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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 складали 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 критерій оцінювання обрали показники болю, обсяг рухів, осьове навантаження і відновлення функції (працездатності), рентген ознаки мозолеутворення, деформацій або міграцій 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 КФКлК 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.

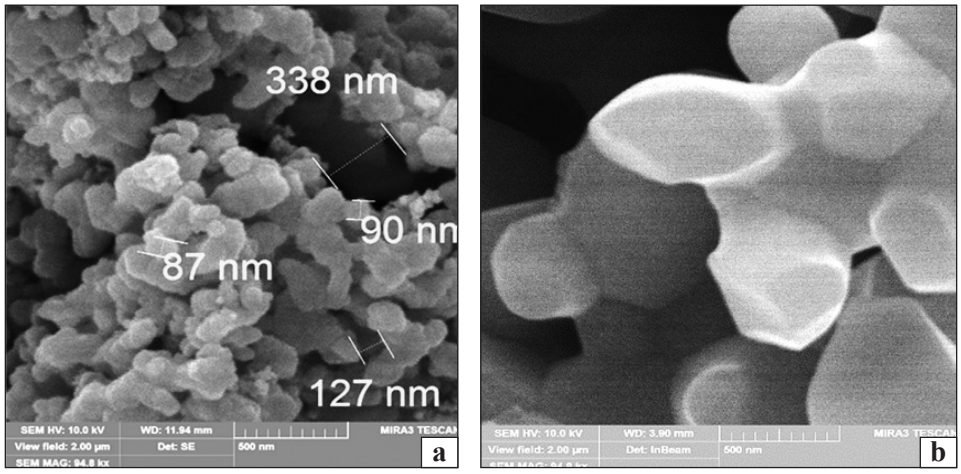

Fig. 1. Microstructure of nanostructured bioactive ceramics modified with silicon (a) and conventional porous two-phase bioactive ceramics (b), same magnification

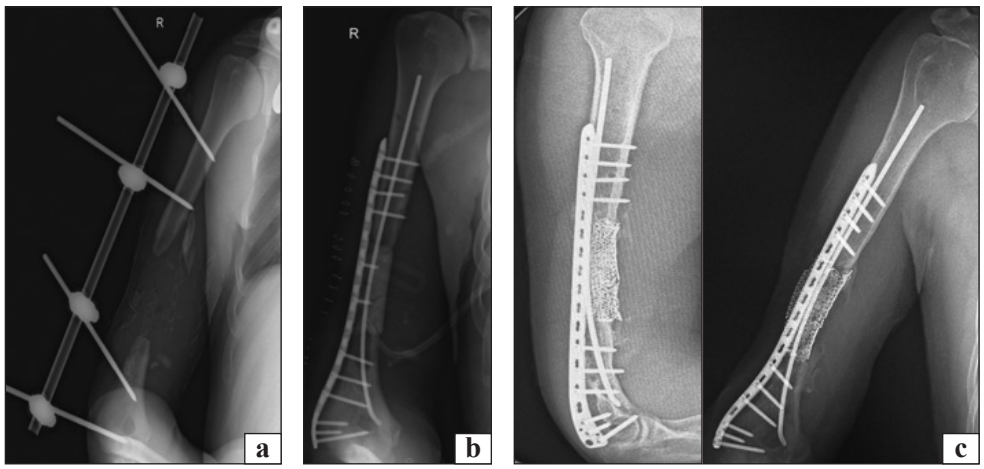

Fig. 2. Combined two-stage bone grafting according to the Masquelet method (radiographs after necrosequestrectomy in the EFD (a) and the 1st stage (conversion of metal osteosynthesis and filling of the defect with a PMMA spacer) (b) and the 2nd with TEN metal fixation with a bone plate and titanium mesh,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

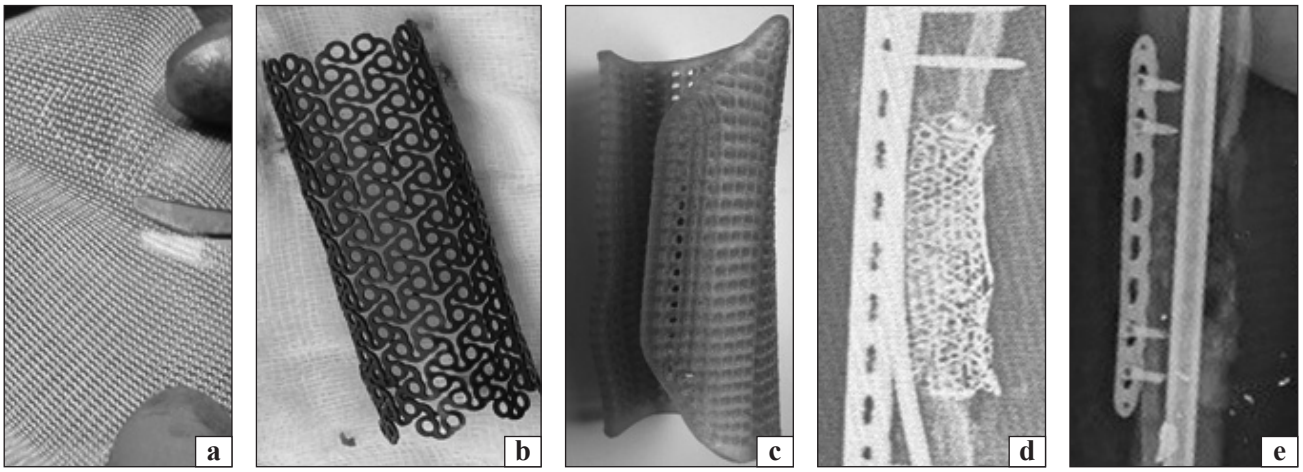

Fig. 3. Examples of using different types of meshes to form a mixture of autospongiosa and SdCPC (biopolymer mesh (a), titanium modeled mesh (b), 3D-modeled biodegradable mesh (c)), examples of the appearance of meshes on X-ray control (radio-contrast titanium (d) and non-radio-contrast biopolymer (e))

Table

Modified 100-point scale for evaluating surgical outcomes

Criteria	Result			Scoring criteria
	excellent	satisfactory	unsatisfactory	
Pain syndrome 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 complications	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 autospongiosa 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

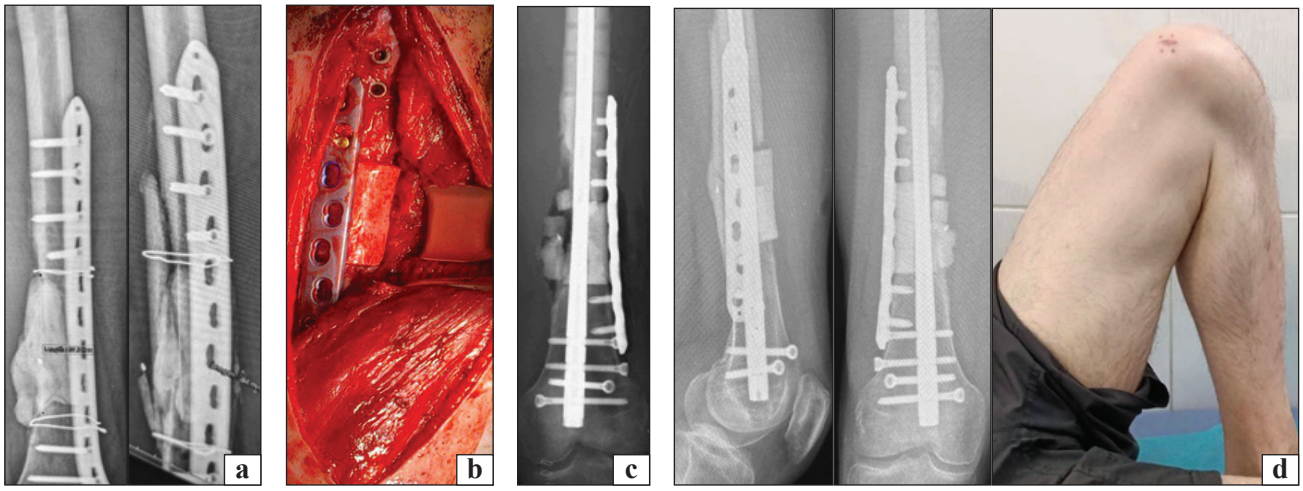

Fig. 4. Example of using 3D modeling in the conditions of using SdCPC products. X-ray of a patient with a defect of the femoral shaft after MOS with a plate and replacement of the defect with a PMMA spacer (a), during the operation, replacement of the defect with a 3D-modeled SdCPC implant (b), in the 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)

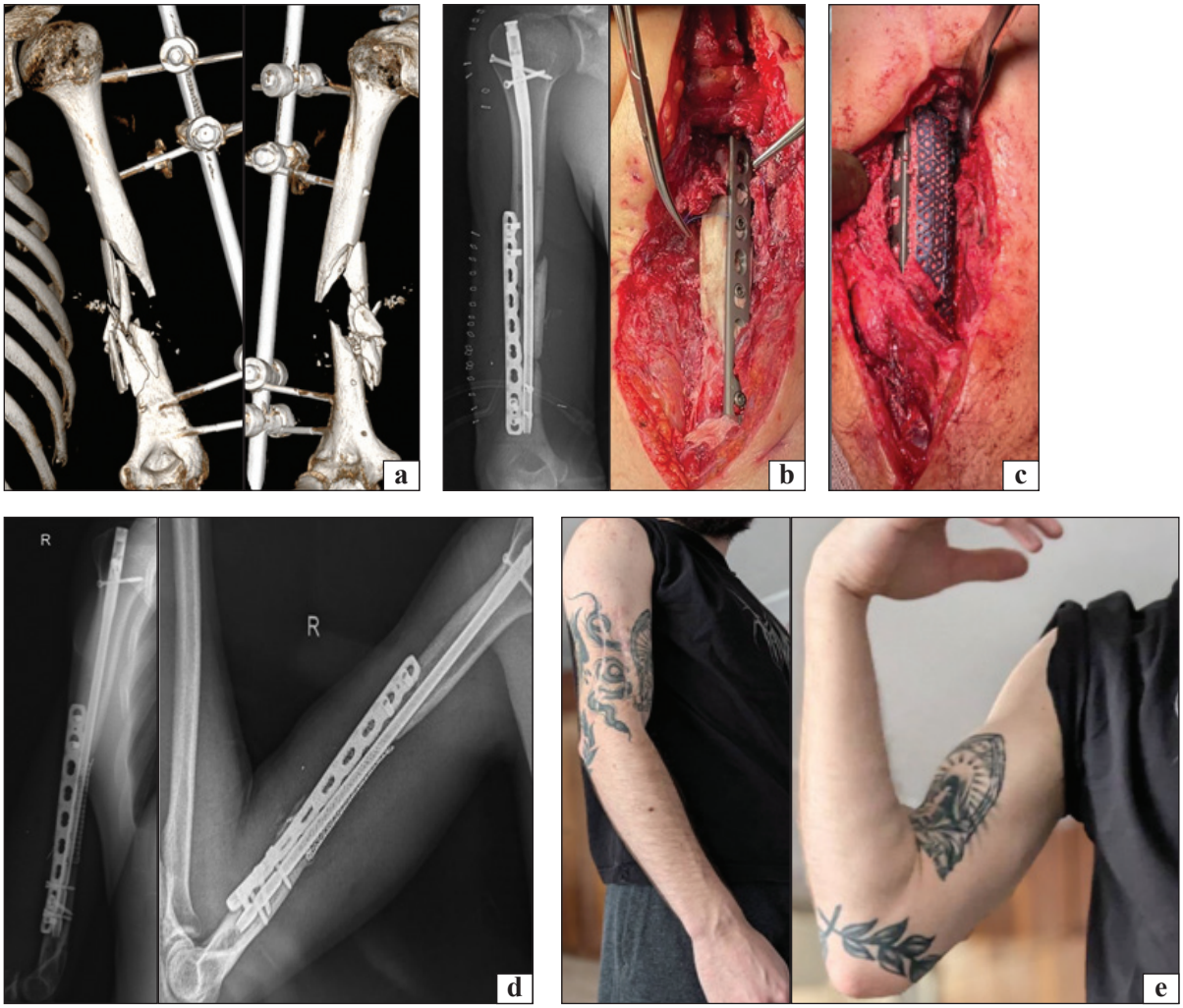

Fig. 5. An example of treatment of a patient using the Masquelet technique with a critical defect of the humeral diaphysis on CT (a), after conversion of external metal osteosynthesis to submerged at the 1st stage with replacement of the defect with a PMMA spacer (b) and at the 2nd stage — plastic surgery of the defect with a mixture of autospongiosa 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 autospongiosa 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., Kolomiyets 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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