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Original article

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Microbial landscape in different types of periprosthetic hip joint infection

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Abstract

Introduction Due to the steady increase in the number of primary total hip arthroplasties, the problem of eliminating periprosthetic joint infection (PJI) has become pressing. The rise of antimicrobial-resistant PJI pathogens significantly complicates and prolongs treatment, contributing to the development of chronic infection, sometimes with latent clinical manifestations.

The **aim** of this study was to identify the microbial landscape characteristics in different types of hip joint PJI.

Materials and Methods Microbiological studies of 96 patients with hip joint PJI were analyzed: Group 1 ($n = 16$) with type I PJI; Group 2 ($n = 80$) with type II and type III PJI. Patients in Group 1 underwent the DAIR procedure and those in Group 2 underwent two-stage revision hip replacement.

Results A total of 103 microbial isolates were obtained from 96 patients: 16 (15.5 %) Gr(–) and 87 (84.5 %) Gr(+). Among Gr(+), MRSA, MRSE, and MRSH were detected in 18 isolates, and among Gr(–), ESBL+ was detected in 16 isolates. The predominant pathogens in the PJI structure were *S. aureus* (52.9 %), *S. epidermidis* (19.5 %), *E. cloacae* (37.5 %), *P. aeruginosa* (18.6 %), and *E. coli* (18.6 %). Associations were more common in type 1 PJI (25 %) than in chronic forms (18.4 %). Microbial associations were detected in 20 cases (19.4 %). Culture-negative infection (CNI) was detected in 16 patients (16.7 %) in both groups. Relapse of PJI in patients with microbial associations occurred in three cases (15 %). In CNI cases, recurrence developed in four cases (25 %).

Discussion The growth of Gr(–) flora in early PJI exceeded that in the chronic one: 31.3 % and 9.2 %, respectively. DAIR is ineffective in such conditions. *S. aureus*, as a causative agent of bone and joint infections, exists in a quasi-dormant state which contributes to chronicity.

Conclusion Gram-negative microorganisms and their associations dominate in the etiology of early PJI (type I), while gram-positive pathogens predominated in chronic types (types II and III). Culture-negative infection was a more common cause of early PJI than of chronic types (25.0 % and 16.1 %, respectively). No statistically significant differences were found between the groups in the detection of methicillin-resistant staphylococci or gram-negative bacteria ESBL+.

Keywords: hip joint, periprosthetic joint infection, revision arthroplasty, culture-negative infection, microbial landscape

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INTRODUCTION

Due to the steady increase in the number of primary total joint replacements performed worldwide, the problem of eliminating complications, and primarily of periprosthetic joint infection (PJI), has become pressing [1, 2, 3]. PJI diagnosis is challenging. Identification of specific pathogens is important and is the basis for the targeted use of antibacterial agents [4]. Traditionally, infectious agents are identified through microbiological tests (MBT) of the synovial fluid and intraoperative tissue biopsies. However, the growth of microorganisms during culture tests may be not revealed and this failure reaches 40 % for various reasons:

- biofilm formation;
- inert pathogen formation;
- identification of agents in an appropriate nutrient medium;
- use of antibiotics before tests for pathogens;
- colonization of the osteocyte-lacunar-tubular network of cortical bone [5];

The growth of antimicrobial-resistant pathogens causing PJI significantly complicates and prolongs treatment. These pathogens include staphylococcal strains resistant to three or more classes of drugs, fluoroquinolone- and carbapenem-resistant gram-negative bacteria, and fungal microflora [6, 7, 8].

All of the above contribute to the development of chronic infection, in some cases with latent clinical manifestations. This complicates diagnosis and accounts for a significant rate of treatment failures in patients with orthopedic infection [6, 9].

The **aim** of this study was to identify the microbial landscape characteristics in different types of hip joint PJI.

MATERIAL AND METHODS

Study design A retrospective analysis of the results of MBI punctures and tissue intraoperative biopsies from 96 patients with PJI of the hip joint (ICD-10: Z96.6) treated from 2015 to 2020 at the surgical department for infection of the Sverdlovsk Regional Clinical Psychoneurological Hospital for War Veterans was conducted.

Inclusion criteria Patients with PJI clinical and laboratory signs who underwent surgical treatment in a hospital setting.

Exclusion criteria Patient without PJI signs

The study was approved by the institutional ethics committee of the War Veterans' Hospital (Yekaterinburg, protocol dated November 9, 2015, No. 9.2/2015) and conducted in accordance with the 1975 Helsinki Declaration (revised in 2008). All patients signed informed consent. Detailed information that would identify the patients included in the study is not available.

According to the classification of deep infection after total hip arthroplasty (Coventry – Fitzgerald – Tsukayama [10]), the subjects were divided into two groups. Group 1 included 16 patients with early PJI, corresponding to type I according to the Tsukayama classification. Group 2 included 80 (83.3 %) patients with chronic PJI, of which 39 cases (48.75 %) were type II and 41 cases (51.25 %) were type III. Our study did not include patients with PJI type IV.

In most cases, patients in group 1 underwent the DAIR (Debridement, Antibiotics, and Implant Retention) procedure. Group 1 also included patients with extensive musculoskeletal defects from previous surgeries and severe medical conditions, for whom revision hip replacement

was not possible. These patients underwent resection hip arthroplasty and removal of implant components.

Patients in group 2 underwent two-stage revision hip arthroplasty.

The study groups were comparable in terms of age and gender characteristics ($p > 0.05$) (Table 1). The analysis revealed no statistically significant differences between the early ($n = 16$) and chronic PJI ($n = 80$) groups. Stratification by age < 65 years and ≥ 65 years, did not find statistically significant differences ($p = 0.059$).

Table 1

Age and gender of included patients

Parameter for comparison		Group 1	Group 2	P-value
		Early PJI ($n = 16$)	Chronic PJI ($n = 80$)	
Males	n	10	42	0.464
	%	62.5	52.5	
Females	n	6	38	
	%	37.5	47.5	
Age, years ($M \pm SD$)		63.7 ± 11.1	57.9 ± 12.2	0.656
< 65 year old	n	8	59	0.059
	%	50.0	73.8	
≥ 65 year old	n	8	21	
	%	50.0	26.2	

Pyoinflammatory complications after previous revision procedures developed in eight (50 %) patients in group 1 and 41 (51.3 %) patients in group 2.

In 41 (83.7 %) of 49 revision procedures, pathogens were detected in tissue biopsies during the previous stages of treatment with MBI tests.

After the first stage of two-stage revision arthroplasty, recurrent infection occurred in seven (8.8 %) patients in Group 2. Recurrent infection after the DAIR procedure was observed in one (6.25 %) patient in Group 1.

In 15 patients (18.75 %) in group 2, negative-pressure wound therapy (NPWT) was used at stage 1 of revision arthroplasty due to severe purulent soft tissue destruction, necrosis, and sclerotic changes in bone tissue [11–14]. One case of recurrent PJI was identified in this group of patients (6.7 %).

Upon admission to the hospital, all patients had their complaints and anamnestic data collected, a general and local examination was performed, and local signs of inflammation were identified. To identify implant instability and pathological changes in adjacent bone structures, all patients underwent radiographic studies of the affected joints, and X-ray fistulography was performed in the presence of external fistulas [1, 5].

Laboratory tests included determination of the white blood cell count, ESR, and C-reactive protein levels in the blood and serum [15, 16]. For bacteriological and cytological examination of the puncture, a diagnostic puncture of the periprosthetic cavity was performed regardless of the presence of a fistula [17, 18].

Microbiological (culture) study

Biomaterial obtained through diagnostic puncture of the periprosthetic cavity and intraoperative tissue biopsies were analyzed. Biopsies were homogenized before seeding. Biomaterial was collected in a sterile container according to sample collection guidelines and delivered to the laboratory within two hours.

After vortexing, 10 µl of the puncture fluid was plated onto culture media with a sterile calibrated loop using the depletion seeding method.

Culture tests were performed on the following culture media:

- 5 % sheep blood agar (Columbia Agar base, Bio-Rad, France; defibrinated sheep blood, E&O Laboratories, Scotland),
- chocolate agar (Columbia Agar base, Bio-Rad, France; defibrinated sheep blood, E&O Laboratories, Scotland),
- yolk-salt agar (nutrient agar for microbial cultivation GRM-agar, State Research Center for Applied Microbiology and Biotechnology, Russia),
- Sabouraud agar with 2 % glucose and chloramphenicol (SIFIN diagnostics, Germany).

To enrich and isolate anaerobes, 100 µl of puncture fluid was inoculated into thioglycollate medium in tall-column tubes (State Research Center for Applied Microbiology and Biotechnology, Russia). The inoculated Petri dishes were then placed in an aerobic incubator at $37 \pm 1^\circ\text{C}$. Blood and chocolate agar dishes were incubated in an atmosphere containing 5 % CO_2 . The cultures were incubated for up to 72 hours and their growth was assessed after 24, 48, and 72 hours.

Identification of the grown colonies was performed using phenotypic methods (Gram staining, oxidase and catalase tests, etc.) and a WalkAway 40 Plus bacteriological analyzer (Beckman Coulter, USA).

Antibiotic susceptibility was determined by the disk diffusion method according to the standard procedure described by EUCAST, as well as using a WalkAway 40 Plus bacteriological analyzer (Beckman Coulter, USA).

Susceptibility categories were interpreted according to the current EUCAST criteria: Clinical breakpoints — bacteria (<https://www.eucast.org/>).

Statistical analysis was performed using Jamovi software (version 2.6.17, Australia) and Microsoft Excel (version 16.75.2, USA). The mean and standard deviation ($M \pm SD$) were used to describe quantitative data with a normal distribution, and the median and interquartile range (IQR) corresponding to the lower (Q1) and upper (Q3) quartiles were used for non-normally distributed data. The normality of data distribution was tested using the Shapiro-Wilk test. Categorical data were described using absolute values and percentages (n, %). Comparison of groups by quantitative indicator with a normal data distribution was performed using the Student's t-test or the Mann – Whitney U test for non-normally distributed data. To assess differences between groups based on categorical characteristics, 2×2 contingency tables were constructed. In cases where the expected frequency exceeded 5, the Pearson χ^2 test was used. In cases where the expected frequencies were low (< 5), the Fisher exact test was used. Differences between the groups were considered statistically significant at $p < 0.05$.

RESULTS

Analysis of the clinical PJI manifestations upon admission to the hospital (Table 2) revealed a high rate of fistulas and wounds, which were detected in 93.8 % of patients in group 1 with early PJI and in 80.0 % of patients in group 2 with chronic PJI. Hyperemia of the skin in the area of the affected joint was recorded in 87.5 % of cases in group 1 and in 67.5 % of cases in group 2. Pain in the involved joint was reported in the majority of patients in both groups. An increase in body temperature to febrile values was relatively rare. No statistically significant differences in these clinical manifestations were found between the groups ($p > 0.05$).

Table 2

Detection of diagnostically significant clinical manifestations of PJI upon admission to hospital

Clinic Exact Fisher's test al manifestations	Group 1		Group 2		P-value Exact Fisher's test
	Early PJI (n = 16)		Chronic PJI (n = 80)		
	a6c.	%	a6c.	%	
Sinuses/wounds	15	93.8	64	80.0	0.289
Hyperemia of the skin in the area of the affected joint	14	87.5	54	67.5	0.139
Pain in the affected joint	13	81.3	71	88.8	0.415
Body temperature rise to febrile levels	2	12.5	18	22..5	0.510

Recurrence of PJI after stage I was observed in seven (8.8 %) patients in group 2. Stage II revision hip arthroplasty was performed in 64 (80 %) patients.

One patient with type I PJI in group 1 underwent two-stage revision hip arthroplasty after DAIR, which yielded a positive result.

Two or more comorbidities (diabetes mellitus, systemic diseases, obesity, HIV infection, hepatitis B and C, injection drug abuse, etc.), which are risk factors for PJI [1], were observed in nine (56.3 %) cases in group 1 and in 58 (72.5 %) observations in group 2.

Analysis of laboratory parameters of inflammatory activity upon admission (Table 3) revealed no statistically significant differences between the groups ($p > 0.05$). The mean white blood cell count was higher in the early PJI group ($p = 0.298$). The ESR level was also higher in group 1, but the differences did not reach statistical significance ($p = 0.130$). The C-reactive protein concentration tended to be higher in early PJI ($p = 0.055$).

Table 3

Laboratory parameters of inflammatory activity in patients with early and chronic periprosthetic joint infection

Parameter	Group 1	Group 2	P-value
	Early PJI (n = 16)	Chronic PJI (n = 80)	
White blood cell count, 10 ⁹ /l	7.85 ± 1.97	7.30 ± 2.60	0.298
ESR, mm/hour	41.25 ± 20.20	30.68 ± 18.65	0.130
C-reactive protein, mg/L	115.63 ± 44.73	74.97 ± 55.94	0.055

A total of 103 microbial isolates were obtained by the MBT from 96 patients with PJI, including 16 (15.5 %) gram-negative and 87 (84.5 %) gram-positive microorganisms (Table 4; Figures 1 and 2).

Table 4

Structure of the microbial landscape in the isolates of the studied groups

Agent/group	Group 1		Group 2		Total (n = 103)	
	Early PJI (n = 17)		Chronic PJI (n = 86)			
	n	%	n	%	n	%
Gram-positive microorganisms	11	64.7	76	88.4	87	84.5
<i>Staphylococcus aureus</i>	7	41.2	39	45.3	46	44.7
<i>Staphylococcus epidermidis</i>	1	5.9	16	18.6	17	16.5
<i>Enterococcus faecalis</i>	1	5.9	7	8.1	8	7.8
Other CNI**	2	11.8	12	13.9	14	13.6
Gram-negative microorganisms	6*	35.3*	10*	11.6*	16	15.5
<i>Enterobacter cloacae</i>	4	23.5	2	2.3	6	5.8
<i>Pseudomonas aeruginosa</i>	1	5.9	2	2.3	3	2.9
Other gram-negative pathogens***	1	5.9	6	7.0	7	6.8

Note: * — differences between groups are statistically significant ($\chi^2 = 6.06$; Pearson criterion $p = 0.014$); ** — the category "Other coagulase-negative staphylococci (CNS)" includes: *Staphylococcus hominis*, *S. capitis*, *S. warneri*, *S. intermedius*; *** — the category "Other gram-pathogens" includes: *Escherichia coli*, *Acinetobacter baumannii*, *Klebsiella pneumoniae*, *Proteus mirabilis*.

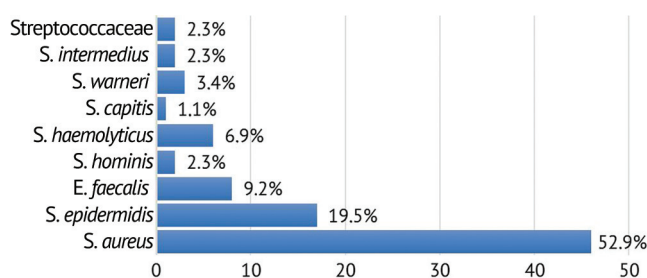


Fig. 1 Species structure of gram-positive bacteria (%)

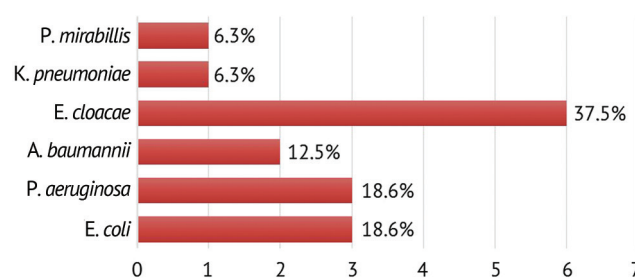


Fig. 2 Species structure of gram-negative bacteria (%)

Analysis of the microbial composition of the isolates (Table 4) revealed statistically significant differences between early and chronic PJI ($\chi^2 = 6.06$; $p = 0.014$). In the early PJI group ($n = 17$ isolates), gram-negative microorganisms were isolated in 35.3 % of cases, compared with only 11.6 % in the chronic one ($n = 86$ isolates). In contrast, gram-positive flora prevailed in chronic PJI.

Among gram-positive bacteria, MRSA (methicillin-resistant staphylococcus *aureus*), MRSE (methicillin-resistant staphylococcus *epidermidis*), and MRSH (methicillin-resistant staphylococcus *hominis*) were found in 18 (20.7 %) isolates (two isolates (11.1 %) in group 1, and 16 (88.9 %) in group 2). In the structure of gram-negative bacteria, ESBL+ were found in 16 (25 %) cases (two (12.5 %) in group 1, and 14 (87.5 %) in group 2, respectively).

Microbial associations were detected in 20 (19.4 %) cases from the total number of microorganisms ($n = 103$): associations of Gr(+) and Gr(−) bacteria were found in seven cases (35 %); Gr(+) associations in 10 (50 %); Gr(−) associations in three (15 %) cases. Four associations (20 %) containing three or more pathogens were detected.

In 16 patients (16.7 %) of both groups, despite the clinical and laboratory picture of PJI, the MBT results were negative.

Relapses of PJI in patients with microbial associations were noted in three (15 %) of 20 cases. Recurrence was recorded in four (25 %) patients with culture-negative infection (CNI).

Figure 3 shows a comparative assessment of the microbial landscape of the pathogens in groups 1 and 2.

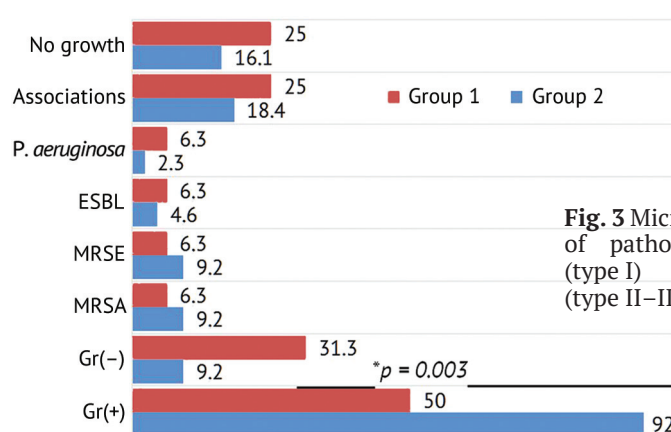


Fig. 3 Microbial landscape of pathogens of early (type I) and chronic (type II–III) PJI %

Analysis of the microbial landscape among patients also revealed significant differences in the distribution of pathogens between early and chronic periprosthetic joint infection ($\chi^2 = 8.94$, $p = 0.003$). In the early PJI group ($n = 16$), gram-negative bacteria were detected in 31.3 % of cases ($n = 5$), which is significantly more frequent compared to chronic PJI ($n = 80$), where gram-negative bacteria were found in only 9.2 % of cases ($n = 7$). In contrast, gram-positive bacteria predominated in chronic infection — 92 % ($n = 74$) versus 50 % ($n = 8$) of cases in the early type.

These findings confirm that gram-negative bacteria have a significant impact on the development of early PJI, while the chronic disease is predominantly associated with gram-positive bacteria.

In patients in group 2 who underwent NPWT at stage 1 of revision arthroplasty ($n = 15$), only gram-positive flora was detected in intraoperative MBT. A total of 12 microbial isolates were obtained in this group. Three cases (20 %) had CNI. Associations were obtained in one case (6.7 %), and MRSA/MRSE was detected in three cases (20 %).

Among patients with revision interventions at previous treatment stages ($n = 49$), microbial associations were detected in 12 (24.5 %) (four (33.3 %) in group 1 and eight (66.7 %) in group 2). Three (25 %) of these patients experienced recurrent PJI. Two patients subsequently underwent repeat debridement with cement spacer change. Recurrent infection was observed in four (25 %) patients with CNI in group 2.

DISCUSSION

Analyzing the microbial landscape, one can note the leading role of gram-positive flora in the causes of PJI development (group 1 — 50 %; group 2 — 92 %) [6, 19–22]. The growth of gram-negative flora in early PJI significantly exceeded similar indicators for chronic infection: 31.3 % and 9.2 %, respectively. These microorganisms represent a serious problem for all orthopedists involved in primary and revision arthroplasty due to the steadily increasing resistance of microflora to many antibacterial drugs [23]. The involvement of gram-negative bacteria in the etiology of PJI complicates and prolongs the treatment process [24]. The effectiveness of the DAIR technique in such conditions may decrease significantly.

The incidence of *P. aeruginosa* in the early PJI was 6.3 % and 2.3 % in the chronic PJI. *P. aeruginosa* can be the cause of early/postoperative nosocomial infections [25]. According to various authors, *P. aeruginosa* is the cause of nosocomial infections in more than 15 % of cases [26–28].

Microbial associations pose a challenge in treating patients with PJI. In our study, the incidence of polymicrobial infections in PJI type I was 25 %, and in PJI types II–III, it was 18.4 %. Microbial associations complicate the choice of etiotropic antibiotic therapy, which often leads to worse treatment outcomes compared to monomicrobial microflora [29, 30].

In chronic PJI, *Staphylococcus aureus* is isolated in 52.9 % of cases, characterized by the growth of resistant strains [6, 19–22]. The numbers of MRSA/MRSE/MRSH strains in our study were comparable.

Methicillin resistance is not a decisive virulence factor. However, methicillin-resistant *S. aureus* (MRSA) strains often express higher levels of virulence factors that facilitate their survival and dissemination [31].

In clinically complex cases with severe soft tissue destruction, we used NPWT at the first stage of revision arthroplasty [11]. *S. aureus* was found in 83.3 % of isolates from this group of patients. Several significant features of *S. aureus* contribute to tissue damage, particularly in PJI. *S. aureus* is capable of producing a number of toxins, including alpha-toxin, exfoliative toxins (ETA, ETB, ETC), enterotoxins, and Panton-Valentine leukocidin. Moreover, *S. aureus* has many secreted enzymes and cell wall proteins that mediate tissue invasion, such as coagulase, DNase, hyaluronidase, collagenase, and fibronectin-binding proteins. Most virulence factors are encoded by additional genes, which may or may not be present in a given *S. aureus* strain. In vitro studies also show that *S. aureus* strains rapidly aggregate in the presence of human synovial fluid and develop into macroscopic colonies within 24 hours, which ultimately transform into a biofilm resistant

to antibiotics [32]. Synovial fluid components such as fibrinogen, fibronectin, and free DNA may induce bacterial aggregation, which is thought to play a role in the pathogenesis of PJI.

Proctor et al. studied *S. aureus* due to its frequent association with bone and joint infections and its well-characterized ability to exist in a quasi-dormant state (the so-called small-colony SCV phenotype), which potentially contributes to the chronicity of the disease [33].

In our study, culture-negative PJI was detected in 25 % of cases in group 1 and in 16.1 % of group 2. This is consistent with global data, according to which culture-negative PJI occurs in 5 % to 42 % of cases [21, 34–38]. This fact often complicates the choice of antimicrobial drugs. Currently, molecular methods, including polymerase chain reaction (PCR) and sequencing, are recommended for diagnosis. These methods have demonstrated improved microbial identification in culture-negative PJI [37, 38]. Moreover, often undetected but present cultures in traditional tests are the result of microorganisms in a biofilm state. It has been found that culturing puncture fluid and removed implants treated with ultrasound increases the exit of microbes due to the destruction of the bacterial biofilm and the sensitivity of PCR [37].

CONCLUSION

Gram-negative microorganisms and their associations dominated in the etiology of early PJI (type I), while gram-positive pathogens prevailed in chronic types (types II and III). Culture-negative infection was a more common cause of early PJI than of chronic types (25.0 % and 16.1 %, respectively). No statistically significant differences were found between the groups in the detection of methicillin-resistant staphylococci or gram-negative bacteria ESBL+.

Conflict of interest Not declared.

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MSCT-semiotics of pin tract osteomyelitis

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Abstract

Introduction Inflammation at the wire tract sites in patients treated with transosseous osteosynthesis is one of the most common complications. Bone manifestations of inflammation are quite common in clinical practice, yet characteristic radiographic findings have not been well described.

The **aim** of this study was to identify the nature of radiographic bone changes in patients with pin tract osteomyelitis at various inflammatory sites.

Materials and Methods The study included 22 patients with chronic pin tract osteomyelitis (PTO) that developed following transosseous osteosynthesis with the Ilizarov fixator. To assess structural bone changes, multislice computed tomography (MSCT) was used, including analysis of axial sections and multiplanar reconstructions (MPR) in the sagittal and coronal planes of the femur and tibia. Bone density (Hounsfield units, HU) in the inflammation area was quantitatively assessed, and the morphology of the wire tract canals (width, wall contours, and the presence of sequesters) was analyzed to identify patterns relevant for treatment decisions.

Results The data obtained indicate the presence of specific radiographic manifestations of osteomyelitis, characteristic of chronic osteomyelitis of any origin, especially in the late stages of inflammation. The most prominent symptoms of osteomyelitis in the early stages include characteristic changes in the wire tract canals: widening and blurring of the contours, increased density, and the appearance of periostitis around the wire tract. Wire canals in the metaphyseal regions are characterized by increased wall density and low density of the canal contents. In the diaphysis, the wire canals have walls with irregular contours and no density differences from the cortical plate. Small sequesters featuring the density of 650–700 HU are often visualized within the canal. "Walled-in" sequesters are also characteristic of pin tract osteomyelitis in the diaphysis.

Discussion The literature has devoted considerable attention to soft tissue inflammation, its prevention, and treatment methods during transosseous osteosynthesis. However, the radiographic semiotics of pin tract osteomyelitis have been limited, primarily presenting clinical cases without detailed analysis of bone changes. Pin tract osteomyelitis is characterized by general manifestations of osteolysis and increased density of the wire canal contours. A distinctive feature of pin tract osteomyelitis in the diaphysis is the presence of "button-shaped" sequesters, confirmed by MSCT. Information on the location and nature of the changes allows clinicians to more effectively plan the extent of surgical intervention and select the optimal treatment strategy, taking into account the characteristics of the lesion and bone condition.

Conclusion Wire tract canals in the metaphyseal regions are characterized by increased wall density. In the diaphysis, the wire tracts are wider than in the metaphysis, with walls of irregular contours and no density differences with the cortical plate. Sequestra in the metaphysis have half the density of those in the diaphysis and vary in shape and size.

Keywords: transosseous osteosynthesis, tibia, pin tract osteomyelitis, wire tract, MSCT, radiomorphological changes

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INTRODUCTION

External fixation has become a key tool in the arsenal of the orthopedic surgeon and is used in both in traumatology and reconstructive surgery. The clinical and biological advantages of transosseous osteosynthesis with the Ilizarov apparatus have been well studied. However, according to some authors, the key disadvantage of this type of fixation is inflammation and infection at the exit sites of transosseous elements, referred to in the foreign literature as pin track / tract / site infection (its incidence varies from 9 to 100 %) [1–4]. As noted by Shields et al., with a high incidence of inflammation around wires or pins, the occurrence of complications should be viewed not so much as an adverse event, but rather as an expected event of percutaneous treatment methods [5]. In such circumstances, minimizing inflammatory reactions becomes critically important to prevent the progression of infection, the development of pin tract osteomyelitis (PTO) and bone defects [6].

Classifications of inflammatory changes associated with the insertion of wires and pins have been presented in a number of studies which are based on subjective symptoms, radiographic signs, or microbiological analysis [2, 7, 8]. Thus, Checketts et al. [9] described a classification system for inflammation in the area of pins, consisting of three stages of superficial inflammation and three stages of severe inflammation [9]. The Gordon scale is a six-point classification system based on the presence of pain, radiographic results, and the appearance of erythema, serous or purulent discharge [10]. Rahbek et al modified this classification system by excluding the subjective symptom of pain and including a separate assessment for serous discharge [11]. An algorithm for detecting inflammation around the wires using only images has been proposed, which does not depend on subjective complaints of pain, radiographic results or microbiological studies, and simplifies home monitoring and early detection of inflammation around the wires using a set of high-quality digital images of “Gordon foci” [12].

Bone manifestations of inflammation around wires are quite common in clinical practice. However, radiographic manifestations have not been described despite being crucial for assessing bone quality in the area of inflammation to determine the extent of surgical intervention. A small number of foreign and domestic publications on PT osteomyelitis, primarily clinical cases, presented one or two radiographic symptoms of osteomyelitis, which is insufficient to determine its semiotics and severity [1, 13, 14, 15, 16].

The **aim** of this study was to identify the nature of radiographic bone changes in patients with pin tract osteomyelitis at various inflammatory sites.

MATERIAL AND METHODS

Study design

Inclusion criteria: age 18–60 years; availability of a complete set of radiographic images and a multislice computed tomography (MSCT) archive available to post-process the data.

MSCT was used to examine patients treated with transosseous compression-distraction osteosynthesis (TCDO) and pin osteomyelitis without other complications.

The study group included 22 patients diagnosed with osteomyelitis of the tibia and femur.

The control group consisted of seven patients with tibia fractures treated with transosseous osteosynthesis that did not develop PTO.

The average age of patients in the study group was 46.3 ± 9.9 years, and males were a majority (78.2 %). Of the 22 patients included in the study, 19 had previously been treated for tibia fractures, and three patients had undergone ankle arthrodesis. In one patient, the femur was fixed following a tibia

fracture. PTO signs were detected three to six months after the start of transosseous osteosynthesis treatment in 14 patients and in six cases after one year. Two patients with the purulent-inflammatory process that began in the area of the pin tracts continued as chronic osteomyelitis for over 10 years.

In the control group, five of the seven patients were males. The average age was 44.7 ± 7.2 years. All patients in the control group were treated for tibia fracture using the Ilizarov fixator.

The studies were performed on Toshiba Aquilion-64 and GE Light Speed VCT computed tomography systems. Total and local bone density in HU was measured in various areas. Bone structure in the inflamed area and the features of the wires canal were examined using axial sections and multiplanar reconstructions (MPR) in sagittal and coronal projections of the femur and tibia (855 images). Bone density in Hounsfield units (HU) in the inflamed area was quantitatively assessed, and wire canal morphology (width, wall contours, and the presence of sequestra) was analyzed. In the control group, which had no complications, the wires canal width was determined after wire removal.

The study was conducted in accordance with the ethical standards of the World Medical Association's Declaration of Helsinki and of the Russian Ministry of Health, and was approved by the Ethics Committee of the Ilizarov National Medical Research Center of Traumatology and Orthopedics. All patients signed informed consent for publication of their data without identification.

Statistical processing of density parameters was performed using the Attestat program built into Microsoft Excel. The distribution type was determined using the Shapiro-Wilk test for samples with 50 or fewer observations. When assessing the normality of the sample distribution, most criteria revealed an abnormal data distribution, therefore, nonparametric statistical methods were used for analysis. Rates and proportions (in %) were used to describe qualitative data. The Mann-Whitney test was used to compare independent data. Comparison of mean values of two paired (dependent) groups was performed using the one-sample Wilcoxon test, described by the median (Me) and percentiles. Comparison of two qualitative independent groups of nominal data was performed using the Pearson chi-square (χ^2) test. Differences were considered statistically significant at p value < 0.05 .

RESULTS

Bone density in the proximal tibial metaphysis at the level of the wire tract varied within the range: from (223.4 ± 25.8) HU to negative Hounsfield values, mainly in the central parts of the metaphysis. The density of the wire tract walls in the metaphyseal parts always exceeded the bone density, (376.7 ± 85.4) HU, reaching (792.8 ± 69.7) HU in some areas ($p < 0.02$). The contents of the pin tract had a lower density, not exceeding (179.4 ± 65.7) HU. In some cases, the density of the contents of the wire tract was significantly lower, (12.5 ± 3.8) HU (Fig. 1).

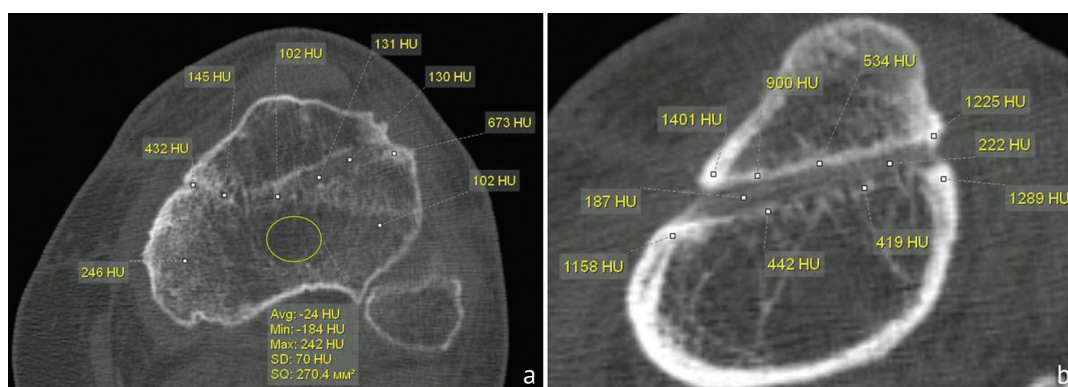


Fig. 1 MSCT of the tibia of a 50-year-old female patient diagnosed with PTO: axial sections: (a) bone and the contents of the wire tract density measurements; (b) density of the walls of the wire tract measurements

Progression of PT osteomyelitis resulted in the formation of bone defects of varying shape and length in the area of the wire canal that had clear contours and a significant increase in the density of its walls. In transcortical wire insertion through the proximal tibial epiphysis, the density of the fragment located externally to the wire canal was lower than the density of the cortical plate of the main part of the bone in 52 % of patients. Wire canals in the area of the proximal or distal metaphysis or epiphysis of the tibia and the distal metaepiphysis of the femur were characterized by an increase in the density of the canal walls, manifesting as a clear demarcation line from the adjacent areas of spongy bone with a decrease in its density. The density of the cortical plate differed in some sections by (189.7 ± 96.5) HU. The density of sequestrs in the metaepiphysis was less than the density of the cortical plate in 89.5 % of cases, (675.5 ± 93.9) HU (Fig. 2).

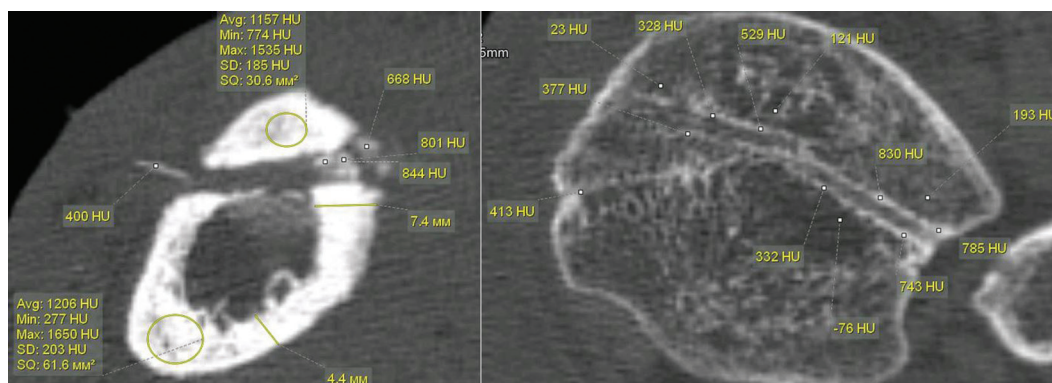


Fig. 2 MSCT of the lower leg of a 55-year-old patient with PTO, axial sections

The pattern of PT osteomyelitis in the proximal tibia depended on the duration of the disease and the level of wire insertion. Characteristic features included decreased bone density, resorption zones in the epiphysis, and significant bone destruction in the metaphysis with denser areas at the edges of the destruction. The inflammatory process was always accompanied by significant architectural changes, resorption zones, and areas of rarefaction. The wire tracts had a characteristic appearance in this bone part: distinct boundaries with a higher density than the adjacent bone areas (Fig. 3).

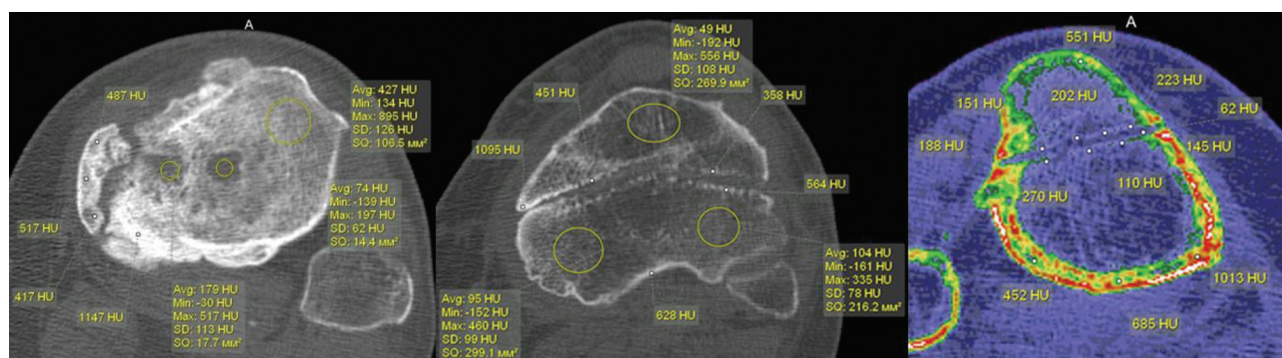


Fig. 3 MSCT of the lower legs of PTO patients, axial sections at the level of the proximal tibia

The wire canal was wider in the area of the cortical plate. The density of the wire canal walls increased to 480 [420;620] HU (median) (Fig. 4 a). If PTO was localized in the distal third of the tibia and the disease progressed for a long time (more than a year), changes in this part were manifested by areas of destruction, disruption of bone structure, the appearance of zones of rarefaction and sclerosis. In all cases, the inflammatory and destructive process spread to the bones of the foot, accompanied by defects, structural changes with disruption of the organotypic structure of the bones, and zones of resorption (Fig. 4 b, c).

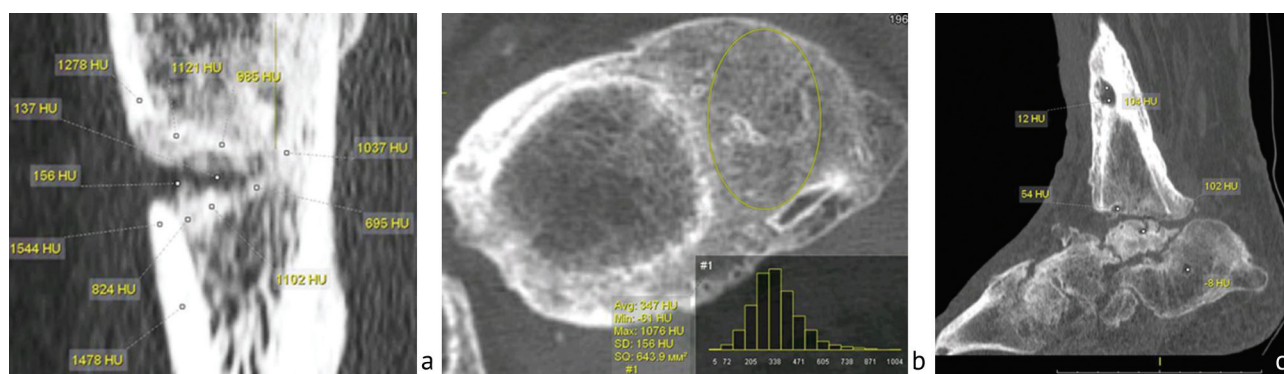


Fig. 4 MSCT of the lower legs of PTO patients: (a) 34-year-old female patient, MPR in the sagittal plane; (b) 56-year-old patient, axial section, massive periosteal layers assimilated with the cortical plate; (c) MPR of the same patient in the sagittal plane

In the diaphysis, inflammatory changes were lower, especially in cases where prompt measures were taken to eliminate the source of infection (early surgical drainage and adequate antibacterial therapy). The data were obtained from an analysis of patients' records with rapid resolution of the inflammatory process based on the comprehensive treatment within the first one to two weeks of the disease onset. In cases of prolonged disease progression (usually more than three to four weeks), wide wire canals and sequestra developed.

An increased width and unclear contours of the wire canal along with an increased density of its walls were registered in the early PTO stages. The width of the canal was compared with its dimensions after wire removal in patients without an inflammatory process (control group). The median width of the wire canal in the diaphysis in those cases was 1.6 [1.4; 1.7]. The width of the wire canal after pin removal in septic osteomyelitis in the diaphysis varied significantly, from 3.5 mm to 7.0 mm. The median width of the wire canal in the diaphysis in PTO patients was 4.1 mm [interquartile range 3.8; 5.1 mm]. For comparison, the width of the wire canal in the epiphysis was smaller and was 2.6 mm [2.8; 3.1 mm], what is associated with the anatomical features of the structure of the proximal tibia in this zone (Fig. 5).

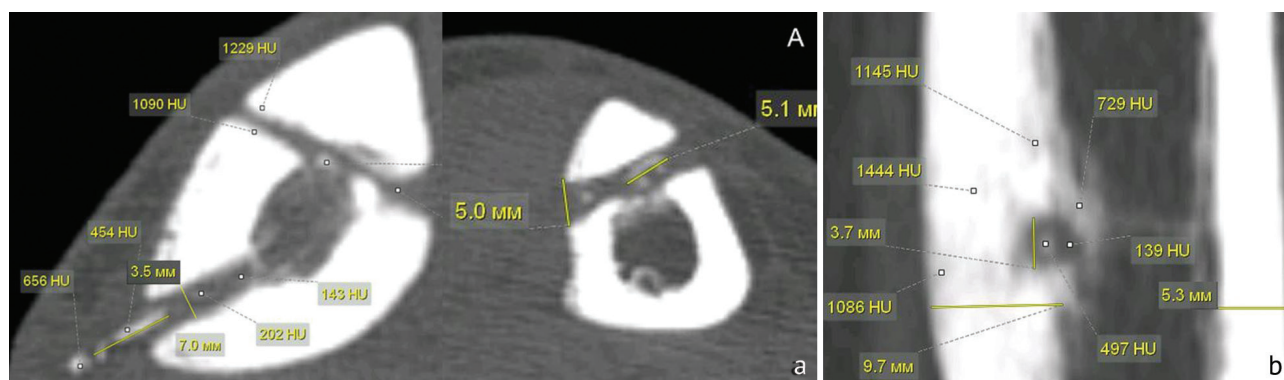


Fig. 5 MSCT of the lower leg of PTO patients aged 36 (a) and 42 (b). Width of the wire tract: (a) axial section; (b) MPR in the sagittal plane

A characteristic location of an "embedded" sequestrum in the cortex with inflammation localized at the level of the middle third of the diaphysis, identified by MSCT, was observed in five patients from the study group. This type of sequestrum is a narrow circular area of necrotic bone surrounded by a radiolucent halo, which is a characteristic sign of an active infectious process and reactive inflammation in the surrounding tissues. We reached this conclusion based on a comparison

of MSCT images with clinical data and microbiological results that confirmed infection in the focus. In the literature, such sequestra are described as "button-shaped" due to their shape and limited size [17, 18, 19] (Fig. 6).

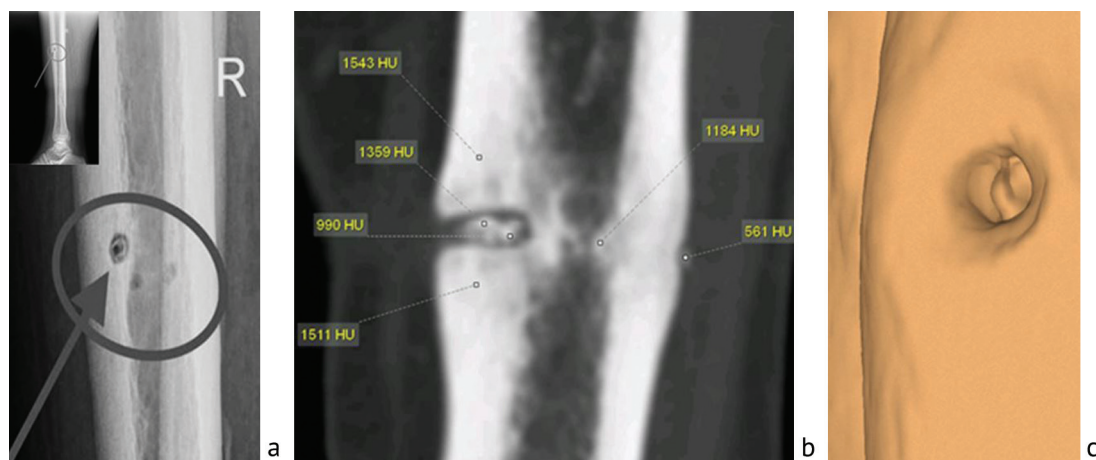


Fig. 6 X-ray of the lower leg of a 46-year-old patient with PTO in the lateral projection, circular "button-shaped" sequestrum (a); MSCT of the lower leg of a 52-year-old patient with PTO, walled-in sequestrum, MPR in the frontal plane (b); 3D reconstruction, visual representation of the circular "button-shaped sequestrum" (c)

The incidence of such "button-shaped" sequestra in our sample was approximately 15 %. The size and shape of sequestra in the metaphysis and diaphysis varied significantly. In the diaphysis, sequestra were more often rectangular in shape, with the horizontal side two to three times longer. In the metaphysis, sequestra were of indeterminate shape in 85.6 % of cases and varied in size, but were no larger than 5 mm in 80.5 %. Sequestra in different bone parts varied in density. In the metaphysis, the density was (652.4 ± 45.8) HU, while in the diaphysis it was (1388.6 ± 92.7) HU ($p < 0.01$).

Figure 7 shows the density of necrotic and normal bone areas. The median for necrotic bone was 1388 [1315;1430] and 1248 [1198;1302] for unchanged bone ($p < 0.05$).

Table 1 presents data on the density of the walls of the wire canal in transcortical insertion of the wire in various parts of the tibia.

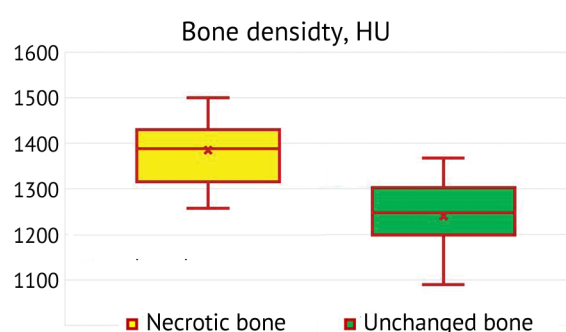


Fig. 7 Density in the area of necrotic and unchanged bone

Table 1

Density of the walls of the wire canal in transcortical insertion of the wire through the tibial tuberosity and diaphysis

Involved area	Density value, HU	
	M	σ
Density of the walls of the wire canal in the metaphysis	798.5	69.4*
Density of the walls of the wire canal in the diaphysis	1289.6	74.8

Note: * $p < 0.035$ — significant difference in the density of the walls of the wire canal in the metaphysis and diaphysis

DISCUSSION

According to a number of authors, the use of the Ilizarov transosseous osteosynthesis method is accompanied by such a frequent complication as inflammation at the site of wire/pin insertion [20, 21]. The nature and severity of the inflammatory process are determined by many factors and are either remediable soft-tissue inflammation or can lead to pin tract osteomyelitis with various

consequences such as severe bone destruction and defects. In the literature, considerable attention has been devoted to soft tissue inflammation, methods of its prevention and treatment, whereas the radiological semiotics of osteomyelitis has been described in a small number of works, which are mainly case reports without a detailed description of the nature of bone changes [22, 23, 24, 25].

Our data demonstrate both the presence of specific radiographic manifestations of pin tract osteomyelitis and signs characteristic of chronic osteomyelitis of any etiology, especially in the late stages of infectious process. The most characteristic radiographic bone changes in PT osteomyelitis, which appear in the early stages within one to three weeks of the disease onset, include: osteolysis around the pin or wire; increased bone density; and the appearance of linear or crest-like periostitis around the pin tract. To objectively evaluate these changes, we compared radiographic data with pin tracts in patients without osteomyelitis, as well as with the contralateral limb, where inflammation was not detected. This allowed us to identify pathological changes that deviate from the anatomical norm.

The wire tracts in the metaphyseal regions are characterized by increased density of their walls and low-density of the canal contents with areas having negative Hounsfield values, indicating the presence of inflammatory or necrotic material. In the diaphysis, the wire tracts were wider than in the metaphysis; the canal walls had irregular contours and showed no density differences with the cortical plate. Small sequestra with a density of 650–700 HU were often visualized within the canals.

The PTO in the diaphysis is also characterized by so-called "walled-in" sequestra in the cortical plate, which follow the contours of the wire canal and resemble a "button-like sequestra" when examined using 3D CT. This phenomenon is confirmed by data from other studies, where similar shapes of sequestra were described with inflammation localized in the cortical bone layer in the early stages of chronic osteomyelitis [13, 14].

In patients with a long course of osteomyelitis (more than three to four weeks) or recurrences of the disease, the radiomorphological picture of destructive changes in the metaphyseal bone did not differ from that of typical chronic osteomyelitis. Specifically, when chronic osteomyelitis was localized in the tibial metaphysis, the inflammatory and destructive processes also spread to the bones of the foot. We also noted anatomical changes (defects, uneven contours), decreased bone density, and areas of sclerosis and resorption. These data are supported by the results of a number of clinical and radiographic studies [26, 27] and allow us to consider them to be reliable and reproducible. In the presence of chronic infection, sequestration is the main diagnostic sign of chronic osteomyelitis. However, sequestra can also be observed in other diseases, such as eosinophilic granuloma and osteoid osteoma, where the so-called "button-like" sequester has also been described [17, 18, 19]. These studies describe in detail the characteristics of "button" sequester and its clinical significance, which is important to consider in differential diagnosis.

Given the specific bone changes in PTO that were identified in this study and depend on the location of the inflammatory process, this work may be useful for clinicians when planning the extent of surgical intervention. The key idea is that the extent and nature of pathological changes in the diaphysis and metaphysis in PTO vary significantly. In planning a surgery, these data allow for an estimate of the required extension of the intervention, which is important for choosing a surgical technique (considering the location of inflammation in the diaphysis or metaphysis), as well as for preparing patients based on their clinical, laboratory, and MSCT status. Thus, information on radiographic and MSCT features, as well as the timing of disease manifestation, facilitates a more accurate and individualized approach to treating patients with pin tract osteomyelitis.

CONCLUSION

Early radiographic signs of pin tract osteomyelitis include widening of the wire canal, increased density of its walls, blurred contours, and the formation of linear or ridge-like periostitis around the wire. In the metaphyseal regions, the wire canals are characterized by increased wall density (200–400 HU), low-density contents, including areas with negative HU values, and clear demarcation zones, reflecting the presence of an inflammatory process with the formation of boundaries between the affected and healthy tissue. In the diaphysis, the canals are wider, the walls have irregular contours, and a density comparable to that of the cortical plate (500–700 HU), which requires differential diagnosis with other diseases, such as tumor process or benign bone tumors.

Sequestra in PTO exhibit marked variability depending on their location. In the metaphysis, sequestra have a density half that in the diaphysis (250–350 HU versus 600–700 HU), are smaller in size, and have an irregular shape. In the diaphysis, "walled-in" sequestra in the cortex are typical, as are the fragments with a density of up to 800 HU, surrounded by a demarcation zone with a density of 100–150 HU. A pathognomonic sign of a long-term (more than three to four weeks) PTO in the diaphysis is a sequestrum that follows the contour of the wire canal, a so-called "ring-shaped" or "button" sequestra, confirming the connection between sequestra formation and the inserted wire zone.

Conflict of interests The authors declare no obvious or potential conflicts of interest related to the publication of this study.

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Informed consent The patients signed informed consent for the publication of their information in the study without identification.

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Original article

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Effect of *IL-17A* and *PPARG* gene polymorphism on the course of purulent complications after treatment of patients with lower limb bone injuries

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Abstract

Introduction Epidemiological studies have shown a link between genetic factors and the development of purulent complications after treatment in traumatology and orthopedics. Studies on candidate genes help identify mutations associated with diseases, which is important for diagnosis and prevention. The polymorphisms of the *IL-17A* and *PPARG* genes are of particular interest. The *G197A* polymorphism in the *IL-17A* gene may increase the risk of autoimmune and infectious diseases. The *C1431T* polymorphism in the *PPARG* gene is often associated with metabolic disorders, including obesity and diabetes type 2. Both polymorphisms are significant for developing methods to predict and treat purulent complications, as their impact on patient health can be substantial.

Purpose To study the influence of *IL-17A* and *PPARG* gene polymorphisms on the course of purulent complications after treatment of patients with lower limb bone injuries.

Materials and methods Candidate genetic study: identification of the *PPARG C1431T* gene polymorphism and the *IL-17A G197A* gene polymorphism in the genome of 114 patients treated at Solovyev Hospital in Yaroslavl for purulent complications after treatment of lower limb injuries during various periods from 2018 to 2024.

Results Analysis showed that the baseline for the *PPARG* gene (rs3856806) is at the level of allele C (82 % and 89 %), predominantly in the C/C genotype (70 % and 80 %). For *IL-17A* (rs2275913), the baseline corresponds to allele G, with the A/A genotype occurring in 46 % and 42 % of groups. Hardy – Weinberg equilibrium was found for *PPARG* but not for *IL-17A*, indicating the influence of this polymorphism on complication recurrences. Associations were identified between SNPs and comorbidities such as diabetes and hypertension, confirming the relationship between gene polymorphisms and the risk of purulent complications.

Discussion The study revealed that the mutant T allele is associated with an increased risk of metabolic disorders and complications, as confirmed by both our own observations and data from other authors. In the non-recurrence group, C/C homozygotes were found in 70 % of cases, while in the recurrence group this number reached 80 %, which partially agrees with previous studies that noted the impact of this polymorphism on the metabolic profile.

Conclusion The study of *PPARG* and *IL-17A* polymorphisms highlighted the importance of considering mutations when predicting recurrence of infectious complications in patients with lower limb injuries. The study of *PPARG* and *IL-17A* polymorphisms can be used to build predictions about the progression of complications and their recurrences, taking into account covariates such as BMI, hypertension, coronary heart disease, and diabetes. A connection has been established between these gene mutations and the recurrence of complications in patients with lower limb injuries.

Keywords: complication, lower limb bone injury, genes, polymorphism, *PPARG*, *IL-17A*

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INTRODUCTION

Epidemiological studies of purulent complications following treatment of injuries and orthopaedic diseases have shown an association between disease development and heredity, demonstrating the significant influence of genetic events on the development and progression of such complications. Various approaches are used to study the genetic factors involved in the pathogenesis of the disease, including heredity analysis in family studies, differential gene expression studies, and genomic variation analysis [1]. Visscher et al argue that genomic variation analysis can be implemented by comparing individual candidate genes or conducting genome-wide association studies [2]. Candidate genetic research plays a key role in medicine, contributing to a better understanding and treatment of diseases, including purulent complications in traumatology and orthopedics [3].

The pathogenesis of purulent complications following treatment is a complex multifactorial process, the mechanism of which is currently not fully understood [4]. The overall influence of some genes on the occurrence of purulent complications in the population may be ineffective. The impact of specific genetic polymorphisms depends on the interaction of genotype and environmental factors, as well as epigenetic mechanisms that may be specific to the pathophysiology of each individual patient [5, 6].

To study the etiopathogenesis of recurrent purulent complications after treatment of patients with lower limb injuries, the gene encoding interleukin 17A (*IL-17A*) was selected. This cytokine plays an important role in regulating the immune response. It is involved in inflammatory processes and may be associated with various diseases (autoimmune and infectious). Polymorphisms in the *IL-17A* gene can affect the expression level of this cytokine and its function. One such polymorphism is *G197A* (rs2275913), which is a guanine to adenine substitution at position 197 of the *IL-17A* gene. Previously, studies have shown associations of the *G197A* polymorphism with an increased risk of autoimmune diseases and infectious conditions; however, we have not found any studies of its effect on the risk of complications specifically in traumatology and orthopedics [7]. In general, the *G197A* polymorphism is an important genetic factor that can influence the risk of developing various diseases. Thus, some studies have noted that the minor A allele may be associated with an increased risk of developing autoimmune diseases and aplastic anemia [8, 9]. It has also been determined that the *G197A* polymorphism can influence the risk of developing infectious diseases: individuals with the minor A allele may have an increased risk of developing infections caused by certain viruses and bacteria [10]. Therefore, we believe that studying the prognostic role of SNPs in genes encoding the cytokine *IL-17A* in the development of purulent complications is a promising direction in the search for genetic markers of an unfavorable course of diseases. Further research is needed to more fully understand the role of this *G197A* polymorphism in the development of purulent complications.

The *PPARG* gene encodes the peroxisome proliferator-activated receptor, which plays a key role in regulating metabolism and insulin sensitivity. The *C1431T* polymorphism (rs3856806) may affect protein function and glucose metabolism. Some studies have linked the *C1431T* polymorphism to an increased risk of obesity, diabetes type 2, and cardiovascular disease. Song et al believe that the *C1431T* polymorphism may influence the risk of developing various diseases associated with metabolic disorders [11]. Polymorphisms in the *PPARG* gene may affect protein function and its ability to regulate metabolism. One such polymorphism is *C1431T* (rs3856806), which is a cytosine to thymine substitution at position 1431 of the *PPARG* gene. Overall, the *C1431T* polymorphism is an important genetic factor involved in the risk of developing various diseases that can lead to the development and recurrence of purulent complications. This is especially

important if the patient has impaired carbohydrate tolerance or prediabetes without a history [13], which can trigger a cascade of pathological reactions that, without proper attention and adjustment of concomitant therapy, will lead to the persistent purulent complications and/or their exacerbation.

The gene polymorphisms described above are consistent with the view that a minimal risk of suppuration in patients serves as a prerequisite and/or intermediate step in the development and recurrence of purulent complications. Lamagni and Gu point to the importance of comprehensively assessing risk factors and selecting an individualized treatment strategy [14–16]. The important role of each gene cannot be ruled out, but in this study, we sought to narrow the scope of our research and determine the potential for practical application of knowledge of genetic polymorphisms in a specific patient in predicting purulent complications after treatment.

Purpose To study the influence of *IL-17A* and *PPARG* gene polymorphisms on the course of purulent complications after treatment of patients with lower limb bone injuries

MATERIAL AND METHODS

A candidate genetic study to identify polymorphisms of the *PPARG* C1431T and *IL-17A* G–197A genes in patients' genomes was conducted at the Yaroslavl State Medical University. The patients were treated for purulent complications resulting from lower extremity injuries. The allele-specific polymerase chain reaction (AS-PCR) method with the SNP-EXPRESS-RT real-time fluorescence detection scheme was used.

The study was conducted as part of a doctoral dissertation entitled "Treatment of purulent complications and prediction of their outcomes in patients with mid-distal lower extremity injuries." The study was approved by the Ethics Committee of the Yaroslavl State Medical University (meeting dated June 14, 2024, No. 68).

Inclusion criteria Patients with:

- 1) History of acute injuries to the knee joint, lower leg, ankle joint and foot (fractures, dislocations, ligament ruptures);
- 2) Purulent-inflammatory complications (osteomyelitis, purulent arthritis, phlegmon, abscess) that developed during treatment and during the first year after treatment;
- 3) Age range: 18–75 years;
- 4) Informed consent for participation in the study.

Exclusion criteria:

- 1) History of chronic diseases that could influence the development of purulent complications (oncological diseases, HIV infection);
- 2) Administration of immunosuppressive therapy;
- 3) Frequency of recurrence of purulent-inflammatory complications is less than one year;
- 4) History of genetic diseases associated with immune disorders.

Thus, 114 patients treated at the Solovyov Hospital (Yaroslavl) in various periods from 2018 to 2024 were selected. Comorbid pathologies were identified in 93 (81.6 %) patients (Table 1).

Two groups of patients were formed:

- group 1 ($n = 50$): patients with a history of purulent complication and no recurrence within one year;

- group 2 ($n = 64$): patients with a history of established purulent complication and its recurrence one or more times within one year.

Table 1

Distribution of examined patients by types of comorbid pathology ($n = 114$)

Pathology	Number of cases	
	абс.	%
Obesity (prediabetes)	9	7.9
Diabetes	21	18.4
Hypertension	25	21.8
Ischemic heart disease	10	8.7
Vascular diseases of the lower extremities (venous thrombosis and thrombophlebitis), atherosclerosis)	17	14.8
Various combinations	11	9.6
Total	93	81.6

Development of a complication or its recurrence (Table 2) was determined upon hospitalization of the patient in a specialized hospital with the implementation of all necessary clinical diagnostic measures and algorithms within the framework of current protocols and clinical recommendations.

Table 2

Complication type and its occurrence in the groups

Complication type	Total ($n = 114$)		Group 1 ($n = 50$)		Group 2 ($n = 64$)	
	n	%	n	%	n	%
Posttraumatic osteomyelitis	49	42.9	17	34.0	32	50
Purulent arthritis	19	16.7	11	22.0	8	12.5
Phlegmon	9	7.9	6	12.0	3	4.7
Suppuration (abscess) of the postoperative wound (scar) area	37	32.5	16	32.0	21	32.8

The material studied for analysis was whole venous blood of patients, with blood sampling from patients in group 2 (with established recurrence of complications) performed directly at the stage of hospitalization, and blood sampling from group 1 (without recurrence after treatment) was performed individually.

Reagents used:

- Reagent kit for the analysis of single nucleotide polymorphism by the AS-PCR method C1431T in the *PPARG* gene Mutation-2 *PPARG* SNP-express RV undiluted - 100 (Litech, Russia);
- Reagent kit for the analysis of single nucleotide polymorphism by the AS-PCR method G-197A in the *IL-17A* gene Interleukin 17A mutation SNP-express RV undiluted - 100 (Litech, Russia);
- SYBR Green (Thermo Fisher Scientific, USA).

The amplification reaction was carried out using the DTlight (TU 9443-003-96301278-2010, modification 4S1) and DTprime (TU 9443-004-96301278-2010, modification 5M3) detection amplifiers manufactured by NPO DNA-Technology LLC (Protvino). The devices used ensured the implementation of qualitative and quantitative studies by the allele-specific polymerase chain reaction (ASPCR) method without the stage of PCR products electrophoresis in agarose gel using reagent kits based on the principles of fluorescence detection.

PCR results were detected using intercalating agents (SYBR Green I with an emission wavelength of 520 nm). The amount of accumulated PCR amplification product was assessed directly during

temperature cycling. Quantitative analysis was based on the standard PCR curve and analysis of fluorescent signal accumulation in the FAM channel using appropriate mathematical tools.

The results were interpreted based on the presence (or absence) of an intersection of the S-shaped fluorescence curve with a threshold line set at the appropriate level, which determines the presence (or absence) of a threshold cycle (Ct) value for a given DNA sample in comparison with the final cycle values.

Statistical processing of the results was performed using Haplostats Version 1.9.7 (2024), a program designed for statistical analysis of haplotypes with traits and covariates when the linkage phase is ambiguous (Daniel J. Schaid, Jason P. Sinnwell, USA). To find a compromise between the accuracy and complexity of the model, information criteria were used, namely, the Akaike information criterion (AIC) and the Bayesian information criterion (BIC). Differences were considered statistically significant at $p \leq 0.05$.

RESULTS

A descriptive statistics procedure was performed on the distribution of the frequency of alleles and genotypes of candidate genes in a patients' sample of two groups (Table 3).

Table 3

Distribution of allele and genotype frequencies of candidate genes in a patients; sample of two groups

SNP	Allele / genotype		Total ($n = 114$)		Group 1 ($n = 50$)		Group 2 ($n = 64$)	
			n	%	n	%	n	%
<i>PPARG</i> rs3856806	C	–	196	0.86	82	0.82	114	0.89
	T	–	32	0.14	18	0.18	14	0.11
	C/C	norm/homozygote	86	0.75	35	0.7	51	0.8
	C/T	heterozygote	24	0.21	12	0.24	12	0.19
	T/T	mutation	4	0.04	3	0.06	1	0.02
	Hardy – Weinberg equilibrium, p		0.23		0.17		0.55	
<i>IL-17A</i> rs2275913	G		144	0.63	68	0.68	76	0.59
	A		84	0.37	32	0.32	52	0.41
	G/G	norm/homozygote	23	0.2	8	0.16	15	0.23
	G/A	heterozygote	38	0.33	16	0.32	22	0.34
	A/A	mutation	53	0.46	26	0.52	27	0.42
	Hardy – Weinberg equilibrium, p		0.0026		0.099		0.022	

Based on the table, it can be concluded that the baseline for *PPARG* (rs3856806) in both groups is at the C allele level (82 % and 89 %) and is predominantly C/C (normal/homozygous) genotype (70 % and 80 %, respectively). The baseline for *IL-17A* (rs2275913) is at the G allele level and is predominantly A/A (mutation) genotype (46 % and 42 % in both groups, respectively).

The Hardy-Weinberg equilibrium ($p > 0.05$) for *PPARG* (rs3856806) was met and amounted to 0.23, indicating no clear influence of this SNP on potential covariates in the two groups. However, a more detailed study of its influence is warranted. Calculating the Hardy – Weinberg equilibrium for *IL-17A* (rs2275913), it was clearly not met in both groups, including in group 2 (recurrence of the complication): 0.0026 and 0.022, respectively. This indicates an influence of this polymorphism on recurrence of the complication.

Next, we analyzed the data comparing statistical models with different numbers of parameters (covariates: gender, age, BMI, comorbidity). The results are presented in Table 4 and Table 5.

Table 4

Comparison of statistical models for *PPARG* (rs3856806) with different numbers of parameters (covariates: gender, age, BMI, comorbid underlying pathology)

Model	Genotype	Group 1 (n = 50)		Group 2 (n = 64)		OR (95 % CI)	AIC	BIC
		n	%	n	%			
Codominant	C/C	35	70.0	51	79.7	1.00	152.7	185.5
	C/T	12	24.0	12	18.8	0.64 (0.22–1.81)		
	T/T	3	6.0	1	1.6	0.35 (0.03–4.65)		
Dominant	C/C	35	70.0	51	79.7	1.00	150.9	181
	C/T–T/T	15	30.0	13	20.3	0.59 (0.22–1.60)		
Recessive	C/C–C/T	47	94.0	63	98.4	1.00	151.4	181.5
	T/T	3	6.0	1	1.6	0.39 (0.03–5.14)		
Overdominant	C/C–T/T	38	76.0	52	81.2	1.00	151.4	181.5
		12	24.0	12	18.8	0.67 (0.23–1.90)		

It was found that the lowest values of the AIC and BIC criteria are in the dominant model that includes the C/C and C/T–T/T genotypes, which can also impact the risk of recurrence of the complication.

Table 5

Comparison of statistical models for *IL-17A* (rs2275913) with different numbers of parameters (covariates: gender, age, BMI, comorbidity)

Model	Genotype	Group 1 (n = 50)		Group 2 (n = 64)		OR (95 % CI)	AIC	BIC
		n	%	n	%			
Codominant	G/G	26	52.0	27	42.2	1.00	153.5	186.3
	G/A	16	32.0	22	34.4	1.42 (0.51–4.01)		
	A/A	8	16.0	15	23.4	1.27 (0.38–4.23)		
Dominant	G/G	26	52.0	27	42.2	1.00	151.5	181.6
	G/A–A/A	24	48.0	37	57.8	1.37 (0.55–3.41)		
Recessive	G/G–G/A	42	84.0	49	76.6	1.00	152	182.1
	A/A	8	16.0	15	23.4	1.09 (0.36–3.33)		
Overdominant	G/G–A/A	34	68.0	42	65.6	1.00	151.7	181.8
		16	32.0	22	34.4	1.32 (0.50–3.45)		

Analysis of the rs3856806 polymorphism of the *PPARG* gene revealed significant differences in the distribution of genotypes between patient groups.

DISCUSSION

According to Song et al., the mutant T allele is associated with an increased risk of metabolic disorders [11], which is confirmed by our observations. In the group without recurrence, C/C homozygotes accounted for 70 %, while in the group with recurrence it reached 80 %. These data are partially consistent with the results of Aisyah et al., who also noted an association of this polymorphism with changes in the metabolic profile [13]. Analysis of the obtained data shows that the baseline for SNP *PPARG* (rs3856806) in both groups is at the level of the C allele (82 % and 89 %) and prevails among C/C homozygotes (70 % and 80 %, respectively). On the one hand, this indicates the potential stability of this polymorphism in the populations under consideration; on the other hand, it makes sense to consider the potential inheritance of a condition that results in the metabolic syndrome even in normal weight patients.

In a comparative analysis of statistical models, we used the Akaike information criteria (AIC) and the Bayesian information criterion (BIC) and the model that considered all parameters demonstrated the best fit (AIC = 145.6; BIC = 158.3). According to Lamagni et al., a comprehensive

approach to risk factor analysis allows for more accurate predictors of complications [14], and the criterion values obtained confirm the importance of both genetic and clinical factors.

The genotype frequency distribution complied with the Hardy – Weinberg law ($p > 0.05$), which is consistent with the recommendations for conducting such studies [2]. As noted by Loos and Yeo, compliance with this principle is an important condition for the reliability of the results of genetic studies [1]. Despite the representativeness of the sample (p values for all analyzed polymorphisms exceeded the threshold value), a non-transitional Hardy – Weinberg equilibrium can be distinguished for *IL-17A*, obtained with values of 0.0026 and 0.022 both in the total sample and in the group with recurrence of complications, which may also indicate a significant effect of this SNP on the risk of recurrence. Similar data were described by Hijazi et al who studied the polymorphism of genes that have impact on the development of complications after arthroplasty [16].

The use of multivariate regression analysis allowed us to identify independent predictors of the development of complications with OR = 2.34 (95 % CI: 1.87–3.12, $p < 0.001$). A number of studies devoted to the problems of complications in traumatology emphasize the need to use modern statistical methods that significantly improve the accuracy of predicting disease outcomes in combination with an analysis of the interaction of genetic factors with the clinical characteristics of patients [17, 18]. Our study confirmed the importance of considering both genetic markers and clinical parameters in predicting treatment outcomes.

Analysis of the dynamics of changes in carbohydrate metabolism parameters revealed significant differences between patient groups. Hashemian et al. believe that treatment options have different effects on metabolic parameters depending on the patient's genetic profile [12]. These data are supported by our observations that showed a significant correlation between genotype and treatment response.

Interesting parallels can be drawn with studies of genetic predisposition to chronic inflammatory processes [5]. As shown in the work of Novakova et al., different loci can play different roles in the development of inflammatory diseases [3]. Similar mechanisms are likely involved in the development of purulent complications, such as osteomyelitis, following bone injuries [19].

To test the robustness of the results obtained, additional analysis was conducted using various statistical methods [8]. As noted by Rushdy et al., the use of multiple analytical methods increases the reliability of the conclusions [7]. All methods used confirmed the significance of the identified associations, indicating a high level of reliability of the data obtained.

The analysis of the distribution of allele and genotype frequencies revealed important patterns in the two patient groups studied. As demonstrated in the work of Paradowska-Gorycka et al., these differences may serve as potential markers of the risk of developing complications [8]. Of particular interest are the data on the distribution of the mutant T/T genotype, which was observed in 6 % of patients without recurrence and only 2 % with recurrence. Information about a particular identified genetic polymorphism (mutation) was communicated to each patient in accordance with all ethical frameworks and with a full explanation, as incorrect information may cause moral and psychological discomfort and concerns regarding the patient's health [20].

CONCLUSION

The candidate genetic study of polymorphism of *PPARG* (rs3856806) and *IL-17A* (rs2275913) in patients with infectious complications and its recurrence following treatment highlighted their importance for predicting unfavorable course of complications and their recurrence within a year after the treatment. The prognosis is possible in complex consideration covariates such as BMI

and comorbidities: hypertension, coronary heart disease, and diabetes. This study has established a clear link between the presence of a mutation in both the *PPARG* gene (rs3856806) and the *IL-17A* gene (rs2275913) in the context of complication recurrence in patients with lower limb injuries.

Conflict of interest The authors declare that they have no competing interests.

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Prospects for using acetylsalicylic acid in combination with antibacterial drugs against the leading pathogens of osteomyelitis

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Abstract

Introduction Acetylsalicylic acid (ASA) is one of the promising candidates for enhancing the action of antibacterial drugs.

Purpose To evaluate *in vitro* the effect of aspirin in combination with antibacterial drugs on the growth of microbial cultures of clinically significant bacterial strains in osteomyelitis.

Materials and methods The object of the study is clinically significant bacterial strains *K. pneumoniae* ($n = 12$), *P. aeruginosa* ($n = 12$), *S. aureus* ($n = 12$), *S. epidermidis* ($n = 12$), isolated from wounds of patients with chronic osteomyelitis. The experiment was divided into four series: control group; group of ASA administration; group of antibiotic administration; group of ASA + antibiotic administration. Antibacterial effect was assessed by the absence of a bacterial growth zone around the discs.

Results There was no growth of microorganisms on Petri dishes when ASA (0.05 %) was incubated with gram-negative bacteria (*K. pneumoniae*, *P. aeruginosa*). In the case of *S. aureus* bacteria, the number of CFU was reduced compared to the control group. There was no growth on plates with *S. epidermidis*. When polymyxin was incubated with *P. aeruginosa*, slight bacterial growth was recorded on Petri dishes, while only individual colonies were observed with *K. pneumoniae*. When incubated together with polymyxin and aspirin (0.03 %), there was no growth of microorganisms on plates with *K. pneumoniae*, while slight growth was noted on plates with *P. aeruginosa*. Gentamicin suppressed the growth of *S. aureus* bacteria (an insignificant number of bacteria was noted on the plates). ASA (0.03 %) enhanced the bactericidal properties of gentamicin (there was no bacterial growth on the plates).

Discussion The absence of growth on plates with *S. epidermidis* bacteria under the influence of ASA, even without antibiotics, suggests that one of the mechanisms of its action may be the suppression of adhesion and biofilm formation. The presence of a pronounced effect of ASA on gram-negative bacteria (*K. pneumoniae*, *P. aeruginosa*) may be associated with the effect on the outer membrane of microbial cells, while aspirin had a lesser effect on gram-positive bacteria (*S. aureus*) and only reduced metabolic activity.

Conclusion Our study demonstrated that acetylsalicylic acid exhibits synergism with a number of antibiotics *in vitro* and significantly enhances their bactericidal activity against clinical isolates associated with osteomyelitis.

Keywords: acetylsalicylic acid, chronic osteomyelitis, *S. aureus*, *S. epidermidis*, *K. pneumoniae*, *P. aeruginosa*

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INTRODUCTION

Osteomyelitis is a severe infectious and inflammatory disease of bone tissue caused primarily by bacterial pathogens such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and some other pathogens [1–4]. Despite current advances in antimicrobial therapy, osteomyelitis remains challenging to treat due to the ability of microbes to form biofilms, resistance to antibiotics, and chronic inflammation [5–7]. Therefore, a pressing area of research is the search for new therapeutic strategies that would include a combination of antibacterial drugs with adjuvant agents that can enhance their effectiveness.

Acetylsalicylic acid (ASA) is a promising candidate for enhancing the action of antibacterial drugs. In addition to its well-known anti-inflammatory and antiplatelet effects, aspirin has been shown to modulate antibiotic activity, inhibit bacterial biofilm formation, and influence the immune response [8–11]. In recent years, evidence has emerged of its synergistic effects with certain antibacterial drugs against resistant strains of microorganisms [12].

Purpose To evaluate *in vitro* the effect of aspirin in combination with antibacterial drugs on the growth of microbial cultures of clinically significant bacterial strains in osteomyelitis

MATERIAL AND METHODS

The object of the study is clinically significant bacterial strains *K. pneumoniae* ($n = 12$), *P. aeruginosa* ($n = 12$), *S. aureus* ($n = 12$), *S. epidermidis* ($n = 12$), isolated from wounds of patients with chronic osteomyelitis.

The analysis of biomaterials obtained from patients was performed in accordance with accepted international standards (UK SMI). Species identification of microbial cultures was performed using MALDI-TOF mass spectrometry. The susceptibility of bacteria to antimicrobial drugs (*K. pneumoniae* — to ciprofloxacin, cefepime, imipenem, meropenem; *P. aeruginosa* — to ciprofloxacin, cefepime, imipenem, meropenem, amikacin, piperacillin/tazobactam; *S. aureus* and *S. epidermidis* — to vancomycin, gentamicin, ciprofloxacin, erythromycin, ceftiofloxacin), included in the formulary list of the Center, was determined according to the EUCAST criteria (European Committee on Antimicrobial Susceptibility Testing, Version 9.0, valid from 2019-01-01).

Inclusion criteria: clinical strains within the same taxonomic group, characterized by similar susceptibility to the tested antibacterial agents. Only methicillin-sensitive staphylococcal strains were included in the experiment.

Reference strains of bacteria belonging to four taxonomic groups were used as test cultures: *Pseudomonas aeruginosa* ATCC 27853, *Klebsiella pneumoniae* ATCC 700603, *Staphylococcus aureus* ATCC 29213, *Staphylococcus epidermidis* ATCC 14990.

The experiment tests were 4 series:

- control series: suspensions of the studied cultures were prepared, containing 5×10^6 CFU/ml (colony forming units) of bacteria;
- second series (0.03 % ASA, 300 µg/ml): in the second part of the experiment, 1 ml of ASA was added to test tubes with cultures containing 5×10^6 CFU/ml of bacteria and incubated at room temperature for 30 min;
- third series: polymyxin (5 mg/ml) in the case of gram-negative bacteria and gentamicin (40 mg/ml) in the case of gram-positive bacteria were incubated at room temperature for 30 min together with suspensions containing 5×10^6 CFU/ml of microbial cells;

— fourth series: bacterial suspensions (5×10^6 CFU/ml) were incubated with a combination of ASA (0.05 %) + antibiotics (polymyxin or gentamicin) for 30 min.

Polymyxin is active against resistant gram-negative bacteria (*P. aeruginosa*, *A. baumannii*, *K. pneumoniae*, *E. coli*) and is the drug of choice for treating infections caused by carbapenem-resistant bacteria. Polymyxins act by disrupting the outer membrane of gram-negative bacteria (acting as a detergent). Gentamicin has high bactericidal activity against staphylococci.

To obtain a lawn, microbial suspensions in each experimental series were applied using a cotton swab to the surface of Mueller-Hinton agar. Antibiotic discs were placed on the surface and incubated for 24 hours in an incubator at 37 °C. Simultaneously, inoculations were made on Schaedler sheep blood agar (with hemin and vitamin K1) to monitor microbial cell growth. The results were assessed after 24 hours.

Antibacterial activity was assessed by the absence of a bacterial growth zone around the discs.

All experiments were performed in triplicate, and data are presented as mean (M) and standard deviation (SD). Statistical tests were performed using Gnumeric 1.12.17. Group comparisons were performed using Student's t-test after preliminary determination of sample distribution using the Anderson-Darling test. The significance threshold for all tests was $p < 0.05$.

This study was conducted as an in vitro study, without the participation of animals or humans.

RESULTS

Combined incubation of ASA (0.05 %) and gram-negative bacteria (*K. pneumoniae*, *P. aeruginosa*) did not show microbial growth on Petri dishes. In the case of *S. aureus* bacteria, the CFU count was reduced compared to the control group. There was no growth on the dishes containing *S. epidermidis* (Fig. 1).

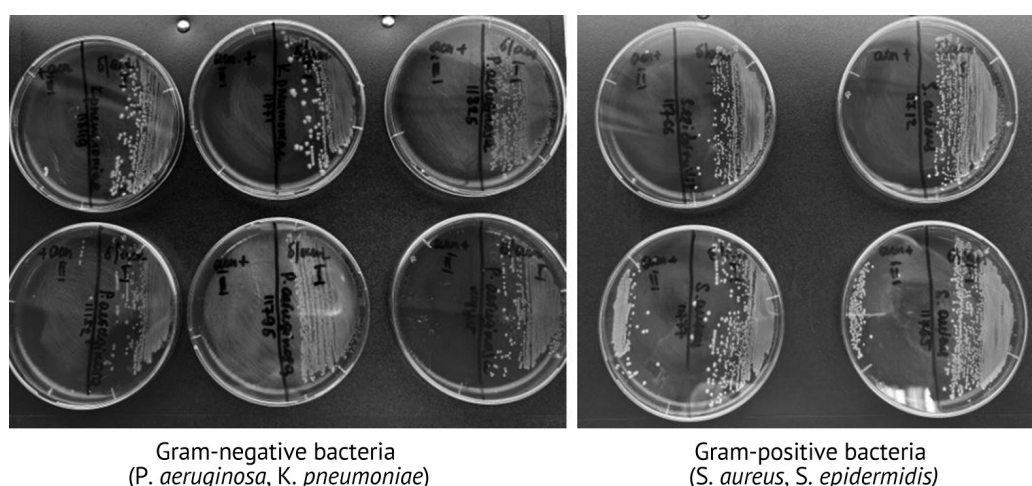


Fig. 1 Effect of ASA on growth of bacteria *P. aeruginosa*, *K. pneumoniae*, *S. aureus*, *S. epidermidis*. In dishes: control series is on the right and the series with ASA is on the left

When polymyxin was co-incubated with *P. aeruginosa*, slight bacterial growth was observed in Petri dishes; only isolated colonies were observed in the case of *K. pneumoniae*. Incubation of polymyxin and 0.03 % ASA showed no microbial growth of *K. pneumoniae* in dishes and slight growth was observed in the dishes with *P. aeruginosa*. Gentamicin inhibited the growth of *S. aureus* (a small number of bacteria were observed in the dishes). 0.03 % ASA enhanced the bactericidal properties of gentamicin (no bacterial growth was observed in the dishes) (Fig. 2).

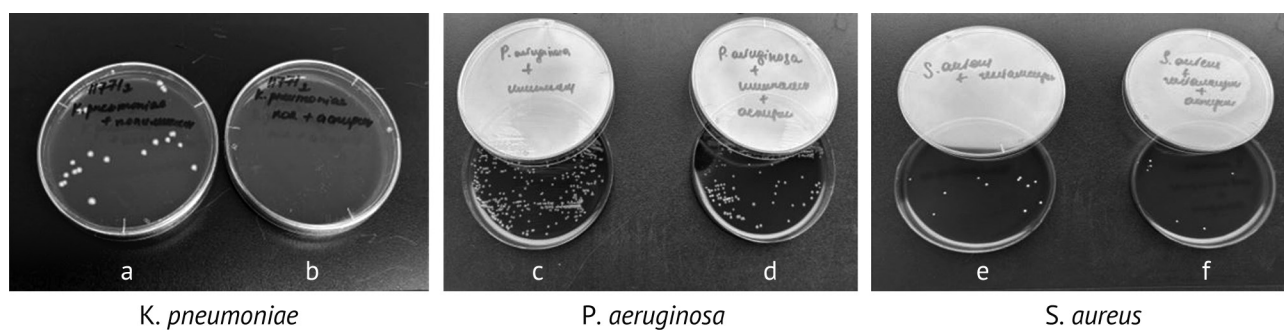


Fig. 2 Effect of ASA on the growth of microbial cultures *K. pneumoniae*, *P. aeruginosa*, *S. aureus* in blood agar after incubation with an antibiotic and a combination of an antibiotic with ASA: (a, c) polymyxin (5 mg/ml); (b, d) polymyxin (5 mg/ml) + ASA (0.03 %); (e) gentamicin (40 mg/ml); (f) gentamicin (40 mg/ml) + ASA (0.03 %)

Differences in bacterial growth inhibition zones were also observed during antibiotic susceptibility tests that used different ASA concentration (Fig. 3 b, c). For *K. pneumoniae* strains and ASA (0.03 %) use, the bacterial growth inhibition zones did not differ from the control group; however, the number of viable cells on the agar surface was lower (Fig. 3 d).

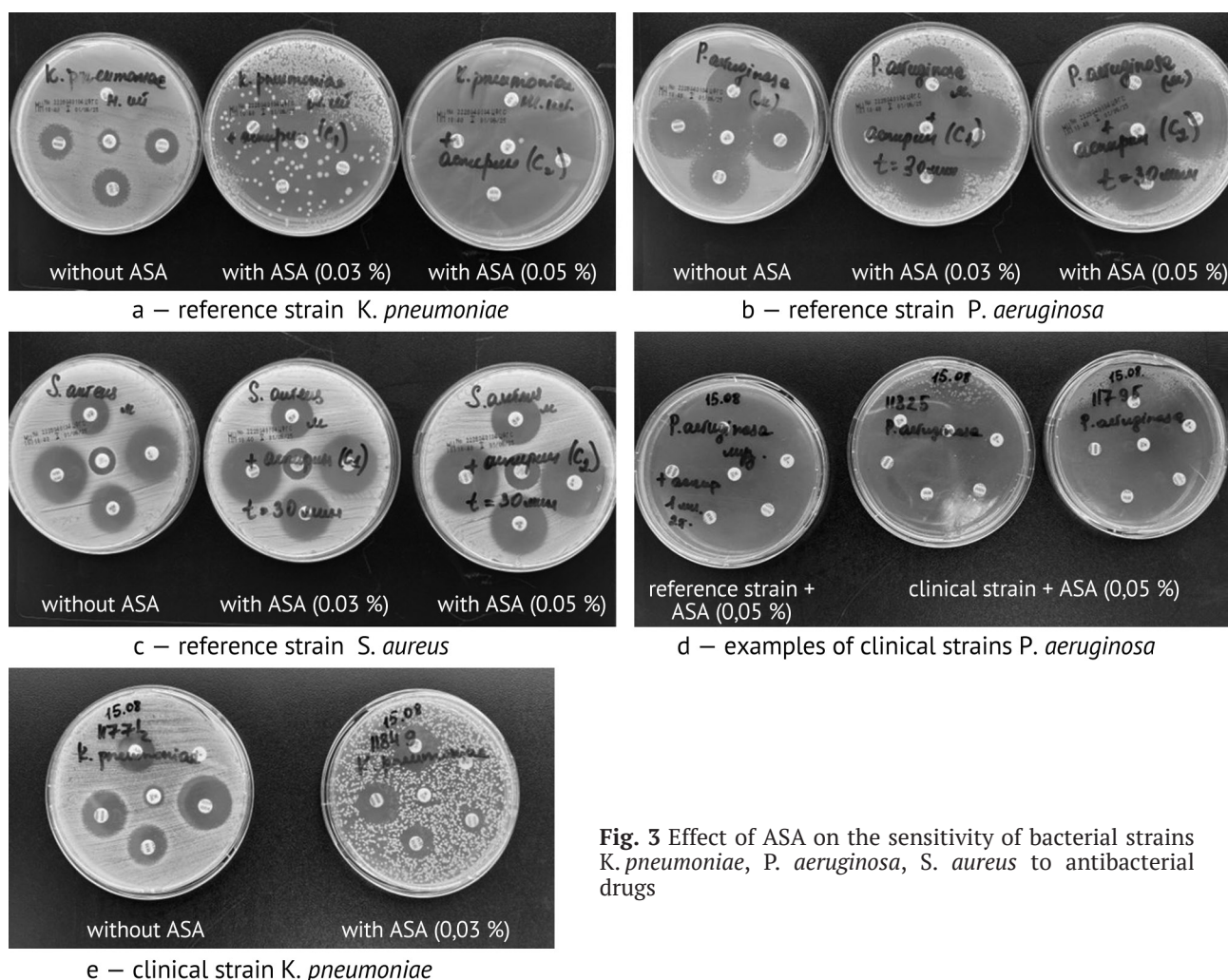


Fig. 3 Effect of ASA on the sensitivity of bacterial strains *K. pneumoniae*, *P. aeruginosa*, *S. aureus* to antibacterial drugs

In the ASA group, significant differences in growth inhibition zones were observed for clindamycin and cefoxitin compared with the control series for clinical *S. aureus* strains (Table 1). For *S. epidermidis* strains, differences in the growth inhibition zone were noted for clindamycin (Table 2). In dishes with *P. aeruginosa* plates, significant changes in growth inhibition zones were observed for imipenem, meropenem, cefepime, and ciprofloxacin (Table 3).

Table 1

Diameter of the bacterial growth inhibition zone for *S. aureus*

Drug (mcg)	Diameter of the bacterial growth inhibition zone <i>S. aureus</i> , mm	
	Control series, $n = 12$	ASA (0.05 %), $n = 12$
Clindamycin (2)	25 ± 2	$32 \pm 2^*$
Cefoxitin (30)	29 ± 3	$33 \pm 2^*$
Vancomycin (5)	19 ± 1	19 ± 1
Gentamicin (30)	23 ± 2	24 ± 2
Ciprofloxacin (5)	25 ± 3	25 ± 2
Erythromycin (15)	26 ± 2	28 ± 3

Note: n – number of strains, * – significance of differences between the control series and the experimental series with ASA, $p < 0.05$

Table 2

Diameter of the bacterial growth inhibition zone for *S. epidermidis*

Drug (mcg)	Diameter of the bacterial growth inhibition zone <i>S. epidermidis</i> , mm	
	Control series, $n = 12$	ASA (0.05 %), $n = 12$
Clindamycin (2)	24 ± 2	$29 \pm 2^*$
Cefoxitin (30)	25 ± 2	26 ± 2
Vancomycin (5)	19 ± 1	19 ± 1
Gentamicin (30)	25 ± 3	24 ± 2
Ciprofloxacin (5)	26 ± 2	25 ± 2
Erythromycin (15)	25 ± 2	27 ± 2

Note: n – number of strains, * – significance of differences between the control series and the experimental series with ASA, $p < 0.05$

Table 3

Bacterial growth inhibition zone for *P. aeruginosa*

Antibacterial drug (mcg)	Bacterial growth inhibition zone <i>P. aeruginosa</i> , mm	
	Control series, $n = 12$	ASA (0.05 %), $n = 12$
Imipenem (10)	24 ± 3	$30 \pm 2^*$
Meropenem (10)	29 ± 2	$33 \pm 1^*$
Cefepime (30)	28 ± 3	$32 \pm 2^*$
Piperacillin/tazobactam (30/6)	26 ± 2	26 ± 3
Amikacin (30)	22 ± 2	25 ± 2
Ciprofloxacin (5)	28 ± 2	$33 \pm 2^*$

Note: n – number of strains, * – significance of differences between the control series and the experimental series with ASA, $p < 0.05$

DISCUSSION

Nonsteroidal anti-inflammatory drugs (NSAIDs) are used as anti-inflammatory, analgesic, and antipyretic medications. However, there is evidence of the effects of NSAIDs on bacteria and associated infections [13]. Data on the in vitro activity of NSAIDs against planktonic bacteria and biofilms are currently contradictory [14–17].

One of the NSAIDs, acetylsalicylic acid, is a synthetic derivative of salicylic acid. ASA has a complex action that depends on its dosage. Its anti-inflammatory, antipyretic, and analgesic effects (medium/high doses of ~500–1000 mg are used) are mediated by inhibiting cyclooxygenase enzymes (COX-1 and COX-2), which are involved in the synthesis of prostaglandins which are substances that cause pain and swelling during inflammation. Its antiplatelet effect (low doses of ~75–100 mg are used) is mediated by blocking COX-1 in platelets.

Various studies have reported data on the effect of ASA on platelets after exposure to bacteria (*Staphylococcus aureus*, *Enterococcus faecalis*, *Streptococcus pyogenes*, *Escherichia coli*) [18, 19].

It has been shown that clinical strains of *S. aureus* can cause platelet activation, expression of cell death markers, and release of inflammatory factors [18, 19]. Acetylsalicylic acid limits the effect of *S. aureus* on platelets by reducing the rate of cell death, restoring their numbers, and decreasing the contribution of platelets to inflammation associated with the presence of bacterial pathogens in the blood.

Currently, the ability of aspirin to have an effect on the formation of biofilms by microorganisms, to exhibit synergism with antibiotics thus increasing the permeability of bacterial cell walls and making them more vulnerable, to modulate the body's immune response are being studied [8-12]. Kupferwasser et al concluded that the sensitivity of *MRSA* to β -lactam antibiotics increases in the presence of aspirin [9]. Another study demonstrated an increased activity of vancomycin against resistant enterococci in the presence of aspirin [20]. A number of studies provide data on the bacteriostatic effect of ASA on gram-positive bacteria and the absence of any effect on gram-negative bacteria [13]. El-Mowafy et al observed a decrease in bacterial motility when studying the QS-inhibitory effect of ASA on *P. aeruginosa* [21]. Another study showed that exposure to ASA for 1.5 hours resulted in the removal of 30 % of biofilms formed by *S. epidermidis* and *P. aeruginosa* on polystyrene [22].

There are data in the literature that confirm the formation of resistant bacterial populations after exposure to NSAIDs, including ASA [14, 23].

In our study, the lack of growth in the dish with *S. epidermidis* bacteria in the presence of ASA, even without antibiotics, suggests that one mechanism of action may be the suppression of adhesion and biofilm formation [24]. ASA's pronounced effect on gram-negative bacteria (*K. pneumoniae*, *P. aeruginosa*) may be due to its impact on the outer membrane of microbial cells. However, the drug had a lesser effect on gram-positive bacteria (*S. aureus*) by only reducing metabolic activity. Aspirin, being a weak acid, can also disrupt membrane integrity and increase membrane permeability [8].

Our results suggest that ASA enhances the activity of polymyxin. The enhanced bactericidal activity of gentamicin in the presence of ASA against *S. aureus* may be related to the ability of salicylates to suppress protein synthesis and disrupt bacterial energy metabolism, which increases the efficiency of aminoglycoside accumulation within the cell [13].

This study is primarily descriptive in nature. Future plans include determining the MIC (minimum inhibitory concentration) and FIC (fractional inhibitory concentration) indices to confirm synergism, studying the effect of ASA on mature biofilms, and evaluating the effectiveness of the combination in relevant in vivo osteomyelitis models.

CONCLUSION

Our study demonstrated that acetylsalicylic acid exhibits synergism with a number of antibiotics in vitro and significantly enhances their bactericidal activity against clinical isolates associated with osteomyelitis.

Conflict of interests Not declared.

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Postural control in assessing the effectiveness of motor recovery following total hip arthroplasty

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Abstract

Introduction Postural control (PC) is a predictor of gait recovery and can be performed in the early postoperative period following total hip arthroplasty (THA) for adequate appraisal of the treatment and recovery of orthopedic patients. The search for PC markers is practical for relevant evaluation of the effectiveness of motor rehabilitation following THA of one (contralateral) hip or both joints.

The **objective** was to establish specific features of PC assessing effectiveness of motor rehabilitation in patients with hip osteoarthritis after unilateral and bilateral THA.

Material and methods A total of 40 patients with grade III–IV hip osteoarthritis were examined as Group 1 ($n = 21$) with unilateral THA of the contralateral hip joint and Group 2 ($n = 19$) with bilateral THA. The PC was assessed using an inertial sensor placed at the L4–L5 projection to record angular and spectral parameters of postural fluctuations from the vertical in the coronal and sagittal axes. Examinations were performed on admission and upon discharge after a course of motor rehabilitation in the inpatient medical rehabilitation department.

Results Improvements in the PC during the inpatient rehabilitation were accompanied by greater deviations in the coronal plane and less deviations in the sagittal plane in the unilateral THA group suggesting frontal instability. There was no increase in frontal axis deviations with sagittal deviations being maintained in the bilateral THA group. Models for predicting the effectiveness of motor recovery were offered.

Discussion Objective indicators of the PC in patients with hip osteoarthritis treated with unilateral or bilateral THA, were obtained with inertial sensor technology and could be used to identify compensatory musculoskeletal mechanisms, determine markers of the effectiveness of rehabilitation and adjust recovery programs.

Conclusion Motor rehabilitation of THA patients suggests that bilateral arthroplasty destabilizes the biomechanics of the hip joint to a lesser extent, limiting excessive deviations in the frontal plane and slows down restoration of statokinetic stability due to proprioceptive insufficiency.

Keywords: postural control, equilibrium balance, hip osteoarthritis, methodology, rehabilitation, hip replacement, Steadis

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INTRODUCTION

Osteoarthritis (OA) is the most common disease of the hip joint, affecting over 4.1 % of the adult population. The increasing number of hip replacement surgeries, coupled with the relative safety, technological advancement, and affordability of the method, makes it the preferred option, with a frequency of 3.3 cases per 10,000 patients treated, and a steady increase in the number of primary and revision surgeries [1, 2].

A steady increase in the incidence of osteoarthritis has been observed, associated with increased life expectancy and physical inactivity [3]. Objective assessment and visualization of functional impairments in patients with HO treated with unilateral or bilateral hip arthroplasty, are challenging in clinical practice. For elderly patients, two-stage hip arthroplasty (6-8 months between surgeries) is preferable in some cases, while unilateral hip arthroplasty (e.g., with aseptic necrosis of the femoral head) can significantly alter gait patterns and the hip joint, necessitating their correction. Gait analysis is an accepted method for assessing functional recovery to allow for a simultaneous evaluation of the function and potential patient activity. The gait test may be difficult early post-op due to pain, functional limitations, and a need for additional support devices in some cases, which may affect accuracy of the results.

Physiological balance of vertical stance, Pediatric Balance Scale (PBS) is a recognized predictor of gait restoration to allow for the assessment of the balance maintenance strategy (physiological "A" or compensatory-adaptive "H"), statokinetic and proprioceptive correction in accordance with clinical recommendations based on objective effectiveness criteria, and the selection of technical rehabilitation aids early post-op [4, 5]. With the algorithms and parameters developed, traditional stabilometry has some limitations and disadvantages. For example, of the external coordinate system adjusted and reset with the feet positioned and strictly centered/at the intermalleolar point, which is often inaccurate (for example, during decompensation and shift of the body's overall center of mass toward the contralateral limb) [6]. Inertial sensor technology, which does not require platform installation, appears more attractive. The validity and appropriateness of information from inertial sensors (designated IMU in foreign literature) were reported in some studies in comparison with the readings of traditional stabilometric platforms [7, 8]. The sensor is capable of distinguishing the three planes of oscillation with a specific frequency [9], and also classifying PBS readings, for example, under the influence of maximum anaerobic fatigue [10], in cerebral palsy in children [11], in the dynamics of stroke [12], depending on the location of application/registration [13]. A method for assessing the PBS using inertial sensors [14] was offered with the normative database being integrated into the automatic "Stadis-Balance" Protocol. The approach to analyzing the amplitude-frequency characteristics of oscillations was adopted by analogy with the author's method for assessing the extent of stress of compensatory mechanisms in case of knee dysfunction [6].

The **objective** was to establish specific features of postural control assessing effectiveness of motor rehabilitation in patients with hip osteoarthritis after unilateral and bilateral THA.

MATERIAL AND METHODS

The study was performed between January and June 2025 in the inpatient medical rehabilitation department of the Ivanovo Regional Hospital for War Veterans. Inertial sensor technology (Neurosens sensor, Neurosoft LLC, Ivanovo, Russia) with Steadis-Balance software (No. RZN 2018/7458 dated July 11, 2022) was used. The sensor was placed in the L4–L5 projection (Fig. 1), the actual center of mass of the human body. The examinations were produced in the Biomechanics laboratory at the same time at a comfortable temperature upon patient admission to the department and

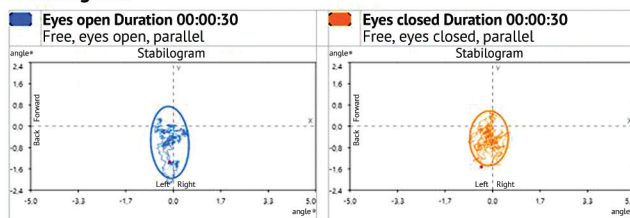
upon discharge. Transient processes were monitored by preliminary monitoring without recording for 1–2 minutes, followed by 30-second recordings with both eyes open and closed (Romberg test). When necessary, support was provided by symmetrical, central unloading (two patients required a walker with a brake lock).



Fig. 1 An example of an inertial sensor installed during a patient examination and balance training using biofeedback

An automatic protocol (Fig. 2) was generated immediately after the examination. The sensor's angular deviations in the lumbosacral spine were recorded in the frontal and sagittal planes (mean deviation and variance in degrees from the vertical; velocity; area; oscillation length and its ratio to the ellipse area; Romberg coefficient as the ratio of the area with the eyes closed to open). Spectral parameters were presented as the prevailing frequency and 60 % of the oscillation frequency power along the axes.

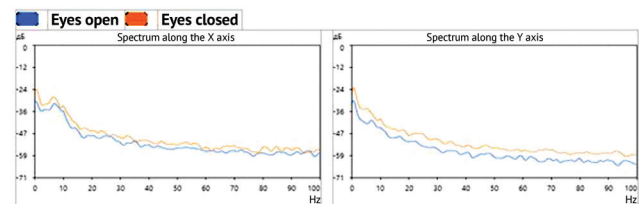
Romberg test



Angle parameters

Description		Eyes open	Eyes closed
Average deviation along the X-axis	$\sim X, ^\circ$	-0.12	-0.12
Average deviation along the Y-axis	$\sim Y, ^\circ$	-0.60	-0.44
X-axis deviation variance	$D X, ^\circ$	0.07 (< 0.04)	0.08 (< 0.09)
Y-axis deviation variance	$D Y, ^\circ$	0.29 (< 0.24)	0.17 (< 0.31)
Rate	$V, ^\circ / s$	1.05 (< 1.89)	1.39 (< 2.38)
Area of an ellipse	S, m^2	2.77 (< 1.70)	2.13 (< 2.78)
Area to path length ratio	$LFS, ^\circ$	0.088 (< 0.035)	0.051 (< 0.053)
Romberg's coefficient	RC	0.77	

■ Eyes open ■ Eyes closed



Spectral parameters

Description		Eyes open	Eyes closed
Fundamental frequency on the X-axis	$F X, Hz$	0.067 (< 4.902)	0.133 (< 4.792)
Fundamental frequency on the Y-axis	$F Y, Hz$	0.100 (< 0.205)	0.133 (< 0.243)
60 % frequency on the X-axis	$F60 X, Hz$	0.167 (< 7.413)	0.233 (< 6.532)
60 % frequency on the Y-axis	$F60 Y, Hz$	0.100 (< 2.432)	0.300 (< 1.027)

Automatic conclusion

• Proprioceptive system dominance



Fig. 2 An example of an automatic protocol for analyzing the PBS

Additionally, the patients' PBS oscillation accelerations were assessed in emulation mode to allow for further identification of up-and-down oscillations in the frontal plane, and criteria for determining the degree of compensatory strain were identified. In addition to the standard Individual Rehabilitation Program, all patients received stabilization training using biofeedback in a game-based environment (7 to 20 minutes, 10 times daily) in accordance with clinical recommendations.

The study included 40 patients with hip arthritis without comorbidities in the decompensation stage, cognitive limitations, diseases of the lumbosacral spine (LSS) and other joints of the lower limbs. The patients were divided into two groups: group 1 ($n = 21$): patients treated with endoscopic replacement of one hip joint (after the first stage of THA); group 2 ($n = 19$): patients treated with endoscopic replacement of both hip joints (Table 1). The groups did not differ significantly in gender and age to allow comparison of the findings. Examinations were performed on admission and upon discharge after an inpatient rehabilitation course, which included PBS training using a biofeedback mechanism.

Table 1

Characteristics of the study groups

Description		Group 1 ($n = 21$)	Group 2 ($n = 19$)
Males	abs.	10	10
	%	48	53
Average age of men, years		60.10 ± 3.23	53.20 ± 5.76
Females	abs.	11	9
	%	52	47
Average age of females, years		63.18 ± 3.53	69.33 ± 1.86
Purpose of inclusion		Evaluation of the impact of unilateral THA on the BVS in the absence of other THA	Assessing the impact of the transition from unilateral to bilateral THA on the BVS

Purpose of inclusion Evaluation of the impact of unilateral THA on the BVS in the absence of other THA Assessing the impact of the transition from unilateral to bilateral THA on the BVS

Statistical processing of the variables was performed using IBM SPSS Statistics v/23.0. The normality of the distribution of the quantitative data was confirmed using the Shapiro – Wilk test. The significance of differences was assessed using the Student's t-test (for independent and dependent groups), and correlation relationships between parameters were assessed using Spearman's rank correlation. The significance level was taken as $\alpha = 0.05$. The results are presented as ($M \pm m$), where M is the arithmetic mean and m is the standard error of the mean. In the group of frontal deviations, the absolute value was adopted for the X indicator, without considering the side of the involvement.

The study was performed in accordance with ethical principles for medical research involving human subjects stated in the Declaration of Helsinki developed by the World Medical Association of 1964, Federal Law No. 323 "On the Fundamentals of Health Protection of Citizens in the Russian Federation" dated November 21, 2011, Federal Law No. 152 "On Personal Data" dated July 27, 2006.

RESULTS

Oscillations with the inclusion of individual nodes/joints (according to the type of passive closure in flexion contracture) were simulated using the Adams program (Fig. 3). Visual confirmation of highly synchronized oscillations of the spinal ACO and hip joint was obtained with unilateral "closure" with an almost twofold increase in oscillation power (Fig. 3 b, c), and with bilateral "closure" with an increased oscillations in the underlying balance levels (Fig. 3 c, d). A significant

influence of peri- and paraarticular compensation mechanisms on the PBS (with an increase in oscillation power in the frontal plane) was established: correlation analysis using the Spearman criterion showed a significant correlation between the average noticeable and strong high degrees of interrelationship of positive direction (at $p \leq 0.05$) according to the Jerk indicators $r = 0.64$; PWR $r = 0.7$ and F50 $r = 0.70$.

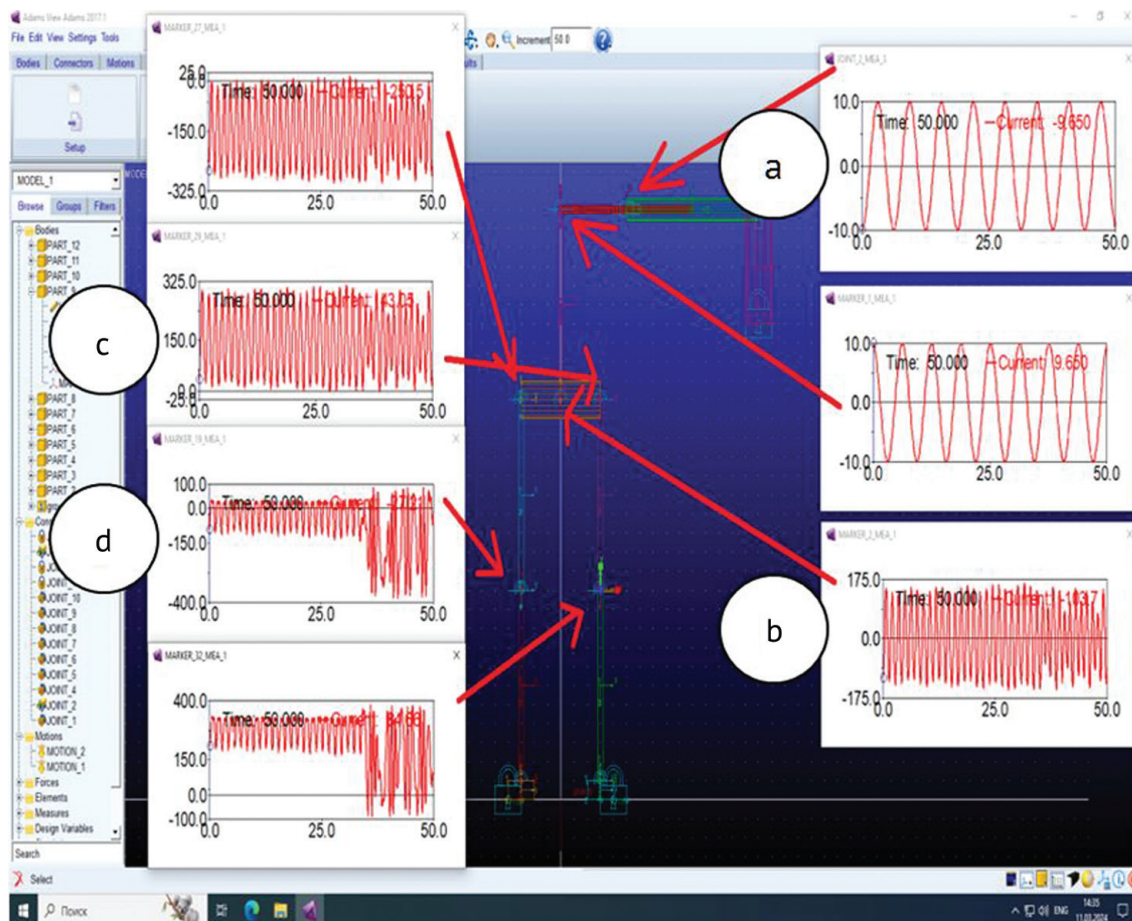


Fig. 3 Modeling of oscillations simulated with the Adams program: (a) deflection/force application node; (b) spectrum of oscillations of central genesis in the lumbosacral spine; (c) spectrum of oscillations in the hip joint; (d) spectrum of oscillations in the knee joint

All indicators of the automatic protocol were analyzed; the results are presented in Table 2.

Visual system predominated in maintaining the PBS in both groups. Clinical condition and motor capabilities improved over the course of medical rehabilitation in a different manner in the two groups, reflecting the restoration of central control of balance through various strategies and synergies.

With all the transformations of the PBS under the influence of rehabilitation, the more pronounced central control of the PBS upon admission reduced its contribution in the group of unilateral THA due to the increased contribution of the so-called “hip strategy” (a significant decrease in the length of the trajectory of oscillations of the angle from the vertical ($L, ^\circ$) with an increased speed of oscillations before/after rehabilitation with open eyes, with an increase of 60 % in the power of oscillations in the sagittal plane when closing the eyes and a decrease in deviations along the Y-axis), in contrast to group 2 without an increase in deviations in the frontal plane X with preservation along the sagittal Y-axis.

Table 2

Vertical stance balance measured with the Romberg test upon admission and after medical rehabilitation (MR), $M \pm m$ ($n = 40$)

	Eyes open (EO)				Eyes closed (EC)				<i>p</i>
	Group 1 (unilateral THA), <i>n</i> = 21		Group 2 (bilateral THA), <i>n</i> = 19		Group 1 (unilateral THA), <i>n</i> = 21		Group 2 (bilateral THA), <i>n</i> = 19		
	on admission	after MR	on admission	after MR	on admission	after MR	on admission	after MR	
	1	2	3	4	5	6	7	8	
RC					2.18 ± 0.62	1.69 ± 0.30	1.85 ± 0.34	1.73 ± 0.39	
~X, °	0.11 ± 0.02	0.08 ± 0.01	0.15 ± 0.03	0.14 ± 0.03	0.11 ± 0.03	0.11 ± 0.2	0.16 ± 0.03	0.16 ± 0.04	
~Y, °	−0.02 ± 0.09	0.07 ± 0.08	−0.01 ± 0.11	0.001 ± 0.09	0.19 ± 0.12	0.18 ± 0.13	−0.18 ± 0.17	0.09 ± 0.16	<i>p</i> ₇₋₈ ≤ 0.001
D X, °	0.04 ± 0.02	0.01 ± 0.002	0.03 ± 0.005	0.03 ± 0.01	0.05 ± 0.02	0.02 ± 0.002	0.06 ± 0.02	0.03 ± 0.006	<i>p</i> ₇₋₈ ≤ 0.05
D Y, °	0.13 ± 0.03	0.12 ± 0.03	0.18 ± 0.03	0.23 ± 0.09	0.21 ± 0.04	0.13 ± 0.01	0.27 ± 0.04	0.16 ± 0.02	<i>p</i> ₇₋₈ ≤ 0.05
L, °	35.02 ± 1.59	38.56 ± 1.17	43.40 ± 3.8	38.61 ± 2.99	45.86 ± 4.06	46.40 ± 3.25	59.94 ± 7.84	48.49 ± 5.09	<i>p</i> ₁₋₂ ≤ 0.05 <i>p</i> ₃₋₄ ≤ 0.1 <i>p</i> ₇₋₈ ≤ 0.05
V, °/c	1.17 ± 0.5	1.29 ± 0.4	1.45 ± 0.1	1.29 ± 0.10	1.53 ± 0.14	1.55 ± 0.11	2.00 ± 0.26	1.62 ± 0.17	<i>p</i> ₁₋₂ ≤ 0.05 <i>p</i> ₃₋₄ ≤ 0.1 <i>p</i> ₇₋₈ ≤ 0.05
S, °2	1.06 ± 0.45	0.63 ± 0.11	1.12 ± 0.19	0.90 ± 0.18	1.46 ± 0.47	0.75 ± 0.09	1.92 ± 0.45	1.02 ± 0.20	<i>p</i> ₇₋₈ ≤ 0.05
LFS, °	0.02 ± 0.008	0.02 ± 0.002	0.02 ± 0.003	0.02 ± 0.003	0.03 ± 0.007	0.02 ± 0.001	0.03 ± 0.003	0.02 ± 0.002	<i>p</i> ₇₋₈ ≤ 0.05
F X, Γ _{II}	0.56 ± 0.27	0.55 ± 0.27	0.20 ± 0.08	0.08 ± 0.02	1.04 ± 0.49	0.52 ± 0.26	0.17 ± 0.04	0.25 ± 0.11	
F Y, Γ _{II}	0.10 ± 0.007	0.12 ± 0.02	0.10 ± 0.02	0.08 ± 0.006	0.11 ± 0.02	0.11 ± 0.02	0.10 ± 0.02	0.11 ± 0.02	
F60 X, Γ _{II}	4.05 ± 0.63	3.71 ± 0.41	2.90 ± 0.51	4.15 ± 0.63	3.42 ± 0.59	3.34 ± 0.39	2.70 ± 0.47	2.84 ± 0.59	<i>p</i> ₃₋₄ ≤ 0.05
F60 Y, Γ _{II}	0.25 ± 0.06	0.28 ± 0.05	0.18 ± 0.03	0.17 ± 0.02	0.24 ± 0.04	0.34 ± 0.04	0.23 ± 0.03	0.31 ± 0.03	<i>p</i> ₅₋₆ ≤ 0.1 <i>p</i> ₇₋₈ ≤ 0.1

The markers identified suggested an increase in the proprioceptive contribution to statokinetic stability in the A-synergy in the absence of significant correlation strength with the main compensation mechanisms; no signs of a decrease in frontal instability (as measured by ($\sim X, ^\circ$), the average deviation along the X-axis) were found. In addition, a noticeable direct correlation was found between the change in frontal deviation ($\sim X, ^\circ$) and the 60 % frequency indicator along the Y-axis ($r = 0.52$; i.e., an increase in frontal deviation was accompanied by increased frequency power in the sagittal plane), indicating an increase in the contribution of the H-synergy (hip strategy) to statokinetic stability.

With similar responses to motor rehabilitation, the bilateral THA group demonstrated more stable and functionally significant changes, with a trend toward improved statokinetic stability using the energy-efficient "central" approach and an increased contribution of A-synergies to the PBS. More stable functional changes, with physiological deviations predominantly seen in the sagittal plane (ankle, central A-strategy), were observed in the early rehabilitation period in the bilateral THA group due to improved proprioceptive sensitivity (Romberg's test with eyes closed before and after the course of medical rehabilitation, Table 2, columns 8 and 9).

The stress of the compensatory mechanisms with active closure of the hip joint (greater centralization of the hip joint with unchanged oscillation along the X-axis, reliable decreases in the deviations of the deflection angle along both axes, significant decreases in the oscillation length, velocity, and area of the ellipse of the deflection angle) was determined with an increase in the power of oscillation along the sagittal axis. A clinically significant point was the identification of a noticeable strength of correlations between the oscillation along the X-axis (frontal deviations) of the reverse direction with the LFS indicator, the ratio of the oscillation area to the length ($r = -0.53$) and direct ($r = 0.52$) with 60 % of the oscillation power along the X-axis, which reflects concordant/decompensatory changes.

All protocol parameters were analyzed in the classification discriminant model by forced inclusion, and if the significance was less than 0.05, the predictors were included in the discriminant model to establish a risk group for a poor prognosis for the success of motor rehabilitation:

- with unilateral THA (group 1) — development of frontal instability (deviation along the X-axis);
- with bilateral THA (group 2) — development of sagittal instability (oscillation velocity).

According to the model, the most significant discriminants were the indicators with open eyes and the Romberg coefficient in unilateral THA: displacement along the X-axis (°) (Xeo — significance 0.009 with Wilks' Lambda 0.695); 60 % of the oscillation power along the Y-axis (°) (60Yeo — significance 0.015 with Wilks' Lambda 0.725); Romberg coefficient (significance 0.063 with Wilks' Lambda 0.829), included in the analysis with a stable trend with an accuracy level of 83.3 %:

$$F1 = -0.894 + 0.199 \times RC - 6.105 \times Xeo + 2.619 \times 60Yeo$$

(centroid for the group with a poor rehabilitation prognosis = 1.575, for the group with a satisfactory prognosis = -0.787).

For bilateral THA, the following indicators were most significant discriminants for eyes closed: the dispersion of oscillations along the Y axis (°) (VSec — significance 0.001 with Wilks' Lambda 0.421); the area of the ellipse of oscillations S (°²) (Sec — significance 0.047 with Wilks' Lambda 0.748); the ratio of the area to the length of oscillations LFS (°) (LFSec — significance 0.027 with Wilks' Lambda 0.698) with an accuracy level of 87.5 %:

$$F1 = -1.802 + 11.677 \times ARec - 0.104 \times Sec - 32.378 \times LfSec$$

(centroid for the group with poor rehabilitation prognosis = -1.316, for the group with satisfactory = +1.24).

Therefore, unilateral THA significantly impacts the biomechanics of the hip joint, necessitating the inclusion of objective methods for monitoring hip joint function in rehabilitation programs, predicting the effectiveness of rehabilitation, and selecting the most effective ones. Bilateral THA has a lesser destabilizing effect on hip joint biomechanics, limiting excessive oscillations in the frontal plane, but it limits the restoration of statokinetic stability due to proprioceptive sensitivity (proprioceptive insufficiency).

DISCUSSION

Innovative treatment methods are introduced into clinical practice, significantly outpacing methods for objective assessment of the results [11–13, 15]. Restoration of the gait and activity is the primary request after THA in most cases [16]. Given the long postoperative period, not only the restoration of gait is required, but also restructuring and retraining the patient needs to learn physiological gait pattern not returning to normal, but compensating changes that have occurred [16–18]. Irreversible changes are a specific challenge that would require objectification and visualization. The multidisciplinary nature of patient care requires accurate numerical results in addition to descriptive results using modern rehabilitation technologies and methods to select their optimal combinations. Traditional clinical and laboratory examination methods addressing issues of anatomical and functional recovery, do not "visualize" a person's ability to function and activity — the targets of modern medical rehabilitation.

Balance function and a person's ability to maintain balance while standing and walking are significant characteristics of a person's overall condition and a predictor of overall motor activity, such as gait quality. The inverted pendulum biomechanical model is often used to simulate balance employing either a single-link or multi-link model depending on the objectives [19–21]. Objective study of the PBS function using instrumented methods has been known since the late 20th and early 21st centuries. A platform with force sensors, which has at various times been

called "posturography," "stabilometry," and "stabilography" is the most common method used [7]. With the algorithms and parameters developed, traditional 2D stabilometry has a number of limitations and disadvantages that are critical for orthopedic patients [6]. The 3D stabilometry technology using inertial/sensor sensors/accelerometers (referred to as IMUs in foreign literature) in clinical practice addresses these issues with PBS automatically provided with an amplitude-frequency spectrum of postural oscillations across the full range of compensatory mechanisms, including higher levels of compensation, that has a role in interpretation in trauma and orthopedic patients. From a biomechanical point of view, the issues of the hierarchy of central and peripheral mechanisms in the implementation of PBS control are still debatable, but most authors are inclined to the leading "central" mechanism of direct control in the presence of "automatic" generation of corrective muscle efforts in response to disturbances in equilibrium, which actualizes the interpretation of equilibrium frequencies [9, 19, 21–23].

For healthy individuals, the human body is modeled as a one-dimensional inverted pendulum, capable of rotating at the ankle joint in the sagittal plane as a single rigid body. In this case, the knee and hip joints are in a closed state, allowing direct measurement of the controlled variable (angular accelerations at the ankle joint) ignoring movements in other joints of the lower limbs. This strategy is called the ankle (A(ankle) strategy), and the mechanisms involved are called ankle synergy. The A-strategy is characterized by a predominant contribution of ankle rotation to the kinematics of movement from with antigravity restoration of the overall center of mass occurring with "slow" perturbations in the sagittal plane.

When the intact hip joint is locked due to pain, or after THA with the joint flexed, the limb shortens, triggering a cascade of compensatory mechanisms during gait including knee extension, ankle dorsiflexion, limited flexion/extension range of motion in the intact joint, sagittal instability in the lumbosacral spine, etc. For the lumbosacral joint, these changes manifest as a shift in basic balancing movements to the so-called H(hip) strategy. Overall, these movements become more energy-intensive, with the primary load shifting to the gluteal and quadriceps muscles, involving the opposite joint and underlying structures. The need to generate corrective force moments in altered joints and changes in oscillations in each specific case should be considered in terms of the limited high-frequency feedback [20, 21]. For orthopedic patients, the central mechanism is the higher hierarchical level of the spinal PCO and the A-strategy of the PBS, while the peripheral mechanism is additional inclusions of the H-strategy, and their relationships for various diseases require further research. Accelerometric, gyroscopic and magnetometric sensors in IMU systems allow for the simultaneous recording of changes in three mutually perpendicular planes (frontal, horizontal, and sagittal) with a higher frequency than traditional stabilometric platforms, expanding the clinical applications. The reproducibility and stability of IMU parameters using inertial sensor technology have been repeatedly demonstrated in other studies, both in healthy individuals with various developmental and age related characteristics [23, 24], and in patients with mobility impairments [25, 26, 27], cognitive limitations [28–30], and vestibular and neurological diseases [31, 32]. A certain limitation with use of inertial sensor technology is the "accumulation of error" during long-term observations [7, 21], which should be taken into account when limiting the analysis to time and marker (PBS - two samples of 30 seconds).

Lugade et al. [33] reported the importance of identifying frontal and sagittal instability for adequate recovery after THA. The design of the study allowed us to demonstrate that both unilateral and subsequent contralateral THA addressing issues of anatomical restoration, limit and "multilayer" the functional biomechanics of the support moments of standing. Unilateral THA maintaining the central mechanism of balance, high synchronization of oscillations in the hip joint and the lumbar spine, significantly increases the load on the higher hierarchical level of compensation and contributes to the H-strategy and synergy to a greater extent, being more rigid in normalizing the PBS, since it is additionally limited by the altered, diseased joint without THA.

Bilateral THA is less asymmetrical but is more associated with proprioceptive impairment due to the consequences of orthopedic surgery. We found no studies demonstrating the effects of unilateral or bilateral THA on PBS and its changes during motor rehabilitation in the early postoperative period. A number of authors offer variations on the vertical balance test (standing on foam rubber, with arms crossed, etc.), clarifying the mechanisms and extent of proprioceptive impairment in statokinetic stability. The study advances the goal of standardizing the methodology for assessing the hip joint dysfunction for integration into clinical practice. The findings and the identified trends can facilitate objective monitoring and support of the rehabilitation process and improve interdisciplinary care for patients with hip arthritis in the pre- and postoperative periods following two-stage THA.

The study is limited in sample size, preventing the development of a definitive algorithm for the population of patients with hip arthritis. The discriminant analysis revealed significant discriminants, criteria for unilateral and bilateral THA, which encourages further research with a larger sample size, comorbidities to be considered and validation using scale scores for machine learning. Based on the findings and considering the works on the application of inertial sensor technology, the authors of the article suggest that a promising non-invasive, safe and effective method can be used for assessing the balance of equilibrium in a vertical stance to characterize postural control in the dynamics of THA and rehabilitation of patients with hip arthritis.

CONCLUSION

Bilateral THA has a lesser destabilizing effect on hip biomechanics by limiting excessive oscillations in the frontal plane, but it slows the recovery of statokinetic stability due to proprioceptive insufficiency. Contralateral THA has a more significant effect on hip joint biomechanics due to increased frontal instability in the hip PBS strategy.

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Ethical Approval The study was performed in accordance with generally accepted ethical principles, norms and rules for conducting scientific research.

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Effect of bariatric surgery on postoperative outcomes of total hip replacement in patients with hip osteoarthritis

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Abstract

Introduction Bariatric surgery is the most effective treatment of morbid obesity, which is common in patients with hip osteoarthritis. However, the extent to which weight loss after bariatric surgery affects the outcomes and complication rates of total hip arthroplasty (THA) has not been adequately explored.

The **aim** of the study was to determine the impact of bariatric surgery on the results of THA and functional restoration of the lower limbs facilitating a lower risk of postoperative complications.

Material and methods A retrospective-prospective cohort, single-center, controlled study included patients with hip osteoarthritis grades 3–4 as described by I. Kellgren and I. Lawrence in 1957. Patients were referred for THA, had a history of morbid obesity (body mass index $> 40 \text{ kg/m}^2$) and underwent bariatric surgery. The parameters assessed included body mass index, pain, functional status of patients measured with the Harris hip score and complication rate.

Results The findings suggested a significant statistical difference ($p < 0.001$) in pain intensity on the first day after surgery measured in patients of the study group and the comparison group with (6.3 ± 2.3) and (7.4 ± 2.3) scores, respectively. The modified Harris Hip Score measured at 12 months of surgery reached the maximum with (90.2 ± 10.3) scores in the study group and (86.5 ± 11.6) scores in the comparison group, with a statistically significant difference in the measurements, $p = 0.021$. The Kaplan – Meier estimator showed a five-year survival rate of THA being 94.6 % (5.4 % complications) in the study group and 77.2 % (22.8 % complications) in the comparison group.

Conclusion The bariatric surgery used in patients with morbid obesity and grade 3–4 hip osteoarthritis prior to THA facilitated a statistically significant risk of postoperative complications reduced to 17.4 % and the five-year survival rate of THA increased to 94.6 %.

Keywords: morbid obesity, hip osteoarthritis, bariatric surgery

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INTRODUCTION

Obesity is a chronic disease with rising prevalence worldwide [1]. Obese individuals, with a body mass index (BMI) $> 30 \text{ kg/m}^2$, have a higher risk of lower extremity osteoarthritis (OA) [2] due to increased stress and inflammatory adipokines [3–7]. With the increasing prevalence of obesity and an aging population, the incidence of OA continues to rise and rising obesity trends result in more total knee arthroplasty (TKA). Over one million total hip arthroplasties (THA) and total knee arthroplasties (TKA) are performed annually in the United States [8].

There is no consensus on the preoperative management of patients with obesity and osteoarthritis of the hip and knee joints [9–14]. These patients have a higher risk of postoperative complications including infections, dislocations and early revisions [13, 15–19]. The results of THA can be associated with many factors, for example, the local factor of fat thickness or circumference of the proximal femur increasing the risk of implant dislocation [20] and other factors may have an impact on the results of the surgery. Bariatric surgery (BS) can positively affect some of these factors due to weight loss, reducing the risk of obesity-related comorbidities including diabetes, hypertension and dyslipidemia [21–23].

Obese OA patients can benefit from BO performed prior to THA reducing postoperative complications [24–26] and hip pain and improving functional outcomes [27]. However, the optimal balance between the benefits of weight loss and a lower risk of orthopedic complications remains unresolved.

The **aim** of the study was to determine the impact of BS on the results of THA and functional restoration of the lower limbs facilitating a lower risk of postoperative complications.

MATERIAL AND METHODS

A retrospective-prospective cohort single-center controlled study was performed at the Clinic of Orthopedics and Joint Pathology of Sechenov University (approved by the LEC of Sechenov University on March 14, 2024, No. 06-24).

The treatment group consisted of patients ($n = 62$) with hip arthritis grades 3–4 according to the K&L classification (I. Kellgren and I. Lawrence, 1957) treated with total hip arthroplasty over a five-year period (from January 1, 2014 to January 1, 2019). The patients had a history of morbid obesity (BMI $> 40 \text{ kg/m}^2$), who had undergone BO at the time of inclusion in the study. The comparison group ($n = 91$) included patients with hip arthritis and morbid obesity, similar in gender and age.

Inclusion criteria:

- patients, regardless of gender and age, with idiopathic osteoarthritis of the hip joint, characterized by pain scored above 3 on the VAS, clinical and radiological signs of hip arthritis K&L grade 3–4, with a history of morbid obesity (BMI $> 40 \text{ kg/m}^2$), who underwent BO before THA, confirmed by medical documentation.
- available written informed consent for the processing of medical history data and participation in the study.

Non-inclusion criteria:

- severe deformities of the hip joint (valgus, varus, primary defects of bone tissue, hip dysplasia);
- patients undergoing conservative treatment for obesity;
- systemic autoimmune diseases (rheumatism, connective tissue diseases, systemic necrotizing vasculitis), severe uncorrected forms of diabetes mellitus (glycosylated hemoglobin $> 9 \%$), blood

diseases (thrombopenia, thrombocytopenia, anemia with Hb < 90 g/l), immunotherapy and/or treatment with corticosteroids, cytostatics within six months prior to inclusion in the study.

Exclusion criteria:

- patient refusal to participate in the study;
- lack of possibility of dynamic monitoring and control during the established period (60 months).

Over a five-year period, 13 patients (8.5 %) were excluded from the study: three patients from the treatment group and 10 patients from the comparison group. A total of 140 patients were subjected to the final analysis: 59 patients from the treatment group and 81 patients from the comparison group, including 36 male (25.7 %) and 104 female patients (74.3 %), with an average age of 63.2 ± 7.0 years (range, 48–72 years).

Primary uncemented THR was produced for the patients following examination, confirmation of the diagnosis of hip arthritis and indications for THR with the results being assessed over a five-year period after surgery.

The patients' weight and height were measured during examination and a telephone interview to calculate BMI (kg/m²). The height was assumed to be a constant value, and the patient reported weight based on self-weighing. Pain was assessed using a 10-point visual analogue scale (VAS) [28]. The anteroposterior view and frog-leg lateral radiograph of the hip joint were used to identify radiographic signs of a hip pathology. Osteoarthritis was assessed according to the K&L classification using radiography showing subchondral sclerosis, subchondral cysts, osteophytes of the femur or acetabulum, or narrowing of the joint space [29].

The modified Harris Hip Scale (mHHS) was used to measure outcome after THA. The mHHS has a maximum of 91 points (pain — 44 points, function — 47 points). A telephone interview was used for survey research. The result was multiplied by 1.1 to obtain the maximum possible number of points — 100 [30, 31, 32]. The "Function" section included questions about the distance the patient can walk, his ability to put on shoes and socks, his ability to use public transport, the need to use a cane or crutches, limping, the ability to climb stairs and the ability to sit on a regular chair for an hour [33]., according to a systematic review by N. Ramisetty et al. reported the Harris Hip Scale as the most frequently used measure to explore outcomes of THA [34].

Patients could describe their pain during the clinical examination using the Visual Analog Scale (VAS) with an average score of 2.9 ± 1.1 and the Intermediate Pain Scale (IPS) with an average score of 55.7 ± 10.1 . A comparative analysis of the patient examination by groups is presented in Table 1.

Table 1

Comparative analysis between groups of patients

Description		Treatment group (n = 59)	Comparison group (n = 81)	p*
Male	abs.	12	24	0.217
	%	20.3	29.6	
Female	abs.	47	57	
	%	79.7	70.4	
Age (years)		63.2 ± 7.3	63.3 ± 6.8	0.941
BMI (kg/m ²)		$44.5 \pm 2.7\#$	43.9 ± 2.8	0.273
VAS (score)		3.0 ± 1.1	2.8 ± 1.1	0.284
IPS (score)		55.2 ± 10.7	55.2 ± 10.2	0.996

Note: * t-test for equality of means in independent samples; #BMI in the treatment group were borrowed from medical records before BS

According to medical records, the average BMI measured (44.5 ± 2.7) kg/m² in patients of the treatment group prior to BS and (35.5 ± 2.6) kg/m² after BO, the weight decreased by 20.2 %.

BS in patients of the treatment group performed (14.2 ± 1.4) months before THA: sleeve gastrectomy — in 44 (74.6 %), interintestinal anastomosis — in 12 (20.3 %), combined surgery — in three (5.1 %) patients. The treatment study group included overweight patients, stages 1 and 2 obesity (Table 2).

Table 2

Distribution of patients in the treatment group by stage of obesity and gender after BS

Stage of obesity	BMI, kg/m ²	Number of patients		Male		Female	
		abs.	%	abs.	%	abs.	%
Normal	20–24.9	–	–	–	–	–	–
Overweight	25–29.9	3	5.1	3	25.0	–	–
Stage 1	30–34.9	16	27.1	2	16.7	14	29.8
Stage 2	35–39.9	40	67.8	7	58.3	33	70.2
Stage 3	40 and over	–	–	–	–	–	–

It should be noted that all patients left the morbid obesity group, but not a single patient achieved a normal BMI. Only three men transitioned to the overweight group, and none of the women achieved this. Thus, the majority of patients transitioned to the obesity groups of stages 1 and 2 (56 patients, 94.9 %). When interviewed, many patients reported that their weight significantly decreased for up to six months after surgery and then began to increase again; however, we were unable to collect accurate, reliable data.

Parameters evaluated postoperatively included pain measured with the Visual Analog Scale (VAS) next day, after three, seven and 14 days; functional outcome measured with IPS at three and 12 months, and then every 12 months up to 60 months; the presence of early postoperative complications in the first three months after surgery. We then determined the Survival rate of THA and the pattern of revision surgeries were evaluated every 12 months up to 60 months.

Statistical analysis was performed using the IBM SPSS Statistics 22 software package. The weighted mean difference (WMD) was used in the obese group to determine BMI, to assess pain (VAS), and to score on the Harris Hip Injury Scale with corresponding 95 % CI (CI). The Mann-Whitney test was used to assess early and late postoperative complications and the Kaplan-Meier method was used for THA survival.

RESULTS

The preoperative VAS scores were similar in both study groups and showed no statistically significant difference ($p < 0.001$). The score increased sharply next day after the surgery showing no statistically significant difference ($p < 0.001$). The scores had decreased after three days but the difference was statistically significant, $p = 0.003$. The pain was arrested after seven and 14 days with no difference between the groups. By the end of the 12-month observation period, the VAS scores were significantly lower at 12 months than before the surgery with no statistical difference in the groups, $p = 0.243$ (Fig. 1).

The mHHS were similar in both groups before surgery, $p = 0.364$. The hip joint function gradually increased postoperatively in a progressive manner with a statistically significant difference at three months $p = 0.021$, at six months $p = 0.003$, and reached the maximum at 12 months with a statistically significant difference in the results $p = 0.021$ (Fig. 2).

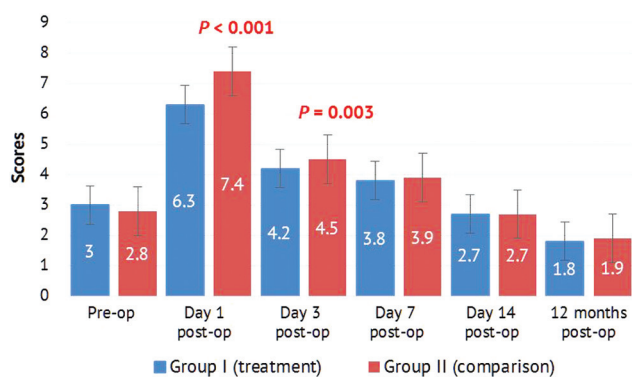


Fig. 1 Dynamics in pain measured with VAS during the study

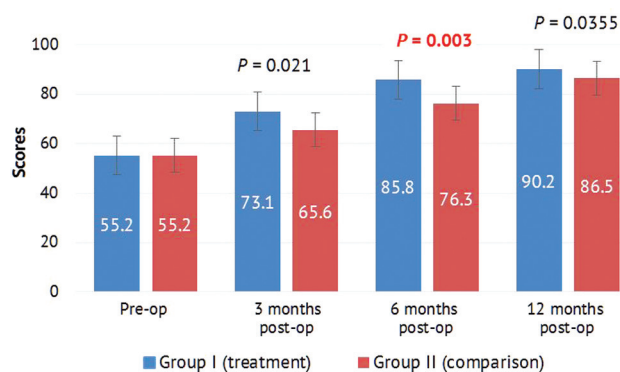


Fig. 2 Dynamics in function measured with IPS

The five-year survival rate (absence of complications) (60 months) using the Kaplan – Meier method was 94.6 % (5.4 % complications) in the treatment group and 77.2 % (22.8 % complications) in the comparison group. The use of BS in patients with hip arthritis K&L stage 3–4 facilitated a risk of complications reduced by 17.4 % (Log Rank (Mantel-Cox) $p = 0.006$), which is presented in Fig. 3.

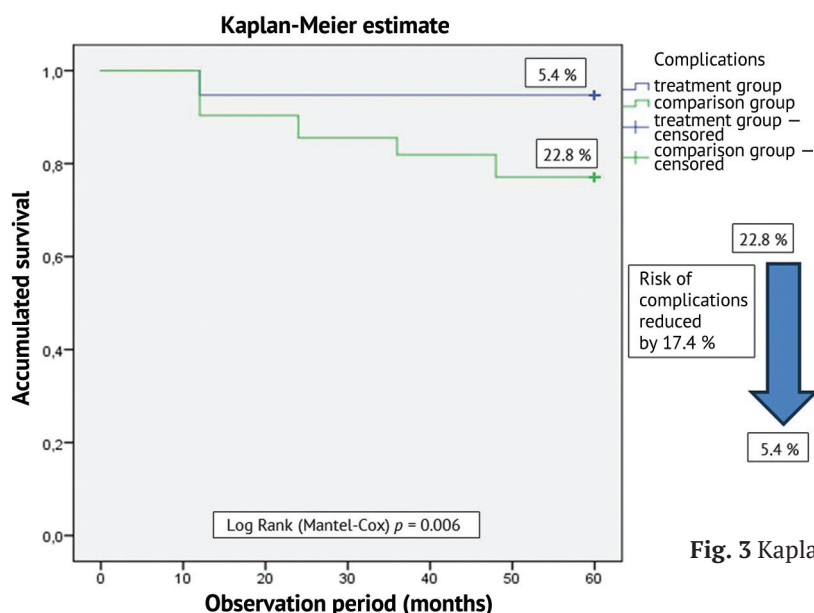


Fig. 3 Kaplan-Meier estimate

Superficial surgical site infections occurred in 2.4 % of patients in the comparison group and were absent in patients in the treatment group. Deep and periprosthetic joint infections were twice as common in patients in the comparison group: 1.8 % in the treatment group and 3.6 % in the comparison group (Table 3). The four cases of deep infection and one of the two cases of superficial infection in our series required removal of the implant and a two-stage revision surgery within the first two years of the study. Deep vein thrombophlebitis of tibia occurred in one case in the treatment group early post-op (1.8 %), and sciatic nerve neuritis developed in one patient in the comparison group (1.2 %). These complications did not require revision surgery. Periprosthetic fractures (2.4 %), aseptic loosening (4.8 %), and prosthetic component wear (3.6 %) were observed in patients of the comparison group, and occurred in the final two years of follow-up. Early revision surgeries were not associated with surgical site infection.

Dislocation of implants occurred in both groups and were not common for patients with BMI < 40 kg/m² who underwent BS; the complication was observed in 1.8 % of cases of the treatment group (revision intervention was not required) and in 4.8 % of cases of the comparison group (all underwent one-stage revision surgeries).

Table 3

Types of complications

Complications	Treatment group (n = 59)		Comparison group (n = 81)		p-value*
	abs.	%	abs.	%	
Superficial SSI	–	–	2	2.4	–
Deep SSI	1	1.8	3	3.6	0.04
Periprosthetic fractures	–	–	2	2.4	–
Aseptic loosening	–	–	4	4.8	–
Wear of prosthetic components	–	–	3	3.6	–
Thrombophlebitis, pulmonary embolism	1	1.8	–	–	–
Dislocated implant	1	1.8	4	4.8	≤ 0.01
Neurological disorders	–	–	1	1.2	–
Total	3	5.4	19	22.8	< 0.001

Note: *Mann – Whitney test

DISCUSSION

Patients with a BMI > 40 kg/m² have a relative risk for THA that is more than 30 times higher than patients with a BMI < 25 kg/m² [35]. Surgery related weight loss is the most effective treatment in obese patients, and some authors suggest that it reduces obesity-related comorbidities and prolongs life [36, 37].

There are associations between obesity and the risk of OA of lower-limb joints and between obesity and complications after THA, it is important to understand whether obesity is a modifiable risk factor before THA. The aim of our study was to investigate a positive or a negative effect of BS on THA outcomes. We found that the use of BS in patients with K&L grade 3–4 hip arthritis provides a 17.4 % reduction in the risk of complications including postoperative superficial and deep complications. The most important finding was a reduced number of revision surgeries after BS, which is confirmed by data from other studies [38].

Some authors reported no greater risk of re-operation after BS and subsequent TKA [39, 40, 41], other authors suggested a higher rate of re-operation in patients with BS and TKA compared to TKA patients with low BMI [42, 43, 44], and a reduced risk of re-operation in TKA patients after BS was reported in one study [45].

Studies exploring the effect of BS on the incidence of early postoperative complications after THA yielded mixed results [38, 39, 42, 46]. In-hospital complications may be less common in those who underwent BS before THA than in morbidly obese patients [38]. No difference in early complications was reported in three studies [39, 47, 48] including 233 patients who were stratified by the time interval between BS and THA. Complications being most common in patients who had BS before THA were reported in the largest study assessing the effect of BS on early complications, including 5914 patients. It should be noted that a potential confounding factor was that preexisting comorbidities were also more common in this group [38, 42, 45–47, 49–51].

There is no consensus based on current evidence for the need of BS to be performed before THA, and each study should be critically reviewed. In several comparative studies, imbalances in comorbidity between study groups may have confounded their analyses and biased them against BS cohorts, as it is known that morbidly obese patients who underwent BS tend to have a higher baseline comorbidity rate than morbidly obese patients who did not undergo BS [52, 53].

Given that obese patients represent an increasing proportion of patients undergoing THA, risk optimization in this more medically complex patient population is essential. Obese patients are

more likely to experience complications, including superficial and deep infection, acute kidney injury, cardiac arrest, and re-operation after THA [16, 54]. Obesity also increases the medical costs associated with THA [55].

BS is evaluated as a potential way to reduce the risk of surgery in morbidly obese patients, but given the risks of a second elective surgery, it is crucial that orthopedists provide recommendations to the patients based on an understanding of the current literature. No studies have assessed whether weight loss after BS eliminates the need for THA. Increased mobility and exercise after BS may increase the number of patients requiring subsequent THA [56]. This issue remains controversial, as some researchers suggest that reduced patient complaints are associated with weight loss after BS [57].

Further studies are needed to assess the proportion of patients requiring THA after BS, and it would be useful to compare BS with conservative management of obesity before hip surgery to determine how outcomes differ [47]. Finally, sleeve gastrectomy is becoming increasingly popular and is superior to laparoscopic Roux-en-Y gastric bypass [58]. There is a controversy regarding the impact of BS on early, short-term, and long-term postoperative complications after THA. The impact of different types of BS on THA outcomes remains to be elucidated. Ideally, prospective studies with a higher level of evidence are needed to draw definitive conclusions regarding the impact of biologic therapy on THR outcomes. Our study demonstrated that very few patients lose weight before joint replacement surgery. This highlights the need for targeted non-surgical weight loss interventions for patients awaiting joint replacement.

CONCLUSION

The use of bariatric surgery in patients with morbid obesity and grade 3–4 hip arthritis before THA allows for a statistically significant reduction in the risk of postoperative complications by 17.4 % and an increase in the five-year survival rate of THA to 94.6 %.

Conflict of interest None of the authors has any potential conflict of interest.

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Informed Consent Informed consent was obtained from all patients for being included in the study.

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Original article

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Metabolic bone abnormalities underlying nonunion in revision foot surgeries

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Abstract

Introduction Revision foot surgery has increased in recent decades with the increasing surgical procedures. Nonunion is common after arthrodesis and osteotomies. From an economic perspective, revision surgery can be associated with greater length of disability imposing an additional financial burden on healthcare facilities. Impaired bone metabolism is one of the key factors leading to the risk of nonunion and a revision surgery.

The **aim** of the study was to determine the impact of metabolism bone abnormalities on the incidence of nonunion in revision foot and ankle surgery.

Material and methods A prospective study with retrospective control was conducted to compare two groups of patients aged 45 to 70 years who required revision foot surgery. The retrospective control group ($n = 36$) consisted of patients who had no bone metabolism assessment prior to revision foot surgery. The prospective group ($n = 42$) consisted of patients who underwent bone metabolism assessment preoperatively and subsequent correction if needed. Revision surgery was produced in the hindfoot and midfoot due to failed arthrodesis of the corresponding joints. AP and lateral weight-bearing radiographs of the foot, the Salzmänn view and a CT scan of the feet were produced preoperatively.

Results The mean period from the initial consultation to surgical treatment was longer in the prospective group than in controls: (16.0 ± 4.0) weeks and (8.0 ± 1.7) weeks, respectively. There were no significant differences in the mean period of consolidation/ankylosis measuring (10.0 ± 2.2) weeks in controls and (8.0 ± 1.5) weeks in the prospective group. A statistically significant difference was found in the frequency of non-unions between the two groups showing 14 % ($n = 5$) in controls and 2.4 % ($n = 1$) in the prospective group.

Discussion The findings demonstrated clinical effectiveness of a comprehensive approach to revision foot surgery including optimization of biological factors for bone union. Protocol for preoperative assessment and correction of bone metabolism can significantly improve outcomes of revision procedures reducing the risk of recurrent nonunions and the need for revisions.

Conclusion The time from initial consultation to revision surgery was longer in the prospective group of patients with no statistically significant differences in the time to bone consolidation. The nonunion rate was higher in the control group with no diagnosis and correction of bone metabolism diagnostics performed, highlighting the importance in reducing the rate of revision foot and ankle surgeries.

Keywords: nonunion, revision surgery, bone metabolism, foot surgery, osteoporosis

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INTRODUCTION

Revision foot surgery has increased in recent decades with the increasing surgical procedures. Nonunion is common after arthrodesis and osteotomies [1, 2]. The nonunion rate with triple arthrodesis varies from 0 % to 29 % [3]. One of the key parameters leading to the risk of nonunion and the need for subsequent revision surgery is impaired bone metabolism, which can manifest itself in various forms [4]. Impaired bone metabolism is one of the key factors leading to the risk of nonunion and a revision surgery [4].

The preoperative protocol for revision surgery includes three sequential stages: diagnosis, planning and revision surgery. The diagnostic stage is initiated by a comprehensive clinical examination using instrumentation and laboratory methods. The primary goal of this stage is to identify the key factors that led to the failure of the previous surgical intervention [5].

There are mechanical and biological etiological factors of poor outcomes. Mechanical factors are associated with failure to adhere to surgical procedures, while biological factors are caused by pathophysiological changes in the patient's body and bone metabolism disorders.

The diagnosis of mechanical factors is based primarily on clinical and instrumentation examination. Most significant mechanical factors include instability of metal fixation, neglected alignment, underestimated role of ligaments, and, conversely, overreliance on soft tissue techniques.

A comprehensive and detailed examination is required for a patient to identify the biological factors that would necessitate a revision surgery. Biological factors are important with all mechanical conditions met, considering the age 65 and over, and concomitant somatic diseases. Involutional processes in the foot and an increased risk of osteoporosis are characteristic features of aging, more pronounced in females [6]. The aging foot [7] may develop a range of structural and functional changes and chronological age does not always correlate with the patient's functional status.

Although age is a significant risk factor for osteoporosis and other degenerative changes of the foot [8, 9], it should not be considered the sole or decisive criterion when planning treatment. A patient's functional status can vary significantly within a single age group, due to individual lifestyle factors, genetic factors, and comorbidities.

Therefore, a patient's age should be considered a warning factor requiring a thorough bone assessment and overall functional status, but not as an absolute contraindication to certain treatments. An individualized approach with a range of factors allows for optimized treatment strategies and improved outcomes in older patients.

Bone metabolism is a complex biochemical and biomechanical process regulated by numerous factors, some of which can be quantified and diagnosed. Foot deformities have a significant impact on bone metabolism, as explained by the mechanostat theory, also known as Wolff's law or Frost theory [10]. According to this theory, areas of the foot that are not subjected to adequate mechanical loading undergo adaptive changes, leading to a decrease in bone mineral density.

In addition to mechanical factors, biochemical disorders affect significantly bone metabolism. Vitamin D deficiency which plays a critical role in calcium homeostasis and bone mineralization is one of the key factors contributing to the development of osteoporosis [11].

A comprehensive assessment of bone metabolism and the detection of osteoporosis can be produced with the following laboratory tests [12]:

- *blood test*: complete blood count, coagulogram, blood biochemistry (glucose, creatinine, urea, total bilirubin, AST, ALT, total calcium, ionized calcium, phosphorus, alkaline phosphatase), blood vitamin D, osteocalcin;
- *urine test*: general urine analysis, dioxypyridinoline, urine calcium and phosphate (24 hours).

The results of these studies should be interpreted by specialists in bone metabolism (endocrinologists or the staff at hospitals for osteoporosis treatment). This is necessary for an accurate assessment of bone metabolism, the selection of optimal treatment strategies [13], and prioritizing correction of metabolic disorders over revision surgery. A comprehensive approach to diagnosis and correction of bone metabolism disorders allows us to optimize the management of patients with foot deformities and minimize the risk of postoperative complications.

The **aim** of the study was to determine the impact of metabolism bone abnormalities on the incidence of nonunion in revision foot and ankle surgery.

MATERIAL AND METHODS

A prospective study with retrospective control was conducted between 2018 and 2023 at the N.N. Priorov National Medical Research Center for Trauma and Orthopedics.

Inclusion criteria for the study:

- age from 18 to 75 years;
- the need for revision surgery for foot pathology.

Non-inclusion criteria:

- age under 18 and over 75 years;
- severe decompensated somatic diseases;
- congenital systemic bone diseases;
- infectious bone lesions (osteomyelitis);
- impaired mechanical principles of fixation.

The retrospective control group ($n = 36$) included patients who underwent revision foot surgery without prior bone metabolism assessment between 2018 and 2021. There were 83 % female ($n = 30$) and 17 % male ($n = 6$) patients. The mean age was 63.0 ± 5.4 years. The prospective group ($n = 42$) included patients who underwent preoperative bone metabolism assessment and subsequent correction, if necessary, between 2021 and 2023. The group included 81 % female ($n = 34$) and 19 % male ($n = 8$) patients. The mean age was 61.0 ± 7.5 years.

The age of the patients ranged between 45 and 70 years. All patients included in the study lived normal lives and had no enhanced functional demands. There were no professional athletes or individuals whose daily activity levels significantly exceeded the average. The age limit (18–75 years) allowed for the inclusion of both relatively young patients without significant mobility limitations and older patients with moderate ankle impairments. None of them experienced extreme limitations in work or mobility. All patients underwent revision surgery on the hindfoot and midfoot due to failed consolidation after previous operations to correct acquired deformities.

Pathologies detected included:

- rigid flat-valgus deformity, not aggravated by severe decompensated somatic diseases;
- posttraumatic arthrosis of the ankle joint, subtalar joint and midfoot joints;
- acquired deformities resulting from aseptic necrosis of the foot bones (Müller – Weiss syndrome).

Osteosynthesis was performed using pre-modeled miniplates or cannulated screws, no external fixation used. Bone allografts were employed intraoperatively if needed. The surgical procedure was performed by a single surgical team of Department No. 13, the N.N. Priorov National Medical Research Center of Traumatology and Orthopedics. The distribution of the joints repaired with revision surgery is presented in Table 1.

Table 1

Distribution of patients by localization of the segment repaired with revision surgery

Localization of failed ankylosis	Control group (n = 36)		Prospective group (n = 42)	
	abs.	%	abs.	%
Talonavicular joint	6	17	8	19
Subtalar joint	15	42	15	36
Ankle joint	10	28	9	21
Two or more joints	5	14	10	24

With the bias towards revision surgeries for combined nonunions in various parts of the foot in the prospective group, the groups can be considered representative.

As part of the study, instrumentation examination of patients included:

- AP, lateral and Salzman weight-bearing radiographs of the foot to assess the alignment of the foot;
- computed tomography of the contralateral limb to assess the bone condition, the volume of resection and bone grafting.

In the prospective group, laboratory tests were used to assess bone metabolism and subsequent correction parameters if needed (Table 2). Vitamin D deficiency (<30 ng/ml) was detected in 76 % of patients. Hypocalcemia and decreased osteocalcin indicate impaired bone remodeling processes. The parameters (e.g., vitamin D and calcium supplementation) were corrected to achieve target values, which might have contributed to the reduced nonunion rate in the second group. Table 2 presents the quantitative values of bone metabolism parameters in the prospective group.

Table 2

Bone metabolism measured in patients of the prospective group (n = 42)

Description	Average value $\pm$ SD	Reference values	Patients with deviations	
			abs.	%
Vitamin D (ng/ml)	25.0 $\pm$ 6.4*	30–100	32	76
Total calcium (mmol/l)	2.12 $\pm$ 0.15	2.15–2.55	19	45
Ionized calcium (mmol/L)	1.02 $\pm$ 0.08	1.12–1.32	22	52
Phosphorus (mmol/L)	0.87 $\pm$ 0.12*	0.81–1.45	10	24
Alkaline phosphatase (U/L)	98 $\pm$ 32	40–150	5	12
Osteocalcin (ng/ml)	14.5 $\pm$ 4.1*	11–43	13	31

The study assessed the time to achieve consolidation based on computed tomography results. Consolidation criteria included the presence of a "cortical bridge" and the formation of a trabecular bone pattern across the fracture line, which is a generally accepted approach.

The average time from the initial consultation to surgery was also assessed. This parameter is indirectly related to the economic costs of patient treatment, as increased disability reduces the cost-effectiveness of the model used. The nonunion rate as a key factor in comparison of the effectiveness of the approaches was assessed after revision surgery in the retrospective and prospective groups. The Pearson chi-square test was employed for statistical analysis due to its effectiveness and ease of use in assessing significant differences between groups.

RESULTS

The statistical analysis showed that the average time from the initial consultation to surgical treatment was longer in patients of the prospective group than in the controls measuring (16.0 ± 4.0) and (8.0 ± 1.7) weeks, respectively. The difference was caused by 3–4 weeks required for laboratory tests and subsequent interpretation in the prospective group. Appropriate conservative therapy aimed at correction of bone metabolism was administered for patients with metabolic disorders, with follow-up testing. With reference values recorded patients could undergo surgical treatment. In some cases, surgery could be performed alongside the therapy prescribed (for example, for isolated vitamin D deficiency) to reduce the waiting time for surgical intervention.

There were no statistically significant differences in average consolidation time that measured (10.0 ± 2.2) weeks in the prospective group and (8.0 ± 1.5) weeks in the control group. The phenomenon could be associated with the fact that of bone metabolism correction helps restore human biology rather than stimulates it. Consolidation time cannot be expected to reduce.

The incidence of nonunions was 14 % ($n = 5$) in the retrospective group and 2.4 % ($n = 1$) in the prospective group. The distribution of patients by location of nonunions after revision surgery is presented in Table 3.

Table 3

Localization of nonunions after revision surgery

Localization of failed ankylosis	Control group ($n = 36$)		Prospective group ($n = 42$)	
	abs.	%	abs.	%
Talonavicular joint	0	0	0	0
Subtalar joint	2	5.6	0	0
Ankle joint	2	5.6	0	0
Two or more joints	1	2.8	1	2.4
Total	5	14.0	1	2.4

The chi-square test revealed that the differences in nonunion rates between the control and prospective groups were not statistically significant at the 0.05 significance level. There was a trend toward a lower nonunion rate in the prospective group, which could be the subject of further study. Statistically significant differences are likely to be found with calculations in larger groups to allow for convincing conclusions about the effectiveness of the model used.

DISCUSSION

Literature review suggests that nonunion is a statistically significant complication in revision foot surgery.

Chrea et al. reported postoperative complications in foot and ankle procedures affecting patient satisfaction with the outcomes regardless of preoperative expectations [14]. This effect persists even after full functional recovery.

Greer et al. reported nonunion rates after foot and ankle arthrodesis ranging between 0 % and 36 % with the mean of 10 % to 11 % [15]. Chraim et al. [16] reported 20 % of the nonunion rate after subtalar joint arthrodesis. Rao [17] reported 100 % of patients with nonunion after ankle arthrodesis having vitamin D deficiency. Controllable risk (vitamin D, smoking) and uncontrollable risk (diabetes) should be assessed when establishing the diagnosis of ankle nonunion after arthrodesis [17].

Cardoso et al. suggested that determining who is at risk of developing nonunion is essential to reducing nonunion rates and improving patient outcomes [18]. The authors identified several evidenced-based modifiable risk factors related to adverse outcomes after foot and ankle arthrodesis. Patient-related risk factors that can be improved before surgery include smoking cessation, good diabetic control ($HbA_{1c} < 7\%$) and vitamin D supplementation ($< 7\%$). The impact of smoking on the outcomes of foot and ankle surgeries is greater than that of other segments.

Nicotine reduces prostacyclin levels, leading to vasoconstriction and tissue hypoperfusion. There is evidence suggesting a link between smoking, low bone mineral density and delayed fracture healing. Diabetes mellitus also negatively impacts bone reparative capacity. Hyperglycemia and insulin deficiency lead to apoptosis of chondrocytes and osteoblasts, which can contribute to the development of nonunions after foot surgery. Poorly controlled glucose levels in diabetic patients lead to a twofold increase in the risk of postoperative nonunions. Vitamin D levels are low in 70 % of patients with musculoskeletal disorders and very low in 22 % of patients undergoing elective foot and ankle procedures. Low vitamin D levels decrease intestinal absorption of calcium and phosphate, causing an increase in parathyroid hormone, which leads to increased osteoclast activity and decreased bone density [18].

Anciano et al. reported vitamin D deficiency in failed foot and ankle arthrodesis. A total of 13 patients who developed a nonunion agreed to have vitamin D level obtained, and 11 of 13 patients had a low vitamin D level (mean = 14.6 ng/mL, range = 9–24 ng/mL). Five patients underwent revision arthrodesis after normalization of vitamin D levels, and four out of five patients went on to successful union. The authors concluded that hypovitaminosis D may be a modifiable risk factor for nonunion after major foot and ankle arthrodesis. The authors concluded that hypovitaminosis D may be a modifiable risk factor for nonunion following a major foot and ankle arthrodesis procedure. Orthopedic surgeons should consider vitamin D screening and supplementation in patients undergoing elective arthrodesis procedures [19].

Combined vitamins D3 and K2 therapy plays a central role in calcium metabolism. Vitamin D3 improves calcium absorption, while vitamin K2 activates osteocalcin and matrix Gla protein, which promotes targeted bone mineralization and reduces the risk of soft tissue calcification. Although we did not use such preparations in our series, their inclusion in the preoperative preparation protocol could improve calcium metabolism in osteoporotic patients or resistance to vitamin D monotherapy [20]. It can be concluded that modifiable risk factors, including impaired bone metabolism, increase the risk of nonunion during foot and ankle surgery, and early diagnosis and bone metabolism regulation can reduce the incidence of nonunion and re-operation rate [21].

No measurements of hormonal levels (e.g., parathyroid hormone, testosterone, and estrogen levels) in the series, which is a limitation. Given the known impact of endocrine disorders on bone metabolism, further study of this relationship would be practical. Hormonal profile screening

in all patients prior to revision surgery may be challenging due to economic and organizational constraints. It can be performed selectively, for example, in patients with refractory mineral metabolism disorders or suspected endocrinopathies. Assessment of bone metabolism is essential for candidates for foot revision surgery and further studies are scheduled for better understanding of the correlation between bone metabolism and surgical outcomes.

CONCLUSION

The time from initial consultation to revision surgery was expectedly longer in the prospective group of patients due to the time required for bone metabolism assessment and regulation. There was no statistically significant difference in the time to bone consolidation between the groups. The nonunion rate was higher in the controls who did not undergo diagnosis or regulation of bone metabolism. Timely diagnosis and treatment can help reduce the incidence of revision surgeries related to nonunion due to impaired bone metabolism.

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Original article

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Functional outcome of mid-sole percutaneous plantar fasciotomy versus open plantar fasciotomy in treatment of refractory plantar fasciitis

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Abstract

Background Plantar fasciitis is one of the main causes of heel pain, which is one of the most prevalent complaints in foot and ankle clinics. Surgery may be necessary if conservative therapies have failed. The appropriate surgical technique has been debated, open plantar fasciotomy and percutaneous plantar fasciotomy are the two common surgical techniques.

The **aim** of the study is to compare the outcomes of open release versus percutaneous midsole release of the plantar fascia in this study to treat recalcitrant heel pain.

Methods A prospective study was conducted on 54 patients who had unresponsive plantar fasciitis following conservative treatment for at least six months. 20 patients in the 54 enrolled cases had open plantar fascia release, whereas the remaining 34 patients had percutaneous mid-sole plantar fascia release. All patients' surgical outcomes were evaluated using the Foot and Ankle Disability Index (FADI) both before and after the procedure and a follow-up period of one year was used to assess the functional results.

Results The percutaneous plantar fasciotomy group's mean foot and ankle disability index score improved statistically significantly from 39 ± 6 preoperatively to 101 ± 3 postoperatively, compared to 38 ± 5 preoperatively and 98 ± 2 postoperatively for the open plantar fasciotomy group at the final follow-up. Two patients in the percutaneous group experienced numbness at the site of surgery, compared to seven in the open group. By the time of the last follow-up, there had been no recurrence of pain.

Discussion We performed a percutaneous release of the mid-sole plantar fascia with a minimum incision and little dissection. We could thus access the plantar fascia effectively while preserving the surrounding tissues and maintaining optimal cosmetic results. Open plantar fascia release is the most conventional technique. However, disadvantages of the surgery include large wound, longer postoperative recovery time, and potential postoperative occurrence of complex regional pain syndrome.

Conclusion Both open and percutaneous plantar fascia releases resulted in a considerable improvement in the patients' limb function and pain symptoms. The long-term curative results of the two surgical treatments were identical. Due to fewer postoperative problems, percutaneous plantar fascia release is a superior procedure.

Keyword: percutaneous plantar fascia release, heel spur, plantar fasciitis, open plantar fasciotomy, plantar fasciopathy

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INTRODUCTION

The most frequent cause of plantar heel discomfort is plantar fasciitis, which accounts for one million patient visits annually in the United States of America [1]. Even so, uncertainty surrounds the precise histology of plantar fasciitis. Current theories suggest that it is not caused by an inflammatory process but rather by myxoid degeneration, micro tears in the plantar fascia, collagen necrosis, and angiofibroblastic hyperplasia of the plantar aponeurosis [2]. In fact, a more appropriate term for the condition is plantar fasciosis or plantar fasciopathy; these terms continue to gain traction [3, 4].

The plantar fascia is a densely packed, subcutaneous structure that supports the foot's medial longitudinal arch and runs from the medial tubercle of the calcaneus to the metatarsal heads [5, 6]. It functions as a truss when the foot absorbs stresses in the loading phase of gait, and as a beam for the metatarsals when they experience bending forces, as in gait propulsion [6].

In many cases, patients may not improve after six months or longer of conservative treatment; hence, surgery may be recommended. The technique type is influenced by the three main etiologic factors for heel pain, which are thought to be entrapment neuropathy, plantar fasciitis, and bone spurs [7]. Numerous surgical techniques have been attempted, with varying outcomes and specifics. The most often performed operations include release of the plantar fascia with or without calcaneal spur excision, Steindler stripping, neurolysis of the first branch of the lateral plantar nerve, and endoscopic plantar fasciotomy [8].

A risk factor for plantar fasciitis could be anything that puts mechanical strain on the plantar fascia. Extrinsic and intrinsic factors are the two categories of risk factors. The patient's intrinsic variables include tight calf muscles, decreased ankle dorsiflexion range, obesity, and pes planus and pes cavus [9].

Jogging on hard surfaces, going barefoot, suddenly increasing the volume and/or intensity of one's jogging, and standing for extended periods of time are examples of extrinsic factors that are related to the environment and training [9].

Each year approximately one million office-based physician visits result in a diagnosis of plantar fasciitis [1]. Most patients initially seek care from their primary care physician [1]. Women are more likely than males to suffer from plantar fasciitis, which is most common in those between the ages of 45 and 64 [1, 10]. People with flat (planus) or high-arched (cavus) feet, long-distance runners, military personnel, people in jobs that require a lot of standing, and people who are obese or sedentary are among the other groups who are at risk [10, 11]. Bilateral plantar fasciitis may be seen in up to one-third of the affected individuals [12].

Approximately 85 % to 90 % of patients with plantar fasciitis respond well to non-surgical treatment [12]. Among the methods employed include corticosteroid injections, stretching, counter strain technique, orthoses, rest, over-the-counter (OTC) NSAIDs, ultrasound therapy, and extracorporeal shock wave therapy (ESWT). Eighty percent of individuals treated conservatively do not experience a long-term recurrence of pain, even though treatment may be needed for six months or more [1, 13].

A multimodal evidence-based approach is required for the conservative management of plantar fasciitis, according to current recommendations [14]. Only when conservative treatment has failed for at least six to twelve months is a partial or total plantar fasciotomy recommended [14]. If more than 40 % of the plantar fascia is surgically released, it may negatively impact other foot ligamentous and bony components [15]. However, according to Davies et al. [16], 75 % of patients who had surgery after failed conservative treatment reported a significant or total improvement in heel pain.

Many operative procedures have been tried with different details and results. The most commonly used procedures are release of the plantar fascia with or without calcaneal spur excision, Steindler stripping, neurolysis of the first branch of the lateral plantar nerve, and endoscopic plantar fasciotomy [17].

DuVries [18] excised the spur and freed the plantar fascia by making a medial linear incision. Hassab and El-Sherif [19] introduced calcaneal decompression using several drill holes from the medial to the lateral cortex of the calcaneus. Complications from these conventional procedures included

numbness around the incision and medial heel, delayed wound healing, persistent swelling around the medial heel, plantar fat pad violation, and a stump neuroma within a painful scar after a transected medial calcaneal nerve [20].

The **aim** of the study is to compare the outcomes of open release versus percutaneous midsole release of the plantar fascia in this study to treat recalcitrant heel pain.

MATERIALS AND METHODS

This prospective case series study was conducted in accordance with the 1975 Declaration of Helsinki and ethical guidelines established by the responsible committee for continuing medical education at the Nineveh Health Directorate. Informed consent was obtained from each patient prior to their inclusion in the study.

Two surgeons conducted the operations for this study at the orthopedic department of AL-Mosul General Hospital and Sinjar General Hospital. The study involved 54 patients who underwent surgery in the period from January 2023 and December 2024. The sample was divided into group one (20 patients) treated with open approach for plantar fascia release and group two (34 patients) treated with percutaneous midsole plantar fascia release. Each patient in those two groups was followed up for one year postoperatively

All those patients failed to respond to a conservative trial of at least sixth months. Conservative measures included one or more of the following: activity modification, orthotics, change footwear, non-steroidal anti-inflammatory therapy, physical therapy (ultrasound, stretching, and ice), immobilization, and local steroid injections. According to Hale and Hertel's [21] analysis of the sensitivity and reliability of the FADI scales, the former are sensitive to the differences between healthy and CAI (chronic ankle instability) subjects; responsive to functional improvements in CAI subjects following rehabilitation; and reliable in identifying functional limitations in CAI subjects. The Foot and Ankle Disability Index scale (FADI) [21–24] was used as a function-specific self-report. Four stages were used to evaluate the patients using the FADI score (Table 2), and the findings were documented for comparison. Time points recorded are as follows: 1 — one week; 2 — one month; 3 — six months; 4 — one year.

Exclusion criteria

- Patients with peripheral neuropathy;
- Systemic arthropathies;
- Concurrent neurologic symptoms;
- Generalized inflammatory disorders (rheumatoid arthritis or sero-negative disorders);
- Wounds or skin lesions at the plantar aspect of the foot;
- Prior surgery for a painful heel;
- Time of less than six months of complaint.

Surgical technique

Percutaneous Method Technique

Following the delineation of medial and lateral margins of the central band of the plantar fascia, the procedure was performed using local anesthesia with xylocaine 2 % infiltration just distal to the fat pad of the heel. A stab wound done with blade size 15 at the med portion of central band and once the plantar fascia encountered a medial 30–40 % of the band was severed with 3 to 4 movements of the blade from the lateral to medial side, excessive manipulation should be avoided to decrease postoperative scarring (Fig. 1). In most of the cases the wounds were about 3–4 mm and no suturing was required, but if needed the wound margins were approximated with a single stitch prolene 4–0 in simple type suture. A gauze and bandage was applied.

The patients were allowed ambulating the next day as tolerated. Dressing changed at day 5 and stitch was removed on day 14.



Fig. 1 The steps of mid sole percutaneous plantar fasciotomy: a — pre-operative marking; b — mark the site of local anaesthesia; c — site of percutaneous plantar fasciotomy

Open Surgical Technique (Fig. 2)

Under general anaesthesia, supine position, tourniquet of the leg, prep and drape then putting the leg in external rotation and flexing the knee.

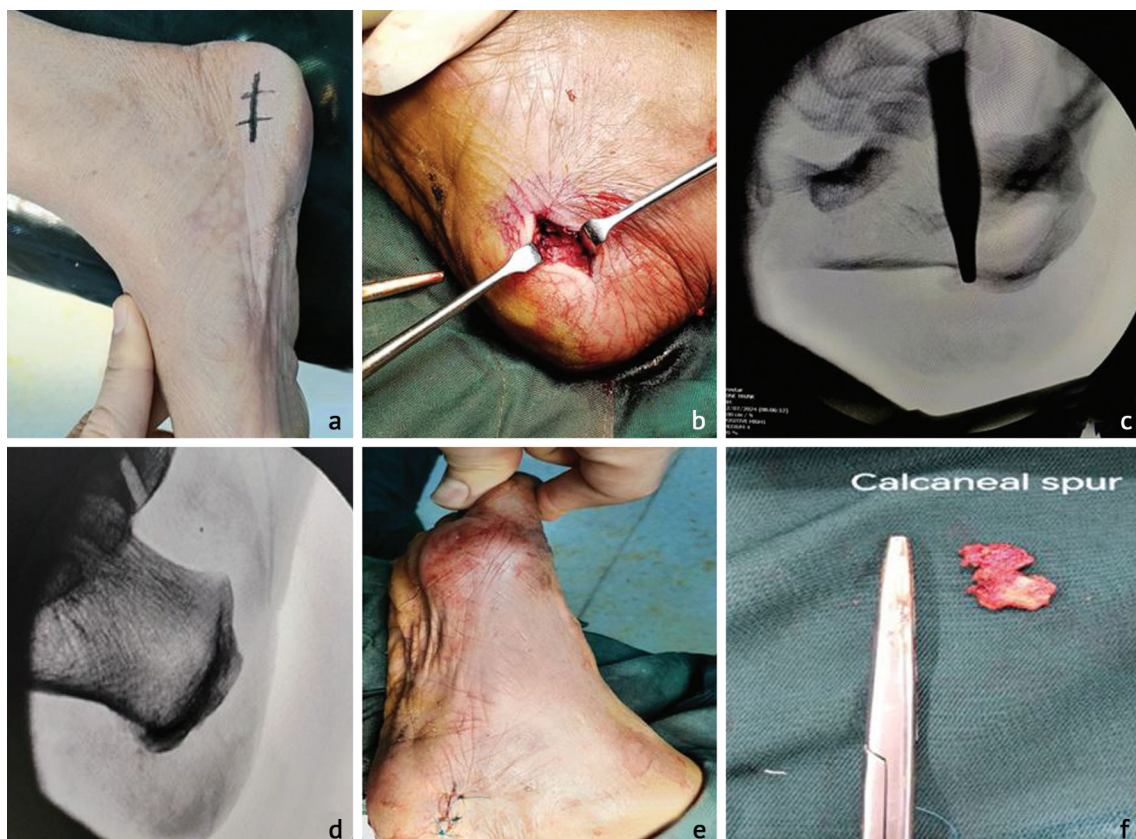


Fig. 2 The steps of traditional open plantar fasciotomy: a — preoperative marking; b — identify the plantar fascia; c — identify the calcaneal spur under fluoroscopy; d — fluoroscopy after excision of spur; e — suture of the wound by 3/0 nylon; f — calcaneal spur

A transverse incision of 4 cm was performed on the medial side of the calcaneus, where the dorsal and plantar skins meet. The dissection proceeded superficially to the plantar fascia, where it separates all of the areolar tissue and fibrous bands that secure the skin to the fascia, stripping all the muscle

attachment from the entire plantar surface of the calcaneus (Fig. 2). The plantar calcaneal spur was identified and removed using an osteotome chisel with bone mallet. Then half the width of the plantar fascia was divided longitudinally distal to its attachment on the calcaneus bone. The skin was closed in one layer with simple stitch, tourniquet was deflated and dressing with cotton and bandage were applied.

Statistical analysis

Data analysis was done using SPSS (Statistical Package for Social Sciences) software version 26 (IBM Corporation, USA). Mean ($\pm$ standard deviation) were used to present the numerical data, as appropriate. Paired t test was used to compare change from baseline to post procedure values. Student's t-test was used to compare numerical variables between the two. Chi-squared test was used to compare categorical variables. A p value of < 0.05 was considered statistically significant for all statistical tests.

RESULTS

The study included 54 subjects; the mean age was 44.6 ± 5.2 years, with 18 (33.3 %) males and 36 (66.7 %) females. Thirty-four of them (63 %) had percutaneous method of surgical treatment, while the other 20 (37 %) had open method of surgical treatment. There was no significant difference in terms of age, gender, or job between those who received the percutaneous method of surgical treatment and those who received the open method ($p > 0.05$), although the percutaneous method subjects tended to be younger (mean age 43.5 years), Table 1.

Table 1

Comparison of demographic characteristics between the groups of percutaneous and open methods ($n = 54$)

Characters		Percutaneous Method ($n = 34$)	Open Method ($n = 20$)	p -value
Age (years), mean $\pm$ SD		43.5 ± 4.8	46.4 ± 5.4	0.068
Gender	Male	9 (26.5 %)	9 (45 %)	0.163
	Female	25 (73.5 %)	11 (55 %)	
Job	Home maker	16 (47.1 %)	9 (45 %)	0.798
	Worker	6 (17.6 %)	5 (25 %)	
	Employee	12 (35.3 %)	6 (30 %)	

Mean FADI (Foot and Ankle Disability Index) scores at various time points before and after the procedures for each method showed significant improvement from pre-procedure to each of post-procedure follow up at one week, one month, 6 months, and one year ($p < 0.01$ in all comparisons of pre-procedure versus each of the post-procedure time point (Table 2).

Table 2

Comparison of the mean of FADI score from pre-procedure to different time points post-procedure, stratified by percutaneous method and open method, with comparison between the two groups ($n = 54$)

Time point	Percutaneous method (<i>n</i> = 34)	Open method (<i>n</i> = 20)	<i>p</i> -value comparing between two groups
	FADI score		
Pre-procedure	39 ± 6	38 ± 5	0.404
1 week post	67 ± 14	52 ± 4	< 0.001
1 month post	86 ± 12	65 ± 4	< 0.001
6 months post	95 ± 5	83 ± 5	< 0.001
1 year post	101 ± 3	98 ± 2	< 0.001

Comparing the FADI scores between the two groups, the mean FADI score at pre-procedure was 39 for the percutaneous group and 38 for the open group, with no significant difference ($p = 0.404$), while at later follow-up FADI scores were significantly better (higher) in the percutaneous group: at 1 week post-procedure, the percutaneous group showed a significantly higher FADI score with its mean of 67 versus 52 for the open group ($p < 0.001$), at one-month post-procedure, the percutaneous group showed a significantly higher FADI score with the mean of 86 versus 65 for the open group

($p < 0.001$). Similarly, at 6 months and one year post-procedure, the percutaneous group showed a significantly higher FADI score with the mean of 95 and 101 (at 6 months and one year, respectively) versus 83 and 98 (at 6 months and one year, respectively) for the open group ($p < 0.001$ for both comparisons).

Figure 3 illustrates the significant improvement in the mean FADI score over time with each procedure, and highlights the significantly higher FADI scores in the subjects who underwent the percutaneous method compared to the open method.

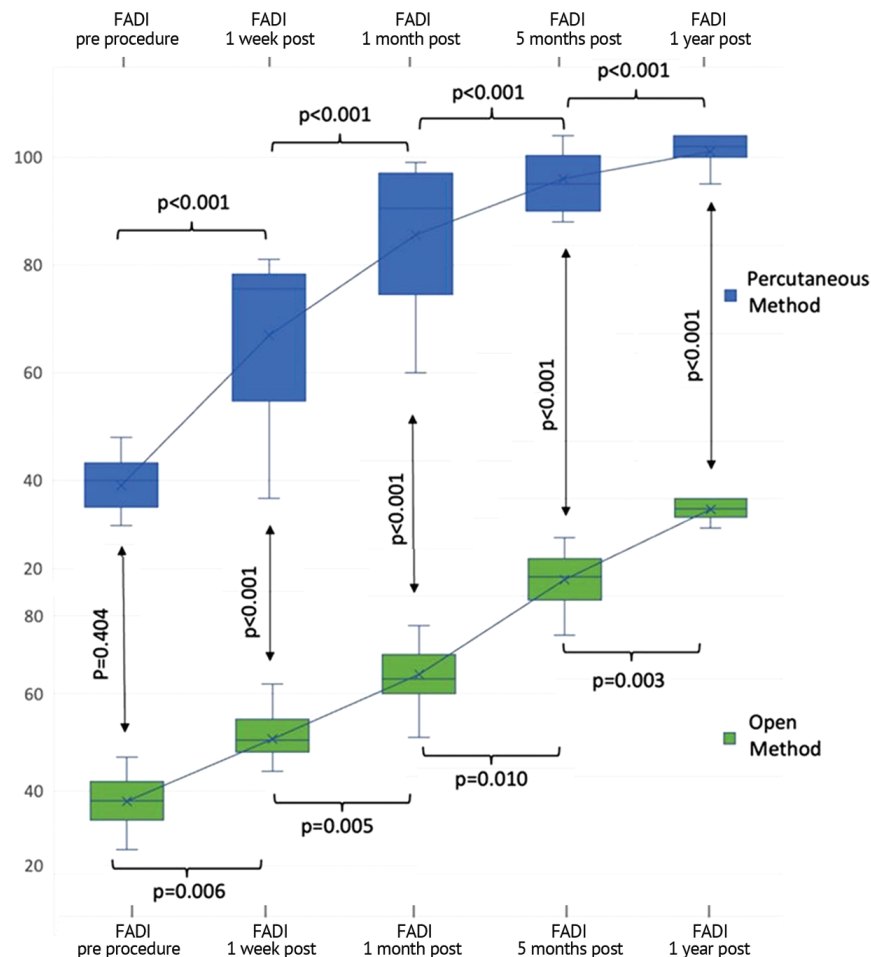


Fig. 3 Comparisons in the mean of FADI score from pre-procedure to different time points post-procedure, stratified by percutaneous method and open method, with comparison between the two groups

Looking at the rate of complications, operative site numbness occurred in only 5.9 % of the subjects in the percutaneous group, compared to 35 % in the open group, with a significant difference ($p = 0.007$), indicating that the percutaneous method had less incidence of this complication. In terms of wound infection, there was none reported in the percutaneous group (0 %), while 5 % of the open group experienced this complication, with no significant difference (p -value = 0.834), Table 3.

Table 3

Comparison of complications between the groups of percutaneous and open methods ($n = 54$)

Complication	Percutaneous Method (<i>n</i> = 34)	Open Method (<i>n</i> = 20)	<i>p</i> -value
	No. (%)		
Operative site numbness	2 (5.9)	7 (35)	0.007
Wound infection	0	1 (5)	0.834

In summary, the data suggests that the percutaneous method results in better functional outcomes (higher FADI scores) at all post-procedure time points compared to the open method, with fewer complications, particularly operative site numbness.

DISCUSSION

Plantar fasciitis is a common condition that results in heel pain due to inflammation of plantar fascia. Relieving heel pain and inflammation are the main objectives of treatment for plantar fasciitis.

It is prevalent among adults in the age between 40 and 70 years old. Employees who work standing, runners, and obese patients with a body mass index (BMI) of greater than 30 kg/m² are the high-risk groups experiencing more severe pain. In light of this, the American Orthopaedic Foot and Ankle Society advise patients with plantar fasciitis to undergo conservative treatment for at least six months prior to surgery [25–30].

When conservative treatments fail to provide relief for refractory plantar fasciitis, surgical options may be considered like the traditional medial heel open release of plantar fascia or mini open midsole plantar fascia release with or without calcaneal decompression by multiple drilling. In our study, we compare the medial open plantar fascia release and the percutaneous midsole plantar fascia release without calcaneal drilling. The open technique leads to larger and more painful scars, requires significantly more dissection, has a longer postoperative recovery period, and can lead to numbness and nerve entrapment [25].

In a 1998 retrospective analysis, it was discovered that the miniinvasive group returned to preoperative activities the quickest, whereas the open heel spur group took the longest time to recover [26].

We performed a percutaneous release of the mid-sole plantar fascia with a minimum incision and little dissection, which ensured a simple operation with fewer adhesions after surgery and a shorter recovery period.

An important consideration for the outcome of this surgical treatment is the location of the incision. Employing a small transverse incision, we can access the plantar fascia effectively while preserving the surrounding tissues and maintaining optimal cosmetic results. The positioning of the incision not only adheres to anatomical considerations, allowing for better surgical exposure and access, but also aligns with physiological principles that reduce postoperative discomfort and minimize complications associated with scarring.

Furthermore, the technique promotes faster healing as the incision mimics the natural lines of tension within the skin, allowing for more efficient tensile strength and alignment during the recovery process. Overall, this approach enhances the surgical outcome by balancing effective intervention with patient comfort and aesthetic considerations [27].

The ideal amount of plantar fascia release is a topic of debate. Barrett and Day [28] recommended total plantar fascia resection. However, after more experience and assessment of postoperative problems, they recommended releasing only the medial portion of the plantar fascia. They believed that if the lateral fibers of the plantar fascia remained intact, the calcaneocuboid joint's locking mechanism would remain intact. This mechanism is essential for foot biomechanics during walking and running and aids in maintaining the foot arch, surgeons aim to preserve this stability while still alleviating the pain associated with plantar fasciitis by addressing the inflamed or degenerated medial portion [29–31].

Barrett and Day initially proposed complete resection of the plantar fascia but later adjusted their stance based on clinical experiences and outcomes. Their recommendation to only release the medial one-third of the plantar fascia aims to reduce the risk of complications such as instability of the foot, excessive dorsal flexion, and over-pronation, which can arise from more extensive procedures [28].

The study findings demonstrated that percutaneous plantar fascia release had a lower average operating time than open plantar fascia release. As previously noted, we owe this outcome to the very straightforward operation process of the method. Our postoperative protocol called for immediate weight-bearing and little activity. By doing so, the plantar fascia would be put under tension, preserving the fasciotomy site and preventing fibrosis and re-adherence. At the most recent follow-up, none of our patients experienced any issues with the stability of their lateral column. The most

conventional technique is open plantar fascia release. The results state that 50–95 % of patients were satisfied with their open release procedure after surgery [32, 33]. However, disadvantages of the surgery include large wound, longer postoperative recovery time, and potential postoperative occurrence of complex regional pain syndrome.

Compared to standard open medial release, the mid-sole plantar fasciotomy had fewer problems; however, a plantar incision carries the risk of severe plantar fibrosis, delayed healing, and plantar scarring [28]. In our study, none of the patients developed plantar fibrosis and scarring. Only two patients (5.9 %) developed operation site numbness. However, in the standard open medial plantar fascia release numbness at operation site occurred in 7 patients (35 %) of the open method group.

Calcaneal spur is another name for calcaneal osteophytes. A number of researchers thought that calcaneal osteophytes were a major cause of heel discomfort, and some even called it calcaneal osteophyte syndrome [34].

According to Johal and Milner's research, plantar fasciitis and calcaneal osteophytes are positively correlated. However, the asymptomatic calcaneal osteophytes could not be explained by the concept [35].

In this study, no calcaneal osteophyte resection was performed on any of the patients in the percutaneous plantar fasciotomy group.

All patients had significant improvement postoperatively. We might have hypothesized that the frequency of heel discomfort and calcaneal osteophytes did not significantly correlate.

Limitation

Our findings may be impacted by a number of factors due to the prospective study design limitations, including selection bias, a small sample size, and the absence of a long-term follow-up period, in contrast to randomized clinical trials. So, further studies are recommended to assess the efficacy of mid-sole release of the plantar fascia with long-term follow-up needed to evaluate the long-term results regarding the instability and recurrence.

CONCLUSION

Our research indicates that patients with refractory plantar fasciitis can benefit greatly from both open and percutaneous plantar fascia release in terms of pain relief and limb function. Percutaneous midsole plantar fascia release may be a preferable choice when choosing surgical therapies for refractory plantar fasciitis because it has demonstrated higher postoperative function scores.

Conflict of interest Not declared.

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Effect of rocker bottom shoes on plantar pressure distribution in patients with osteoarthritis of first metatarsophalangeal joint

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Abstract

Introduction Surgical strategy for patients with grades 3–4 osteoarthritis (OA) of the first metatarsophalangeal (MPT) joint is generally accepted. There is a variety of conservative treatments including NSAIDs, orthopedic insoles, physical therapy and pharmacological blockade to be offered for patients having contraindications or unwilling to undergo surgery. However, the role of orthopedic footwear can be underestimated.

The **aim** of the study was to evaluate results of dynamic in-shoe pedobarography with standard shoes and rocker bottom shoes used by patients with grades 3–4 OA of first MPT joint.

Material and methods Plantar pressure was evaluated in 12 patients wearing standard shoes and rocker bottom shoes. Major biomechanical parameters were analyzed to evaluate the force, walking speed and distribution of plantar pressure.

Results The in-shoe dynamic pedobarography revealed a significant decrease in the values of peak ($p = 0.011$) and average ($p = 0.019$) pressure for the whole foot and the forefoot ($p = 0.029$) with use of rocker bottom shoes. A decreased length of the stance phase was noted ($p = 0.027$). No changes were found in walking speed ($p = 0.604$), duration of the swing phase ($p = 0.495$) and duration of the step cycle ($p = 0.721$).

Conclusion A significant decrease in plantar pressure and the force in the forefoot was observed in patients with first MPT joint OA using rocker bottom shoes compared to those using shoes with a standard sole, with no differences in time indicators and walking speed.

Keywords: hallux rigidus, osteoarthritis, rocker bottom shoes, pedobarography

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INTRODUCTION

Osteoarthritis (OA) of the first metatarsophalangeal (MTP) joint is one of the most common foot pathologies. Bilateral condition is diagnosed in 79 % of cases, and the disease is more common for women [1]. The disease often affects middle-aged patients, who develop major clinical manifestations, such as pain and limited joint motion in advanced stages of the condition that can lead to disability [2, 3].

Severe stages of the disease are normally treated with surgery, which may include arthrodesis, total replacement of the 1st metatarsal joint, cheilectomy and shortening osteotomies of the first metatarsal bone [4, 5].

If there are contraindications to surgery or the patient's unwilling to undergo it, conservative treatment may be necessary as the primary management. Conservative treatment for OA of the first MTP joint include a combination of NSAIDs, physical therapy, and specialized orthopedic insoles [6, 7]. With a variety of available orthopedic products that would help relieve pain during everyday physical activity the role of orthopedic footwear can be underestimated [8, 9].

Dynamic pedobarography is commonly used to assess changes in the kinematics of the lower limbs [10, 11], the repeatability and reproducibility of its use are confirmed by scientific publications [12, 13].

The **aim** of the study was to evaluate results of dynamic in-shoe pedobarography with standard shoes and rocker bottom shoes used by patients with grades 3–4 OA of first MTP joint.

MATERIAL AND METHODS

Study design

Study type: Prospective, single-center, non-randomized cohort study. The study included patients scheduled for treatment at the S.S. Yudin City Clinical Hospital for grade 3–4 OA of the first MTP joint.

Inclusion criteria:

- patient consent to participate in the study;
- clinically and radiologically confirmed diagnosis of "osteoarthritis of the first MTP joint grade 3–4»;
- surgical intervention intended for treatment of OA of the 1st MTP joint;
- patients aged 18 years and older;
- the ability to walk 100 m or more without rest;
- the patient must wear closed shoes to allow the examination to be produced;
- absence of orthopedic insoles in the patient's shoes.

Non-inclusion criteria:

- previous surgical interventions for OA of the 1st MTP joint;
- concomitant pathology of the lower extremities;
- concomitant systemic diseases;
- NSAIDs used in the previous 2 weeks;
- intra-articular injections performed in the previous 3 months.

Patients were selected for the study during a preoperative consultation or during hospitalization prior to surgery.

The diagnosis of grade 3–4 first MTP joint OA was made by the consulting physician based on a patient's medical history, clinical examination and radiographic findings (Fig. 1).



Fig. 1 Dorsal plantar radiography of a patient included in the study showing radiographic signs of OA of the 1st MTP joint of both feet

The study group consisted of 12 individuals including nine (75 %) female and three (25 %) male patients. The mean age of the patients was 63.3 years (range, 45–71).

The average VAS score in the study group measured (7.0 ± 2.3) points (range, 3 to 10), the AOFAS HS (American Orthopedic Foot and Ankle Society Hallux Scale) questionnaire scored (47.6 ± 14.1) (range, 27 to 69). The range of motion of the first MCP joint was (11.6 ± 6.5)° (range, 5 to 25).

Patients were examined for a range of motion in the first MTP joint using a goniometer, the severity of pain assessed with the VAS and AOFAS questionnaires, dynamic pedobarography performed using the patient's shoes (Fig. 2) and orthopedic shoes with a sole rounded in the anteroposterior direction (Fig. 3).



Fig. 2 Examples of standard patient footwear



Fig. 3 Orthopedic rocker-bottom shoes

Step Analysis

Examinations were performed by a single investigator using a single protocol. First the patients used standard shoes, and then they were requested to use rocker-bottom shoes. After an adaptation period (15 minutes of walking), patients performed four walking tests each 10 meters long indoors

on a hard surface using standard shoes. The first and the last steps were excluded from the analysis. Then the patients were asked to use rocker-bottom shoes. We did not determine the number of steps for each test due to the different stride lengths. The patients chose to walk at a speed they wanted.

In-shoe dynamic pedobarography was performed using a Tekscan F-Scan64 system (Tekscan Inc.), which consists of a 0.229 mm thick insole equipped with 64 100 Hz sensors (one sensor per 1 cm²) measuring a pressure range of 852 kPa. The in-shoe sensors were connected to a transmitter, which transmitted data to a personal computer via Bluetooth. Specialized software was used to evaluate and analyze the measurements.

The insole size was selected individually for each patient based on their shoe size. The peak pressure (kPa), average pressure (kPa), force (kg), walking speed (steps/min), and stride phase time (sec) were measured. Distribution across foot regions was performed automatically using software.

Statistical analysis

The results obtained during the study were analyzed using the Jamovi 2.6.13 statistical program. The normality of distribution was tested using the Shapiro – Wilk test. For a normal distribution, the data were presented as mean values with the minimum and maximum values. In non-normal distribution samples, quantitative data were described using the median (Me) and the lower and upper quartiles. Plantar pressure was analyzed using the Mann – Whitney U parameter for two independent groups. Statistical significance was determined using the p-test of 5 % ($p \leq 0.05$).

RESULTS

Comparison of biomechanical parameters of walking in standard shoes and rocker-bottom shoes showed no statistically significant differences in gait speed, swing phase time, step cycle time and ground contact time of both feet (Table 1).

A statistically significant decrease in peak and average pressure, stance phase time walking in rocker-bottom shoes as compared to standard shoes. Analysis of strength parameters revealed differences in overall strength and forefoot strength. However, no changes were observed in hindfoot strength (Tables 2 and 3).

Table 1

Step cycle time values

Description	Measurements		<i>p</i>
	Standard shoes	Rocker-bottom shoes	
Walking speed, steps/min	46.80 ± 3.70 (41,20–51,00)	48.01 ± 4.60 (41.20–50.90)	0.604
Step cycle time, sec	1.28 ± 0.90 (1.17–1.46)	1.21 ± 0.15 (1.18–1.44)	0.721
Stance phase, sec	0.73 ± 0.09 (0.71–0.87)	0.63 ± 0.09 (0.47–0.83)	0.027
Swing phase, sec	0.55 ± 0.10 (0.44–0.66)	0.56 ± 0.10 (0.47–0.66)	0.495

Table 2

Strength and time indicators measured in the study groups

Description	Strength, kg			Contact time, sec		
	Standard shoes	Rocker-bottom shoes	<i>p</i>	Standard shoes	Rocker-bottom shoes	<i>p</i>
Hindfoot	53.9 ± 27.8 (33.7–85.5)	57.1 ± 27.3 (43.4–117.7)	0.088	0.53 ± 0.12 (0.4–0.64)	0.56 ± 0.09 (0.5–0.67)	0.706
Forefoot	83.7 ± 30.2 (60.9–139.7)	51.6 ± 20.6 (28.6–68.4)	0.020	0.52 ± 0.12 (0.45–0.62)	0.53 ± 0.12 (0.45–0.67)	0.847
Foot	134.3 ± 43.9 (99.7–183.7)	84.6 ± 30.7 (55.0–138.2)	0.026	0.71 ± 0.90 (0.64–0.82)	0.70 ± 0.20 (0.67–0.72)	0.216

Table 3

Pressure measured in the study groups

Type of pressure	Standard shoes	Rocker-bottom shoes	p
Peak pressure, kPa	759.3 ± 196.7 (568–961)	412.7,4 ± 222.3 (255–667)	0.011
Average pressure, kPa	386.0 ± 103.2 (313–566)	217.0 ± 94.5 (208–420)	0.019

Analysis of peak and average pressure with use of standard shoes allows us to conclude that 10 (83.3 %) patients had peak pressure in the forefoot (Fig. 4).

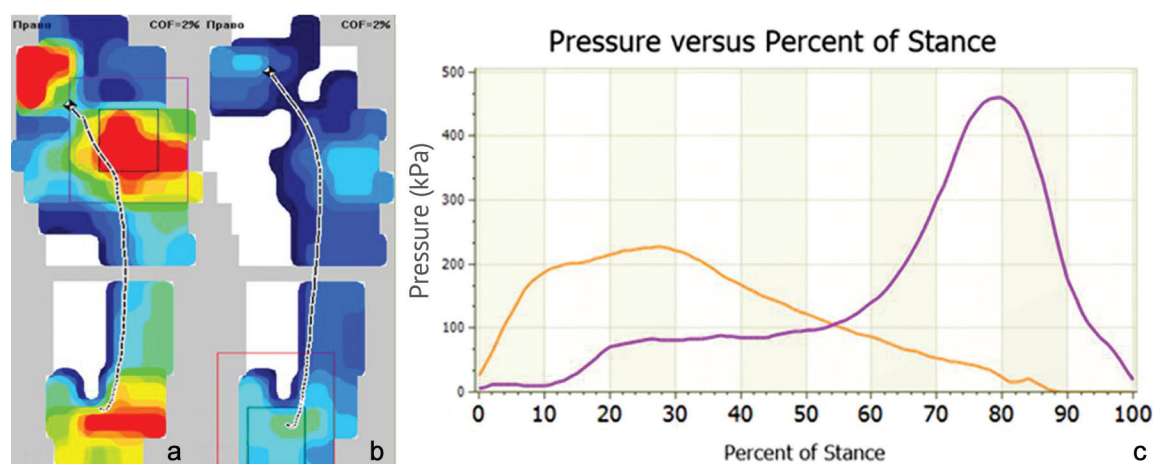


Fig. 4 Dynamic pedobarography of the patient showing (a) pressure distribution on the foot with use of standard shoes; (b) pressure distribution on the foot with use of rocker-bottom shoes; (c) graphical representation of changes in pressure distribution with use of standard shoes (graph marked in orange) and rocker-bottom shoes (graph marked in purple). A decrease in the red indicator suggests a significant reduction in plantar pressure when using orthopedic shoes. In shoes with a rolling sole, The peak pressure zone is shifted to the rearfoot with use of rocker-bottom shoes. The square red indicator confirms a change in the location of the maximum pressure zone.

Peak pressure was measured in the rearfoot in seven (70 %) of 10 cases using rocker-bottom shoes. No statistically significant difference was observed in peak pressure ($p = 0.101$) or strength ($p = 0.088$) in the rearfoot with use of standard shoes and rocker-bottom shoes. This suggests that changes in rolling occur due to a decrease in forefoot parameters.

DISCUSSION

The motion in the first MTP joint is crucial for the foot biomechanics. Extension of the first MTP joint with the forefoot rolling over results in the "winch mechanism", which elevates the medial longitudinal arch, supinates the rearfoot, and ultimately produces an energetically efficient toe push-off during the propulsive phase of the gait [2].

Impaired motion of the first metatarsal joint leads to changes in gait biomechanics, with a decrease in peak pressure under the head of the first metatarsal bone [14]. Internal rotation of the foot occurs, and the center of pressure during the step shifts laterally, increasing the load on the lateral part of the foot, and overloading of the lesser rays [15]. These changes correspond to a low-gear roll, which occurs through the oblique axis connecting the second and fifth metatarsal bones [16]. Pronation of the hindfoot can be observed in patients with limited range of motion of the first metatarsal joint [17].

We found a limited number of publications evaluating the long-term results of conservative treatment of patients with OA of the first MTP [18]. J. Grady et al. reported the largest series evaluating the results of conservative treatment of OA of the first MTP [19]. The effectiveness of treatment based on the reduction in pain was 55 %, with 84 % of patients using orthopedic insoles.

Conservative treatment of patients with OA of the first MTP using orthopedic insoles is based on several approaches. The first involves limited extension of the first MTP reducing the time of loading on the first ray with use of Morton's extension insoles which have an extended frame in the projection of the first MTP (Fig. 5). A drawback with the method includes greater lateralization of the load vector when rolling over the forefoot [20]. Limited movement of the first MTP can be caused by pronation of the rearfoot.

The second approach to conservative treatment for OA of the first MTP joint is based on the formation of an internal longitudinal arch and correction of hindfoot pronation, using insoles with a cast-arch support [21]. Additional space is needed for orthopedic insoles in the shoe, and their use can be difficult due to osteochondral exostoses at the first MTP joint and limited space in the forefoot.

In this case, the selection of footwear for the patients becomes crucial. Rocker-bottom shoe-wearing is one of the most commonly used modifications of therapeutic footwear to allow patients with various foot and ankle pathologies benefit from its use [22, 23]. Although the role of footwear in the treatment of patients with OA of the first MTP joint was reported as early as the beginning of the 20th century, there is a paucity of publications devoted to this topic [24, 25].

The rounded shape of the sole stimulates foot rollover as the body weight passes through the support point [26]. Pressure distribution in this case occurs primarily on the midfoot [27]. The design of the sole, which is provided by softening and rigid inserts, provides additional cushioning during heel strike and limits extension in the forefoot enhancing the effect of the sole shape. Limitations in foot joint motion in the sagittal plane affect the kinematics of the lower limbs [28, 29].

Limited motion of the first MTP leads to an artificial decrease in the efficiency of the "winch mechanism", which is impaired in patients with stage 3–4 OA of the first MTP. A decreased force of the toe pushoff with the forefoot rolling over results in a longer double support phase, smaller oscillations of the body's center of mass and step length [9, 30, 31]. However, rocker-bottom shoes do not affect the speed of movement, which is consistent with the results of our study [32]. Limited extension of the first MTP joint in patients with OA can reduce pain intensity by using a semi-rigid and rounded sole in the toe area of shoes and a rocker-bottom. The sole shape can reduce the load and pressure in the forefoot [33], as confirmed by the results of our study, increasing the peak pressure and force in the rearfoot [34].

CONCLUSION

Results of in-shoe dynamic pedobarography suggested a reduction in plantar pressure and the force in patients with OA of the first MTP joint with use of rocker-bottom shoes compared to the values recorded with use of standard shoes. The rocker-bottom design has no effect on walking speed or step time. The reduction in peak plantar pressure and force occurs primarily in the forefoot.

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Informed consent The patients gave informed consent for publication of the findings without identification.



Fig. 5 Morton insole with extended frame in the projection of 1 MTP

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Surgical treatment of type IV ZwiPP – Rammelt calcaneal fractures using customized resection templates

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Abstract

Introduction Calcaneal fractures account for approximately 2 % of all fractures and are common in younger population. Treatment of the patients can be challenging with involved articular and soft tissue component. Conventional methods can be ineffective for complex and rare type IV and type V ZwiPP – Rammelt fractures necessitating development of new surgical approaches.

The **objective** was to explore short-term (10 months of observation) outcomes of patients with type IV ZwiPP – Rammelt calcaneal fractures using a new technology. The technique suggested improved accuracy of remodeling osteotomy due to three-dimensional reconstruction of the broken foot during preoperative planning and creation of customized resection templates with additive technologies.

Material and methods A prospective, hypothesis-generating study was performed for 13 patients with type IV ZwiPP – Rammelt calcaneal fractures. There were 6 males and 7 females with the mean age of 45.5 ± 13.02 years. The patients were treated with the new method which employed 3D reconstruction of the broken foot using MSCT images, fabrication of customized resection templates using FDM printing, their sterilization with ethylene oxide, precision osteotomy of the calcaneus through an L-shaped approach and subtalar arthrodesis. The results were assessed at 77 weeks using AOFAS, EFAS, FFI and VAS scales.

Results Functional parameters significantly improved at ten months with the EFAS increased by 2.5 times (to 34.0 scores, $p = 0.0002$), AOFAS improved by 1.6 times (to 80.0 scores, $p = 0.0002$), FFI increased by 1.57 times (to 38.0 scores, $p = 0.0002$). Pain improved with the VAS decreasing by half from 60 mm to 30 mm ($p = 0.001$).

Discussion The technique demonstrated several advantages with the possibility of multiplanar osteotomies, precise template fixation and control of resection parameters facilitating anatomical restoration.

Conclusion Short-term outcomes of patients with type IV ZwiPP – Rammelt calcaneal fractures showed that custom-made resection templates were practical for accurate surgical technology, improved functional outcomes, pain relief using the effective technique.

Keywords: malunited calcaneal fracture, posttraumatic deformity of the hindfoot, subtalar arthrosis, subtalar arthrodesis, calcaneus, correcting osteotomy of the calcaneus, customized resection templates, additive technologies

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INTRODUCTION

Calcaneal fractures account for approximately 2 % of all skeletal fractures, accounting for 70 % of tarsal fractures, and are associated with spinal fractures in 10–12 % of cases [1]. The fractures are common in younger population. There are still no epidemiological studies on large sample sizes on the incidence of disability resulting from calcaneal fractures [2]. The consequences of calcaneal fractures remain a complex problem for diagnosis and treatment due to a combination of severe extra-articular deformities of the heel and injury to soft tissues including vessels and nerves of the foot [3, 4]. A consensus has emerged among professionals on the need to improve methods for diagnosing and treating the consequences of calcaneal fractures [5].

Conservative treatment, although ineffective, is acceptable as a preoperative preparation of the patient for surgical treatment, which is the major option.

Diagnostic and clinical treatment strategy relies on current classifications of post-traumatic deformities of the calcaneus including Zwipp – Rammelt grading system [6]. There is a common opinion among medical community that subtalar arthrodesis *in situ* is indicated for subtalar osteoarthritis resulting from Zwipp – Rammelt type 1 injury, and distraction subtalar arthrodesis is indicated for lesions Zwipp – Rammelt types 2-3 (including simultaneous osteotomies according to Dwyer, Romash, etc.). Improvement of surgical treatment methods allows the use of arthroscopic, percutaneous and other techniques, as evidenced by literature data [7]. In select circumstances, joint-preserving surgical techniques may be considered even at a long term (1 year or more) [8]. There is a possibility to avoid bone grafting of calcaneal defects in the hope of the spontaneous repair with stable bone fixation to be provided using screws and plates [9].

The unequivocal ineffectiveness of the above-mentioned surgeries is driving researchers worldwide to seek new approaches to treating this severe condition. With the known patterns of calcaneal fracture, there are a variety of options for the consolidation of malpositioned bone, requiring an individualized approach to surgical planning.

Reconstructive surgery of calcaneal injuries suggests a pathogenetic approach in the treatment of the lesions, characterized by the intention to return the deformed calcaneus to the anatomical shape as close as possible. The founder of this direction is M.M. Romash initiated the approach in 1993 using oblique osteotomy of the calcaneus and continues the development of the approach using the advantages of current diagnostic methods [10, 11]. Yu Guang-Rong reported reconstruction of the thalamic part of the calcaneus as an attempt to reconstruct the original anatomy of the calcaneal fracture Zwipp – Rammelt types 4–5 [12, 13].

Despite accumulated global experience, diagnostic and treatment difficulties have been observed in the management of malaligned calcaneal fractures, classified as Zwipp – Rammelt type 4–5 lesions, which are most severe and rare. The injuries can be complicated by aseptic necrosis of the calcaneus, degenerative changes in adjacent joints, abnormal spatial orientation of the talus, etc. aggravating the clinical scenario and treatment approaches.

The **objective** was to explore short-term (10 months of observation) outcomes of patients with type IV Zwipp – Rammelt calcaneal fractures using a new technology. The technique suggested improved accuracy of remodeling osteotomy due to three-dimensional reconstruction of the broken foot during preoperative planning and creation of customized resection templates with additive technologies.

MATERIAL AND METHODS

Characteristics of the Study Population

The study included data from 13 patients with posttraumatic calcaneal deformities of Zwipp – Rammelt type 4 recruited between April 2023 and April 2025. The patient follow-up period was at least 10 months from the date of surgical treatment. The authors obtained consent from the patients to participate in the study and publish the results without identifying the patients.

Fifteen patients meeting the inclusion criteria were identified through screening. Of these, 13 patients were included in the final analysis of the results in full compliance with the study protocol. The study did not involve blinding or randomization procedures due to the expected small number of patients and was designed as a prospective, hypothesis-generating case series with a continuous enrollment of patients meeting the inclusion criteria.

The study included six men (46.2 %) and seven women (53.8 %), with an average age of 45.5 ± 13.02 years and a body mass index (BMI) of 27.4 ± 5.84 kg/m², being considered as overweight (pre-obese).

The median follow-up period was 77 weeks (minimum 41 weeks, maximum 106 weeks), or approximately 1.5 years from the date of surgery.

Inclusion criteria for the study included age from 18 to 70 years, regardless of gender; post-traumatic deformities of the calcaneus Zwipp – Rammelt type 4.

Exclusion criteria included active infection, uncontrolled diabetes mellitus with concomitant neuropathy, Charcot arthropathy, critical limb ischemia, obliterating atherosclerosis, neuromuscular disorders with paralysis, decompensated systemic diseases, psychoneurological disorders.

Methods of clinical and instrumentation measurements

Radiographic findings, multispiral computed tomography (MSCT), scales and questionnaires for assessing the functional and clinical condition of the foot and ankle including AOFAS Ankle-Hindfoot (American Orthopedic Foot & Ankle Society), EFAS (European Foot and Ankle Society), FFI (Foot Function Index), and the VAS visual analog pain scale were used to evaluate the treatment results [17–20]. These diagnostic tools were used both before treatment and during the follow-up period of patients.

Biostatistical analysis

Descriptive statistics were used to describe the indicators selected during the study. For interval variables, the median and quartiles, mode, and minimum and maximum values in the sample were calculated due to the small samples. Intragroup comparisons of interval variables were performed using the nonparametric Wilcoxon signed-rank test. With the small size of the study sample, tabulated results for interval variables were presented using nonparametric statistics as the median and first and third quartiles (Me [Q1; Q3]). A minimum sample size was not calculated due to the exploratory, hypothesis-generating nature of the study. Given the case series design, no control group was included in the study (results were compared with available literature), and blinding and randomization procedures were not produced. Statistical analysis of the study data was performed using IBM SPSS v25.0 software.

Technology for the production of a custom-made calcaneal resection template [16]

The first stage involved preparation of a custom-made resection template to be used during the surgical procedure. For this purpose, a virtual model of the calcaneus was created using design software based on the patient's MSCT scan (Fig. 1). During the second stage, the actual resection

block was manufactured using FDM 3D printing technology from plastic (PA2200) (Fig. 2a). The block was tested on a plastic model of the injured foot to verify the congruence of the product's surfaces and the anatomical structures of the foot (Fig. 2b). The finished implant was sterilized using ethylene oxide gas sterilization in accordance with GOST ISO 11135 at a temperature of 30 to 55 °C.

To precisely position the instrument during resection, the template is equipped with filing guides for the pendulum saw blade. Their orientation corresponds to the fracture consolidation lines determined during 3D reconstruction of the foot. The model features three key fixation points: the anterior process of the calcaneus, the distal pole of the fibula, and the calcaneal tuberosity, ensuring stability during surgery.

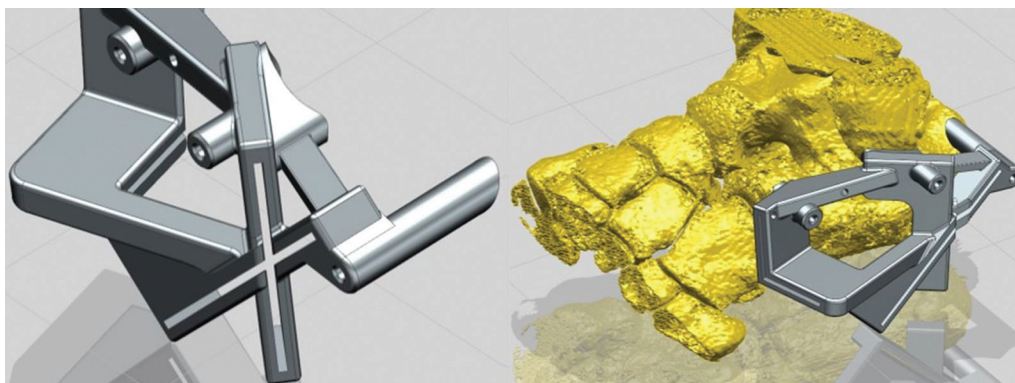


Fig. 1 Custom-made resection block of the calcaneus: a computer 3D model of the resection template and a virtual diagram of intraoperative positioning of the custom-made resection template on a 3D reconstruction of the patient's calcaneus

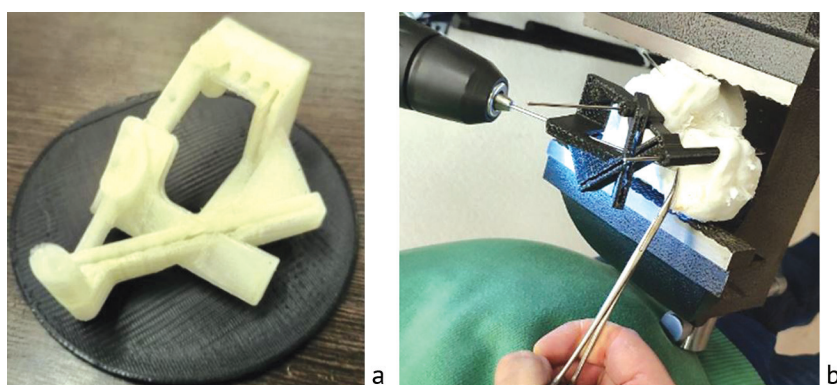


Fig. 2 A custom-made PA2200 cutting block (a); preoperative testing of the block on a plastic model of the patient's injured foot (b)

Surgical Technique

The leg is prepared in a clean operating room with the patient in the intact lateral position, exsanguinating the limb using a pneumatic tourniquet. The surgical field is prepared according to a standard protocol, including double antiseptic skin preparation with povidone-iodine (10 %) or chlorhexidine bigluconate (0.5 %). An L-shaped approach to the calcaneus is performed and the skin, subcutaneous fat, and fascia are dissected layer by layer, preventing damage to the sural nerve. The calcaneus is skeletonized with a single fasciocutaneous flap to its lateral wall, the distal pole of the fibula and subtalar joint are exposed. A custom resection template is placed at the fixation points selected during preoperative planning using 2 mm Kirschner wires.

Using an oscillating saw, osteotomies are produced along the grooves in the template corresponding to the consolidation lines with the calcaneus fragments being mobilized (Fig. 3). Remnants of the articular cartilage and scar tissue are removed from the articulating surfaces of the subtalar

joint down to the bleeding subchondral bone using a thin osteotome, curettes, and round and oval burs of various diameters. Following this, multidirectional osteoperforation of the articular surfaces is performed using a 2 mm Kirschner wire.

After osteoperforation, final reduction of the calcaneus and subtalar arthrodesis are performed using internal metal constructs in a position close to the anatomically correct position. The resulting bone defects are filled with the autograft obtained during surgery. The pneumatic tourniquet is removed, hemostasis established, the wound closed layer by layer with interrupted tension-free sutures, drained, and a sterile dressing is applied. Immobilization of the foot and ankle is performed with a deep posterior removable plaster cast with the foot in a neutral position.

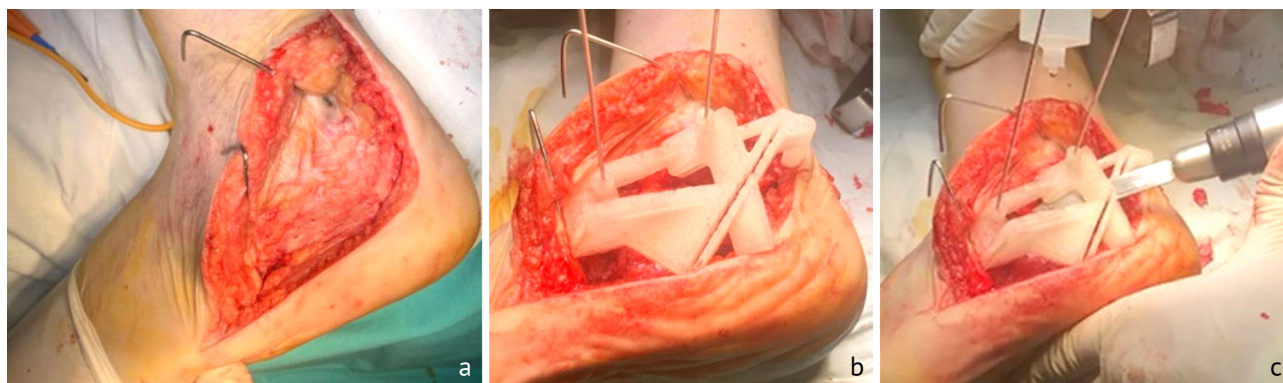


Fig. 3 Stages of surgical intervention: (a) performing an extended L-shaped approach to the calcaneus with the formation of a cutaneous-fascial flap; (b) positioning and fixing a custom-made resection template on the support points using 2 mm Kirschner wires; (c) performing a multi-plane (remodeling) osteotomy of the calcaneus using an oscillating saw in accordance with the template guides.

RESULTS

The descriptive statistics for the scale parameters in the patients who underwent operative treatment with the method we developed, are presented in Table 1. Baseline preoperative patient characteristics showed a high median value on the FFI scale, indicating significant limitations in the patients' functional and daily activities. This was confirmed by the low median values measured with the AOFAS Ankle-Hindfoot and EFAS scales and high median pain VAS score of 60 mm (Table 1), indicating significant functional limitations and severe pain, as well as their negative impact on the overall well-being of the patients.

The surgical outcomes at the end of patients' participation in the study were characterized by a significant improvement in the indicators on all the scales (Table 1). The median value on the EFAS scale increased almost 2.5 times compared to the initial value, up to 34.0 [33.00; 38.00] scores (Z -score = -3.182 ; $p = 0.0002$). The median values increased 1.6 times on the AOFAS Ankle-Hindfoot scale, up to 80.0 [76.00; 91.00] scores (Z -score = -3.184 ; $p = 0.0002$). The median parameters improved 1.57 times on the FFI scale, up to 38.0 [34.00; 47.00] scores (Z -score = -3.180 ; $p = 0.0002$).

Patients' pain sensations according to the VAS scale decreased significantly: from the initial "moderate pain", subjective pain sensations decreased by half to "mild pain" in the form of a median value of 30.0 [20.00; 30.00] mm (Z -score = -2.952 ; $p = 0.001$).

Some patients reported the highest pain scores on the VAS scale at the start of the study (90–100 mm, "unbearable pain") due to damage to both heels. In such cases, the reduction in pain after surgery could have been even more pronounced, which should have a positive impact on the patients' quality of life.

Table 1

Descriptive statistics values for scale parameters in the study population pre- and postoperatively ($n = 13$)

Scale	Period	Scoring							
		The mean	Standard deviation	Max	Min	Mode	Median	Q1	Q3
EFAS	pre-op	13.0	4.74	23	5	15.0	14.0	11.00	15.00
	post-op	35.2	5.55	43	22	34.0	34.0	33.00	38.00
AOFAS Ankle-Hindfoot	pre-op	48.9	11.46	80	32	45.0a	49.0	42.00	52.00
	post-op	81.6	12.22	102	56	76.0a	80.0	76.00	91.00
FFI	pre-op	87.2	20.46	120	39	75.0	91.0	75.00	99.00
	post-op	39.2	11.63	63	20	20.0a	38.0	34.00	47.00
VAS	pre-op	62.3	18.78	100	30	50.0a	60.0	50.00	70.00
	post-op	25.4	16.13	50	0	30.0	30.0	20.00	30.00

Note: The sample contains several mode values, the smallest of which is shown.

As a **clinical example** of the use of the technology we developed, the treatment result of a patient with post-traumatic Zwipp – Rammelt type 4 calcaneal deformity is presented at 12 months of surgery. The patient was 53 years old with, had no bad habits, was engaged in physical labor, normosthenic body build (weight 95 kg, height 195 cm; BMI 25.8 kg/m², which corresponded to the upper limit of the norm), and led an active lifestyle associated with regular physical labor. The patient's professional activity (construction worker) required systematic heavy physical activity, which placed greater demands on the musculoskeletal system.

The patient's history of chronic diseases revealed the following: stage 1 hypertension with a risk of cardiovascular complications of 4; permanent atrial fibrillation; gastroesophageal reflux disease. The patient received regular therapy with Concor at a dosage of 5 mg once daily. In 2002, broken fibula of the left ankle joint was repaired with metal osteosynthesis.

In 2018, the patient sustained a comminuted intra-articular fracture of the left calcaneus as a result of a domestic accident (a fall from a three-meter height). The injury was treated surgically at a local clinic. Open reduction and internal metal fixation of the left calcaneus was performed for the patient. The postoperative period was uneventful. External immobilization of the operated limb to be fully unloaded was recommended for eight weeks. The patient initiated gradual weight-bearing on the lower limb after immobilization. Physiotherapy, massage and exercise therapy were administered as part of his rehabilitation at a local clinic.

However, no significant improvement in the patient's condition was noted at one-year follow-up: pain and swelling persisted, and the hallux valgus of the rear left foot progressed. A year after the surgery, the patient sought examination and treatment at the S.S. Yudin City Clinical Hospital's Foot Surgery Center, aimed at improving his quality of life, facilitating his professional and daily physical activities.

At the time of presentation, the patient reported severe pain at the back of his left foot, localized in the subtalar joint and fibular pole, as well as decreased functional activity. His unassisted ambulation was limited to 3,000 steps per day, after which he was forced to take nonsteroidal anti-inflammatory drugs to reduce pain. The patient developed progressive limitation of dorsiflexion in his left ankle and discomfort with use of standard shoes, due to persistent deformity of the posterior portion of his left foot (Fig. 4). The complaints indicated persistent functional impairment in his left foot, requiring a thorough diagnostic examination and a comprehensive approach to further treatment strategy.



Fig. 4 Appearance of the left foot of the patient: (a) a rear view (hallux valgus of the hindfoot on the left side); (b) medial side (post-traumatic flatfoot); (c) lateral surface (soft tissues swollen at the calcaneofibular site) [16]

Radiographic examination revealed post-traumatic osteoarthritis of the subtalar joint of the left foot (Kellgren – Lawrence grade 3); a negative Bohler angle indicating impaired anatomy of the calcaneus; "horizontalization" of the talus and a decreased talocalcaneal height caused by post-traumatic changes; a consolidated fracture of the left calcaneus, Zwipp – Rammelt type 4 and fixation with screws healed bone fusion in a displaced position; a consolidated fracture of the fibula, fixed with a metal construct (plate and screws) after an injury in 2002. The phenomenon of "horizontalization" of the talus caused a progressive limitation of dorsiflexion in the left ankle joint, which led to the formation of anterior impingement at the site (Fig. 5).

MSCT of the left calcaneus was produced to clarify the course of the fracture lines, bone alignment and degree of consolidated calcaneus. The scan indicated the initial articular-depression nature of the fracture, pronounced calcaneofibular impingement demonstrating the shape and relative position of the consolidated calcaneal fragments and metal constructs (Fig. 6).

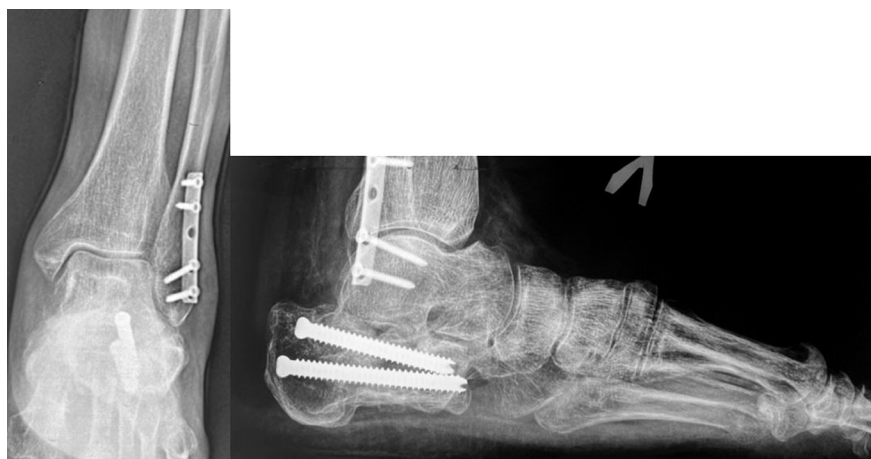


Fig. 5 Coronal and lateral weight-bearing radiographic views of the left foot



Fig. 6 MSCT of the left foot in the coronal, sagittal and axial planes [16]

The patient was finally diagnosed with post-traumatic deforming osteoarthritis of the left subtalar joint Kellgren – Lawrence grade 3; Zwipp – Rammelt type 4 malaligned consolidated fracture of the left calcaneus; consolidated fracture of the fibula of the left ankle joint fixed with a locking plate; fixed valgus deformity of the left calcaneus with calcaneofibular conflict; anterior impingement of the left ankle joint and contracture of the left ankle joint.

Definitive diagnosis was established and indications for surgical intervention identified to include removal of the metal constructs, remodeling osteotomy of the calcaneus with simultaneous subtalar arthrodesis, internal screw fixation, autologous bone grafting, and percutaneous Vulpius achillotomy. There were some difficulties during preoperative planning related to identifying the lines of the previous calcaneus fracture. This created potential difficulties in accurate reproduction of the profiled osteotomy lines in the operating room, which could have impacted the duration and accuracy of the surgical procedure. To explore the spatial characteristics of the calcaneus fragments, a plastic model was created using a three-dimensional reconstruction and 3D printing technology. The approach allowed for the use of a visual-tactile analysis method, facilitating a more detailed understanding of the injury (Fig. 7).

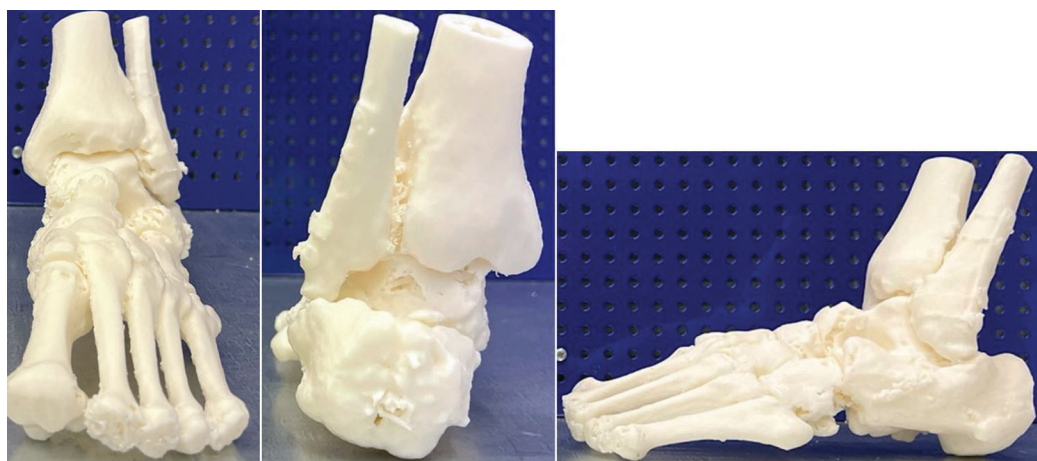


Fig. 7 3D model of a broken left foot made of plastic: front, back and side views

A model of the damaged bone structures of the foot revealed lateral calcaneofibular impingement and valgus deformity of the hindfoot on the left. The surgical treatment indicated included remodeling osteotomy of the left calcaneus, corrective subtalar arthrodesis, internal fixation with metal constructs, bone autografting of the calcaneus defects and a Vulpius achillotomy. The scope of surgical intervention is determined by the need to correct the hindfoot deformity on the left and lateral calcaneofibular impingement, and eliminate anterior impingement in the left ankle joint. The condition caused pain and created inconvenience in the patient's daily life, difficulties in the use of standard footwear and significantly reduce the patient's quality of life.

Preoperative planning was associated with significant difficulties in analyzing the primary, secondary, and tertiary healing lines of the calcaneus at the site of previous fracture lines. These lines can be easily visualized even in consolidated fractures, which is the basis for planning remodeling osteotomy. With difficulties anticipated for the osteotomy, a custom resection template was created to help determine healing lines in the wound, given bone consolidation and previous surgery.

With a custom-made resection block made, the patient underwent surgery using the method developed to achieve the deformity correction (Fig. 8). Given the in following bone reduction, a percutaneous Vulpius achillotomy was performed for the Achilles tendon significantly tensioned and resulted in almost completely restored range of motion in the left ankle.

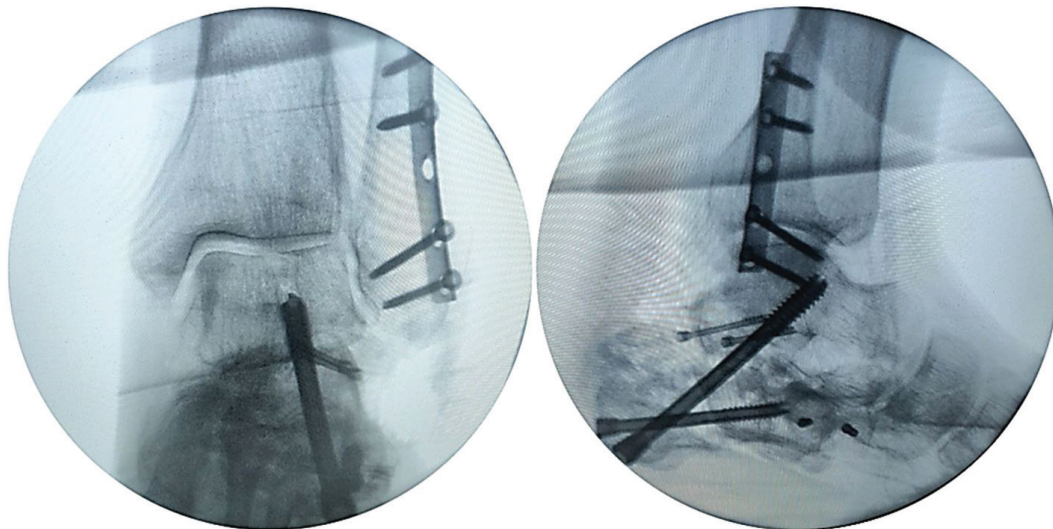


Fig. 8 Intraoperative control using image intensifier in anteroposterior and lateral projections

The calcaneus deformity was corrected based on preoperative planning. The position of the bone fragments and the metal construct placed was assessed as satisfactory.

The patient's postoperative period was uneventful, the wound healed by primary intention, and the sutures were removed after 21 postoperative days. With the wound healed and postoperative swelling settled, the plaster cast was replaced with a circular polymer cast, with immobilization continued for two months. Then the patient underwent a follow-up examination with radiographs and MSCT of the operated left calcaneus. The diagnostic procedures indicated bone union of the artificial left calcaneus fracture, formation of a subtalar bone fusion and stable positioning of the metal constructs. The patient was allowed to bear some weight on the operated limb, prescribed restorative and rehabilitation treatment recommended to include physiotherapy, massage and exercise therapy in a rehabilitation center.

The patient could regain axial loading on the limb within a month and return to work. Dynamic observation of the patient was continued, and the final treatment result was assessed at 12 months after the surgery. The follow-up examination showed the correction of the hindfoot on the left maintained, there was no lateral calcaneofibular impingement, and the talar deviation angle, calcaneal inclination angle, Meary angle, malleolar growth, and calcaneal width restored (Fig. 9a). MSCT demonstrated a consolidated artificial fracture of the left calcaneus with the formation of a subtalar bone fusion with screw fixation, and a consolidated fibula fracture fixed with locking plate (Fig. 9b).

The surgical outcome was visually evaluated with a 3D reconstruction of the left foot using MSCT obtained at 12 months after surgery. Using these data, a plastic model of the foot was created using additive manufacturing (3D printing) and compared with the original plastic model printed prior to surgery during the preoperative planning stage (Fig. 10). Lateral calcaneofibular impingement and hallux valgus were corrected. Photographs of the left foot models demonstrated ankle growth increased by 10 mm as compared to the preoperative model (Fig. 10b).

Comparison of the measurements of topographic-anatomical parameters of preoperative and postoperative foot models showed the values being closer to corresponding to the anatomical norm of the healthy contralateral limb (Table 2).



Fig. 9 Radiography and MSCT imaging of the patient's left foot at 12 months of surgery: weight-bearing AP and lateral views (a), MSCT reconstruction in the coronal, sagittal and axial planes (b)

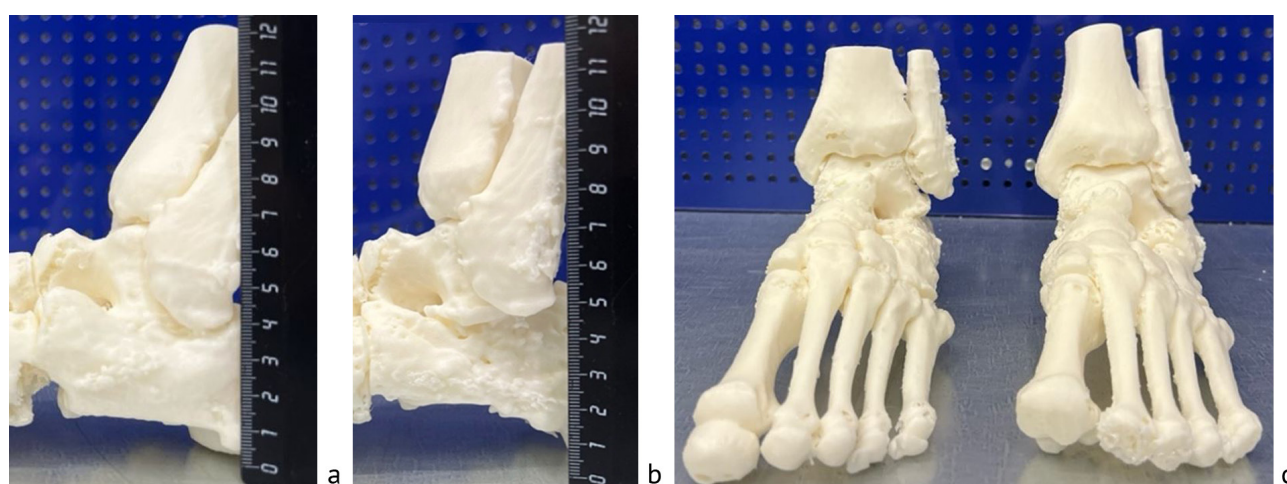


Fig. 10 Photographs of the simulated left foot showing (a) preoperative side view; (b) side view at 12 months; (c) front view of both models (on the left: control postoperative model of the operated foot, on the right: preoperative model)

Table 2

Evaluation of anatomical parameters of the foot

Description	Hindfoot of the left (injured) foot		Hindfoot of the right (normal) foot
	pre-op	at 12 months of surgery	
Angle of deviation of the talus, °	11	20	22
Calcaneal inclination angle, °	11	16	18
Miri angle, °	9	4	2°
Talocalcaneal height, mm	67	73	76
Calcaneal width, mm	53	43	34
Ankle growth, mm	35	45	46

The postoperative results demonstrated a significant improvement in the condition of the injured foot compared to baseline values obtained before the corrective reconstructive surgery on the left calcaneus (Table 3). The patient showed a high level of physical activity at 12 months, taking up to 12,700 steps per day. He was able to return to his normal work activities indicating positive changes in his quality of life.

Table 3

Assessment of the clinical and functional condition of the patient's left foot

Scale/Questionnaire	Assessment, score	
	Pre-op	At 12 months post-op
AOFAS Ankle-Hindfoot	45	76
EFAS	12	22
FFI	101	50
VAS	5	2

None of the 13 patients experienced any complications. One patient experienced postoperative wound healing by secondary intention due to superficial skin necrosis, which resolved within one month.

DISCUSSION

Surgical treatment of patients with post-traumatic calcaneal deformity is challenging. Effective management of the cohort of patients is difficult to be arranged in trauma and orthopedic departments, given the current structure of specialized trauma and orthopedic care. Improved outcomes for this category of patients treated at a specialized foot and ankle surgical centers are associated with the institution's organizational technologies, specialists' expertise in foot biomechanics, diagnostic and therapeutic techniques, experience and creative and innovative approaches to treatment [21].

It is generally accepted that while patients with moderate consequences of calcaneal fractures (Zwipp – Rasmelt types 1-3) can be successfully treated with well-known methods (distraction subtalar arthrodesis or subtalar arthrodesis *in situ*), patients with Zwipp – Rasmelt types 4-5 injuries require an individual approach and different technical methods and operations for correction.

This type of injury is rare. Zwipp et al. reported 245 patients with calcaneal fractures with 12 % of patients having consequences of Zwipp – Rasmelt type 4 injuries and 7 % of patients having

consequences of type 5 injuries, i.e. 29 and 3 patients, respectively [22]. Our series of 13 patients with similar types of injuries appears sufficiently representative for a hypothesis-generating study considering the rarity of the diseases and the impossibility of randomization due to the unethical nature of forming comparison groups with surgical intervention options that are obviously inferior in terms of expected treatment outcomes.

Many authors suggested a procedure combining subtalar arthrodesis and Dwyer osteotomy for this cohort of patients, which is acceptable for type 2-3 injuries, but leads to the formation of a "zigzag" deformity of the calcaneus in type 4-5 injuries. Moreover, the formation of varus deformity of the calcaneus, described as a typical complication [13], in our experience, can result in failure of suturing the surgical wound. Specific diagnostic and treatment techniques can be applied for the group of patients with consequences of Zwipp - Rammelt type 4-5 injuries. The technology was first reported by M.M. Romash, who offered an original osteotomy of the calcaneus along the primary fracture line in 1993, which had a scientific and practical role at that time [10].

Fracture lines are complex and may run in different directions, creating typical fracture patterns. This can pose a challenge for surgical planning, as the fracture lines become invisible after one year or more from the injury, leaving the surgeon with no reference points for osteotomies. However, these lines are visible on computed tomography (CT) images which can be practical for preoperative osteotomy planning. The simultaneous use of custom-made resection blocks allows for adjustment of the direction and depth of the osteotomy in the surgical wound. Based on this fact, we offered an original operation of remodeling osteotomy of the calcaneus, which can be combined with subtalar arthrodesis [14] and have been successfully using since 2009, 8–12 months after the injury, while the lines of consolidated bone remain available for identification [15].

Our research aimed at improving the accuracy of shaped osteotomies of the calcaneus and bring them into precise correspondence with the planned anatomical landmarks during preoperative planning led to the creation of a surgical treatment method using individually manufactured resection templates we patented in the Russian Federation [16]. There are publication reporting the use of resection blocks in a similar scenario. Lee et al. used intraoperatively a custom-made resection template for Zwipp – Rammelt type 4 post-traumatic calcaneal deformity with good clinical and radiographic results [23]. The disadvantages of the method used by colleagues from Singapore include the inability to firmly fix the template during manipulations and fix the angle of attack of the oscillating saw blade, and the limitation of resection to one plane. The disadvantages were adjusted by incorporating several sawing planes, fixation points, and programmed directions for osteotomies into the template [16]. Identifying consolidation lines during preoperative planning allows for calcaneal osteotomies to be performed along "old" fracture lines correcting multiplanar hindfoot deformities. We believe that reduction of displaced bone fragments and subtalar arthrodesis in a functionally advantageous anatomical position can improve patient outcomes.

Functional results could be compared with published results of treatment of this cohort of patients due to the absence of a comparison group in our study. Schepers et al. [24] reported the findings of 21 studies in the systematic review (average follow-up period of 40 months) with a total of 456 patients with late complications of consolidated comminuted intra-articular calcaneal fractures with bone displacement. The patient underwent arthrodesis of the subtalar joint with bone grafting and distraction (in 93 % of cases as a salvage intervention). Functional outcomes measured

with the modified AOFAS scale at final follow-up averaged 73 scores (range, 64 to 83). Almost all studies included in the review were retrospective case series with level IV evidence. Subtalar joint arthrodesis with bone grafting and distraction was performed in 93 % of cases.

In our series, the AOFAS-Hindfoot scores were recorded with a median of 80.0 [76.00; 91.00] scores (Z -score = -3.184; $p = 0.0002$) at the time of postoperative observation, which even exceeded the pooled average values on the AOFAS scale published by Schepers et al. [24]. The value of the minimum clinical significance of changes on the AOFAS scale has not been determined for this type of lesions in world practice, and no conclusion can be made about the significance of a difference of 7 scores.

We concluded that patients with Zwipp – Rammelt type 4 injuries can be treated with open reduction, internal fixation and deformity correction if the cartilage is intact (assuming a high risk of complications), while primary arthrodesis and osteotomy can be recommended for patients with a destroyed joint. Multistage reconstruction is practical for severe deformities, and corrective osteotomy is critical for restoring biomechanics.

Qiang et al. [25] suggested that primary subtalar or triple arthrodesis is recommended for irreparable cartilage damage, that type 4 severe intra-articular calcaneal fractures accompanied by a deformity require precise anatomical reconstruction to restore subtalar function, and modern surgical treatment methods (minimally invasive osteosynthesis, 3D navigation) can facilitate accurate reduction. Therefore, our method improves clinical efficacy and provides more predictable treatment outcomes for patients with post-traumatic deformity due to Zwipp – Rammelt type 4 injuries. The use of customized resection templates for calcaneal remodeling osteotomy in this patient population is practical, as the clinical and prognostic outcomes of other surgical approaches described in the literature will be inferior to those treatment method proposed by the authors.

Limitations of the Study

The main limitation of the study is the relatively small patient sample, which is due to the rare nature of the injury type. Therefore, the study was designed as a hypothesis-generating prospective case series, without a comparison group or statistical power calculation. Therefore, the primary focus is on descriptive statistics and a comparison of pre- and post-treatment patient condition, which may aid in calculating the sample size required for future studies of the patient population.

The second limitation is the lack of comparison groups and failure of randomization due to the unethical nature of forming groups based on surgical intervention options that are obviously inferior in terms of expected treatment outcomes.

CONCLUSION

The use of additive technologies in reconstructive calcaneus procedures allows for the creation of precise 3D models of the injured foot, facilitating a detailed analysis of the spatial and geometric structure of the deformity and the development of an optimal correction strategy. The creation of custom-made cutting blocks for precision osteotomies according to the preoperative plan facilitates accurate restoration of the anatomy of the injured calcaneus. Analysis of surgical outcomes demonstrates significant improvements in functional and pain scores measured with the EFAS, AOFAS Ankle-Hindfoot, FFI and VAS scales. A significant reduction in pain in patients with initially severe pain has a positive impact on their quality of life.

Conflict of interest None declared.

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Histomorphometric evaluation of the synovial membrane during osteosynthesis of intra-articular metaepiphyseal fractures with titanium screws in lambs (an experimental morphological study)

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Abstract

Introduction The complexity of treating intra-articular fractures in children is due to the anatomical features of the joint, its biomechanics, and the tendency to develop post-traumatic arthritis. This necessitates a detailed study of the structural organization of all elements of the joint synovial environment.

The **aim** of this study was to evaluate, using an experimental model, the severity of structural changes in the synovial membrane of the carpal joint during osteosynthesis of intra-articular metaphyseal fractures with titanium screws.

Materials and Methods The study was performed on six outbred male lambs (46.1 ± 3.0 days old, weighing 15.7 ± 2.0 kg). An oblique intra-articular metaphyseal fracture of the radius on the right limb was modeled. Fracture fixation was performed with two cannulated cancellous bone screws made of Ti6AL4V titanium. The experimental periods were 120 ($n = 3$) and 365 ($n = 3$) days after surgery. Histomorphometric analysis of the synovial membrane was performed using an AxioScope.A1 microscope and Zenblue software (CarlZeissMicroImagingGmbH, Germany). The synovium of the contralateral joint served as a control.

Results In the control joint, fibroblast-like synoviocytes predominated in the synovial membrane lining layer; no signs of synovitis were detected. After 13.5 months, a decrease in lining layer thickness ($p = 0.0326$) and synoviocyte density ($p = 0.0009$) was noted. In the experimental joint, mild synovitis, hyperplasia of the lining layer, increased synoviocyte density and macrophage-like synoviocyte representation (more than 50 % per field of view), formation of synovial villi, and the presence of focal and diffuse lymphohistiocytic infiltrates were detected after 120 days. After 365 days, signs of synovitis were absent, fibroblast-like synoviocytes predominated in the lining layer; elevated synoviocyte density values persisted ($p = 0.0141$), and lining layer thickness values were comparable to the control ($p = 0.1301$).

Discussion Non-bioresorbable fixators used for osteosynthesis of intra-articular fractures can cause a number of complications, including infection, pain, and arthritis. It was established that macrophage and fibroblastic synoviocytes perform various pro- and anti-inflammatory functions and can both prevent inflammation by forming an anti-inflammatory barrier and contribute to the development of synovitis.

Conclusion Osteosynthesis of intra-articular metaepiphyseal fractures of the distal articular end of the radius in lambs using titanium screws provoke mild synovitis after 120 days of the experiment. This synovitis was characterized by thickening of the lining layer, an increase in the numerical density of synoviocytes and in macrophage synoviocytes, and the presence of a lymphohistiocytic infiltrate. By the end of the experiment, the synovial membrane inflammation reversed, and histological signs of synovitis were absent.

Keywords: intra-articular fracture, titanium screws, lambs, synovial membrane, histomorphometry

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INTRODUCTION

Upper limb fractures account for a significant portion among all injuries in children, for up to 84 % of all limb fractures, according to various sources. The most common upper limb fractures are distal radius fractures, which make 10 to 35 % of all skeletal injuries [1, 2, 3, 4].

The main principles of surgical treatment of intra-articular fractures in children include: precise restoration of normal joint anatomy and alignment of bone fragments [2, 5]; ensuring stable fixation of the fracture using orthopedic means (external fixators, pins, screws, plates, wires, bioresorbable fixators) [6, 7, 8, 9]; minimally invasive techniques to reduce damage to soft tissues, blood vessels and growth zones, for complete restoration of joint function and minimization of complications [10].

The choice of treatment strategy for intra-articular metaphyseal fractures of the forearm bones in children remains relevant and not fully resolved issue in modern traumatology and orthopedics [3, 11].

Currently, there is no consensus on the choice of surgical treatment method for distal radius fractures in children. Treatment results using the methods presented in the literature are contradictory, with a high rate of complications and unsatisfactory treatment outcomes. The most common complications include malunion or slow fracture healing, post-traumatic arthritis, limb growth retardation, infections, vascular and nerve damage, pseudarthrosis, and muscle atrophy [12, 13, 14, 15].

The complexity of treating children with such fractures is related to the anatomical features of the joint, its biomechanics, the tendency for bone tissue to grow around the joint (periarticular ossification), and the development of contractures [2], which necessitates a detailed study of the structural organization of all elements of the joint's synovial environment.

The condition of the synovial membrane is crucial for the successful healing of an intra-articular fracture, maintaining a healthy joint environment, and preventing complications. It has been established that intra-articular fractures are associated with increased concentrations of proinflammatory cytokines and degradative enzymes produced by synovial cells [16]. Despite a growing understanding of the role of the synovial membrane in joint pathology, quantitative data on the structure of this tissue remains incomplete.

It is impossible to obtain information on the structural reorganization of the synovial membrane at the stages of osteosynthesis in clinical studies; experimental studies on animals are necessary.

The **aim** of this study was to evaluate, using an experimental model, the severity of structural changes in the synovial membrane of the carpal joint during osteosynthesis of intra-articular metaphyseal fractures with titanium screws.

MATERIAL AND METHODS

Study design

The study was conducted on six mongrel male lambs aged (46.1 ± 3.0) days and weighing (15.7 ± 2.0) kg. The study periods were 120 and 365 days (three animals per period).

Inclusion criteria: clinically healthy lambs in the period of active growth that did not have any diseases of the locomotor system.

Exclusion criteria: diseases of the locomotor system (rickets, limb deformities).

A complete oblique intra-articular metaphyseal fracture of the distal radius, corresponding to type 4 according to the Salter-Harris classification was modeled in all animals [17]. The osteotomy line was located on the anterior surface of the radius and passed through the metaphysis, growth plate, and epiphysis to the center of the articular surface of the bone. In all cases, the wrist joint capsule was dissected until the articular surface of the radius was exposed. The osteotomy was performed with an oscillating saw. Complete instability of the free fragment was considered a sign of an intra-articular fracture.

Fracture fixation was performed using two cannulated titanium Ti6AL4V bone screws with a partial thread of 3.5 mm (Registration Certificate No. FSR 2012/14220 dated April 8, 2021). Initially, the bone fragment was reduced and temporarily fixed with two 1.0 mm osteosynthesis wires. Screw insertion did not penetrate the radial growth plate. First, a guide wire was inserted in the medio-lateral direction at the insertion point. Next, a 2.5-mm cannulated drill was used to drill a canal for the screw along the wire. The drill was then removed, and a cannulated screw was inserted along the wire. The screw was tightened until complete stability of the bone fragment. Osteosynthesis was performed first at the metaphysis level, then at the epiphysis level of the radius. Fixation of the fragments at the level of the radial epiphysis was performed in a similar manner. After osteosynthesis of the fracture, the temporary wires were removed. The surgical wound was closed layer by layer with interrupted 3/0 Vicryl sutures.

Surgical interventions were performed under general anesthesia. Premedication consisted of 1 % diphenhydramine (0.02 mg/kg), 0.1 % atropine sulfate (0.02 mg/kg), and 2 % rometar (0.1 mg/kg) solutions. Anesthesia was administered using 1 % propofol emulsion at a dose of 4 mg/kg/min.

To prevent fragment displacement during the postoperative period, the limb was temporarily immobilized with a thermoplastic splint at 25–30° of carpal flexion. Immobilization was discontinued on days 10–14. To prevent the development of inflammatory processes, the animals were also given painkillers (intramuscular ketoprofen 50 mg, 0.5 ml) and antimicrobial drugs (intramuscular ceftriaxone 1.0, 7–10 mg/kg). The surgical wound was treated with solutions of 3 % hydrogen peroxide and furacilin 1:5000. Sutures were removed on days 10–14. Bone screws were not removed during the entire study.

Study object: synovial membrane of the carpal joint

In vivo examinations In the postoperative period, the general condition of the animals, the intensity and nature of motor activity were assessed; local examination assessed the course of surgical wound healing, the presence of hematomas, edema, the occurrence of segment deformity, and the range of motion of the limb in the carpal joint.

Radiographic study Radiography was performed in the frontal and lateral projections using a CANON CXDI-401C COMPACT veterinary flat-panel detector (Canon Inc. Medical Equipment Group, Japan); a TOSHIBA Rotanode Model E7239, N 10G749 X-ray tube (Japan). The current was 2.5–3.2 mA, the voltage was 43–44 kV, the focal length was 90 cm, and the exposure was set automatically.

Ethical approval The study was conducted in accordance with the principles of the European Convention ETS No. 123 for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (with the appendix of 15.06.2006, Strasbourg) and the rules of good laboratory practice (GOST 33044-2014, GOST 33215-2014, GOST 34088-2017, PS SanPiN 3.3686-21). Institutional ethics committee dated 29.11.2024 No. 1 (76).

Euthanasia Animals were euthanized after premedication with a 1 % diphenhydramine solution (0.02 mg/kg) and 2 % rometar (0.1 mg/kg), followed by the administration of a lethal dose of barbiturates.

Histomorphological study

The synovial membrane of the carpal joint was dissected using a scalpel and placed in a fixative (10 % neutral formalin). Further standard histological processing was performed using a HISTOSAFE™ INFILTRA™ tissue vacuum processing apparatus (ErgoProduction LLC, Russia).

Sections (3–5 µm thick) were prepared from paraffin blocks using a Thermo Scientific HM 450 microtome (USA), which were then stained with hematoxylin and eosin or Masson's three-color method.

An AxioScope.A1 microscope with an AxioCam ICc 5 camera was used to obtain digital images of the sections. Zenblue software (CarlZeissMicroImagingGmbH, Germany) was used to determine the following parameters: thickness of the outer layer (µm) and the numerical density of synoviocytes per 1 mm of the lining layer length. Measurements and calculations were performed on average in 10 fields of view at 1000× magnification from each animal.

The severity of synovitis was assessed using the semi-quantitative scale of Krenn et al. [18] (0–1 point — no synovitis; 1 ≤ 4 points — mild synovitis; 5–9 points — severe synovitis) in 10–15 visual fields at 400× magnification from each animal. The synovial membrane of the carpal joint of the contralateral limb was examined as a conditional control.

Statistical methods Quantitative data were processed using Microsoft Excel spreadsheets. The Kolmogorov test was used to evaluate the distribution of samples. The measure of central tendency of the morphometric parameters is presented as the median and quartiles, minimum and maximum values (Me (p25; p75) [min–max]). The nonparametric Mann–Whitney test was used to analyze differences between the compared groups; differences were considered significant at $p < 0.05$.

RESULTS

The postoperative period was uneventful. The surgical wound healed by primary intention without septic complications. All lambs experienced limited motor and weight-bearing function of the limb during splint immobilization, thus carpal contracture developed. When immobilization was discontinued, limb function gradually recovered. On the 14th day after surgery, carpal flexion, at the time of splint removal, was 45–50°; by the 30th day after surgery, it was 170°. By the 45th day of observation, carpal flexion was fully restored (180°) and remained so until the end of the study.

Radiographic signs of fracture healing were recorded by the 30th day after surgery. Areas of complete restoration of the cortical plate were noted. The osteotomy line of the epiphysis and articular surface was filled with newly formed bone tissue. The articular surface line was anatomically correct, with no areas of layers or overgrowth. The height of the joint space was uniform throughout. The growth plate was continuous and had no areas of ossification in the projection of the osteotomy line (Fig. 1 a). By the 120th day, the osteotomy line was not visualized. The articular surface had no pathological formations. The joint space was clearly visible. The growth plate was open. Deformities of the articular surface were not noted (Fig. 1 b). At the final stage (365 days after surgery), radiographs showed complete bone remodeling in the osteotomy zone. The articular surfaces of the carpal joint had anatomically correct contours. No pathological changes in bone structures were detected (Fig. 1 c).



Fig. 1 Radiographs of lamb limbs in the AP and lateral views: (a) 30 days of fixation; (b) 120 days of fixation; (c) 365 days of fixation

Morphological characteristics of the synovial membrane of the carpal joint of the contralateral limb

The synovial membrane of the carpal joint of the contralateral limb had a normal structure (Fig. 2 a, b). After 120 days (the animals were 5.5 months old), the synovial membrane had a predominantly smooth surface, folds were poorly expressed, and synoviocytes of the lining layer

were arranged in two to three layers (Fig. 2 a). After 365 days (the animal age was 13.5 months old), the synovial membrane had a folded surface over a greater area, and synoviocytes were arranged in one to two layers (Fig. 2 b). As the age of the animals increased, the thickness of the lining layer and the numerical density of synoviocytes significantly ($p < 0.05$) decreased (Table 1), and the proportion of the fibrous component in the lining layer increased. The cells of the lining layer were polymorphic; the majority, based on their morphological characteristics, belonged to fibroblast-like synoviocytes; those cells had a flattened or polygonal shape (Fig. 2 c). Cell density in the upper subsynovial layer was normal in most cases, but in some cases it was characterized as slightly elevated, with fibroblasts and fibrocytes predominating (Fig. 2 d). The deep subsynovial (collagen-elastic) layer was more saturated with collagen fibers with areas of adipose tissue; as the experimental duration continued to increase, the proportion of the fibrous component and the thickness of the collagen fiber bundles grew. No inflammatory infiltrate was detected.

Krenn et al. [18] evaluation confirmed absence of synovitis (Table 1).

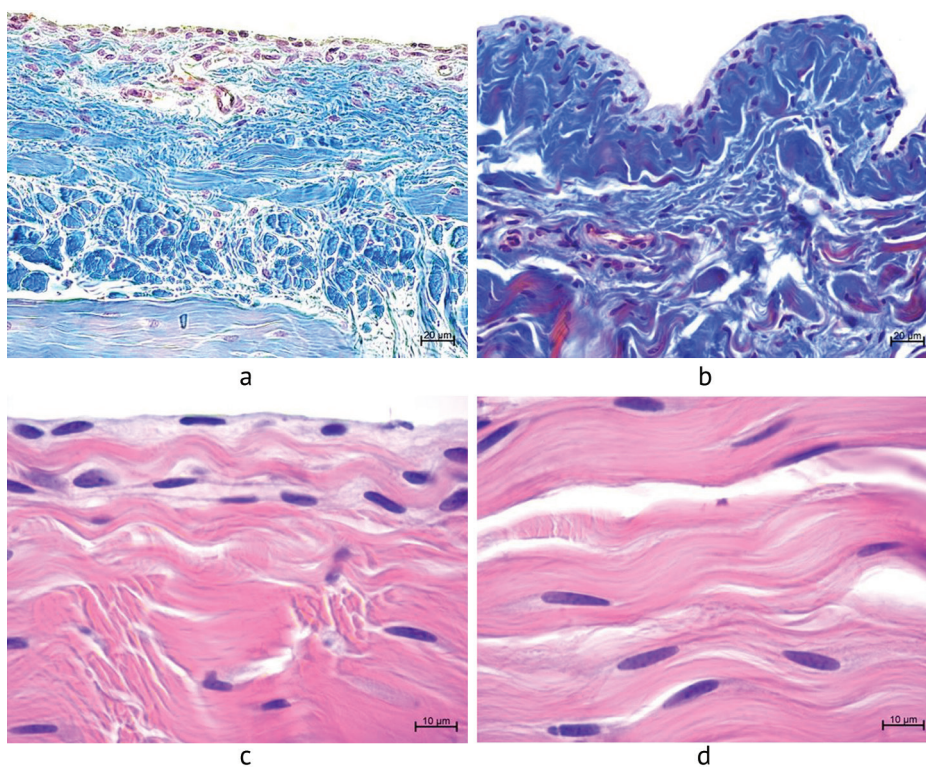


Fig. 2 Synovial membrane of the contralateral carpal joint of a lamb:

(a) 120 days of the experiment (the animals were 5.5 months old), general appearance; (b) 365 days of the experiment (the animals were 13.5 months old), general appearance, folded surface; (c, d) 365 days of the experiment (the animals were 13.5 months old), fibroblast-like synoviocytes of the lining layer (c), fibroblasts, fibrocytes in the subsynovial layer (d). Paraffin sections, stained with Masson's three-color method (a, b), hematoxylin and eosin (c, d). Magnification $\times 400$ (a, b), $\times 1000$ (c, d)

Table 1

Semi-quantitative and quantitative characteristics of the synovial membrane of the carpal joint

Parameter		Thickness of the lining layer (mcm)	Synoviocyte density	Synovitis score
		Me ($p_{25};p_{75}$)	[min–max]	Me ($p_{25};p_{75}$)
Control	120 days	36.73 (28.54;37.42) [23.18–41.16]	179.11 (130.26;203.53) [113.97–219.81]	0 (0;1)
	365 days	23.63 (20.19;28.04) [13.71–32.78] $p^{120-365} = 0.0326$	97.69 (89.55;146.54) [73.27–179.11] $p^{120-365} = 0.0009$	1 (0;1)
Experiment	120 days	42.65 (30.72;48.51) [25.86–52.42] $p^{c-e} = 0.0002$	219.81 (203.53;269.66) [187.25–284.94] $p^{c-e} = 0.0009$	3 (3;4)
	365 days	25.74 (22.43;28.57) [20.32–34.07] $p^{c-e} = 0.1301$ $p^{120-365} = 0.0001$	138.41 (113.97;162.82) [97.69–187.25] $p^{c-e} = 0.0141$ $p^{120-365} = 0.0011$	1 (0;1)

Note: The Mann – Whitney test was used; the differences were statistically significant at $p < 0.05$, p^{c-e} — comparison of control and experiment, $p^{120-365}$ — comparison of experimental term

Morphological characteristics of the synovial membrane of the carpal joint of the experimental limb

After 120 days of the experiment, a statistically significant ($p < 0.05$) increase in the thickness of the lining layer and the numerical density of synovial cells (Table 1), located in two to three layers (Fig. 3 a) were seen in the synovial membrane of the experimental joint relative to the control (Table 1). The proportion of macrophage-type synoviocytes increased (more than 50 % in the field of view). Such cells had an eccentrically located nucleus, cytoplasmic outgrowths, and foamy cytoplasm with granular inclusions (Fig. 3 b). In the upper collagen-elastic layer, cellularity was increased, and an inflammatory infiltrate of focal and diffuse distribution was revealed (Fig. 3 c) that consisted mainly of lymphocytes, plasma cells, and histiocytes. In some cases, the formation of synovial villi was noted (Fig. 3 d).

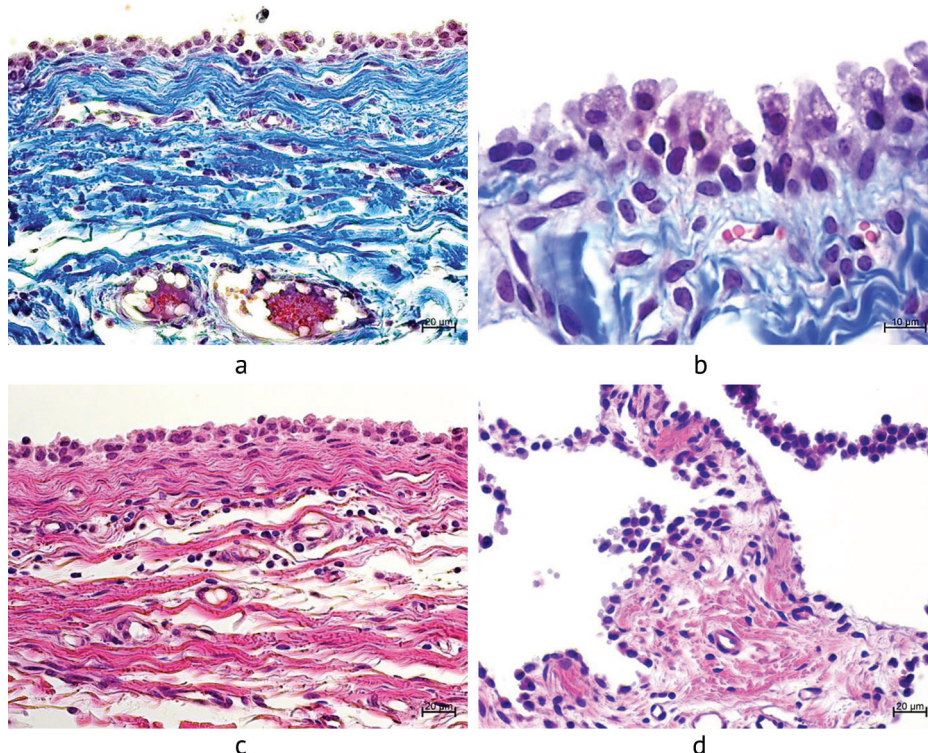


Fig. 3 Synovial membrane of the carpal joint of a lamb in the experiment time-point of 120 days: (a) lining and collagen-elastic layers; (b) macrophage-type synoviocytes; (c) diffuse and perivascular inflammatory infiltrate; (d) formation of synovial villi. Paraffin sections, stained with Masson's three-color method (a, b), hematoxylin and eosin (c, d). Magnification $\times 400$ (a, c, d), $\times 1000$ (b)

Semi-quantitative assessment of the synovial membrane according to Krenn et al. [18] revealed mild synovitis (Table 1).

After 365 days of the experiment, synoviocytes in the lining layer were arranged in one to three layers in most cases (Fig. 4 a); synovial cells had characteristics of the macrophage and fibroblast types (Fig. 4 b); a tendency towards a decrease in the proportion of macrophage-type cells (about 30 % in the field of view) compared to the previous period of the experiment and a decrease in the values of the thickness of the lining layer and the numerical density of synoviocytes were noted. Compared with the controls, the differences in the parameter "thickness of the lining layer" were statistically insignificant ($p > 0.05$), the values of the numerical density were statistically significantly ($p < 0.05$) higher (Table 1). Over a large area, the synovial membrane had a folded surface (Fig. 4 c). In the upper collagen-elastic layer, cellularity in most cases was normal, and inflammatory infiltrate was not detected.

Semi-quantitative assessment of the synovial membrane showed no synovitis (Table 1).

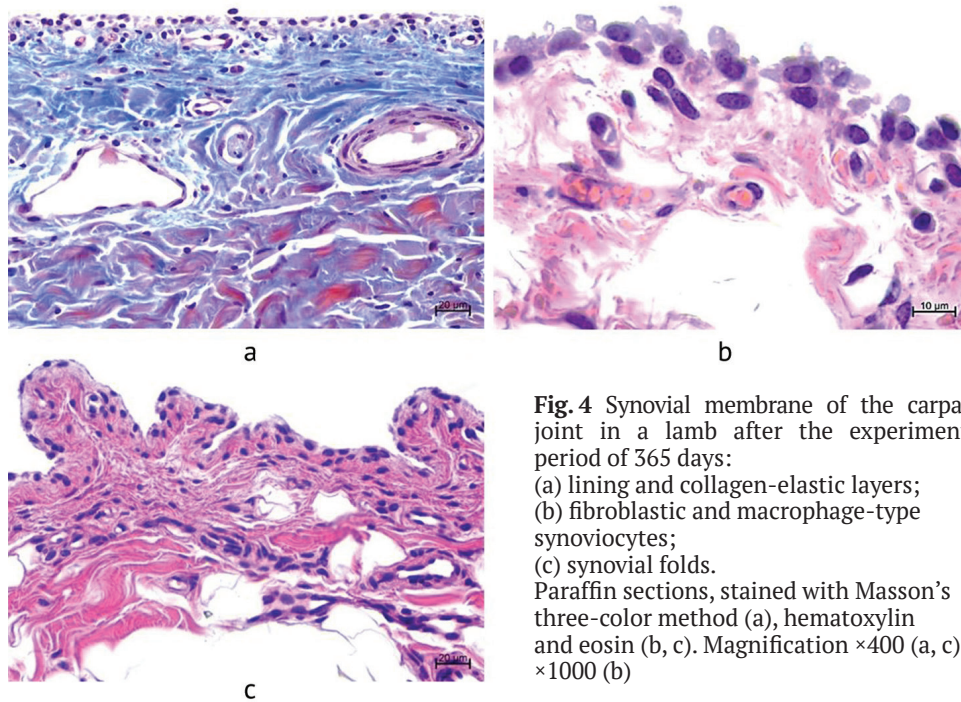


Fig. 4 Synovial membrane of the carpal joint in a lamb after the experiment period of 365 days:
(a) lining and collagen-elastic layers;
(b) fibroblastic and macrophage-type synoviocytes;
(c) synovial folds.
Paraffin sections, stained with Masson's three-color method (a), hematoxylin and eosin (b, c). Magnification $\times 400$ (a, c), $\times 1000$ (b)

DISCUSSION

The synovial membrane plays a key regulatory role in determining the composition of the synovial fluid and differs from other barrier membranes in its unique architecture. The intima (lining inner layer) of the human synovial membrane normally contains approximately 90 % fibroblast-like and 10 % macrophage-like synoviocytes. The collagen-elastic layer (subintima) consists of elastic and collagen fibers (collagen types I, III, IV, V, and VI), laminin, fibronectin, and proteoglycans. It also contains fibroblasts and macrophages, sympathetic and sensory nerves, blood and lymphatic vessels [19, 20].

For extrapolating experimental data to clinical settings, sheep are the most suitable animal model for studying the musculoskeletal system, as they are close to humans in terms of joint morphology, weight, and bone size [21, 22, 23]. There are a few publications in the literature on the structure of the synovial membrane of the sheep knee joint at different ages [24, 25]. Despite a growing understanding of the role of the synovial membrane in joint pathology, quantitative data on the structure and function of this tissue remain incomplete.

This study provides the first data on the structural reorganization of the synovial membrane of the sheep carpal joint at different ages. At 5.5 and 13.5 months of age, fibroblastic synoviocytes predominated in the synovial lining layer, and histological signs of synovitis were not detected. It was established that as the animals continued growing, the topography of the intimal layer changed from a smooth surface at 5.5 months to a folded surface at 13.5 months. Histomorphometric measurements revealed a decrease in the thickness of the intimal layer and the numerical density of synoviocytes, while light-optical measurements revealed an increase in the proportion of the fibrous component in the intimal layer.

In a number of experimental and clinical studies, signs of synovitis were detected during osteosynthesis of the limb segment adjacent to the joint [26] and after joint arthroplasty [27, 28]. In an experiment on adult dogs, tibial bone defect was managed using a combination of Ilizarov non-free bone grafting and the Masquelet method and signs of synovitis in the knee joint were

detected in 70 % of cases one month after removal of the apparatus [26]. Sugimura et al. report that the severity of synovitis reaches a peak six months after total knee arthroplasty and reduces after one to two years [28].

In this study, after 120 days of the experiment, the assessment according to Krenn et al. [18] showed mild synovitis in all animals. Structural changes in the synovial membrane were expressed by hyperplasia (due to thickening of the lining layer), an increase in the numerical density of synoviocytes and an increased number of macrophage-like synoviocytes (more than 50 % in the field of view), the formation of synovial villi, and the presence of lymphohistiocytic infiltrate of focal and diffuse types.

It is known that both types of synovial cells, macrophages and fibroblasts, perform various pro- and anti-inflammatory functions and can both prevent inflammation by forming an anti-inflammatory barrier that promotes the constant clearance of danger signals coming from the synovial fluid and accumulating due to mechanical stress, and contribute to synovial inflammation [29, 30]. Macrophage-type synoviocytes participate in phagocytosis, produce proteolytic enzymes that damage cartilage, and pro-inflammatory mediators, enhancing the immune response and activating fibroblast-like synovial cells. After activation, fibroblast-like synoviocytes secrete proinflammatory cytokines (TNF- α , IL-1 β and IL-6) and, through the expression of cadherin-11, CD44 and matrix metalloproteases, acquire migratory and invasive properties, forming synovial pannus [20, 31, 32].

Non-bioresorbable fixators used in osteosynthesis of intra-articular fractures can cause a number of complications, such as infection, persistent pain (most often due to synovitis), and arthritis. Titanium fixators (screws and plates) are widely used for osteosynthesis of fractures and in maxillofacial oncology due to their biocompatibility and favorable mechanical properties, which closely match bone elasticity [33, 34].

Under the experimental conditions studied, structural changes in the synovial membrane were reversible during osteosynthesis of an intra-articular metaepiphyseal fracture of the distal radius using titanium screws. By the end of the experiment, after 365 days, no histological signs of synovitis were detected. Fibroblast-like synoviocytes predominated in the synovial membrane, elevated synoviocyte density values persisted, and the thickness of the synovial membrane lining was comparable to that of the control.

CONCLUSION

Osteosynthesis of intra-articular metaepiphyseal fractures of the distal articular end of the radius in lambs using titanium screws provoke mild synovitis after 120 days of the experiment. This synovitis was characterized by thickening of the lining layer, an increase in the numerical density of synoviocytes and in the number of macrophage synoviocytes, and the presence of a lymphohistiocytic infiltrate. By the end of the experiment, the synovial membrane inflammation reversed, and histological signs of synovitis were absent.

Conflict of interest Not declared.

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Ethical statement The study was conducted in accordance with the principles of the European Convention ETS No. 123 for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (with the appendix of 15.06.2006, Strasbourg) and the rules of good laboratory practice (GOST 33044-2014, GOST 33215-2014, GOST 34088-2017, PS SanPiN 3.3686-21). Protocol of the institutional committee dates to 29.11.2024 No. 1 (76).

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Original article

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The surgical approach for osteosynthesis of metaepiphyseal fractures of the distal tibia

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Abstract

Introduction The optimal surgical approach is essential for osteosynthesis of intra-articular fractures of the distal tibial metaphysis (pilon fractures). None of the existing approaches provides complete visualization of the articular surface, increasing the risk of complications and inadequate reduction.

The **objective** was to optimize the choice of surgical approach in preoperative planning of internal osteosynthesis of intra-articular fractures of the distal metaepiphysis of the tibia (pilon) based on 3D prototyping and standardized marking of the articular surface.

Material and methods An algorithm developed was based on a full-size 3D prototype and CT data. The articular surface of the tibia was divided into nine standard zones. The surgical approach was selected depending on the location of the key fragment (occupying $> 2/3$ of the zone) or the fracture line exit point. The method was used in 12 patients with AO/OTA 43-C pilon fractures. Surgical time, blood loss, the quality of postoperative fracture reduction categorized according to the Burwell-Charnley criteria, functional outcomes measured with AOFAS and VAS FA grading scales, and radiographic union determined with the mRUST scale were assessed at six months.

Results and discussion The mean operating time was (65.08 ± 7.03) min, blood loss was (119.3 ± 18.51) ml. The wounds healed by primary intention without infectious complications. The quality of reduction was anatomical in eight patients and acceptable in four patients. The mean AOFAS (78.67 ± 8.68) and VAS FA (41.08 ± 5.05) scores indicated good functional recovery. The mean mRUST score (13.5 ± 1.43) suggested complete consolidation. The method objectified the surgical approach avoiding subjectivity and allowed for personalized intervention by combining approaches for optimal visualization of all fragments, including hard-to-reach ones (e.g., Tillaux-Chaput fragment).

Conclusion The method integrating 3D planning and a standardized coordinate system improves reposition accuracy, reduces morbidity, and improves functional outcomes in patients with complex pilon fractures.

Keywords: intra-articular fracture, distal tibia metaepiphysis, pilon fracture, 3D-model, surgical approach, osteosynthesis, selection algorithm

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INTRODUCTION

Osteosynthesis of metaepiphyseal fractures of the distal tibia is a procedure that requires high surgical skill and clinical equipment. Surgical approach, surgical technique, timing of the procedure and postoperative rehabilitation are essential for successful outcome. Pilon fractures often result from high-energy trauma and are accompanied by massive destruction of the articular surface of the tibia and severe damage to the soft tissue. Careful treatment of soft tissues during the surgical approach is essential for healing. A variety of surgical approaches to the distal tibia have been reported to include medial, anteromedial, anterolateral, lateral, posterolateral and posteromedial approaches. Each of the approaches allows for visualization of a portion of the pilon to reduce the corresponding fragment of the articular surface [1]. The concept of osteosynthetic stability forms the basis of the column theory. According to the theory, the distal tibia is divided into three columns (lateral, medial, and posterior) with each requiring separate fixation. This often necessitates a combination of different approaches. The main problem is that increasing their number during surgical intervention allows for greater stability of the construct increasing the risk of complications (infection, soft tissue necrosis, non-union), which poses a difficult task for the surgeon with the optimal balance to be found between reliable fixation and minimal surgical trauma [2]. Mayorov et al. developed the concept of "preoperative 360° visualization", which is based on a comprehensive analysis of radiographic and CT findings [3]. The concept allows for a detailed study of the individual characteristics of the fracture architecture, precise visualization of all components of the injury, determination of the most appropriate surgical approaches, selection and optimal placement of implants. The approach enables thorough preoperative planning improving the precision of the surgical intervention. However, the study does not provide a clear step-by-step algorithm for selecting a surgical approach. Fracture morphology would be a key point in the approach to be selected. Cole et al. examined the distribution of fracture lines and the location of major bone fragments in 38 cases of comminuted AO/OTA 43-C3 fractures of the distal metaphysis of the tibial tuberosity and concluded that a good understanding of fracture morphology should guide the choice of surgical approach [4]. However, this study did not provide a detailed explanation of how to choose a surgical approach based on the specific distribution of fracture lines and bone fragments.

Kleinetz et al. explored the effectiveness of four surgical approaches to the distal tibia (anteromedial, anterolateral, posteromedial, and posterolateral) and the effect of instrumental distraction on the visualization of the articular surface using cadaveric material [5]. In the study, the authors used a standardized technique for marking the articular surface to objectively assess the accessibility of various anatomical zones through surgical approaches: the articular surface was divided into segments to enable a quantitative assessment of which part is accessible and corresponds to each of them.

The markings were performed using a coordinate system based on anatomical landmarks (e.g., the anterior and posterior edges of the articular surface). A unique identifier was assigned for each zone to facilitate comparison of the accessibility of areas between different surgical approaches. For each approach, the percentage of the articular surface visible was assessed with and without distraction. Visible zones were marked, and the percentage of accessible surface was calculated using specialized software. The researchers concluded that most approaches provided extremely limited visibility without distraction, with maximum visibility achieved with the posterolateral approach (30 %) and minimum visibility seen with the anteromedial approach. With distraction, visibility of the articular surface increased significantly, with the anterolateral (up to 72 %) and anteromedial (up to 63 %) approaches, in particular. However, neither approach provided complete visualization of the articular surface.

Three-dimensional technologies used for planning of surgical treatment of patients with fractures of the distal metaepiphysis of the tibial tuberosity are reported by Parshkov et al. [6]. Compared with traditional methods, the use of 3D technologies for planning osteosynthesis of pilon fractures, including the choice of surgical approach, allowed us to achieve a significant reduction in surgical time, in intraoperative blood loss and in radiation exposure. The quality of bone reduction and functional treatment outcomes were significantly better in the 3D group.

However, analysis of the outcomes revealed some errors and complications, which can be divided into three groups:

- 1 – Three-dimensional model preparation and printing errors. Initially, there were issues with CT data segmentation (inclusion of artifacts, missing small fragments), printing defects due to low-quality filament, and incorrect printer calibration. These were resolved by manually correcting the STL files and using higher-quality materials.
- 2 – Errors in planning of a surgical approach. An extended incision was required in 4 % of cases in the 3D group and in 7 % of the controls.
- 3 – Postoperative complications. Wound dehiscence occurred after suture removal in one patient of the 3D group and in two controls. In all cases, the dehiscence width did not exceed 3 mm and its length did not exceed 2 cm. Sterile skin strips were used for treatment; re-suturing was not required. No deep suppuration was observed in either group.

While clear and effective methods exist to prevent complications of the first group (errors in preparing and printing 3D models), preventing complications of the second and third groups requires optimizing surgical approach(es) that can be difficult to identify. Therefore, there is no universal surgical approach. An optimal algorithm to be employed for surgical approach requires a compromise between visualization and the risk of complications considering the condition of the soft tissues.

The **objective** was to optimize the choice of a surgical approach in preoperative planning of internal osteosynthesis of intra-articular fractures of the distal metaepiphysis of the tibia (pilon) based on 3D prototyping and standardized marking of the articular surface.

MATERIAL AND METHODS

Description of the method

A 3D prototype was produced as part of preoperative planning using computed tomography (CT) and DICOM files that were converted to STL format and printed on a 3D printer. Markings were made on the articular surface using the results of the cadaveric study reported by Kleinertz et al. [5] connecting the extreme anterior point and the extreme posterior point on the distal aspect of the tibia adjacent to the medial malleolus, and the segment was considered as the inner side of the square. The posterior, lateral, and anterior sides were completed accordingly. The resulting large square was divided into nine equal internal squares, smaller in size: anteromedial, anterocentral, anterolateral, midmedial, midcentral, midlateral, posteromedial, posterior central and posterolateral (Fig. 1), corresponding to nine zones located on the articular surface.

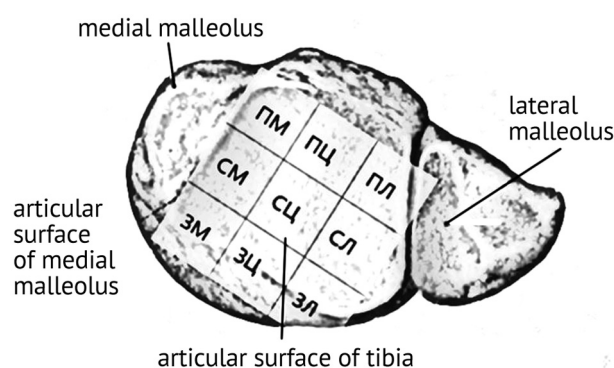


Fig. 1 Marking of the articular surface of the pilon included anteromedial (AM), anterocentral (AC), anterolateral (AL), mid-medial (MM), mid-central (MC), mid-lateral (ML), posteromedial (PM), posterior central (PC), posterolateral (PL) aspects

The largest fragment was identified on the articular surface of the 3D prototype (hereinafter referred to as the key fragment) and reduced first with the coordinates determined on the markings. If more than two-thirds of the fragment corresponded to a specific square, the coordinates were assigned to that square. If two fragments of the same size were present, two approaches were selected in the same manner. If a fragment was located within two or more squares, the coordinates of the fracture line exiting onto the anterior or posterior surface were determined, rather than the fragment itself. The method proved to be inappropriate in the absence of fragments covering more than two-thirds of the fragments with treatment using a compression-distraction device.

Depending on the location of the fragment and the exit point of the fracture line in a certain square, an approach was chosen from the classical approaches of AO described:

Square	Approach
anteromedial	anteromedial
anterocentral	anterolateral
anterolateral	Передне-латеральный
mid-medial	Задне-медиальный
mid-central	anterolateral, задне-латеральный
mid-lateral	anterolateral, задне-латеральный
posteromedial	posteromedial
posterior central	posterolateral
posterolateral	posterolateral

anteromedial (AM), anterocentral (AC), anterolateral (AL), mid-medial (MM), mid-central (MC), mid-lateral (ML), posteromedial (PM), posterior central (PC), posterolateral (PL) aspects

The study was conducted between January 1, 2024 and December 31, 2024 at the Trauma Department of the University Clinic of the N.A. Semashko Scientific and Educational Institute of Clinical Medicine of the Russian University of Medicine. The study was approved by the Ethics Committee of the Russian University of Medicine (protocol No. 12-23 dtd December 15, 2023).

The study included 12 patients with intra-articular fractures of the distal metaepiphysis of the tibia (10 patients with type 43C2 and two patients with type 43C3). The fractures were repaired with an external fixator upon admission. With the frame applied CT findings were used to create a 3D model to determine the surgical approach according to the specified technique. Internal osteosynthesis was performed with the edema settled. The period between the dates of hospitalization and surgery was (8.2 ± 3.2) days. Duration of the intervention and volume of blood loss were assessed intraoperatively using the gravimetric method. The surgery time was (65.08 ± 7.03) minutes, blood loss was (119.3 ± 18.51) ml.

The postoperative wounds healed on time, no purulent-inflammatory complications were registered. The effectiveness of reposition was assessed according to the Burwell-Charnley criteria [7]: the result was rated as anatomical ($n = 8$) and fair ($n = 4$). No poor outcomes were observed. Functional results were assessed at six months using the AOFAS AHS scale [8] and the VAS FA visual analogue scale [9]. AOFAS scored (78.67 ± 8.68) and VAS FA scored (41.08 ± 5.05) that suggested a good functional recovery of the ankle joint and a high degree of patient satisfaction. The fracture consolidation index according to the modified mRUST scale [10] measured (13.5 ± 1.43) suggesting complete fracture consolidation.

Clinical instance

A 52-year-old patient was diagnosed with a closed, multi-comminuted, intra-articular fracture of the distal metaphysis of the left tibia with bone displacement. The trauma resulted from a fall from a four-meter height onto straight legs. Six hours after admission, the left tibia and the foot were fixed with an external fixator. Then a CT scan was produced to allow a full-size 3D prototype to be fabricated (Fig. 2). The articular surface of the prototype was marked (Fig. 3), and the key fragments were identified on posterolateral and anterolateral aspects and the fracture exit points determined in the antero-central and posteromedial quadrants.



Fig. 2 3D reconstruction of computed tomography data of the fracture and the 3D prototype

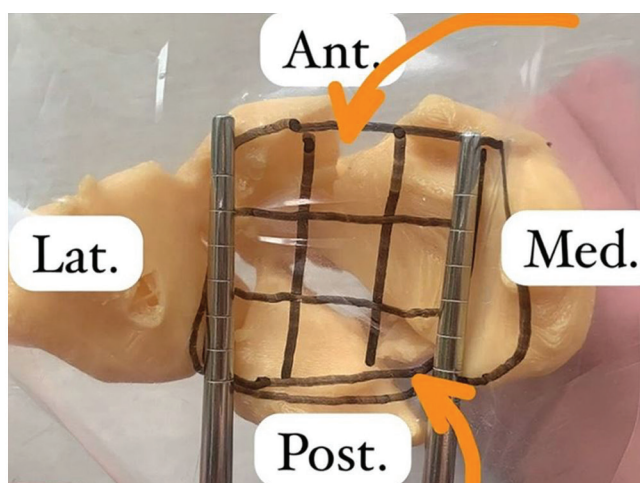


Fig. 3 Marking the articular surface of the 3D prototype indicating the exit points of the fracture lines on the anterior and posterior aspects of the tibia

Posteromedial and anterolateral surgical approaches were used based on the data obtained. Osteosynthesis was performed using these approaches and an anterolateral plate and a 1/3 tubular plate were placed posteriorly (Fig. 4). The posteromedial approach allowed for complete visualization of the posterior aspect of the broken tibia, the bone reduced ad oculos, and the 1/3 premodeled tubular plate placed using a 3D prototype. The patient was then turned supine, and an anterolateral approach was performed. The metadiaphyseal component of the fracture was fixed with an anterolateral premodeled L-plate, and the anterolateral fragment (Chaput) was fixed with a screw. The approach allowed for visualization of the anterior edge of the fibular notch for precise reduction of the Chaput fragment.

The postoperative period was uneventful, and the wounds healed by primary intention.

The patient was encouraged to exercise the operated ankle joint for eight weeks. The treatment outcome was rated as satisfactory at a six-month follow-up examination. The AOFAS AHS scored 82 and the VAS-FA scored 41 suggesting excellent results. Radiographs (Fig. 5) showed a mRUST score of 13 being consistent with a fracture in the consolidation stage. No signs of fixator migration or secondary displacement were detected.



Fig. 4 AP and lateral intraoperative views



Fig. 5 Radiographs at a 6-month follow-up

DISCUSSION

Understanding the precise morphological characteristics of a distal tibial metaphysis fracture is a key to successful treatment. The classical surgical approaches offered by T. Ruedi and M. Allgower for repair of pilon fractures are widely used today. However, the morphological variations of these fractures are extremely diverse, and mechanically copying these principles and surgical approaches can lead to unexpected outcomes and treatment failure in some severe cases.

Assal et al. recommend choosing a surgical approach based on the biomechanics of the injury in order to place a support plate on the compression side [11]. Experts from the AO group, Buckley and Sands, suggest taking into account the size of the anterolateral fragment when choosing an approach [12]. An anteromedial approach can be recommended for larger fractures and fractures with the proximity to the medial malleolus. An anterolateral approach is practical for smaller anterolateral fragments and a more lateral location of the fracture plane. The disadvantage of this method includes the lack of definition of the anterolateral fragment, clear criteria for a “larger” or “smaller” size, and “proximity of the fracture line to the medial malleolus.”

Liu et al. reported a meta-analysis of 19 articles (733 patients) on surgical approaches and treatment outcomes in open reduction and internal fixation of pilon fractures and found out 30 % of operations were performed using the anterolateral approach. The average complication rate was 16 %, the lowest rate was observed with the medial (11.7 %) and anterior (11.8 %) surgical approaches, the highest rate of adverse events seen with the posterolateral (23 %) and anteromedial (22.8 %) approaches. The most severe complications were recorded with the anterolateral approach (12 cases). The most common complications included wound dehiscence (21 %), delayed union or nonunion (19 %) and soft tissue infection (17 %). The difference in complication rates could be associated with the surgical approach, the fracture type or other factors including surgical technique, operative time, use of antibiotics. There was no comparison between different surgical approaches [13]. Babovnikov et al. reported the use of an arcuate postero-internal approach and extended incision to the anterior aspect if needed in case of fragmentation of the posterior and medial portions of the tibial metaepiphysis [14]. The approach could ensure good visual control of the entire articular surface. An anterior approach could be used along the medial edge of the tendon of the tibialis anterior muscle with impaired anterior and central parts of the articular surface of the metaepiphysis with an arcuate continuation to the lateral aspect along the anterior articular surface. This study, systematizing extensive clinical experience in the treatment of patients with intra-articular fractures of the distal tibial metaepiphysis, had limitations. The choice between the only two approaches

reduces possibilities of visualization and fixation of the bone fragments. Neither approach can provide a complete overview of the anterolateral fragments (Chaput), which may worsen the accuracy of reposition and long-term results. In addition, the postero-medial approach can be associated with a risk of injury to the neurovascular bundle.

Urrutia et al. reported a comprehensive cadaveric analysis comparing eight distinct surgical approaches to tibial pilon fractures and found that the anteromedial approach yielded the largest exposed area (18.36 cm²), whereas the anterolateral approach provided the greatest exposed segment (72°). The posteromedial approach proved most effective for exposing the Volkmann fragment, and the anterolateral approach was optimal for accessing the Tillaux – Chaput fragment [15].

Puha et al. offered CT scans to be used for assessment of the articular surface of the tibia with external fixator in place. The authors distinguished medial, central, anterior, and lateral fragments; a medial approach was chosen for fixation of the medial and central fragments, an anterior approach to be used for fractures with predominantly anterior fragments, and an anterolateral approach for fractures with a large lateral component or for simultaneous fixation of the fibula [16].

Mironov et al. suggested using Tang's four-column classification when choosing a surgical approach with the anterior-medial approach being practical for severe injury to the medial column; the anterolateral approach to be employed for injuries to the lateral column; and the posterior approach to be used for damage of the posterior column [17]. However, no mention of the method was there with regard to simultaneous injury to several columns, and the approach was not specified for cases of posterior column damage.

Cole et al. explored distribution of fracture lines and the position of the main fragments in 38 patients with comminuted intra-articular fractures of the distal metaepiphysis of the tibial femur using CT scans and noted three major fragments in the anterolateral, medial, and posterolateral zones. The authors emphasized that understanding of the fracture morphology facilitated a rational choice of surgical approach [4]. No specific algorithm was offered for approach selection. Many authors reporting treatment strategies for the fractures would recommend the use of CT data when choosing an approach [18-20].

Zhao et al. suggested that a CT-based surgical approach would allow for precise restoration of the articular surface and stable fixation of the fracture to ensure good functional outcomes and reduced complication rate. A posteromedial approach can be used in the presence of large posterior fragments extending into the tarsal canal or medial malleolus, while the anterior tibial femur and fibular fractures can be visualized through an anterolateral approach. A posterolateral approach can be used to reduce the posterior fragment of the tibia and lateral malleolus in case of small posterior malleolar fragments without extension into the tarsal canal, and the anterior fragments can be visualized through an anteromedial approach with correction of the incision position depending on the location of the central impression fragment [21]. An advantage of the method is associated with use of CT findings. However, the authors of this publication focused on the posterior portions of the ankle joint, preventing the approach from being universal across the entire range of morphological variants of pilon fractures.

Unlike previous studies, the method offered an objective quantification of the location of key fragments using standardized markings of the articular surface. This eliminates subjectivity in the approach selection and allows for precise determination of which fragment requires primary reduction. This method allows for a combination of classic approaches depending on a specific

fracture morphology, ensuring better visualization of all fragments, including the anterolateral (Chaput) aspects to reduce the risk of inadequate reduction. The method can address injuries to multiple columns suggesting specific approaches for each case, including posterior fragments (e.g., posterolateral or posteromedial approaches). The method is based on 3D prototyping to allow precise fracture modeling and determination of optimal approaches, reducing the risk of soft tissue necrosis, optimizing fragment visualization, reducing the incidence of infectious complications and wound dehiscence.

CONCLUSION

The method developed is a synthesis of modern 3D planning technologies, standardized topographic analysis, and a personalized approach. Its implementation in clinical practice The modality can optimize the choice of surgical approach for osteosynthesis of pilon fractures, improving the reduction, stability of fixation and providing a safe procedure. The approach facilitates improved surgical treatment of patients with complex intra-articular fractures of the distal tibial metaphysis.

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Surgical treatment of chronic longitudinal radioulnar dissociation (Essex-Lopresti injury)

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Abstract

Introduction An Essex-Lopresti lesion is a fracture of the radial head and a rupture of the interosseous membrane of the forearm, resulting in disruption of the longitudinal relationship between the radius and ulna, leading to longitudinal radioulnar dissociation. Most Essex-Lopresti injuries are diagnosed late, and surgical treatment is challenging even for an experienced orthopaedic surgeon.

The **objective** was to demonstrate and analyze the results of multicomponent surgical treatment first applied for a patient with a chronic Essex-Lopresti injury.

Material and methods A 29-year-old patient was diagnosed with a chronic Essex-Lopresti injury first treated with multicomponent surgical treatment including replacement of the radial head, Adams – Berger ligament reconstruction for the distal radioulnar joint, ulnar corrective shortening osteotomy, interosseous membrane reconstruction using synthetic graft, lateral ulnar collateral ligament reconstruction with an autograft.

Results Pain improved and range of motion increased in adjacent joints at six months. A follow-up X-ray of the forearm showed a consolidating fracture of the ulna.

Discussion Multicomponent surgical treatment of chronic Essex-Lopresti injury ensures restoration of the anatomical relationships of the forearm bones and correction of associated ligamentous injuries improving clinical and functional outcomes even with delayed treatment. Early diagnosis and timely reconstruction of the forearm structures are essential for prevention of irreversible changes providing functionality of the upper limb.

Conclusion The study demonstrated the potential of a multi-component surgical approach as a single-stage treatment for patients with chronic Essex-Lopresti injury.

Keywords: elbow joint instability, forearm instability, radioulnar dissociation, reconstruction of the forearm interosseous membrane, distal radioulnar joint plasty, corrective osteotomy, Essex-Lopresti injury

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INTRODUCTION

An Essex-Lopresti injury, or longitudinal radioulnar dissociation, is characterized by damage to the radial head, interosseous membrane, and distal radioulnar joint, caused by high-energy trauma [1]. An Essex-Lopresti injury is relatively rare among musculoskeletal injuries, accounting for less than 1 % of all radial head fractures [1, 2], but is one of the most severe forearm injuries.

The forearm is normally stabilized by the integrity of the bony and soft tissue stabilizers at the elbow and distal radioulnar joints, as well as the interosseous membrane between the radius and ulna. An injury missed and undiagnosed or not treated in time can lead to longitudinal instability of the forearm or longitudinal radioulnar dissociation [1]. An Essex-Lopresti injury results from an axial load on the forearm caused by a fall on an outstretched arm with the mechanical force being transmitted from the wrist to the elbow through the forearm bones [2].

This rare condition was first described by Curr and Coe in 1946 [3]. In 1951 Peter Essex-Lopresti described the injury as a fracture of the head of the radius, rupture of the interosseous membrane and triangular fibrocartilaginous complex [4, 5]. However, the Essex-Lopresti injury (ELI) of the forearm is a rare and serious condition which is often overlooked due to the lack of knowledge of this pathology in the medical community [6], leading to a poor outcome in 80 % of cases [7].

Surgical interventions used to treat patients with Essex-Lopresti injuries, include radial head arthroplasty [8, 9, 10]; interosseous membrane reconstruction [11–15]; ulnar shortening osteotomy combined with distal radioulnar joint reconstruction [16, 17]. There is no standardized approach to treatment of this cohort of patients.

The **objective** was to demonstrate and analyze the results of multicomponent surgical treatment first applied for a patient with a chronic Essex-Lopresti injury combined with varus instability of the elbow joint.

MATERIAL AND METHODS

A 26-year-old man was admitted to the Trauma and Orthopedic Department of Volgograd Regional Clinical Hospital No. 1 in June 2024. He reported pain and limited range of motion in his left upper limb due to an injury to his left forearm sustained in January 2024, resulting from a fall from a height of 2–3 meters. Immediately after the injury, he was admitted to the emergency department and a radiograph of his left elbow showed a fracture-dislocation of the head of the left radius. With the plaster cast applied, the patient was referred to the inpatient trauma and orthopedic department. He was examined by the department's specialists who recommended conservative therapy. Over the next four months, treatment recommended by specialists at other clinics included exercise therapy, physical therapy, and removal of the radial head without any reconstructive interventions.

The VAS scored 5. Local status of the left upper limb showed forearm flexion of 120°, forearm extension of 140°, pronation of 45°, supination of 50°, wrist extension of 45°, wrist flexion of 20° (Fig. 1). Computed tomography of both forearms revealed a comminuted consolidated fracture-dislocation of the head of the left radius, head of the left ulna dislocated relative to the distal portion of the left radius by 7 mm (ulna "+") (Fig. 2).

The Essex-Lopresti injury was first diagnosed based on the above complaints, local status and radiographic data [3]. A combined procedure involving radial head replacement, distal radioulnar joint reconstruction, corrective ulnar osteotomy, and interosseous membrane grafting were recommended for the patient. The patient was informed of adverse events and complications, and consent for surgical treatment was obtained.



Fig. 1 Preoperative range of motion showing (a) flexion and extension of the forearm; (b) pronation and supination; (c) extension and flexion of the wrist



Fig. 2 Computed tomography of the left and right forearms

The surgery was performed on July 11, 2024 as planned. The first stage involved a Kocher approach to the radial head. The approach revealed a chronic injury to the ulnar lateral collateral ligament of the elbow and degenerative fiber changes. The radial head was removed. Trial components of the head and endoprosthetic stem were inserted to compensate for the length of the lost bone. A cemented stem with a 24–12 mm modular head (ChM, Warsaw, Poland) was impacted (Fig. 3). The next step included radiographic control of the wrist joint (Fig. 4a),

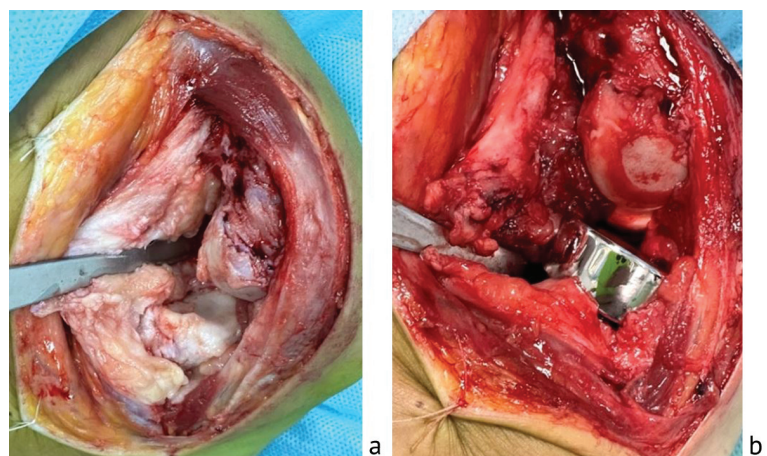


Fig. 3 Lateral approach to the elbow joint showing (a) the radial head and humeral condyle; (b) endoprosthetic radial head implanted

access to the lower third of the forearm, shortening corrective osteotomy of the ulna, fixation with an AO LCP titanium plate, and Adams – Berger reconstruction of the distal radioulnar articulation with a braided FiberWire thread (Arthrex, Naples, FL, USA) (Fig. 4b) [17, 18]. The distal radioulnar articulation was additionally fixed with a Kirschner wire.

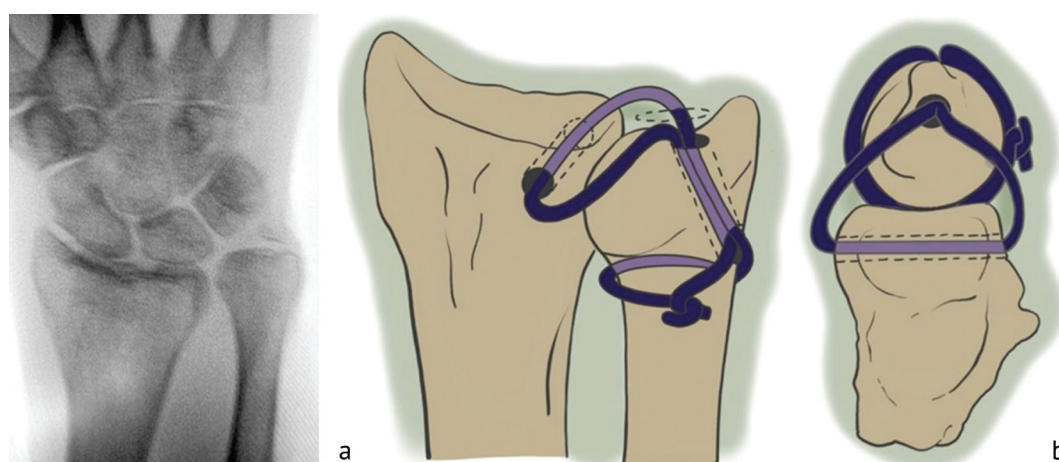


Fig. 4 Radiograph before osteotomy and diagram of the distal radioulnar joint operation: (a) AP radiographic view showing the wrist joint, ulna “+”; (b) schematic technique of the Adams – Berger ligament reconstruction

Access to the middle third of the radius was obtained. A Kirschner wire was placed through the radius and ulna in such a way that with the holes formed for the graft placement, the angle relative to the long axis of the ulna was approximately 21° and corresponded to the force vector of the central bundle of the interosseous membrane. The exit points of the wires from the cortical layers facing the interosseous membrane were located at 35 % of the ulna length and 55 % of the radius length from the styloid processes, which corresponded to the anatomy of the central part of the interosseous membrane [11]. Bone tunnels were created through the wires using a cannulated drill. An artificial graft with TightRope (Arthrex) buttons was placed with the forearm being in a neutral position (Fig. 5).

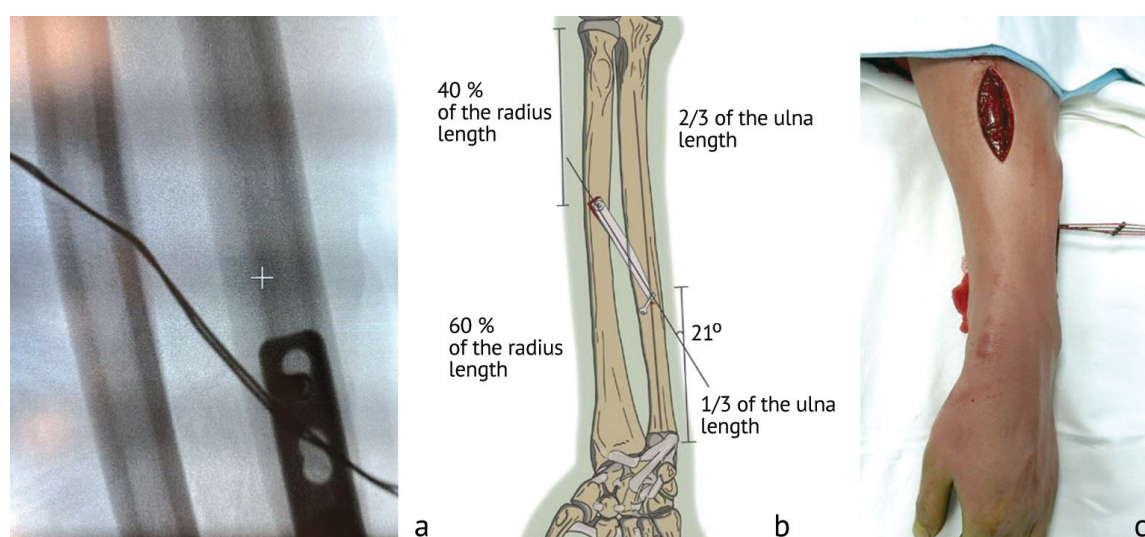


Fig. 5 Reconstruction of the interosseous membrane: (a) a guide for the interosseous ligament; (b) a schematic location of the interosseous ligament graft; (c) an artificial interosseous ligament graft implanted

The final stage included autografting of the ulnar lateral collateral ligament using a fragment of the triceps brachii aponeurosis fixed to the humerus and ulna with titanium Corkscrew (Arthrex)

anchors (Fig. 6). Radiographic examination was performed (Fig. 7). A plaster cast was applied postoperatively from the upper third of the humerus to the metacarpal heads with the elbow joint positioned at 90° and the wrist extended at 15°.

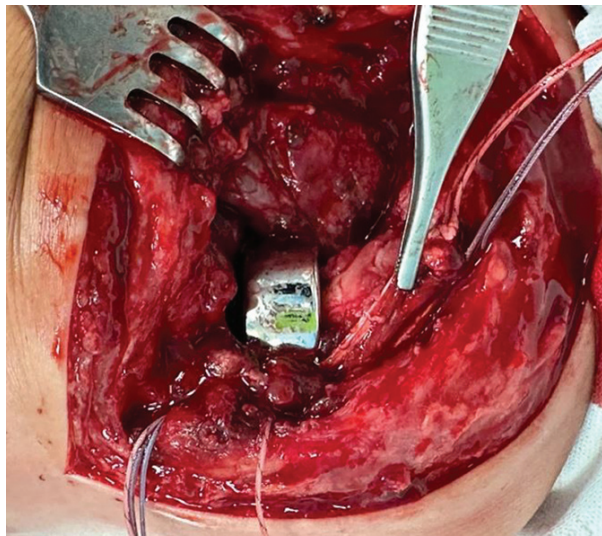


Fig. 6 Plastic surgery of the ulnar lateral collateral ligament using a fragment of the triceps aponeurosis. Endoprosthesis radial head, anchor threads



Fig. 7 Postoperative radiographs of the forearm

RESULTS

The postoperative period was uneventful. The sutures were removed after 12 days. Exercise therapy was administered for the elbow after two weeks. The Kirschner wire was removed after six weeks, and exercise therapy initiated for the wrist.

The surgery was followed by six-month rehabilitation. Follow-up radiographs and CT scans were performed at six months. Radiographs of the forearm showed a healing ulna fracture (Fig. 8).



Fig. 8 Radiographs of the upper limb at six months of surgery

The pain VAS scored one on examination. The Mayo wrist score indicated good functionality [19]. The range of motion increased in the left hand with the forearm flexion measuring 160°, forearm extension of 170°, pronation of 85°, supination of 75°, wrist extension of 65°, wrist flexion of 45°

(Fig. 9). The patient could participate in everyday life and return to his professional activities as a tent manufacturer.



Fig. 9 Range of motion at six months of surgery: (a) flexion and extension of the forearm; (b) pronation and supination; (c) extension and flexion of the wrist

DISCUSSION

Restoration of the forearm stability after an Essex-Lopresti injury is challenging, as there is no definitive treatment strategy [5]. It is impossible to predict the outcome of an undiagnosed Essex-Lopresti injury in each individual case, due to its rarity, low awareness among physicians, and the failure to perform additional diagnostic tests (computed tomography, radiography of adjacent joints).

The clinical observation demonstrates a successful approach to the treatment of chronic, undiagnosed Essex-Lopresti injury that resulted from initial strategy failure.

Five mutually complementary interventions to be simultaneously implemented are the key elements of the surgical approach offered:

- the congruence to be restored in the proximal radioulnar joint through replacement of the radial head [8–10];
- reconstruction of the interosseous membrane [11–15];
- reconstruction of the distal radioulnar ligaments using a Adams – Berger technique [16,17];
- osteotomy of ulna [16,17];
- autografting of the lateral ulnar collateral ligament [20].

It is important to note that the five components combined within a single operation has not been reported in the available literature, which emphasizes the novelty of the case presented.

Restoration of the interosseous membrane is essential for the longitudinal stability of the forearm in patients with Essex-Lopresti injury. A variety of methods offered for the purpose include: single- or double-bundle technique using sutures [12], use of a fascia lata allograft [13], autografting from hamstrings when an allograft cannot be used [14], and use of a bone-tendo-bone (BTB) patellar tendon graft [15].

An artificial graft with TightRope buttons (Arthrex) was used in our case. In case of a concomitant injury to the ligamentous stabilizers of the elbow joint reconstruction is to be considered [20, 21]. Autografting of the lateral ulnar collateral ligament was produced for our patient. Comprehensive restoration of all major stabilizers of the forearm prevents recurrent instability and is an important factor in preventing post-traumatic arthritis [22].

Increased range of motion, reduced pain intensity were observed at a six-month follow-up, and the patient could return to daily activities without significant limitations at work and at home, which confirms the effectiveness of the integrated approach.

Despite the limitations associated with the single-case study design, the results obtained are encouraging and suggest the potential value of the comprehensive approach to treating the challenging cases. The surgical team should be prepared to potentially expand the surgical procedure and reconstruct as many forearm stabilizers as possible.

CONCLUSION

This clinical case was the first to demonstrate the feasibility and effectiveness of a single-stage, multicomponent surgical intervention in the treatment of a patient with a chronic Essex-Lopresti injury. The uniqueness of the approach lies in the synergistic combination of radial head replacement, interosseous membrane reconstruction with an artificial graft, distal radioulnar joint reconstruction using the Adams – Berger technique, ulnar osteotomy, and autografting of the ulnar lateral collateral ligament. The treatment strategy resulted in significant functional improvement in a specific patient, ensuring forearm stability and pain relief.

Conflict of interest None of the authors has any potential conflict of interest.

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Ethical Approval The study was conducted in accordance with ethical standards and legislation of the Russian Federation.

Informed consent The patients gave informed consent for publication of the findings without identification.

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Clinical case

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Polysegmental distraction osteosynthesis in combination with a telescopic transphyseal rod for Ollier's disease

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Abstract

Introduction The use of combined techniques for long bone lengthening in patients with Ollier disease is of interest due to issues of both external fixation time reduction and improvement in the strength properties of the lengthened bone. The uniqueness of the presented clinical case is simultaneous femur and tibia lengthening over a titanium telescopic rod in the femur and tibia combined with external osteosynthesis and osteotomies.

The **purpose** of this study is to demonstrate the stages and results of polysegmental bone lengthening in a child with Ollier disease using a technique combining the Ilizarov fixator and a titanium telescopic rod.

Material and methods This clinical case is a five-year-old patient with Ollier disease without comorbidities, but with a significant discrepancy in the length of the lower limbs, impaired weight-bearing ability, and impaired gait biomechanics. Surgical treatment included multisegmental femur and tibia lengthening over a titanium telescopic rod inserted retrograde into the femur and antegrade into the tibia, simultaneous osteotomies and placement of a wire-and-halfpin external fixator.

Results Exceptional data were obtained confirming the possibility of the titanium telescopic rod extension during distraction by more than 20 % without locking or loss of fixation of the threaded parts in the epiphyses. The elongation amounted to 11.4 cm (femur: 5.8 cm; tibia: 5.6 cm). The overall external fixation index was 12.02 days/cm. At a 12-month follow-up after dismantling the Ilizarov apparatus, growth of the elongated bones and telescoping of the femoral rod continued.

Discussion This combined technique is consistent with the current concept of extended telescopic reinforcement in children with genetic diseases. The divergence of the titanium rod components both during the distraction period and during the first year after completion of limb lengthening demonstrates the feasibility of this combination and the reliability of using a telescopic titanium rod. This study demonstrates for the first time that rapid divergence does not predispose to locking of titanium rods and continues with growth.

Conclusion This case demonstrates the effectiveness of using a combination of telescopic intramedullary titanium rods and external fixation for simultaneous lengthening of two adjacent segments in a child with Ollier disease. The findings on further natural growth of the lengthened segments along with telescoping of the rod are unique.

Keywords: telescopic rod, Ollier disease, limb lengthening

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INTRODUCTION

Multiple enchondromatosis, or Ollier disease, is a rare pathology of the human skeleton (one case per 100,000), characterized by multiple enchondromas or cartilaginous masses in the metaphyseal and diaphyseal regions of long and/or short bones of the extremities [1–4]. Treatment of diseases accompanied by low bone strength properties (Ollier disease, osteogenesis imperfecta, polyostotic fibrous dysplasia, metabolic osteopathies) is symptomatic and aimed at eliminating and preventing significant bone deformities. Intramedullary telescopic rodding is a key element of osteosynthesis [5–10]. Reinforcement technologies simultaneously used with external fixation have been described in foreign and domestic literature [8–12]. Lengthening over a rigid rod using an external fixator or its analogues eliminates the risk of fractures after removal of the external fixator and significantly shortens the rehabilitation period [13–16]. In pediatric orthopedics, telescopic rods inserted transphyseally for deformity correction and fixed in the proximal and distal epiphyses provide bone reinforcement throughout the body growth period [6, 16–18]. The uniqueness of the clinical case presented is due to the combination of simultaneous femur and tibia lengthening over a titanium telescopic rod implanted in the femur and tibia simultaneously with external osteosynthesis and osteotomies.

The **purpose** of this study is to demonstrate the stages and results of polysegmental bone lengthening in a child with Ollier disease using a technique combining the Ilizarov fixator and a titanium telescopic rod.

MATERIAL AND METHODS

A patient with radiographically and genetically confirmed Ollier disease and no concomitant somatic diseases applied for surgical treatment at the age of five. Prior to his presentation to the Ilizarov Center, the patient had not undergone any surgical treatment. Shortening of the femur and tibia had increased as the child grew and was 18 cm at hospitalization.

Chondromatous lesions were located in the proximal and distal femur and tibia, affecting the epimetaphyseal zones. They were thickened bone sections with typical mineralization defects and alternating areas of mineralization and radiolucent inclusions (Fig. 1). Functional limitations included decreased walking ability, the need for assistance, and the use of shoes with significant compensation for the shortening of the left lower limb.

For studying the child's treatment outcomes, we identified key points of his examination: admission, surgery, day 10 and day 30 of distraction phase, the end of distraction, achievement of union, the period immediately after removal of the external fixator (EF), six months after EF removal, and 12 months after EF removal. At each of those points, we performed radiography in the frontal and lateral views, clinical examination of the child, and measurement of the lengthening amount (distraction gaps). We also studied the formation of distraction regenerates, assessed the position of the ends of the telescopic rod, and compared the lengths of separation of bone fragments and rod components.



Fig. 1 Lower limb radiographs at admission

For telescopic reinforcement, a titanium intramedullary telescopic rod was used (RU No. RZN 2017/5875 dated July 10, 2017, included in the set of implants and instruments for pediatric orthopedics "Orthokid", TU 9437-001-73747729-2014).

Stages of the surgical lengthening over a telescopic rod

Initially, retrograde transphyseal femoral rodding was performed through a medial parapatellar approach. A guide wire was drilled under the guidance of an image intensifier through the apex of the intercondylar fossa along the medullary canal to the level of the antecurvatum deformity in the lower third of the femur through a 1-cm skin incision. Next, an osteotomy was performed at the apex of the deformity with a chisel. The guide wire was then advanced to the proximal femur. The canal was drilled along the wire using a 5.7-mm cannulated drill from the kit. Next, the guide wire was removed, and the inner portion of the telescopic rod was inserted into the growth plate of the greater trochanter using a T-handle. Subsequently, the outer (hollow) portion of the 5.5-mm diameter telescopic rod was inserted, with the threaded portion immersed strictly into the distal epiphysis. The length of the outer portion was determined intraoperatively and shortened accordingly. The final step in the femur involved screwing the inner portion of the rod into the greater trochanter so that the entire threaded portion was proximal to its growth plate. The protruding portion of the inner element was cut as short as possible. The osteotomy wound was irrigated and sutured layer by layer.

From the same parapatellar approach, a guide wire was inserted antegrade under radiographic control, entering through the intercondylar space along the medullary canal to the level of the deformity in the upper third of the tibia. An osteotomy at the apex of the deformity was performed through a 1-cm approach. An osteotomy of the fibula was also performed through a 1-cm skin incision in the lower third of the tibia. Next, a cannulated 5.8-mm drill was used to drill the canal down to the distal metaphysis, and the inner portion of the telescopic rod was advanced to a level directly above the distal growth plate. Next, the correspondingly shortened outer portion, 5.5 mm in diameter, was inserted, and the threaded portion was screwed into the proximal tibial epiphysis using a cannulated screwdriver, that did not extend beyond the growth plate line. The final step in placing the tibial telescopic rod was to screw the threaded portion into the distal epiphysis so that the entire thread was distal to the growth plate line. Cutting off the protruding portion of the internal component was performed immediately before irrigation and layer-by-layer suturing of the parapatellar approach. Radiographic checks of the entire limb confirmed the correct placement of the telescopic rods (Fig. 2).

The wire-and-halfpin variant of the external fixator consisted of two tibial rings, a ring over the lower third of the femur, and a segmental short arch at the level of its upper third. The distal femoral ring and the distal tibia ring had only 1.8 mm wires at the metaphyseal level. The proximal femoral arch used only 4.5-mm halfpins screwed into the proximal metaphysis, and the proximal tibia ring had a combination of wires and a half-pin, also located at the metaphyseal level (Fig. 3). At the knee joint, hinges were used to connect circular supports.



Fig. 2 Radiograph taken during surgery after osteotomies, introduction of intramedullary rods and before placement of the external fixator

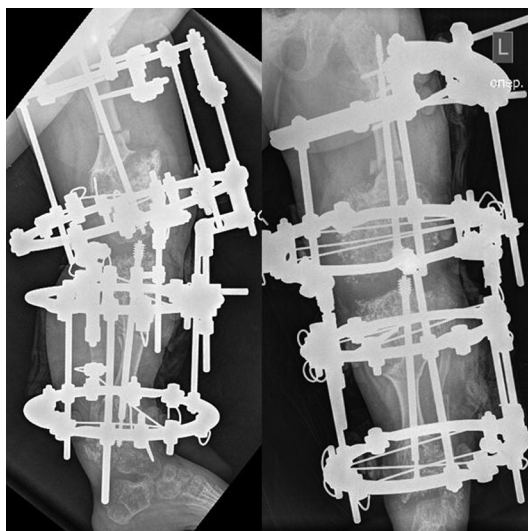


Fig. 3 Radiographs taken after completion of combined osteosynthesis

RESULTS

The immediate postoperative period was uneventful. The patient was able to stand upright on the second postoperative day, being assisted. Three days after surgery, distraction was initiated in the femur and tibia. The initial distraction rate was 1 mm per day.

A 10-day follow-up image revealed no separation of the fibula fragments, which was considered premature consolidation and necessitated a repeat osteotomy and insertion of an additional wire to secure the proximal fibula fragment (Fig. 4). Subsequent radiographs showed normal separation of the bone fragments (Fig. 5). The structure of the distraction regenerate was represented by longitudinal bands with a high degree of mineralization, and the periosteal component of developing bone callus was clearly visible. Extension of the telescopic rod parts occurred without any locking and, consequently, without loss of fixation of the threaded parts in the epiphyses and apophysis of the greater trochanter.

At the end of the second month of lengthening, given the cumulative relative lengthening of more than a third of the lower limb's length, distraction was stopped. Throughout the distraction period, the patient maintained the ability to walk with crutches and functional weight-bearing.

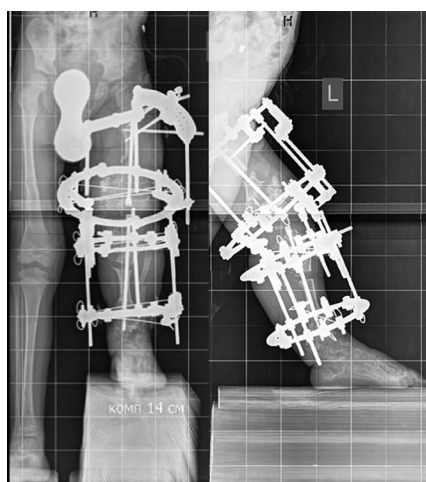


Fig. 4 Radiographs on the 10th day of lengthening

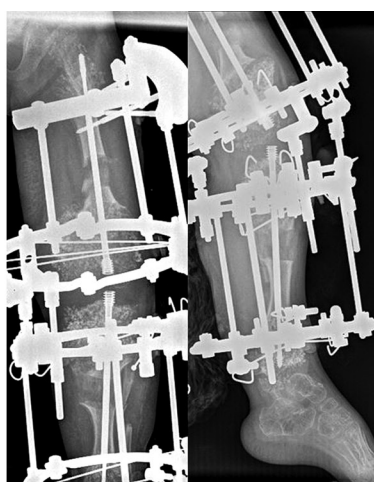
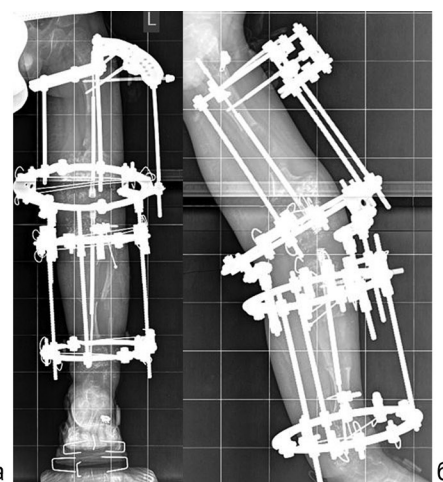


Fig. 5 Radiographs during the distraction period: (a) 30 days of distraction, (b) 60 days of distraction



The patient spent the fixation period at his home. His limb condition was monitored via correspondence, with radiographs taken every 30 days. Bone union was confirmed radiographically after 30 days of fixation (Fig. 6). However, due to the remote distance from the Ilizarov Center, the patient was only able to attend it for removal of the fixator after a long enough period.

The fixator was removed under general anesthesia, leaving the titanium telescopic rods *in situ* (Fig. 7). Post-removal radiographs showed the correct position of the telescopic rods, adequate extension, and maintenance of fixation of the threaded parts in the epiphyses and apophysis of the greater trochanter. A plaster cast was applied for 10 days. Weight-bearing was allowed on the first postoperative day.

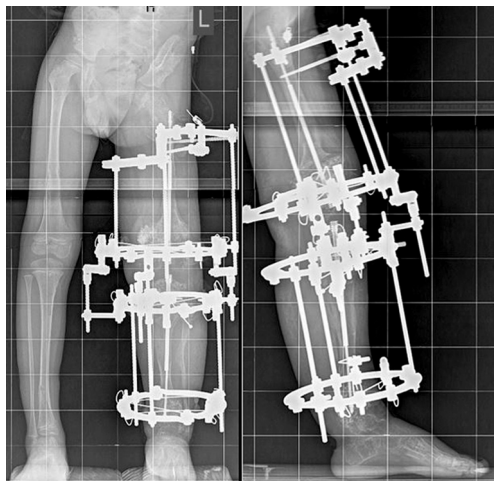


Fig. 6 Radiographs of the lower limb, 30 days of fixation period



Fig. 7 Radiographs after external fixator removal

Follow-up checks were performed at six and 12 months after removal of the external fixator. The elongated segments continued growing; there was no recurrence of deformities, and correct telescoping of the titanium rods were noted without locking or protrusion into the knee or ankle joints. Bone callus remodeling showed all the characteristics of a healthy bone tissue remodeling without the inclusion of chondromatous foci in its structure (Fig. 8).



Fig. 8 Radiographs taken 6 (a) and 12 (b) months after external fixator removal

The resultant quantitative treatment parameters were:

- Femur lengthening by 5.8 cm, tibia lengthening by 5.6 cm, which totally amounted to 24.5 % of the initial limb length,
- The total external fixation index was 12.02 days/cm,
- Considering the treatment outcome, as well as the complication that occurred, which required an unplanned intervention in the period before dismantling the Ilizarov apparatus, but did not lead to a deterioration in the achieved result, the lengthening outcome can be classified as corresponding to grade IIa according to the Lascombes classification [19].

DISCUSSION

Lengthening of long bones in children suffering from diseases associated with low bone strength (Ollier disease, osteogenesis imperfecta, polyostotic fibrous dysplasia, metabolic osteopathies) is rarely used in surgical practice. This is due to the difficulty of performing external osteosynthesis, which must continue for a long time what may be impossible in the conditions of impaired bone strength [20–22].

On the other hand, telescopic transphyseal reinforcement is the method of choice for mechanical strengthening of long bones in such conditions [7, 15, 16]. Difficulties with the use of telescopic rods include cases of non-extension, locking, and loss of fixation of threaded parts in the epiphyses [22, 23].

The feasibility of combining intramedullary reinforcement and external fixation for deformity correction in children with osteogenesis imperfecta has been demonstrated: this combination provided both mechanical and functional advantages [5, 24, 25].

Further development of this approach was envisaged in the use of this combined technique not only for deformity correction but also for limb lengthening.

This clinical case demonstrated the feasibility of this approach without compromising the formation of the distraction regenerate and its maturation time in big lengthening magnitude (polysegmental distraction osteosynthesis). Furthermore, the clinical case demonstrated the safety of using a titanium telescopic rod as an internal fixator without the risk of deformity and/or locking during accelerated telescoping, even during distraction. However, some doubts about the rod's quality had been raised, based on the nature of the alloy used.

The success of such surgeries depends on both the precision of the procedure itself (correct placement of the telescopic rod, minimizing blood loss and trauma by using a single approach to implant two telescopic rods, and restoring acceptable anatomical relationships in the operated segments) and ensuring stable external fixation providing weight-bearing of the lower limb to ensure early axial loading. This approach enabled to significantly shorten the time of external fixation required for lengthening two segments, prevented complications such as bone fragment displacement in the postoperative period, and long-term deformity recurrence during natural growth.

CONCLUSION

This clinical case demonstrated the feasibility of lengthening long bones in patients with Ollier disease using an external fixator along with simultaneous placement of a transphyseal titanium telescopic rod. The study of this lengthening procedure showed for the first time that "accelerated" extension of the rod components during distraction does not lead to sliding locking and, consequently, to the loss of the required fixation of the threaded components in the epiphyses. Furthermore, no delay in the formation and maturation of the distraction regenerate was observed. One year

after dismantling the Ilizarov apparatus, the growth of the elongated segments continued and divergence of the telescopic rod components was observed. It reflects the preserved function of prolonged limb reinforcement both after reconstructive interventions and in the presence of transphyseal reinforcement.

Conflict of interests The authors declare no conflict of interest.

Source of funding None.

Ethical statement This study was approved by the Ethics Committee of the Ilizarov Center (protocol dated November 29, 2024, No. 1(76)).

Informed consent The patient's authorized representatives provided written informed consent for surgical intervention and processing of anonymous data.

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Efficacy of platelet-rich plasma in the treatment of pain syndrome in knee osteoarthritis: a meta-analysis of the studies with a 6-month follow-up

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Abstract

Introduction The scientific literature database contains numerous studies comparing the efficacy of platelet-rich plasma (PRP) and hyaluronic acid (HA) preparations in knee osteoarthritis, but the results are contradictory due to methodological limitations and high heterogeneity of treatment protocols.

Purpose To compare the data from scientific studies on the effectiveness of using PRP and medium molecular weight HA preparations in the treatment of patients with knee osteoarthritis.

Materials and methods A search of randomized controlled trials was conducted in PubMed, Embase, and the Cochrane Library published in the period 2017–2024 using the following keywords: osteoarthritis, knee joint, intra-articular injections, platelet-rich plasma, hyaluronic acid, WOMAC, and meta-analysis. Studies that examined patients diagnosed with knee osteoarthritis of any severity who received intra-articular injections of PRP or HA and assessed pain using the WOMAC were reviewed. After rigorous selection, four studies with identical treatment protocols were included.

Results The meta-analysis included 4 studies involving 333 patients (164 in the PRP group and 169 in the HA group). The mean WOMAC pain score at 6 months after the start of treatment was 4.52 (SD = 1.59) in the PRP group and 4.95 (SD = 2.07) in the HA group. The effect size of Hedges' g was 0.26 (95 % CI: –0.61 to 1.14; $p = 0.336$). Egger's test did not reveal a statistically significant publication bias ($p = 0.06$).

Discussion Our study revealed no significant differences between the use of PRP and HA, which contradicts several previous meta-analyses. This may be due to the use of more stringent inclusion criteria in our analysis and the evaluation of HA preparations with only medium molecular weight.

Conclusion This meta-analysis was aimed to compare the effectiveness of using PRP and medium molecular weight HA in the treatment of patients with knee osteoarthritis and did not reveal statistically significant differences between the groups in severity of pain using the WOMAC system six months after the start of treatment, which indicates comparable effectiveness of these therapy methods.

Keywords: hyaluronic acid, platelet-rich plasma, injections, intra-articular, osteoarthritis, knee, pain measurement, treatment outcome, meta analysis

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INTRODUCTION

Osteoarthritis (OA) of the knee joint is a degenerative disease characterized by progressive destruction of the articular cartilage, damage to the subchondral bone, synovium, and ligaments, and is one of the leading causes of chronic pain and disability among the adult population worldwide [1]. The issues of large joint OA diagnosis and treatment is socially significant, since the disease leads to a significant decrease in quality of life, limitation of daily activities, and loss of ability to work. According to epidemiological studies, the prevalence of OA of the knee joint among the adult population varies from 10 to 30%, and the incidence is more common in women and the elderly [2]. The main symptoms of OA are pain, joint stiffness, lameness, and limited mobility, which significantly reduces the quality of life of patients.

Currently, both conservative and surgical methods are used to treat patients with OA. Conservative treatment is aimed at reducing pain, improving joint function, and slowing disease progression. Conservative methods include drug therapy, including the use of nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, and slow-release symptomatic medications, as well as physiotherapy, exercise therapy, orthotics, and intra-articular injections [3, 4]. Current surgical techniques, such as high corrective osteotomies and total joint arthroplasty, are effective in late-stage patients with joint deformities, significant mobility limitations, and severe pain. However, surgical intervention is associated with risks such as infectious complications, thromboembolism, and implant instability. The postoperative rehabilitation period does not always lead to full restoration of joint function.

Conservative treatment is preferred in the early stages of the disease. Currently, intra-articular injections of hyaluronic acid (HA) are widely used in conservative treatment. HA is a natural component of synovial fluid and provides lubrication, cushioning, and nutrition to the articular cartilage. The introduction of exogenous HA can improve the viscoelastic properties of synovial fluid and stimulate natural repair processes, promoting cartilage regeneration and maintaining synovial homeostasis [5, 6]. HA relieves pain, reduces inflammation, and improves joint mobility. However, the effect of HA injections is temporary, lasting from several weeks to several months.

In recent years, platelet-rich plasma (PRP), an autologous biological product obtained from the patient's own blood by centrifugation, has been used in the treatment of patients with knee OA. PRP contains a high concentration of platelets, which, when activated, release a variety of growth factors that stimulate cartilage regeneration [7, 8]. PRP injections can relieve pain, improve joint function, and slow the progression of degenerative changes. Clinical studies by Raeissadat et al. and Filardo et al. showed that PRP injections significantly relieve pain and improve joint mobility compared to control groups, with the effect persisting for 6–12 months after treatment [9, 10].

The scientific literature contains numerous studies comparing the efficacy of PRP (PRP therapy) and HA preparations in knee OA. However, the results of the studies remain contradictory due to methodological limitations such as the lack of standardized protocols, small sample sizes, insufficient blinding, and short-term follow-up [11–13]. Moreover, high heterogeneity in PRP preparation protocols has been revealed, as well as differences in platelet concentrations, activation methods, and intra-articular administration algorithms, as well as in the frequency and duration of treatment courses. These factors significantly complicate the comparison of study results and are the main sources of controversy when comparing the efficacy of PRP and HA used for knee OA [14]. We suppose that the results of our study could help determine which method provides more efficient and long-lasting pain relief in knee OA, which is critical for choosing the optimal treatment strategy.

The **purpose** of the study was to compare the data from scientific studies on the effectiveness of using PRP and medium molecular weight HA preparations in the treatment of patients with knee osteoarthritis.

MATERIAL AND METHODS

Our meta-analysis was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The study protocol was registered in the PROSPERO international registry. A literature search was conducted in three major electronic databases: PubMed, Embase, and the Cochrane Library for the period from January 2018 to December 2024. The search strategy included a combination of the following MeSH terms and keywords: osteoarthritis, knee joint, intra-articular injections, platelet-rich plasma, hyaluronic acid, WOMAC, and meta-analysis. Terms were combined using Boolean operators AND/OR to create an optimal search string. A manual search of the reference lists of the selected articles was additionally conducted. Pain severity in the analyzed studies was assessed using the WOMAC scale six months after the start of intra-articular injections for knee OA.

Inclusion and exclusion criteria

Criteria for inclusion of articles in the study: patients with a confirmed diagnosis of knee joint osteoarthritis of any severity; interventions — PRP injections (for the treatment group) and HA injections (control group); main outcomes: assessment of pain severity using the WOMAC after six months; secondary outcomes were based on the IKDC, Lekken and VAS. Only randomized controlled clinical trials were selected for analysis.

Exclusion criteria: studies of patients with bilateral knee osteoarthritis, non-randomized studies and publications from which data could not be extracted for analysis.

Selection of studies had four phases:

1. Identification: 192 literature sources were found in electronic databases; four additional publications from other sources were identified; the total number of identified studies was 196.
2. Screening: At this stage, two independent researchers conducted an initial screening of the titles and abstracts of the identified articles to exclude irrelevant publications based on the following criteria: lack of data on targeted interventions, population not relevant to the study topic, results not related to the objectives of the analysis. After removing duplicates, 170 publications remained. All publications were screened based on titles and abstracts. 11 full-text articles met the inclusion criteria; 159 publications were excluded from the study at the screening stage.
3. Final selection: full texts of the articles that passed the initial selection were analyzed for compliance with inclusion and exclusion criteria. In case of disagreement between researchers, the issue was resolved through discussion, and if necessary, a third researcher was involved to make a final decision.

Publications were excluded due to the following reasons: missing WOMAC data at six-month follow-up ($n = 2$); missing data on total WOMAC score ($n = 1$); lack of a control group in the study design ($n = 2$); review articles without original data ($n = 2$).

4. Outcome: Four studies met all inclusion criteria and were used for quantitative synthesis (meta-analysis).

The study selection process is schematically presented in a PRISMA diagram (Fig. 1).

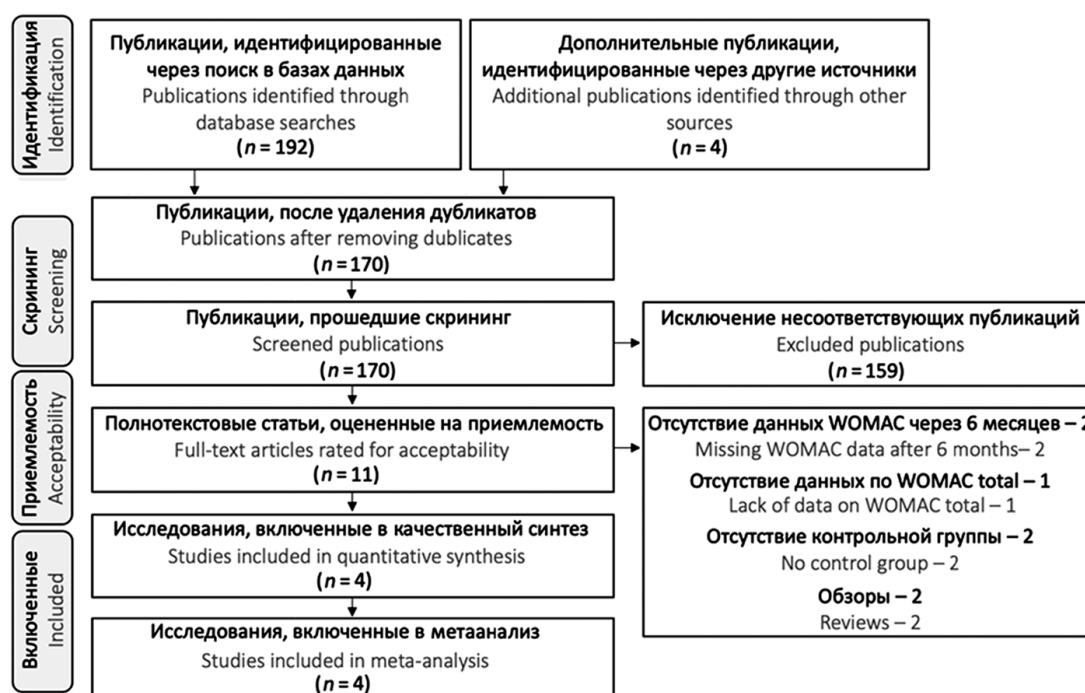


Fig. 1 PRISMA flowchart of the selection process of studies for inclusion in a meta-analysis on the effectiveness of intra-articular injections for knee osteoarthritis management

Data extraction

Data were extracted by two independent investigators using a standardized form including the following data: author, year of publication, country, number of participants in the study, age, gender, body mass index (BMI), classification, duration of follow-up, dosage and number of injections. The WOMAC index was chosen to evaluate the effectiveness of treatment because it is a generally accepted comprehensive indicator that covers data on pain and functional limitations in OA patients. If the study did not provide absolute values, but relative ones (difference in WOMAC values between the study baseline and six months follow-up), the data were recalculated into absolute values to unify the results and ensure their correct generalization. In particular, such an action was performed with the data of the study by Raeissadat et al [9]. Also, to unify the results, all time values measured in months or days are converted to weeks. Other information, such as demographic characteristics and dosages, was necessary to control potential confounding factors and to assess the homogeneity of the study groups.

Risk of bias assessment

Risk of bias assessment was performed independently by two investigators using the Cochrane Risk of Bias Tool. Aspects such as random sequence generation, concealed allocation, blinding of participants and personnel, incomplete outcome data, and publication selectivity were considered. This approach allowed us to minimize bias and increase the reliability of the data obtained.

Statistical analysis

Stata 12.0 (StataCorp., College Station, TX, USA) was used for data analysis. The primary outcomes (pain and function according to the WOMAC) were calculated using the standard mean difference (SMD) with a 95% confidence interval. The SMD was chosen to account for differences in measurement scales between studies, making it the preferred method for meta-analyzing the data from sources that used different assessment scales. Heterogeneity was assessed using the I^2 statistic, with values of 25 %, 50 %, and 75 % interpreted as low, moderate, and high levels of heterogeneity, respectively.

The random-effects method was used for the meta-analysis, which accounts for potential heterogeneity between studies and allows for more general conclusions. A p value of < 0.05 was considered statistically significant, providing sufficient confidence in the analytical results.

RESULTS

The studies included in the meta-analysis covered data on 333 patients treated for knee OA: 164 patients in the PRP group and 169 patients in the HA group.

The meta-analysis showed no statistically significant difference in the baseline pain levels between the PRP and HA groups (Hedges' $g = 0.25$, standard error = 0.20, 95 % CI: $-0.38 - 0.88$; $p = 0.205$). The mean baseline pain level varied due to distorted pain perception depending on the baseline disease stage, as well as on concomitant aggravating pathological conditions. Thus, some publications either did not provide data on the severity of the underlying disease or provided only partial data. Baseline data on the WOMAC pain score for each study are presented in Table 1.

Table 1

Comparison of mean values on the WOMAC pain index before the start of therapy

Author, year, reference number	PRP			HA			Study weight, %	Proportion of cases (95 % CI)
	M	SD	Total of patients	M	SD	Total of patients		
Duymus et al, 2017 [20]	15.40	2	33	16.6	1.10	34	23.15	0.74 [0.25;1.25]
Raeissadat et al, 2021 [9]	9.69	1.30	52	9.44	1.60	49	27.25	0.00 [-0.39;0.39]
Su et al, 2018 [21]	9.57	1.45	25	9.60	1.19	30	21.86	-0.17 [-0.71;0.37]
Wang et al, 2022 [22]	4.2	0.42	54	4.38	0.43	56	27.75	0.42 [0.04;0.80]

Note: M — mean value; SD — standard deviation; CI — confidence interval

Six months after the start of treatment, the mean WOMAC pain score decreased in both the PRP and HA groups. The mean pain score was 4.52 (SD = 1.59) in the PRP group and 4.95 (SD = 2.07) in the HA group. However, the difference in pain score between the groups at six months did not reach statistical significance ($p = 0.336$). The Hedges' g effect size was 0.26 (95 % CI: -0.61 to 1.14). The results for each study included in the meta-analysis are presented in Table 2.

Table 2

Comparison of mean values on the WOMAC pain index six months after the start of therapy

Author, year, reference number	PRP			HA			Study weight, %	Proportion of cases (95 % CI)
	M	SD	Total of patients	M	SD	Total of patients		
Duymus et al, 2017 [20]	9.4	1.70	33	9.7	1.60	34	24.43	0.18 [-0.30;0.67]
Raeissadat et al, 2021 [9]	4.69	0.90	52	5.64	0.70	49	26.44	0.12 [-0.27;0.51]
Su et al, 2018 [21]	4.7	0.70	25	5.56	0.82	30	22.35	1.10 [0.54;1.70]
Wang et al, 2022 [22]	2.87	0.35	54	2.79	0.38	56	26.78	-0.22 [-0.60;0.16]

Note: M — mean value; SD — standard deviation; CI — confidence interval

The analysis of the results reported in the study by Raeissadat et al revealed that the system for quantitatively assessing treatment effectiveness presented changes in WOMAC pain as negative values relative to the baseline, thus necessitating the use of a data standardization method to ensure comparability of the results [9].

A meta-analysis showed that six months after the start of treatment, the Hedges' effect size for the total WOMAC score increased to 0.79 compared to baseline. However, this effect was not statistically significant ($p = 0.282$).

Egger's test was used to assess potential publication bias, the results of which are presented in Table 3.

Table 3

Egger's test results

Parameter	Value	Standard error	95 % CI
Intercept	11.14	3.48	0.05–22.23
Slope	–2.26	0.77	–4.70–0.18

Note: t-criterion = 3.20; p -value = 0.086

Egger's test did not reveal statistically significant publication bias ($p = 0.086$), which is graphically confirmed in Figure 2.

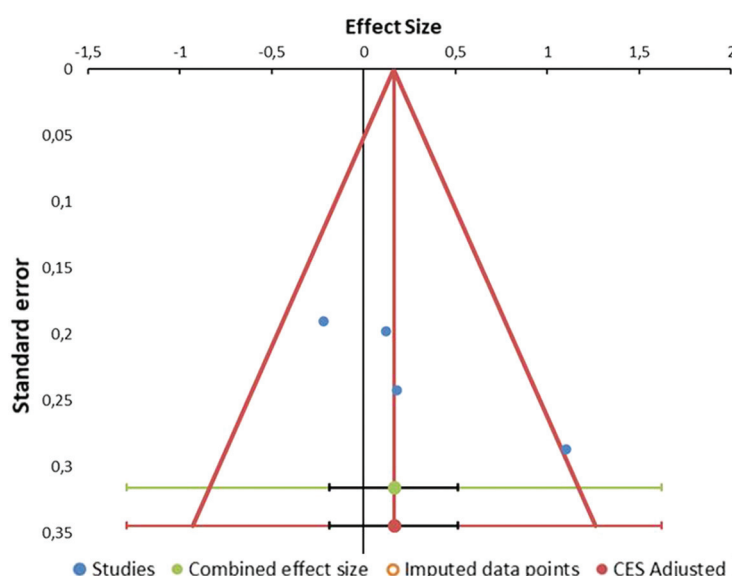


Fig. 2 Funnel chart

A funnel chart is a graphical method for assessing publication bias. Ideally, when there is no publication bias, the points on the graph should be distributed symmetrically around a vertical line through the summary effect size. Funnel plot asymmetry may indicate publication bias. In the present meta-analysis, the funnel plot appears relatively symmetrical, which may indicate the absence of publication bias and correlates with the results of the Egger's test.

DISCUSSION

The objective of this meta-analysis was to evaluate the efficacy of PRP compared with HA in reducing knee OA pain six months after treatment initiation. The findings of 333 patients included into the study from four randomized controlled trials revealed no statistically significant differences between the two methods in the WOMAC pain score, highlighting the need for a more in-depth analysis of factors influencing treatment outcomes. It is possible that factors such as patient characteristics and methodological differences in approaches may have influenced the results, confounding potential differences.

The efficacy of PRP and HA may depend on OA severity: patients with early-stage disease often respond equally well to both treatments, while in advanced stages of OA, the response to PRP and HA injections may differ. Including information on patients with varying degrees of OA severity

in the meta-analysis could have resulted in differences in the efficacy of PRP and HA being obscured. Thus, studies involving patients with early-stage osteoarthritis showed that HA injections are less effective in patients with more severe stages of the disease [15–22].

Individual patient's characteristics such as age, gender, genetic predisposition, comorbidities, lifestyle, and physical activity level can also influence the outcome of PRP and HA [23–28]. Elderly patients often have lower regenerative potential, which decreases the effectiveness of PRP. Men and women respond differently to treatment due to differences in hormonal levels. Genetic predisposition also affects tissue regeneration. Patients with comorbidities such as diabetes may have increased inflammatory responses, which impairs treatment outcomes. Lifestyle, including physical activity level, is also critical: active patients may respond better to therapy due to improved circulation and metabolism, while patients with obesity or diabetes may respond worse due to greater joint inflammation.

The authors of the studies under presented review did not always considered genetic predisposition and individual differences in regenerative potential, which could have impacted the accuracy of the results. It is important to conduct studies with similar patients' characteristics to determine which patients may benefit most from PRP or HA therapy and how treatment can be personalized [29, 30].

The lack of standardization of PRP preparation and administration protocols is also an important factor affecting treatment outcomes. To standardize protocols, it is necessary to determine the optimal centrifugation parameters, platelet concentration, and leukocyte content, as well as uniform methods of PRP administration. The introduction of standardized instructions would reduce variability and improve the comparability of results between studies. The reviewed publications used different methods of PRP preparation and centrifugation, with different platelet and leukocyte concentrations [29–32]. Su et al. [21] used PRP without leukocytes, while other researchers used PRP with different leukocyte contents, which could affect the results, since leukocytes contribute to the development of inflammatory reactions [26]. Also, differences in PRP administration methods (volume and number of injections, intervals between them) could affect the degree of treatment effectiveness [32–34]. The use of different anticoagulants could also affect the biological activity of PRP [19, 24, 36].

The quality of plasma obtained for PRP can vary depending on the equipment and methods used in laboratories. Even small changes in centrifugation speed or time can significantly alter the composition of the final product, which directly impacts treatment efficacy [37]. It is important to standardize not only the primary steps of PRP preparation but also ancillary processes, such as sample collection and processing. The introduction of standardized recommendations for patient preparation can also reduce variability in results. Thus, the use of anticoagulants or other medications prior to the procedure can alter platelet reactivity and thereby affect treatment outcome [38–40].

PRP administration methods depend on the physician's technique, the injection site (intra-articular or periarticular), and even the depth of injection [41]. This is another aspect requiring standardization. The development of detailed recommendations for injection technique could minimize these differences and contribute to increased reproducibility of treatment outcomes. Thus, the need for standardization covers the entire process from plasma preparation to patient interaction and procedure execution, requiring a comprehensive approach and the participation of specialists from various fields such as clinicians, researchers, and rehabilitation specialists.

A limitation of this meta-analysis is a small number of included studies (only four), which lowers statistical power and increases the risk of random errors. The small number of studies increases the likelihood that the results may be due to chance and not reflect the true picture of the effectiveness of treatment methods. To improve statistical reliability, it is necessary to conduct larger studies to ensure a sample sufficient for reliable conclusions. High heterogeneity ($I^2 = 79.74\%$) indicates significant differences in study design, patient characteristics, and treatment methods used [32, 35–39, 42]: age of participants, OA stage, presence of comorbidities, level of physical activity. Differences in the methods of PRP preparation and administration could also aggravate the heterogeneity of the data. Different approaches to patient selection also contributed: some studies included patients with minimal symptoms, while others included patients with severe osteoarthritis [40–47].

Some studies showed a significant influence on the overall effect [21, 22], likely due to differences in methodology and disease stage of the participants. This highlights the need for sensitivity analyses to identify sources of heterogeneity and their contribution to the meta-analysis results. Heterogeneity may also be related to the methods of assessing treatment effectiveness; the use of different scales for assessing pain and functionality makes it difficult to compare results [48–51]. To address these shortcomings, large, well-designed studies with more homogeneous participant characteristics and standardized treatment protocols are needed.

Potential publication bias should also be considered, as results with positive outcomes are published more often than neutral or negative ones. This leads to a distorted view of the effectiveness of interventions. Registered study protocols and study transparency can help reduce the risk of publication bias and improve the quality of meta-analyses [52]. To increase statistical power and the reliability of results, large multicenter studies are needed to collect more data and provide more reliable conclusions [37, 53–55].

This meta-analysis assessed the treatment effect six months after the start of injection therapy, but longer follow-up (12 months or more) is required to identify more consistent differences between groups. Long-term follow-up would allow us to detect delayed effects that are not evident in the short term, as well as to evaluate the stability of the achieved improvements and potential long-term changes in the cartilage tissue condition. The studies showed that the effect of PRP can last longer than that of HA, especially when followed for more than six months [56–58]. Such studies will help to evaluate possible delayed side effects and changes in cartilage tissue structure and determine whether the beneficial effects can accumulate with repeated injections [38, 47, 58–62].

Repeated courses of therapy can enhance the regenerative effect and improve clinical outcomes. Long-term studies will help better understand how individual factors, such as genetic predisposition and physical activity level, influence the duration and stability of the treatment effect [63–66]. In addition to pain, changes in the cartilage tissue, improvements in joint mobility, and overall quality of life should also be assessed.

To assess potential publication bias in the meta-analysis, the Egger and Begg & Mazumdar tests were used, which revealed no statistically significant bias ($p = 0.06$ for the Egger test). Trim and Fill analysis also confirmed the stability of the results. However, it is important to remember that these methods have limitations, and their interpretation should be done with caution [41]. Additional approaches are necessary to minimize bias and ensure maximum reliability and robustness of the findings.

Further research should focus on several key aspects. First, it is necessary to examine the impact of osteoarthritis severity on the efficacy of PRP and HA, stratifying patients by severity to develop

more targeted treatment strategies. Second, individual factors (age, gender, body mass index, comorbidities, lifestyle, and genetic predisposition) should be considered to develop personalized treatment approaches [44, 67, 68].

Standardized protocols for PRP preparation and administration are needed to reduce data heterogeneity and more accurately in assessing treatment efficacy. It is important to standardize all steps of the process—from blood collection and processing to centrifugation parameters and administration methods [16]. Standardization should include monitoring of plasma quality, platelet concentration, white blood cell count, and the use of anticoagulants. Recommendations for patient preparation before the procedure can also improve the reproducibility of results.

Finally, large, multicenter studies with long-term follow-up are needed to evaluate the long-term effects of PRP and HA, as well as their impact on functional outcomes and patient quality of life [69–71]. Such studies should aim to identify the benefits of combination therapy and examine the impact of repeated courses of therapy.

Thus, the primary goal of conservative treatment in OA is to stabilize degenerative and inflammatory processes in the joint, which can help prolong joint function and delay the need for total joint arthroplasty [72]. In this regard, multicenter studies will help improve our understanding of the mechanisms of action of PRP and HA and contribute to the development of recommendations aimed at increasing treatment effectiveness and improving the quality of life in knee OA patients.

CONCLUSION

The meta-analysis aimed at a comparative assessment of the effectiveness of PRP and HA of average molecular weight in the treatment of Knee OA patients did not reveal statistically significant differences between the groups of patients in the severity of pain measured with the WOMAC score six months after the start of treatment, which indicates comparable effectiveness of these methods of therapy.

However, it is necessary to consider the limited number of studies included in the analysis, high heterogeneity between them and the lack of standardized protocols for the preparation and administration of PRP. For a more accurate comparative assessment of the effectiveness of PRP and HA, future large and well-designed studies with a long follow-up due to the severity of the disease, patient characteristics and standardized methods for the preparation and administration of PRP are needed.

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