Analysis of the use of transosseous osteosynthesis in the treatment of patients with diabetic neuroosteoarthropathy complicated by chronic osteomyelitis

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Abstract

Relevance Diabetic neuroosteoarthropathy (DNOAP) complicated by chronic osteomyelitis (CO) is one of the most common complications (up to 7.5%) in patients with diabetes mellitus. Treatment failure of such patients leads to amputation of the segment, and in some cases, to death. The use of the method of transosseous osteosynthesis is the only alternative method in the struggle for the limb salvage. Purpose Based on X-ray morphological criteria for assessing bone quality, to determine the optimal assembly of the external fixation device (EFF), which provides favorable conditions for restoring limb weight-bearing capacity in the treatment of patients with DNOAP complicated by infection. Materials and methods The analysis of radiographs and the clinical course of the reparative process in 49 patients (mean age 55.5 ± 9.4 years) with DNOAP complicated by chronic osteomyelitis was carried out. Two groups were distinguished based on the Ilizarov apparatus assembly: wire-based (WB) used in 25 patients; hybrid construct (HC) in 24 patients. The X-ray obtained in Jpeg format were analyzed using specialized Hi-scene software. The density of the bones of the foot was studied by MSCT. Results Comparison of the indicators of bone optical density in both study groups showed that there was an insignificant increase in the postoperative period Od of the calcaneus by 25% after treatment in patients from the HC group, and in the WB group by 43% in the distal tibia. At the same time, we noted a significant increase in the Od values of the tibia in the postoperative period in patients from the HC group and in the body of the calcaneus in patients from the WB group. MSCT showed that the density of the calcaneus before treatment in patients with DNOAP in the region of the calcaneal tubercle was 194.37 ± 49.05 HU, in the region of the body it was 205.47 ± 38.36 HU, in the region of the distal tibia 280.00 ± 40.30 HU. The analysis of the results of bone osteosynthesis of the affected segment showed that the rate of satisfactory outcomes after dismantling the device in patients from the HC group was significantly higher than in the WB group (56%) and amounted to 75%. Discussion As is known, pronounced osteoporosis of the bones of the lower leg and foot is often characteristic of patients with diabetes mellitus complicated by DNOAP and chronic osteomyelitis. A possible arsenal of treatment methods that allow solving the problems of stable arrest of the osteomyelitic process and restoring limb support in such patients is very limited. The optimal choice of the Ilizarov apparatus assembly type has an impact on the outcome of treatment of patients with this pathology. Conclusion Based on X-ray morphological criteria for assessing bone quality, our study showed a decrease in optical and densitometric bone density in patients with DNOAP complicated by chronic osteomyelitis compared to the norm. The use of wire-based assembly of the apparatus does not provide sufficient conditions for the solution of the set of the surgical tasks in this category of patients. The introduction of half-pins into the apparatus system provides the necessary fixation time with the possibility of functional load on the operated segment in patients in the postoperative period.

Keywords: diabetic neuroosteoarthropathy, chronic osteomyelitis, bone optical density, osteoporosis, external fixation device, Ilizarov method


INTRODUCTION

Charcot diabetic neuroosteoarthropathy (DNOAP) is one of the frequent and severe complications occurring in 7.5% of all patients with diabetes mellitus [1, 2, 3]. DNOAP is often characterized by multicomponent deformity of the foot, often accompanied by chronic wound and associated pyoinflammatory processes [4, 5, 6].

Currently, there are two treatment concepts (conservative and operative) for patients with DNOAP, the choice of which is guided by the Chantelau clinical and radiological classification [2, 3, 6, 7, 8]. In the acute period (active stage), according to the Chantelau classification, a conservative method of treatment is used that comprises limb immobilization with a circular bandage of the Total Contact Cast system [3, 7, 8, 9]. Fixation of the limb is carried out until the complete restructuring of the bone (chronic stage). Next, the fixator is removed and the patient is recommended to wear special orthopedic shoes [3, 7].

However, if DNOAP is complicated by infection process, the use of circular dressings becomes impossible. Thereby, inadequate treatment leads to amputation of the segment, and even to death in some cases (15-25%) [1,10].

Under these conditions, the use of the method of transosseous osteosynthesis is one of the alternative methods in the struggle for limb salvage [2]. However, due to osteoporosis, its use may be complicated...
by the external fixator apparatus instability (EFA). For this reason, in order to avoid the development of purulent septic complications and/or destruction of the bone at the points of wire insertion, it is necessary to dismantle the EFA prematurely, not achieving bone consolidation [11].

Additional causes of apparatus instability include a number of factors: inadequate load on the operated limb due to weakened pain and tactile sensitivity; insufficient strength of the apparatus, misjudged features of limb biomechanics [2]. Under these conditions, the study of bone quality is the most important task, since it underlies the choice of a treatment method and preventive measures [4, 5, 12, 13].

**Purpose** Based on radiographic morphological criteria for assessing bone quality, to determine the optimal assembly of the external fixation apparatus (EFA) that would provide favorable conditions for restoring limb weight-bearing capacity in the treatment of patients with DNOAP complicated by infection.

**MATERIAL AND METHODS**

It is a monocenter retrospective study of evidence level IV. Radiographic data and MSCT before treatment, radiography and the clinical course of the reparative process before and after surgery were studied in 49 patients with DNOAP complicated by chronic osteomyelitis. They were treated at the Clinic of Purulent Osteology (CPO) in the period from 2017 to 2020. The average age of patients was 55.5 ± 9.4 years. All patients were obese with an average BMI 31.2 ± 5.6. The duration of diabetes mellitus was 9.5 ± 6.5 years. The average target glycated hemoglobin (HbA1c) at the time of contacting the Clinic was 7.22 ± 1.8 %. Only 5 (10.2 %) patients received oral hypoglycemic drugs as the basic therapy for diabetes mellitus (glycated hemoglobin index 6.7 ± 0.6 %). Most of the patients (44; 89.8 %) were on insulin replacement therapy (glycated hemoglobin index 7.3 ± 1.8 %).

After the necessary complex of diagnostic measures in the preoperative period, all patients underwent surgical treatment aimed at debridement of the osteomyelitic focus, stabilization of the affected area of the foot and Ilizarov osteosynthesis of the segment.

**Radiography** To determine the grade of destructive changes and bone density, radiography of the foot and lower leg was performed in the AP, lateral, AP plantar and axial projections, under load and without it. Studies were performed upon admission to the clinic, on days 7-10, as well as monthly in the postoperative period and after the end of fixation in the apparatus. RADIOTEX systems were used, registration certificate FS No. 2006/527; RAYMAT ASI, registration certificate MZ-FS No. 2006/2099, CLINOMAT, registration certificate MZ-FS No. 2006/559. The radiographs in jpeg format were analyzed using the specialized Hi-scene software designed for reading and computer processing of digital results of radiological study [14]. The study of optical density was performed in all patients before and after treatment in predetermined areas of the distal metaphysis of the tibia and calcaneal body (Fig. 1).

![Fig. 1 Areas to study bone density (red squares)](image)

To analyze the optical density (OD) of the bone on the radiographic image at the symmetrical points of the calcaneus and distal metaphysis of the tibia, image areas of the same size were selected, on which a distribution histogram was constructed with color contrasting of the degree of mineralization. The obtained quantitative data (median, mean value of the dispersion and image brightness) from the selected fragments were introduced into a database in the Microsoft Excel 2010 editor for direct calculation of the optical density. Further calculations were made using the same editor using the following formula 1 [14].

Measurement of the optical density (OD) was carried out in arbitrary units (i) according to formula

$$OD_i = \log \left( \frac{I_i - I_m}{I_0} \right)$$

where $OD_i$ is the optical density of the $i$-th image element; $I_i$ is the intensity of the $i$-th element of the image; $I_m$ is the average intensity of soft tissue shadow; $I_0$ is the average background intensity.

**MSCT** The studies were performed on a GE Light Speed VCT computed system. MSCT was performed using a special reconstruction algorithm "BONE". Axial sections were processed in the multiplanar reconstruction (MPR) mode in the coronal and sagittal planes. VRT reconstructions were used. Measurements in the study of MSCT data were made using the RadiAnt DICOM Viewer program.
Before treatment, the total and local density (Hounsfield units (HU)) of the foot bones was measured with the construction of histograms. The architectonics of the calcaneus, talus, navicular, cuboid bones, and distal tibia were also studied (Fig. 2).

![Fig. 2 MSCT of DNOAP patient’s foot. MPR in the sagittal plane to determine bone density in the calcaneus, talus, tibia and tarsal bones (a), VRT reconstruction (b)](image)

**Treatment methods**

All patients were divided into 2 groups according to the type of apparatus assembly used: group 1 – wire-based (WB) assembly; group 2 – hybrid construct (HC).

The WB-group included 25 patients aged 55.6 ± 9.23 years with a BMI of 30.99 ± 5.23. The level of HbA1c glycemia in the patients of this group at the time of contacting the clinic averaged 7.42 ± 1.57 %. Osteosynthesis in patients of this group was performed using the traditional placement of the fixator on the lower leg and foot with transcortically inserted wires and fixed in a tensioned state in two rings on the lower leg and 2 half-rings or a single U-shaped support on the foot.

The HA-group included 24 patients aged 55.7 ± 7.57 years, with a BMI of 33 ± 4.8 and an HbA1c level of 7.35 ± 1.18 %. A distinctive feature of the frame assembly in this group was the introduction of half-pins into the EFA system as additional transcortical fixing elements (Fig. 3).

![Fig. 3 Frame assembly for tibia and foot osteosynthesis that includes half-pins](image)

**RESULTS**

The treatment of all DNOAP patients involved a surgical intervention aimed at eradication of the osteomyelitic process and osteosynthesis of the affected foot with EFA, segment stabilization until complete consolidation at the junction of the bones, confirmed by X-ray.

Radiographs of the feet of 20 people aged 53 ± 77.9 years with a BMI of 28.6 ± 73.22 without concomitant diagnosis of diabetes mellitus and orthopedic pathology of the foot and ankle joint, who applied to the clinic with infection in the bones of the upper limb were analyzed and served as a comparison group.

Statistical processing was carried out in Microsoft Excel spreadsheets using the Attestat program (version 9.3.1, author I.P. Gaydyshev, Rospatent Certificate No. 2002611109). Quantitative data are presented as medians and quartiles (ME [Q1; Q3]), for samples where the normality of the distribution was rejected. In cases with a normal distribution, quantitative data are presented as \(M \pm \sigma\), where \(M\) is the mean, \(\sigma\) is the standard deviation. The significance of differences was determined by the Mann-Whitney test with a significance level of \(p < 0.05\).

All studies were carried out in accordance with the ethical standard of the Declaration of Helsinki of the World Medical Association "Ethical principles for conducting scientific medical research involving human subjects" as amended in 2000 and "Rules of Clinical Practice in the Russian Federation", approved by the Order of the Ministry of Health of the Russian Federation dated June 19, 2003 No. 266. Patients signed an informed consent for the publication of data obtained from studies, without identification of individuals.
However, in the late postoperative period, there was instability of the external fixation apparatus in the area of the inserted fixation elements (wires, half-pins). Radiographically, this was characterized by bone resorption around transcortically placed wires and/or half-pins (Fig. 4).

Bone resorption around transosseous fixation elements (wires, half-pins) was observed in all patients with DNOAP treated by the method of transosseous osteosynthesis in our clinic. It should be noted that, depending on the type of EFA configuration used, we observed similar bone changes at different time intervals of the postoperative period (Table 1).

For this reason, in order to avoid or stop infection, the apparatus was dismantled in some cases prior to consolidation at the junction of the bones of the affected foot.

Thus, in the period up to 2 months, due to the developed instability, the device was dismantled in 48% of patients included in the WB-group and in 20.5% of cases in the HC group. At the same time, the average time of fixation in the device in patients of the WB-group was $59 \pm 11$ days and $60 \pm 12$ days in the HC-group. In the postoperative period from 2 to 4 months, EFA was dismantled in 32% of patients in the WB-group ($99 \pm 17$ days) and in 37.5% of patients in the HC group on day $107 \pm 14$. In the late postoperative period (more than 4 months), EFA was dismantled in 20% of patients from the WB-group on average after $181 \pm 37$ days and in 42% of patients from the HC-group on average after $186 \pm 36$ days.

Consolidation at the fragment junction of the operated segment in the area of surgical intervention was achieved in 56% of patients in the WB-group and in 75% of cases in the HC-group (Table 2). It should be noted that cases of achieved bone union were recorded regardless of the time interval in the postoperative period.

Based on Table 2, we revealed the highest rate of bone union in the two groups after more than 2 months of fixation in the postoperative period. However, in 3 (12%) patients from the WB-group, we observed complete consolidation of the bones of the operated segment within a period of 2 months of fixation. A similar pattern of bone union of the operated segment after dismantling of the EFA before 2 months of fixation was observed in the HC-group in 3 (12.5%) patients.

### Table 1

<table>
<thead>
<tr>
<th>Patients’ group</th>
<th>Distribution of patients based on fixation time in the frame</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>up to 2 months</td>
</tr>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>WB (n = 25)</td>
<td>12</td>
</tr>
<tr>
<td>HA (n = 24)</td>
<td>5</td>
</tr>
<tr>
<td>p (T ≤ t) two-sided</td>
<td>0.48</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Patients’ group</th>
<th>Distribution of patients based on consolidation time</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>up to 2 months</td>
<td>from 2 to 4 months</td>
</tr>
<tr>
<td></td>
<td>abs.</td>
<td>%</td>
</tr>
<tr>
<td>WB (n = 25, 100 %)</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>HC (n = 24, 100 %)</td>
<td>3</td>
<td>12.5</td>
</tr>
<tr>
<td>p (T ≤ t) two-sided</td>
<td>0.87</td>
<td>0.15</td>
</tr>
</tbody>
</table>
At admission to the clinic, the indicators of optical density (extinction) of bones, both on healthy and on the contralateral side, were lower in all 49 patients with DNOAP (Table 3) than in a similar age group who do not suffer from diabetes mellitus and do not have orthopedic foot pathology. Thus, the index of normal optical density of the body of the calcaneus was 2.52 [1.52; 3.05] units and 2.26 [1.72; 2.99] units at the level of the distal metaphysis of the tibia. At the same time, in the WB-group, the average optical density of the calcaneal body before treatment was 0.76 [0.65; 1.17] units and 0.93 [0.77; 1.32] units in the area of the distal metaphysis of the tibia. In the HC-group, extinction values before treatment of the calcaneal body were 0.92 [0.76; 1.25] units (43.8 % of the norm) and distal metaphysis of the tibia – 0.91 [0.73; 1.26] units (40.9 % of the norm).

Comparison of the results of bone optical density (Table 3) in two groups (HC and WB) of patients with DNOAP and apparently healthy people (normal) of a similar age group showed a significant decrease in bone extinction in patients with diabetes mellitus both before and after treatment.

Optical density of the calcaneal body before treatment (Table 3) in the WB-group (0.76 [0.65; 1.17] units) was lower than in patients in the HC-group (0.92 [0.76; 1.25] units). At the same time, the extinction of the distal metaphysis of the tibia in the WB-group of patients was 0.93 [0.77; 1.32] units, which was comparable to the same indicator in the HC-group – 0.91 [0.73; 1.26] units.

The comparison of the optical density of the bones of the groups (HC and WB) showed that there was a statistically insignificant increase in Od of the calcaneus in the postoperative period by 25 % (p = 0.16) after treatment in patients from the HC-group, and in the WB-group by 43 % (p = 0.28) of the distal tibia. At the same time, we noted a significant increase in Od values in the postoperative period of the tibia (58 %, p = 0.53) in patients from the HC-group and in the body of the calcaneus (53 %, p = 0.96) in patients from the WB-group.

MSCT data showed that the density of the calcaneus before treatment in patients with DNOAP in the region of the calcaneal tubercle was 194.37 ± 49.05 HU, in the region of the body - 205.47 ± 38.36 HU, in the region of the distal tibia 280.00 ± 40.30 HU. In 35 % of patients, MSCT revealed symptoms of Menckeberg’s arterial mediacalcinosis (Fig. 5).

### Table 3

<table>
<thead>
<tr>
<th>Location site</th>
<th>Period of study</th>
<th>Norm (Od) (n = 20)</th>
<th>WB-group (Od) (n = 25)</th>
<th>HC-group (Od) (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ME [Q1; Q3]</td>
<td>ME [Q1; Q3]</td>
<td>%</td>
</tr>
<tr>
<td>Calcaneous</td>
<td>Before treatment</td>
<td>2.52 [1.52; 3.05]</td>
<td>0.76 [0.65; 1.17]</td>
<td>53↑</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td></td>
<td>1.2 [0.83; 1.6]</td>
<td>0.92 [0.76; 1.25]</td>
</tr>
<tr>
<td></td>
<td>P-value</td>
<td></td>
<td>0.96</td>
<td>0.16</td>
</tr>
<tr>
<td>Tibia</td>
<td>Before treatment</td>
<td>2.26 [1.72; 2.99]</td>
<td>0.93 [0.77; 1.32]</td>
<td>43↑</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td></td>
<td>1.12 [0.87; 1.44]</td>
<td>0.91 [0.73; 1.26]</td>
</tr>
<tr>
<td></td>
<td>P-value</td>
<td></td>
<td>0.28</td>
<td>0.53</td>
</tr>
</tbody>
</table>

Note: ↑ – increase

Fig. 5 MSCT of the feet of patients with DNOAP. MPR in the sagittal plane, determination of the density of the calcaneus, talus, tibia (a), VRT, arterial mediacalcinosis (arrows) (b)
The analysis of the results (Table 2) of EFA osteosynthesis of the bones of the affected segment showed consolidation in both groups. However, the rate of satisfactory outcomes after dismantling the device in patients from the HC-group was significantly higher than in the WB-group (56 %) and amounted to 75 %.

DISCUSSION

Treatment of patients suffering from diabetic Charcot neuroosteoarthropathy complicated by chronic osteomyelitis is one of the most difficult issues of orthopedics and other clinical disciplines due to expressed changes in bone and soft tissues [15, 16, 17]. Various methods have been proposed to eliminate foot deformities and treat chronic osteomyelitis that complicates the course of DNOAP [2, 8, 11, 18]. We used transosseous osteosynthesis based on the frame with inserted wires or a hybrid construct of the Ilizarov apparatus. The results of the study revealed pronounced osteoporosis of the bones of the leg and foot in patients with diabetes mellitus, which accompanies neuro/osteoarthropathy and chronic osteomyelitis. At the same time, the data of indirect bone optical density demonstrated, from the point of view of X-ray monitoring, the well-known pathogenetic processes of osteopenia in patients with diabetes mellitus, caused by neuropathy and mediacalcinosis [19], which was clearly visualized by MSCT. The role of osteoporosis in the development of osteoarthropathy was also noted in the works of other authors [20].

MSCT could reveal disorders in the architectonics in the subchondral tibial layer which was the formation in this zone of longitudinally located groups of bone trabeculae, separated by wide zones of resorption or rarefaction. Moreover, the obtained data on the density of the calcaneous and other bones of the foot enabled to assess their quality for planning surgical intervention. The data obtained are consistent with the study by Barwick et al, that indicated that the CT method is reliable in assessing bone density in Hounsfield units, can be used as an indicator of the risk of foot disease progression, to predict the success of treatment [21]. MSCT is an important tool for detecting destruction processes, the presence of fractures and dislocations and plays an important role in preoperative planning both in other types of osteomyelitis and in DNOAP, having proved its diagnostic efficiency [22, 23, 24].

It is known that the dissociation of bone remodeling processes in patients with DNOAP, while they maintain the load on the limb, leads to changes in both the quantity and quality of bone tissue, which, in turn, further provokes a decrease in the strength of the trabecular mass [19]. This is facilitated by a decrease in collagen synthesis, disorders of calcium metabolism and bone remodeling [25].

At the same time, the redistribution of blood flow in the lower extremities of patients with DNOAP due to a pronounced increase in its linear velocity in the acute stage of DNOAP compared to the chronic stage, contributes to the enhancement of osteoresorption processes [26]. Therefore, the implementation of the discovered by G.A. Ilizarov in 1986 law “the impact of the adequacy of loads and blood supply on bone formation” acquires special significance [27]. The functional rest of the affected segment due to its stabilization in the system of the external fixation ensures the transition from the acute to the chronic stage of DNOAP. Thereby, the task of maintaining such conditions during the entire period of fixation of the affected segment in the frame until complete consolidation in the contact zone of the bone tissue remains important. Thus, the creation of a stable EFA system enables to achieve the effect described above.

CONCLUSION

Optical and densitometric bone density is significantly decreased in patients with diabetic Charcot neuro-osteoarthropathy complicated by chronic osteomyelitis versus the norm.

The WB-based assembly of the apparatus for treatment of patients with DNOAP complicated by chronic osteomyelitis and osteoporosis does not provide sufficient conditions for the consolidation of the bones of the operated segment and increases the risk of system instability in the early postoperative period.

The introduction of half-pins into the apparatus system increases the duration of stable fixation until complete consolidation at the junction of the bones in the intervention area and provides a functional load on the operated segment in patients in the postoperative period.

Conflict of Interest The authors do not have any conflict of interests to declare.

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