INTRODUCTION
Open fractures of the lower leg bones are often the result of high-energy events, including vehicle collisions (> 50%), a direct blunt blow to the tibia, sports injuries, or falls from a height [1, 2]. Over the past decades, scientific advances in wound care, prophylactic antibiotic therapy, fracture stabilization, and soft tissue reconstruction have made it possible to relieve and improve the condition of patients. However, the infectious marker is still a serious complication due to an open fracture of the lower leg bones. Treatment of these injuries requires a thorough and team approach. Therefore, the main principles of therapy are as follows: timely administration of antibiotics, careful surgical debridement of the wound, stable fixation of the fracture and replacement of soft tissue defects. Treating patients with high-energy injuries of the lower extremities is a long-term process and leads to a high percentage of unsatisfactory results. Therefore, these arguments serve as a convincing basis for studying this problem thoroughly and searching for the best ways to solve it [3].

THE AIM
To analyzed the long-term results of treating patients with open fractures of the lower leg bones after one year and after five years and also assess the problems faced by the patients during this time period.

MATERIALS AND METHODS
During 2008–2016, 76 patients with open fractures of the lower leg bones which belong to the type III fractures according to the Gustilo-Andersen classification were treated at the Orthopedic and Traumatology Center of the Kyiv Region Clinical Hospital “OTC KRCH” which is the municipal non-profit enterprise of the Kyiv Region Council. A retrospective study was carried out to evaluate the results of the final treatment of patients after one year and after five years. In the course of the analysis of results, 8 (10.53%) patients left the experiment after 5 years: communication with 5 patients was lost; 1 patient died (according to relatives).
Patient treatment results were assessed using clinical and radiological methods. The following criteria were taken into account: X-ray image of the fracture union; subjective feelings of a patient; if there are any biomechanical disorders; efficiency restoration and if there are movement restrictions in adjacent joints, deformities and shortening.

The assessment was carried out using a modified Neer-Grantham-Shelton 100-point scale of anatomical and functional results of treating fractures of long bones [4]. The motion range of the knee and ankle joint, as well as the functional status of the ankle joint were analyzed using the American Orthopedic Foot and Ankle Score (AOFAS) (scores from 0 to 100). The quality of life of patients was assessed using the 36-Item Short Form Survey (SF-36).

Pain intensity, patient satisfaction with the effect of surgical treatment and therapy in general, daily work and sports activity were assessed using a 10-point VAS scale. The remaining variables are expressed as M ± SD, and categorical variables are expressed in percent. The Kolmogorov-Smirnov test was used to assess the normal distribution. Student’s t-test was used for parametric variables when comparing groups. The Mann-Whitney U test was used for nonparametric variables. Fisher’s test was used for the comparison of groups in terms of quality indicators. The correlation was assessed with Pearson’s method. Differences were considered statistically significant if the probability of events was more than 95% in the general population and the risk of error did not exceed 5% (p < 0.05).

Among all patients who took part in the study, type IIIA injuries were observed in 41 (53.95%), type IIIB – in 26 (34.21%), type IIIC – in 9 (11.84%). The exclusion criteria from the study were such factors as the patients who are under 18 years old and who had gunshot fractures of the lower leg bones. The average age of the patients was 39 ± 6.5 years at the time of injury. The total number of patients under observation included 59 (78%) men and 17 (22%) women. In 36 (47.37%) patients injuries were caused by a road traffic accident, in 17 (22.37%) patients – due to a fall from a height, in the remaining 23 (30.26%) patients – by a home accident.

All patients were divided into two groups during treatment. Group I included 47 (61.84%) patients for whom the fixation method was changed from the external fixation to the internal one (with an intramedullary nail or a plate). Patients for whom the final treatment of an open fracture was carried out in an external fixation device (EFD) of the AO type or using the Ilizarov apparatus without changing the fixation method were included in group II, which consisted of 29 (38.16%) patients.

**RESULTS**

The treatment approach for all patients included initial surgical debridement (ISD) and fracture stabilization with external fixation devices. The medical staff conducted a second examination within 24–72 hours, if necessary. In all patients, wound healing occurred within 30 days (on average 24 ± 4.5 days). At the first stage, skin defects were closed applying temporary methods: in 7 patients – with an artificial skin; in 24 patients – with a VAC system; further, autodermoplasty with a split flap was used in 14 cases, skin-fascial flaps were used in 19 cases, and free microsurgical flaps were used in 3 cases.

When evaluating the treatment of patients in group I, 32 (68.09%) of them underwent a one-stage removal of an external fixation device and osteosynthesis of fragments during the first 7-10 days: with an intramedullary nail in 9 (28.13%) patients and a plate in 23 (71.87%) patients. In 3 (20.0%) patients, osteosynthesis was performed with an intramedullary locking nail, in 12 (80.0%) patients – with a plate. The decision to change the fixation method was made taking into account two parameters:

1) clinical (primary wound healing, no necrosis and signs of inflammation);
2) laboratory (WBCs, ESR, CRP, and IL-6).

The dynamics of laboratory blood parameters were studied on the first day of injury, before and after the repeated examination, as well as before changing the fixation method.

In the course of treatment of patients of group I, specific complications were observed. In 4 (8.51%) patients, there was early suppuration in the fracture area after osteosynthesis with a plate. To stabilize the position, surgical interventions were performed to eliminate the focus of infection and to preserve the internal fixation device if possible. As a result of treatment, 3 (6.38%) patients showed elimination of the source of inflammation and subsequent fracture consolidation; one (2.13%) patient was diagnosed with chronic osteomyelitis. The therapy of chronic infection was conducted along with the fracture treatment with the external fixation device. In addition, repeated surgical interventions were performed to eliminate the source of infection, and repeated necrosectomies were performed. The soft tissue defect was treated with the VAC system. Antibiotic therapy was prescribed taking into account intraoperative inoculation.

As a result of the treatment, it was possible to stop the infection and to heal the tibia. As a result, a pseudarthrosis of the tibia was formed in 5 (10.64%) patients; in 12 (80.0%) patients – with an intramedullary locking nail, in 12 (80.0%) patients – with an intramedullary nail.

All patients underwent repeated surgical interventions to heal the fracture which made it possible to observe the consolidation of the fracture on X-ray images within 8-24 months.

After 1 year, final indicators were assessed in group I according to a modified Neer-Grantham-Shelton 100-point scale of anatomical and functional results of treating long bone fractures. Good results were observed in 27 (57.45%) patients, satisfactory – in 14 (29.79%) patients, unsatisfactory – in 6 (12.77%) patients. The average shortening of the affected limb was 1.42 cm; average extension and flexion in the knee joint were 167.5 degrees and 95 degrees, respectively; average dorsal extension and plantar flexion of the ankle were fixed at 110 degrees and 80 degrees.
Dynamics was observed in 30 (73.17%) patients, satisfactory – in 9 (21.95%) patients, unsatisfactory – in 2 (4.88%) patients. The average shortening of the affected limb was 1.42 cm; the average extension and flexion in the knee joint were 177.5 degrees and 60 degrees, respectively; average dorsal extension and plantar flexion in the ankle joint were 122 degrees and 75 degrees, respectively. The average score according to the AOFAS was 92.5 ± 5.3 points.

Evaluation of the survey data according to the HRQoL scale showed statistically significantly reduced results of the quality of life in age groups. The average pain intensity according to the visual analogue scale (VAS) was 2.8; the average score of patient satisfaction with the surgical effect was 9.2 points; overall satisfaction with treatment was 8.6 points; the average score of deterioration in daily and sports activity was 4.0 and 4.8 points, respectively.

The final treatment of patients in group II was carried out in an external fixation device: 25 (86.21%) patients – in rod devices, 4 (13.79%) patients – in an Ilizarov apparatus. In 3 (10.34%) patients of this group who had open fractures of type IIIC, amputation of the lower limb at the lower third of the thigh was performed. Acute suppuration was registered in 6 (20.69%) patients, which was followed by the development of chronic osteomyelitis (noted in one (3.45%) patient). Its treatment included repeated surgical interventions in order to eliminate inflammation in the bone tissue, as well as antibiotic therapy taking into account seeding tissue samples taken during the operation. The effect of the measures taken was observed when the fracture was fused and there was no inflammatory process in the projection of the lower leg bones.

In 7 (24.14%) patients, nonunion of the lower leg bones was observed. During the treatment of 4 (66.67%) patients, we achieved the complete union of the fragments and elimination of the inflammatory process; 2 (33.33%) patients were diagnosed with chronic osteomyelitis, which was confirmed radiographically and clinically. These patients, like the previous ones, who had an infection, underwent surgical treatment to remove the foci of the infectious process, fracture treatment with an external fixation device, antibiotic therapy and treatment of soft tissue defects using VAC systems. Elimination of chronic osteomyelitis and registration of complete fusion were observed within 1 year and 1.5 years after the start of therapy.

In group II, the final indicators were assessed after 1 year according to a modified Neer-Grantham-Shelton100-point scale of anatomical and functional results of treating fractures of long bones. Thus, good dynamics was observed in 9 (31.03%) patients, satisfactory – in 8 (27.59%) patients, unsatisfactory – in 12 (41.38%) patients (p = 0.012 in comparison with group I). The average shortening of the affected limb was 1.67 cm; average extension and flexion in the knee joint were 172.3 degrees and 100 degrees, respectively; average dorsal extension and plantar flexion of the ankle were fixed at 110 degrees and 80 degrees, respectively. The average score according to the AOFAS was 79.8 ± 6.5 points.

After 5 years, the results were assessed in 27 patients, 2 of them refused to take part in further research. As a result, good results according to the Neer-Grantham-Shelton scale were noted in 8 (29.63%) patients, satisfactory – in 9 (33.33%) patients, unsatisfactory scores were noted in 10 (37.04%) patients (p < 0.0001 in comparison with group I). The average shortening of the affected limb was 1.67 cm; average extension and flexion in the knee joint were 175.3 degrees and 70 degrees, respectively; average dorsal extension and plantar flexion of the ankle were at 100 degrees and 85 degrees, respectively. The average score according to the AOFAS was 82.1 ± 5.9 points.

The evaluated results of the questionnaire survey according to the HRQoL scale in age groups also showed statistically significant underrating of the quality of life. The average pain intensity according to the visual analogue scale (VAS) was 2.6; the average score of patient satisfaction with the surgical effect was 8.5 points; overall satisfaction with treatment was 8.4 points. The average score of deterioration in daily and sports activity was 3.8 and 4.2 points, respectively.

When analyzing the long-term results of treating type III open fractures of the lower leg bones according to the Gustilo-Andersen classification, the number of good indicators in group I increased by 15.72%, and in group II – by 2.3%. The number of unsatisfactory results in group I decreased by 7.89%, and in group II – by 4.34% (p < 0.01).

A significant inverse correlation (p < 0.01) was observed between the intensity of pain and all subgroups of the SF-36 (r = -0.428 – -0.757), AOFAS, VAS scores, especially in terms of life satisfaction, deterioration in daily, work and sports activity. Additionally, there was a positive correlation between the level of dorsal extension in the ankle joint and subgroups of the SF-36 general health scale (r = 0.358; p = 0.035). The SF-36 also shows an inverse correlation between total treatment time and patient satisfaction with the result (r = 0.358; p = 0.003), limb functioning (r = -0.344; p = 0.04), mental health problems (r = -0.339; p = 0.032).

Thus, treating patients with type III open fractures of the lower leg bones according to the Gustilo-Andersen classification by changing the fixation method from external fixation to internal one leads to significantly better results than the use of osteosynthesis with external fixation devices.

**DISCUSSION**

Today, the treatment of patients with open fractures of the lower leg bones is a relevant issue for an orthopedic traumatologist. In their practice, fractures of the lower leg bones are common – from 23 to 35.5% of all injuries...
Stable fixation of the fracture is a necessary step in treating patients with open fractures of the lower leg bones. In this regard, the method of controlled transosseous osteosynthesis, the founder of which is Academician G.A. Ilizarov, is the "gold standard." This method is indispensable in the treatment of fractures and post-traumatic defects of the leg bones complicated by osteomyelitis. In this regard, the method of controlled transosseous osteosynthesis is used to treat patients with open fractures of the lower leg bones in the current conditions. The reasons for the unsatisfactory results of treating patients with open injuries of the lower leg bones are: lack of consensus among traumatologists regarding the choice of optimal treatment approach for patients, taking into account the severity of the open injury; insufficiently thorough primary surgical treatment of wounds; limited use of drainage and soft tissue plastic closure techniques.

When treating all patients with open fractures, we adhered to a consistent approach with regard to this matter. At the initial stage (when the patient was admitted to us), initial surgical debridement and stabilization of a fracture with an external fixation device were performed in order to create optimal conditions for wound healing and fracture union.

Initial surgical debridement includes radical debridement of a wound, intraoperative irrigation of a wound and its closure. This set of measures is always used to prevent infection after severe trauma to a limb.

Moreover, we believe that additional surgical treatment plays an important role in the further assessment of tissue viability. On day 2-4 our patients (83% of the total number of patients) were re-examined to assess the quality of initial surgical debridement, which was carried out primarily in other hospitals. We actively used the VAC system (in 86% of cases) for temporary wound closure. This method promotes effective alignment of the wound edges, edema, forms granulation tissue and improves blood supply, as well as ensures the evacuation of separated and infected wound material. Such measures ensure rapid wound healing and subsequently allow the use of flaps for the final closure of soft tissue defects. It should be noted that the final closure of wounds is recommended no later than in 3 weeks.

Stable fixation of the fracture is a necessary step in treating patients with open fractures of the lower leg bones. In this regard, the method of controlled transosseous osteosynthesis is used to treat patients with polytrauma and with the development of compartment syndrome.

Some authors consider the use of an external fixation device as the most biologically justified method of skeletal stabilization which helps to maintain blood supply to the soft tissues of the lower leg. The advantages of this method are the relative speed and ease of use, access to soft tissues during their further reconstruction.

It should be emphasized that when an external fixation device is used for a long period there are often inflammation of the soft tissues around the pins and nails, neurotrophic disorders in the lower leg and foot, lymphostasis, and persistent contractures of nearby joints. The external fixation devices require constant medical supervision and patient care. In addition, their use significantly reduces the patient's quality of life. Therefore, many authors consider the optimal solution to replace the external fixation device with the internal one after wound healing to adapt the fragments, as well as to improve the functional and social rehabilitation of patients.

In this regard, the OTC KRCH successfully used a two-stage approach of operative fixation of bone fragments in case of lower leg open injuries. To improve the results of treatment, we removed the external fixation device and changed the osteosynthesis method in 61.84% of patients. The operation to change the method was carried out only if: the patients did not have deep purulent complications and showed normalization of body temperature; there were no laboratory signs of inflammation (WBCs, ESR, CRP, and IL-6).

Changing the fixation method from the external to the internal one made it possible to adapt the fragments, perform bone grafting, and ensure stable osteosynthesis of the fracture.

When evaluating the results of treating patients with open fractures of the lower leg bones within 1 year and 5 years after the injury, we took into account complications that arose in the late period. The evaluation of the treatment method's effectiveness was based on clinical data, X-ray images, as well as information on the degree of impairment of the static and dynamic functions of the limb. The following signs were noted in patients for whom the fixation method was changed from external to internal after 1 year and after 5 years:

1. reducing the risk of developing pyoinflammatory complications by 65% (OR = 0.35 (95% CI: 0.07-1.7; p = 0.127));
2. there is no rotational instability of bone fragments;
3. there is no delayed consolidation and development of false joints;
4. the physiological axis of the injured limb is restored;
5. it is possible to refuse to use an external fixation device.

When analyzing the intensity of the pain syndrome after 5 years according to the VAS scale in both groups, patients note relatively minor pain and relative satisfaction with surgical and general treatment. Despite this fact, professional and sports activity was significantly weaker throughout the subsequent life of most patients. Every aspect of their quality of life was underrated according to the 36-Item Short Form Survey (SF-36) – physical limitations and psychological problems became the main reasons that led to this fact. The overall duration of treatment correlates...
with low patient satisfaction and an increase in the level of physical limitation, which leads to further problems, including psychological ones. Such an indicator as the intensity of pain became the main factor that negatively correlated with the patients’ quality of life.

Patients of both groups (more in group II) showed slight limitations in the range of motion in the knee and ankle joints. Limited dorsal extension of the ankle joint negatively correlates with the general health condition, as shown in the SF-36. Low scores according to the American Orthopedic Foot and Ankle Score (AOFAS) indicate limited motion in the ankle joint. Additionally, the AOFAS correlates with patient satisfaction with the result, deterioration in their daily life, including professional and sports activity. This emphasizes the importance of restoring the ankle joint for the person's daily active participation in social activities.

Moreover, the limitation of foot extension is further correlated with the limitation of activity in daily life and general health, as seen in the SF-36. These results prove that bone union in combination with successful soft tissue closure of the nonunion site should be the primary goal of treatment in such patients, despite the duration of therapy and the additional number of surgical interventions. Moreover, the limitation of movement in the ankle joint, which may arise as a possible result of prolonged immobilization or the formation of scar tissue, should be taken into account during the rehabilitation period.

In our patients, the average amplitude of extension in the ankle joint was > 75 degrees in group I and > 80 degrees in group II after five years. At the same time, there is a significant limitation of movement in everyday life, for example, when walking on an uneven surface and going up/downstairs.

CONCLUSIONS

1. Treating patients with high-energy injuries of the lower leg bones is a long-term process and leads to a high percentage of unsatisfactory results. In this regard, it is important to apply an integrated approach, minimize risks to the patient’s health and study the verified opinion of specialists, taking into account all factors to achieve an optimal therapeutic and surgical effect.

2. For the successful treatment of open fractures of the lower leg bones, an adequate initial assessment of the injury and readiness for multistage processes regarding the implementation of a whole complex of procedures are required: initial surgical debridement, fracture stabilization with an external fixation device, and, if necessary, the use of “second look” and timely closure of skin defects. Changing the fixation method from the external to the internal one will help improve patient treatment results. The main evaluative characteristics are such indicators as uncomplicated wound healing combined with the absence of laboratory and clinical signs of inflammation.

3. Despite the long period of rehabilitation of patients, we did not notice a significant improvement in the quality of their life. According to the evaluated SF-36, AOFAS, VAS scores, the patients experienced the greatest discomfort due to pain, decreased limb functioning, inability to return to their previous work and usual lifestyle. These observations were carried out in a group of patients with significant soft tissue trauma, for whom it was impossible to change the treatment method by replacing the external fixation with the internal one.

4. The urgent need to continue research in this field and find rational solutions is due to the factors described in this article. The problem of patients diagnosed with an open fracture of the lower leg bones has not been resolved yet and is far from obtaining more favorable outcomes.

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