplasty [15].

The advantage of the FJS-12 is that it takes into account the patient's subjective comfort in everyday life and is more sensitive to minor changes and problems, which eliminates the limitations of its use for assessing long-term results of arthroplasty, especially in individuals with a high level of functionality, which is impossible when using traditional scales [14].

Conclusions

The Forgotten Joint Score-12 scale is a reliable and sensitive tool for assessing the results of hip and knee arthroplasty. It allows obtaining accurate data on the subjective perception of patients about their condition, contributes to the improvement of surgical techniques and helps to determine the optimal approaches to the treatment of patients who are indicated for knee or hip arthroplasty. The Forgotten Joint Score-12 scales for knee and hip joints translated by us into Ukrainian are absolutely correct and validated, which provides a guaranteed opportunity for Ukrainian-speaking specialists to use them correctly in their daily practice.

Conflict of interest. The authors declare no conflict of interest.

Prospects for further research. Conducting clinical trials using the FJS-12 to evaluate the results of treatment of hip/knee diseases in Ukraine.

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UKRAINIAN-LANGUAGE VALIDATED SCALES FORGOTTEN JOINT SCORE-12 FOR PATIENTS AFTER HIP AND KNEE ARTHROPLASTY

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Quality criteria for minimally manipulated biotechnological products based on autologous bone marrow aspirate for use in traumatology and orthopedics

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Autologous biotechnological products based on bone marrow (BM) are a source of stem cells, in particular, hematopoietic and multipotent mesenchymal stromal cells, and act as one of the alternative therapeutic agents that can slow cartilage degeneration, improve its repair and, ultimately, prevent joint replacement. Objective. To develop quality and safety criteria of minimally manipulated biotechnological products from autologous bone marrow for use in patients with pathology of the musculoskeletal system. Methods. The material for the development of quality and safety criteria for the manufacture and use of biotechnological products from autologous red bone marrow aspirate was 85 patients with osteoarthritis and aseptic necrosis of the hip and knee joints, who used biotechnological products made from it. Cell counts in the myelogram and CFU-analysis of MMSK-BM were performed in all patients. Results. As a result of the development of quality and safety criteria for biotechnological products from BM aspirate, 3 types of it were established: 1 — polymorphic (with the presence of progenitor cells of all types within the normal range), 2 — moderately cellular (with the presence of all types of progenitor cells, but some of them below the norm), 3 — hypocellular (with the presence of most types of progenitor cells, some of them below the norm). Functional quality criteria of biotechnological products from BM aspirate were developed on the basis of CFU-analysis and calculation of seeding efficiency coefficient (KEP) of MMSK-BM. Conclusions. Quality and safety criteria of biotechnological products based on autologous bone marrow aspirate based on the results of myelograms and CFU analysis have been established. According to the results of myelograms, type 1 BM aspirate was evaluated as excellent for the further manufacture of a biotechnological product, type 2 — good, type 3 — satisfactory. According to the results of the KUOf analysis, the KEP indicator < 0.001 % was evaluated as unsatisfactory, the KEP indicator within the range of 0.001–0.003 % — satisfactory, the KEP indicator > 0.003 % — good. The KEP < 0.001 % — unsuitable for use.

Аутологічні біотехнологічні продукти на основі кісткового мозку (КМ) є джерелом стовбурових клітин, зокрема гемопоетичних і мультипотентних мезенхімальних стромальних клітин. Вони являють собою один із альтернативних терапевтичних засобів, який може сповільнити дегенерацію хряща, покращити його репарацію та запобігти ендопротезуванню суглоба. Мета. Розробити критерії якості та безпеки маломаніпульованих біотехнологічних продуктів з аутологічного КМ для застосування в пацієнтів із патологією опорно-рухового апарата. Методи. Для отримання біотехнологічних продуктів використано аспірат червоного кісткового мозку 85 пацієнтів з остеоартрозом та асептичним некрозом кульшового та колінного суглобів. В усіх зразках проводили підрахунок клітин у мієлограмі та КУОф-аналіз мультипотентних мезенхімальних стовбурових/стромальних клітин кісткового мозку (ММСК-КМ). Результати. Під час розробки зазначених якостей біотехнологічних продуктів з аспірата КМ встановлено 3 його типи: 1 — поліморфний (клітини-попередники усіх типів у межах норми); 2 — помірноклітинний (присутні всі типи клітин-попередників, але деякі з них нижче норми); 3 — гіпоклітинний (із наявністю більшості типів клітин-попередників, деякі з них нижче норми). Розроблено функціональні критерії якості біотехнологічних продуктів з аспірата КМ на підставі КУОф-аналізу й обчислення коефіцієнта ефективності посіву (КЕП) ММСК-КМ. Висновки. Виявлено критерії якості та безпеки біотехнологічних продуктів на основі аутологічного аспірата КМ за результатами мієлограм та КУОф-аналізу. За результатами мієлограм тип 1 аспірата КМ оцінювали, як відмінний для подальшого виготовлення біотехнологічного продукту, тип 2 — добрий, тип 3 — задовільний. За КУОф-аналізом показник КЕП < 0,001 % визначали як незадовільний, у межах 0,001–0,003 % — задовільний, у разі > 0,003 % — хороший. Аспірат КМ із КЕП < 0,001 % розцінювали непридатним для застосування. Ключові слова. Регенеративна ортопедія, регенеративна ін'єкційна терапія, остеоартроз, асептичний некроз, кульшовий суглоб, колінний суглоб.

Key words. Regenerative orthopedics, regenerative injection therapy, osteoarthritis, avascular necrosis, hip, knee

Introduction

Recent advances in biotechnology and regenerative medicine have significantly expanded the range of applications of biotechnology products, in particular in traumatology and orthopedics. Currently, the source of cell and tissue products for the treatment of diseases and injuries of the musculoskeletal system is red bone marrow (BM) [1, 2], as it is considered to be one of the most accessible sources of multipotent mesenchymal stem/stromal cells (MMSCs) in the adult body [3, 4]. Therefore, discussing the prospects and effectiveness of using biotechnology products obtained from these tissue sources for the treatment of osteoarthritis and aseptic necrosis of the hip and knee joints is a rather relevant issue. Most often, BM concentrates containing MMSCs are used in clinical practice today [5, 6].

Autologous biotechnological products based on BM are a source of stem cells, in particular HSCs and MMSCs, and are one of the alternative therapeutic agents that can slow down cartilage degeneration, improve its repair and, ultimately, prevent joint replacement [7, 8]. MMSCs are able not only to directly differentiate into chondrocytes, but also produce many biologically active substances that have immunomodulatory and anti-inflammatory effects, stimulate angiogenesis and are inducers of chemotaxis for endogenous progenitors. Due to their high proliferative potential *in vitro*, paracrine effects and ability to restore damaged cartilage and bone tissue *in vivo*, MMSCs are considered an effective tool for cell therapy of musculoskeletal pathologies. Among the studied sources of stem and progenitor cells, red bone marrow MSCs (BM-MMSCs) can be considered the most promising in terms of availability, safety, and expected therapeutic efficacy [7]. Key prognostic characteristics of the therapeutic efficacy of BM-based biotechnology products for regenerative orthopedics are cellularity indicators and the ratio of cell types in the myelogram (hemopoietic cells) and during the CFU analysis of stromal cells (BM-MMSCs).

Purpose: to develop criteria for the quality and safety of minimally manipulated biotechnological products from autologous bone marrow for use in patients with musculoskeletal disorders.

Material and methods

The study was conducted at the Department of Tissue and Cell Therapy of the State Institution "ITO NAMS of Ukraine" in the period from 2021 to 2024. Informed consent was obtained from all patients before the study and treatment. The study was

performed in compliance with the principles of bioethics (protocol No. 1 of the meeting of the Bioethics Committee of the State Institution "Institute of Traumatology and Orthopedics of the NAMS of Ukraine" dated 11 January 2021).

During the study, red bone marrow aspirate from 85 patients with osteoarthritis and aseptic necrosis of the hip and knee joints was used, from which biotechnological products were subsequently manufactured. BM aspirate from 71 patients was used for cell counting in the myelogram, and from 14 patients for the CFU analysis of MMSC-BM. We isolated red bone marrow from the iliac crest. According to literature sources, this localization prevails over other possible ones in terms of the number of progenitor cells obtained compared to the tibia and calcaneus [9].

We used three approaches for BM aspiration (Fig. 1): anterior parallel (through the iliac wing) (Fig. 1, a), posterior parallel (parallel to the posterior superior iliac spine) (Fig. 1, b, c) and posterior perpendicular (perpendicular to the posterior superior axis of the iliac bone) (Fig. 1, d). Aspiration was performed with an 11G trocar 100 or 150 mm long, after flushing its lumen with a small amount of heparin. After local anesthesia, by manually placing the cannula in the iliac crest, rotating it clockwise and counterclockwise, we simultaneously applied axial force or pressed the trocar to the bone, pushing the cannula through the cortical layer. After its passage, we felt some relief in the movement of the trocar, then we deepened it into the spongy layer of the iliac bone by another 0.5 cm. After making sure that the trocar was in a stable position in the thickness of the bone, we connected a Luer-Lock syringe, then carefully pulled its piston towards us, without much effort, and made sure that there was bone marrow aspiration in its lumen. Having determined its presence, further sampling should be performed slowly, since significant efforts during aspiration will increase the patient's pain syndrome.

Bone marrow sampling from one area leads to a decrease in the number of mesenchymal stem cells due to dilution with peripheral blood, so after filling 2–3 syringes, we changed the depth of sampling. We obtained 100 ml of aspirate to isolate one dose of the mononuclear fraction. To obtain several doses, sampling was performed from several accesses. If necessary, ultrasound or a C-curve was used for navigation.

After completing the BM aspirate sampling procedure, the patients were recommended to remain in a horizontal position for 30 minutes.

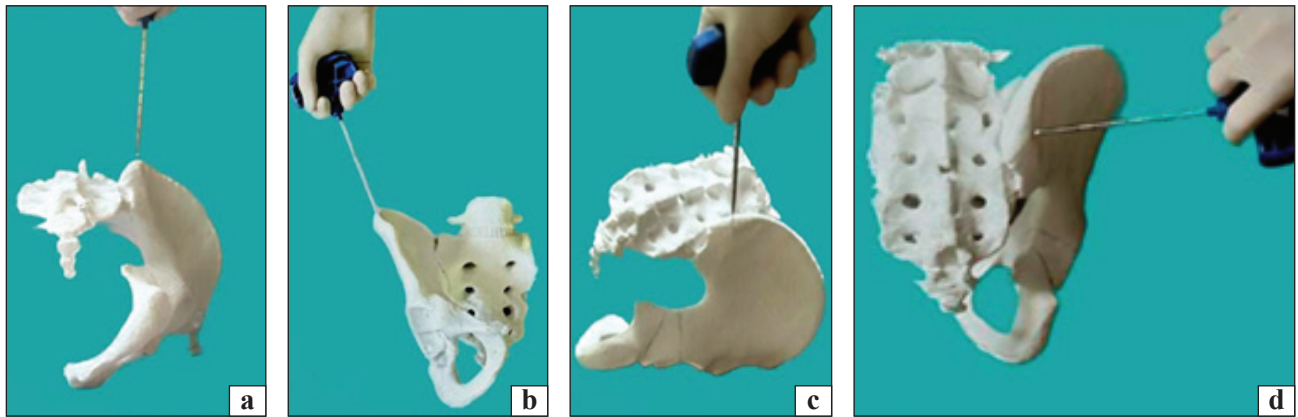


Figure. Accesses to the pelvic bone for collecting BM aspirate: a) anterior parallel; b), c) posterior parallel; d) posterior perpendicular

Table 1

Example of a myelogram of patient G., whose aspirate is unsuitable for further manufacturing of a biotechnological product

Cellular element		Result	Norm (in % according to A. I. Vorobyov)
Reticular cells		—	0.1–1.6
Blasts that do not undergo morphological differentiation		—	0.1–1.1
Myeloblasts		0	0.2–1.7
Neutrophilic granulocytes	Promyelocytes	0.2	1.0–4.1
	Myelocytes	1.4	7.0–12.2
	Metamyelocytes	0.8	8.0–15.0
	Rods	4.0	12.8–23.7
	Segmented	52.0	13.1–24.1
Eosinophilic granulocytes	Promyelocytes	—	0.5–5.8
	Myelocytes	—	0.5–5.8
	Metamyelocytes	0.6	0.5–5.8
	Rods	—	0.5–5.8
	Segmented	—	0.5–5.8
Basophilic granulocytes	Promyelocytes	—	0.0–0.5
	Myelocytes	—	0.0–0.5
	Metamyelocytes	0.2	0.0–0.5
	Rods	—	0.0–0.5
	Segmented	—	0.0–0.5
Elements of erythropoiesis:			
– erythroblasts		0	0.2–1.1
– pronormocytes		0.2	0.1–1.2
– basophilic normocytes		2.2	1.4–4.6

Cellular element		Result	Norm (in % according to A. I. Vorobyov)
Normocytes polychromatophilic		7.2	8.9–16.9
Normocytes oxyphilic		0	0.8–5.6
Promegaloblasts		—	—
Megaloblasts basophilic		—	—
Megaloblasts polychromatophilic		—	—
Megaloblasts oxyphilic		—	—
Elements of lymphopoiesis:			
– lymphocytes		22.4	4.3–13.7
– plasma cells		0.2	0.1–1.8
Elements of monocytopoiesis:			
– monocytes		8.6	0.7–3.1
– mitoses of white germ elements		—	2 : 500
– mitoses of red germ elements		—	3 : 500
Bone marrow indices:			
– leuko:erythro		9.4 : 1.0	3.5–4 : 1.0
– neutrophil maturation		0.04	0.6–0.8
– erythrokaryocyte maturation		0.8	0.8–0.9

Preparation of a bone marrow aspirate smear for counting the cellular composition

Having taken the slide by its long edges, we touched its surface (stepping back 0.5–1 cm from the narrow edge) to a drop of aspirate (but not to the skin). The drop should be small in size, and it

should be placed so that the entire smear fits on the glass, not reaching 1–1.5 cm to its edge. Its fixation was carried out according to May-Grunwald [10]. The smear of the BM aspirate was stained according to Romanovsky: the cell elements were stained in different colors and shades with a mixture

Table 2

Example of a patient C's type 1 myelogram

Cellular element		Result	Norm (in % according to A. I. Vorobyov)
Reticular cells		—	0.1–1.6
Blasts that do not undergo morphological differentiation		—	0.1–1.1
Myeloblasts		0	0.2–1.7
Neutrophilic granulocytes	Promyelocytes	1.2	1.0–4.1
	Myelocytes	10.4	7.0–12.2
	Metamyelocytes	6.0	8.0–15.0
	Rods	15.2	12.8–23.7
	Segmented	26.4	13.1–24.1
Eosinophilic granulocytes	Promyelocytes	—	0.5–5.8
	Myelocytes	—	0.5–5.8
	Metamyelocytes	0.4	0.5–5.8
	Rods	—	0.5–5.8
	Segmented	—	0.5–5.8
Basophilic granulocytes	Promyelocytes	—	0.0–0.5
	Myelocytes	—	0.0–0.5
	Metamyelocytes	0.4	0.0–0.5
	Rods	—	0.0–0.5
	Segmented	—	0.0–0.5
Elements of erythropoiesis:			
– erythroblasts		0.4	0.2–1.1
– pronormocytes		0.4	0.1–1.2
– basophilic normocytes		3.2	1.4–4.6

Cellular element		Result	Norm (in % according to A. I. Vorobyov)
Normocytes polychromatophilic		9.6	8.9–16.9
Normocytes oxyphilic		6.4	0.8–5.6
Promegaloblasts		—	—
Megaloblasts basophilic		—	—
Megaloblasts polychromatophilic		—	—
Megaloblasts oxyphilic		—	—
Elements of lymphopoiesis:			
– lymphocytes		15.6	4.3–13.7
– plasma cells		0.4	0.1–1.8
Elements of monocytopenia:			
– monocytes		4.0	0.7–3.1
– mitoses of white germ elements		—	2 : 500
– mitoses of red germ elements		—	3 : 500
Bone marrow indices:			
– leuko:erythro		4.0 : 1.0	3.5–4 : 1.0
– neutrophil maturation		0.4	0.6–0.8
– erythrokaryocyte maturation		0.8	0.8–0.9

of basic (azure II) and acidic (water-soluble yellow eosin) dyes. Staining was carried out with a ready-made solution of Romanovsky dye for 40 minutes. After complete drying, the smear is ready for counting, which was carried out in the clinical diagnostic laboratory of the municipal non-profit enterprise “Kyiv City Clinical Hospital No. 9”. Based on the results of the smear counting, a myelogram of the corresponding BM aspirate sample was formed.

MMSC-CM CFU analysis

Heparinized (2 units/ml heparin sodium) red bone marrow aspirate, taken from the iliac crest, was seeded in complete growth medium containing MEM alpha modified (BioWest), 10 % ETC (Sigma-Aldrich), 1 ng/ml bFGF (Sigma-Aldrich), antibiotic-antimycotic solution (BioWest), 2 units/ml heparin sodium at the rate of 5.7 million nucleated cells of red bone marrow aspirate per large Petri dish with a diameter of 100 mm (3 dishes with 10 ml of complete growth medium per each bone marrow sample) and cultured for 14 days in a CO₂ incubator at 37 °C and in a 5 % carbon dioxide atmosphere and

96 % humidity. The growth medium in the dishes was changed every third day. After 14 days of cultivation, Petri dishes with colonies (colony-forming units of fibroblasts, or CFUs) were washed with phosphate-buffered saline and fixed for 20 min at room temperature with buffered formalin solution and stained with hematoxylin-eosin solution. Stained colonies were counted.

Results*Morphological criteria for the quality and safety of BM aspirate and biotechnological products made from it*

According to the results of the analysis of myelograms of patients who underwent sampling for the manufacture of a biotechnological product, all variants of the aspirated fluid were divided into 2 types: aspirate of BM and without signs of the presence of BM. The results of determining the type of BM aspirate in 16 samples obtained were polymorphic, in 26 samples — moderately cellular, in 29 — hypocellular.

Table 3

Example of a patient K's type 2 myelogram

Cellular element		Result	Norm (in % according to A. I. Vorobyov)
Reticular cells		—	0.1–1.6
Blasts that do not undergo morphological differentiation		—	0.1–1.1
Myeloblasts		0.2	0.2–1.7
Neutrophilic granulocytes	Promyelocytes	0.6	1.0–4.1
	Myelocytes	12.8	7.0–12.2
	Metamyelocytes	16.0	8.0–15.0
	Паличкоядерні	8.8	12.8–23.7
	Сегментоядерні	27.2	13.1–24.1
Eosinophilic granulocytes	Promyelocytes	—	0.5–5.8
	Myelocytes	—	0.5–5.8
	Metamyelocytes	0.6	0.5–5.8
	Паличкоядерні	—	0.5–5.8
	Сегментоядерні	—	0.5–5.8
Basophilic granulocytes	Promyelocytes	—	0.0–0.5
	Myelocytes	—	0.0–0.5
	Metamyelocytes	0.2	0.0–0.5
	Паличкоядерні	—	0.0–0.5
	Сегментоядерні	—	0.0–0.5
Elements of erythropoiesis:			
– erythroblasts		0.2	0.2–1.1
– pronormocytes		0.6	0.1–1.2
– basophilic normocytes		5.6	1.4–4.6
Normocytes polychromatophilic		9.6	8.9–16.9
Normocytes oxyphilic		0	0.8–5.6
Promegaloblasts		—	—
Megaloblasts basophilic		—	—
Megaloblasts polychromatophilic		—	—
Megaloblasts oxyphilic		—	—
Elements of lymphopoiesis:			
– lymphocytes		13.6	4.3–13.7
– plasma cells		0.2	0.1–1.8
Elements of monocytopenia:			
– monocytes		3.8	0.7–3.1
– mitoses of white germ elements		—	2 : 500
– mitoses of red germ elements		—	3 : 500
Bone marrow indices:			
– leuko:erythro		5.3 : 1.0	3.5–4 : 1.0
– neutrophil maturation		0.8	0.6–0.8
– erythrokaryocyte maturation		0.6	0.8–0.9

When examining the aspirated fluid, two criteria were considered: megakaryocytes in the myelogram as a marker for bone marrow, and the leuko-erythrocyte index. In the absence of megakaryocytes in the myelogram and the leuko-erythrocyte index of more than 20:1, the aspirated fluid is not suitable for further manufacture of a biotechnological product (Table 1).

Conclusion: bone marrow punctate is hypocellular. No megakaryocytes were observed in the preparation. Considering the approximation of the cellular composition of the bone marrow to the cellular composition of the peripheral blood, the absence of megakaryocytes and fragments of the bone marrow reticulum, a significant admixture of blood to the aspirate cannot be ruled out.

In turn, the BM aspirate obtained during collection was divided into 3 types according to the results of myelogram analysis. The first is polymorphic, with the presence of precursor cells of all types within normal limits. This type of aspirate is characterized by the presence of megakaryocytes in the myelogram,

the leuko-erythrocyte index does not exceed 4:1. An example of a myelogram of this type of BM aspirate is given in Table 2.

The bone marrow punctate is moderately cellular, polymorphic. The dimensions of the erythron are preserved (20.0 %), with normal maturation. The granulocytic series is preserved (59.2 %), mature forms of granulocytes prevail. Megakaryocytes are single in the preparation, freely located platelets in sufficient quantity.

Type 2 is moderately cellular (with the presence of all types of precursor cells, but some of them below normal). This variant of the aspirate is characterized by the presence of megakaryocytes in the myelogram, the leuko-erythrocyte index is (5:1)–(10:1).

An example of a myelogram of this type of BM aspirate is given in Table 3.

Therefore, the bone marrow punctate is moderately cellular. The dimensions of the erythron are preserved, closer to the lower limit of the norm, with delayed maturation in young forms. The gran-

Table 4

Example of a patient C's type 3 myelogram

Cellular element		Result	Norm (in % according to A. I. Vorobyov)
Reticular cells		—	0.1–1.6
Blasts that do not undergo morphological differentiation		—	0.1–1.1
Myeloblasts		0	0.2–1.7
Neutrophilic granulocytes	Promyelocytes	0	1.0–4.1
	Myelocytes	2.8	7.0–12.2
	Metamyelocytes	1.6	8.0–15.0
	Паличкоядерні	3.6	12.8–23.7
	Сегментоядерні	42.0	13.1–24.1
Eosinophilic granulocytes	Promyelocytes	—	0.5–5.8
	Myelocytes	—	0.5–5.8
	Metamyelocytes	0.8	0.5–5.8
	Паличкоядерні	—	0.5–5.8
	Сегментоядерні	—	0.5–5.8
Basophilic granulocytes	Promyelocytes	—	0.0–0.5
	Myelocytes	—	0.0–0.5
	Metamyelocytes	0.4	0.0–0.5
	Паличкоядерні	—	0.0–0.5
	Сегментоядерні	—	0.0–0.5
Elements of erythropoiesis:			
– erythroblasts		0	0.2–1.1
– pronormocytes		0	0.1–1.2
– basophilic normocytes		2.4	1.4–4.6

Cellular element		Result	Norm (in % according to A. I. Vorobyov)
Normocytes polychromatophilic		6.4	8.9–16.9
Normocytes oxyphilic		1.2	0.8–5.6
Promegaloblasts		—	—
Megaloblasts basophilic		—	—
Megaloblasts polychromatophilic		—	—
Megaloblasts oxyphilic		—	—
Elements of lymphopoiesis:			
– lymphocytes		32.0	4.3–13.7
– plasma cells		0	0.1–1.8
Elements of monocytopoiesis:			
– monocytes		6.4	0.7–3.1
– mitoses of white germ elements		—	2 : 500
– mitoses of red germ elements		—	3 : 500
Bone marrow indices:			
– leuko:erythro		9.0 : 1.0	3.5–4 : 1.0
– neutrophil maturation		0.1	0.6–0.8
– erythrokaryocyte maturation		0.8	0.8–0.9

ulocytic series is preserved, with normal maturation. Megakaryocytes are single in the preparation.

Type 3 is hypocellular, with the presence of most types of precursor cells, some of them below the norm. This variant of the aspirate is characterized by the presence of megakaryocytes in the myelogram, the leuko-erythrocytic index is (10:1)–(20:1).

An example of a myelogram of this type of BM aspirate is given in Table 4.

The cellularity of the bone marrow punctate was found to be reduced. There are cells of all hematopoietic germs at different stages of maturation.

Type 1 of the BM aspirate was assessed as excellent for further production of a biotechnological product, type 2 — good, type 3 — satisfactory.

Functional criteria for the quality of BM aspirate and biotechnological products made from it

Today, the CFU analysis is considered one of the “gold standards” for determining the frequency of clonogenic MMSC-BM. According to the results of the analysis of the cultivation of nucleated cells of the BM aspirate, the number of colonies in three

samples was counted and the average indicator was determined for each patient. The seeding efficiency coefficient (the percentage of MMSC among all nucleated cells) was calculated using the following formula: SEC (seeding efficiency coefficient) = the average number of colonies in three samples of each patient * 100% / 5.7 million (the number of nucleated cells per 1 large Petri dish). The results of determining the seeding efficiency are given in Table 5.

The SEC index < 0.001% was considered unsatisfactory, within 0.001–0.003% — satisfactory, in the case of > 0.003% — good. Thus, the BM aspirate with SEC < 0.001% was considered unsuitable for use as a biotechnological product. The optimal for use is the BM aspirate with SEC > 0.003 % (i. e. more than 3 clonal colonies of MMSC per 1×10⁵ nucleated cells of the BM aspirate).

Discussion

Today, autologous bone marrow aspirate is increasingly used for the treatment of orthopedic and trauma patients, in particular in conditions

Table 5

Determination of the efficiency of seeding nucleated cells from BM aspirate

Patient No.	Number of nucleated cells in 5 ml of BM aspirate (million)	Number of colonies (CFU) of nucleated cells (NC) in three samples	Average number of nucleated cells colonies	SEC (%)
1	145.0	246	199.00	0.0035
		163		
		188		
2	230.0	203	195.00	0.0034
		157		
		225		
3	79.5	345	336.70	0.0059
		298		
		367		
4	247.0	203	205.33	0.0036
		211		
		202		
5	83.0	139	127.67	0.0022
		126		
		118		
6	242.0	263	209.67	0.0037
		235		
		131		
7	150.0	104	94.66	0.0017
		117		
		63		
8	281.0	289	264.00	0.0046
		271		
		232		
9	77.0	55	78.33	0.0013
		77		
		103		
10	191.0	96	106.33	0.0019
		122		
		101		
11	316.0	88	85.00	0.0015
		87		
		80		
12	86.0	38	24.33	0.004
		24		
		11		
13	106.0	99	121.67	0.0020
		117		
		149		
14	167.0	129	165.67	0.0030
		158		
		210		

of osteoarthritis and aseptic necrosis [11, 12]. Literary sources describe treatment with autologous concentrated BM aspirate mostly as “stem cell therapy” [13, 14]. However, it should be noted that it contains different types of cells, most of which belong to the hematopoietic lineage, not mesenchymal. Our study also confirms this fact. We, like other researchers, found only a small percentage of mesenchymal stem cells in bone marrow aspirate [15, 16]. This fact indicates the feasibility of a more detailed approach to the terminology of biotechnology products. We can only talk about treatment with mesenchymal stem cells if they have been isolated from bone marrow aspirate and cultured *in vitro*.

In the case of using BM aspirate and its derivatives (concentrated BM aspirate, mononuclear fraction of BM aspirate), it is more appropriate to use the term “regenerative therapy”, since the best explanation of the positive effect of biotechnological products from bone marrow aspirate is the paracrine effect of the obtained cell concentrate due to the growth factors it contains [17].

Conclusions

As a result of the development of quality and safety criteria for biotechnological products derived from bone marrow aspirate, three classifications have been established: 1) Polymorphic, which includes the presence of progenitor cells of all types within the normal range; 2) Moderately cellular, where all types of progenitor cells are present, albeit with some below the normal range; and 3) Hypocellular, characterized by the presence of most types of progenitor cells, with several below the normal range. Bone marrow aspirate type 1 was evaluated as excellent for subsequent biotechnological product manufacturing. Type 2 was deemed good, while type 3 was considered satisfactory.

To determine the functional criteria of quality of biotechnological products from BM aspirate, we used CFU analysis and MMSC-BM seeding efficiency coefficient. If the SEC indicator is less than 0.001 %, it is considered unsatisfactory; between 0.001 % and 0.003 %, it is regarded as satisfactory; and greater than 0.003 %, it is deemed good. BM aspirate with SEC < 0.001 % is unsuitable for use.

It has been established that mesenchymal stem cells constitute a minor population in bone marrow aspirate, and the clinical impact of biotechnological products made from bone marrow aspirate is likely to occur at the expense of hematopoietic progenitor cells.

Conflict of interest. The authors declare that there is no conflict of interest.

Prospects for further research. Research on cultured autologous and allogeneic biotechnological products of bone marrow, development of their quality and safety criteria, development of a differentiated and personalized approach to the use of minimally manipulated and cultured biotechnological products in patients with orthopedic and traumatological profile

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Authors' contribution. Shtrafun S. S. — definition of research directions, formulation of conclusions; Golyuk E. L. — analysis of research results, writing of the article; Zubov D. O. — study of functional criteria of quality of bone marrow aspirate and biotechnological products made from it, CFU analysis of multipotent mesenchymal stem/stromal cells; Magomedov S. — processing and preparation of bone marrow aspirate smears for counting the cellular composition; Starodub G. S. — analysis of patients' myelograms; Malova H. K. — counting cells in patients' myelograms.

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QUALITY CRITERIA FOR MINIMALLY MANIPULATED BIOTECHNOLOGICAL PRODUCTS BASED ON AUTOLOGOUS BONE MARROW ASPIRATE FOR USE IN TRAUMATOLOGY AND ORTHOPEDICS

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Features of deformation of the «debris – external core apparatus» model in the case of using structures with different structural geometry

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Objective. To study the linear and angular displacements of the "fragments" during their connection with an external rod apparatus manufactured by HB ORTHO (Ukraine) or Orthofix (USA) under different variants of the geometry of the "fragments – apparatus" structure in order to clarify the mechanical principles of its rational construction. **Methods.** The model was rigidly fixed at one end in a horizontal position, and a transverse force was alternately applied to the opposite end using weights of 1, 2, 3, 4, 5 kg. The experiment involved the study of the magnitude and nature of the displacement of the fragments depending on the following parameters of the rods: the number of rods in the fragment (2 or 3); diameter (5, 6 mm); length of the rod section from the bone to the support (100, 50 mm); length of the bone section between the extreme rods (150, 100 mm); the presence of a multi-plane arrangement of the rods and, in particular, when they formed a 45° angle between them, the number of external supports: one or two, located in parallel or side by side. **Results.** The first most important parameter that influenced the amount of displacement of the distal "fragment" was the distance from the bone to the support. In the case of a distance of 50 mm, the amount of displacement of the fragment is 2–4 times less than in the case of 100 mm. The second parameter that influenced the displacement of the fragments was the length of the bone section between the extreme rods screwed into the fragment. If it is reduced by 30 %, the displacement increases by 64% and almost does not depend on whether 2 or 3 rods were used. It is possible to significantly reduce the displacement of the distal fragment (at least twofold) by inserting rods in different planes, in particular, by positioning the rod so that in the proximal fragment near the fracture in a plane that is 45° to the frontal plane. With a gradual transverse load, the deformation of the structure at the initial stages (1, 2, 3 kg) is elastic in nature and with an increase (up to 4–5 kg), residual deformation occurs due to: movement of the clamp on the cylindrical support; plastic deformation of the rods, which is inherent in HB ORTHO devices (Ukraine).

Мета. Дослідити на фізичній моделі лінійні та кутові переміщення «уламків» під час їхнього з'єднання зовнішнім стрижневим апаратом виробництва «HB ORTHO» (Україна) чи пристроєм «Orthofix» (США) за різних варіантів геометрії конструкції «уламки – апарат» для з'ясування механічних принципів її раціональної побудови. **Методи.** Модель одним кінцем жорстко закріплювали в горизонтальному положенні, а до протилежного почергово прикладали поперечну силу, використовуючи гирі масою 1, 2, 3, 4, 5 кг. Експеримент передбачав дослідження величини та характеру переміщень уламків залежно від таких параметрів стрижнів: кількість в уламку (2 або 3); діаметр (5, 6 мм); довжина ділянки стрижня від кістки до опори (100, 50 мм); довжина ділянки кістки між крайніми стрижнями (150, 100 мм); наявність різноплощинного розташування стрижнів і зокрема, коли вони утворювали між собою кут 45°, кількість зовнішніх опор: одна або дві, розташовані паралельно чи поряд. **Результати.** Першим за значущістю параметром, який впливав на величину переміщення дистального «уламка» є відстань від кістки до опори. У разі відстані в 50 мм величина переміщення уламку в 2–4 рази менша, ніж за 100 мм. Другим параметром, який впливав на переміщення уламків є довжина ділянки кістки, що знаходиться між крайніми стрижнями загвинченими в уламок. За зменшення її на 30 % величина переміщення збільшується на 64 % і майже не залежить від того, було заведено 2 чи 3 стрижні. Суттєво зменшити переміщення дистального уламка (мінімум удвічі) можна шляхом різноплощинного заведення стрижнів, зокрема розташувавши стрижень щоб він знаходився в проксимальному уламку поблизу перелома в площині, яка розташована під 45° до фронтальної. За ступеневого поперечного навантаження деформації конструкції на початкових етапах (1, 2, 3 кг) мають пружний характер, зі збільшенням (до 4–5 кг) виникає залишкове викривлення через: переміщення затискача на циліндричній опорі; пластичну деформацію стрижнів, яка притаманна апаратам «HB ORTHO» (Україна). **Ключові слова.** Перелом стегнової кістки, зовнішній стрижневий апарат, навантаження.

Keywords. Femoral fracture, external fixation device, loading

Introduction

The prevalence of numerous gunshot fractures in the extremities has shifted the priority of methods for fragment fixation, with the use of external rod devices (ERDs) emerging as a prominent area of focus for new theoretical concepts and practical applications. When connecting ERDs, a non-rigid structure is created, allowing for certain movements. This differs from structures that use a plate or an intramedullary locked rod. Studies on experimental models and patients have shown that during the connection of ERDs, the linear movement of their ends was within 0.6–16 mm [1, 3, 11], and with bone osteosynthesis 0.017–0.07 mm [2]. The difference was one or two orders of magnitude. We have already drawn attention to the fact that the presence of movement of the fragment(s) under load is not a sign of an unstable state of the structure, provided that it is elastic (temporary). Accordingly, it was proposed to use the terms “rigid structure” in relation to the connection of fragments with a plate or a blocked rod and “elastic structure” for those connected by an external rod (spoke) apparatus. In both cases, these will be stable structures [4].

As our previous studies have shown, elastic deformations of the fractured segment with the specified movements of the ends of the fragments at the first stages of hardware treatment of diaphyseal fractures do not disrupt the process of union, but on the contrary, lead to the formation of periosteal bone regenerate. The mechanisms of its formation under conditions of elastic movements of fragments are given in our publications [5]. However, as practice shows, there is a risk of their re-displacement during the use of the ERD [7]. It is expected and can be largely prevented with the appropriate knowledge, experience and technical capabilities.

In the modern scientific literature there is a lack of information on the substantiation of mechanically and geometrically rational designs of “fragments – ERD” for fractures of a certain localization. Attention is focused on the selection of places for insertion of rods taking into account the anatomical and topographic features of vessels, nerves and tendon-muscle formations [9, 10] as well as on the study of the strength of devices or their elements using different materials [6, 14].

The works confirm the principle of expediency of using multi-plane rod insertion to achieve more reliable fixation of fragments [12, 13].

Our clinical data [7] indicates that from 2022 to 2024, external rod devices manufactured by “HB OR-

THO” (Ukraine) and the “Orthofix” device (USA) were commonly used in treating gunshot fractures of the extremities. Moreover, in 87.5 % of patients, these devices were used as the main method of fixing fragments (without replacing them with submerged osteosynthesis).

Purpose: to study on a physical model the linear and angular movements of “fragments” during their connection by an external rod device manufactured by “HB ORTHO” (Ukraine) and the “Orthofix” device (USA) for different variants of the geometry of the “fragments – device” structure to clarify the mechanical principles of its rational construction.

Material and methods

We studied models using the Ukrainian-made “HB ORTHO” and foreign-made “Orthofix” (Galaxy Fixation Gemini model) [8], which were most often used to treat gunshot fractures in Ukraine in the period 2022–2024 [7]. Although these devices are structurally different, they are related in functional purpose; they are commonly used for temporary fixation of fragments in the case of open fractures for the period until the wound heals. Their characteristic feature is that they provide for the possibility of creating different geometry of the structure depending on the localization of the fracture, soft tissue damage, as well as the surgeon’s ideas about its mechanical reliability.

The situation of a femur fracture was chosen as the basis, when the fragments were fixed with a rod apparatus. Clinical practice shows that in this case, a condition always arises when the damaged limb is horizontal and at the same time the distal fragment is subjected to a transverse force of the limb mass, and the proximal fragment may be subjected to a force in the opposite direction as a result of tension of the *m. iliopsoas* (Fig. 1). The force acting downwards is of considerable magnitude, especially if the tibia is in an extended position, since the extension of the lever increases the moment of force. This situation is extremely dangerous due to the possibility of repeated displacement of the fragments if they are fixed with a rod apparatus. Recent experience in the treatment of gunshot fractures shows that it is most difficult to hold the fragments with the apparatus when the fracture is localized in the upper half of the femur [7]. If the tibia is bent to a right angle, the moment of force will significantly decrease. When the injured limb is in a vertical position, the load vector coincides with the axis of the femur, and the foot interacts with the supporting surface (which neutralizes the force of the mass of the distal fragment), the situation becomes less dangerous. Biomechanical studies on a physical model have shown that in

the case of axial loading, the fragments connected by the ERD move significantly less than in the case of transverse loading [3].

The physical model (Fig. 2) was a cylindrical wooden (beech) bar 400 mm long, 35 mm in diameter, corresponding to the average anthropometric dimensions of the femur. In the middle, the bar was sawn transversely and the ERD was connected using geometrically different schemes in accordance with the experimental plan. The “fragment – ERD” model thus obtained was rigidly fixed at one end in a horizontal position and a transverse force was applied to the opposite end in stages using weights weighing 1, 2, 3, 4, 5 kg. The movement of the fragments was recorded photometrically, with a camera fixed on a tripod, while the model was located on graph paper. The linear displacement of the distal (a) “fragment” of the model between standardly selected points was measured with a metal ruler and its angular displacement (b). The measurements were performed under load and after removal of the corresponding weight. If there was a residual displacement (a1), it was also recorded and measured. For each variant of the construction of the study structure, the average value of the displacement values was taken as a basis. After each experiment, the connection of the rods with the external support was renewed, the nuts were tightened as much as possible.

The experiment involved studying the magnitude and nature of the displacements of the fragments depending on a number of key (in our opinion) geometric parameters of the “fragments – ERD” structure. We were interested in the dependence of the magnitude of the displacements of the fragments on the following parameters (Fig. 3):

- the number of rods in the fragment (N) — 2 or 3;
- the diameter of the rods (D) — 5 or 6 mm;
- the length of the rod section from the bone to the support (L) — 100 or 50 mm;
- the length of the bone section between the extreme rods (H) — 150 or 100 mm;
- the presence of a multi-planar arrangement of the rods and when they formed an angle (G) of 45°;
- number of external supports: one or two, located parallel to each other.

In total, an experiment was conducted on the movements of the distal fragment using 15 variants of the “fragment – ERD” design configurations using the “HB ORTHO” (10) and “Orthofix” (9) apparatus (Table 1).

The studies were performed in the biomechanics laboratory of the State Establishment “Professor M. I. Sytenko Institute of Spine and Joint Pathology of the National Academy of Medical Sciences of Ukraine” (head of the laboratory, Doctor of Medical Sciences O. A. Tyazhelov).

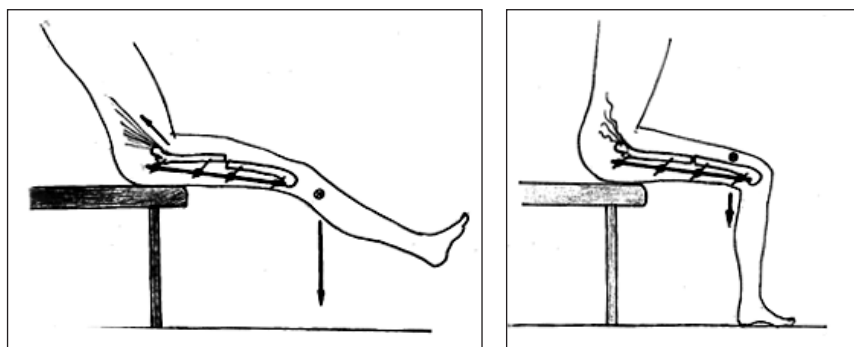


Fig. 1. Schemes illustrating the mechanics of displacement of femoral fragments in different limb positions

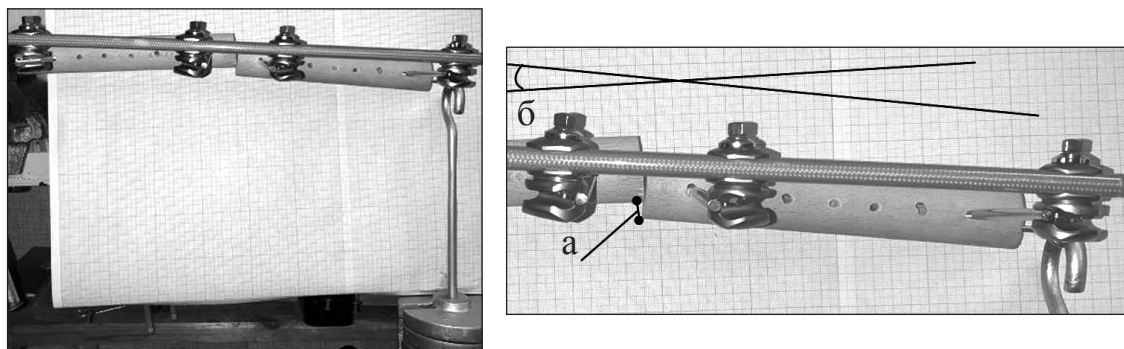


Fig. 2. General view of the model under load and deformation: a — linear displacement of the distal “fragment”; b — angular displacement of the distal “fragment”

Results

In the case of transverse loading of the model, the distal fragment was found to move uniformly in space in the sagittal plane. Its longitudinal axis moved at an angle and in width, as shown in Fig. 2.

The magnitudes of the displacement of the distal “fragment” under the action of the maximum (5 kg) transverse load for different geometric parameters of the model are given in Table 1.

The experiment showed that both linear and angular displacements of the distal fragment relative to the proximal one under the action of a step load correlate with each other in their magnitudes. Therefore, the magnitudes of the linear displacement (a) of the fragment under a step load were cho-

sen as the main criterion, by which the deformation of the structures can be compared with each other.

At the beginning, we will consider the linear displacements (a) in the case of fixation of the fragments with the “HB ORTHO” apparatus in the geometric parameters indicated in ordinal numbers 1–4 of Table 1 (Fig. 4).

This series of experiments demonstrated the behavior of the model in the case of using rods with a diameter of 5 mm and a length of 200 mm, which were included in the specified apparatus. With a rod section length of 100 mm (from the support to the bone), there was a significant movement (a) of the distal fragment, up to 33.8 mm in the case of inserting 2 rods into each fragment and 41.7 mm when inserting 3. With a reduction in the length of the rod section between

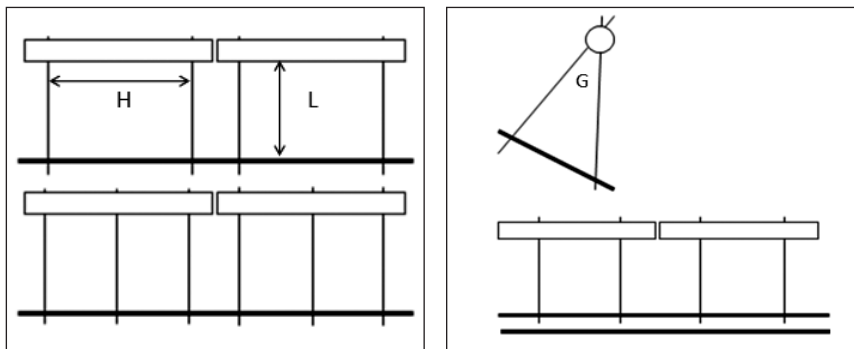


Fig. 3. Some basic schemes illustrating the geometric parameters of the “fragment – ERD” structure

Table 1

Displacement of the distal “fragment” under the action of the maximum (5 kg) transverse load of the model with different geometric parameters of the “fragment – ERD” design

№ 3/n	Geometrical parameter of the design						Distal fragment displacement at maximum load (5 kg)			
	number of rods in fragments N	rod diameter D (mm)	rod section length L (mm)	bone section length H (mm)	angle between planes G (deg.)	number of external supports	«HB ORTHO»		«Orthofix»	
							linear A (mm)	angular B (deg.)	linear A (mm)	angular B (deg.)
1	2	5	100	150	—	1	33.8	14.0	—	—
2	3	5	100	150	—	1	41.7	17.1	—	—
3	2	5	50	150	—	1	6.8	4.0	—	—
4	3	5	50	150	—	1	10.0	6.0	—	—
5	2	6	100	150	—	1	23.9	14.0	13.8	11.0
6	3	6	100	150	—	1	18.2	12.0	11.0	13.0
7	2	6	50	150	—	1	4.0	7.9	4.0	6.0
8	3	6	50	150	—	1	4.7	3.0	3.0	5.0
9	2	6	100	100	—	1	—	—	23.1	9.9
10	3	6	100	100	—	1	—	—	18.8	15.0
11	2	6	50	100	—	1	—	—	9.0	4.0
12	3	6	50	100	—	1	—	—	9.0	5.0
13	2	6	100	150	10	1	25.2	13.0	—	—
14	2	6	100	150	45	1	—	—	10.0	12.0
15	2	5	100	150	—	2	17.0	14.0	—	—

the support and the bone to 50 mm, the movement decreased, compared to the previous situation, by 4–5 times, to 6.8 mm and 10 mm, respectively. We draw attention to the fact that the magnitude of the movement did not significantly depend on whether 2 or 3 rods were inserted into each of the fragments. It was not possible to compare the obtained data with those obtained when using the Orthofix device, since its equipment did not include rods with a diameter

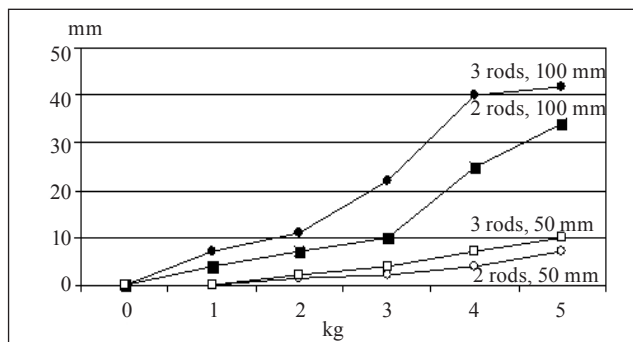


Fig. 4. Linear displacements (a) in the case of stepwise loading of the model with geometric parameters indicated under numbers 1–4 of the Table

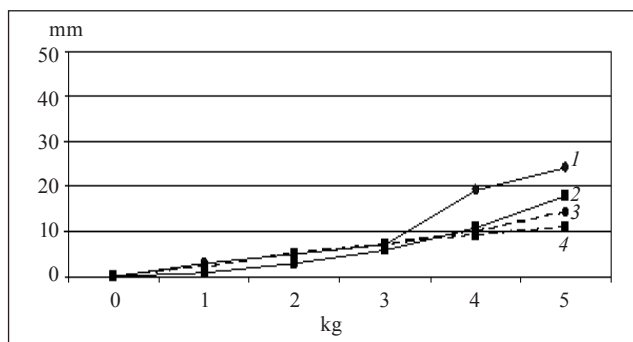


Fig. 5. Linear displacements during stepwise loading of the models with geometric parameters indicated under numbers 5 and 6 of the table using the devices "HB ORTHO" (1 — 3 rods, 100 mm; 2 — 3 rods, 100 mm) and "Orthofix" (3 — 3 rods, 100 mm; 4 — 3 rods, 100 mm)

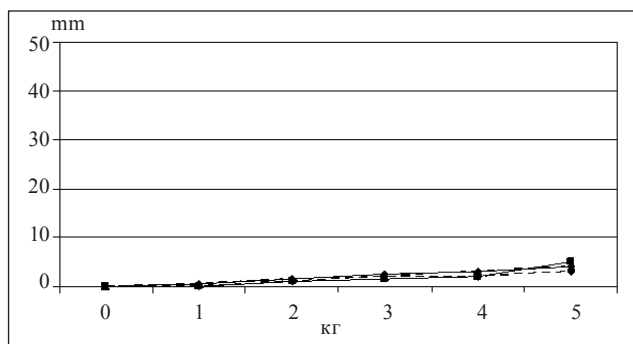


Fig. 6. Linear displacements during stepwise loading of the models with geometric parameters indicated under numbers 7 and 8 of the table using the devices "HB ORTHO" and "Orthofix"

of 5 mm and a length of more than 100 mm. This was done in a series of experiments, where rods with a diameter of 6 mm were provided and used.

The second series of work consisted of comparing the displacements in the case of using the "HB ORTHO" and "Orthofix" devices with similar geometric parameters and using rods with a diameter of 6 mm (numbers 5–8 in the Table) (Fig. 5).

The first thing that was found was that when fixed with the "Orthofix" device, the displacements A were significantly smaller — by 40 %, compared to the "HB ORTHO" device — 23.9 mm, 18.2 mm and 13.8 mm, 11 mm, respectively, for a rod section length of 100 mm. But after reducing the rod sections to 50 mm, there was no difference in the magnitude of the displacements and at the same time they were 2–4 times smaller than for a rod section length of 100 mm. It is also clear that the displacement magnitude was not significantly affected by the number of rods in each of the fragments (2 or 3).

The study of the deformation of the structure identified a significant feature. During the initial stages of loading (1, 2, 3 kg), the deformation was elastic; meaning that after the load was removed, the "fragments" returned to their original position. In the case of the following stages of loading (4 and 5 kg), after its removal, a residual deformation of the structure appeared, which in mechanics is characterized as plastic. Therefore, it can be stated that the "fragments – ERD" structure during stepwise transverse loading deforms according to the elastic-plastic type. When comparing the magnitude of the residual deformation at the maximum load (5 kg) with the use of the "Orthofix" apparatus, it was 43 %, and with the "HB ORTHO" apparatus — 76.5 %. We present graphs that reflect the linear movements of the ends of the "fragments" during stepwise loading of models using the "HB ORTHO" and "Orthofix" apparatuses with similar geometric parameters and the use of rods with a diameter of 6 mm (Fig. 6).

An examination of the deformed structures revealed that the residual deformation of the "fragment – ERD" structure arose due to the rotation of the clamps on the cylindrical external support, which are located near the fracture, as well as due to the plastic deformation of the rods in this zone (Fig. 7).

To prevent the movement of the clamp with the rod on the cylindrical support, an additional support can be used, which was fixed on the same rods. The effectiveness of such a structure was tested in an experiment on a model. When using two supports in the structure of the "HB ORTHO" apparatus, the linear movement of the "fragment" was reduced by half (17 mm),

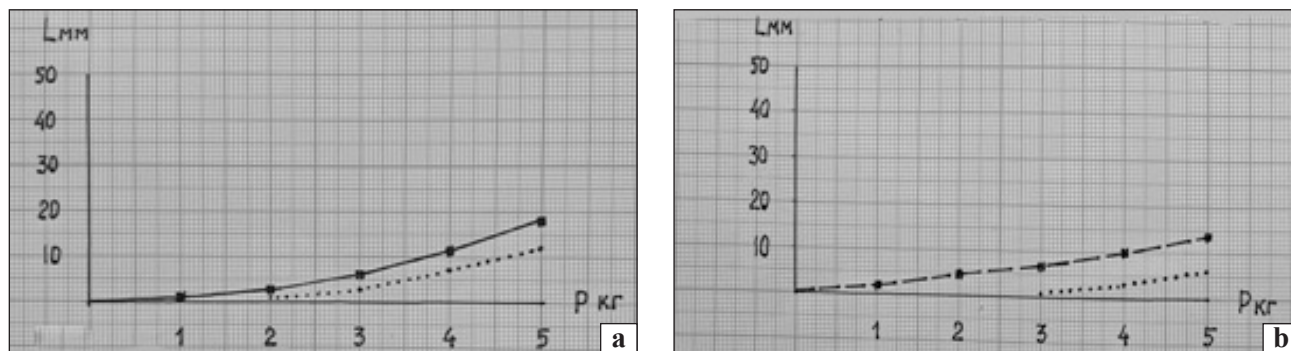


Fig. 6. Graphs showing linear displacements of the ends of the “fragments” during stepwise loading of the models and using the devices “HB ORTHO” (a) and “Orthofix” (b)



Fig. 7. General view of the deformed “fragment – ERD” structure with a demonstration of the connecting node and the rod, in which residual deformation occurs

compared to the structure with one support (33.8 mm). But the main thing was that with two attachment points for each rod, the occurrence of residual deformations was significantly reduced — 2 and 22 mm.

Thus, the results obtained in the above part of the experiment revealed that the most vulnerable to deformation is the structure in which all the rods are located in the frontal plane and the external support is located at a distance of 100 mm from the bone. The experiment allowed us to identify the key zone of deformation of the structure — the rod with the clamp, which is located in the proximal “fragment” near the fracture (Fig. 7). There is an assumption that this is caused by the torque of the force on the rod lever. The larger the lever, the greater the force that deforms. The torque can be counteracted by changing the location of the specified rod in such a way that the vector of the deforming force coincides with its axis. The ideal option would be to bring it into the sagittal plane, in which the deforming force acts. But considering that this is not desirable when fixing femoral fragments, a compromise option can be used, to place it in a plane that is located at an angle of 45° to the sagittal and frontal planes. The experiment showed that with such a construction of the geometry of the “fragment –

ERD” structure, the displacement is reduced by half, unlike the structure when all the rods are located in the frontal plane (Fig. 8).

Fig. 9 shows graphs that display the magnitude of the displacement of the distal “fragment” during step loading depending on the length of the bone section located between the extreme rods of each of the fragments (the parameters are indicated in points 5 and 9 of the table). It can be seen that it moves non-linearly, the distance between the fragments begins to increase in the case of a load of 4 and 5 kg. With a decrease in the distance between the rods in each of the “fragments” by one third (from 150 to 100 mm), the magnitude of the displacement at maximum load increased by 64% (14 and 23 mm, respectively). In addition, we performed mathematical calculations of the magnitude and directions of the forces that arise in the places of attachment of the rods to the external support and in the zone of their contact with the bone under the action of an external force in the sagittal plane (according to the experimental conditions). 4 options were selected, when the “fragments” are connected by the “Orthofix” apparatus using two rods in each “fragment”, the distance between the rods is 150 or 100 mm, and the distance from the “fragment” to the external support is 100 or 50 mm (items 5, 7, 9, 11, Table 1).

First, we will determine the magnitude of the forces in the rods at the point of their contact with the distal “fragment”. To do this, we will represent it as a beam on two supports, where the function of the supports is performed by the rods (Fig. 10).

To determine the support reactions, it is assumed that the body is in a static position (without movement, in a state of equilibrium), and at the same time the sum of all forces and moments of forces acting on the body is zero. Thus:

$$R_1 = \frac{P \cdot (H_1 + H_2)}{H_2}, \quad (1)$$

$$R2 = - \frac{P \cdot H1}{H2}. \quad (2)$$

When transferring these loads to the external support at the location of the clamps, we have, in addition to the action of bending forces $R1$, $R2$, $R3$, $R4$ in the sagittal plane, the appearance of an additional one, which twists the external support. This torque is determined by formula (3):

$$MR = L \cdot R, \quad (3)$$

where L is the distance between the distal “fragment” and the external support (the length of the rod), R is the load on the rod at the point of its contact with the distal fragment.

Now we can calculate the magnitude of the stresses that arise in the external support at the points of attachment of the rods (Fig. 11).

Similarly, we find the reactions of the support $R3$ and $R4$.

$$R3 = \frac{R1 \cdot (H1 + H2 + H3 + H4) - R2 \cdot (H3 + H4)}{H4}. \quad (4)$$

$$R4 = \frac{R1 \cdot (H2 + H3) - R2 \cdot H3}{H4}. \quad (5)$$

Based on the formulas and actual geometric dimensions, we calculate all the forces and torques acting on the external support at the places of attachment of the rods under the action of an external load of 5 kg (Table 2).

Having all the forces and moments of forces acting on the external support, we can construct diagrams that characterize the distribution of stress in its various areas (Fig. 12).

The obtained digital data revealed the following patterns:

1) in the case of a transversely directed force acting on the end of the distal “fragment” in the “fragment – ERD” design model, the highest level of loads occurs on the external support, directly at the nodes of connection of the rods with it. For example, for option number 5: if at the point of connection of rod 1 with the bone only a force of 56.9 N acts, which is located in the sagittal plane and a moment arises that bends the fragment, then at the point of its

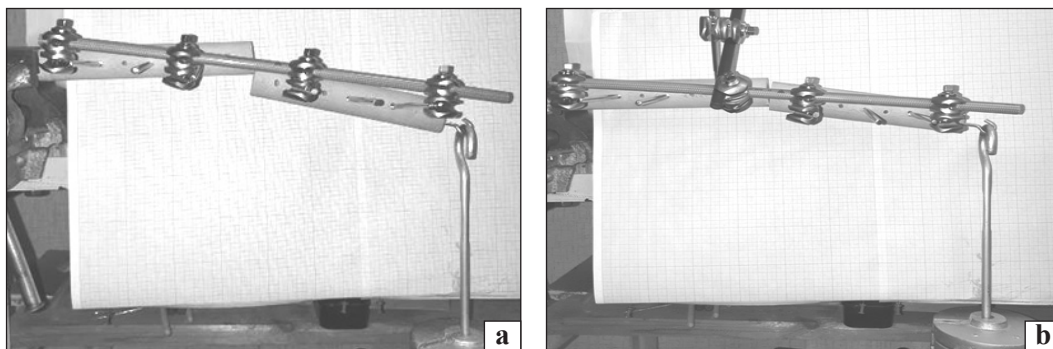


Fig. 8. The magnitude of the distal “fragment” displacement at maximum load of the model with the use of the “Orthofix” device, provided that all rods are located in the frontal plane (a) and during the insertion of one rod, which is in the proximal fragment in a plane that is at 45° to the frontal plane (b) (structure parameters 9, 14 in Table 1)

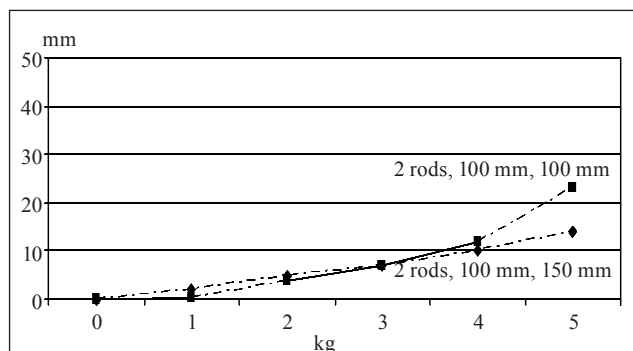


Fig. 9. Distal “fragment” displacement graphs during stepwise loading of the model using the “Orthofix” device under conditions of distance between the extreme rods of 150 and 100 mm with the same other parameters (items 5 and 9 of Table 1)

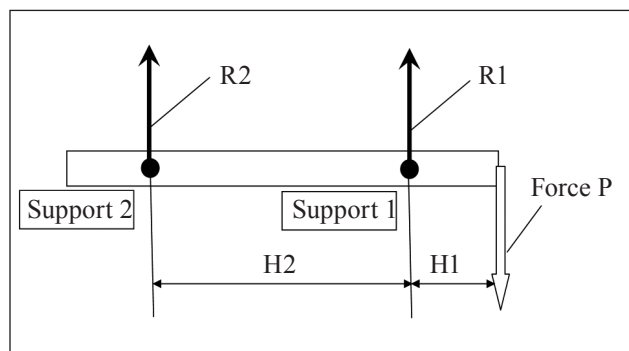


Fig. 10. Scheme for calculating the reactions of supports for the distal fragment, where P is the force with which the structure is loaded, $R1$ and $R2$ are the reactions of the supports, $H1$ is the distance from the point of application of the load to 1 support (1 rod), $H2$ is the distance between the supports (rods)

connection with the external support a torque of 5.7 N*m is added to these forces;

2) the load on the external support is not distributed evenly (consider example No. 11 of Table 1):

– the greatest in the sagittal plane is at the point of contact of rod 3 with the external support (122.6 N), and the least is in the area of location of rod 2 (7.8 N). Other zones have an intermediate load (rod 1 — 56.9 N, rod 4 — 73.5 N);

– the load in the sagittal plane creates stress in the external support, which leads to its bending. The stress that bends the external support is distributed as follows: from rod 1 it increases to 7.35 N*m (in rod zone 2), from rod 2 it continues to increase, but less actively and reaches 12.24 N*m in rod zone 3, and then decreases to 0;

– there is also a torque, which between 1 and 2 rods reaches 3.7 N*m, then between 2 and 3 rods decreases to 2.5 N*m, after 3 rod is equal to 0 (provided that 3 rod can completely absorb all the torque). It should be noted that in the sections between 1–2

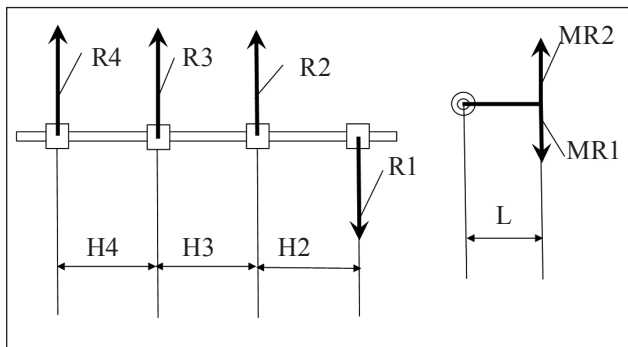


Fig. 11. Scheme for calculating the forces acting in the external support at the points of its connection with the rods, where R1 and R2 are the forces acting on the rod; R3, R4 are the reactions in the supports transmitted to the proximal fragment, MR1 and MR2 are the torques; H2 is the distance between the rods on the distal “fragment”, H3 is the distance between the second and third rods close to the “fracture”, H4 is the distance between the rods on the proximal “fragment”

and 3–4 rods the torque is absorbed by the “fragment – ERD” structures, which are connected by rods, and in the section between 2–3 rods this load is perceived only by the central section of the external support. Therefore, the most loaded is the support zone with clamps between 2 and 3 rods, which explains the appearance of deformations on the model of 3 rod in the form of plastic deflection and scrolling of the clamp on the support;

3) there is a direct relationship between the rod length (L) and the acting torque. Halving the rod's length (from 100 to 50 mm) reduces the torque on it by half (from 5.7 to 2.85 N*m).

Conclusions

In the case of connecting the “fragments” with external rod devices, a structure is formed, which, under the action of a transverse load of 1–5 kg on

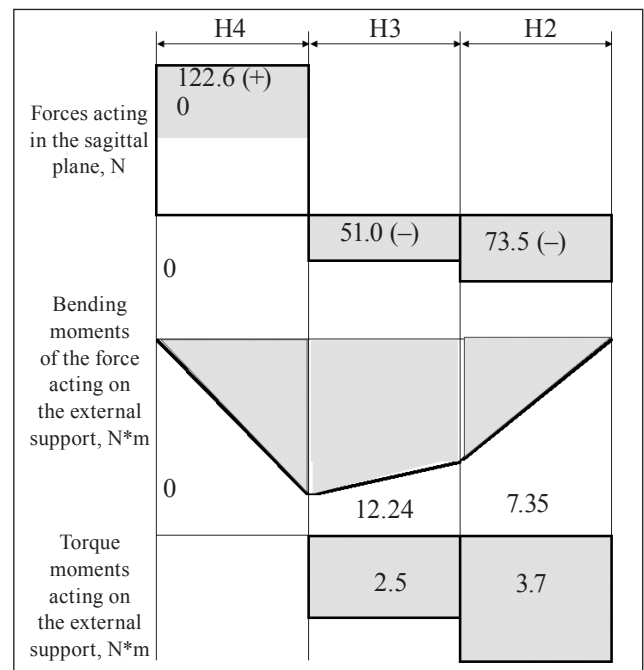


Fig. 12. External support load diagrams

Table 2

Calculation of all forces and torques acting on the external support at the rod attachment points for structures with two rods in debris

No. in Table 1	Geometrical parameter of the structure, mm					Magnitude of all forces and torques at maximum load (5 kg)						
	Distance from the loading point to the first rod, H1	Distance between the first and second rods H2, H4	Distance between the second and third rods (zone of “fracture”), H3	Distance between the third and fourth rods, H4	Rod length (distance between the fragments and the external support) L	R1, (H)	MR1, (H*m)	R2, (H)	MR2, (H*m)	R3, (H)	MR3, (H*m)	R4, (H)
5	25	150	50	150	100	56.9	5.70	7.8	0.8	122.6	5.0	73.5
7	25	150	50	150	50	56.9	2.85	7.8	0.4	122.6	2.5	73.5
9	50	100	100	100	100	73.5	7.30	24.5	2.5	171.6	5.0	122.6
11	50	100	100	100	50	73.5	3.65	24.5	1.2	171.6	2.5	122.6

the distal “fragment”, moves in width and at an angle. At the same time, the linear displacement of the end of the distal “fragment” near the fracture occurs within 1–41.7 mm, depending on the geometry of the formed “fragment - device” structure.

The first parameter in terms of significance that affects the displacement of the distal “fragment” is the distance from the bone to the support. At a distance of 50 mm, the displacement of the fragment is 2–4 times smaller than at 100 mm.

The second is the length of the bone section between the extreme rods screwed into the fragment. With a decrease of 30 %, the displacement increases by 64 % and almost does not depend on whether 2 or 3 rods were inserted.

Under stepwise transverse loading, the deformation of the structure at the initial stages (1, 2, 3 kg) is elastic in nature and with an increase (up to 4–5 kg) a residual deformation occurs, which is associated with the movement of the clamp on the cylindrical support or plastic deformation of the rods, which was inherent in the devices “HB ORTHO” (Ukraine).

Recommendations

The regularities that we discovered experimentally and through mathematical calculations can be used to improve external fixation devices and methods for connecting fragments with them.

1. When connecting fragments with external rod devices “HB ORTHO” and “Orthofix”, in cases where the external support is located at a distance of 100 mm from the bone or more, there is a risk of their repeated displacement, and in order to reduce it, it is necessary to have the information provided and learn to anticipate dangerous situations when the patients perform movements. The treatment method should include teaching the patient the procedure for transitioning from a horizontal position to a vertical one and vice versa and the “correct” way of walking with crutches.

2. When performing the operation of connecting fragments with an external rod apparatus for a diaphyseal fracture, the following principles should be observed:

- screw rods into each of the fragments at the maximum permissible distance from each other (within the diaphysis);

- place the external support as close as possible to the surface of the segment. A distance of 1–3 cm is rational;

- in the case of a bone fracture in the middle part of the diaphysis, it is advisable to use two rods in each of the fragments;

- use two-plane insertion of rods in the presence of a short fragment and a significant layer of soft tissues.

The manufacturer of the HB ORTHO device should pay attention to the design shortcomings identified as a result of the study and improve the device and its equipment.

Conflict of interest. The authors declare that there is no conflict of interest.

Prospects for further research. It is expected that the proposed methodology for studying the movement of fragments will be used to evaluate the properties of other fixation devices intended for the treatment of fractures.

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Authors' contribution. Popsuyshapka O. K. — justified the feasibility of the study, developed its methodology, conducted the study, analyzed the results, wrote 70% of the text of the article. Subbota I. A. — conducted the study, performed mathematical calculations, wrote the relevant part of the text.

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FEATURES OF DEFORMATION OF THE «DEBRIS – EXTERNAL CORE APPARATUS» MODEL IN THE CASE OF USING STRUCTURES WITH DIFFERENT STRUCTURAL GEOMETRY

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Mathematical modeling of the muscles responsible for shoulder joint flexion in upper obstetric paralysis

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Objective. To determine the degree of change in muscle length and torque of the shoulder joint during flexion in conditions of the pathological position of the upper limb in Erb-Duchenne syndrome. *Methods.* The analysis of the change in muscle length and torque of the shoulder joint was performed at flexion within 50°–60°. In the Erb syndrome clinic, the torque value of the joint is reduced due to weakness or paralysis of the muscles that provide stability and mobility of the shoulder joint. *Verification* of the appearance of the model was carried out according to the 3D-model obtained from the CT scan of the patient. *Results.* After analyzing the work of the muscles responsible for the flexion of the shoulder joint, it was determined that a decrease in muscle strength leads to a decrease in the moment of force acting on the joint, a change in the length of the force lever affects the moment of force, a change in the angle between the force and the arm of the force leads to a decrease in the muscle's efficiency. Internal rotation of the humerus reduces the length of the muscle, which is demonstrated in the models. When lifting the arm with a load, the muscle shortens and its length decreases accordingly. Other muscles not represented in the model do not contribute to the generation of torque of the shoulder joint due to their lack of direct connection to the humerus, but they are responsible for the movement of the scapula and clavicle. A decrease in their strength, a change in the direction of the force vector leads to significant changes in the ratio of the anatomical structures of the shoulder girdle with high individual variability. *Conclusions.* A change in the direction of the force vector of a muscle and its length during bending lead to changes in motor activity: a decrease in the moment of the joint leads to a limitation of the amplitude of movements in the joint, the balance between different muscles acting on the joint is disturbed, it can lead to its instability and deforms. Biomechanical changes limit the functionality of the joint and cause pain syndrome. The identified biomechanical changes indicate the need to correct the specified pathological conditions.

Мета. Визначити ступінь зміни довжини м'язів та крутного моменту плечового суглоба під час згинання в умовах патологічного положення верхньої кінцівки в разі синдрому Ерба-Дюшенена. *Методи.* Проаналізували зміни довжини м'язів і крутного моменту плечового суглоба за флексії в межах 50°–60°. За умов синдрому Ерба величина крутного моменту суглоба знижується через слабкість або параліч м'язів, які забезпечують стабільність і рухливість плечового суглоба. *Верифікацію* вигляду моделі проводили відповідно до 3D-моделі, яку отримали з КТ пацієнта. *Результати.* Розглянувши роботу м'язів, відповідальних за флексію плечового суглоба визначили, що зменшення сили м'яза призводить до зниження моменту сили, яка діє на суглоб, зміна довжини важеля сили впливає на момент сили, зміна кута між силою і плечем сили спричинює зменшення ефективності м'яза. Внутрішня ротація плечової кістки зменшує довжину м'яза, що продемонстровано на моделях. У разі згинання плечового суглоба довжина м'яза зменшується, причому в базовій і деформованій моделях однаково, хоча початкова довжина м'яза деформованої моделі менше, ніж у базовій. Інші м'язи, які не наведені в моделі, не впливають на створення крутного моменту плечового суглоба через відсутність їхнього прямого з'єднання з плечовою кісткою, але вони відповідають за рух лопатки та ключиці. Зменшення їхньої сили, зміна напрямку вектора дії сили призводить до значних змін співвідношення анатомічних структур плечового поясу з високою індивідуальною варіабельністю. *Висновки.* Зміни напрямку вектора дії сили м'яза та його довжини під час згинання спричинюють зміни в руховій активності: зменшення моменту суглоба спричинює обмеження амплітуди рухів у суглобі, порушується баланс між різними м'язами, які діють на суглоб, може призвести до його нестабільності та деформації. Біомеханічні зміни обмежують функціональність суглоба й обумовлюють больовий синдром. Виявлені біомеханічні зміни свідчать про необхідність корекції означених патологічних станів. *Ключові слова.* Акушерський параліч, синдром Дюшенена-Ерба, плечовий суглоб, момент суглоба, сила м'яза, моделювання.

Key words. Obstetric brachial plexus palsy, Erb-Duchenne syndrome, shoulder joint, joint moment, muscle strength, modeling

Introduction

Obstetric brachial plexus palsy occurs most often as a result of nerve damage in the shoulder area during difficult vaginal birth due to excessive forces applied to the shoulder, which cause it to stretch [1, 2]. It is observed in approximately 1–4 cases per 1,000 newborns. Anatomically, it occurs on both sides, but more often on the right.

Three main types are distinguished by the level of damage:

- upper (Duchenne-Erb palsy), when the C_V – C_{VI} roots are injured. Characteristic manifestations of the syndrome are the adducted and rotated inward arm, “waiter's hand pose”, impaired abduction and external rotation of the shoulder, limited forearm flexion;

- middle (Remak's palsy) — damaged C_{VII} roots, characterized by impaired extension of the forearm, extension of the hand and fingers. It can often be combined with the previous type;

- total (Dejerine-Klumpke paralysis) — roots C_V – C_{VIII} are affected. Signs include complete paralysis of the entire arm, “hanging arm”. Damage to T_1 can cause Horner syndrome (ptosis, miosis, enophthalmos).

In this study, we consider Erb-Duchenne syndrome. Erb's point is a place in the upper trunk of the brachial plexus, located 2–3 cm above the clavicle [3], formed by the union of the C_V and C_{VI} roots, which later converge. Damage to the axillary, musculocutaneous and suprascapular nerves leads to impaired nerve transmission and muscle atrophy and, as a result, to clinical manifestations of Erb's syndrome [4].

Surgical intervention at an early age (up to a year) increases the chances of partial or even complete restoration of limb functions. However, even with successful reconstruction, patients may have some residual movement impairment and may require long-term rehabilitation [5].

In medical practice, there are instances when conservative treatment of brachial plexus paralysis syndrome does not achieve the desired outcome, and early surgical intervention is not performed. The course of the disease for 4–10 years leads not only to the progression of muscle imbalance, but also to deformation of the bones of the upper limb with the involvement of the humeral head, often accompanied by its subluxation or dislocation. Changes in the anatomical proportions of the components of the shoulder joint cause violations of both the length of the muscles and the vector of their action, which, in turn, leads to a disorder of the movements of the upper limb.

The main goal of treatment of patients with a long course of Erb's syndrome is to restore the “hand-mouth” movement, that is, to provide basic conditions for self-service. It is the ability to perform the specified actions that allows the patient not only to eat independently, but also to perform most of the daily exercises [6].

Purpose: to determine the degree of change in muscle length and the magnitude of their torque in the shoulder joint during flexion in conditions of pathological position of the upper limb in the case of Erb-Duchenne syndrome.

Material and methods

The specificity of Erb's syndrome is the magnitude of the joint torque, which is reduced due to weakness or paralysis of the muscles that provide stability and mobility of the shoulder joint. In particular, the reduced torque affects the child's ability to abduct and externally rotate the shoulder, which limits the functionality of the hand. The joint torque is determined by muscle strength, shoulder length (perpendicular from the line of force to the axis of rotation) and the direction of force [7, 8].

The greatest force a muscle can develop when its fibers are stretched to the optimal length (individual for each). Given that the length of the lever (joint bones) does not change, the torque will be affected only by the muscle strength and the angle of its action. In the case of a long-term state of imbalance of the muscles of the joint, namely the weakening of those that abduct the shoulder back and the preservation of muscle strength from the side of the clavicle, the direction of action of the muscle force vector of the entire upper limb changes. This leads to a change in the joint torque and the direction of movement of the limb. The pathological position of the shoulder, such as pressing against the body, causes a decrease in the length of the muscles responsible for its abduction, which prevents full flexion of the joints of the arm, even if the innervation of the control muscles is intact.

The work is based on the DAS-3 model, which is part of the Dynamic Arm Simulator project for real-time modeling of the musculoskeletal system of the shoulder and arm. The main parameters of the basic model and the mathematical foundations are presented by E. Chadwick et al. [9].

The model consists of 138 muscles and 6 joints: supraclavicular, sternoclavicular, humeral, humeral-ulnar, humeral-radial and radiocarpal (Fig. 1, a).

In the modified model, the location of the humeral head in the joint was changed to the outside

by 45°, and the bones of the humerus were raised, which led to a corresponding change in the location of the entire shoulder joint (Fig. 1, b, c) and rotation of the elbow joint to the outside. The wrist was flexed at 30°, the arm was pressed against the body, internally rotated in the shoulder joint, the forearm was pronated, and the elbow joint was extended. The size of the scapula was reduced by 20 %. Verification of the appearance of the model was carried out according to the 3D model obtained using a CT scan of the patient (Fig. 2).

The analysis of changes in muscle length and torque of the shoulder joint was carried out with flexion within 50°–60°.

Results

The shoulder joint (*articulatio humeri*) is the most mobile joint of the bones. Its anatomical structure allows the upper limb to perform a wide range of movements, such as external and internal rotation, flexion, extension, abduction and adduction of the arm. With the help of the joint, various actions are performed by the upper limb. The most important movement that provides the possibility of self-service is the ability to

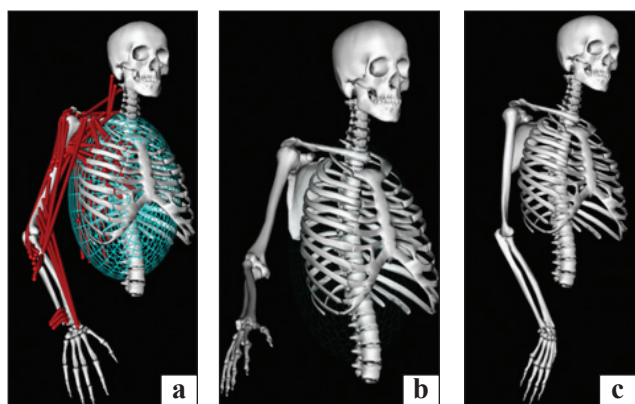


Fig. 1. DAS-3 model: basic models with muscles and contact geometry elements (a) and without muscles (standard joint arrangement) (b); c) modified model according to the description of the location of the shoulder girdle joints in Duchenne-Erb syndrome

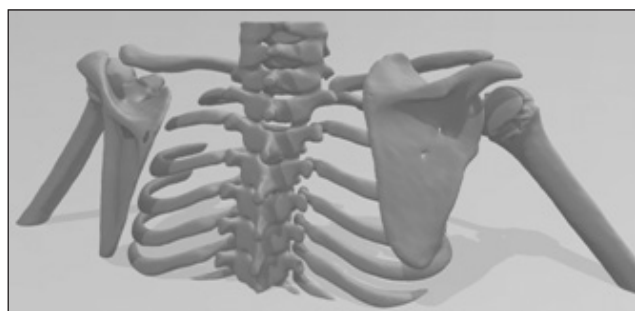


Fig. 2. 3D image obtained from the patient's CT scan

bring the palm to the mouth. Let us examine the functioning of the muscles responsible for this action.

The front part of the deltoid muscle (*m. deltoideus*) raises the arm forward, facilitating shoulder joint flexion. It is located in the area of the acromial, clavicular and scapular spine. Its acromial part (middle fibers) abducts the arm, while the clavicular and scapular play a significant role in stabilization, providing a stable plane of abduction. The clavicle can act as a flexor and internal rotator of the upper limb, while the scapula (posterior fibers) can extend and rotate the arm outward.

In the model, the deltoid muscle is represented by two muscle groups: *deltoid_clavicle* (4 fibers) and *deltoid_scapula* (11 fibers). The extreme fibers of the anterior and posterior parts of the muscle are analyzed in both the basic (N) and deformed (D) models (Fig. 3, c).

Assessment of the work of the anterior part of the muscle shows that normally, during flexion in the shoulder joint, the length of the fibers located dorsally increases most significantly (*N_delt_clav 4*), i. e., when the shoulder is raised, the muscle travels a longer path than its ventral part (*N_delt-clav 1*) (Fig. 3, a). In the deformed model, we observe a completely different picture, namely: internal rotation of the shoulder joint and medial adduction of the humerus lead to a greater stretching of the dorsal part (*D_delt_clav 1*) than the anterior part (*D_delt_clav 4*) (Fig. 3, a). The change in muscle length in the deformed model is less than in the baseline model.

The dorsal and ventral fibers of the posterior part of the *m. deltoideus* (Fig. 3, b) during flexion of the shoulder joint have the opposite direction of change in length, which is preserved during deformation of the model. But in the latter, the dorsal fibers are less stretched than in the normal one due to the reduced size of the scapula, i. e. due to the reduction in the length of the muscle itself. The anterior fibers of the posterior part of the *m. deltoideus* change their length little due to their more central location.

The *biceps brachii* muscle helps to raise the arm and supinates the forearm. It consists of a short and long head. The long head is located on the lateral side of the biceps brachii muscle, and the short head is on the medial side. The biceps brachii muscle is able to generate movements in the shoulder and elbow joints.

For the execution of the “hand-mouth” movement, *m. biceps brachii* controls both the shoulder and elbow joints, while the length of both heads of the muscle decreases, i. e. during the movement the muscle shortens. Normally, when the shoulder joint is flexed, the long head of *m. biceps brachii long head*

practically does not change its length. It is important to note that the observed phenomenon occurs when the arm is raised without any load, resulting in muscle shortening and a decrease in length. This scenario is not under consideration.

In the deformed model, a parallel trajectory of the reduction of the attachment points of both heads of the muscle can be observed, this is due to the fact that during internal rotation of the shoulder joint (Fig. 4, a) the long head of the muscle, which originates precisely at the head of the humerus, rotates to the middle position, i.e. becomes parallel to the short one, and the degree of contraction depends only on the initial length of the muscles.

During elbow flexion (Fig. 4, b) the trajectories of muscle length reduction are parallel, but in the deformed model they converge, for the reason already indicated.

The pectoralis major muscle (*m. pectoralis major*) is responsible for flexion and adduction of the arm and is the largest superficial muscle of the anterior chest wall. It has two heads: clavicular and sternocostal. In the model it is represented by two muscle groups *m. pectoralis major_clavicle* (2 fibers) and *m. pectoralis major_terez* (6 fibers) (Fig. 5, c). We analyze the extreme fibers of the sternocostal muscle and both clavicular fibers.

Changes in the length of the fibers of the clavicular head of *m. pectoralis major* occur unidirectionally due to their parallel arrangement, which is displayed on the graph (Fig. 5, a). A decrease in the length of the fibers during the function of flexion in the shoulder joint was recorded. The length of the corresponding muscles also changes in the deformed model.

The nature of the change in the length of the sternocostal part of the *m. pectoralis major* in the basic and deformed models is the same (Fig. 5, b). The fibers located caudal to the elevation of the shoulder increase, and in the coronary, on the contrary, decrease. In the deformed model, the process of muscle length changes is similar, but they are noticeably smaller.

It is noted that the *m. pectoralis major* is innervated by the T_I–T_{II} roots and is not injured in Erb's syndrome. Its function is preserved, unlike the muscles of the back. It is the predominance of the strength of the anterior group of muscles that leads to internal rotation and adduction of the humerus.

The coracobrachialis muscle (*m. coracobrachialis*) is involved in flexion and adduction of the arm. It starts from the beak-shaped process of the scapula, located on the supramedial part of the humerus. Its main function is to flex and adductorize the hu-

merus, and promote internal rotation of the arm. In the model, it is represented by three parallel fibers (Fig. 6, c). Let us analyze the change in the length of the longest fiber.

Internal rotation of the humerus reduces the length of the muscle, which is demonstrated in the models. During flexion of the shoulder joint, the length of the muscle decreases, and in the basic and deformed models it is the same, although its initial size in the deformed model is smaller than in the basic one.

We have considered the main muscles that provide movements in the shoulder joint. All of them, except for the pectoralis major muscle, are innervated by the roots of the C_V–C_{VI}, that is, they change their functionality in the case of Duchenne-Erb syndrome. A decrease in innervation, depending on the degree and location of the damage, leads to a decrease in muscle strength, sometimes to complete paralysis. That is, the mobility of the joint, which is characterized by its torque, changes, because the muscle strength, length and angle of action of its force vector affect it, provided that the length of the limb is preserved. We do not consider muscle paralysis. In the model with a deformed humerus, we reduce the strength of the muscles that innervate the joint by 50 %. Of course, this is conditional, because there is a large variability in both the change in muscle strength and the angle of their action during joint rotation.

Let us consider how a change in muscle strength and the vector of its action affect the torque of the joint. Therefore, it can be influenced only by the muscles that pass through the joint, or directly by the movement of its components. Let us analyze not individual muscle fibers, but the influence of the entire array on the joint. As the modeling showed, in the deformed model we observe a significant decrease in the torque of the joint. Thus, this torque, which is created by the clavicular part of the deltoid muscle, in the basic model has a characteristic increase in the phase from 20° to 30°. With an increase in the angle of flexion of the shoulder joint, further movement is intercepted by the muscles of the humerus (*m. biceps*), in the deformed model we observe a moderate increase in the action of the deltoid muscle throughout the entire time of flexion. The torque in the deformed model is noticeably less than in the basic one (Fig. 7, a).

The action of the scapular part of the deltoid muscle on the torque of the shoulder joint continues throughout the flexion phase. In the deformed model, the action of the scapular part of the deltoid muscle is

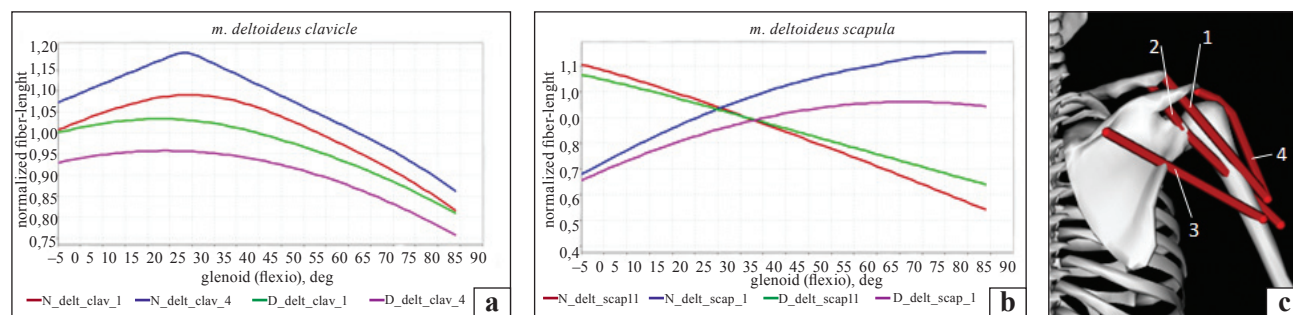


Fig. 3. Change in the normalized length of the *m. deltoideus* muscle during flexion of the shoulder joint: a) anterior section; b) posterior section; c) fibers of the *m. deltoideus* muscle: 1 — *delt_clav* 1; 2 — *delt_clav* 4; 3 — *delt_scap* 1; 4 — *delt_scap* 11

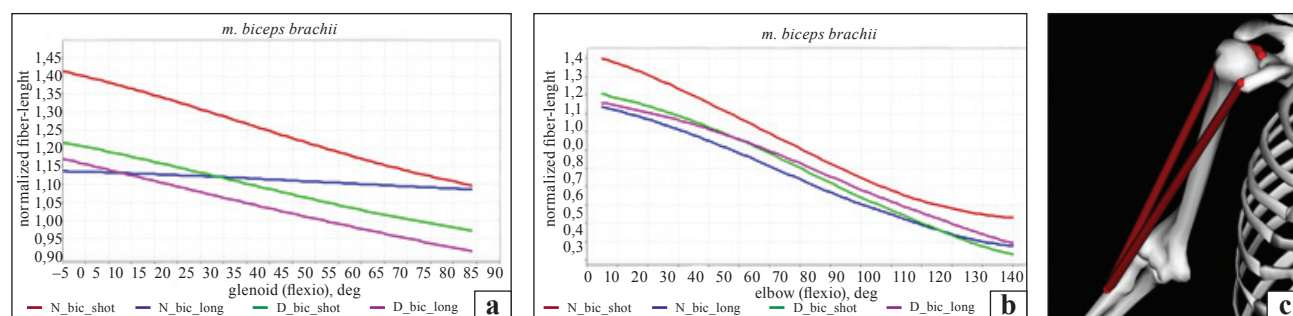


Fig. 4. Change in the normalized length of the *m. biceps brachii* muscle: a) during flexion of the shoulder joint; b) during flexion of the elbow joint; c) appearance of muscles in the model

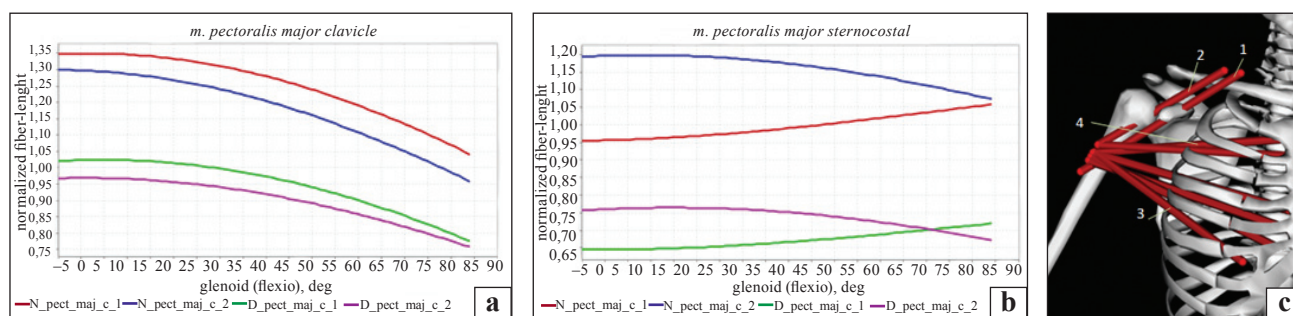


Fig. 5. Change in normalized length of *m. pectoralis major* during flexion of the shoulder joint: a) clavicular head of the muscle; b) sternocostal; c) *m. pectoralis major*: clavicular part 1 — *pect_maj_c* 1; 2 — *pect_maj_c* 2; costal part 3 — *pect_maj_t* 1; 4 — *pect_maj_t* 6

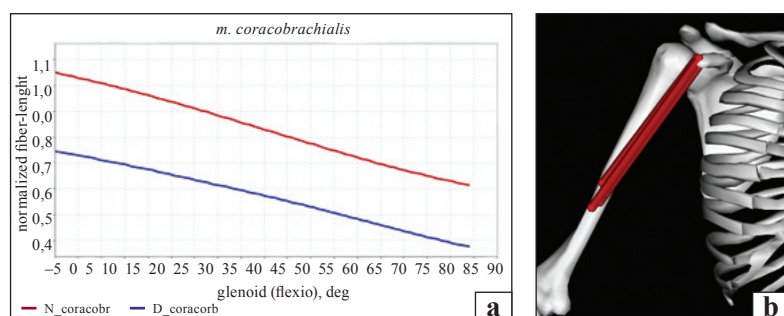


Fig. 6. Change in normalized length of *m. coracobrachialis* during flexion of the shoulder joint: a) in the basic and deformed models; b) *m. coracobrachialis*

practically constant, but at the initial stage it exceeds the corresponding torque in the basic one, which may indicate constant muscle tension (Fig. 7, b).

The pectoralis major muscle (*m. pectoralis major*) simultaneously acts from two structures of the joint,

the clavicle (Fig. 7, c) and the sternum (Fig. 7, d). Even without changing the force, in the deformed model the torque of the clavicular part of the muscle is less than in the basic one. In the thoracic one, on the contrary, it increases.

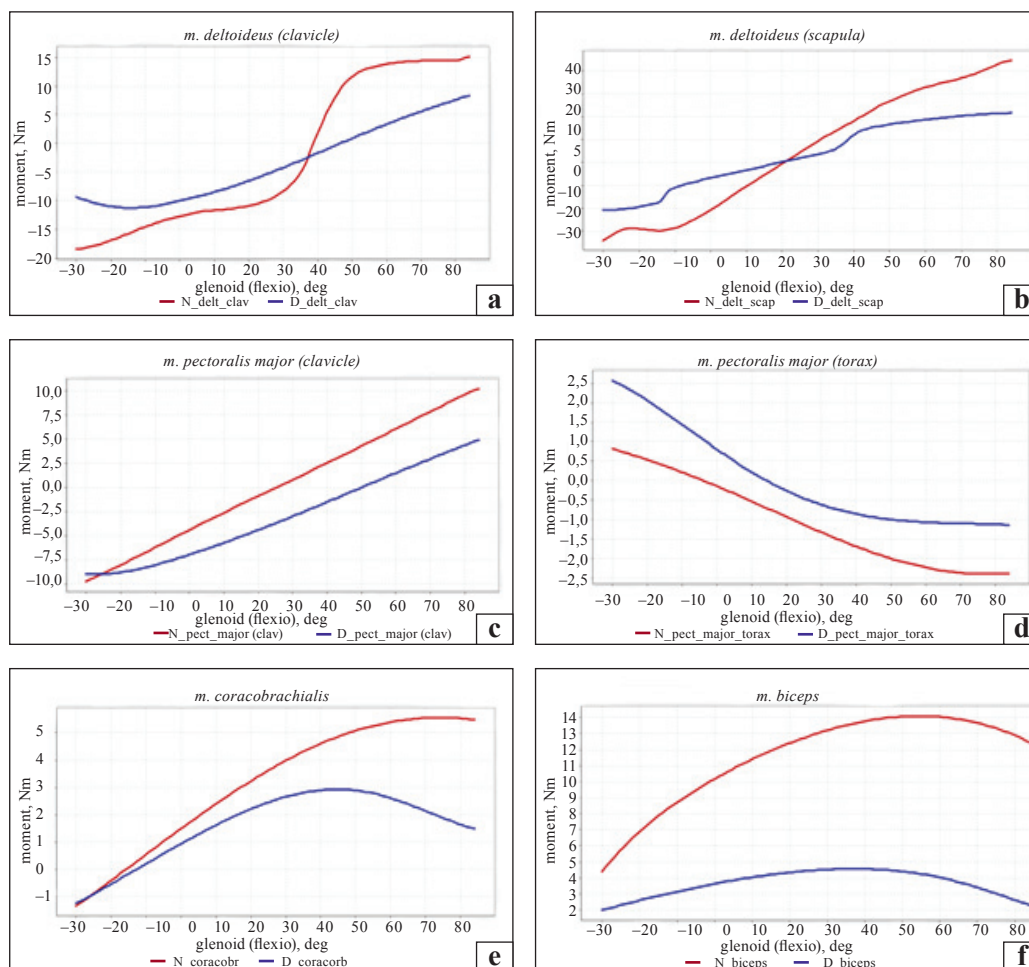


Fig. 7. Torque of the shoulder joint created by the muscles responsible for its flexion: a) *m. deltoideus (clavicle)*; b) *m. deltoideus (scapula)*; c) *m. pectoralis major (clavicle)*; d) *m. pectoralis major (thorax)*; e) *m. coracobrachialis*; f) *m. biceps*

The coracobrachialis muscle (*m. coracobrachialis*) takes an active part in raising the shoulder. In the basic model, its force is not changed. In the deformed state, the changes led to a significant decrease in the moment in the shoulder joint (Fig. 11, c) and were more gradual than in the baseline state.

The strength of both heads of the biceps is reduced, which led to a significant decrease in the moment, almost to the complete absence of muscle activation.

Other muscles do not affect the creation of the torque of the shoulder joint due to the absence of their direct connection with the humerus, but they are responsible for the movement of the scapula and clavicle. A decrease in their strength, a change in the direction of the action vector leads to significant violations of the ratio of the anatomical structures of the shoulder girdle with high individual variability.

Conclusions

Our findings allowed us to make the following generalizations: a decrease in muscle strength leads to

a decrease in the moment of force acting on the joint. This means that the muscle becomes less effective in creating movement in the joint. A change in muscle length due to prolonged restriction of mobility affects the torque of force.

A change in the angle of action of the muscle force causes a disruption of the normal biomechanics of the joint and can lead to a decrease in muscle efficiency.

Disruption of the function of one muscle causes a loss of synergy: the joint work of the muscles. Injuring one can affect the work of other muscles that are part of the synergistic group and additionally reduce the torque of the joint.

The data presented indicate significant changes in the motor activity of the joint: a decrease in torque leads to a limitation of the function (amplitude) of movements, a violation of the balance between different muscles that act on the joint, causes its instability and deformation. Biomechanical changes limit functionality and cause pain syndrome. The identi-

fied biomechanical changes indicate the need to correct the indicated pathological conditions.

Conflict of interest. The authors declare the absence of a conflict of interest.

Prospects for further research. In the future, it is of interest to study the possibility of glenoid remodeling after surgical interventions for muscle transpositions of the shoulder girdle.

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Authors' contribution. Karpinska O. D. — development of the mathematical model, data calculation, writing the text; Hrytsenko A. M. — collection and processing of materials, editing the text.

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MATHEMATICAL MODELING OF THE MUSCLES RESPONSIBLE FOR SHOULDER JOINT FLEXION IN UPPER OBSTETRIC PARALYSIS

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DOI: <http://dx.doi.org/10.15674/0030-59872025182-89>**The efficiency of surgical treatment and rehabilitation in the recovery of patients with a acetabular posterior wall fractures****M. L. Ankin¹, V. O. Ladyka¹, O. O. Glynyana², M. M. Barylovych¹**¹ Shupyk National Medical Academy of Postgraduate Education, Kyiv. Ukraine² Bogomolets National Medical University, Kyiv. Ukraine

Fractures of the posterior wall of the acetabulum are one of the most difficult injuries to treat in Orthopedics and traumatology. The most common causes of this fracture are road traffic accidents, falls from heights, and injuries resulting from military actions. There is a high risk of post-traumatic arthritis at later stages and avascular necrosis, often leading to future disability. Objective. to assess the efficiency of surgical treatment and rehabilitation in patients with acetabular posterior wall fracture. Methods. The study was conducted at the Kyiv Regional Clinical Hospital and Kyiv City Clinical Hospital No. 8 from 2021 to 2023. A total of 44 patients aged 19 to 68 participated in the study. Treatment outcomes and rehabilitation measures were assessed using the Matta and Harris Hip Score scales. All patients underwent open reduction and internal fixation of the posterior wall of the acetabulum with plates and screws. The Kocher-Langenbeck surgical approach was used in all cases. Clinical and radiological results were analyzed at 3, 6, and 12 months in all patients. Results. The Harris Hip Score in the main group was (81.51 ± 4.03) points at 6 months and (87.09 ± 5.31) points at 12 months. In the control group, the scores were (75.43 ± 4.45) at 6 months and (84.01 ± 4.17) at 12 months ($p < 0.01$). Conclusions. Early closed reduction of hip joint dislocation and surgery with reconstruction of normal joint anatomy and stable fracture fixation is crucial for efficiency of surgical treatment.

Перелом задньої стінки кульшової западини є однією з найскладніших травм, з якою стикаються ортопеди-травматологи. Найпоширенішими його причинами є дорожньо-транспортні пригоди, кататравми й ушкодження внаслідок воєнних дій. Високий ризик розвитку посттравматичного артрозу на віддалених етапах чи аваскулярного некрозу, часто призводить у подальшому до інвалідизації. Мета. Оцінити ефективність хірургічного лікування та реабілітаційних заходів щодо відновлення пацієнтів із переломом задньої стінки кульшової западини. Методи. Здійснено проспективний аналіз хворих, яких лікували на базі КНП КОР «Київська обласна клінічна лікарня» та КНП «Київська міська клінічна лікарня № 8» у період з 2021 по 2023 роки. До дослідження було залучено 44 пацієнти, середній вік яких становив $(42,2 \pm 13,1)$ року. Результати лікування та реабілітаційні заходи оцінювали за шкалами Матта й Harris Hip Score. Усім хворим виконано оперативне втручання — остеосинтез задньої стінки кульшової западини пластинами та гвинтами. Хірургічний доступ Кохера-Лангенбека використовувався у всіх випадках. Проаналізовано клініко-рентгенологічні результати через 3, 6 і 12 місяців. Результати. Показники, отримані за шкалою Harris Hip Score через 6 міс. в основній групі склали $(83,51 \pm 4,03)$ бала, через 12 місяців — $(87,09 \pm 5,31)$; у контрольній групі через 6 міс. — $(75,43 \pm 4,45)$ бала, через 12 — $(84,01 \pm 4,17)$ ($p < 0,01$). Висновки. На ефективність хірургічного лікування пацієнтів із переломами задньої стінки кульшової западини впливають: вчасне закриття усунення вивиху головки стегнової кістки, проведення оперативного втручання в найбільш ранній термін із відновленням нормальної анатомії суглоба, стабільною фіксацією перелому та ранній початок реабілітаційних заходів. Ключові слова. Перелом, реабілітація, задня стінка кульшової западини.

Keywords. Fracture, rehabilitation, posterior wall of the acetabulum

Introduction

Fractures of the posterior wall of the acetabulum are the most common type of injury to the acetabulum, often high-energy and combined with injuries to other organs. Surgical treatment is indicated in case of fractures of the acetabulum that lead to instability and incongruence of the joint, as well as in cases of injuries with the presence of bone fragments or soft tissues within this localization.

This group of fractures is characterized by a high level of early and late post-traumatic complications, which lead to disability in 73–88 % of cases [1]. Treatment tactics can vary from closed or open reduction of the dislocation of the femoral head, arthroscopy, osteosynthesis, and even hip arthroplasty [2]. Posterior hip fracture is intra-articular, presents a high risk of developing post-traumatic arthrosis, avascular necrosis in the late stages, and often causes disability. The percentage of these complications increases significantly with displaced fractures and largely depends on achieving anatomical reduction [3]. A well-performed surgical intervention is an important component, but no less important is comprehensive rehabilitation, which should complement the measures taken and help reduce secondary disorders. Rehabilitation treatment should be aimed at improving mobility in the hip joint, increasing strength, endurance, and functional independence of the patient in the shortest possible time.

Purpose: to evaluate the effectiveness of surgical treatment and rehabilitation measures in the recovery of patients with posterior hip fracture.

Material and methods

The study was carried out in compliance with the provisions of the Helsinki Declaration of Human Rights (2000), the Constitution and legislation of Ukraine on healthcare. The issues of bioethical expertise and ethics of scientific research were considered and approved by the commission of the P. L. Shupyk National Institute of Health of Ukraine (protocol No. 11 dated 16.11.2021). Informed consent was obtained from all patients included in the study.

A prospective analysis of 44 medical records of patients who were inpatients at Kyiv Regional Clinical Hospital and Kyiv City Clinical Hospital No. 8 in the period from 2021 to 2023 was conducted.

A physical examination was performed, radiographs before and after surgery, and computed tomography results were studied. The reduction was assessed using the Matt scale, and hip joint function was assessed using the Harris Hip Score scale.

The results were calculated using mathematical statistical methods.

Postoperative assessment of the reduction was performed using the Matt scale: anatomical (displacement up to 1 mm), imperfect (2–3 mm), unsatisfactory (more than 3 mm) [4]. Clinical and radiological results were analyzed after 3, 6, and 12 months in all patients in the postoperative period. A separate task was to study the effectiveness of intervention in the case of fractures of the posterior wall of the hip socket using the Harris Hip Score scale. The following indicators were assessed using it: “Pain”, the maximum score of 44 meaning the absence of pain, while severe pain at rest means 0 points; for the categories “Function”, “Amplitude of movements” and “Deformity” — 47, 5 and 4 points, respectively. The assessment of function is based on 4 categories: preservation of usual daily activity — 14 points, absence of lameness — 11, absence of need for assistive devices during walking — 11, duration of walking — 11. Preservation of preoperative range of motion is assigned 5 points, absence of deformity — 4. The maximum number of points for one joint that can be obtained by assessing the patient’s condition using the Harris Hip Score scale is 100. The sum of points from 100 to 90 is considered excellent, from 89 to 80 — good, from 79 to 70 — satisfactory, and less than 70 — unsatisfactory [5]. The gender distribution is as follows: men — 28 (63.6 %), women — 16 (36.4 %). The average age was (42.2 ± 13.1) years. The main mechanisms of injury: road accidents — 19 patients (43.2 %), due to military actions — 16 cases (36.4 %), catatraumas — 9 subjects (20.4 %) (Fig. 1).

Right-sided injury was recorded in 23 people (52.3%), left-sided — in 21 (47.7 %). Unremoved dislocation of the femoral head during hospitalization was diagnosed in 19 patients (43.2 %), the period of dislocation reduction from 1 to 26 days, average — (8.9 ± 2.6) days. The criteria for excluding patients from the study were complex fractures, which were combined with damage to internal organs (rectum, bladder) and craniocerebral trauma.

The primary task for traumatologists was closed reduction of dislocation of the femoral head at the earliest possible date. Closed reduction was successfully performed on the day of injury in 11 (57.9 %) patients, in the first 3 days after injury in 5 (26.3 %) patients, and delayed reduction was performed in 3 (15.8 %) cases. The time of surgical intervention from the moment of injury ranged from 1 to 26 days, with an average of (10.8 ± 3.8) days.

The Kocher-Langenbeck surgical approach was used in all cases. Reduction was performed using

traction devices on the operating table to fix the patient at the intact area at the level of the posterior superior iliac spine and femoral diaphysis. All patients underwent the following interventions: osteosynthesis of the posterior wall of the acetabular fossa with plates and screws. The size of the plate depended on the number and size of the fragments. The main goal of osteosynthesis was to achieve anatomical reduction and stable fixation of the fracture. During the operation, revision of the *n. ischiadicus* and its protection from intraoperative damage.

For all patients, the management protocol included: after hospitalization, the imposition of a skeletal traction system over the supracondylar zone of the femur, ultrasound Dopplerography of the vessels of the lower extremities before and after osteosynthesis, surgical intervention for the timely detection of thrombotic complications.

Rehabilitation measures, which were an important component of the patients' recovery, began the day after their hospitalization.

The acute period (the patient was on skeletal traction) included therapeutic interventions: familiarization with the method of treatment of the injury, rehabilitation measures, possible complications and

measures to avoid them; cold therapy (to reduce pain and sensitivity). The following exercises were also performed:

- for a healthy lower limb (LL) — flexion/extension in the knee, hip, supracalcaneal-tibial joints, abduction/adduction in the hip joint;
- raising the pelvis with support on a healthy lower limb (prevention of bedsores);
- for the upper limbs (UL) — sitting in bed with support on a Balkan frame;
- for an injured LL — ideomotor, movements in the supracalcaneal-tibial joint;
- respiratory — diaphragmatic breathing, training in full exhalation, coughing and expectoration of secretions, use of a breathing simulator for the prevention of respiratory complications.

According to the results of the obtained reposition according to the Matt scale, patients were divided into two identical groups, the main ($n = 22$) and the control ($n = 22$).

The control group ($n = 22$) was engaged in the traditional program of medical institutions, which included: performing therapeutic exercises (general-developing, isometric, passive, passive-active and active), early verticalization of patients, movement with assistive devices, therapeutic massage, cold and magnetolaser therapy.

In the main group ($n = 22$), the developed program was used, which included, in addition to traditional ones, modern methods and means of rehabilitation: cryotherapy, TENS therapy, myofascial release, soft tissue mobilization (with elastic floss tape, blade), a set of therapeutic exercises with Thera-bend, on spheres and hemispheres (Table 1). The rehabilitation program after surgery included three periods, which are given in Table 1.

In addition to the listed methods and means in the acute period, an important aspect was the early mobilization of patients. At the beginning, verticalization was carried out with the mandatory use of compression therapy (elastic bandaging or compression stockings), learning to move with means for additional support. Patients who did not have excess weight and coordination problems moved with inguinal crutches without loading the operated limb, only the first toe was allowed to touch the floor, individuals with high risk factors for falling walked with the help of a walker. During training to walk on crutches, a two-support technique was used, in which the point of support was on the healthy LL, the crutches and the damaged limb acted as one whole, and the healthy one as a separate unit. Patients were taught to climb stairs using first the healthy

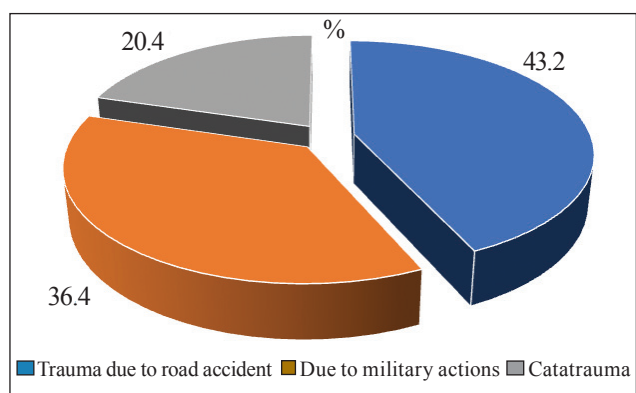


Fig. 1. Distribution of patients in the prospective group by mechanism of traumatic injury

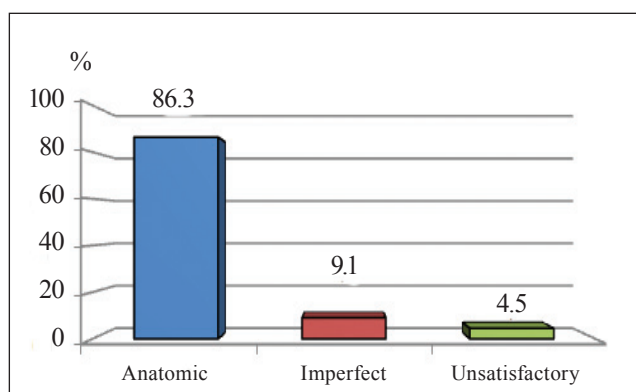


Fig. 2. Results of reduction according to the Matt scale

hip joint, then carry crutches simultaneously with the operated limb, and when descending the stairs, first lower the crutches and the damaged, and then the healthy hip joint.

In the presence of pronounced edema of the operated hip joint, elevation was performed 2–3 times a day for 20–30 minutes. Initially, the amplitude of movements in the operated hip joint was limited due to edema, inflammation, and initial adhesion between the lateral vastus femoris muscle and the tensor fascia latae femoris muscle, so movements were performed passively and passively-actively for several days. Patients were advised to avoid hyperextension, internal rotation, and lifting of the operated straight hip joint in the hip joint. Active therapeutic exercises for the gluteus maximus muscle and its strengthening were limited in the first 6 weeks due to the possibility of hip hyperextension.

The main aspect was the functional activity and independence of the patient: they were taught to roll over to the uninjured side, sit up independently, get out of bed, dress using the injured limb, and undress using the healthy limb. Initially, the patients needed help, and later they independently performed daily activities with the use of assistive devices (elevated

toilet seat, reach devices for putting on socks and pants) to reduce the load on the operated joint.

Therapeutic exercises were performed according to pain tolerance, the visual analogue scale (VAS) score was within 4 points [6]. Further change in the load on the operated limb was selected according to the results of the radiograph, fracture stability and the course of union.

Results

The average term of radiographic consolidation of the fracture was (12 ± 3) weeks. Among the patients in the postoperative period, the following complications were diagnosed: post-traumatic sciatic nerve neuropathy, in the main group in 1 (4.54 %) person and in the control group in 2 (9.09 %); heterotopic ossification in 4 (18.2 %) patients in the main group and in 7 (31.8 %) in the control group; aseptic necrosis of the femoral head in 6 (27.3 %) patients in the main group and 9 (40.9 %) in the control group.

After surgical treatment, an assessment was made using the Matt scale: in 38 patients (86.5 %) anatomical reduction of up to 1 mm was achieved, in 4 (9 %) it was not ideal (up to 2–3 mm), and in 2 patients (4.5 %) it was unsatisfactory (more than 3 mm), the results are shown in Fig. 2.

Table 1

Rehabilitation program for patients after surgical treatment for a fracture of the posterior wall of the acetabulum

Period	Acute	Post-acute	Prolonged
Task	1. Management of edema and pain 2. Early mobility and verticalization 3. Strengthening of the upper shoulder girdle muscles and healthy NC 4. Adaptation to load 5. Prevention of contracture in the hip joint	1. Management of edema and pain 2. Improvement of muscle strength, functional indicators in the hip joint 3. Improvement of balance and coordination 4. Maintenance of physical fitness 5. Return of the patient to self-care	1. Restoration of full function in the hip joint 2. Restoration of the correct gait pattern 3. Restoration of muscle strength 4. Return to professional activity
Methods and means	1. Cryotherapy 10 min 3 times a day (5 procedures) 2. Mechanotherapy on the CPM device 20 min once a day (10 procedures) 3. Lymphatic drainage massage 10–15 min (10 procedures) 4. Active therapeutic exercises in all joints of a healthy LL and UL 5. Passive, passive-active and active movements in the operated joint 6. Isometric tension of the quadriceps muscles 7. Isotonic exercises for the supracalcaneal-tibial joints 8. ADL training (skills in daily life)	1. Therapeutic exercises (general-developing, special, stretching, breathing, isometric, movements with a scar) 2. Myofascial release, mobilization of soft tissues (elastic floss tape, blade) 3. TENS therapy (once a day for 10 min) 4. Functional mobility training (moving in bed, walking up stairs) 5. ADL training (using aids for dressing, hygiene, etc.)	1. Therapeutic exercises (functional, stretching, with resistance to increase muscle strength with Theraband), coordination on spheres and hemispheres) 2. Mechanotherapy (Nautilus exercise bike to strengthen the quadriceps) 3. Heat compresses were applied remotely to the spasmed muscles before performing the exercises

The assessment of the results using the Harris scale in subgroups, carried out using the Shapiro-Wilk test, showed compliance with the parameters of the normal distribution ($p = 0.382\text{--}0.573$), which allows using the arithmetic mean (M) and standard deviation (SD) for descriptive statistics of the results. At the same time, the presence of the number of observations in subgroups less than 30 ($n = 22$), made it advisable to use non-parametric criteria for comparing the results between groups (Mann-Whitney test) and in time course (Wilcoxon test).

The results of treatment according to the Harris Hip Score scale are given in Table 2.

A statistical analysis of the influence of the timing of surgical intervention on the achievement of anatomical reduction of the fracture was performed (Table 3).

A study of the patterns of development of aseptic necrosis depending on the timing of the elimination of dislocation of the femoral head is given in Table 4.

Discussion

A significant part of domestic and foreign works presents conservative and surgical methods of treatment for fractures of the posterior wall of the acetabulum. The authors emphasize that the recovery of patients is influenced by a number of factors, including the type of fracture, damage to the femoral head, concomitant injuries, timing of the operation, quality of osteosynthesis and surgical access [3, 7, 8]. Complications in the case of fractures of the acetabulum

include postoperative infection, sciatic nerve damage, heterotopic ossification, thromboembolic complications, malunion and nonunion [9].

N. Kaple, M. Lakhwani provide rehabilitation measures for the recovery of patients with this type of fracture using the skeletal traction method. However, it requires a long stay of the patient in a horizontal position, which makes it impossible to quickly restore functional indicators in the hip joint and contributes to an increase in risks from the cardiovascular, respiratory systems and musculoskeletal system. Pressure ulcers, infections of the spinous canal and urinary tract, thrombosis, pneumonia are possible side effects of prolonged bed rest [10].

Most authors emphasize the importance of surgical treatment for a fracture of the posterior wall of the acetabular fossa and high-quality reconstruction of the fracture [3, 9, 11]. We believe that the best method of surgical intervention in patients with posterior acetabular fractures is a bridge-like bone metal osteosynthesis (the plate is located from the ischial tuberosity to the roof of the acetabular cavity) using the Kocher-Langenbeck approach. The main goal is to achieve anatomical reduction, which directly affects the outcome of treatment. A mandatory task during surgery is revision, protection and analgesia of the sciatic nerve.

A fairly small part of the studies is devoted to rehabilitation measures [10, 12], which are an important component of the prevention of pre- and postoperative complications in patients with posterior acetabu-

Results of assessing hip joint function using the Harris Hip Score (M $\pm$ SD)

Table 2

Stage (months)	Harris Hip Score criteria and groups		P (MW)
	main (n = 22)	control (n = 22)	
Pain level			
3	33.04 ± 4.01	30.19 ± 4.16	0.0250*
6	38.47 ± 4.41	34.51 ± 4.73	0.0060*
12	42.26 ± 4.52	39.36 ± 3.69	0.0240*
P (3–6)	0.0001*	0.0020*	—
P (3–12)	0.0001*	0.0001*	—
HHS (general)			
3	78.03 ± 4.15	69.14 ± 4.38	0.0001*
6	83.51 ± 4.03	75.43 ± 4.45	0.0080*
12	87.09 ± 5.31	84.01 ± 4.17	0.0380*
P (3–6)	0.0090*	0.0040*	—
P (3–12)	0.0001*	0.0001*	—

Notes: P (MW) — comparison between groups according to the Mann-Whitney test (* — difference is statistically significant); P (3–6), P (3–12) — assessment of indicators in dynamics according to the Wilcoxon test (* — difference is statistically significant); M $\pm$ SD — arithmetic mean and standard deviation.

lar fractures. Most programs include therapeutic exercises, massage and verticalization of the patient, but do not take into account a comprehensive approach involving educational work with the patient, the use of mechanotherapeutic means, physiotherapeutic, myofascial techniques for working with muscles and postoperative scar, which improves and accelerates recovery.

Studying the analysis, we believe that the result is influenced by the quality of reposition, the timing of surgical intervention from the moment of injury, early start of rehabilitation measures. The best result was found in patients who underwent surgery within 21 days from the moment of injury, achieved anatomical reposition and began rehabilitation measures immediately from the moment of hospitalization to the hospital. Among the rehabilitation measures, the following had the greatest impact: a comprehensive approach, early mobilization of the patient, measures to reduce swelling and stiffness in the hip joint,

increase muscle strength, improve daily activities and activity.

Clinical case number 1

A 52-year-old patient Z. was treated in the conditions of Communal Non-Profit Establishment Kyiv City Clinical Hospital No. 8. The injury was received as a result of a road accident on 27.06.2023. Diagnosis: closed fracture of the posterior wall of the left acetabular fossa with displacement, condition after removal of the dislocation of the left femoral head (28.06.2023).

He underwent conservative treatment at the Central Regional Hospital and was hospitalized in the Kyiv City Clinical Hospital No. 8 on 03.07.2023. Rehabilitation measures began on 04.07.2023. Surgical intervention was performed on 10.07.2023 — open reduction of fragments of the left acetabular fossa, metal osteosynthesis of the fracture with a plate and screws. Evaluation of results according to the Harris scale: after 3 months — (79.12 ± 2.41) points, after 6 months — (83.02 ± 3.84) , after 12 months — (85.42 ± 3.12) .

Clinical case No. 2

A 60-year-old patient G. was treated in the conditions of the Communal Non-Profit Establishment of Kyiv Regional Council “Kyiv Regional Clinical Hospital”. She received the injury as a result of a fall from a height on 03.12.2021. Diagnosis: closed fracture of the posterior wall of the left acetabular fossa with displacement. Hospitalized to the CNP KRC “Kyiv Regional Clinical Hospital” on 03.12.2021. Rehabilitation measures were started on 04.12.2021.

Table 3
Analysis of the influence of the timing of the surgical intervention on fracture reduction

Duration of surgery (number of days)	Patient distribution	Frequency of anatomical reduction
Up to 7	36 (81.8 %)	34/36 (94.4 %)
7–21	5 (11.4 %)	3/5 (60.0 %)
21 and more	3 (6.8 %)	1/3 (33.3 %)
p (χ^2)	—	p = 0.002*

Note. P (χ^2) is a comparison between groups (* — the difference is statistically significant).

Results of the study of the patterns of development of aseptic necrosis

Day of dislocation reduction	Patient distribution	Frequency of initial signs of ANFH	Necrosis index (Koo and Kim)		
			A	B	C
First	11 (57.9 %)	8/11 (72.7 %)	6 (54.5 %)	2 (18.2 %)	—
Up to 3	5 (26.3 %)	5/5 (100.0 %)	1 (20.0 %)	4 (80.0 %)	—
3–26	3 (15.8 %)	3/3 (100.0 %)	—	2 (66.7 %)	1 (33.3 %)

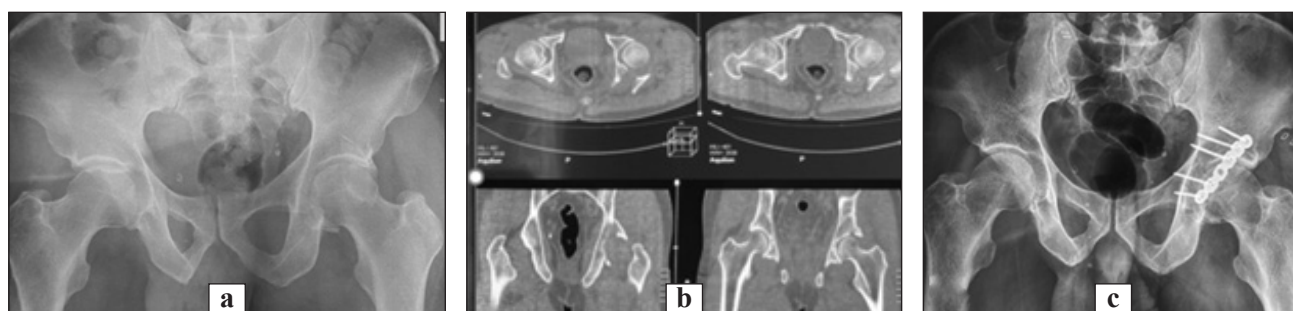


Fig. 3. Radiographs and CT scans of the posterior acetabular fracture of patient Z.: a), b) fracture of the posterior wall of the left acetabular fossa; c) condition after osteosynthesis of the acetabular fossa with a plate and screws

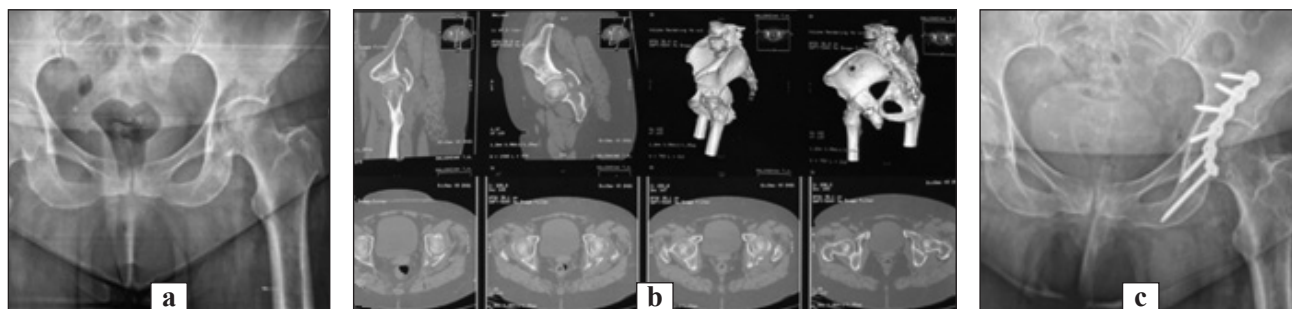


Fig. 4. Radiographs and CT scans of the posterior acetabular fossa fracture of patient G.: a, b) fracture of the posterior wall of the left acetabular fossa; c) condition after osteosynthesis of the acetabular fossa with a plate and screws

Surgery was performed on 06.12.2021 — open reduction of fragments of the left acetabular fossa, metal osteosynthesis of the fracture with a plate and screws. Evaluation of results according to the Harris scale: after 3 months — (80.02 ± 2.11) points, after 6 months — (83.21 ± 3.78) , after 12 months — (88.62 ± 5.37) .

Conclusions

The effectiveness of surgical treatment of patients with fractures of the posterior wall of the acetabulum is influenced by closed removal of the dislocation of the femoral head and surgical intervention at the earliest possible date with restoration of normal anatomy of the joint, stable fixation of the fracture. The statistical analysis showed that removal of the dislocation of the femoral head on the first day after the injury reduces the risk of aseptic necrosis by 26.3 % compared to a later date of removal of the dislocation. When surgical intervention is performed within the first 7 days after the injury, the possibility of achieving anatomical reduction of the fracture is 94.4 %, while if the intervention is performed within the period of 7–21 days or more, it is 60 and 33.3 %, respectively.

The proposed rehabilitation program for the main group: therapeutic exercises, cryo- and TENS-therapy, myofascial release, soft tissue mobilization (elastic floss tape, blade), a set of therapeutic exercises with Thera-band, on spheres and hemispheres contributed to the restoration of functional indicators in the hip joint according to the Harris Hip Score scale in comparison with the control group after 3 months by 12 and after 6 months by 10.7 %.

Conflict of interest. The authors declare the absence of a conflict of interest.

Prospects for further research. In the future, research on optimizing the comprehensive treatment of patients with hip joint damage is of interest.

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Authors' contribution. Ankin M. L. — concept and design, collection and processing of materials, editing of the text; Ladyka V. O. — analysis of the received data, editing of the text; Glynyana O. O. — analysis of the received data, writing and editing of the text; Barylovych M. M. — analysis of the received data, writing and editing of the text.

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THE EFFICIENCY OF SURGICAL TREATMENT AND REHABILITATION IN THE RECOVERY OF PATIENTS WITH A CETABULAR POSTERIOR WALL FRACTURES

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SHORT REPORTS AND NOTES FROM PRACTICE

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DOI: <http://dx.doi.org/10.15674/0030-59872025190-95>**Use of individual instrument for high tibial valgus osteotomy in varus gonarthrosis****M. L. Golovakha¹, S. A. Bondarenko², R. Hart³, W. Orljanski⁴**¹ Zaporizhzhia State Medical and Pharmaceutical University. Ukraine² Clinic «Motor Sich». Ukraine³ MHA Wiener Gesundheitsverbund Klinik Ottakring. Austria⁴ «Wiener Privat klinik». Austria

The work purpose was to present a new method of preoperative planning of high valgus tibial osteotomy with an individual instrument. Methods. Computed tomography (CT) of the lower extremities of a patient with stage II varus gonarthrosis was used. Bone segmentation from surrounding tissues, modeling of the lower extremities, correction of the tibia axis, and construction of individual blocks for resection were performed. The individual instrument is a block for performing osteotomy with depth indication and a hole for the upper middle screw of the T-shaped plate and two individual wedges for opening the osteotomy to the marks applied to them. The surgical intervention was performed with fluoroscopy control after knee arthroscopy. Partial removal of the medial meniscus and microfracture of the cartilage defect of the medial femoral condyle were performed simultaneously. Results. The planned correction of the tibia was accurately reproduced, which was confirmed by CT after surgery. In the postoperative period, there were no complications with wound healing, loading of the limb was started after 3 weeks, walking with a cane after 6, and without additional support after 10. X-rays were performed after 6, 12 weeks and 6, 12 months after the operation. A year later, the full range of motion and symmetrical walking were restored. The individual instrument allowed for quick and accurate placement of the plate, and wedges for opening the osteotomy helped to correctly reproduce the correction and hold it during osteosynthesis. Conclusion. The use of the proposed individual instrument for high valgus tibial osteotomy was convenient, simplified some stages of the surgical intervention, and ensured accurate planned correction of the angular deformity.

Мета. Навести нову методику передопераційного планування високої вальгівуючої остеотомії великогомілкової кістки з виготовленням індивідуального інструмента. Методи. Використано комп'ютерну томографію (КТ) нижніх кінцівок пацієнта з варусним гонартрозом II стадії. Було здійснено сегментування кістки від навколишніх тканин, моделювання нижніх кінцівок, корекція осі великогомілкової кістки та побудова індивідуальних блоків для резекції. Індивідуальний інструмент — це блок для виконання остеотомії із вказанням глибини й отвором під верхній середній гвинт Т-подібної пластинки та два індивідуальні клини для розкриття остеотомії до нанесених на них міток. Оперативне втручання проведено з рентгеноскопичним контролем після артроскопії колінного суглоба. Одночасно здійснено парціальне видалення медіального меніска та мікрофрактуризацію дефекту хряща медіального виростка стегнової кістки. Результати. Заплановану корекцію великогомілкової кістки точно відтворено, що підтвердило КТ після втручання. У післяопераційному періоді не було ускладнень із загоєнням рани, навантаження кінцівки розпочато через 3 тижні, ходьба з тростиною — через 6, а без додаткової опори — через 10. Рентгенографію проводили через 6, 12 тижнів та 6, 12 міс. після операції. Через рік відновлено повний обсяг рухів та симетричну ходьбу. Індивідуальний інструмент дозволив швидко та точно встановити пластинку, а клини для розкриття остеотомії допомогли правильно відтворити корекцію й утримувати її під час остеосинтезу. Висновок. Використання запропонованого індивідуального інструмента для високої вальгівуючої остеотомії великогомілкової кістки було зручним, спростило деякі етапи проведення оперативного втручання та забезпечило точну заплановану корекцію кутової деформації. Ключові слова. Остеотомія, індивідуальний інструмент, гонартроз.

Key words. Osteotomy, individual instrument, gonarthrosis

Introduction

Corrective osteotomy of the tibia is one of the widely used surgical methods that allow preserving the knee joint for a long period of time [1, 8, 9]. It is combined with arthroscopy, as well as various chondroplasty techniques. Using corrective osteotomy, we can restore the function of the knee joint against the background of various deformities for a period of at least 8 years [3, 8, 11]. The problematic issues lie simultaneously in several planes:

- at what stage should the patient be offered osteotomy;
- how best to replace the cartilage defect;
- within what limits should the axis of the knee joint be corrected;
- how to ensure the accuracy of the planned correction of the deformity?

Purpose: to present a new method of preoperative planning of high valgus osteotomy of the tibia with the manufacture of an individual instrument.

Material and methods

The study was approved by the ethics committee of the Zaporizhzhia State Medical and Pharmaceutical University (protocol No. 8 dated 26.12.2022), the patient's informed consent was obtained.

This study presents the result of the treatment of a 53-year-old patient L. with secondary osteoarthritis of the knee joint and varus deformity (Fig. 1), who underwent corrective osteotomy using an individual instrument. Body mass index — 32 kg/m², varus deformity with a peak in the proximal tibia, without significant damage to the lateral knee joint, stage II by Kellgren-Lawrence classification.

The study used computed tomography (CT) of the patient's lower limbs with a slice thickness of 0.8 mm. The design was carried out in two stages: 1) segmentation of the bone from the surrounding tissues was performed in the Materialise Mimics 26.0 software; 2) modeling of the lower limbs, correction of the tibia axis and construction of individual blocks for resection were performed in the Geomagic FreeForm Plus software (Fig. 2).

The basis for planning an osteotomy in the knee joint area is the femur. Therefore, the sagittal and frontal planes of the model were installed on it and the slope of the “knee joint line” was assessed, which in three-dimensional modeling does not look like a line, but a plane. This is determined by the structure of the femur — in this case, the slope of the knee joint plane was normal. The software restored the correct mechanical axis of the limb by means of a virtual high valgus opening osteotomy (Fig. 3).

After compensating for the deformity, we measured the correction angle and planned the osteotomy level, the position of its plane and the position of the plate for osteosynthesis (Fig. 4). Finally, we designed an individual instrument consisting of a cutting block with holes for guide wires along the osteotomy plane and a channel for the upper middle screw of the Tomofix plate [2], as well as two individual wedges for opening the osteotomy with marks of their insertion depth (Fig. 5). The patient data, the depth of the osteotomy and the drilling of the channel for the upper middle screw of the plate were applied to the cutting block. After approval, the tibial model, cutting block and wedges were printed from the medical photopolymer resin Dental SG Resin (Fig. 6).

After surgery, a CT scan of the knee joint was performed and the accuracy of the instrument was assessed by comparing the radiographic parameters of the osteotomy planning and the data after the intervention. The operation was performed according to a known technique with fluoroscopy control after knee arthroscopy [5, 8, 9]. Partial removal of the medial meniscus and microfracture of the cartilage defect of the medial femoral condyle were performed simultaneously. During the surgical intervention, after the proximal tibia was isolated, we applied the individual cutting block to the model and to the bone alternately, trying to achieve maximum compliance of the block position. The stages of the surgical intervention of the double high valgus osteotomy of the tibia are shown in Fig. 7.

Results

To verify the accuracy of the application of the individual instrument for corrective osteotomy, we performed a virtual installation of individual cutting guides and wedges in a three-dimensional model, which was built using a CT scan of the patient after surgery. Thus, Fig. 8 shows a model of the lower limb after surgery, an open osteotomy, virtually “inserted” wedges and an applied individual template for cutting.



Fig. 1. X-ray of the knee joint of a 53-year-old patient L. before surgery

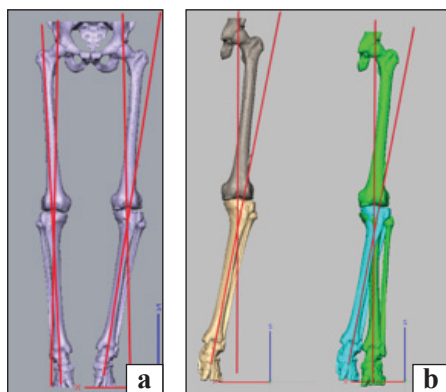


Fig. 2. Limb model for planning osteotomy, determining deformation and assessing the limb axis (a); measuring the required correction angle (b)

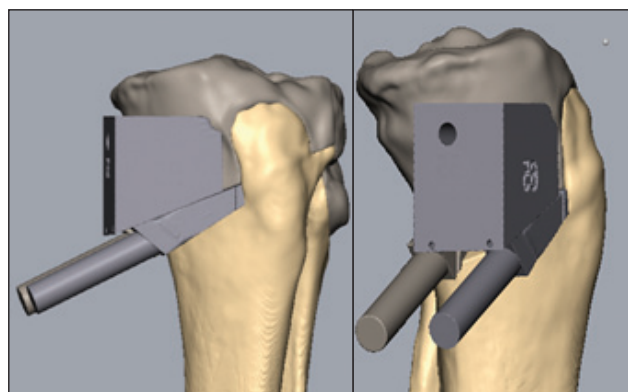


Fig. 5. Designing individual wedges to hold the osteotomy opening and the hole for the upper middle screw of the plate

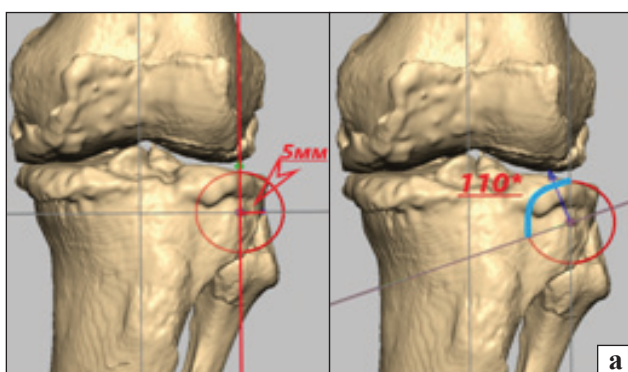


Fig. 3. Osteotomy planning: a) the upper point of the osteotomy at the level of the fibular head, which is 5 mm from the cortical layer; b) double osteotomy design

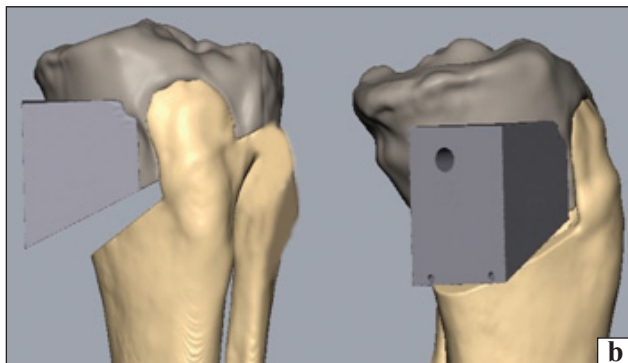


Fig. 4. Modeling the plate position

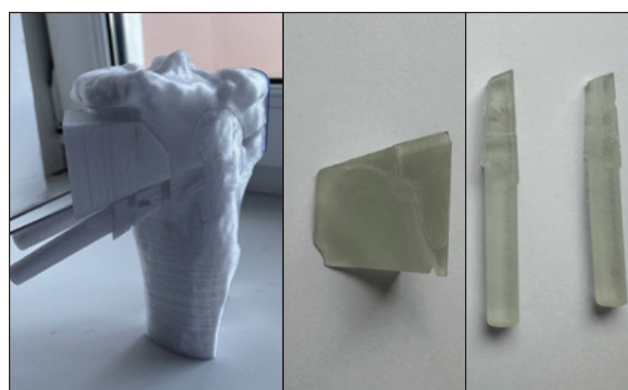


Fig. 6. Tibia model, individual block and wedges for osteotomy opening

In (Fig. 8, b, c) it is clearly seen that the wedges absolutely “laid” in the open osteotomy, and the template for cutting — on the surface of the tibia.

A comparative analysis of the primary radiographic indicators used for osteotomy planning and correction was conducted based on post-operative results. CT was used before and after surgical intervention (Fig. 9, Table).

As a result of the analysis, no significant deviations from the plan presented on the radiographs were identified (Fig. 10).

In the postoperative period, there were no complications with wound healing, the patient began to load the limb 3 weeks after the operation according to the protocol after microfracture of the knee cartilage defect. Walking with a cane was allowed after 6 weeks, and without additional support after 10. Radiography was performed 6 and 12 weeks and 6, 12 months after the operation. One year post-intervention, the patient exhibited full range of motion and symmetrical gait. The Knee Society Score (KSS) was 173 points, the Hospital for Special Surgery (HSS) score was 92, and the Lequesne index was 3.

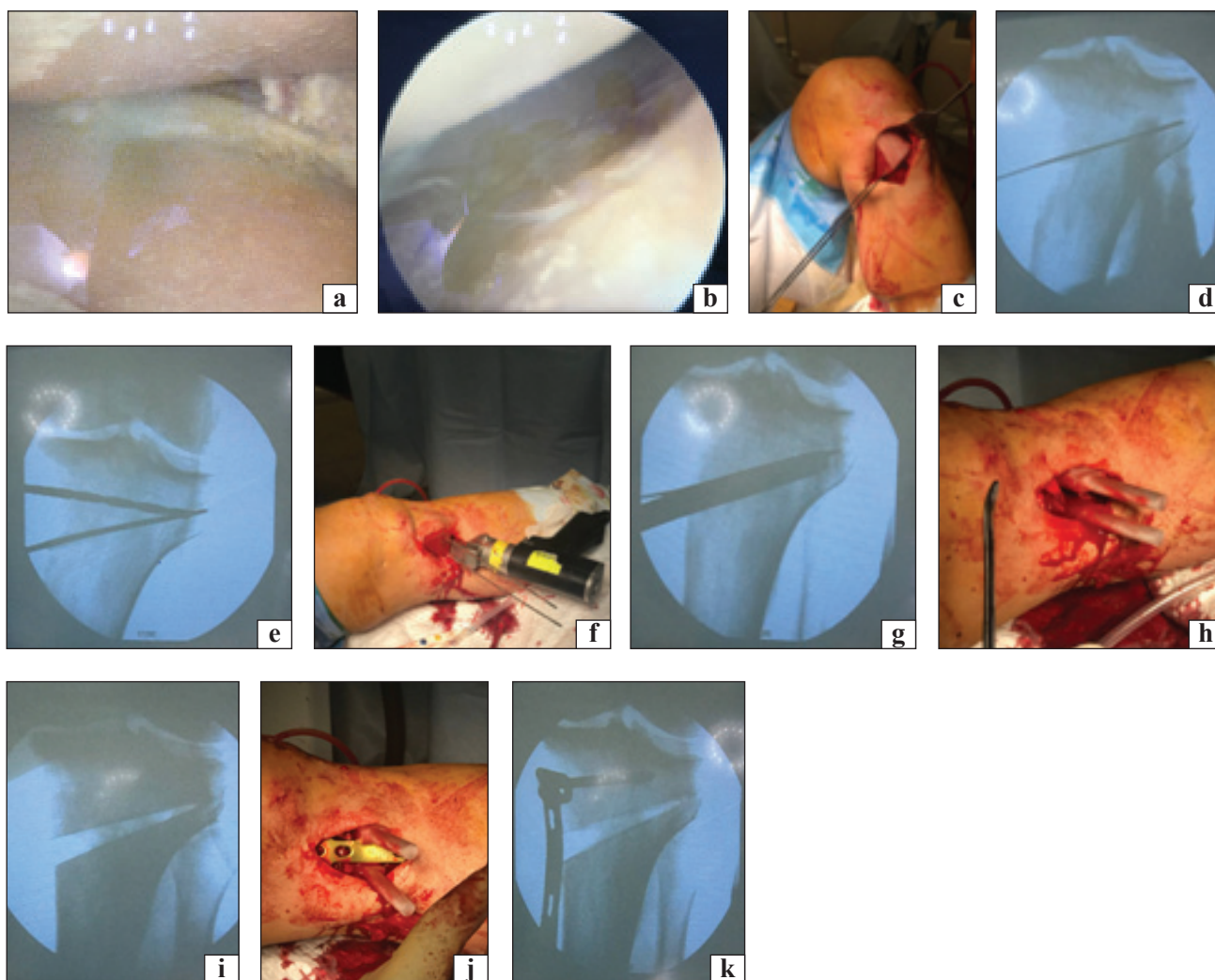


Fig. 7. Stages of surgical intervention with an individual instrument for high valgus osteotomy of the tibia: medial (a) and lateral (b) parts of the knee joint; c) installation of an individual conductor and insertion of guide wires; d) fluoroscopy check; e) drilling of a hole for the middle proximal screw; f) osteotomy along the lower edge of the individual block; g) fluoroscopy control of the depth of the osteotomy; h) after opening the osteotomy, individual wedges are installed; i) X-ray control - plastic wedges do not cover the bone; j) installation of the plate through the middle proximal hole on a pre-drilled channel and insertion of the screw; k) X-ray of plate installation

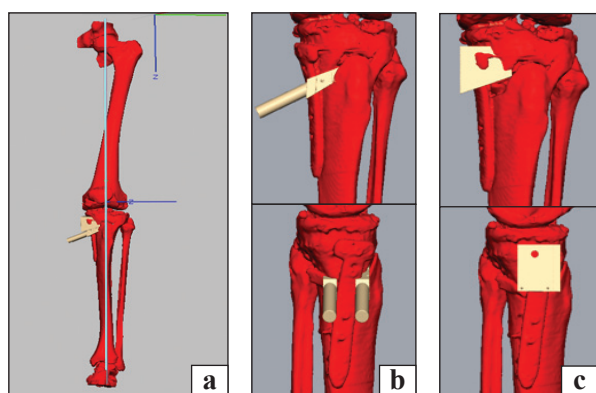


Fig. 8. Three-dimensional model of the limb after osteotomy with installation of models of individual wedges for opening and individual conductor for cutting: a) the mechanical axis of the lower limb is determined; comparison of the results of the installation of wedges (b) and conductor (c)

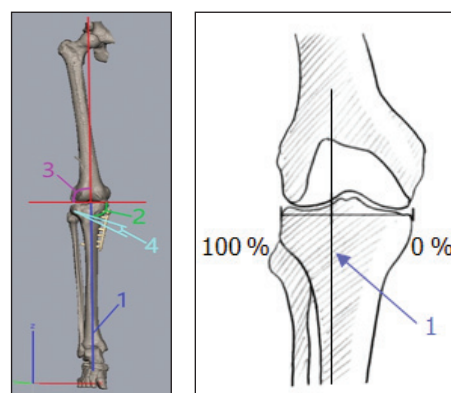


Fig. 9. Scheme of comparison of the results: 1) the point of the mechanical axis of the limb on the tibial plateau (in percent); 2) the value of the mechanical proximal medial tibial angle; 3) data of the mechanical distal lateral femoral angle; 4) the angle of opening of the osteotomy

Table

Radiographic parameters planned and obtained as a result of surgical intervention

Patient	Osteotomy opening angle		Limb axis position, %		Medial tibial angle, °		Lateral femoral angle, °	
	plan	after intervention	plan	after intervention	plan	after intervention	plan	after intervention
1	11.0	11.0	58.0	58.1	87.0	87.1	87.0	87.2

**Fig. 10.** Radiography after surgery: a) frontal and b) lateral projections

The metal structure was subsequently removed. The observation lasted for 4 years (Fig. 11) and showed a satisfactory functional result, the patient did not notice any deterioration in his condition, although the radiography corresponds to stage III gonarthrosis.

Discussion

As a result of the surgical intervention, the individual instrument allowed to quickly find the osteotomy plane, did not require an increase in the length of the skin incision, and did not interfere with fluoroscopy control. The planned hole for the upper middle screw allowed for a quick and accurate installation of the plate. Individual wedges for opening the osteotomy helped to correctly reproduce the correction and maintain it during osteosynthesis, regardless of the fluoroscopy data.

Our study has a number of shortcomings. To obtain more accurate and generalized conclusions, further comparative studies are required, which should include a larger number of patients and consider long-term results. In addition, it is important to anticipate the individual characteristics of each case and the optimal choice of treatment method taking into account clinical and anatomical factors. Particular attention should be paid to the comparative analysis of the effectiveness of the operation with an individual instrument and convection technique, as well as the study of long-term results and patient satisfaction.

In general, published articles in recent years confirm the prospects and effectiveness of using individual instruments for tibial osteotomy in varus gonar-

**Fig. 11.** Radiography 4 years after surgery

throsis [4, 6, 7, 10]. Further studies will allow us to clarify and supplement the obtained data, which will contribute to improving the results of surgical treatment of this pathological condition [10, 11].

Individual three-dimensional osteotomy planning has a significant advantage as it enables the detection of limb deformation, rotation, and the position of the knee joint plane. It also allows for accurate determination of both the level and height of the osteotomy opening. An individual conductor and wedge-spacers that are non-contrast for fluoroscopy facilitate the work during the operation, and a predetermined position of the plate for osteosynthesis simplifies and speeds up the operation.

Conclusion

The use of the proposed individual instrument for high valgus osteotomy of the tibia was convenient, simplified the main stages of the surgical intervention and ensured accurate planned correction of angular deformation.

Conflict of interest. The authors declare the absence of a conflict of interest.

Prospects for further research. Conducting an analysis of the results of using an individual instrument for high valgus osteotomy of the tibia to determine the accuracy of the instrument's operation, ease of use and studying the analysis of the immediate and long-term results of its use.

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Authors' contribution. Golovakha M. L. — planning the work, setting goals and objectives, developing instrument models, performing surgical interventions; Bondarenko S. A. — construction of three-dimensional models and their 3D printing, statistical analysis; Hart R. — reviewing the work and preparing

the manuscript; Orlyansky V. — planning of surgical interventions and analysis of results.

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USE OF INDIVIDUAL INSTRUMENT FOR HIGH TIBIAL ALGUS OSTEOTOMY IN VARUS GONARTHROSIS

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DIGEST AND REVIEWS

УДК 616-053.9:[616.71-007.234+616.74-007.23]](048.8)

DOI: <http://dx.doi.org/10.15674/0030-59872025196-106>**Osteosarcopenia: epidemiology, risk factors and modern management strategies****D. Yu. Kurylo, N. V. Grygorieva**

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Osteosarcopenia is a combination of osteoporosis and sarcopenia that has been identified as a distinct geriatric syndrome, which has recently attracted increasing attention from the medical community. Unfortunately, to date, there are no unified criteria for defining this syndrome, which affects the determination of its epidemiology and prevention methods. The coexistence of osteoporosis and sarcopenia in an individual is associated with an increased risk of falls and fractures, reduced functional capabilities and quality of life, and a heightened risk of mortality; thus, it holds significant medical and social importance. The aim of this review was to analyze the current literature on osteosarcopenia, including its prevalence, pathogenesis, risk factors, and management. Methods. A review of literature sources was carried out in the electronic scientometric databases PubMed, Scopus, Web of Science and Google Scholar using the keywords: "osteoporosis", "sarcopenia", "osteosarcopenia", "sarcoporosis" for 2019-2024 with additional inclusion in the analysis of earlier publications which have a recognized scientific value. Both cohort and prospective studies, as well as meta-analyses and systematic reviews, were analyzed. The results of this work included clarifying terminology, determining the global prevalence of osteosarcopenia, and analyzing risk factors and key components of its pathogenesis, particularly in subjects with comorbidities (such as diabetes and obesity). Scientific studies on the most explored pharmacological and non-pharmacological approaches to treating osteosarcopenia were also reviewed, with a focus on methods that require further research to confirm their effectiveness. Conclusions. Given the prevalence of osteosarcopenia and the associated risks, further investigation, especially within the Ukrainian population, is highly relevant and necessitates new research to improve the management of this geriatric syndrome.

Остеосаркопенія є поєднанням остеопорозу та саркопенії, яке було виділено, як окремий геріатричний синдром, що останнім часом привертає все більше уваги медичної спільноти. На жаль, сьогодні немає єдиних критеріїв щодо його визначення, що впливає на вивчення епідеміології та методів профілактики. Поєднання остеопорозу та саркопенії в однієї особи асоційовано з підвищенням ризику падінь і переломів, зниженням функціональних можливостей та якості життя, зростанням ризику смертності, тому має вкрай важливе медико-соціальне значення. Мета. Проаналізувати сучасні літературні джерела, які вивчають остеосаркопенію, її поширеність, патогенез, фактори ризику та менеджмент. Методи. Огляд літератури здійснено в електронних наукометричних базах даних PubMed, Scopus, Web of Science та Google Scholar із використанням ключових слів: «остеопороз», «саркопенія», «остеосаркопенія», «саркопороз» за 2019–2024 роки з додатковим включенням до аналізу більш ранніх робіт за умови їх визнаної наукової цінності. Розглянуто як когортні та проспективні дослідження, так і метааналізи й систематичні огляди. Результатом цієї роботи є уточнення термінології, визначення поширеності остеосаркопенії у світі, аналіз факторів ризику й основних ланок патогенезу, зокрема і в осіб із супутньою патологією (цукровий діабет, ожиріння тощо). Проаналізовані наукові роботи стосовно найбільш вивчених медикаментозних і немедикаментозних підходів у лікуванні остеосаркопенії з розглядом методів, які потребують подальшого вивчення для підтвердження своєї ефективності. Висновки. Ураховуючи поширеність остеосаркопенії та ризику, які пов'язані з нею, її подальше вивчення, зокрема й в українській популяції, є вкрай актуальним і потребує проведення нових науково-дослідних розробок для покращення менеджменту цього геріатричного синдрому. Ключові слова. Остеопороз, саркопенія, остеосаркопенія, саркопороз.

Key words. Osteoporosis, sarcopenia, osteosarcopenia, sarcoporosis

Introduction

As human life expectancy has increased due to improved living conditions and medical advances, the proportion of the elderly in the world population has increased significantly. According to current projections, the number of people aged 60 years and older will continue to increase, from 1.1 billion in 2023 to 1.4 billion in 2030 [1]. This will contribute to a rise in the number of age-associated diseases and conditions, and their study is becoming increasingly relevant. The main geriatric syndromes include cognitive impairment, depression, chronic pain, polypharmacy, certain functional limitations, urinary or fecal incontinence, constipation, orthostatic hypotension, syncope, pressure ulcers, vision, hearing or sensory impairment, falls, frailty, malnutrition, or loss of muscle mass and strength (sarcopenia) [2–4]. The presence of the latter in combination with osteoporosis in one person has been singled out as a separate geriatric phenomenon, which has been combined with the terms “osteosarcopenia” (OSP) or “sarcoporosis” [6]. However, today there is no consensus in the world on the definition of this condition. Some scientists define OSP as a combination of osteoporosis, instrumentally confirmed by two-photon X-ray absorptiometry (DXA) and sarcopenia, others in the presence of low bone mineral density (BMD, osteopenia or osteoporosis) and sarcopenia or in the case of an osteoporotic low-traumatic fracture in combination with sarcopenia [7–10]. OSP poses a threat to the elderly due to the increased risk of a number of complications characteristic of both diseases, therefore it requires more attention and in-depth study. In recent years, there has been an increasing number of high-quality studies studying this syndrome. Regrettably, the Ukrainian-language literature contains only limited research on the study of OSP as evidenced by references [11, 12].

Purpose: to analyze modern literary sources on osteosarcopenia, its epidemiology, pathogenesis, risk factors and possible ways of prevention and treatment.

Material and methods

A review of literature sources was carried out in the electronic scientometric databases PubMed, Scopus, Web of Science and Google Scholar using the keywords: “osteoporosis”, “sarcopenia”, “osteosarcopenia”, “sarcoporosis” for

2019–2024 with additional inclusion in the analysis of earlier studies provided that their recognized scientific value was recognized. Both cohort and prospective studies, as well as meta-analyses and systematic reviews, were analyzed.

Results

Definition of osteosarcopenia

As noted above, OSP combines two diseases: sarcopenia and osteoporosis.

The term “sarcopenia” was first proposed to describe the loss of skeletal muscle mass by I. Rozenberg in 1989, and in 1998 R. Baumgartner used this term to characterize a syndrome associated with an increased risk of falls and physical weakness [13, 14]. According to the latest European guidelines issued by the European Working Group on Sarcopenia in Older People (EWGSOP) in 2019, it is a progressive and generalized skeletal muscle disease associated with an increased risk of falls, fractures, impaired motor activity and mortality [15].

The definition of “osteoporosis” was first proposed by the World Health Organization (WHO) in 1994 [16]. This disease is characterized by a decrease in bone density and impaired bone microarchitecture and leads to an increased risk of falls and fractures, and, as a result, to disability and increased mortality [17].

To describe the combination of osteoporosis and sarcopenia, G. Duque and colleagues first proposed the term “osteosarcopenia” [18]. The latter is characterized by low BMD (according to WHO standards osteopenia (according to the assessment of DRA values by T-criterion from -1 to -2.5 standard deviations (SD)) or osteoporosis (T-criterion ≤ -2.5 SD) or the presence of a low-energy osteoporotic fracture regardless of the state of bone tissue and low muscle mass and decreased function (sarcopenia)), which are established using criteria related to muscle mass, strength and functional capabilities of the subject.

However, there is still ongoing debate about the definition of OSP, and studies use different inclusion criteria to identify patients, which makes it difficult to compare its incidence and consequences. For example, in a meta-analysis by N. Veronese et al. [7], osteoporosis and sarcopenia are combined for the diagnosis of OSP, using generally accepted criteria for their establishment. In another meta-analysis by S. Chen et al., other OSP criteria were used for consideration: a combination of sarcopenia with low BMD (osteopenia or osteoporosis) or sarcopenia with osteoporosis [10]. In some publications, scientists define OSP as a combination of sarcopenia and low BMD (osteopenia or osteoporosis) [19–23], while other scientists consider the presence of sarcopenia and osteoporosis as criteria for determining OSP [24–28].

It should be noted that different researchers use not only different data on the assessment of bone tissue status (osteopenia, osteoporosis or low-traumatic fractures), but also different criteria for determining sarcopenia (EWGSOP, Asian Working Group for Sarcopenia (AWGS), Foundation for the National Institutes of Health Sarcopenia Project (FNIH), Sarcopenia Definitions and Outcomes Consortium (SDOC), etc.). Differences in the definition of OSP complicate the study of its epidemiology and require a unified approach, including outlining management and prognosis strategies.

Epidemiology of Osteosarcopenia

A meta-analysis by N. Veronese et al., which included 14,429 individuals (mean age 70 years, 64.5 % women, OSP criteria included a combination of osteoporosis by DXA and sarcopenia), showed that the prevalence of OSP was 12.72 % (95 % confidence interval (CI): 9.65–15.78) [7]. Another observation [10] analyzed data from 64,404 individuals aged 46.6–93 years to determine the overall incidence of OSP in the adult population worldwide and used different combinations of criteria. The results showed that the overall prevalence of this syndrome was 18.5 % (95 % CI: 16.7–20.3 %), including 15.3 % (95 % CI: 13.2–17.4) in men and 19.4 % (95 % CI: 16.9–21.9) in women. The authors found significant differences in the prevalence of OSP among people who were hospitalized (24.7 %) and living in the community (12.9 %) ($p = 0.001$).

The use of different criteria in the study of the epidemiology of OSP significantly affected the frequency of diagnosis of the syndrome. Thus, the prevalence of sarcopenia combined with osteopenia or osteoporosis was 20.7 % (95 % CI: 17.1–24.4), and sarcopenia alone with osteoporosis confirmed by DXA was 16.1 % (95 % CI: 13.3–18.9) [10]. Another meta-analysis that studied the prevalence of OSP was conducted by T. Huang et al. [29]. They analyzed 31 studies involving 15,062 subjects aged 64.1 to 84.8 years. The following diagnostic criteria for sarcopenia were used: 8 studies — AWGS, 16 — EWGSOP, 2 — FNIH, 3 — Japan Society of Hepatology (JSH), and the remaining 2 — two other sets of diagnostic scales. In 16 studies, OSP was considered the combination of sarcopenia and low BMD, and in 15 — the presence of osteoporosis and sarcopenia. Thirteen studies were conducted in Asia, 8 in Europe, 6 in Oceania, and 4 in the Americas. The prevalence of OSP ranged from 1.5 to 65.7 % with an overall rate of 21 % (95 % CI: 0.16–0.26). It was higher in women, at 28 % (95 % CI: 21–35 %), and in men, at 14 % (95 % CI: 9–20 %). It has been shown to be

more common in European populations (26 %; 95 % CI 11–45 %) than in Asian populations (18 %; 95 % CI 13–24 %). It is higher in South America (23%; 95 % CI 5–48 %) than in North America (11 %; 95 % CI 8–15 %), while in Oceania it is 21 % (95 % CI 10–34 %). Among those living in the community, the prevalence of OSP was lowest (12 %; 95 % CI 7–18 %), compared with those receiving inpatient (26 %; 95 % CI 18–36 %) or outpatient care (33 %; 95 % CI 16–53 %) [29].

The heterogeneity of the results of the above-mentioned meta-analyses on the epidemiology of OSP is apparently related to differences in the populations included in the analysis, study designs (cohort, cross-sectional), and criteria for defining OSP. According to some scientists, the presence of an osteoporotic fracture is an important criterion for OSP. Thus, B. Kirk et al. found that the prevalence of OSP among the elderly living in the community varies within 5–37 %, with the most significant indicators in patients with a history of fractures: ~46 % for people with low-traumatic fractures and from 17.1 to 96.3 % with a femur fracture [9]. The inclusion criteria for this study were the definition of OSP, which included the combination of osteopenia or osteoporosis according to DXA or a current low-energy fracture regardless of BMD together with sarcopenia. In a later study by this author, which included 481 community-dwelling individuals (mean age 78 years, 75.9 % women), the inclusion factors for determining the prevalence of OSP were the combination of osteoporosis or osteopenia and sarcopenia diagnosed according to the SDOC or EWGSOP2 criteria. When the former was used to define sarcopenia, the prevalence of OSP was 37.2 %, and when the latter was used, it was 25.6 % [30].

Thus, to date, the results of individual publications and meta-analyses indicate significant variability in the frequency of OSP, which is caused by different approaches to its definition. Currently, the prevalence of this syndrome in Ukraine has not been studied, which requires research to determine its medical and social significance in our country.

Pathogenesis of osteosarcopenia

A substantial body of evidence has been accumulated, indicating a close connection between muscles and bones. In addition to mechanical influence, genetic and molecular associations and the influence of many endocrine factors are important [31, 32].

The most explained and studied is the mechanical factor in the development of OSP, since such an interaction between muscle and bone is obvious and is emphasized by the “mechanostat” hypothesis. According to this theory, the muscle acts on the bone

with a mechanical force with a certain threshold, which determines the activity of the osteosynthesis or resorption process. An increase in muscle mass leads to stretching of collagen fibers and periosteum, which causes stimulation of osteosynthesis. A decrease in muscle mass and, as a result, a decrease in the mechanical effect on the bone, respectively, activates the processes that cause a decrease in BMD [33].

Furthermore, since muscle and bone are derived from mesenchymal stem cells, they are influenced by the same genetic factors [34]. Genome-wide association studies (GWAS) have confirmed the pleiotropic effects of some genes on bone and muscle. These include genes for growth/differentiation factor 8 (GDF8), glycine-N-acyltransferase (GLYAT), methyltransferase-like 21 C (METTL21C), gamma coactivator 1-alpha (PGC-1 α), myocyte enhancer factor-2 C (MEF2C), sterol regulatory element-binding transcription factor 1 (SREBF1), and others [20, 35]. Vitamin D receptor polymorphisms have also been shown to be associated with sarcopenia and osteoporosis [36].

The relationship between bone and muscle tissue can be mediated by several autocrine, endocrine and paracrine mechanisms. Muscle secretes “myokines” — factors that affect other tissues, including bone metabolism. On the other hand, factors synthesized in bone tissue — “osteokines” (in particular, osteocalcin, osteoprotegerin and sclerostin) — have a regulatory effect on muscle tissue metabolism. Some myokines (insulin-like growth factor-1, irisin, follicle-stimulating hormone, interleukin (IL)-15, etc.) have a positive effect on bone formation, while other myokines (myostatin, IL-6) have a negative regulatory effect on its remodeling [33, 37].

Myostatin (growth and differentiation factor 8) is a well-studied myokine [38, 39] that inhibits skeletal muscle growth and also affects tendons and bones. It not only inhibits muscle differentiation and growth, promotes protein breakdown, affects adipogenesis and bone remodeling, but is also a potent anti-osteogenic factor and a direct modulator of osteoclast differentiation. Myostatin can activate SMAD and protein kinase signaling pathways, suppressing the Wnt/ β -catenin pathway to synergistically regulate muscle and bone growth and metabolism, and is currently being studied as a therapeutic target to inhibit osteoclast formation [39].

Thus, current knowledge about the pathogenesis of OSP allows us to confirm the complex relationships between bone and muscle tissue, and common hormonal and humoral mediators are the object

of study as therapeutic targets for the possible treatment of this syndrome.

Risk factors for osteosarcopenia

In recent years, increased interest in OSP among clinical researchers has led to an increase in the number of publications on its risk factors. As noted above, the relationship between decreased muscle mass and low BMD is explained by the mechanical effect of muscles on the stimulation of osteosynthesis and the humoral dependence of muscle and bone tissue. Therefore, decreased muscle mass and the presence of sarcopenia are important risk factors for osteoporosis, and therefore OSP.

This thesis is confirmed by numerous studies. Thus, in the publication of D. Scott et al. involving 3,334 people (mean age 70 years), it was confirmed that patients with sarcopenia had significantly lower BMD of the lumbar spine and femur, distal radius and tibia than the group without defined sarcopenia and with its probable presence (all $p < 0.05$) [40]. Other studies also confirmed that probable and severe sarcopenia was associated with osteoporosis ($p < 0.05$). At the same time, low muscle strength, as measured by hand dynamometry, and low physical capacity, as assessed by the 4-meter test, were associated with osteoporosis ($p < 0.02$).

Low muscle strength and physical capacity were associated not only with osteoporosis ($p < 0.001$) but also with osteopenia ($p < 0.05$). In addition, probable sarcopenia was associated with osteopenia at the femoral neck ($p < 0.01$) [41].

Sung-Young Jang et al. found an association between low muscle mass and osteoporosis in the lumbar spine and femoral neck in both men (lumbar spine: odds ratio (OR) = 1.73; 95 % CI: 1.08–2.76; femoral neck: OR = 3.39; 95 % CI: 1.69–6.80) and women (lumbar spine: OR = 1.52; 95 % CI 1.17–1.97; femoral neck: OR = 2.09; 95 % CI 1.56–2.80). The association between low muscle mass and osteoporosis was significant in men and women across age groups, except for men aged 50–64 years [42].

A retrospective cohort study of 140 postmenopausal women demonstrated that the most common risk factors for OSP were insufficient protein intake (79.3 %) and dietary calcium intake (65.7 %), low physical activity as measured by the SPPB test (53.6 %), and hyperlipidemia (33.6 %). It was also found that dynamometry indicators are decisive for the occurrence of OSP (relative risk (RR) = 0.86; 95 % CI: 0.80–0.92), and a decrease in handgrip strength using a hand dynamometer by one unit increases the risk of OSP by 1.16 times (95 % CI: 1.09–1.25) [19]. Similar results were obtained by T. Tiftik et al.,

who found a relationship between low dynamometry values (< 22 kg) and a 1.6-fold increase in the risk of osteoporosis [43].

Risk factors that influence the development of OSP were also investigated by T. Huang et al. [29]. The results showed that female gender (OR = 5.10; 95 % CI: 2.37–10.98; $p < 0.0001$), older age (OR = 1.12; 95 % CI: 1.03–1.21; $p = 0.008$), and history of fractures (OR = 2.92; 95 % CI: 1.62–5.25; $p = 0.0003$) significantly increased the risk of developing OSP, while elevated parathyroid hormone (PTH) levels (OR = 2.41; 95 % CI: 0.59–9.87; $p = 0.22$) and high body mass index (BMI) (OR = 1.01; 95 % CI: 0.63–1.62; $p = 0.97$) did not have a statistically significant association with OSP. On the other hand, low BMI was found to be a significant factor associated with the development of OSP, according to the results of a retrospective study by H. Okamura et al. (OR = 1.71; 95 % CI: 1.46–2.00; $p < 0.01$) in all age groups (65–74, 75–84 and 85 years and older) [25]. In a publication by P. Suriyaarachchi et al. with the participation of 400 subjects (mean age 79 years, 65 % women), it was reported that individuals with elevated blood PTH levels and normal calcium were more common in the OSP group than in the group without sarcopenia and osteopenia (OR = 6.88; 95 % CI: 1.9–9.2) [23]. This suggests that elevated PTH levels may be a risk factor for the development of OSP, but this suggestion requires further study.

A study of 2,353 community-dwelling Australians identified risk factors associated with OSP, such as physical inactivity (OR: 0.64; 95 % CI: 0.46–0.88), low BMI (OR: 0.84; 95 % CI: 0.81–0.88 for men and 0.77; 95 % CI: 0.74–0.80 for women), increased body fat (1.46; 95 % CI: 1.11–1.92 for men and 2.25; 95 % CI: 1.71–2.95 for women) and older age (in men, prevalence ranged from 14.3 % in the 60–64 age group to 59.4 % at age 75) and older. In women, the corresponding figures ranged from 20.3 to 48.3 %, $p < 0.05$) [9].

Osteosarcopenia and comorbidity

Osteosarcopenia and obesity

Since scientific studies [9] have shown that increased fat mass is a risk factor for OSP, and fat, muscle, and bone cells originate from the same mesenchymal precursors, it is worth considering the relationship between adipose tissue and OSP.

Fatty infiltration of bones and muscles is common in patients with osteoporosis and sarcopenia. With age, the composition of body tissues changes with an overall increase in the percentage of fat in the body and a decrease in muscle mass, while total body weight may remain stable. This condition is com-

monly called “sarcopenic obesity,” and its presence leads to impaired functional capacity and increased disability among older people [44]. That is why in recent years the combination of sarcopenia, osteoporosis and obesity has been increasingly studied as a condition called “osteosarcopenia obesity”.

Today, it is known about the protective effect of adipose tissue on bone mass, which can be partially explained by the well-documented relationship between the level of extraglandular estrogen synthesis and the number of adipocytes. According to some authors, muscle strength in obese individuals may be greater than in people without it. This may indicate a positive effect of excessive adipose tissue on muscles, associated with chronic overload, which can increase muscle size and strength [44]. Thus, in the study by H. Okamura et al., not a single patient from the OSP group had obesity [25], which could indirectly indicate the absence of its negative effect on the development of OSP and isolated cases of combination with OSP. But in the observation of A. Polito with the participation of 1,344 postmenopausal women aged 50 years and older, the prevalence of osteosarcopenic obesity was 32 % [45].

A cross-sectional study of 542 community-dwelling Southeast Asians aged 21–90 years reported that the prevalence of OSP and osteosarcopenic obesity was 1.8 % and 0 % in those aged 21–59 years; 12.9 % and 2.8 % in those aged ≥ 60 years; 17.3 % and 4.1 % in those aged ≥ 65 years; and 25.5 % and 7.0 % in those aged ≥ 75 years, respectively [20]. It was also found that the risk of osteosarcopenic obesity was influenced not only by age, sex, and race, but also by alcohol consumption. However, it was not a reliable predictor of functional impairment in the subjects.

It has now been proven that bone and muscle homeostasis is linked to adipose tissue through neurohumoral connections. High levels of adipose tissue, independent of BMI, are lipotoxic, affecting the function and structure of other tissues. Lipotoxicity and local inflammation are reflected in the biosynthesis of proinflammatory cytokines, including IL-6 and tumor necrosis factor- α [46]. Adipokines, including leptin, resistin, and adiponectin, which are released from adipose tissue, are also able to regulate both muscle and bone metabolism. Exercise-induced stimulation of bioactive cytokines through the interaction of muscle, bone, and fat enhances muscle anabolism, bone formation, mitochondrial biogenesis, glucose utilization, and fatty acid oxidation, and attenuates chronic inflammation. At the same time, the release of lipolytic myokines (IL-6, irisin, and leukemia inhibitory factor) induced by physical exercise activates thermo-

genesis, promoting the transformation and darkening of adipocytes [37].

Therefore, the association of OSP with obesity continues to arouse interest in the scientific community, prompting the emergence of new studies regarding osteosarcopenic obesity.

Osteosarcopenia and diabetes mellitus

Recent study has shown that type 2 diabetes mellitus (T2DM) is a significant risk factor for OSP. A. Moretti et al. [47] in a case-control study demonstrated that postmenopausal women with T2DM had a 5-fold increased risk of OSP compared with those without T2DM (50 vs. 17 %; OR = 5.0; 95 % CI: 1.05–23.79; $p = 0.04$), and their hand strength was significantly lower ((10.09 ± 4.02) kg vs. (18.40 ± 6.83) kg, respectively; $p = 0.001$) [47].

L. M. Pechmann et al. in the observation with the inclusion of women and men with DM2 (mean age (65.1 ± 8.2) and (68.8 ± 11.0) years) also confirmed a higher prevalence of OSP (11.9 vs. 2.14 %, respectively, $p = 0.01$), sarcopenia (12.9 vs. 5.4 %, respectively, $p < 0.03$) and fractures (29.9 vs. 18.5 %, respectively, $p = 0.02$) in patients with DM2 compared to the control group and lower hand strength indicators ((24.4 ± 10.3) kg vs. (30.9 ± 9.15) kg, respectively, $p < 0.001$). The mean Trabecular Bone Score (TBS) values were (1.272 ± 0.11) and (1.320 ± 0.12) , respectively ($p = 0.001$). According to multivariate analysis, age, larger waist circumference, fractures and osteoporosis increased the risk of low TBS. TBS was also found to be associated with complications of T2DM ($p = 0.03$), but not with its duration or glycemic control [48]. According to the results of studies highlighted in the systematic review by A. Polito et al., T2DM patients with TBS have lower BMI, waist circumference, body fat percentage and worse β -cell function. It has been concluded that β -cell function may be a factor in counteracting the development of OSP, and the focus on its preservation in individuals with DM2 is a preventive measure to prevent the development of OSP [45].

Therefore, considering that DM2 has an adverse effect on muscle and bone health, which leads to the development of OSP and, as a result, impaired functional ability of patients, there is a need to timely establish algorithms for the detection of this condition, its treatment and prevention.

Osteosarcopenia and the risks of falls and fractures

In a study by W. Sepúlveda-Loyola et al. involving 253 individuals (77 % women; mean age (77.9 ± 0.42) years), a significant association between sarcopenia and the risk of falls was demonstrated,

and OSP classified as severe sarcopenia significantly increased the frequency of falls (OR = 2.83–3.63; $p < 0.05$) [8]. Similar results were obtained by other researchers. Thus, according to the observational data of B. Kirk et al., the presence of OSP increases the risk of falls by 54 % (hazard ratio (HR) = 1.54; 95 % CI: 1.20–1.97) [9]. An even greater increase in the risk of falls in individuals with OSP was demonstrated in the study by Z. Teng et al. (OR = 1.62; 95 % CI: 1.28–2.04) [49].

On the other hand, OSP has been associated with fracture risk. The disease was classified as severe sarcopenia (according to the EWGSOP2 and FNIH definitions) and resulted in an increased fracture rate (OR = 3.86–4.38; $p < 0.05$) [8].

A significant increase in fracture risk in the presence of OSP was found in the publication by B. Kirk et al. (HR = 2.13; 95 % CI: 1.61–2.81; pooled results of 7 studies) [9], while a later follow-up found that the probability of recurrent fractures (≥ 2 vs 0–1) was significantly higher in individuals with OSP compared with those with osteopenia or osteoporosis regardless of definition, after adjustment for age, sex, alcohol intake, smoking, BMI, lowest DXA T-score, physical activity, and comorbidities (SDOC: HR = 1.63; 95 % CI: 1.03–2.59; $p = 0.04$; EWGSOP2: HR = 1.83; 95 % CI: 1.12–3.01, $p = 0.02$) [30]. An even greater increase in fracture risk in individuals with OSP was demonstrated in a study by Z. Teng et al. (OR = 2.46; 95 % CI: 1.83–3.30) [49].

Osteosarcopenia and mortality risk

To date, the results of existing publications indicate that OSP not only affects the functional activity and quality of life of patients, but also increases the risk of mortality.

Thus, in a meta-analysis conducted by N. Veronese et al. with the participation of 14,429 people (mean age (70 ± 6) years, 64.5 % women), it was found that OSP significantly increased the risk of mortality by 53 % (OR = 1.53; 95 % CI 1.28–1.78) [7].

Other researchers demonstrate even higher mortality rates in patients with OSP. In the work of B. Kirk et al. it was confirmed that OSP significantly increases the risk of mortality (OR = 1.75; 95 % CI: 1.34–2.28, analysis based on the results of 5 observations) [9]. A significant increase in the risk of mortality in the presence of OSP was also demonstrated by the results of the study by Z. Teng et al. (OR = 1.66; 95 % CI: 1.23–2.26) [49]. It is clear that the results of these studies are important to consider when examining patients to ensure timely detection and treatment of OSP. In addition, the proven high risks of falls, fractures and mortality in people with

OSP emphasize the urgency of continuing to study this syndrome with a targeted focus on its timely diagnosis and treatment.

Osteosarcopenia therapy

There are presently two methodologies utilized for the treatment of OSP: non-pharmacological and pharmacological interventions.

The most effective non- pharmacological approach is to ensure rational physical activity, which has been shown to improve bone [50] and muscle strength [51]. In addition, according to some researchers, the use of nutritional supplements enriched with nutrients, in particular sufficient amounts of vitamin D and protein, can improve physical performance and be an effective tool for the prevention and treatment of OSP [36].

The randomized controlled trial FrOST (Franconian osteopenia and sarcopenia trial) evaluated the effect of dynamic resistance exercise on the treatment of OSP in elderly men. For this purpose, BMD and appendicular fat-free mass index (AFMI) were studied in 43 subjects aged 73–91 years who led a sedentary lifestyle. Physical training in the study group was performed on simulators with high intensity, speed and resistance twice a week, and both groups (study and control) received sufficient amounts of protein, calcium and vitamin D daily. After 12 months of observation, the exercise group showed preservation of BMD at the level of the lumbar spine, while the control group was diagnosed with its decrease ($p < 0.001$; standardized mean difference (SMD) = 0.90). The IAMS index increased in the study group, while it decreased in the control group ($p < 0.001$; SMD = 1.95). Proximal femoral BMD did not differ significantly between groups ($p = 0.06$; SMD = 0.65), while changes in maximal hip extensor strength were significant ($p < 0.001$; SMD = 1.92) in the high-intensity resistance exercise group [51]. The results of this randomized trial suggest that dynamic resistance exercise may be a promising tool for the treatment of OSP. It should be noted that strategies aimed at preventing falls in patients with OSP may also have important practical value. These may include the addition of balance training exercises, safety assessment and risk reduction in the home, and the use of assistive devices that reduce falls. However, there is a lack of high-quality work examining this issue in individuals with OSP.

Currently, much attention is paid to the development of the effectiveness of dietary strategies, in particular the rational consumption of various macro- and micronutrients in the management of both sarcopenia and osteoporosis, but there are no studies that

would study the feasibility of using these strategies in the prevention of OSP.

It has now been proven that vitamin D supplementation affects the increase in muscle strength, reducing the risk of falls and mortality, and this relationship is stronger in older people and people who are deficient in this vitamin. To ensure the maintenance of bone and muscle health, daily intake of vitamin D₃ at a dose of 800–1000 IU/d; calcium 1300 mg/d; 1.2–1.5 g/kg protein/d (with 2.5–3 g leucine at each meal) is recommended [9]. Addressing vitamin D deficiency in older adults and promoting its optimal intake through diet or supplementation may be a valuable tool in the management of OSP.

Currently, some studies suggest that adding creatine to resistance training increases gains in both muscle strength and mass compared with exercise training alone. A recently published meta-analysis of randomized clinical trials demonstrated a positive effect of creatine supplementation with resistance training on both upper (4 studies, $n = 97$, $p = 0.05$) and lower body strength (4 studies, $n = 100$, $p = 0.03$) compared with a control group, provided that the follow-up period was at least 24 weeks [52]. Although this approach requires further scientific evidence, creatine supplementation has also been suggested by other authors [9] to increase muscle strength (3–5 g/d) in older adults.

It is likely that a combination of high-intensity resistance exercise, balance exercises, protein supplements, vitamin D, calcium, and creatine may be an effective treatment for OSP in the elderly, but this issue requires further detailed study.

The literature does not provide well-defined strategies for the pharmacotherapy of OSP or sarcopenia. On the other hand, both antiresorptives (bisphosphonates, denosumab, etc.) and bone formation stimulants are used to treat osteoporosis and its complications. Recently, reports have appeared confirming the positive effect of antiresorptives not only on BMD, but also on the state of skeletal muscles and the risk of falls, which may be promising in the treatment of OSP. Thus, in a retrospective cohort study conducted by T. Rupp et al. [53], a positive effect of denosumab was demonstrated not only on BMD, but also on changes in hand muscle strength ($p < 0.001$), which was also observed in the group using bisphosphonates (alendronate and ibandronate) ($p = 0.001$). However, in patients who used denosumab, the results were better than in the case of using bisphosphonates or placebo (the dynamics of changes in muscle strength per year in the control group was $(-6.05 \pm 10.22) \%$; during treatment with

bisphosphonates ($+0.78 \pm 8.23$) %; with denosumab ($+5.14 \pm 25.49$)%. In addition, treatment with denosumab resulted in better results in the sit-stand test and a significant increase in lower limb strength compared with the group that received bisphosphonates (the dynamics of changes per year was in the control group ($+5.82 \pm 12.74$) %; in the group of patients that received bisphosphonates, ($+0.95 \pm 8.61$) %, denosumab ($+8.20 \pm 14.38$) %). However, the dynamics of the time index during this test did not show significant differences between the three groups [53].

The positive effect of denosumab on lower limb muscle strength may explain the reduction in the risk of falls during its use, which is confirmed by the results of a placebo-controlled study conducted by P. Chotiarnwong et al. [54], but this relationship still needs further study.

In a prospective study conducted by M. Pizzonia et al., the effects of alendronic acid and denosumab on BMD, TBS and AFMI were compared in 98 patients over 65 years of age with osteoporotic hip fracture. According to the results, an early trend towards improvement in BMD and its quality was observed in the group receiving alendronic acid compared with those receiving denosumab (femoral neck BMD: 64.0 vs. 46.7 %; total femur: 68.0 vs. 53.3 %; lumbar spine: 84.0 vs. 53.3 %, respectively); TBS (48.0 vs. 20 %, respectively). However, the denosumab group showed better results in the AFMI index [55]. In a study by N. Bonnet et al., appendicular muscle mass (AMM) and hand strength were assessed in postmenopausal women treated for osteoporosis for three years. Both denosumab and bisphosphonates (alendronate and zoledronate) resulted in improvements in BMD compared with the control group, in which no medication was administered ((0.12 ± 0.29) g/cm² and (0.04 ± 0.12) g/cm² vs. (-0.07 ± 0.19) g/cm², respectively, both $p < 0.05$). In contrast, only the denosumab group showed an increase in BMD and strength in both hands ((0.66 ± 2.2) kg and (3.22 ± 10.0) kg, respectively, versus (-0.06 ± 0.39) kg and (-0.07 ± 6.6) kg with bisphosphonates; and (-0.36 ± 1.03) kg and (-1.39 ± 2.4) kg, respectively, in untreated patients, both $p < 0.05$). Changes in BMD and hand strength correlated with changes in lumbar spine BMD ($r^2 = 0.82$ and $r^2 = 0.81$, both $p < 0.001$) only in the denosumab group [56].

There is little scientific evidence to support the positive effects of denosumab on muscle strength, but the available studies encourage further study of its mechanisms to expand the possibilities of drug treatment of OSP in the future. And a combination of non-pharmaceutical and pharmaceutical

approaches in treatment, with individual selection of the most effective drug, will provide the best result in OSP treatment.

Conclusion

With an aging population, OSP is a significant global issue, impacting quality of life and increasing healthcare system burdens. Given the mechanisms of OSP development, it is necessary to ensure a multidisciplinary approach for the timely detection, effective treatment and prevention of this important geriatric syndrome. Continued research in these fields is essential to establish clear protocols and standardized recommendations for managing patients with OSP and individuals at increased risk of its occurrence in the near future.

Conflict of interest. The authors declare that there is no conflict of interest.

Prospects for further research. An analysis of the available literature indicates the important medical and social significance of osteosarcopenia, however, data on its epidemiology are contradictory, and those related to its management are insufficient. The above is the basis for further research in Ukraine on the study of epidemiology, risk factors of osteosarcopenia and possibilities of its prevention and treatment.

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OSTEOSARCOPENIA: EPIDEMIOLOGY, RISK FACTORS AND MODERN MANAGEMENT STRATEGIES

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Hemostatic system disorders in patients with coxarthrosis of III–IV stages after total hip arthroplasty (literature review)

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Objective. To analyze the current state of diagnosis and prevention of hemostatic disorders in patients with Kellgren-Lawrence grade III–IV coxarthrosis after total hip arthroplasty based on scientific literature. *Methods.* A search was performed in PubMed, Web of Science, Google Scholar and Scopus. Using MeSH and keywords such as: "inflammatory markers", "coxarthrosis", "thromboembolism", "tranexamic acid", "anticoagulants", "inflammation", "fibrinolysis", "D-dimer", "arthroplasty", "hypercoagulability", "plasminogen". *Results.* An important issue in the prevention of thromboembolic complications during total hip arthroplasty is to determine the dynamics of fibrinolysis disorders. Thus, it was found that hip arthroplasty is characterized by an increase in inflammatory markers in the blood and hemostatic disorders. *Conclusions.* In clinical orthopedics, after hip arthroplasty in patients with coxarthrosis of III–IV stages, complications often occur in the form of hemostatic disorders, which are accompanied by the development of deep vein thrombosis of the extremities, in severe cases — pulmonary embolism. These complications are monitored based on the results of determining the markers of the hemostatic system, which are examined before and after surgery. It has been proven that there are many different factors that affect the development of hemostatic disorders in the body. The age factor, as elderly patients have their own metabolic characteristics and altered rheological properties of blood. Increased body weight, in particular, obesity, is also an important factor that cannot be ignored in clinical practice. To date, clear clinical and laboratory criteria for assessing the hemostatic system and a list of biochemical markers of connective tissue to monitor the condition of patients before and after joint replacement in the context of modern anti-coagulant regimens remain to be defined.

Мета. На основі досліджень наукової літератури проаналізувати сучасний стан діагностики та профілактики порушень у системі гемостазу у хворих із коксартрозом III–IV ст. за Kellgren-Lawrence після операцій тотального ендопротезування кульшового суглоба. *Методи.* Здійснено пошук у PubMed, Web of Science, Google Scholar і Scopus. З використанням MeSH і ключових слів, таких як: «маркери запалення», «коксартроз», «тромбоемболія», «транексामова кислота», «антикоагулянти» «запалення», «фібриноліз», «Д-димер», «ендопротезування», «гіперкоагуляція», «плазміноген». *Результати.* Важливим питанням профілактики тромбоемболічних ускладнень під час тотального ендопротезування кульшових суглобів є визначення динаміки порушень фібринолізу. Встановлено, що ендопротезування кульшового суглоба характеризується збільшенням маркерів запалення в крові та порушенням гемостазу. *Висновки.* У клінічній ортопедії після операцій ендопротезування кульшових суглобів у хворих із коксартрозом III–IV стадій часто виникають ускладнення у вигляді порушень системи гемостазу, які супроводжуються розвитком тромбозу глибоких вен кінцівок, у важких випадках — тромбоемболією легеневої артерії. Контроль цих ускладнень проводиться за результатами визначення маркерів системи гемостазу, які досліджуються до та після оперативного втручання. Доведено, що існує велика кількість різноманітних чинників, які впливають на розвиток порушень системи гемостазу в організмі. Віковий фактор, адже пацієнти похилого віку мають власні особливості метаболізму, а також змінені реологічні властивості крові. Збільшення маси тіла, зокрема, ожиріння, також є важливим чинником, який не можна не враховувати в клінічній практиці. На сьогодні залишаються не до кінця визначені чіткі клініко-лабораторні критерії оцінювання системи гемостазу та перелік біохімічних маркерів сполучної тканини для контролю стану пацієнтів до та після ендопротезування суглобів на фоні застосування сучасних схем призначення антикоагулянтів. Ключові слова. Гемостаз, ендопротезування, кульшовий суглоб, тромбоемболія, плазміноген.

Keywords. Hemostasis, endoprosthesis, hip joint, thromboembolism, plasminogen

Introduction

Total hip arthroplasty is an effective method of treating patients with grades III–IV coxarthrosis by Kellgren-Lawrence, as it allows 85–95 % to obtain positive results and restore the musculoskeletal function of the lower extremities [1]. However, during such operations, severe thromboembolic complications (deep vein thrombosis, pulmonary embolism) occur in 24–62 %. Therefore, blood loss control is an important aspect of orthopedic surgery [2]. Hemorrhagic shock from trauma has been proven to be a cause of mortality in both the military and the civilian population. It is also known that effective hemostasis during surgery is of great importance for medical practitioners, as it prevents diffuse bleeding from capillaries and venules, which close the surgical field and increase the time of surgery and the risk of infection [3].

The study of hemostasis system disorders in patients after total joint replacement surgery is currently relevant and requires further study [2–6].

Purpose: based on analysis of scientific literature, to assess the current state of diagnosis and prevention of hemostasis system disorders in patients with grades III–IV coxarthrosis by Kellgren-Lawrence after total hip replacement surgery.

Material and methods

A search was conducted in PubMed, Web of Science, Google Scholar and Scopus. Using MeSH and keywords such as: “inflammatory markers”, “coxarthrosis”, “thromboembolism”, “tranexamic acid”, “anticoagulants”, “inflammation”, “fibrinolysis”, “D-dimer”, “endoprosthetics”, “hypercoagulation”, “plasminogen”. A comprehensive review of publications and meta-analyses was conducted to evaluate the functionality of the hemostasis system in patients undergoing endoprosthetic procedures. The study criteria were original and clinical studies, presented in English, high level of evidence, year of publication (2012–2025).

In total, 1,723 sources were identified by searching the literature in electronic databases, and 73 potentially suitable publications were selected from them during a detailed review. Ultimately, 46 publications were retained following further analysis.

Results and discussion

During joint replacement, localization of bleeding is especially important for obtaining satisfactory surgical results. Considering that it is very difficult to arrest bleeding from both intramedullary canals and bone surfaces mechanically, the use of pharmacolog-

ical agents (epinephrine, desmopressin, tranexamic acid, aminocaproic acid, etc.) may be a reasonable addition for this purpose [3, 7].

The fibrinolytic system of the blood is involved in hemostasis, removing blood clots after vascular damage is repaired. In recent years, scientists have evaluated the effectiveness and safety of antifibrinolytic agents in reducing perioperative bleeding [8–10].

Some conditions that clearly require the use of antifibrinolytic drugs include trauma, postpartum hemorrhage, cardiac surgery, spinal surgery, and knee or hip replacement [11–23]. There is currently little research on the perioperative features of the fibrinolytic system. The physiology of fibrinolysis, its relationship to thrombus structure, and perioperative preparation have been described [24]. Pathophysiological mechanisms relevant to clinical practice and their possible designs are discussed according to the proposed classification [25]. Today, there is a need to provide physicians with a broader understanding of the normal functioning of fibrinolysis, the mechanisms of possible deviations from the norm in the perioperative period, the pathophysiological rationale supporting the current indications for antifibrinolytic drugs, and some recent results obtained during their use [26–28].

An important issue in the prevention of thromboembolic complications during total hip arthroplasty is determining the dynamics of fibrinolysis disorders. Their diagnosis involves an assessment of the level of fibrinolytic activity, indicators of fibrin degradation products and thromboelastography results, which are decisive for prescribing therapy to prevent thrombosis. Blood was taken from patients who underwent arthroplasty to study the level of D-dimer and fibrin degradation products before, during and after surgery within 6, 12, 24 and 48 hours. Thromboelastography indicators and D-dimer levels correlated with coagulation and fibrinolysis data, all were within normal limits, although higher than before surgery. In addition, the dynamics of D-dimer and fibrin degradation products correlated with blood loss during surgery. As a result, they were found to be quite effective and informative diagnostic indicators for predicting fibrinolytic activity in the postoperative period, in particular, 6 hours after the intervention [29]. In addition, postoperative complications, such as venous thromboembolism, cerebrovascular and cardiac diseases, were the main sources of mortality risk in the early postoperative period [30–33]. Therefore, acute deep vein thrombosis is an absolute contraindication for elective hip or knee arthroplasty. Surgery may displace existing thrombi, which will lead to potentially

life-threatening complications, such as pulmonary embolism.

In the following studies, inflammatory markers were determined after hip arthroplasty. 70 subjects of different sexes were examined, the average age of which was (68.4 ± 10.9) years. Inflammatory markers were determined before, the next day, and 5 days after surgery. Thus, after surgery, their significant increase was found, in particular, C-reactive protein by almost 10 times. Interleukin-6 increased significantly the day after surgery, but decreased on the 5th day. The number of leukocytes and the ratio of neutrophils and lymphocytes, as well as platelets and lymphocytes, was significantly increased compared with the indicators before surgery. Thus, it was established that hip arthroplasty is characterized by an increase in inflammatory markers in the blood and impaired hemostasis. Therefore, determining their number can provide useful information for monitoring patients at risk of cardiovascular thromboembolic complications [34–35].

F. Hartono et al. evaluated the clinical significance of deep vein thrombosis after total hip and knee arthroplasty, which was accompanied by metabolic changes in biochemical markers, namely collagen types I and IV, tissue factor, P-selectin and nitric oxide. Patients were classified into three categories: the first group received total arthroplasty, the second group underwent hemiarthroplasty, and the third group received open reduction internal fixation. In all groups of patients, thromboprophylaxis was not performed.

Blood tests were carried out on the 3rd and 6th day after the intervention. Deep vein thrombosis was detected, which was confirmed by ultrasound Doppler and venography 6 days after the operation. Deep vein thrombosis was diagnosed in 18 patients (10 after total arthroplasty, 5 after hemiarthroplasty, 3 after open reduction internal fixation). Thus, the risk of this complication in patients after total arthroplasty was found to be 3.5 times higher than after open reduction internal fixation. Moreover, biomarkers (type I collagen) and nitric oxide underwent changes as early as 3 days after the operation. This study established that traumatization of the metaepiphyseal spongy bone tissue of the joints affects the frequency of deep vein thrombosis, confirmed by an increase in biochemical markers. Three days after the operation, they became the most informative for predicting the development of thrombosis. Other biochemical parameters used in the study (type IV collagen, tissue factor, and P-selectin) were not diagnostic. The authors also emphasize the need for further research on this topic [36].

O. E. Dahl et al. emphasize that hip joint implantation with bone cement intraoperatively affects the development of cardiovascular and vascular complications. They proved that patients after prosthetics using cement often posthumously detected microemboli and fibrin deposition in the lungs. The reasons for such changes are, apparently, the launch of the hypercoagulation mechanism and the local reaction to methyl methacrylate, based on which bone cement is created. A significant amount of toxic substances is formed at the implantation site, which, together with cell fragments, are released by damaged tissues. These fragments are transported by blood to the lung tissue, where they accumulate with the development of microcirculation disorders and the formation of emboli. Thus, circulatory disorders occur in the lungs with concomitant hypercoagulation, which can cause significant dysfunction of various organs and tissues with an impact on the brain, cardiovascular system, renal blood flow, and also lead to hemodynamic disorders. In a number of patients, these changes lead to fatal outcomes, particularly in the elderly with femoral neck fractures. Thus, the pathophysiological mechanisms underlying the above-mentioned abnormalities in cemented hip arthroplasty may have serious consequences in the form of hypercoagulable complications due to cell destruction and toxic reactions to bone cement, which are also associated with vasoactive substances [37]. A. Abedi et al. indicate that the risk of venous thromboembolism (VTE) increases after total hip and knee arthroplasty. Although most VTE prophylaxis regimens are prescribed postoperatively, activation of the blood coagulation system begins during the intervention. During prosthetic repair, after reaming the femur for prosthesis installation, it is manifested by increased levels of thrombin-antithrombin complex, prothrombin fragment 1+2, fibrinogen peptide A and D-dimer. Intraoperative heparin significantly reduces the level of fibrinopeptide A and prothrombin F1.2, which indicates a decrease in the synthesis of thrombin and fibrin, but does not affect the thrombin-antithrombin complex [38]. F. J. Conway et al. investigated the role of vitamin C in the development of connective tissue impairment and hemostasis after hip arthroplasty. Ascorbic acid is a well-known water-soluble vitamin that has many diverse metabolic functions in the human body. In particular, it has the properties of a universal antioxidant that can protect cells from damage, as well as an effect on hemostasis. In addition, vitamin C is involved in the synthesis of some hormones, collagen, carnitine, as well as the formation of bile salts and affects the normal absorption of iron

by the human body. There are also publications that prove that there is a correlation between the content of ascorbic acid in human blood plasma and the systemic inflammatory process, which is controlled by the concentration of C-reactive protein in the blood. Changes in the content of vitamin C and tocopherol in the blood of patients and their correlation with tissue damage by free radicals as components of systemic inflammation were revealed. During the observation, blood tests were performed 1, 2, 3 and 90 days after hip replacement. It determined such biochemical markers as ascorbic acid, malondialdehyde, cholesterol, C-reactive protein, tocopherol and albumin levels. A significant decrease in the blood content of vitamin C was found by 74, tocopherol by 36, cholesterol by 40, malondialdehyde by 38, albumin by 29 %. At the same time, the content of C-reactive protein increased by as much as 160 times due to the systemic inflammatory process after surgery. Three months after surgery, all indicators that were analyzed at the beginning of the study returned to their previous values.

As a result, it was found that the content of ascorbic acid can be an important and informative biochemical marker in the case of the development of a severe systemic inflammatory response in patients after surgical interventions on hip joint replacement. Therefore, a decrease in the content of vitamin C in the blood is apparently associated with its use by the body as an antioxidant to support the regenerative capacity of tissues and repair damage during the intervention, which caused a severe systemic inflammatory reaction [39]. N. Guler et al. investigated the mechanisms of fibrinolysis disorders in patients after total hip joint replacement, which, in their opinion, remains an incompletely studied issue. As is known, violations of the fibrinolytic link of hemostasis in various inflammatory processes and their activation after surgical interventions are not always sufficiently pathogenically justified. We investigated the fibrinolysis system disorders in patients in the first 24 hours after surgery for total hip arthroplasty. They can lead to both thrombosis and bleeding in clinical practice. We studied the medical histories of 98 patients who underwent arthroplasty. Among the fibrinolysis indicators, D-dimer and plasminogen activator inhibitor, as well as tissue plasminogen activator were determined using the enzyme-linked immunosorbent assay method, and the antiplasmin indicator was also studied. The level of fibrinolysis markers, except antiplasmin, before surgery was found to be significantly higher in patients compared to clinically healthy individuals. However, the percentage of anti-

plasmin before surgery was lower than in the control group. The levels of plasminogen activator inhibitor and D-dimer in patients were elevated, and the level of antiplasmin was lower, compared to the values before surgery. Changes in tissue plasminogen activator are insignificant. No correlation between the content of plasminogen activator inhibitor and D-dimer was also established.

The results obtained by the authors confirm the violation of the fibrinolysis system in patients after surgery for total joint replacement. They also determined that during surgical intervention, control of the fibrinolysis system is mandatory, since its violation can lead to complications in the form of bleeding, hematomas and the need for blood transfusion [40]. A. Burleson et al. conducted a study on the influence of perioperative factors on the fibrinolysis system in patients who underwent endoprosthetic repair of large joints. It is widely recognized that the majority of patients requiring total joint replacement, particularly hip and knee, are elderly individuals who often present with concomitant diseases, an elevated body mass index, and impaired carbohydrate metabolism. All these factors can affect the fibrinolysis system both before and after surgery. The authors revealed the influence of age, body mass index and the use of tranexamic acid in the treatment of patients on the fibrinolysis system. A total of 99 patients who underwent total hip and knee arthroplasty were examined. Blood tests were performed on patients before surgery and on the first day after surgery, and the levels of D-dimer, plasminogen activator inhibitor, and tissue plasminogen activator were determined using enzyme-linked immunosorbent assay methods, as well as the level of antiplasmin. Data on the age, sex, hemoglobin level, and body mass index of patients were systematized during the study of their medical histories.

Blood levels of D-dimer and tissue plasminogen activator were shown to have a positive correlation with the age of patients, while the antiplasmin index before surgery was negatively correlated with age. Body mass index is associated only with the preoperative level of tissue plasminogen activator. The type of surgical intervention had no effect on the value of fibrinolysis. There was no significant difference in the D-dimer, plasminogen, tissue plasminogen activator, or antiplasmin data between patients who received tranexamic acid and those who did not. The concentration of D-dimer and tissue plasminogen activator showed significantly lower results in individuals who received this acid. The data obtained by the authors confirmed that the advanced age

of patients and an increased body mass index affect the disruption of the fibrinolysis system after endoprosthesis repair, while the use of tranexamic acid reduces its level [41, 42].

Tranexamic acid is a potent antifibrinolytic agent with recognized efficacy. Its use during joint endoprosthesis repair is approved by clinical boards [43]. The use of tranexamic acid covers almost 95 % of patients after endoprosthesis worldwide [44]. The MATTER study (Tranexamic Acid in Surgery) included 896 patients and found a 6.5% reduction in mortality in patients receiving tranexamic acid [45].

Currently, therapeutic attention is focused on the fibrinolytic system, including the mechanisms regulating the formation and activity of plasmin on cell surfaces, fibrin, and extracellular matrix proteins, the effects of plasminogen/plasmin on platelet aggregation induced by various agonists, and its pro-inflammatory function. Charithani B. Keragala et al. reported that plasminogen administration improves thrombolysis and accelerates wound healing. Most of these findings have been based on in vitro or animal studies, but the use of antifibrinolytic agents to reduce bleeding in patients has been shown to have clinically significant benefits, including a reduced risk of infection that is independent of their hemostatic properties [46].

Conclusions

In clinical orthopedics, after hip joint replacement surgery in patients with grades III–IV coxarthrosis, complications are often observed in the form of hemostasis system disorders, accompanied by the development of deep vein thrombosis of the extremities, and in severe cases, pulmonary embolism. These complications are monitored based on the results of determining hemostasis system markers, which are examined before and after surgery.

Today, there is no clear consensus among orthopedic specialists, as well as anesthesiologists, therapists and specialists in hemostasis disorders regarding the rational, safe and effective use of anticoagulants, in particular, their correct combination in order to minimize the risks of postoperative complications from the blood coagulation/anticoagulant system.

Numerous factors have been identified that significantly impact the development of disorders within the hemostasis system. They include age factor, because elderly patients have their own metabolic characteristics, as well as altered blood rheological properties. Weight gain, in particular obesity, is also an important factor that cannot be ignored in clinical practice. In addition, cardiovascular disorders are re-

flected in the development of arterial hypertension, changes in the structure of vessels, and cause the formation of thrombi and microthrombi. All this must be taken into account when choosing the prevention of hemostasis system disorders in patients who require joint replacement.

Today, clear clinical and laboratory criteria for assessing the hemostasis system and a list of biochemical markers of connective tissue for monitoring the condition of patients before and after joint replacement against the background of the use of modern anticoagulant prescription schemes remain incompletely defined.

Conflict of interest. The author declares the absence of a conflict of interest.

Prospects for further research. Development of an algorithm for the diagnosis and treatment of patients with grades III–IV coxarthrosis is a further perspective of our research.

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HEMOSTATIC SYSTEM DISORDERS IN PATIENTS WITH COXARTHROSIS OF III–IV STAGES AFTER TOTAL HIP ARTHROPLASTY (LITERATURE REVIEW)

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At the beginning of 2025, the manual "Recommendations of the World Congress of Experts on Joint Replacement" was published, recommended by the Scientific and Publishing Council of the National Academy of Medical Sciences of Ukraine and intended for a wide range of users.

The relevance of this practical guide is due to the fact that the current world level of orthopaedics and traumatology is inevitably associated with the development of joint replacement. Despite the long history of organ-preserving surgeries and the high level of modern radiological diagnostics, it is arthroplasty that has significantly expanded the possibilities of treating various joint pathologies. Due to the technological sophistication of operations, this technique has taken a leading position in orthopaedics, especially in the treatment of complex clinical cases. In Ukraine, the development of arthroplasty is proceeding at a rapid pace, catching up with what was lost during the economic downturn.

However, the lack of awareness of modern approaches among domestic orthopaedic surgeons leads to severe complications. That is why the publication of this edition will be a reliable tool for specialists in their practical work.

The manual has a logical structure and covers the key aspects of modern arthroplasty practice. The main sections include selection of indications for surgery, prevention of complications, analysis of topical clinical issues that arise in daily practice, as well as analysis of modern techniques and features of their application. The publication covers not only the issues of primary and revision arthroplasty, but also certain approaches to preventing unsatisfactory results and the development of complications, including the prevention and treatment of periprosthetic infection.

This guide presents 58 topical and controversial issues, each of which has been subject to consensus among global experts. All material is based on current evidence, thorough literature review, and expert opinion from leading specialists from around the world, which underscores the importance of the issues covered. Each statement corresponds to the most current trends in the field of arthroplasty, where theoretical basis and professional experience are combined, making it a relevant guide for orthopaedic traumatologists of all levels.

The practical guide "Recommendations of the World Congress of Experts on Joint Replacement", prepared by Stanislav Bondarenko and Javad Parvizi, is of practical value and is recommended for a wide range of readers. It is structured in such a way that every specialist can quickly find the necessary information and apply it in their practice. The presentation of the material is based on the latest developments and implementations of the world's leading orthopedists, anaesthetists, surgeons and rehabilitation specialists, making it an indispensable guide for the development of future medicine.