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Comparative evaluation of the results of using the Ilizarov apparatus and an orthopedic hexapod in the treatment of patients with flexion knee joint contractures

L.N. Solomin[1], S.A. Rokhoev[2]✉

[1] Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russian Federation

[2] Turner National Medical Research Center for Children's Orthopedics and Trauma Surgery, St. Petersburg, Russian Federation

Corresponding author: Saigidula A. Rokhoev, 09saga@mail.ru

Abstract

Relevance When soft tissue release is ineffective in the treatment of persistent flexion contractures of the knee joint, external fixation devices are used. Orthopedic hexapods can be used as an alternative to the traditional Ilizarov frame with a uniaxial hinge.

Purpose To conduct a comparative analysis of the effectiveness of the clinical use of an orthopedic hexapod and the Ilizarov fixator with a uniaxial hinge in the treatment of patients with flexion contractures of the knee joint.

Materials and methods A total of 67 cases of flexion contracture of the knee joint due to spastic paresis were analyzed. All patients underwent posterior release surgery followed by the application of an external fixation device (EFD). Patients were divided into two groups: the study group (n = 35) treated using the "Orto-SUV" orthopedic hexapod, and the comparison group (n = 32) treated using the Ilizarov fixator with a uniaxial hinge. Patients were also subdivided based on the presence or absence of a preoperatively diagnosed posterior tibial subluxation. The duration of treatment stages, range of motion in the knee joint and functional outcomes (assessed with KSS, Lysholm, and LEFS systems) were evaluated at 2 days, 6 months, and 12 months after frame removal.

Results The use of the orthopedic hexapod significantly reduced the duration of the extension stage compared to the Ilizarov fixator. However, the overall duration of external fixation in both groups did not differ significantly. No statistically significant differences were found between the groups at any follow-up time-point for the main functional indicators: range of motion (flexion and extension) and overall lower extremity function (LEFS score). However, according to specialized knee joint assessment scales (KSS and Lysholm), patients in the study group demonstrated significantly better results at 12 months. The complication rate in both groups was comparable.

Discussion Factors affecting functional outcomes in both groups included preoperative tibial subluxation and patient compliance with postoperative recommendations. A specific factor affecting functional outcomes for a uniaxial external fixator is the precise positioning of the hinge on the flexion-extension axis to avoid iatrogenic knee instability. The total duration of external fixation and overall lower extremity function (LEFS) in the compared groups did not differ statistically, indicating no significant advantage of using one type of device over the other.

Conclusion With the orthopedic hexapod, the extension stage was significantly shorter than with the Ilizarov fixator; however, the total duration of externalfixation in both groups did not differ significantly. No statistically significant differences were found between the groups at any follow-up point in terms of the main functional indicators, range of motion (flexion and extension), and LEFS. Based on the KSS and Lysholm scales, patients in the study group demonstrated significantly better results at 12 months. Complication rates were comparable in both groups.

Keywords: contracture, knee joint, flexion contracture, external fixation, Ilizarov apparatus, orthopedic hexapods

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INTRODUCTION

Flexion contractures of the knee joint mostly develop in diseases accompanied by spasticity syndrome and significantly impair the patients' quality of life, depriving them of the ability to move without additional supports [1–4]. In long duration of contracture, secondary changes in the soft tissues develop and conservative treatment fails [5, 6]. To eliminate persistent flexion contracture of the knee joint, a "posterior release" is performed, including neurolysis of the peroneal nerve, myolysis, tenolysis, lengthening and transfer of the tibia flexors, as well as posterior capsulotomy of the knee joint [7–11]. Regardless of the quality of the posterior release performed, the maximum possible one-stage elimination may be limited due to severe pathological retraction of the muscle-tendon complex and the neurovascular bundle. Therefore, to avoid their traction damage, the "soft tissue" operation may be supplemented by a "hinged" external fixation apparatus, most often it is the Ilizarov apparatus [12–15].

The available studies have shown that uniaxial hinge devices that ate traditionally used for movement exercises do not correspond to the kinematics of the knee joint [16, 17]. To comply with this kinematics, an external fixation device (EFD) must provide movements based on a virtual hinge [18]. Orthopedic hexapods meet this requirement, the effectiveness of which has already been proven in the treatment of persistent extension contractures of the knee joint [19]. However, a comparison of the clinical effectiveness of an orthopedic hexapod and a uniaxial hinge external fixator in the treatment of persistent flexion contractures of the knee joint has not yet been conducted.

Purpose To conduct a comparative analysis of the clinical effectiveness of the orthopedic hexapod and the uniaxial hinge Ilizarov apparatus in the treatment of patients with flexion contractures of the knee joint.

MATERIAL AND METHODS

Study design This is a retrospective, non-randomized cohort study. It is based on S.A. Rokhoev's dissertation, "Substantiation of the Use of an Orthopedic Hexapod in the Treatment of Patients with Knee Joint Contractures" (St. Petersburg, 2022).

Patients

The study was conducted at the Vreden National Medical Research Center of Traumatology and Orthopedics. The study included patients treated between 2005 and 2021. Sixty-seven cases of combined (posterior release + external fixation device) treatment for knee flexion contractures resulting from spastic paresis were analyzed. The causes of spastic paresis included traumatic brain injury (TBI), sequelae of cerebral palsy (CP), and acute cerebrovascular accidents (CVA).

The study group, which used the Ortho-SUV orthopedic hexapod in addition to the posterior release, included 35 patients. Of these, 14 were analyzed prospectively and 21 were analyzed retrospectively.

The comparison group, which combined the posterior release and the Ilizarov frame with a uniaxial hinge, included 32 patients.

The gender, age, and etiological characteristics of patients in both groups are presented in Table 1. Both groups were comparable in etiology, gender, age, contracture duration, and concomitant posterior tibial subluxation ($p > 0.05$).

Both groups included patients with preoperatively diagnosed posterior tibial subluxation. Accordingly, those patients were divided into subgroups 1 and 2.

Table 1

Distribution of patients in both subgroups by main characteristics, *n*/%, Me [Q1; Q3]

Group		Study group (orthopedic hexapod)		Comparison group (uni-axial apparatus)	
Number of patients		35		32	
Age		32 [27;43]		28 [26;37]	
Gender		*n*	%	*n*	%
Males		21	60	19	59.4
Females		14	40	13	40.6
Etiology	CP	17	48.5	18	56.2
	TBI	10	28.5	8	25.0
	CVA	8	22.8	6	18.7
Disease duration	3–5 years	14	40	9	28.1
	6–10 years	4	11.4	5	15.6
	↑10 years	17	48.5	18	56.2
Associated tibial subluxation		Subgroup 1		Subgroup 2	
		n	%	*n*	%
Number of patients		12	34.3	8	25

Surgical technique

All patients first underwent a posterior release through two approaches (medial and lateral) in the paraarticular region at the level of the lower third of the femur. The lateral approach was used for exploration and neurolysis of the common peroneal nerve (Fig. 1a) from the lower third of the femur to its entry into the intermuscular septum. Following this, depending on the degree of tension, either distal fractional lengthening of the biceps femoris (*n* = 26, 38 %) or Z-lengthening of its distal tendon (*n* = 41, 62 %) was performed. This approach was also used to visualize and protect the popliteal neurovascular bundle (PNVB).

The medial approach was used to isolate the sartorius, semitendinosus, semimembranosus, and gracilis muscles. The semimembranosus and sartorius muscles were fractionally lengthened if they were tense. The gracilis tendon was dissected distally at the junction of the muscularis and the tendinous portion, while the semitendinosus tendon was transected at its most distal portion (Fig. 1c). If tension was detected in the heads of the gastrocnemius muscles, they were bluntly dissected at their femoral attachment. Similarly, if tension was detected in the plantaris muscle, it was "slided." Finally, a posterior capsulotomy of the knee joint was performed (Fig. 1d); if tension was severe, fractional lengthening of the dorsal fascia was performed. The leg was then extended until tension was felt in the NVB. The proximal end of the semitendinosus and the distal end of the gracilis tendon were sutured in a side-to-side fashion while maintaining their moderate tone.

In all analyzed cases, full acute extension of the lower leg was impossible due to tension in the NVB and the surgery was supplemented by the placement of a femur-to-tibia external fixator (EF). To prevent traction neuropathy, the joint was fixed at +10° of flexion relative to the angle at which the NVB tension occurred.

Both groups had similar fixator configurations, including a basic support at the level of the lower third of the thigh and a mobile support t the level of the middle third or the junction of the middle and upper thirds of the tibia. In the study group, to avoid contact between the struts and the skin at placement of the mobile support at the level of the middle third of the tibia, a "free" sector-type support was added (Fig. 2 a). In the frontal plane, the supports were oriented perpendicular to the overall mechanical axis of the limb, and in the sagittal plane, each module was oriented perpendicular to the anatomical axes of the femur and tibia.

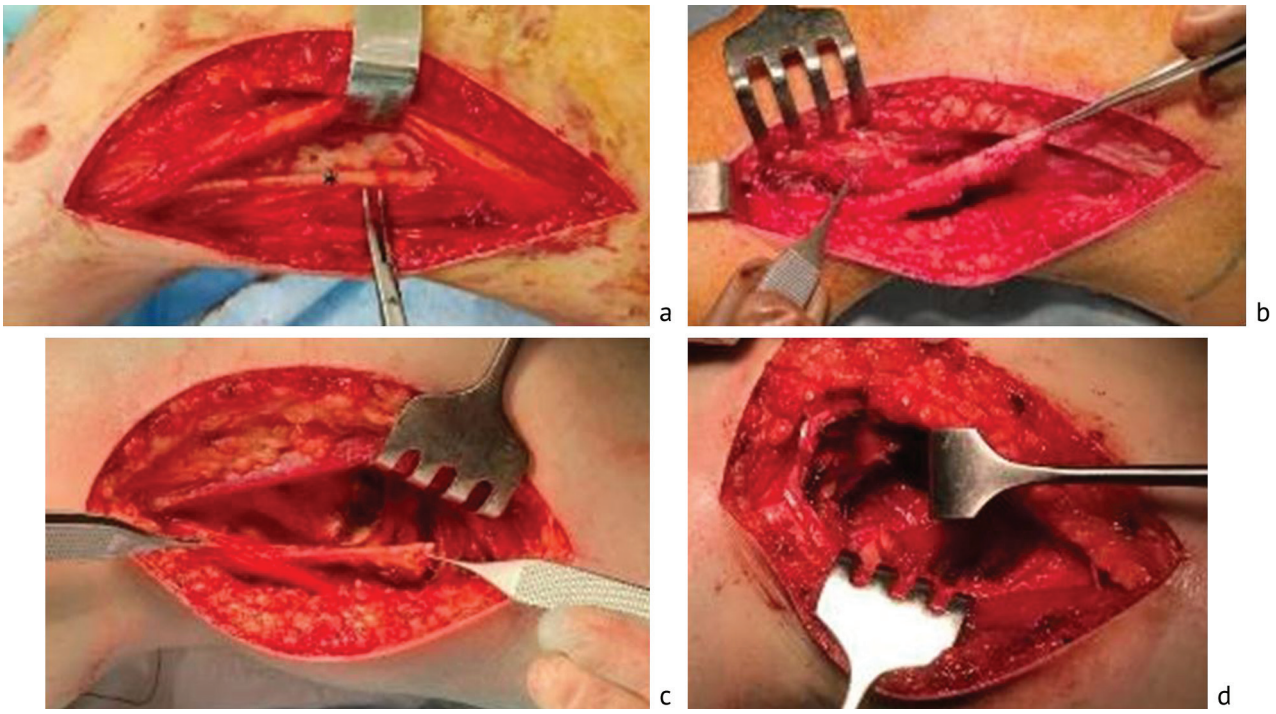

Fig. 1 Stages of posterior release: (a) neurolysis of the peroneal nerve; (b) lengthening of the distal biceps tendon; (c) fractional lengthening of the semimembranosus muscle, dissection of the gracilis muscle at the transition from the muscular to the tendinous part, and the semitendinosus muscle in its most distal part; (d) posterior capsulotomy

In the study group, the basic and mobile supports were connected by six struts of an orthopedic hexapod [20]. On the first day after surgery, X-ray control of the knee joint was performed in two projections. Checking radiographs were opened in the orthopedic hexapod software (SUV-Software v.7.2). For the calculation, a distraction rate of 5–7 mm was set at the initial stage. Then, using the multi-stage correction option, staged (every 10°) calculations of leg extension were performed. Considering the possibility of the "rebound" phenomenon (recurrence of contracture due to soft tissue retraction), "hyperextension" of the lower leg within 5–7° was added to the calculations in the software (Fig. 2b). The initial rate of extension was 2.5° per day in four steps. Distraction began on the second to fourth days after surgery; next, lower leg extension was initiated. The initial extension rate could be accelerated or slowed depending on pain severity. Upon completion of the extension period, the orthopedic hexapod struts were dismantled, and the base and mobile supports were connected with fixation hinges.

The above parameters were based on the works of Herzenberg et al., Balci et al., which noted the occurrence of the rebound phenomenon and provided recommendations for the prevention of this complication [14, 21]. In the work of Volkov and Oganesyan, recommendations were given for the rate of lower leg extension in the EFD of 2–6° per day [22]. In our study, using a computer program for an orthopedic hexapod, we expected to complete a staged extension equal to 10° in four days. The formula was as follows: 10°/4 days = 2.5° per day, which is close to the minimum values recommended by the authors and, in our opinion, is optimal for the initial rate.

In the comparison group, the basic and mobile supports were connected by axial hinges positioned under image intensifier control in the projection of the knee joint flexion-extension axis [23]. Passive movements were performed using rotation hinges (Fig. 3). The initial distraction rate was 8 mm (an average of 2–2.5° per day) in four steps; it was also adjusted, as in the patients in the study group and depended on pain [22].

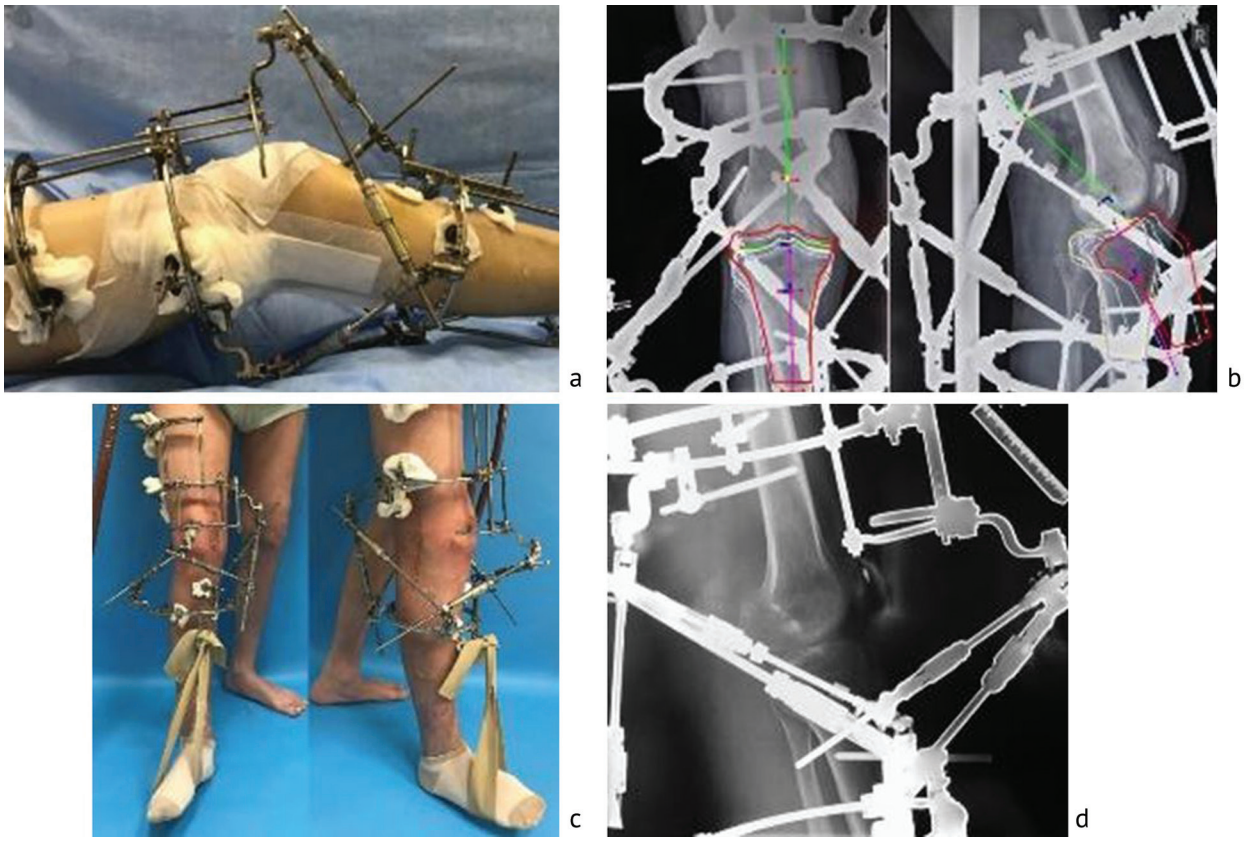

Fig. 2 Application of the orthopedic hexapod: (a) appearance after placement of the orthopedic hexapod; (b) calculation of lower leg extension in a computer program; (c, d) a photograph and a radiograph in lateral projection after completion of the lower leg extension stage

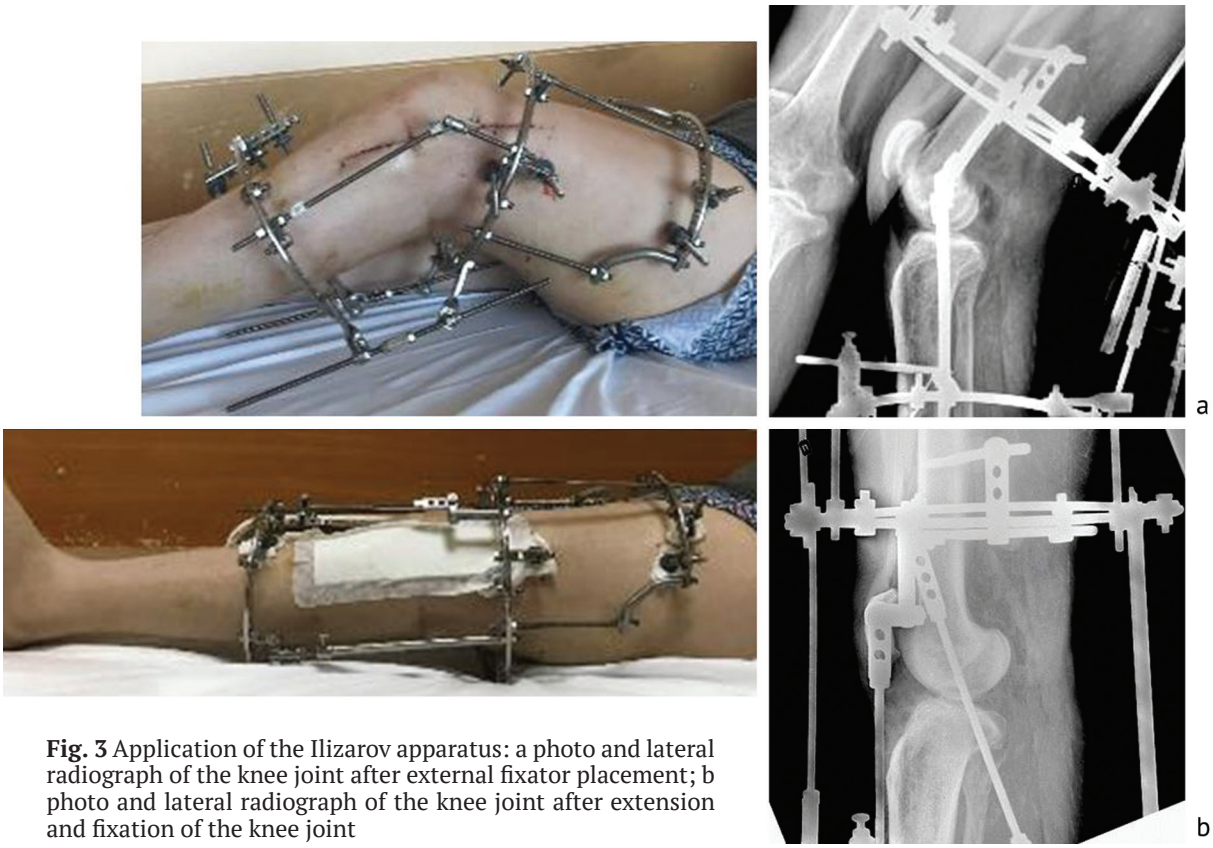

Fig. 3 Application of the Ilizarov apparatus: a photo and lateral radiograph of the knee joint after external fixator placement; b photo and lateral radiograph of the knee joint after extension and fixation of the knee joint

In both groups, after completion of the extension stage, the knee joint was immobilized in a hyperextension with the EF for six weeks. After that, the device was removed, and the knee joint was immobilized for another three weeks with a plaster cast or orthosis. The postoperative care and rehabilitation protocol for both groups was generally similar. In both groups, from the moment the EF was removed, patients were recommended to undergo rehabilitation courses, including physical therapy sessions with a physician, mechanotherapy, electrical muscle stimulation of the quadriceps, and therapeutic massage.

Some differences were observed in patients included in the subgroups with posterior tibial subluxation. In 12 patients (34 %) from subgroup 1, after calculating the extension magnitude, correction of subluxation was additionally calculated using the "multi-stage correction" software option. In eight patients (25 %) from subgroup 2, posterior tibial subluxation was corrected after joint extension by moving the mobile support anteriorly. The postoperative rehabilitation and care protocol after EF removal were generally the same as described above. However, given the concomitant preoperative subluxation, such patients in both subgroups were recommended to immobilize the knee joint in the EF for eight weeks rather than six.

Comparison of the results

For comparison, the duration of different treatment stages (Fig. 4), range of motion and, in particular, extension deficit after EF dismantling were analyzed according to the criteria of Herzenberg et al. [21]. According to the proposed criteria, an extension deficit of < 5° was considered excellent, of 6–15° — good, 16–29° — fair, and > 30° — poor. Complications of the treatment were assessed according to the classification of Caton [24]. The function of the knee joint and the lower limb as a whole was assessed using the Lysholm, KSS (Knee Society Score) and LEFS (Lower Extremity Functional Scale) questionnaires [25–27]. The listed parameters were assessed before surgery, on the second day after EF dismantling, six and 12 months after EF dismantling. In prospectively examined patients from the study group (n = 14), the parameters were additionally assessed at three and nine months after EF dismantling.

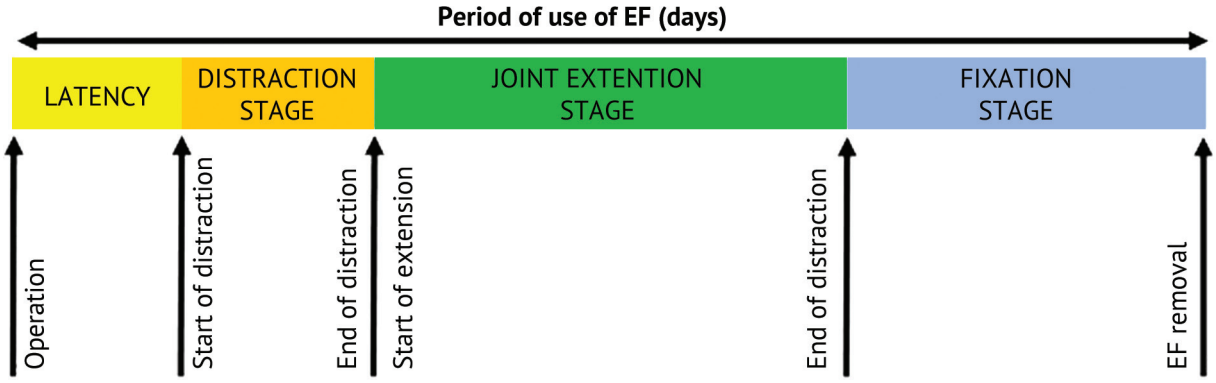

Fig. 4 Treatment stages in the patients with flexion knee joint contractures

Statistical analysis

The data were recorded in Microsoft Excel spreadsheets. Statistical analysis was performed using Statistica v.10 and jamovi 2.6.17. Normality of distribution was determined using the Shapiro – Wilk test. Due to the abnormal distribution of most analyzed numerical variables, nonparametric statistical methods were used. Quantitative parameters in two independent groups were assessed using the Mann – Whitney U test. Given the use of nonparametric methods, quantitative data were presented as medians (Med) and lower and upper quartiles (Q1:Q3). Statistical processing

and analysis of nominal data were performed using the Chi-square test (with Yates' correction for small groups) and Fisher's exact test. For the analysis of dependent samples in the same group and the study of dynamic parameters after surgery, the Wilcoxon and Friedman tests were used.

Patients signed informed consent for examination, treatment, collection, storage and analysis of medical records for scientific and educational purposes, as well as their publication.

RESULTS

Since the posterior release operation, full extension (from 35° to hyperextension of 5°) in the knee joint in the study group was achieved in an average of 22 [18;27] days, and in the comparison group (from 30° to hyperextension of 5°) in 24.5 [21;31] days (Table 2; Table 3).

In a comparative analysis, a significantly shorter extension period was observed in the study group ($p < 0.05$). Comparison of the average duration of the fixation period found similar indicators ($p > 0.05$): 46 days in the study group and 45 days in the comparison group (Table 2). The total duration of EF in both groups also did not have significant differences ($p < 0.05$): 78 days in the study group and 76.5 days in the comparison group (Table 2).

Table 2

Comparative characteristics of treatment stages

Stage	Stage duration, days Med [Q1; Q3]		
	Study group	Comparison group	*p*-value
Latent stage	3.0 [2;4]	3.0 [2;5]	> 0.05
Distraction stage	3.0 [2;3]	3.0 [2;3]	> 0.05
Extension stage	22.0 [18;27]	24.5 [21;31]	< 0.05
Fixation stage	46.0 [43;54]	45.0 [43;50]	> 0.05
Total time with the EF on	78.0 [68;86]	76.5 [71;89]	> 0.05

Assessment of the range of motion (maximum flexion and extension) of the knee joint after dismantling the EFD found comparable ($p < 0.05$) rates of reduction in the magnitude of maximum flexion in both groups: on average from 130° to 30° in the study group and from 122° to 33° in the comparison group, while the achieved full extension was maintained (Table 3).

Table 3

Goniometric knee joint examination data

Study time point	Goniometric indicators, degrees, Med [Q1; Q3]			
	Study group		Comparison group	
	Maximum flexion	Extension deficit	Maximum flexion	Extension deficit
Preoperatively	130 [130;135]	65 [55;70]	122 [120;135]	67 [55;72]
After release	130 [130;135]	35 [30;45]	122 [120;135]	30 [20;40]
Day 2 after frame removal	30 [25;35]	0 [0;0]	33 [24;35]	0 [0;0]
Follow-up, 6 months	80 [65;85]	0 [0;0]	79 [58;84]	0 [0;0]
Follow-up, 12 months	110 [97;120]	0 [0;0]	104 [95;108]	0 [0;0]

Evaluation of the average flexion in the knee joint showed a comparable ($p < 0.05$) increase from 30° to 80° in the study group and from 33° to 79° in the comparison group six months after EF dismantling, and an increase from 80° to 110° in the study group and from 79° to 104° in the comparison group after 12 months.

At six months from the moment of EF dismantling, one case of extension deficit of 7° was detected in the study group, which increased during the follow-up at 12 months from the moment of EF removal. In the comparison group, at six months from the moment of EF cessation, the extension

deficit was found in three patients: 7° in two (6.25 %) and 5° in one (3.1 %). After 12 months, the extension deficit was also equal to 7° in two (6.25 %) patients, and in the third, the extension deficit increased by 3° (to 8°). Moreover, the average extension deficit noted at six and 12 months from the moment of EF removal was 0° in both groups ($p < 0.05$). According to the extension deficit assessment criteria of Herzenberg et. al. [23], 12 months after the EF dismantling in the study group, excellent results were noted in 34 cases (97.14 %), and one was good (2.86 %). In the comparison group, excellent results were recorded in 29 cases (82.85 %) and good in three cases (9.37 %).

The joint and limb function assessment data using the specialized KSS, Lysholm, and LEFS scales are presented in Table 4. In both groups of this study, an improvement in mean scores compared to preoperative functional indices was noted on all three scales.

One year after EF removal, all patients in the study group (100 %) had excellent joint function scores according to the KSS scale. In the comparison group, excellent joint function results according to the KSS scale were recorded in 27 patients (77.14 %), and good ones in five patients (15.6 %).

One year after EF removal, 32 patients (91.42 %) in the study group had excellent joint function according to the Lysholm scale, and three (8.58 %) had good function. In the comparison group, 23 patients (71.87 %) achieved excellent joint function according to the Lysholm scale, while the remaining nine patients (28.12 %) had good results.

At 12 months after EF removal, the LEFS score showed a slight limitation of lower limb function in all patients (100 %) in both study groups.

A comparative analysis of the KSS and Lysholm scores recorded after EF removal at six and 12 months revealed significantly better knee function in the study group ($p < 0.05$). Assessment of the lower limb function using the LEFS scale showed that the mean scores obtained were comparable ($p < 0.05$) at all follow-ups.

Table 4

Results of joint functional assessment at different stages of the study

Study time point	Functional assessment of the joint with scales (points), Med [Q1; Q3]					
	KSS		Lysholm		LEFS	
	Orto-SUV	Ilizarov	Orto-SUV	Ilizarov	Orto-SUV	Ilizarov
Before surger	43.0 [41;45]	43.0 [43;45]	57.0 [55;60]	55.0 [53;60]	15.0 [11;19]	16.0 [14;18]
	$p > 0.05$		$p > 0.05$		$p > 0.05$	
Day 2 after frame removal	55.0 [53;55]	53.0 [51;55]	59.0 [55;61]	5.5 [51;59]	23.0 [22;25]	24.5 [23;26]
	$p < 0.05$		$p < 0.05$		$p > 0.05$	
Follow-up, 6 months	80.0 [75;81]	77.0 [69;81]	85.0 [83;85]	81.0 [71;83]	64.0 [60;67]	62.5 [59;66]
	$p < 0.05$		$p < 0.05$		$p > 0.05$	
Follow-up, 12 months	102.0 [94;103]	100.0 [92;101]	99.0 [93;100]	95.0 [88;99]	74.0 [72;76]	73.5 [70;76]
	$p < 0.05$		$p < 0.05$		$p > 0.05$	

The dynamics of changes in maximum flexion, extension deficit, and mean scores on the functional scales in prospective patients of the study group are shown in Table 5. After EF removal, a fourfold decrease in the maximum flexion angle was recorded compared to preoperative measurements. Moreover, from the moment of EF removal, a gradual improvement was noted: the knee flexion angle increased, reaching good values by nine months and excellent values by 12 months. Excellent functional results according to the KSS scale were recorded at the ninth month after EF removal; however according to the Lysholm scale, this was revealed only at the 12th month. According to the LEFS scale, at six months after EF removal, patients demonstrated only minor limitation of lower limb function.

Table 5

Dynamics of changes in functional indicators according to goniometric study and assessment scales

Time point	Functional indicators of goniometric study and assessment scales, Med [Q1; Q3]				
	Maximum flexion, °	Extension deficit, °	KSS, points	Lysholm, points	LEFS, points
Before operation	130 [130;135]	62.5 [55;65]	41 [39;44]	58.5 [57;60]	15.5 [11;19]
After release	130 [130;135]	30 [25;35]	–	–	–
After EF removal	30 [25;35]	0 [0;0]	55 [52;58]	59 [55;61]	25 [23;27]
3-months follow-up	55 [50;65]	0 [0;0]	65 [61;67]	74 [71;76]	49 [47;53]
6 month follow-up	85 [70;85]	0 [0;0]	81 [75;81]	85 [83;85]	66 [62;67]
9-month follow-up	101 [85;110]	0 [0;0]	100.5 [87;103]	94 [90;99]	72 [71;74]
12 months follow-up	115 [100;120]	0 [0;0]	103 [94;103]	99 [93;100]	74 [72;76]

A comparative analysis revealed that patients with preoperative posterior subluxation of the tibia had a significantly increased duration of EF application ($p < 0.05$) due to both the duration of extension and fixation (Table 6). Patients with preoperatively diagnosed posterior subluxation of the tibia showed a statistically significant ($p < 0.05$) deterioration in the values of maximum flexion as well as in the functional status on all three scales at 12 months after EF removal, compared to those patients in whom the dislocation was not diagnosed (Table 6).

Table 6

Comparison of the evaluation results of various indicators

Indicator	Evaluation, Med [Q1;Q3]			
	Study group		Comparison group	
	No subluxation (n = 23)	Subluxation (n = 12)	No subluxation (n = 23)	Subluxation (n = 8)
Extension duration, days	19 [16;25]	25 [22;28]	22 [20;25]	32.5 [31;36]
Fixation duration, days	44 [42;43]	55 [53;55]	44 [42;46]	54.5 [54;55]
Total time with the AEF on, days	44 [42;46]	86 [83;89]	92 [89;97]	74 [70;78]
Range of motion (maximum flexion, °)				
Immediately after AEF removal	35 [32;37]	22 [20;25]	34 [30;35]	21 [20;22]
At 6 months follow-up	85 [81;87]	61 [55;65]	80 [78;85]	56 [55;57]
At 12 months follow-up	115 [110;120]	95 [93;100]	105 [90;95]	94 [100;112]
Range of motion (extension deficit, °)				
Immediately after AEF removal	0	0	0	0
At 6 months follow-up	0	0	0	0 [0;5]
At 12 months follow-up	0	0	0	0 [0;7]
Evaluation score after 12 months, points				
KSS	103 [102;103]	93 [92;94]	100 [94;102]	90 [90;92]
LYS	99 [99;100]	93 [92;95]	95 [94;99]	85 [85;87]
LEFS	75 [74;76]	71 [69;72]	74 [73;76]	69 [67;70]

The complication rate in the study group was 34.28 % (12 cases), including nine episodes (25.7 %) of superficial soft tissue inflammation around the transosseous elements (category 1) without loss of stability. The inflammatory process was stopped with chloramphenicol ointment and oral antibacterial therapy. In one case (2.85 %), a fracture of the lower third of the femur was diagnosed, due to which the extension procedure was temporarily suspended for EF readjustment and fracture stabilization (category 2). Instability of the proximal support was detected in one case (2.85 %), which required the insertion of additional transosseous elements for its stabilization (category 2), after which the extension procedure was resumed. Infection of the hematoma at the surgical site was reported in one patient (2.85 %), leading to temporary suspension of extension for exploration, debridement, and drainage of the infectious focus, followed by bacteriological examination of the hematoma contents and selection of specific antibiotic therapy. After the purulent-inflammatory process was resolved, extension was resumed (category 2).

In the comparison group, complications were observed in 31.42 % of patients (11 cases): 18.75 % (six cases) of soft tissue inflammation around the transosseous elements (category 1), managed conservatively; 15.63 % (five cases) of minor posterior subluxation of the tibia during the extension stage (category 2), corrected by moving the mobile support after completion of the extension stage. No statistically significant differences in complication rates were found between the groups ($p > 0.05$).

DISCUSSION

The analysis of the duration of the EF treatment stages (Table 3) revealed a statistically significant reduction in the extension stage by 2.5 days (9.8 %) in the study group ($p < 0.05$). This difference is likely due to the fact that in the study group, subluxation correction ($n = 12$) was performed synchronously with extension, in contrast to the comparison group ($n = 8$), where correction was performed in stages: first extension, then subluxation correction by changing the position of the mobile support according to the Ilizarov method. This is also confirmed by the fact that in the orthopedic hexapod subgroup, the extension period in patients with subluxation was, on average, seven days shorter than in similar patients in the comparison subgroup (Table 6).

Another possible factor may be a faster rate of extension due to less pain in patients who underwent joint extension using an orthopedic hexapod. Unfortunately, we cannot confirm this fact definitively, as we did not conduct a visual analog scale assessment in this study. However, even though the extension period in the study group was 2.5 days shorter, the total duration of EF use in the compared groups did not differ significantly. This indicates that there is no significant advantage to using one type of device over the other in terms of treatment duration.

Following EF removal, a decrease in maximum flexion of 76 % in the study group and 72 % in the control group, compared with baseline values, was recorded. This may be due to the fact that prolonged fixation aimed at maintaining full extension of the knee joint contributes to the development of immobilization extension contracture. According to Krupko IL, movement restriction for up to 10 weeks is classified as the unstable contracture phase [28]. This explains successful conservative treatment, as evidenced by dynamic observation data demonstrating a gradual improvement in joint function during rehabilitation measures (Tables 2, 4, 5).

The analysis of maximum flexion parameters revealed no significant differences between the groups at any stage of the study. However, in regard to concomitant preoperative tibia subluxation, all patients with this condition demonstrated lower functional parameters. This is likely due to the longer duration of knee fixation in these patients, which directly impacted joint function.

The analysis of the extension deficit revealed no significant differences between the groups. The obtained data indicate comparable joint extension efficacy using both the orthopedic hexapod and the Ilizarov apparatus. However, recurrence was observed in one patient in the study group (up to 10°) and three patients in the comparison group (two 7° and one 8°). The contracture in those patients was accompanied by posterior subluxation of the tibia. Based on the anamnesis data, it is known that none of those three patients with concomitant preoperative subluxation properly complied with the prescribed three-week period of plaster immobilization after EF removal. It can be assumed that neglected immobilization in the early stage after EF removal contributed to the development of the “rebound” phenomenon. However, a precise determination of the cause is difficult due to the retrospective assessment of minor contracture recurrence in those patients six months after EF removal.

The analysis revealed significantly higher mean scores on the KSS and Lysholm scales at six and 12 months after EF removal in the study group. Knee joint stability is one of the evaluation criteria in the KSS and Lysholm questionnaires. A comparative analysis of the KSS questionnaires (completed by patients and the physician) revealed that the decrease in total scores in the control group was primarily due to symptoms of knee instability. Five patients in the "joint stability" column of the Lysholm questionnaire indicated difficulty with intense physical activity due to joint instability.

After analyzing the clinical history and imaging data, we concluded that instability was caused by overstretching of the capulo-ligamentous structures due to inaccurate positioning of the axial hinge relative to the flexion-extension axis. In these five patients from the comparison group, we observed slight subluxation of the tibia after completing the extension phase. Although the tibia subluxation in these patients was corrected during their hospital stay, instability symptoms due to incorrect positioning of the axial hinges still persisted. Furthermore, overall lower limb function, assessed using the LEFS scale, showed no significant differences between the groups at any follow-up point.

The data of a systematic review devoted to the use of external fixation devices for knee joint contractures demonstrate that the most frequently used device is the Ilizarov device with a single-axis hinge [18]. The overwhelming majority of studies (seven out of eight) mention the use of external fixation devices specifically for flexion contractures of the knee joint [18]. It should also be noted that not all patients underwent a soft tissue release before EF placement. According to the study by Herzenberg et al., with an initial flexion contracture of approximately 60°, posterior release was performed in only eight of 14 patients [21]. The authors did not provide details of the release technique or the extension values achieved after its implementation. The average duration of EF application was 3.5 months (range 1.25–8.5 months), which is longer than in our groups and may be due to the lack of release. Among the eight patients who underwent release, the results were distributed as follows: excellent (extension deficit < 5°) — two cases, good (6–15°) — two cases, fair (16–29°) — two cases, and poor (> 30°) — two cases. The mean residual extension deficit (16°) exceeded the extension deficit observed in both groups of this study. Among the complications mentioned by the authors, there were cases of soft tissue inflammation around the transosseous elements (category 1), without specifying the number of cases.

Balci et al. described the results of combined treatment of flexion contractures of the knee joint using the Ilizarov apparatus and posterior release (6/6 cases) [14]. The release technique included Z-shaped lengthening of the tendons of the medial flexor group, lengthening of the biceps femoris tendon (without specifying the technique), release of the heads of the gastrocnemius muscles and the joint capsule (without details). The authors did not indicate the magnitude of the achieved extension immediately after the release. The average follow-up period was eight years (5.5–10), and the duration of EF application was 4.4 months (2.5–10), which is longer than our results. The initial extension deficit averaged 45° (30–75°), and after eight years of follow-up it was 10° (5–15°), which is also higher than in our study. Complications included one case (16.6 %) of soft tissue inflammation around the transosseous elements (category 1), and one case (16.6 %) of postoperative subluxation of the tibia (category 2). The complication rates could not be conducted with our data due to a small sample size (n = 6) in that study.

Among the analyzed foreign publications, only the study by Vulcano et al. described the use of an orthopedic hexapod (Taylor Spatial Frame), but the authors did not provide any photographic documentation of the use of the structure or data on working with the computer program [29]. According to the study data, posterior release was performed in 19 of 21 patients (90.5 %) before EF placement, but the technical details of the procedure were not described. The follow-up period averaged 13 months (10–18 months). The initial extension deficit averaged 44° (range 10–120°), and at the final examination it was 10° (0–50°), which exceeds similar indicators in both of our groups. The average period of EF application reached three months. Among the reported complications, the authors noted inflammation at the site of the transosseous elements in 15 patients (71 %) (category 1), a hip fracture in one patient (4.8 %), and a complete recurrence of contracture in two patients (9.5 %) (40° in one and 45° in the other one) due to the lack of pharmacological control of spasticity. A significantly lower complication rate was observed in both groups of our study.

In the study of Damsin et al. posterior release was performed in only three of 13 patients, and Huang performed releases in two of 10 patients. We considered only complications that arose during extension in the EF device [30, 31]. Thus, Damsin et al. recorded: one case (7.6 %) of peroneal nerve

neuropathy, three cases (23 %) of impression fracture, three cases (23 %) of tibial subluxation. Huang reported two cases (20 %) of tibial subluxation, one case (10 %) of knee joint instability. In our study, minor tibial subluxation was observed in five patients (15.6 %) in the group with the Ilizarov apparatus what is a lower percentage than in the works of Damsin et al and Huang. However, due to differences in group size, we believe that a comparative analysis of complication rates cannot be completely reliable.

The study by Zhai et al. lacked data on either soft tissue release or possible complications during extension in the EF device, and therefore we did not conduct a comparison with this study [32].

Compared with the results of the above studies, the total duration of Ef application in both our groups was significantly shorter (1.4 times, an average of 28 days). As for functional outcomes, foreign authors also observed lower results. This difference can be attributed to the use of a more effective posterior release technique in our study. During the soft tissue stage, we achieved maximum possible knee extension, limited only by the tension of the neuro-vascular bundle. Thus, in the study group, after the soft tissue stage, the average achieved knee extension was 45 % (41–50 %) of the baseline value, while in the comparison group, after the posterior release, this figure was 53 % (38–60 %). Regarding the complications observed in patients in both subgroups of our study, their incidence generally does not exceed the rates described in the literature and is even significantly lower as compared with some studies.

We followed Caton's classification of complications in our study which fundamental goal is to assess the impact of the complication on the final outcome [24]. Using this classification, it was important for us to indicate not the severity of the complication, but its category, in order to determine whether the complication affected the final outcome. We did not find any significant differences in the impact on the final outcome in this study.

Based on the obtained results of our study, both EF types are undoubtedly an effective adjunct to posterior release surgery in the treatment of persistent flexion contractures of the knee joint. For extension contractures of the knee joint, the use of an orthopedic hexapod has been shown to achieve higher functional indicators in a shorter duration of external fixation [20]. In the case of flexion contractures, with proper surgical technique and correct positioning of the hinge along the flexion-extension axis, the use of an orthopedic hexapod does not offer any evident advantages over the Ilizarov apparatus.

CONCLUSION

The comparison of knee joint range of motion in both groups at all follow-up points showed comparable results. Knee function, assessed using specialized scales, was better in the study group, while overall lower limb function in both groups did not differ at all follow-ups. The orthopedic hexapod allows for faster joint extension; however, a comparative analysis of the overall period of EF application (from placement to removal) demonstrated no advantages for one external fixation type over the other. The results suggest that both EF types are effective in treating patients with knee flexion contractures. For knee flexion contractures associated with tibia subluxation, the orthopedic hexapod is preferable due to its ability to simultaneously achieve extension and resolve tibia subluxation, resulting in a shorter extension stage.

Conflict of interests *Solomin LN is Orto-SUV ltd director, where the Orto-SUV hexapod was developed.*

Source of funding *The study was conducted without sponsorship.*

Informed consent *The authors obtained informed consent for the examination, treatment, collection, storage, and analysis of medical records for scientific and educational purposes, as well as for their publication. The authors confirm that the article does not contain any data that is not suitable for publication.*

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Information about the authors:

Leonid N. Solomin — Doctor of Medical Sciences, Professor, Leading Researcher, solomin.leonid@mail.ru, https://orcid.org/0000-0003-3705-3280;

Saigidula A. Rokhoev — orthopaedic surgeon, 09saga@mail.ru, https://orcid.org/0000-0003-4369-9619.

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Comparative efficacy of surgical methods in the treatment of foot drop associated with isolated peroneal nerve neuropathy

A.A. Grigoryan[1], V.M. Abu Zaalan[2]✉, L.G. Makinyan[1,2], A.M. Mannanov[2], Ch. Moldamyrzaev[1], M.A. Imankulov[1]

[1] Peoples' Friendship University of Russia named after Patrice Lumumba, Moscow, Russian Federation
[2] City Clinical Hospital named after V.P. Demikhov, Moscow, Russian Federation

Corresponding author: Abu Zaalan Vessam Moussa, wsameeexx@gmail.com

Abstract

Introduction Footdrop secondary to isolated peroneal nerve neuropathy is associated with limited mobility affecting the quality of life. Objective data on comparative efficacy of surgical techniques are needed for long-term muscle denervation with nerve interventions being ineffective.

The **objective** was to determine the optimal surgical strategy for restoring dorsiflexion of the foot in case of isolated injury to the peroneal nerve through comparative analysis of the results of tenodesis of the extensor digitorum longus and posterior tibial muscle trasfer.

Material and methods Outcomes of 84 patients with isolated peroneal nerve neuropathy confirmed by electroneuromyography and lasting more than 12 months were prospectively analyzed. The first group included 42 patients treated with tenodesis of the extensor digitorum longus tendon to the anterior border of the tibia using a modified Lambrinudi technique. The second group consisted of 42 patients who underwent transfer of the posterior tibial muscle through the interosseous membrane with fixation to the lateral cuneiform bone using the Bridle technique. Functional assessment was produced using the AOFAS score, measuring dorsiflexion amplitude with goniometry, ankle dorsiflexor strength with dynamometer and stabilometric analysis of gait parameters at checkpoints of three, six, 12, and 24 months after surgery. Statistical processing was performed using parametric and nonparametric criteria at a significance level of < 0.05.

Results Between-the-group comparison revealed a statistically significant advantage of the muscle transfer evaluated with AOFAS ($p = 0.003$) and range of motion measurements ($p = 0.001$). Dynamometry showed dorsiflexion strength restored to 62.4 % of the contralateral limb in the first group and to 78.9 % in the second group ($p < 0.001$). Stabilometric analysis recorded a reduction in the center-of-pressure total trajectory length by 34.8 % with tenodesis and by 51.6 % with muscle transposition relative to preoperative values. The complication rate was 14.3 % after tenodesis and 9.5 % after transfer ($p = 0.386$).

Discussion The superiority of the posterior tibial transfer can be explained by active muscle traction, as opposed to passive stabilization with tenodesis, which ensures a more physiological restoration of motor function. The strength and stabilometric parameters restored correlates with international data on the high effectiveness of active muscle transpositions during long-term denervation. Comprehensive postoperative rehabilitation using modern biofeedback technologies helps optimize the functional results of both techniques.

Conclusion Tibialis posterior muscle transfer demonstrated a statistically and clinically significant advantage over tenodesis of the extensor digitorum longus in restoration of the dorsiflexion function in patients with isolated peroneal nerve neuropathy lasting more than 12 months. The need to integrate personalized rehabilitation programs into the surgical treatment was supported by differences in the recovered ankle function and biomechanical gait parameters.

Keywords: drop foot, common peroneal nerve neuropathy, posterior tibial muscle transfer, tenodesis of the extensor digitorum longus, tendon transfer, functional recovery, stabilometry, comparative study

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INTRODUCTION

Peroneal nerve palsy can progress to foot drop, limb disability, affecting the quality of life [1]. The anatomical location of the peroneal nerve in the region of the fibular head makes it vulnerable to compression injuries of different etiologies, as confirmed by epidemiological studies on the incidence of injuries in this location [2].

With denervation lasting longer than 12 months, neuroreconstructive interventions are less effective due to irreversible structural changes in the muscles and fibrotic processes in the denervated muscles [3]. In such cases, tendon transfer is the method of choice to restore dorsiflexion of the foot.

Modern surgical approaches include different tendon transposition techniques including extensor digitorum longus tenodesis and posterior tibial transfer through the interosseous membrane [4]. However, there are conflicting data regarding the comparative effectiveness of these techniques due to the retrospective nature of the studies, small sample sizes, and the lack of standardized criteria for assessing functional outcomes [5]. The lack of direct comparative studies with use of objective functional assessment hinders the formation of evidence-based clinical recommendations.

This study was conducted to obtain objective data on the comparative effectiveness of the two most common tendon techniques for addressing the foot drop. Evaluation of functional outcomes using validated scales, instrumentation methods for measuring strength and range of motion, modern stabilometric technologies allowed for a comprehensive assessment of the effectiveness of surgical treatment. Analysis of short-term and long-term surgical outcomes over a two-year follow-up period facilitated assessment of the sustainability of the improvement achieved and the identification of potential long-term complications.

The **objective** was to determine the optimal surgical strategy for restoring dorsiflexion of the foot in case of isolated injury to the peroneal nerve through comparative analysis of tenodesis of the extensor digitorum longus and posterior tibial muscle trasfer.

MATERIAL AND METHODS

The study was conducted at the Department of Reconstructive Surgery between January 2018 and December 2023.

Inclusion criteria included age from 18 to 65 years; neuropathy duration more than 12 months; isolated neuropathy of the peroneal nerve confirmed by electroneuromyography; lack of effect from conservative therapy for at least six months, informed consent to participate in the study.

Exclusion criteria included multiple injuries to the nerves of the lower limb; concomitant orthopedic disorders of the foot and ankle; systemic neuromuscular diseases; severe somatic pathology in the decompensation stage; mental disorders that would prevent participation in the study; refusal to participate or violation of the observation protocol.

The sample was selected using a continuous sampling method among patients meeting the inclusion criteria. The study design was a prospective comparative cohort study with parallel groups.

The study included 84 patients with a mean age of 41.3 ± 7.8 years and a male to female ratio of 1.4:1. The first group consisted of 42 patients who underwent tenodesis of the extensor digitorum longus tendon to the anterior border of the tibia using the modified Lambrinudi technique. The second group included 42 patients who were treated with posterior tibial muscle transfer through the interosseous membrane and fixation to the lateral cuneiform bone using the Bridle technique.

Functional assessment was performed using the AOFAS Ankle and Hindfoot Scale evaluating pain, function, and foot alignment on a 100-point scale. Dorsiflexion was measured using a standard goniometer with the patient being in supine position and the tibia being immobilized. The maximum angle between the longitudinal axis of the foot and the anterior surface of the tibia was measured.

Dynamometry of the dorsiflexor strength was performed using a MicroFET2 device (Hoggan Health Industries), measuring force in kg during maximal isometric contraction in a sitting position with the tibia flexed at a right angle. Measurements were expressed as a percentage of the contralateral limb's strength. Stabilometric testing was performed using the Stabilan-01-2 platform (Ritm Design Bureau) in static mode, recording center of pressure fluctuations while standing with eyes open for 30 seconds. The analysis included the center of pressure trajectory length in mm, statokinesiogram area in mm^2, standard deviations in the frontal and sagittal planes, and Romberg's coefficient. Follow-up visits were conducted at three, six, 12, and 24 months postoperatively.

Statistical data processing was performed using the IBM SPSS Statistics version 26.0 package. Normality of distribution was tested using the Shapiro – Wilk test for sample sizes less than 50 observations and the Kolmogorov – Smirnov test for larger sample sizes. For normal data distribution, the parametric Student's t-test for independent samples was used; the nonparametric Mann – Whitney test was used in case of deviation from normal distribution. Quantitative characteristics of the indicators in sample populations were presented as the arithmetic mean and standard deviation for a normal distribution or the median and interquartile range for a distribution different from normal. To assess the homogeneity of the groups, the variation coefficient was calculated as the ratio of the standard deviation to the arithmetic mean, expressed as a percentage. The level of statistical significance was taken as $p < 0.05$.

RESULTS

There were no statistical differences in preoperative parameters in the groups, which ensured the validity of the subsequent comparative analysis. The mean AOFAS score measured (52.4 ± 6.1) in the first group and (51.8 ± 5.9) in the second group with $p = 0.614$. The amplitude of active dorsiflexion ranged between minus (12.3 ± 3.4)° and minus (11.9 ± 3.7)°, respectively (Table 1).

Table 1

Comparison of preoperative parameters between groups

Description	Tenodesis group ($n = 42$)	Muscle transfer group ($n = 42$)	p
AOFAS score	52.4 ± 6.1	51.8 ± 5.9	0.614
Dorsiflexion range (°)	–12.3 ± 3.4	–11.9 ± 3.7	0.738
Dorsiflexion strength (% of contralateral)	32.1 ± 8.7	33.4 ± 9.2	0.523
Length of the trajectory of the center of pressure (mm)	524 ± 87	518 ± 92	0.756
Statokinesiogram area (mm^2)	272 ± 61	268 ± 58	0.782
Standard deviation in the frontal plane (mm)	4.8 ± 1.2	4.9 ± 1.3	0.698
Standard deviation in the frontal plane (mm)	5.1 ± 1.4	5.2 ± 1.5	0.724

Note: AOFAS score showed low variability (CV ≈ 11–12 % in both groups); dorsiflexion range demonstrated moderate variability (CV ≈ 28–31 %); stabilometric indicators suggested moderate variability (CV ≈ 15–20 %).

After 12 months, the tenodesis group showed an increase in AOFAS score to (78.6 ± 8.2), an increase of 26.2 points from baseline at $p < 0.001$. Dorsiflexion range of motion reached (8.4 ± 4.1)°, an increase of 20.7°. In the second group, the functional result was more pronounced: the AOFAS score was (86.3 ± 6.7), an increase of 34.5 points at $p < 0.001$, and range of motion increased to (14.8 ± 3.9)°, with an overall improvement of 26.7°.

Between-the-group comparison revealed a statistically significant advantage of the posterior tibial transfer both in terms of the AOFAS score at $p = 0.003$ and in terms of the range of motion at $p = 0.001$. Dynamometry showed a recovery of dorsiflexion strength to (62.4 ± 11.3) % of the contralateral limb in the first group and to (78.9 ± 9.6) % in the second group at $p < 0.001$ (Table 2).

Table 2

Functional results at 12 months

Description	Tenodesis group (n = 42)	Muscle transfer group (n = 42)	p
AOFAS (score)	78.6 ± 8.2	86.3 ± 6.7	0.003
Increase in AOFAS (score)	26.2	34.5	< 0.001
Dorsiflexion range (°)	8.4 ± 4.1	14.8 ± 3.9	0.001
Dorsiflexion strength (% of contralateral)	62.4 ± 11.3	78.9 ± 9.6	< 0.001
Length of the trajectory of the center of pressure (mm)	342 ± 67	251 ± 48	< 0.001
Statokinesiogram area (mm²)	195 ± 44	154 ± 32	< 0.001
Standard deviation in the frontal plane (mm)	3.2 ± 0.9	2.6 ± 0.8	0.003
Standard deviation in the sagittal plane (mm)	3.6 ± 1.1	2.9 ± 0.7	0.002

Note: AOFAS score showed moderate variability (CV ≈ 10 % in the tenodesis group, CV ≈ 8 % in the muscle transfer group); dorsiflexion range suggested high variability (CV ≈ 49 % in the tenodesis group, CV ≈ 26 % in the muscle transfer group); dorsiflexion strength demonstrated moderate variability (CV ≈ 18 % and 12 %, respectively); stabilometric indicators suggested low variability (CV ≈ 12–20 %).

Stabilometric examination revealed statistically significant improvement in balance control parameters in both groups. The center of pressure trajectory length decreased by 34.8 % with tenodesis and by 51.6 % with muscle transfer relative to preoperative values. The statokinesiogram area decreased by 28.3 % in the first group and by 42.7 % in the second group. The standard deviations in the frontal plane decreased from (4.8 ± 1.2) mm to (3.2 ± 0.9) mm in the tenodesis group and from (4.9 ± 1.3) mm to (2.6 ± 0.8) mm in the muscle transfer group.

The results stabilized in both groups with minor improvement at 24 months. The AOFAS scored (88.1 ± 5.9) and dorsiflexion range measured (15.6 ± 3.2)° in the muscle transfer group. The corresponding indicators scored (79.8 ± 7.8) and measured (9.1 ± 3.8)° in the tenodesis group. Excellent and good results measured with the AOFAS were obtained in 73.8 % of patients in the first group and in 88.1 % of the second group with p = 0.047.

Stabilometric measurements showed the superiority of active muscle transfer at 24 months. The length of the center of pressure trajectory was (267 ± 45) mm in the muscle transfer group versus (324 ± 58) mm in the tenodesis group, with p < 0.001. The statokinesiogram area measured (118 ± 28) mm² versus (156 ± 41) mm², respectively, with p = 0.002 (Table 3).

Table 3

Long-term follow-up at 24 months

Description	Tenodesis group (n = 42)	Muscle transfer group (n = 42)	p
AOFAS (score)	79.8 ± 7.8	88.1 ± 5.9	< 0.001
Dorsiflexion range (°)	9.1 ± 3.8	15.6 ± 3.2	< 0.001
Dorsiflexion strength (% of contralateral)	64.7 ± 10.9	81.2 ± 8.4	< 0.001
Length of the trajectory of the center of pressure (mm)	324 ± 58	267 ± 45	< 0.001
Statokinesiogram area (mm²)	156 ± 41	118 ± 28	0.002
Standard deviation in the frontal plane (mm)	3.1 ± 0.8	2.4 ± 0.6	< 0.001
Standard deviation in the sagittal plane (mm)	3.4 ± 1.0	2.7 ± 0.5	0.001
Excellent and good results (%)	73.8	88.1	0.047

Note: AOFAS score shows moderate variability (CV ≈ 10 % in the tenodesis group, CV ≈ 7 % in the muscle transfer group); dorsiflexion range shows high variability (CV ≈ 42 % in the tenodesis group, CV ≈ 21 % in the muscle transfer group); stabilometric parameters show low variability (CV ≈ 15–18 % in the tenodesis group, CV ≈ 12–17 % in the muscle transfer group).

Complications developed in six patients after tenodesis, representing a rate of 14.3 %, including insufficient correction requiring revision surgery (n = 3), painful scar formation (n = 2), and infected wound (n = 1). Four complications were recorded in the muscle transfer group, representing a rate of 9.5 % including transient plantar flexion weakness (n = 2), forefoot tunnel syndrome (n = 1), and hypertrophic scar (n = 1). The difference in complication rates was not statistically significant at p = 0.386.

DISCUSSION

The findings demonstrated the superiority of posterior tibial transfer over extensor digitorum longus tenodesis in the correction of the footdrop caused by isolated peroneal nerve neuropathy. The difference in functional recovery between the two techniques could be explained by a difference in the mechanism of action: muscle transfer created active muscle traction, whereas tenodesis provided passive stabilization of the foot. These data are consistent with observations demonstrating significant improvements in dorsiflexion and gait after the Bridle procedure for traumatic peroneal nerve injury, with all patients achieving functional recovery without the use of additional orthotic devices [1, 6].

The dorsiflexion strength restored to 78.9 % of the contralateral limb in the muscle transfer group achieved in our series correlates with international data presented by different research groups. Eisenstein et al. emphasized the importance of careful planning and adherence to indications for tendon transpositions, which is confirmed by our findings [2]. Matsakyan et al. reported good results achieved in 12 of 16 patients treated with a minimally invasive method of the posterior tibial tendon transfer demonstrating the reproducibility of the technique in different clinical settings [3]. It is important to note that Medina's modification of the tendon transfer procedure for the correction of extensive necrosis of the anterior muscles of tibia opens up the possibility of individualized surgical approaches depending on the degree of injury to the muscle structures [4].

The lower strength recovery with tenodesis, which amounted to 62.4 % of the contralateral limb, could be explained by the absence of an active muscle component and the dependence of the effect on the tension of the fixed tendon. This observation is consistent with the findings of Wareham et al. who reported the importance of a comprehensive approach to the treatment of patients with neurodegenerative processes. However, our analysis revealed significant differences in long-term functional outcomes between different tendon transposition techniques [5]. McCormick emphasized the importance of determining the etiology of peroneal nerve palsy for choosing the optimal surgical strategy, given the variability of the spectrum of deformities and weakness in the ankle joint, which was reflected in the varying effectiveness of the techniques we used [7].

Stabilometric measurements demonstrated objective improvement in balance control and gait quality, with the reduction in the center of pressure trajectory length being 51.6 % with muscle transfer versus 34.8 % with tenodesis relative to preoperative values. These data correlate with the findings reported by Golubeva et al., who performed a retrospective analysis of 375 patients' data and found that footdrop was characterized by impaired support, stability, symmetry, and rhythm of walking, which significantly impaired quality of life [8]. Chen demonstrated that functional electrical stimulation could restore the physiological pattern of dorsiflexor muscle activation and improve biomechanical gait parameters in patients with implanted neurostimulators, which opens up prospects for combined treatment [9].

The difference of 7.7 AOFAS score and 6.5° in range of motion at 24 months suggested statistical and clinical significance for the daily activities of patients. Wiszomirska reported the importance of an integrated approach to the correction of biomechanical disorders, which is consistent with our observations on the multifactorial nature of functional recovery [10]. Aksenova reported highly

effective comprehensive rehabilitation programs with biofeedback in postoperative restoration of foot function, which emphasizes the need to integrate surgical treatment with modern rehabilitation technologies [11].

The complication rate in our groups was comparable and amounted to 14.3 % after tenodesis versus 9.5 % after muscle transfer, which is consistent with the data of Bashlyachev et al., who reported 80 patients with compression neuropathy of the common peroneal nerve treated with 84 decompression surgeries [12]. The nature of the complications differed significantly between the groups: insufficient correction during tenodesis could be associated with the technical aspects of determining the optimal tendon tension, which requires significant surgical experience. Somov and Domansky developed a technology for intraoperative visual neuromonitoring for reconstructive neuroplasty surgeries, creating a special electrical stimulator ESVM-1, which can potentially reduce the incidence of such complications due to the objectification of tension control [13].

Transient weakness of plantar flexion after muscle transfer is an expected phenomenon and regresses during the process of neuromuscular adaptation within three to four months. This is consistent with the observations of Novikov and Antonova, who reported outcomes of 254 patients after total knee arthroplasty and found that complex intensive restorative treatment, carried out intermittently for at least six months, allowed for the function of the affected nerve restored in 75 % of cases [14]. Leclère reported neurotic muscle transfer and emphasized the importance of drug support for reinnervation processes, which suggested the need for a comprehensive approach to the prevention and treatment of postoperative complications [15].

The time factor plays a critical role in determining the indications for different surgical techniques. Pang et al. reported a retrospective study of 45 patients with common peroneal nerve injuries and found that the optimal time interval to achieve restoration of plantar dorsiflexion to the M3 level was 9.5 months with an area under the receiver operating characteristic curve of 0.871, and for M4 recovery, the optimal period was 5.5 months [16]. Our inclusion criterion for patients with a neuropathy duration of more than 12 months justifies the choice of tendon transfers as the technique of choice when nerve reconstruction is ineffective. Bao et al. demonstrated the appearance of new electrical potentials in the tibialis anterior muscle and long extensors in seven of eight patients 10–15 months after direct transfer of the muscular branch of the soleus muscle of the tibial nerve to the deep peroneal nerve, which emphasizes the importance of early neuroreconstructive interventions [17].

A critical analysis of electrophysiological parameters as predictors of surgical success is an important aspect of our approach. In contrast to the findings of Nikitin et al., who focused on the phenomenology of the conduction block, our study established that the feasibility of direct nerve reconstruction is significantly reduced with denervation lasting more than 12 months [18]. Fominykh et al. explored the effectiveness of neurolysis in compression neuropathy of the peroneal nerve in the fibular canal in 29 patients and obtained excellent treatment results in 89.7 % of cases, which suggests the effectiveness of decompressive interventions in early stages of the disease [19].

Vlasov et al. noted that spontaneous recovery in approximately one third of patients who suffered closed peroneal nerve injuries, but the remaining two thirds may require surgical intervention, with long-term surgical outcomes for nerve restoration or neurolysis of the peroneal nerve being not always satisfactory [20]. This observation substantiates the need to develop alternative surgical strategies for patients with long-term denervation. Liu et al. reported a retrospective cohort study of 387 patients who underwent surgical repair of the injured common peroneal nerve and found that

high preoperative muscle strength reduces the risk of adverse outcome with a relative risk of 0.18, which emphasizes the importance of early surgical intervention before the development of severe muscle atrophy [21].

Lezak's anatomical studies provided a fundamental basis for understanding the characteristics of the peroneal nerve and its branches, emphasizing the importance of precise localization of the compression zone to determine the extent of neurolysis and predict the functional outcome of surgery [22]. Bojovic developed a systematic approach to the diagnosis of tunnel syndromes, including a detailed clinical assessment, differential diagnosis, and integration of additional diagnostic findings, which is reflected in our comprehensive preoperative examination [23]. Fakih reported the importance of careful clinical interviewing and focused physical examination for localizing neuropathy, which is relevant for atypical causes of compression [24].

Specific clinical situations require a specific diagnostic approach considering the pathophysiological mechanisms. Yadav et al. presented a detailed analysis of iatrogenic footdrop syndrome after anterior cruciate ligament reconstruction, in which surgical exploration revealed an intraneural hematoma and nerve trunk contusion, requiring neurolysis with subsequent restoration of function after three months [25]. Lale explored the incidence and causes of footdrop after bariatric interventions, establishing a link between the loss of fat pad around the fibular head and the development of compression neuropathy, which contributes to our understanding of the diverse etiologic factors [26].

Jiménez reported a case of a 13-year-old patient with progressive peroneal nerve palsy caused by an atypical elongated intraneural ganglion cyst, which hampered timely diagnosis and treatment [27]. Peters established the existence of four clinical subtypes of common peroneal nerve neuropathy, including cases with normal electrodiagnostic parameters, which expands the diagnostic spectrum of the disease and emphasizes the need for surgical decompression even in the absence of conventional symptoms [28]. Strother analyzed the demographic characteristics and surgical outcomes of traumatic peroneal nerve injuries, emphasizing the importance of proper patient counseling regarding the complexity of treatment and the variability of results [29].

The pathophysiological mechanisms of foot drop syndrome represent a complex cascade of structural and functional disorders of nerve conduction. Oosterbos reported the efficacy of surgical decompression of the peroneal nerve in the randomized controlled trial FOOTDROP as compared to conservative therapy during a long-term observation of patients over eighteen months [30]. Miroshnikova established the potential of using mesenchymal stem cells to stimulate regenerative processes in injured nerve fibers in an experimental model of neuropathy, which opens up prospects for drug support of surgical treatment [31].

A multidisciplinary approach involving a neurologist, neurosurgeon, and rehabilitation specialist ensures a comprehensive assessment and development of an individualized treatment plan. Intraoperative assessment of nerve fiber viability using electrical stimulation allows for clarification of indications for intraoperative neurolysis, representing an important technical innovation. Mens and Haviv reported the importance of preventive measures for iatrogenic nerve injuries, which furthers our understanding of the etiologic structure of footdrop syndrome [32].

The need for a comprehensive approach to postoperative rehabilitation, including biofeedback and stabilometric monitoring technologies, is confirmed by differences in the recovery of the local ankle function and biomechanical gait parameters. Integrating surgical treatment with personalized

rehabilitation programs represents a promising avenue for further improvement of treatment outcomes for patients with footdrop. Further research should focus on exploring the potential of minimally invasive tendon transposition techniques and the use of biological factors that would stimulate neuromuscular adaptation processes in the postoperative period.

CONCLUSION

Tibialis posterior transfer demonstrates a statistically and clinically significant advantage over extensor digitorum longus tenodesis in restoring foot dorsiflexion function in patients with isolated peroneal nerve neuropathy lasting more than 12 months. A fundamental difference in the mechanism of action — the creation of active muscle traction during muscle transfer versus passive stabilization during tenodesis—provides a more physiological restoration of motor function. Dorsiflexion strength achieved to 78.9 % of the contralateral limb with muscle transfer versus 62.4 % with tenodesis suggests the functional superiority of this method. A comparable complication rate with an advantage in motor restoration justifies the use of tibialis posterior transposition as the method of choice for this pathology.

Comparable complication rates between groups with superior functional outcomes from muscle transfer support its use as the method of choice for isolated peroneal nerve neuropathy with long-term denervation. Transient weakness of plantar flexion after transposition, which regresses during neuromuscular adaptation, should not be considered a barrier to surgery, given the significant superiority of this method in restoring dorsiflexion. In contrast, insufficient correction during tenodesis is a more serious problem, requiring revision surgery and associated with technical difficulties in determining optimal tendon tension.

The findings allow us to recommend posterior tibial transfer as the preferred surgical technique for patients with isolated peroneal nerve neuropathy where denervation has lasted more than twelve months and conservative therapy or neuroreconstructive interventions have failed. Tenodesis of the extensor digitorum longus may be considered as an alternative technique in the presence of contraindications to muscle transfer or technical limitations; however, patients should be informed of its lower effectiveness in restoring strength and range of dorsiflexion.

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Information about the authors:

Artsrun A. Grigoryan — post-graduate student, Artsrun3204@mail.ru, https://orcid.org/0000-0003-0677-2960;

Wessam Mussa Abu Zaalan — post-graduate student, orthopaedic surgeon, wsameeexx@gmail.com, https://orcid.org/0000-0003-3922-3052.

Levon G. Makinyan — Candidate of Medical Sciences, Associate Professor of the Department, Head of Department, dr.makinyan@gmail.com, https://orcid.org/0000-0002-8813-143X;

Albert M. Mannanov — Candidate of Medical Sciences, orthopaedic surgeon, albertmannanov@gmail.com, https://orcid.org/0000-0002-4456-8218;

Chyngis Moldamyrzayev — post-graduate student, moldamirzayev@mail.ru, https://orcid.org/0009-0002-8501-0680;

Mikhail A. Imankulov — post-graduate student, Mikhail.imankulov@mail.ru, https://orcid.org/0000-0002-4398-1801.

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Results of a differentiated approach to open decompression of the median nerve in carpal tunnel syndrome

S.N. Izmalkov[1], O.M. Semenkin[1,2], A.N. Bratiychuk[1]✉, A.K. Usov[2,3], N.A. Demchenko[1], A.E. Guseva[4], K.F. Khairullina[5]

[1] Samara State Medical University, Samara, Russian Federation
[2] Clinical Hospital, Samara, Russian Federation
[3] Samara Regional Clinical Hospital named after V.D. Seredavin, Samara, Russian Federation
[4] MedGard, Samara, Russian Federation
[5] Medical Center Samara School of Ultrasound, Samara, Russian Federation

Corresponding author: Alexander N. Bratiychuk, brat59@bk.ru

Abstract

Introduction Open decompression of the median nerve is a common surgery performed for carpal tunnel syndrome (CTS). Transection of the transverse carpal ligament (TCL) results in impaired hand biomechanics and decreased grip strength when specific anatomy necessitate transection of the thenar muscles along with the ligament.

The **objective** was to compare short-term and long-term surgical results of CTS patients treated with open decompression without thenar muscle reconstruction, with thenar muscle reattachment and with reconstruction of the thenar muscles.

Material and methods A total of 80 patients with idiopathic CTS treated with 92 surgical procedures were included in the study. They were divided into three groups. The first group included 38 patients (39 surgeries) treated with open decompression without reconstruction of the TCL. Forty surgical procedures were produced for 31 patients of the second group including dissection and reattachment of the thenar muscles located at the site of the median nerve dissection. Median nerve decompression followed by TCL reconstruction were performed for 11 patients of the third group treated with 13 surgical procedures.

Results All patients demonstrated positive dynamics with more significant recovery of the hand function achieved after open decompression of the median nerve and reattachment of the thenar muscles and reconstruction of the spinal nerve with the outcome improved at three months and stabilized at six months of the surgery.

Discussion A differentiated approach to treatment ensured the amplitude of the M-response of the brevis muscle abducting the pollicis increased by 15.9 % in the first group, by 34.3 % in the second group, and by 30.5 % in the third group; the impulse velocity along the motor fibers of the median nerve increased by 6.6 %, 13.2 %, and 10.9 %, respectively, at six months. Less improvement in electrophysiological parameters in patients of the first group could be associated with a more advanced surgical technique employed for the patients of the second and third groups.

Conclusion A comparative analysis of the short-term and long-term surgical outcomes of CTS patients revealed clinically significant improvement with both options. However, the hand function recovery was more accomplished in the second and third groups with use of the two methods we developed.

Keywords: carpal tunnel syndrome, transverse carpal ligament, surgical treatment.

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INTRODUCTION

Carpal tunnel syndrome (CTS) is a mononeuropathy of the median nerve caused by its compression by surrounding tissues. The prevalence of CTS is 150–276 individuals per 100,000 population. The condition is progressive, resistant to conservative therapy, prone to recurrence, and necessitates surgical treatment, which is effective in 70–90 % of clinical observations [1].

Idiopathic CTS is one of the clinical forms, without obvious causes (acute trauma, post-traumatic deformities of the hand and the wrist, endocrine, metabolic or chronic systemic diseases, intraneural tumors). The disease can be associated with repeated loads on the hand when bending at the wrist, keeping it in one position for a long time, and playing vibrating instruments. Installers, packers, assemblers, artists, jewelers, office workers, and pianists have a high risk of developing the disease [1].

Open decompression of the median nerve is a common surgery for CTS to facilitate rapid relief of debilitating pain and increased sensitivity in the fingers, achieving lasting clinical improvement. However, transection of the transverse carpal ligament (TCL) can result in impaired biomechanics of the hand and decreased grip strength and pillar pain [2, 3, 4, 5, 6].

Several methods have been proposed by hand surgeons to restore the dissected carpal tunnel [7, 4]. The authors took into account the fact that the carpal tunnel is the anterior border of the carpal tunnel and the attachment of the thenar and hypothenar muscles [3].

It is known that approximately half of the area of the anterior surface of the ligament is occupied by the muscles of the eminence of the thumb (m. flexor pollicis brevis, abductor pollicis brevis) on the radial side [8]. These muscles are attached on the ulnar side in 55 % of clinical observations, in the projection of the site of the supposed ligament dissection [9]. The muscles are either transected or peeled off to the radial side in such situations to allow dissection of the TCL in the ulnar part of the carpal tunnel, avoiding injury to the median nerve and its motor branch during the repair [10].

The procedure can be associated with loss of the thenar muscle attachment after detachment or transection and cause their hypo- or atrophy affecting the restoration of the hand function [11].

To prevent such complications, we developed a method for refixing the muscles of the eminence of the thumb after open decompression of the carpal tunnel [12].

The **objective** was to compare short-term and long-term surgical results of CTS patients treated with open decompression without thenar muscle reconstruction, with thenar muscle reattachment and with reconstruction of the thenar muscles.

MATERIAL AND METHODS

The study included 80 patients with idiopathic CTS treated with open decompression of the median nerve between January 1, 2024, and June 1, 2025. There were 67 female and 13 male patients with a mean age of 58 years (range, 36–86 years). Bilateral surgeries were performed in 12 patients at an interval of at least three months. Surgery on one side was considered one clinical observation. A total of 92 surgical interventions were performed. Right-sided surgery was performed in 61 (66 %) cases and 31 (34 %) patients had left-sided procedures.

The study was a non-randomized, prospective, single-center, longitudinal, parallel-group controlled clinical trial. Inclusion criteria included CTS diagnosed preoperatively and confirmed intraoperatively. Exclusion criteria included the presence of concomitant systemic, metabolic, and endocrine diseases, posttrraumatic conditions of the hand and the forearm, cubital tunnel syndrome, and recurrent CTS. No patients were excluded from the study.

The primary endpoint of the study was to evaluate the effectiveness of surgical treatment of CTS patients by open decompression of the median nerve and re-attachment of the muscles at the eminence of the thumb and open decompression of the median nerve with reconstruction of the TCL as well as to develop recommendations for differentiated surgical treatment depending on the anatomy of the wrist and pathological changes.

Secondary endpoints of the study included the analysis of clinical parameters (power grip of the hand, daily activities, severity of symptoms and functional impairments), ENMG parameters (amplitude of the M-response of the abductor pollicis brevis muscle, distal latency of the motor fibers of the median nerve, impulse conduction velocity in the motor fibers of the median nerve, impulse conduction velocity in the sensory fibers of the median nerve).

The clinical observations were divided into three groups depending on the method of surgical intervention used (Table 1). The first group included 38 patients (39 operations) who had no TCL repair after decompression of the median nerve. The second group consisted of 31 patients (40 operations) who had the muscles at the eminence of the thumb (m. flexor pollicis brevis and m. abductor pollicis brevis) overlapping the line of the intended dissection of the TCL. The muscle attachment site was carefully separated with the underlying superficial part of the ligament. Re-attachment was produced after decompression of the carpal tunnel without reconstruction of the TCL. The operation was performed using the method we developed [11]. The third group included 11 patients (13 operations) who underwent reconstruction of the TCL after decompression of the median nerve, using another method we had developed earlier [13].

The clinical groups (Table 2) were comparable in age, timing of surgery from the onset of the disease, the severity of CTS as classified by Beck [14].

Table 1

Characteristics of the study groups

Study groups	Type of surgical procedure	Number of patients (n = 80)		Number of surgeries (n = 92)	
		abs.	%	abs.	%
No. 1	Open decompression of the median nerve	38	47.50	39	42.5
No. 2	Open decompression of the median nerve and re-ayttachment of the thenar muscles	31	38.75	40	43.5
No. 3	Open decompression of the median nerve and reconstruction of the TCL	11	13.75	13	14.0

Table 2

Characteristics of patients in the study groups

Description		Клинические группы						P^{1-2}; P^{1-3}; P^{2-3}
		No. 1 (n = 39)		No. 2 (n = 40)		No. 3 (n = 13)		
		абс.	%	абс.	%	абс.	%	
Age	< 50 years	9	23.7	11	27.5	4	30.7	> 0.05
	51–60 years	16	41.1	17	42.5	6	46.1	> 0.05
	> 60 years	14	35.2	12	30.0	3	23.2	> 0.05
Timing of surgery from the onset of the disease	< 6 years	27	69.2	28	70.0	9	69.2	> 0.05
	6 < 12 years	8	20.5	7	17.5	2	15.4	> 0.05
	⩾ 12 years	4	10.3	5	12.5	2	15.4	> 0.05
Severity of CTS	mild	10	25.6	12	30.0	4	30.8	> 0.05
	moderate	13	33.3	13	32.5	4	30.8	> 0.05
	severe	16	41.1	15	37.5	5	38.4	> 0.05

Diagnosis of the TCL relied on pain in the hand, mainly at night and in the morning, numbness at the site innervated by the median nerve, duration of the disease and failed conservative treatment, the presence of positive clinical symptoms of Phalen, Tinel, the flick maneuver, the scratch collapse test, ENMG and ultrasound findings. Indications for surgery included CTS diagnosed by a hand surgeon, by ENMG and ultrasound, lack of clinical improvement after a three-month conservative treatment, and negative dynamics in ENMG findings.

The choice of surgical treatment was based on preoperative ENMG and ultrasound findings, intraoperative visualization of pathological changes at the surgical site. The final decision on the surgical technique was made intraoperatively.

Isolated median nerve decompression without posterior ligament reconstruction was performed for patients with severe flexor tenosynovitis detected intraoperatively, preventing full restoration of the TCL (group one). The thenar muscles were separated along with the superficial portion of the underlying ligament and re-attached en bloc after transection if the muscles were identified at the site of the intended TCL transection during ultrasound examination of the carpal tunnel or intraoperatively (group two). Open carpal tunnel decompression and true posterior ligament reconstruction were produced for individuals whose jobs were associated with repetitive and forceful activities that would 'overload' the tendons and muscles (group three).

The effectiveness of surgical treatment was evaluated using eight criteria including four clinical (handgrip strength, daily activities, severity of clinical symptoms, and functional deficiency) and four relied on electroneuromyography (M-response amplitude of the abductor pollicis brevis muscle, distal latency of the median nerve motor fibers, and impulse conduction velocity along the median nerve motor and sensory fibers). The parameters were explored dynamically: preoperatively, at three months of surgery, and at six months post-op. The magnitude of the hand grip strength was measured using a DK-50 hand spring dynamometer (ZAO Nizhny Tagil Medical and Instrumental Plant, Russia). The test was performed on each hand twice with a one-minute interval, with the mean calculated.

The severity of patients' daily activities was determined using the DASH questionnaire [15, 16, 18].

The BCTQ questionnaire was used to evaluate treatment outcomes [17, 18, 19].

The functional status of the peripheral motor and sensory fibers of the median nerve was examined in both hands using standard programs of the Lightbox electromyograph (Neurosoft, Russia), two cables for connecting disposable electrodes with a touch-proof alligator connector (black and red), a ground electrode, and a disposable skin electrode 22×34 mm. The examination was performed according to standard methods [20].

An ultrasound examination was performed on both upper extremities using a Samsung Medison HS 40 system and a linear transducer with a frequency of 3–16 MHz. The scan identified the median nerve, its size, structure, nerve compression sites at the wrist and upper forearm, the location of the thenar muscles in the carpal tunnel, and the condition of the surrounding tissues, muscles, and tendons.

Statistical analysis of the data was performed using SPSS 25 (IBM SPSS Statistics, USA, license no. 5725-A54). The conformity of the quantitative trait values to the normal distribution law was tested using the Shapiro – Wilk and Kolmogorov – Smirnov tests, with the Liliefors correction. Descriptive statistics were presented as the mean and standard deviation (M ± SD). Groups were compared using the Kruskal – Wallis rank analysis of variance, Mann – Whitney tests, the Wilcoxon paired test, and Pearson's χ^2 (for nominal variables).

Boxplots showing the median, quartiles, minimum, and maximum were used to visualize the data. The critical value of the significance level was taken as 0.05 in all cases except for between-the-group comparisons in the analysis of variance, where the Bonferroni correction was applied with a critical value of $p = 0.017$.

Surgical technique

Identical surgical conditions, the surgical approach and stages of the operation in patients of the first group corresponded to the principles we reported earlier [19].

Skin incision and aponeurosis similar to that in the first group was produced in patients of the second group. The TCL was dissected along the ulnar aspect. Moving proximally to the point of intersection with the thenar muscles (Fig. 1a), an incision bending around the apex of muscle attachment was used to dissect the superficial leaf of the ligament along with the muscles. They were retracted outward. Then, the TCL and the deep fascia of the forearm were completely dissected (Fig. 1b). The median nerve was repaired. The dissected muscles and a portion of the ligament were re-attached (sutured back in place or outward up to 3 mm) using a U-shaped suture with two locking loops on each side (Fig. 1c). After this, the palmar aponeurosis was sutured with three to four separate stitches to allow for the thenar muscles to be shifted inwards, reducing the tension at the point of their fixation. Donati sutures were applied to the skin.

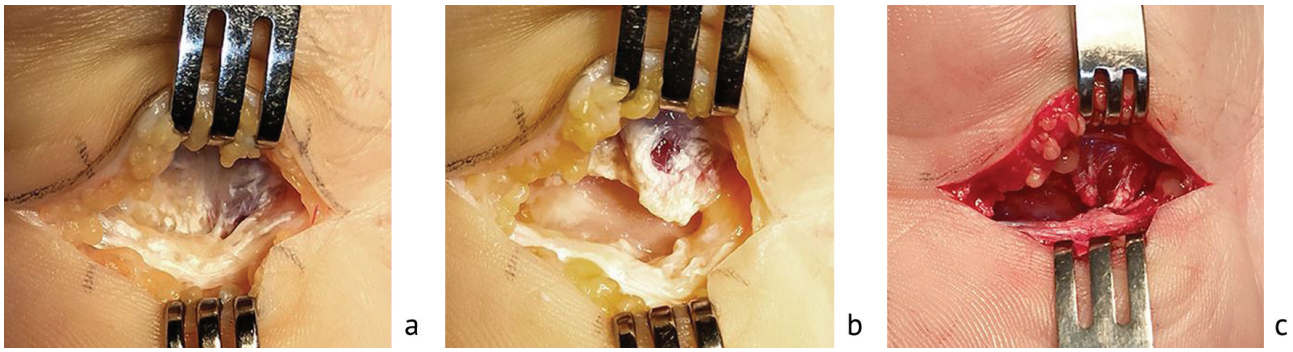


Fig. 1 The thenar muscles located in the projection of the TCL intersection line (a); the transected and abducted thenar muscles (b); appearance of the surgical wound after re-attachment of the thenar muscles (c)

Skin incision and aponeurosis in patients of the third group were similar to those produced in the first and second groups. The TCL was transected, creating two trapezoidal flaps: a radial (proximal) flap and an ulnar (distal) flap. The ligament flaps were re-aligned at their minor bases and joined together after exploration, mobilization, and epineurotomy of the median nerve. The palmar fascia and skin were stitched with separate sutures.

Postoperative management of the patients was performed according to the principles described earlier [19].

The study received a favourable opinion from the Bioethics Committee of Samara State Medical University (Protocol No. 312 dated November 25, 2025). The study was performed in accordance with ethical principles for medical research involving human subjects stated in the 1975 Declaration of Helsinki developed by the World Medical Association as revised in 2008. Information about the patients' personal data was not included.

RESULTS

Between-the-group comparison revealed positive dynamics of clinical and functional parameters in patients of the three groups, which was most evident at six months of surgery.

However, there were differences between the groups. The hand grip strength decreased by 35.0 % ($p^{0-3} < 0.001$) at three months, and increased after six months, but did not reach the initial level in patients of the first group (Table 3). The DASH activity of daily living improved by 31.9 % ($p^{0-3} = 0.002$) after three months, but change significantly by 61.1 % ($p^{0-6} < 0.001$) after six months. A similar trend was observed in assessment of the severity of clinical symptoms and functional impairments. The BCTQs index and the BCTQf index improved by 52.8 % ($p^{0-6} < 0.001$) and by 37.7 % ($p^{0-6} < 0.001$), correspondingly, at six months. The ENMG parameters indicated shortening of the distal motor latency by 35.6 % ($p^{0-6} < 0.001$) and the increase in sensory velocity by 72.2 % ($p^{0-6} < 0.001$) after six months, which objectively suggested clinical effectiveness of the median nerve decompression.

Table 3

Changes in clinical and functional parameters in the first group (intra-group comparison)

Description	Normal	Follow-up period			% changes		*p*	
		pre-op	at 3 months	at 6 months	at 3 months	at 6 months	p^{0-3} M–W*	p^{0-6} M–W*
Strength, daN	–	20,32 ± 4,37	13,20 ± 4,52	19,72 ± 3,98	–35,0 %	–2,9 %	< 0,001	0,511
DASH**, score	< 25	38,01 ± 9,99	25,86 ± 17,26	14,80 ± 7,38	–31,9 %	–61,1 %	0,002	< 0,001
BCTQs***, score	1.0	3,32 ± 0,66	2,02 ± 0,73	1,57 ± 0,45	–39,1 %	–52,8 %	< 0,001	< 0,001
BCTQf****, score	1.0	3,10 ± 0,63	2,37 ± 0,92	1,93 ± 0,48	–23,5 %	–37,7 %	0,013	< 0,001
Amplitude, mV	> 6.0	4,92 ± 2,89	4,55 ± 2,91	5,71 ± 2,53	–7,5 %	15,9 %	0,597	0,423
Latency, ms	< 4.2	6,62 ± 2,21	4,55 ± 0,65	4,26 ± 0,83	–31,2 %	–35,6 %	0,001	< 0,001
Motor speed, m/s	> 50	45,57 ± 17,64	48,03 ± 15,49	48,61 ± 16,36	5,4 %	6,6 %	0,351	0,200
Touch speed, m/s	57–71	21,18 ± 15,40	33,22 ± 16,01	36,47 ± 12,09	56,8 %	72,2 %	0,006	< 0,001

Note: * comparison using the Mann – Whitney test; ** questionnaire for assessing functional impairment of the upper limb; *** scale of severity of clinical symptoms; **** scale of severity of functional deficit.

The dynamics in the parameters of patients of the second group (Table 4) was slightly different from those seen in the first group. There was no significant decrease in hand grip strength at three months of the surgery. There was 9.6 % decrease from the initial level ($p^{0-3} = 0.035$). After six months, the grip strength increased by 15.2 % compared to the preoperative value ($p^{0-6} = 0.025$). The results of the clinical tests systematically improved at the follow-up periods, demonstrating a significant increase at six months: daily activities of the limb according to the DASH questionnaire improved by 70.5 % ($p^{0-6} < 0.01$); BCTQs, by 56.3 % ($p^{0-6} < 0.01$) and BCTQf, by 47 % ($p^{0-6} < 0.001$). A similar trend was observed in ENMG parameters. The amplitude of the M-response of the abductor pollicis brevis increased by 34.3 % ($p^{0-6} = 0.008$), distal motor latency improved by 31.7 % ($p^{0-6} < 0.001$), and sensory velocity by 72.4 % ($p^{0-6} < 0.001$).

Table 4

Changes in clinical and functional parameters in the second group (intra-group comparison)

Description	Normal	Follow-up period			% changes		*p*	
		pre-op	at 3 months	at 6 months	at 3 months	at 6 months	p^{0-3} M–W*	p^{0-6} M–W*
Strength, daN	–	20.53 ± 6.58	18.56 ± 4.49	23.65 ± 7.47	–9.6 %	15/2 %	0.035	0.025
DASH**, score	< 25	34.54 ± 15.48	15.15 ± 9.40	10.17 ± 8.09	–56.2 %	–70.5 %	< 0.001	< 0.001
BCTQs***, score	1.0	3.14 ± 0.81	1.59 ± 0.40	1.37 ± 0.38	–49.2 %	–56.3 %	< 0.001	< 0.001
BCTQf****, score	1.0	2.80 ± 0.83	1.83 ± 0.55	1.49 ± 0.48	–34.7 %	–47.0 %	< 0.001	< 0.001
Amplitude, mV	> 6.0	5.51 ± 2.95	6.29 ± 1.79	7.39 ± 2.63	14.3 %	34.3 %	0.277	0.008
Latency, ms	< 4.2	6.12 ± 1.84	4.09 ± 0.56	4.18 ± 0.57	–33.1 %	–31.7 %	< 0.001	< 0.001
Motor speed, m/s	> 50	47.46 ± 12.55	51.56 ± 9.16	53.74 ± 5.35	8.6 %	13.2 %	0.026	0.005
Touch speed, m/s	57–71	24.54 ± 14.56	42.21 ± 7.15	42.30 ± 7.49	72.0 %	72.4 %	< 0.001	< 0.001

Note: *comparison using the Mann – Whitney test; **questionnaire for assessing functional impairment of the upper limb; ***scale of severity of clinical symptoms; ****scale of severity of functional deficit.

Patients in the third group (Table 5) demonstrated less loss of the hand grip strength than patients in the first and second groups three months after the operation, by 2 % ($p^{0-3} = 0.935$), and increase by 24 % seen after six months ($p^{0-6} = 0.05$). There was a significant increase in functional activity of the limb measured with the DASH after six months and it was 76.9 % ($p^{0-6} < 0.001$). Patients in the third group showed the greatest improvement after six months according to the BCTQs questionnaire, with the increase of 61.8 % ($p^{0-6} < 0.001$) in dynamics, and 51.2 % ($p^{0-6} < 0.001$) according to the BCTQf questionnaire.

Table 5

Changes in clinical and functional parameters in the third group (intragroup comparison)

Description	Normal	Follow-up period			% changes		*p*	
		pre-op	at 3 months	at 6 months	at 3 months	at 6 months	p^{0-3} M–W*	p^{0-6} M–W*
Strength, daN	–	22.08 ± 6.05	21.63 ± 5.47	27.38 ± 5.61	–2.0 %	24.0 %	0.935	0.05
DASH**, score	< 25	34.93 ± 19.48	18.67 ± 3.46	8.07 ± 5.83	–46.6 %	–76.9 %	0.065	< 0.001
BCTQs***, score	1.0	2.86 ± 0.81	1.51 ± 0.19	1.09 ± 0.13	–47.1 %	–61.8 %	0.004	< 0.001
BCTQf****, score	1.0	2.38 ± 0.70	1.73 ± 0.37	1.16 ± 0.27	–27.3 %	–51.2 %	0.049	< 0.001
Amplitude, mV	> 6.0	6.83 ± 2.67	6.94 ± 1.79	8.91 ± 2.28	1.6 %	30.5 %	0.693	0.088
Latency, ms	< 4.2	5.61 ± 1.15	3.86 ± 0.38	4.10 ± 0.32	–31.2 %	–26.9 %	0.004	0.003
Motor speed, m/s	> 50	54.46 ± 4.95	56.15 ± 4.00	60.39 ± 6.09	3.1 %	10.9 %	0.456	0.039
Touch speed, m/s	57–71	29.64 ± 11.35	44.82 ± 3.03	47.04 ± 2.81	51.2 %	58.7 %	0.003	< 0.001

Note: * comparison using the Mann – Whitney test; ** questionnaire for assessing functional impairment of the upper limb; *** scale of severity of clinical symptoms; **** scale of severity of functional deficit.

ENMG parameters showed a tendency to normalize: after six months, the shortening of distal motor latency was 26.9 % ($p^{0-6} = 0.004$), and the in motor and sensory speeds increased by 10.9 % ($p^{0-6} = 0.039$) and 58.7 % ($p^{0-6} < 0.001$), respectively. The increase in the ENMG parameters in patients of the third group was smaller than in patients of the first and second groups, which was likely associated with their higher/better preoperative values.

Comparison of clinical and functional parameters between groups showed that hand grip strength decreased three months after surgery in patients of the three groups (Fig. 2a), and decreased to a greater extent in the first group (by 35 %), significantly differing from the second and third groups ($p^{1-2, 1-3} < 0.001$). There were no differences in the measurements of the second and third groups. The average value of the hand grip strength increased in all patients at six months. The hand grip strength significantly exceeded the initial data in the second and third groups (by 15.2 % and 24 %, respectively), and remained 2.9 % lower in the first group as compared to preoperative, significantly differing from the second ($p^{1-2} = 0.006$) and third ($p^{1-3} < 0.001$) groups.

More uniform improvement was seen in activities of daily living of the upper limb, assessed by the DASH questionnaire, as compared to the handgrip strength (Fig. 2b). The upper limb function increased by 61.1 % in the first group, by 70.5 % in the second, and by 76.9 % in the third at six months. The differences between the first and second groups and between the first and third groups were statistically significant ($p^{1-2} = 0.014$ and $p^{1-3} = 0.005$).

The severity of clinical symptoms measured with the BCTQs questionnaire decreased, generally in a consistent manner (Fig. 2c). The severity of symptoms decreased by 52.8 % in the patients of the first group, by 56.3 % in the second, and by 61.8 % in the third group after six months. There were no significant differences between the first and second groups, and the differences between the first and third were statistically significant ($p^{1-3} < 0.001$).

There was positive dynamics in impaired function measured with the BCTQf questionnaire (Fig. 2d). The function improved by 37.7 % in the first group, by 47.0 % in the second, and by 51.2 % in the third group after six months. The differences between the first and second groups, between the first and third groups, were statistically significant ($p^{1-2, 1-3} \leqslant 0.001$).

Along with the clinical data, There were several significant changes in the ENMG parameters, suggesting a uniform improvement in the functional status of the hand. The amplitude of the M-response of the short abductor pollicis muscle increased in the groups (Fig. 2d). It improved by 15.9 % in the first group, by 34.3 % in the second, and by 30.5 % in the third group after six months. The differences between the first and third groups were statistically significant ($p^{1-3} = 0.008$).

The distal motor latency of the median nerve showed positive dynamics at all stages of the study and in all groups (Fig. 2e). This was evident after three months with improvement by almost one third in all groups: by 31.2 % in the first, by 33.1 % in the second, and by 31.2 % in the third group. This unidirectional dynamics dissociated after six months. While distal motor latency continued to progressively decrease in the first group, reaching 35.6 % of the baseline, the dynamics were less pronounced in the second and third groups. There was 31.7 % improvement in the second group and 26.9 % improvement in the third group as compared with the baseline level. In addition, motor latency in the second and third groups returned to normal values (< 4.2 ms).

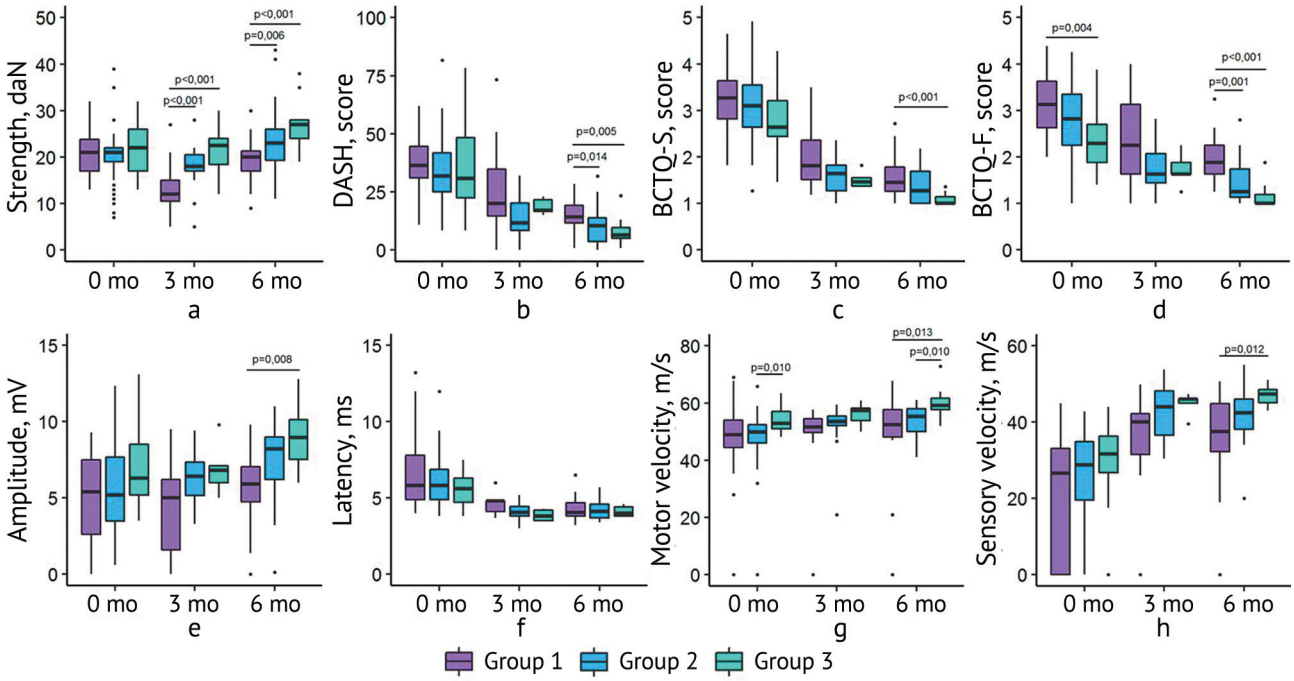


Fig. 2 Dynamics in the parameters: (a) hand grip strength measured (intergroup comparison), daN; (b) daily activities measured with the DASH questionnaire (intergroup comparison), score; (c) results of the BCTQs questionnaire (intergroup comparison), score; (d) results of the BCTQf questionnaire (intergroup comparison), score; (e) the amplitude of the M-response of the short abductor pollicis muscle (intergroup comparison), mV; (f) the distal motor latency of the median nerve (intergroup comparison), ms; (g) the impulse conduction velocity along the motor fibers of the median nerve (intergroup comparison), m/s; (h) the impulse conduction velocity along the sensory fibers of the median nerve (intergroup comparison), m/s

The impulse conduction velocity in the motor fibers of the median nerve gradually increased in the patients (Fig. 2g). The velocity increased by 6.6 % in the first group, by 13.2 % in the second group, and by 10.9 % in the third group at six months of surgery. The differences between the first and second groups, between the first and third groups were statistically significant with a reliability value of $p^{1-2} = 0.013$ and $p^{1-3} = 0.01$.

The impulse conduction velocity in the sensory fibers of the median nerve, similar to the previous ENMG indicators, also improved (Fig. 2h). A particular “jump” occurred in almost all patients three months after the operation: the impulse conduction velocity increased by 56.8 % in the first group, by 72.0 % in the second group and by 51.2 % in the third group. The increase in the velocity was not so evident at six months. The difference in the velocity increase between groups was insignificant at different time points, indicating the clinical effectiveness of the three surgical techniques.

Complications Two patients in the first group were diagnosed with pillar pain 1.5 months after surgery, which resolved spontaneously. Two patients in the second and two patients in the third groups developed short-term pain in the postoperative scar one month later, which might be caused by incomplete removal of skin sutures in the outpatient setting.

Therefore, patients in the three groups experienced clinically significant improvement after surgery. However, based on the magnitude of changes in dynamometry, questionnaire, and ENMG results, it can be concluded that patients in the second and third groups experienced a more rapid and complete recovery of hand function, which was seen after three months and became most pronounced and persistent at six-month follow-up.

We present a ***clinical case*** of a patient from the second group who underwent open carpal tunnel decompression with thenar muscle re-attachment using the technique we developed.

The 47-year-old patient, a lawyer, presented with complaints of sensory disturbances and pain in the first, second, and third fingers of her right hand, which worsened in the morning and after yoga classes. The pain had been gradually increasing over three years. Moderate hand pain and numbness were predominantly nocturnal, waking the patient four to five times. The swelling of the hand developed in the morning, and finger movement became difficult. Her professional, everyday, and athletic activities had significantly decreased. In recent months, she had been treated conservatively with minor improvement.

Initial examination showed no changes in the appearance of the right hand, no thenar muscle hypotrophy, full range of motion in the fingers. She had pain in the projection of the carpal tunnel radiating to the I–II–III fingers. Tinel's and Phalen's tests were positive. Fist grip strength was 22 daN. The activity of daily living measured with the DASH scored 32.5. The results of the BCTQs and BCTQf questionnaires scored 2.55 and 2.88, respectively. ENMG revealed changes characteristic of CTS: the amplitude of the M-response of the short abductor pollicis muscle was 7.2 mV; distal latency of the motor fibers of the median nerve measured 4.6 ms; impulse conduction velocity along the motor fibers of the median nerve was 51.3 m/s; The impulse conduction velocity along the sensory fibers of the median nerve measured 34 m/s. Ultrasound demonstrated increased cross-sectional area (CSA) of the median nerve in the carpal tunnel measuring 16 mm^2 with a norm of < 11 mm^2 [20].

Surgery performed on the right hand in September 2024 revealed the thenar muscles occupying more than half of the anterior surface of the TCL. Open decompression of the median nerve with re-attachment of the muscles at the eminence of the thumb was performed using the method we developed. Neuropathic pain relieved on the second day. The patient scrupulously followed all recommendations. The postoperative period was uneventful.

The wound healed by primary intention. The patient had no complaints, could return to her job, to yoga, she had no numbness or tingling in the hand, no pain at rest or with load, shoe could experience full range of active motion in the fingers at six months (Fig. 3a). Fist grip strength was 26 daN (Fig. 3b). The functional status of the limb and daily activities measured with the DASH scored 0.83. The BCTQ scale showed positive dynamics with BCTQs scoring 1.0, and BCTQf being 1.0. She was satisfied with the treatment results.

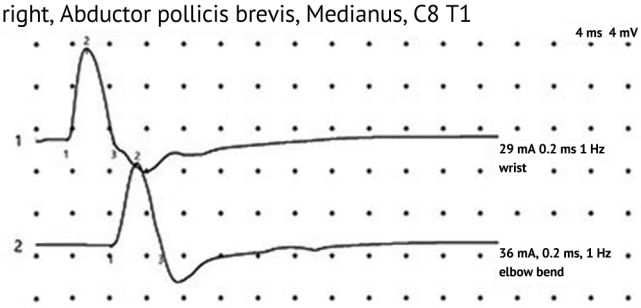
a b

Fig. 3 The range of active movements (extension, flexion) in the fingers at six months after surgery (a); dynamometry measured at six months of surgery was 26 daN in the right hand and 22 daN in the left hand (b)

ENMG revealed improvement in the amplitude of the M-response of the brevis abductor pollicis muscle measuring 8.6 mV; in the distal latency of the motor fibers of the median nerve measuring 3.2 ms; the impulse conduction velocity along the motor fibers of the median nerve measuring 51.5 m/s; in the impulse conduction velocity along the sensory fibers of the median nerve measuring 49 m/s (Fig. 4).

Ultrasound results: the CPS of the median nerve in the carpal tunnel was 8 mm^2 (Fig. 5).

NCV motor
right, Abductor pollicis brevis, Medianus, C8 T1



Additional options

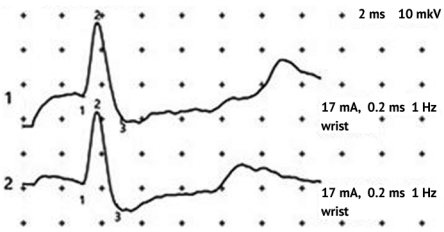
Res. lat., ms	Normal RL, ms	RL off, %	Index therm. Lat.
2.27	< 2.5	(N)	0.299

M-response parameters (amplitude: negative peak)

N	Stimulation point	Dist.	Lat.	Ampl.	Norm	Dev.	Duration	Velocity	Norm	Dev.	T, °C
		mm	ms	mV	ampl., mV	ampl., %	ms	m/s	velocity, m/s	velocity, %	
right, Abductor pollicis brevis, Medianus, C8 T1											
1	Wrist	50	3.2	8.6	> 4.0	(N)	5.1				0.0
2	Elbow bend	245	8.0	7.8			5.6	51.5	> 50.0	(N)	0.0

a

NCV sensory
Antidromic
right, n. Medianus
left, n.Medianus



Nerve action potential (amplitude: negative peak, area: estim ated peak, latency: peak)

N	Stimulation point	Dist. mm	Lat. ms	Norm lat., ms	Dev. lat., %	Ampl. mkV	Norm ampl., mkV	Dev. ampl., %
right, n. Medianus								
1	Wrist	145	3.76	< 4.0	(N)	21.0	> 20.0	(N)
left, n. Medianus								
2	Wrist	125	**3.72**	< 3.5	**+6.29**	20.6	> 20.0	(N)

NCV sensory

N	Segment	Dist. mm	Time ms	Velocity m/s	Norm velocity m/s	Dev. velocity %	Speed increment %
1	Wrist	145	2.96	**44.0**	>50.0	**-2.03**	
2	Wrist	125	2.96	**42.2**	**>50.0**	**-15.5**	

b

Fig. 4 ENMG parameters six months after surgery: (a) M-response of the median nerve of the right hand; (b) impulse conduction velocity along the sensory fibers of the median nerve

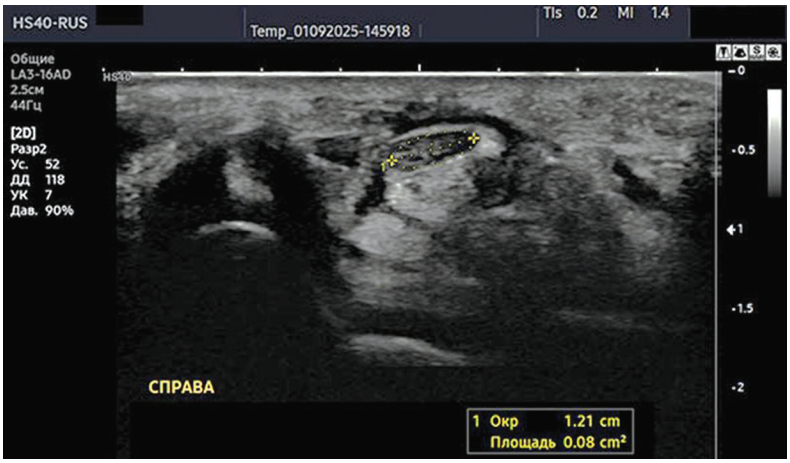


Fig. 5 Ultrasound of the right carpal tunnel six months after surgery

Therefore, the clinical observation illustrated the positive outcome of timely, adequate surgical intervention for idiopathic CTS that resulted in preserved thenar muscles, which occupied more than half of the anterior surface of the CTS, through careful separation from the ligament followed by re-attachment.

DISCUSSION

The effectiveness of surgical decompression of the median nerve in CTS patients has been confirmed by several clinical studies. Gilweg et al. reported a significant reduction in pain and other neuropathic disorders one month after surgery, and a significant improvement in the hand function after six months [21].

Adverse events and complications after open decompression of the median nerve are reported in the literature. The main disadvantages of the surgical modality for CTS patients identified by Belyakov et al. included a high probability for the nerve trunk to be involved in the scar, compression of the median nerve by the edges of the transected ligament, and the chronic trauma in manual workers [22]. Gartsman et al. found that surgery related width of the carpal arch increased by more than 20 % correlates with a handgrip strength decreased by 25.8 % [23]. Luchetti and Amadio reported a decrease in handgrip strength in 16–25 % of clinical observations due to the CTS transected during open decompression of the median nerve [24].

Lluch, Castro-Menéndez et al., Seitz et al. reported the feasibility of TCL reconstruction to facilitate a more rapid and complete restoration of the hand function by increasing grip strength and reducing the risk of pain at the site of the postoperative scar and pillar pain [4, 7, 25]. Netscher et al. reported the maximum strength of the coarse and fine grips reaching the baseline at three months of TCL reconstruction which was significantly higher than similar measurements in no-TCL-reconstruction patients [26]. Kotelnikov et al. also reported the effectiveness of TCL reconstruction with increased grip strength of the hand, improved BCTQs and BCTQf scores, ENMG data in patients aged 18–60 years with a moderately severe condition [27].

Mujadzic et al. reported a fourfold decrease in the incidence and duration of pillar pain in patients treated with a minimally invasive surgical approach (7.2 %) as compared to a standard incision (32.1 %) [5]. Seitz et al. reported a twofold decrease in the incidence of pillar pain and increased hand grip strength in patients after TCL reconstruction (19 %), compared to no-TCL-reconstruction patients (8.6 %) [25]. Kumar et al. reported a statistically significant decrease in the incidence of pillar pain 3–6 months after minimally invasive transection of the TCL ($p = 0.41$). The outcomes at a longer follow-up period did not reach statistically significant values [28].

Bernstein et al. suggested the restored integrity of the palmar aponeurosis being essential for preventing pillar pain. Suturing after open decompression would minimize the risk of re-occurrence [29]. In our series, the palmar aponeurosis was sutured in patients in all three groups. The procedure reduced the time it took to regain hand grip strength, prevented flexor tendon subluxation, and median nerve scarring. The approach could minimize the incidence of pillar pain which was seen in only two clinical cases of the first group with no cases observed in the second and third groups.

Hollevoet et al. reported the site of attachment of the thenar muscles to the TCL being located at the ulnar side of the median nerve in some clinical observations or significantly displaced inward in a cadaver study. The palmar surface of the TCL was 85 % covered by the thenar muscles in some cases,[9]. Alsafar et al. suggested that 50 % of the radial surface of the ligament was occupied by the muscles at the eminence of the thumb (thenar) or lying on the path of the dissection line [8]. In our series, we established that the site of attachment of the thenar muscles to the TCL was located on the ulnar portion in 40 (43.5 %) clinical observations seen in the second group of open decompression of the median nerve and re-attachment.

Jegal et al. reported that the entire surface of the carpal tunnel could be covered by the thenar muscles in clinical practice. In such cases, a carpal tunnel release requires dissection of the muscle bellies of these muscles, increasing the risk of injury to the motor branch of the median nerve, which may have a transligamentous structure. The authors recommended dissecting the thenar muscles radially to allow for the transection of the carpal tunnel along the ulnar portion of the carpal tunnel, simultaneously inspecting the median nerve and its muscular branch to avoid a iatrogenic injury [10]. Green and Morgan reported cases of the thenar muscles located on the ulnar portion of the carpal tunnel, which is an indirect sign of an abnormal origin of the motor branch of the median nerve in 90 % of cases, and can be easily damaged with muscles transection [30].

Chern et al. reported that the TCL transection could result in the thenar muscles losing the attachment site, in atrophy, and the decreased hand function. There was 25 % shortening of the superficial head of m. flexor pollicis brevis (relative to the resting length), 20 % of the ulnar part of m. abductor pollicis brevis (opposition and adduction), 20 % of m. opponens pollicis and 10 % of m. opponens digiti minimi [11]. Fuss and Wagner suggested that it was one of the reasons for the column pain in the postoperative period [2].

Neither clinical nor ENMG signs of injury to the motor branch of the median nerve were associated with decompression of the median nerve and re-attachment of the thenar muscles at a short term or a long term. No one developed pillar pain. Restoration of the thenar muscle attachment site contributed to an handgrip strength increased by 15.2 % at six months of the operation, a 70.5 % improvement in the DASH scores, BCTQ-s improved by 56.3 %, BCTQ-f by 47 %, an amplitude of the M-response of the brevis abductor pollicis muscle increased by 34.3 %, the distal latency of the motor fibers of the median nerve decreased by 31.7 %, motor speed increased by 13.2 % and sensory speed by 72.4 % compared to preoperative measurements. These data suggested a positive effect on the final results of the thenar muscle re-attachment that we used in cases where they occupied more than half of the anterior surface of the TCL.

A differentiated approach to surgical treatment for our CTS patients ensured high-quality outcomes in the three groups. However, the less positive and statistically insignificant differences in intermediate and final results in patients of the first group compared to those in the second and third groups may be caused by more sophisticated surgical techniques employed in the second and third groups. Alternatively, this may be due to the more common severity of CTS in the first group (41.1 % versus 37.5 % in the second and 38.4 % in the third groups), although no statistically significant differences were found (Table 2).

CONCLUSION

Open median nerve decompression for CTS, performed in the three groups of patients, resulted in significant clinical and functional improvement six months after surgery in all clinical observations.

he majority of patients who underwent thenar muscle re-attachment (Group 2) and TCL reconstruction (Group 3) following median nerve decompression using the methods offered showed recovery of clinical, functional, and EMNG parameters within three months and improved significantly within six months compared to patients who had no TCL reconstruction (Group 1).

The anatomy of the wrist, severity of pathological changes at the site, the age and professional characteristics of the patients are essential for the differentiated approach to open median nerve decompression for CTS.

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Information about the authors:

Sergey N. Izmalkov — Doctor of Medical Sciences, Professor, Head of the Department, izmalkov@mail.ru, https://orcid.org/0000-0002-0108-597X;

Oleg M. Semenkin — Candidate of Medical Sciences, orthopaedic surgeon, Associate Professor of the Department, olegsemenkin63@yandex.ru, https://orcid.org/0000-0002-4461-9994;

Alexander N. Bratiychuk — Doctor of Medical Sciences, Professor of the Department, brat59@bk.ru, https://orcid.org/0000-0003-3953-968X;

Alexey K. Usov — Candidate of Medical Sciences, Head of the Department, Associate Professor of the Department, usov82@gmail.com, https://orcid.org/0000-0002-4510-0959;

Nikita A. Demchenko — postgraduate student, orthopaedic surgeon, n.a.demchenko@samsmu.ru, https://orcid.org/0009-0006-4636-5728;

Alena Ev. Guseva —functional diagnostics doctor, alena.guseva@mail.ru, https://orcid.org/0009-0009-5051-0969;

Kira F. Khairullina — ultrasound diagnostics doctor, uzi163k.f.hairullina@mail.ru, https://orcid.org/0009-0008-7852-4759.

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Factors affecting the stability of transpedicular fixation in patients with neglected osteoporotic vertebral fractures

P.G. Mytyga✉, S.V. Masevnin, V.S. Murakhovsky, K.V. Zhdanovich, N.S. Zaborovskii

Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russian Federation

Corresponding author: Pavel G. Mytyga, paveji.official@gmail.com

Abstract

Introduction With increasing life expectancy and an aging population, vertebral fractures are one of the most common fractures associated with low bone mineral density.the problem of vertebral fractures associated with low bone mineral density is becoming increasingly common. Despite a variety of treatment methods, the risk of transpedicular fixation instability in the postoperative period remains.

The **objective** was to identify risk factors for unstable spondylosynthesis in patients with osteoporotic spinal fractures to substantiate an individualized approach to the surgical treatment.

Material and methods This A retrospective single-center study was based on the findings of 82 patients who underwent surgical treatment at the R.R. Vreden National Medical Research Center for Trauma and Orthopedics between 2019 and 2023. Patients were divided into a case group of patients who developed unstable fixation, $n = 8$) and controls (who had no hardware instability, $n = 74$). Potential risk factors included age, body mass index, fixation length, a screw placed in the involved vertebra, screw diameter, the presence and type of bone cement augmentation, the amount of decompression, the presence of local kyphosis and correction technique (Schwab vertebrotomy), duration of surgery and blood loss.

Results A screw placed into the involved vertebra was the only statistically significant ($p < 0.05$) difference between the groups. A logistic regression model was used to identify factors that could improve the hardware stability including intermediate fixation, augmentation of the fractured vertebra, screw augmentation and a larger screw diameter. Laminectomy, facetectomy, advanced age, and excess body weight were identified as factors negatively affecting the stability of the metal construct.

Discussion Patients with osteoporotic vertebral fractures are heterogeneous in age and medical status which complicates selection of optimal surgical approaches. Laminectomy and facetectomy are the main factors impacting stability in case of facet joint resection. Larger-diameter screws and bone cement augmentation are practical for better stability and associated with a risk of specific complications. The screw placed in the broken vertebra is a significant positive factor, as confirmed by other biomechanical and clinical studies. Limitations of the study included the retrospective design, small sample size and cohort heterogeneity, which reduce the statistical power and generalizability of the results.

Conclusion Unstable transpedicular fixation after stabilization is multifactorial in patients with chronic osteoporotic vertebral fractures. Surgical factors are most significant. Laminectomy and facetectomy increase the risk of instability with the screw placed in the broken vertebra and bone cement augmentation helps maintain the stability. The length of fixation, the extent of kyphosis correction and residual kyphosis had no significant effect in the study sample. These results support the need for individualized surgical approaches in osteoporotic patients.

Keywords: osteoporosis, spinal fracture, transpedicular fixation, instability

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INTRODUCTION

Vertebral compression fractures (VCFs) affect many individuals worldwide. Approximately 1.4–1.5 million VCFs occur annually in the general population, of which about a third are caused by systemic osteoporosis [1, 2]. In the Russian Federation, more than 14 million people suffer from osteoporosis, which is approximately 10 % of the country's population, and osteopenia has been diagnosed in 20 million residents. Population studies in Russia show that low bone mineral density, characteristic of osteoporosis, was detected in 33 % of women and 27 % of men over 50 years of age in 2013. The global incidence of fractures related to osteoporosis is expected to increase dramatically in the next few decades and are projected to exceed 21 million cases by 2050 [3].

The majority of fractures (60 to 75 %) are localized in the Th12–L2 which is considered the most vulnerable site. The zone is characterized by a biomechanical transition from the more rigid thoracic spine to the relatively mobile lumbar spine [4]. Based on biomechanical studies on stability three-column concept proposed by Francis Denis, divides a spinal segment into three parts: anterior, middle, and posterior colums [5]. Osteoporotic compression fractures predominantly affect the anterior and middle columns of the vertebra, including the anterior longitudinal ligament and the vertebral body. Preserving the integrity of the posterior column is essential for stability of the spinal motion segment preventing neurological deficiency. Neurological disorders in osteoporotic fractures are relatively rare with no fracture fragments migrating into the spinal canal and causing compression [6, 7]. However, neurological symptoms may develop with the progressing deformity, fracture instability and compression of neural structures which would require timely surgical intervention.

Compression fractures of the spine in systemic osteoporosis constitute a significant proportion of spinal pathology in elderly patients due to biomechanical characteristics of the thoracolumbar junction and requires an adequate clinical approach, considering complications of prolonged immobilization and the risk of cascade fractures.

Literature review has shown that there is no unified and standardized approach to the treatment of patients with pathological fractures of the thoracic and lumbar spine caused by osteoporosis, especially in the absence of neurological symptoms. Patients with osteoporotic vertebral fractures caused by low-energy trauma require a more differentiated and balanced choice of treatment strategy, considering age, concomitant somatic diseases and the severity of bone tissue changes. Surgical treatment with the use of metal fixators can be indicated for some patients [8]. With the variety of techniques, there is no consensus on the indications for surgery in osteoporotic patients. Patients with acute neurological deficit would require surgical management. Somatic risks and condition of the spinal column, including the extent of compression and vertebral deformity, duration of pain and location of the fracture would be essential to consider indications for surgery [9, 10].

The choice of fixation method is complicated by the need to ensure reliable implant stability in the affected bone, the optimal approach and extent of the procedure. Anterior approaches are often associated with greater trauma and do not demonstrate significant advantages over posterior approaches. There is also a high risk of interbody implant instability with use of MESh meshes or expandable implants such as vLift. The use of wide-base implants and proper implant positioning can reduce the risk of implant migration and instability in some cases [11–13].

Surgical interventions performed through a posterior approach carry a risk of instability, when there is no way to create a supporting bone block. Age and comorbidities may increase the risk of complications during revision surgery.

Therefore, the challenge of determining the optimal surgical strategy for osteoporotic patients lies in the choice of a minimally invasive surgical approach maximizing the stability of the implant during the postoperative period.

The **objective** was to identify risk factors for unstable spondylosynthesis in patients with osteoporotic spinal fractures to substantiate an individualized approach to the surgical treatment.

MATERIAL AND METHODS

Study design

The study was a retrospective comparative analysis of the results of surgical treatment of patients with osteoporotic spinal fractures of types OF4 and OF5 who received medical care at the Vreden National Medical Research Center of Traumatology and Orthopedics from 2019 to 2023.

Inclusion criteria:

— patients of either sex over 50 years of age;

— diagnosis of systemic osteoporosis, confirmed by medical documentation;

— the presence of single-level osteoporotic fractures of the thoracic and lumbar spine types OF4 and OF5 according to the AO Spine DGOU classification;

— the period of time since the injury at least six weeks [15];

— surgical intervention including reduction and stabilization performed at the Vreden National Medical Research Center of Traumatology and Orthopedics with use of transpedicular fixation systems;

— the minimum follow-up period of six months.

Non-inclusion criteria:

— scoliotic spinal deformity in the frontal plane with a Cobb angle greater than 10° that developed prior to the fracture;

— peri-implant infection;

— previous surgical interventions on the operated segment;

— fractures of adjacent vertebrae types OF4 and OF5 seen before the intervention;

— patients who were not allowed to undergo surgery due to the severity of the physical status as evaluated with the ASA (American Anesthesiological Association) grading system (ASA IV, ASA V) [16].

Participants

Data from 82 patients were reviewed with the majority being females (n = 70, 85 %). The mean age was 68.99 (SD = 7.12), body mass index (BMI) was 26.53 (SD = 5.10). Most patients (n = 55, 67 %) had ASA third status. Hypertension (ICD 10 code I11.9) and type 2 diabetes mellitus (ICD 10 code E11) were most common comorbidities. Most patients (n = 64, 78 %) had not received treatment for osteoporosis. Preserved neurological function (ASIA classes D and E) was observed in 76 patients (93 %).

Patients were grouped depending on the surgical outcome:

— Control group (n = 74) included patients without signs of fixation instability;

— Case group (n = 8) consisted of patients who developed unstable fixation or fracture of adjacent vertebrae.

Seven patients (88 %) in the Case group had resorption around the screws, and one patient (12 %) had a fracture of the fixation screw. Anthropometric data are presented in Table 1. The two groups were similar in terms of the parameters explored and showed no statistically significant differences.

Table 1

Anthropometric indices of the study cohort

Description	Total (*n* = 82), M (SD)	Control group (*n* = 74), M (SD)	Case group (*n* = 8), M (SD)	*P*
Age (years)	68.99 (7.12)	69.03 (6.98)	68.67 (8.46)	0.8923
BMI (kg/m²)	26.63 (5.10)	26.42 (4.89)	28.57 (7.03)	0.2623
Weight (kg)	70.51 (12.88)	70.01 (12.21)	75.06 (18.44)	0.2950

The patients showed signs of decreased BMD according to densitometry (T-score of 2.80 (SD = 0.64)) and CT (HU 80.78 (SD = 25.31) with the VBQ index measuring 2.34 (SD = 0.02). The characteristics of the groups by type and location of vertebral fractures are presented in Table 2.

Table 2

Distribution of vertebral fractures by type and location

Fracture type and vertebra	All patients (*n* = 82)		Control group (*n* = 74)		Case group (*n* = 8)		*P*
	abs.	%	abs.	%	abs.	%	
Ranking by fracture type (DGOU)							
OF4	72	87.8	65	87.8	7	87.5	0.2932
OF5	10	12.2	9	12.2	1	12.5	0.4241
Ranking by fracture location							
Th12	25	30.9	22	29.7	3	37.5	0.6812
L1	23	28.4	20	27	3	37.5	0.6657
L2	11	13.6	10	13.5	1	12.5	1.000
L4	6	7.4	6	8.1	0		
Th11	5	6.2	5	6.7	0		
L3	4	4.9	4	5.4	0		
Th8	3	3.7	3	4	0		
Other segments	4	4.9	4	5.4	0		

The thoracolumbar junction was most common segments involved. A segmental comparison of fracture types between the Case and Control groups revealed no statistically significant differences.

The criteria and parameters examined

Clinical characteristics:

— age;

— gender;

— BMI;

— risk of surgical treatment evaluated with the ASA grading system;

— history of osteomodifying therapy.

Imaging:

— DXA scans were performed within 12 months;

— BMD (bone mineral density) in Hounsfield units, calculated from the average density of the cross-section of the cancellous bone of the L3 vertebral body [17];

— VBQ (Vertebral Bone Quality): MRI bone quality index, calculated as the ratio of the average T1-weighted signal from the bodies of the L1, L2, L3, L4, L5 vertebrae (broken segments were excluded from the analysis) to the cerebrospinal fluid signal value at the L3 level [18];

— localization and nature of the fracture according to DGOU;

— the angle of local kyphosis calculated as the Cobb angle between the upper endplate of the overlying vertebra and the lower endplate of the underlying vertebra; the formation of the bone block was assessed according to the classification of F. Chistensen [19].

The stability of the construct was assessed by the presence of:

— resorption zones greater than 1 mm around the screws;

— signs of dissociated elements in the construct;

— pain;

— fractures of the upper and lower vertebrae relative to the fixation zone no less than six months after the intervention.

Characteristics of surgery:

— length of fixation;

— diameter;

— size of screws;

— the presence and type of bone cement augmentation used;

— decompression volume;

— the presence and method of correction of local kyphosis (Schwab vertebrotomy) [20];

— duration of operation;

— blood loss;

— postoperative stay;

— complications as classified by Calvien-Dindo [21].

Statistical analysis

The mean and median values, standard deviation (SD), and interquartile range (IQR) were used for descriptive statistics. ROC AUC, accuracy, and sensitivity metrics were used to assess risk factors for the accuracy of the logistic regression model. Statistical processing and multivariate regression analysis were performed using the pandas, numpy, scikit-learn, statsmodels, and matplotlib packages for the Python programming environment.

Ethical Approval

The study was exempt from ethics review because it did not address issues requiring ethical approval. The study does not violate the principles of the Declaration of Helsinki or the requirements of Russian legislation on scientific research ethics.

RESULTS

The characteristics of the interventions performed according to the compared criteria are presented in Table 3.

Table 3

Characteristics of the interventions performed

Description		All patients (*n* = 82)	Control group (*n* = 74)	Case group (*n* = 8)	*P*
Invasiveness of the operation					
Duration (min), M (SD)		119.10 (48.00)	118.75 (48.84)	123.33 (39.71)	0.8239
Blood loss (mL), M (SD)		276.50 (259.60)	268.51 (248.90)	375.00 (384.38)	0.3371
Length of fixation					
Short-segmented (3 segments)	abs.	42	39	3	0.6564
	%	51.2	52.7	37.5	
Long-segmented (⩾ 4 segments)	abs.	39	35	4	1.0000
	%	47.6	47.3	50.0	
Surgical techniques					
Screw placed into the involved vertebra	abs.	36	36	0	0.0377*
	%	44.4	48.6	0.0	
Augmentation of screws	abs.	37	36	1	0.1146
	%	45.1	48.6	12.5	
Vertebral augmentation	abs.	14	14	0	0.3918
	%	17.1	18.9	0.0	
Laminectomy	abs.	20	17	3	0.6344
	%	24.4	23.0	37.5	
Facetectomy	abs.	25	22	3	0.9607
	%	30.5	29.7	37.5	
Screw diameter (mm)	M	6.60	6.60	6.58	0.9267
	SD	0.35	0.35	0.38	

A comparative analysis of the Case and Control groups in terms of intervention invasiveness revealed one statistically significant difference between the groups: screw placed in the involved vertebra. The Case group included only one patient, who underwent cemented vertebral augmentation.

An analysis of surgical invasiveness revealed a large standard deviation in blood loss and operative time due to the wide variability of surgical techniques, ranging from minimally invasive percutaneous fixation as the most gentle method to extensive corrective vertebrotomies with vertebral and intervertebral disc resection.

None of the patients in the study sample experienced complications early post-op.

Schwab corrective vertebrotomies (Table 4) were used to correct local kyphotic deformity, with the exception of types 2 and 5.

Table 4

Comparison of local kyphotic angles and methods of deformity correction

Description		All patients (*n* = 82)	Control group (*n* = 74)	Case group (*n* = 8)	*P*
Angles of local kyphosis					
Baseline (°) M, SD		22.83 (10.68)	22.51 (10.97)	25.77 (7.29)	0.4162
Residual (°) M, SD		14.48 (9.66)	14.23 (9.88)	18.14 (4.38)	0.3848
Corrected (°) M, SD		7.18 (10.66)	7.33 (10.84)	5.80 (9.27)	0.7028
Correction technique					
No correction produced	abs.	71	64	7	1.0000
	%	86.6	86.5	87.5	
Type 1	abs.	6	5	1	1.0000
	%	7.3	6.8	12.5	
Type 3	abs.	1	1	0	1.0000
	%	1.2	1.4	0.0	
Type 4	abs.	3	3	0	1.0000
	%	3.7	4.1	0.0	

No statistically significant differences in radiographic findings were found between the groups in terms of the angles of baseline and residual (postoperative) kyphosis, or the extent and method of correction of local kyphotic deformity.

A multivariate regression analysis was performed to identify factors predicting fixation instability. The logistic regression model demonstrated high predictive ability: ROC-AUC of 0.924, accuracy of 91.5 %, and sensitivity of 98 %. The model results are visualized as odds ratios (Fig. 1).

The length of fixation and residual kyphosis had no effect on the construct stability in the sample.

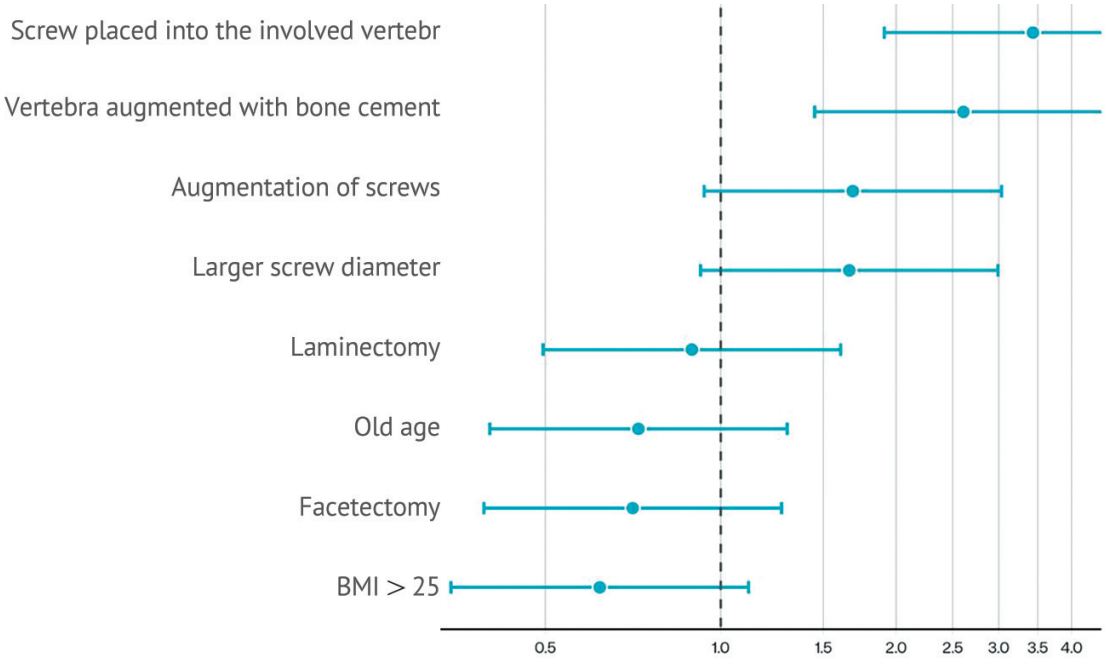

Fig. 1 Odds ratio of maintaining fixation stability

Clinical instance

A 82-year-old (at the time of surgery) patient presented with pain in the thoracolumbar spine, VAS scored 7, without radiating to the legs. The patient reported pain developed acutely after an awkward movement within the bed approximately six months prior to admission, with no significant improvement from conservative treatment. Her medical history included hypertension, coronary artery disease, and renal failure. Radiograph showed unstable compression fracture of the T11 vertebra. Densitometry revealed osteoporosis (Tcr = –3.0). Minimally invasive short-segment fracture fixation without augmentation was performed considering the patient's physical status and the nature of the fracture, (Fig. 2).

The patient stayed at the hospital for six days. Seven months after the procedure, the patient reported a deterioration in her condition, with pain similar to preoperative pain but of lesser intensity. A follow-up CT scan revealed signs of osteolysis around the screws (Fig. 3, red arrow). The patient declined revision surgery.

Based on the study results, it can be hypothesized that the absence of protective factors (vertebral augmentation) and intermediate fixation, which would improve the stability could cause postoperative instability. The posterior supporting structures of the vertebrae were completely preserved in this case. The bone cement reinforcing pedicle screws and the screw placed into the fractured vertebra had a greater impact on stability than the effects on the posterior bony structures of the spinal column; however, this hypothesis requires further investigation.

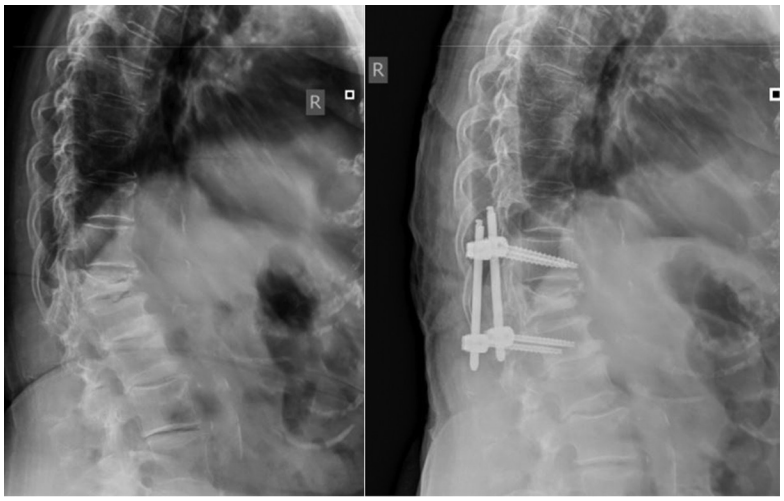

Fig. 2 Preoperative and postoperative radiographs of the patient from the Case group

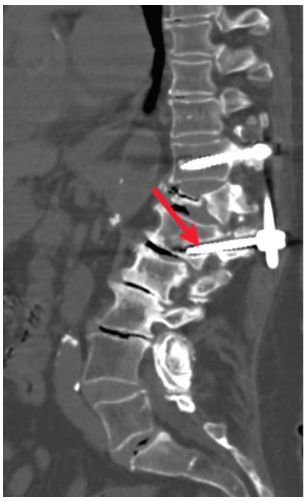

Fig. 3 CT scan of a patient in the Case group seven months after surgery

DISCUSSION

Patients with osteoporotic fractures represent a highly heterogeneous group in terms of age and physical status, making it difficult to select the optimal surgical strategy. The cohort of patients was predominantly females and had no history of antiresorptive therapy. Elderly and overweight patients are the most vulnerable group in terms of implant stability. Treatment strategies for these patients require further study.

Preservation of the neurological status of the group allowed for stabilizing surgical interventions without decompression and extensive resection of the posterior bone structures and had a positive effect on maintaining the stability of the metal construct. Laminectomy and facetectomy are the most significant surgical factor negatively affecting the maintenance of fixation. This can be caused by greater destabilization of the spinal motion segment and is confirmed by the results of other clinical studies [22, 23]. Interestingly, resection of the facet joints has a greater impact on the onset of instability than laminectomy alone.

An Urban wedge, a fragment of the vertebral body protruding into the spinal canal, is a most common cause of neural compression in vertebral fractures. Decompression through an anterior approach and transpedicular fixation would be the optimal surgical treatment strategy to restore the anterior supporting column. Some authors recommend the use of a wide-based interbody implant to improve support [11]; however, this may pose a high risk of interbody implant migration and subsidence [13].

Screws of a larger diameter are practical to improve the primary stability of the construct and maximize the filling of the vertebral pedicle. Biomechanically, this is due to screw fixation in the denser cortical portion of the pedicle and uniform load distribution [24, 25]. The use of large-diameter screws is associated with a high risk of malposition. A mismatch between the implant and pedicle sizes can lead to a fracture of the pedicle and segment destabilization. The length of fixation in the study group had no significant impact on stability. However, with the advent of cement fixation and other screw augmentation techniques, the length of fixation no longer has a significant impact on maintaining stability [26].

Active use of bone cement (augmentation of a fractured vertebra, screws) has a significant effect on the maintenance of structural stability in the postoperative period; in this regard, our results are consistent with literature data [27, 28]. However, the use of bone cement cannot be considered

a safe surgical technique; its use is associated with a greater risk of fractures of adjacent vertebral segments, especially in the case of cement leakage into the intervertebral discs. There are known cases of cement embolism of the cardiac vessels and pulmonary artery, which can lead to death [29, 30]. Cases of compression of neural structures and neurological deficit in patients due to cement leakage into the spinal canal have been reported, and can result in revision surgery [31, 32].

Intermediate fixation with a screw placed into the fractured vertebra was found to be the most significant factor influencing the maintenance of fixation stability in the present series. The surgical technique may be biomechanically justified by the presence of a fixation point preventing rotational and translational deformity of the segment [33]. Our findings are consistent with those of other authors, who also reporte the positive effect of intermediate fixation maintaining structural stability [22].

The issue of deformity correction in patients with osteoporotic fractures is controversial. Our findings suggest that correction of spinal deformity and restoration of the sagittal axis have no significant effect on maintaining the fixation integrity, but this is inconsistent with other studies [34–36]. This discrepancy may be due to the low level of local kyphosis at baseline and the sample size. Residual kyphosis may have a negative impact on the quality of life, but we did not explore this indicator in the present series.

The study has several limitations. First, the retrospective design, relying on existing documentation, increases the risk of selection bias and information bias. We were unable to standardize the observation protocol and the timing of instability onset. Second, the small sample size and the small number of instability cases (eight patients) limit the power of the multivariate analysis, increasing the risk of overfitting the logistic regression model, and do not allow for a reliable assessment of the influence of rare factors. Third, the heterogeneity of the cohort (age, physical status, degree of osteoporosis, comorbidities, lack of standardized osteomodifying therapy, a variety of surgery types) makes it difficult to isolate the effect of individual surgical techniques reducing the generalizability of the results. Furthermore, the minimum follow-up period of six months may be insufficient to detect late mechanical complications and assess the impact of residual deformity on long-term clinical and functional outcomes, which was not specifically reviewed.

CONCLUSION

Instability of transpedicular fixation in patients with chronic osteoporotic vertebral fractures types OF4–OF5 was shown to be multifactorial. Among the variables explored, surgical factors including laminectomy and facetectomy were most significant increasing the risk of fixation instability. In contrast, a screw placed in the broken vertebra and bone cement augmentation contribute to the maintenance of metal construct stability and can be considered biomechanically practical elements of osteosynthesis. The length of fixation, the extent of kyphotic correction and residual kyphosis do not significantly affect the stability of the construct. The findings suggest the need for individualized surgical approaches in the treatment of patients with chronic vertebral fractures and osteoporosis.

Conflict of Interest *Statement None of the authors has any potential conflict of interest.*

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Ethical Approval *The study does not raise ethical issues and does not violate the principles of the Declaration of Helsinki or the requirements of Russian legislation in the field of research ethics.*

Informed Consent *Given the retrospective nature of the study (review of medical records), informed consent from patients was not required.*

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Information about the authors:

Pavel G.Mytyga — Junior Researcher, paveji.official@gmail.com, https://orcid.org/0000-0002-4386-9780;

Sergey V. Masevnin — Candidate of Medical Sciences, Junior Researcher, drmasevnin@gmail.com, https://orcid.org/0000-0002-9853-7089;

Vladislav S. Murakhovsky — Neurosurgeon, drmurakhovsky@gmail.com, https://orcid.org/0000-0002-9985-5636;

Konstantin V. Zhdanovich — Research Assistant, zhdanovich.neuro@gmail.com, https://orcid.org/0000-0002-0237-4351;

Nikita S. Zaborovskii — Candidate of Medical Sciences, Head of the Research Department, dr.nzbr@gmail.com, https://orcid.org/0000-0003-4562-8160.

Original article
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Comparative evaluation of commercial bacteriophages and prospects for their application in the treatment of orthopedic MRSA-infection

E.M. Gordina[1]✉, A.R. Kasimova[1,2], S.A. Bozhkova[1], L.N. Smirnova[1]

[1] Vreden National Medical Research Center for Traumatology and Orthopedics, Saint Petersburg, Russian Federation

[2] Academician I.P. Pavlov First St. Petersburg State Medical University, St. Petersburg, Russian Federation

Corresponding author: Ekaterina M. Gordina, emgordina@win.rniito.ru

Abstract

Introduction Phage therapy is a promising approach to addressing the problem of antibiotic resistance in orthopedic infection pathogens. Staphylococci are the leading etiotropic agents of implant-associated infections, with 15 % of *S. aureus* strains being methicillin-resistant (MRSA). Bacteriophage preparations are available on the Russian pharmaceutical market, and the concentration of phages active against the microbial agent influences their effectiveness.

The **objective** was to compare the activity of commercial bacteriophage kits against methicillin-resistant *Staphylococcus aureus* isolated from patients with orthopedic infections.

Material and methods Clinical strains of *S. aureus* (*n* = 25), consecutively isolated from patient biomaterial in 2025 were examined. Identification was performed using MALDI-TOF MS, and antibiotic susceptibility assessed according to EUCAST v.15. Phage lytic activity was evaluated using meat-peptone agar and a five-point scale with the strain sensitivity to a specific drug determined as sensitive, weakly sensitive, or resistant. Statistical analysis was performed using IBM SPSS Statistics v.26.

Results The *S. aureus* strains included in the study were resistant to cefoxitin. Of the MRSA strains tested, the majority (76 %) were sensitive to PBP 1. A larger number of strains (60 %) were classified as "weakly sensitive" to PBP 3. There were less variations in "non-susceptible" cultures, with only one strain demonstrating resistance to the three bacteriophage preparations. A comparative analysis of antistaphylococcal drugs from various manufacturers revealed differences in the activity against clinical MRSA isolates. There were 84 % isolates being sensitive to PBP 4 and 36 % to PBP 5. One isolate was resistant to the phages tested.

Discussion The differences in the activity of commercial phages could be associated with the composition of the resulting preparations, which had lower affinity for strains isolated from patients in other regions. Given the wide geographical distribution of patients with orthopedic infections hospitalized in federal centers, the ability to choose bacteriophages from a wide range of commercial kits available on the market increases the likelihood of their successful use.

Conclusion Commercial drugs presented on the Russian market were characterized by different lytic activity against clinical strains of MRSA, with Pyophag® and Staphylophag® exhibiting greater activity.

Keywords: bacteriophages, orthopedic infection, *S. aureus*, MRSA

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INTRODUCTION

Since their discovery in the early 20th century, antibiotics have revolutionized medical practice, enabling the control and cure of many infectious diseases [1]. The widespread use of antibacterial drugs has stimulated the development of adaptive resistance mechanisms among bacteria [2–4]. The World Health Organization has recognized antibiotic resistance as one of the top ten public health threats [5]. The need to find alternative treatments that can effectively combat bacterial infections is a priority for the modern healthcare system [6].

The increasing number of orthopedic surgeries involving the use of various metal constructs leads to a corresponding increase in the incidence of infectious complications associated with implants. The incidence of infections associated with orthopedic implants reaches 0.3–5.0 % across all types of surgeries (internal osteosynthesis, joint replacement) [7]. Surgical removal of infected implants and long-term treatment with antibiotics active against the isolated pathogens is the gold standard for treating patients with periprosthetic joint infection. However, problems associated with pathogen resistance to antibiotics and the persistence of biofilms on the surface of implants can lead to recurrent or difficult-to-treat infections, which poses a serious threat to the health and lives of patients [8].

Bacteriophage-based therapy represents a promising approach to addressing the problem of bacterial antibiotic resistance [9–11]. Phage activity is determined by the ability to complete all stages of their life cycle, including adsorption, penetration of genetic material into the cell, replication of genetic material, assembly of phage particles, and lysis of the bacterium [12]. Unlike broad-spectrum antibiotics, which can act on a wide range of bacteria, phages are highly specific, typically targeting only one species or even a specific strain of bacteria [12]. The specificity of phages represents both strengths and challenges in their therapeutic application [13, 14]. The advantage is the specific targeting of pathogenic bacteria while preserving beneficial human microbiota. However, such specificity requires precise microbiological judgment to select an active phage, making administration more challenging compared to broad-spectrum antibiotics [15].

The Russian pharmaceutical market offers a variety of bacteriophage preparations, including those for topical and/or systemic use. The concentration of bacteriophages active against the infectious agent in a preparation directly impacts its efficacy [16], and broader spectrums of activity, allowing for a reduced diversity of phages in cocktails while maintaining the overall range of activity, are a preferred property for therapeutic bacteriophages [17, 18]. Of particular interest is a comparative analysis of the lytic activity of domestic bacteriophage preparations against staphylococcal strains isolated from patients with orthopedic infections.

The **objective** was to compare the activity of commercial bacteriophage kits against methicillin-resistant *Staphylococcus* aureus isolated from patients with orthopedic infections.

MATERIAL AND METHODS

S. aureus cultures were prospectively isolated in 2025 from biomaterial of patients with periprosthetic joint infection and/or osteomyelitis in accordance with international microbiological research standards. Species identification was performed with MALDI-TOF MS using the FlexControl system and MBT Compass 4.1 software, Score ⩾ 2.0. The susceptibility of clinical isolates to antibacterial agents was explored in accordance with EUCAST v.15 requirements.

According to the local committee for the ethical review of clinical and experimental studies, this work is based on microbiological analysis of pathogen susceptibility, which is not subject to review by the ethics committee.

The susceptibility of MRSA (n = 25) to five domestic bacteriophage preparations (DBP):

— DBP 1 — Pyophag® (Mikrogen, Nizhny Novgorod, IMP RU LP-No. (002513)-(RG-RU) of the Russian Ministry of Health),

— DBP 2 — Pyobacteriophag® (Mikrogen, Ufa, IMP RU No. LS-002031 of the Russian Ministry of Health),

— DBP 3 — Sextaphag® (Mikrogen, Perm, IMP RU No. LS-001049 of the Russian Ministry of Health),

— DBP 4 — Staphylophag® (Mikrogen, Nizhny Novgorod, IMP RU No. R N001973-01 of the Russian Ministry of Health);

— PBF 5 — Staphylophag® (Microgen, Perm, IMP RU No. R N001973-01 of the Russian Ministry of Health).

The lytic properties of BP were assessed using meat-peptone agar (MPA). A bacterial suspension (0.5 % McF) was applied to the MPA with a cotton swab, and after 10 minutes, 10 µl of PBP were dispensed in duplicate onto the agar surface. The plates were incubated at 37 °C. After 24 hours, BP activity was assessed on a five-point scale in accordance with the Methodological Recommendations "Rational Use of Bacteriophages in Therapeutic and Anti-Epidemic Practice" (2023). Based on the findings, the strain's sensitivity to a specific drug was determined as sensitive, slightly sensitive, or resistant.

The nonparametric Kruskal-Wallis test in IBM SPSS Statistics Version 26 was used for statistical analysis of differences in the findings between the groups of explored susceptibility and commercial preparations. Dunn's test with correction for multiple comparisons was used for pairwise comparison of groups (post-hoc analysis) with statistically significant differences in the analysis of the activity of the three bacteriophage preparations. With multiple comparisons, a lower critical significance level was used and calculated using the formula: $p = 1 - 0.95^{1/n}$, where n was the number of comparisons performed. For this study, p values < 0.017 were considered statistically significant.

RESULTS

The *S. aureus* strains included in the study (n = 25) were resistant to cefoxitin (MRSA). The bacteriophage preparations tested were active against most clinical MRSA isolates from patients with orthopedic infection; however, differences were revealed when comparing the BPs (Table 1, Fig. 1).

Table 1

Evaluation of the antibacterial activity of bacteriophage preparations against methicillin-resistant *S. aureus*

Attitude to the BP	Tested preparations						
	BP 1		BP 2		BP 3		p
	abs.	%	abs.	%	abs.	%	
Sensitive	19	76	11	44	8	32	0.01
Slightly sensitive	5	20	11	44	15	60	0.01
Resistant	1	4	3	12	2	8	0.05

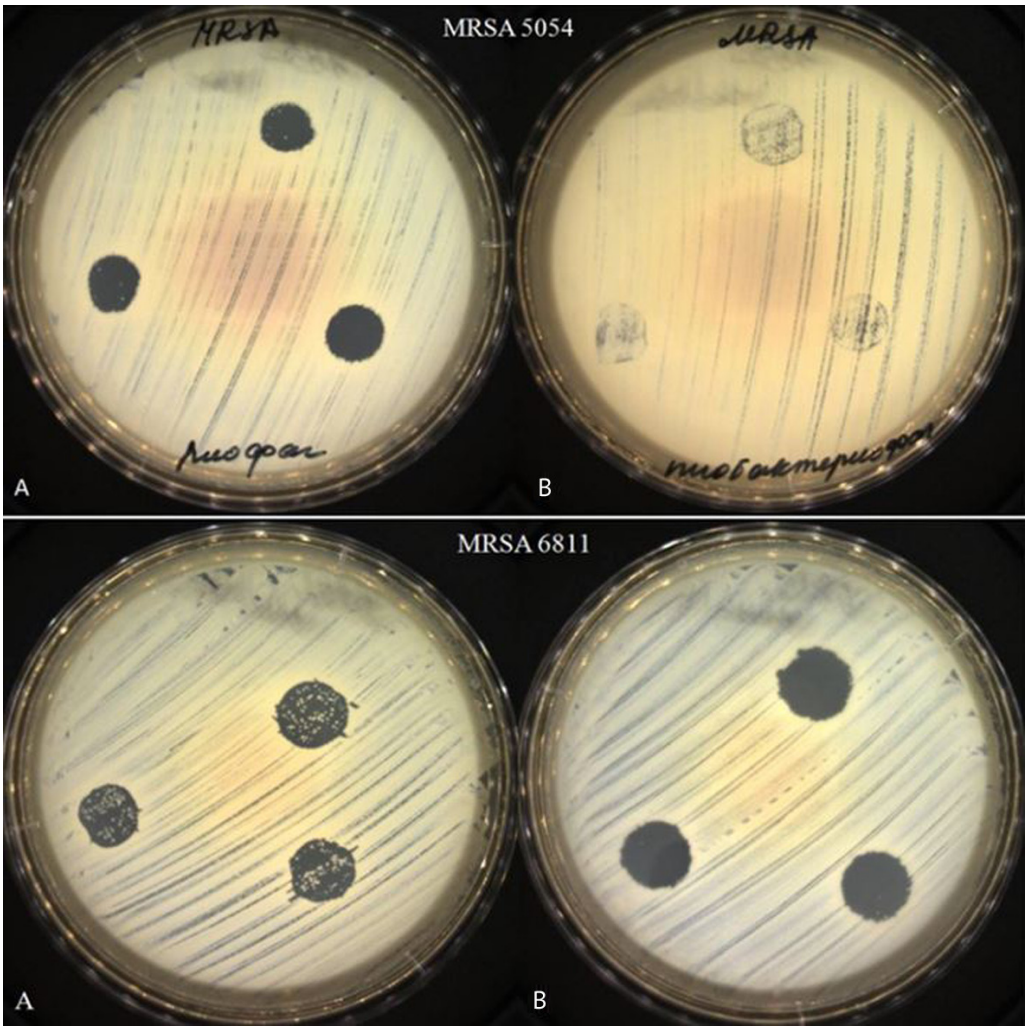

Fig. 1 Photographs of Petri dishes with zones of complete and partial lysis of MRSA cultures: A, BP 1; B, BP 2

Of the MRSA strains tested, a greater number (76 %) were sensitive to BP 1 ($p = 0.004$, pairwise comparison with BP 2). The opposite trend was recorded for the remaining susceptibility gradations: a greater number of strains (60 %) were classified as "slightly sensitive" to BP 3 ($p = 0.003$, pairwise comparison with BP 1, $p = 0.009$, overall). There were less variations in resistant cultures, with only one strain demonstrating resistance to the three bacteriophage preparations tested.

A comparative analysis of antistaphylococcal drugs from various manufacturers revealed differences in their activity against clinical MRSA isolates isolated from patients at our Center (Table 2, Fig. 2). There were 84 % isolates sensitive to BP 4 and 36 % to BP 5 ($p = 0.008$). One isolate was not susceptible to the phages tested.

Table 2

Evaluation of the activity of antistaphylococcal drugs against methicillin-resistant *S. aureus*

Attitude to the BP	Preparations tested				
	BP 4		BP 5		*p*
	abs.	%	abs.	%	
Sensitive	21	84	9	36	0.008
Slightly sensitive	3	12	15	60	0.004
Resistant	1	4	1	4	0.899

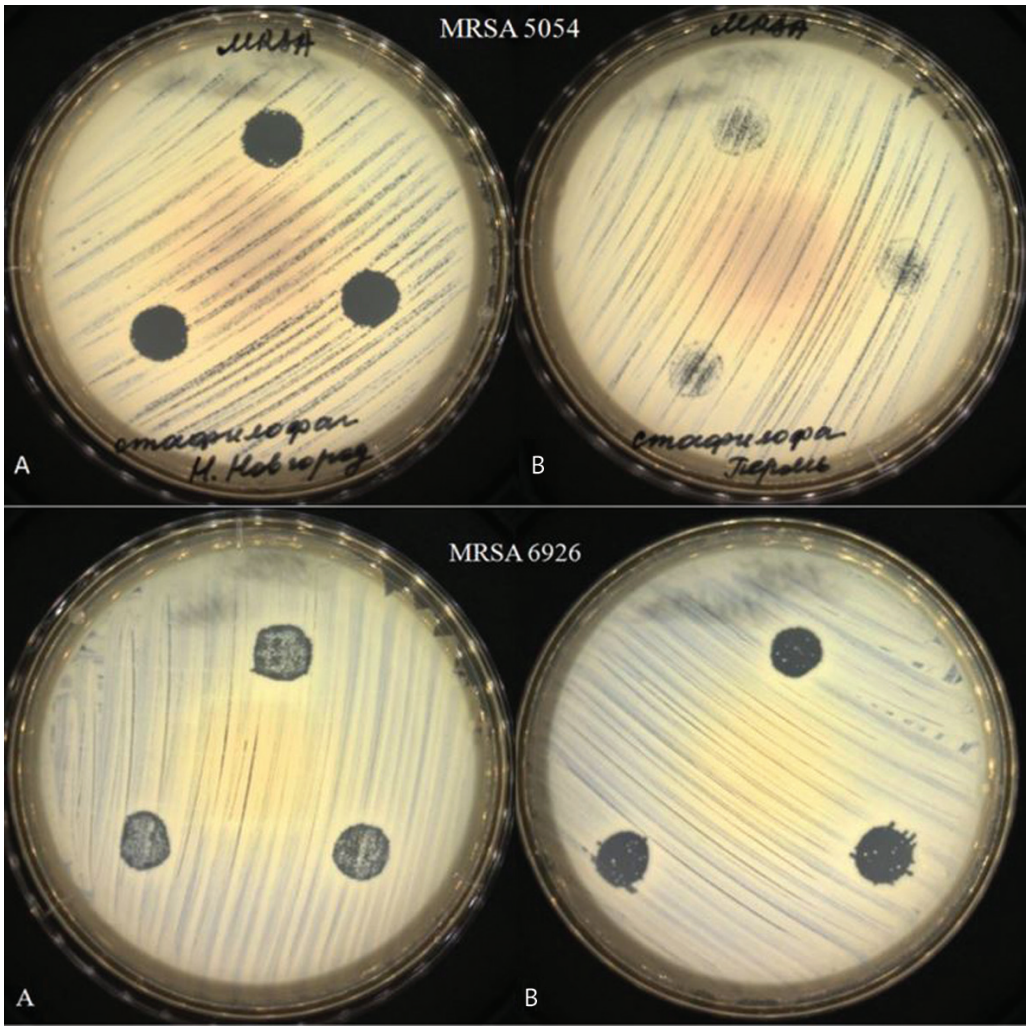

Fig. 2 Photographs of Petri dishes with zones of complete and partial lysis of MRSA cultures: A, BP 4; B, BP 5

DISCUSSION

The presence of antibiotic resistance mechanisms in infectious disease pathogens worsens the prognosis of disease outcome, prolongs treatment periods, significantly increasing healthcare costs. Our 2024 study showed that over a 12-year period, *S. aureus* was the causative agent of orthopedic infection in 33 % of cases with the proportion of methicillin-resistant *S. aureus* strains not decreasing below 15 % throughout the entire period of the study [19]. Tsiskarashvili et al. [20] and Sokolovsky et al. [21] reported *S. aureus* as the most common causative agent of periprosthetic joint infection, in 32 % and 38 %, respectively.

The ability of *S. aureus* to resist a broad spectrum of antibacterial drugs makes it an ideal subject for research using bacteriophages. In recent years, approaches to the selection, production, and delivery of phages have expanded significantly, and improvements in the technologies for their production allow for personalized phage therapy. The promising potential of phages against MRSA has been demonstrated in some trauma and orthopedic cases [22]. Fedorov et al. reported that the addition of a solution of commercial staphylococcal bacteriophage (6 mL per 40.0 g of dry polymethyl methacrylate substance) followed by its introduction through the drainage or by puncture into the periprosthetic area for 10 days increased the effectiveness of one-stage treatment of staphylococcal periprosthetic hip joint infection from 69 % to 96 % [23]. Ferry et al. reported an improvement in three patients with chronic periprosthetic joint infection with use of a phage

cocktail combined with antibiotics [24]. Similar results were reported by Ramirez-Sanchez et al. who described the successful treatment of patients with MRSA infection of the knee joint by intra-articular administration of a phage cocktail [25]. The variety of methods of the use suggested safety of bacteriophages with the significant advantage over antibiotics. The sensitivity of a specific pathogen to a specific bacteriophage preparation (to a specific batch of a commercial kit) is essential for successful phage therapy to ensure elimination of the pathogen and prevent bacterial resistance to the bacteriophage.

Phage susceptibility testing was performed at our Center for the isolated MRSA strains using different commercial preparations. Treatment of patients with periprosthetic joint infection caused by a pathogen sensitive to the available phages was produced with a drainage system inserted from the joint cavity after surgery. Twenty mL of the bacteriophage preparation was injected daily into the periprosthetic area for three to five days using the drainage system, then the drainage system was closed to increase the exposure time of the phages. The drainage system was removed upon completion of phage therapy. In accordance with clinical guidelines, the patients with periprosthetic joint infection received high-dose, etiotropic antibacterial therapy, since bacteriophage therapy did not replace antibiotics but was administered in combination with other antibiotics. A 2023 review [26] described the results of studies on the combined use of lytic bacteriophages and antibiotics for infections caused by resistant *S. aureus* strains.

The authors emphasized that the combined administration of phage and antibiotic could lead to a significant reduction in bacterial growth in many cases, while the reverse antagonistic effect was less common [26]. Treatment outcomes could be influenced by the sequence of therapeutic agents administered; the best results were recorded in cases with the phage therapy preceding antibiotics [27]. It has been established that the use of bacteriophages can alter the sensitivity profile of bacteria to antibacterial drugs and lead to the inclusion of the drug in the treatment regimen [28].

Understanding the pharmacokinetics (PK) and pharmacodynamics (PD) of phages is crucial for optimizing therapeutic efficacy in clinical settings [29]. However, achieving a comprehensive PK/PD understanding for phage therapy is challenging due to the three-way interactions between phages, bacteria, and humans. Every phage–bacteria–patient combination can exhibit a unique PK/PD profile and development of standardized models applicable across diverse clinical settings remains challenging. To date, there is no validated approach for the clinical use of phage therapy, requiring comparative clinical trials or the accumulation and analysis of real-world clinical data on the use of bacteriophages in the treatment of patients with orthopedic infection.

Our comparative study of the activity of commercial bacteriophage kits against clinical MRSA strains isolated from patients with orthopedic infections demonstrated a high level of lytic properties of the phage preparations. It is important to note different levels of antibacterial activity of kits produced at different regional facilities. Pchelin et al. suggested that the search for active bacteriophages planned for use as antimicrobial agents should probably be conducted in habitats geographically close to pathogenic bacterial populations [30].

The differences in the activity of commercial kits may be related to the composition of the resulting preparations, which have lower affinity for strains isolated from patients in other regions. However, the search for active phages is necessary for the prescription of personalized phage therapy selecting a specific bacteriophage against a specific pathogen strain. Given the wide geographical distribution of patients with orthopedic infections hospitalized in Federal Centers, the ability to choose bacteriophages from a wide range of commercial kits on the market increases the likelihood of their successful use.

CONCLUSION

Commercial domestic bacteriophage preparations available on the market exhibited varying lytic activity against methicillin-resistant *S. aureus* isolated from patients with orthopedic infections. Pyophag® and Staphylophag® (Nizhny Novgorod) demonstrated high efficacy compared to other preparations tested. The phage therapy should be considered a promising method for combating infections caused by antibiotic-resistant pathogens in trauma and orthopedic patients in conjunction with established treatment methods after mandatory testing of the pathogen's susceptibility to bacteriophage preparations.

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Information about the authors:

Ekaterina M. Gordina — Candidate of Medical Sciences, Senior Researcher, emgordina@win.rniito.ru, https://orcid.org/0000-0003-2326-7413;

Alina R. Kasimova — Candidate of Medical Sciences, Associate Professor, Associate Professor of the Department, Clinical pharmacologist, kasi-alina@yandex.ru, https://orcid.org/0000-0001-6284-7133;

Svetlana A. Bozhkova — Doctor of Medical Sciences, Professor, Head of the Scientific Department, clinpharm-rniito@yandex.ru, https://orcid.org/0000-0002-2083-2424;

Larisa N. Smirnova — laboratory assistant, lnsmirnova@rniito.ru, https://orcid.org/0000-0002-3307-0131.

Original article
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Translation, cross-cultural adaptation and validation of the Russian language version of the Karlsson – Peterson ankle function score system (KAFS)

T.N. Kubrina[1]✉, E.P. Sorokin[1,2], E.A. Pashkova[1], N.S. Konovalchuk[1], K.A. Demianova[1], Yu.P. Faustova[1], P.M. Preobrazhensky[1]

[1] Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russian Federation

[2] Pavlov First Saint Petersburg State Medical University, St. Petersburg, Russian Federation

Corresponding author: Tatiana N. Kubrina, Kubrina_1998@mail.ru

Abstract

Introduction In 1991, J. Karlsson and L. Peterson proposed a system for assessing the functional state of the ankle joint. This questionnaire assesses pain, activity, instability and disturbances inf daily activities using nine assessment parameters. The Karlsson – Peterson questionnaire has been used actively in foreign studies and literature sources, but despite its widespread use, its original version is in English, and until now there was no official adapted version in Russian.

The **aim** of the study was to translate, cross-culturally adapt and psychometrically validate the Russian version of the Karlsson – Peterson questionnaire for clinical use in patients with chronic lateral instability of the ankle joint.

Materials and methods The study included 60 patients at the preoperative examination stage in a state of clinical stability. The Karlsson – Peterson questionnaire was translated and adapted according to the ISPOR methodology. All patients filled in the Karlsson – Peterson and AOFAS-AHS questionnaires. A total of 39 patients were re-administered after 7–14 days. The following measures were assessed: internal consistency (Cronbach's α), test-retest reliability (ICC), standard measurement error (SEM), minimally significant difference (MDC), extreme effects, and construct validity.

Results The Russian version of the Karlsson – Peterson questionnaire showed high internal consistency ($\alpha = 0.826$) and good reproducibility (ICC = 0.720). SEM was 2.89, MDC was 7.95 points. There were no ceiling or floor effects. Significant correlations were found between the final scores of the Karlsson – Peterson questionnaire and AOFAS-AHS.

Discussion The study demonstrated the reliability, validity, and sensitivity of the Russian version of the Karlsson – Peterson questionnaire. The questionnaire is an informative and clinically interpretable tool for assessing the condition of the ankle joint in patients with chronic ankle instability.

Conclusion The Russian version of the Karlsson – Peterson questionnaire demonstrated high psychometric properties and can be recommended for use in clinical and research practice, as well as for assessing the functional state of patients with chronic lateral instability of the ankle joint to assess the dynamics of changes in the treatment process.

Keywords: Karlsson and Peterson scoring system for ankle function, validation, ankle joint, chronic instability

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INTRODUCTION

Chronic lateral ankle instability is a significant clinical problem in medicine, as it affects a physically active part of the population [1]. This condition is characterized by repetitive supination injuries to the ankle joint and a feeling of instability; it frequently leads to impairment in quality of life and the ability to participate in sports or daily activities [1–4]. This pathology is widespread, as cases of acute injuries to the ligamentous apparatus of the ankle joint account for up to 21 % of all lower extremity injuries [5]. After an acute injury, all patients initially undergo conservative treatment (immobilization, walking not bearing weight on the injured limb, and subsequent rehabilitation). From 10 to 30 % of such patients report a subjective feeling of loss of control over the ankle joint after conservative treatment which has a high risk of developing undesirable consequences and requires surgical treatment [6–8].

High incidence of post-traumatic ankle instability has necessitated the development of a questionnaire to assess ankle function for the diagnosis of this condition and for evaluation of surgical treatment outcomes. Functional assessment of the ankle is an important element in the diagnosis and treatment monitoring of patients with chronic lateral ankle instability [9, 10]. Patient-reported outcome measures (PROMs) are now being used to more accurately convey patient perceptions and functional characteristics [11].

Currently, various questionnaires validated for the Russian-speaking population have been used in ankle surgery practice: FAAM (Foot and Ankle Ability Measure), FADI (Foot and Ankle Disability Index), SEFAS (Self-reported Foot and Ankle Score), MOxFQ (Manchester-Oxford Foot Questionnaire), and others [12–14]. These questionnaires have proven themselves to be reliable tools for assessing ankle condition, but they do not focus on patient's subjective perceptions. The authors searched for a questionnaire suitable for assessing ankle function in patients with chronic ankle instability. Among the many scales used in clinical practice, the Karlsson – Peterson Ankle Function Score (KAFS) stands out for its specificity and focus on patient's subjective sensations [15, 16]. The KAFS scale, popular in orthopedic practice, was proposed by J. Karlsson and L. Peterson in 1995 in Sweden [17]. The assessment is based on nine parameters; pain, swelling, subjective instability, limitations in sports are among them. The main objective of the KAFS is to evaluate the functional state of the ankle joint after injuries or surgeries from the patient's point of view. The questionnaire has been actively used in foreign studies, but at present, a Russian-language version of the KAFS questionnaire validated according to all standards is not presented in the literature. Therefore, cultural and linguistic adaptation is required for the use of this scale in clinical practice.

The **aim** of the study was to translate, cross-culturally adapt and psychometrically validate the Russian version of the Karlsson – Peterson questionnaire for clinical use in patients with chronic lateral instability of the ankle joint.

MATERIALS AND METHODS

Karlsson – Peterson Questionnaire (KAFS)

The KAFS questionnaire was first published by J. Karlsson and L. Peterson in 1991 in a scientific article [15], but a more complete description of the questionnaire and its application for assessing treatment outcomes appeared in 1995 [17]. Thus, 1995 is considered a key year for the popularization and beginning of the active use of this questionnaire in orthopedic practice and scientific research. Important features of this questionnaire include its convenience and speed of completion, as well as high sensitivity to such concepts as pain, subjective instability in the ankle joint, and impairment of daily activities. The questionnaire is completed by the patient independently without the participation of a physician, which demonstrates its focus on the patient's perceptions.

The KAFS consists of three main sections that assess different aspects of the ankle function:

1) Symptoms Score. This section is subjective and assesses the patient's sensations, such as pain, swelling, instability, and stiffness. The maximum score is 30;

2) Function Score. This section assesses the patient's ability to perform daily activities, such as climbing stairs, running, housework, and the need for an orthotic support. The maximum score is 30.

3) Sports Activity Score. This section evaluates athletic activity, such as the patient's activity level, distance, and frequency of training. The maximum score is 40.

The maximum possible score on the KAFS questionnaire is 100 points which indicates an ideal, asymptomatic ankle function and a full return to sports and daily activities without limitations. A score of < 70 points is a poor result and indicates significant, persistent problems.

The advantages of the KAFS questionnaire include its ease of completion, coverage of key aspects, and focus on patient perception.

AOFAS-AHS questionnaire

AOFAS-AHS (American Orthopaedic Foot and Ankle Society ankle-hindfoot scale) is one of the most well-known tools in orthopedic practice. This questionnaire is designed for a comprehensive assessment of ankle, subtalar, and hindfoot function. The AOFAS-AHS combines the patient's subjective assessment of their symptoms with objective data assessed by the physician.

AOFAS-AHS scale has three domains resulting in maximum total of 100 points.

1) Pain. This is the most significant section, assessing the intensity and limitations caused by pain. The maximum score is 40;

2) Function. This section includes several parameters: activity and limitations, requirement for additional means of support, walking distance, and gait. The maximum score is 50;

3) Deformation. This parameter is designed to assess the patient's assessment of the presence of deformity. The maximum score is 10.

A maximum score of 100 points on this questionnaire indicates an ideal outcome (pain-free, full function, perfect alignment). Patients who score < 50 points have a poor outcome.

The Russian version of the questionnaire has been validated and adapted for the Russian-speaking population within the framework of the international standardized protocol EuroQol (European Quality of life) [18], therefore we used this questionnaire to check the construct validity.

Translation and adaptation

Translation and cross-cultural adaptation of the KAFS questionnaire were carried out according to the ISPOR (International Society for Pharmacoeconomics and Outcomes Research) methodology [18, 19]. The KAFS questionnaire, consisting of nine questions, was translated into Russian by a trauma orthopedic surgeon with an advanced level of English and a professional translator. Two parallel versions of the translation were obtained. A working group was created that compared the two translations, discussed discrepancies and created a single synthesized version. Two other independent translators, born in an English-speaking country, translated the synthesized version of the questionnaire back into English. A committee was created, which included methodologists, orthopedic specialists, linguists, and translators (who participated in the translation process). The committee members discussed and resolved all discrepancies,

ensuring the conceptual, semantic and cultural equivalence of the questionnaire. Thus, the final version of the questionnaire was created and approved. To test the functionality of the approved version, pilot testing and cognitive interviews were conducted.

A printed version of the questionnaire was administered to 20 patients with chronic ankle instability. During the cognitive interview, patients were asked questions such as, "How did you understand this question?", "Were any words or phrases unclear to you?", and others.

During this testing and interview, no difficulties in answering or understanding the questions were encountered by the patients, which may indicate high distinguishability and cognitive accessibility of the scale. To assess test-retest reliability, 39 patients re-completed the printed version of the questionnaire 7–14 days after the initial completion in a state of clinical stability. To further assess construct validity, all patients were asked to complete the AOFAS-AHS questionnaire [18].

Karlsson – Peterson questionnaire used for the Russian version

Parameter	Variants of answers	Points
Pain	None	20
	During exercise	15
	Walking on uneven surface	10
	Walking on even surface	5
	Constant	0
Swelling	None	10
	After exercise	5
	Constant	0
Instability	None	25
	1-2 / year (during exercise)	20
	1-2 / month (during exercise)	15
	Walking on uneven ground	10
	Walking on uneven ground	5
	Constant (severe) using ankle support	0
Stiffness	None	5
	Moderate (morning, after exercise)	2
	Marked (constant, severe)	0
Stair climbing	No problems	10
	Impaired (instability)	5
	Impossible	0
Running	No problems	10
	Impaired	5
	Impossible	0
Work activities	Same as pre-injury	15
	Same work, less sports, normal leisure activities	10
	Lighter work, no sports, normal leisure activities	5
	Severe impaired work capacity, decreased leisure activities	0
Support	None	5
	Ankle support during exercise	2
	Ankle support during daily activities	0

Study design

The validation procedure was conducted on a specific patient sample over time in accordance with international guidelines. This study was designed as a prospective, cohort, observational study. All patients and their data were collected at a single institution, making it a single-center study.

Patients' sample

The study group included 60 patients with chronic lateral instability of the ankle joint: 30 women and 30 men aged 18 to 65 years (average age, 36.3 years), hospitalized at the Vreden National Medical Research Center of Traumatology and Orthopedics from January 2023 to April 2024 for surgical treatment: anatomical plastic surgery of the lateral ligamentous complex of the ankle joint according to Brostrom – Gould.

Inclusion criteria: patients of 18 years of age and older who gave their informed consent

Criteria of non-inclusion: written refusal of the patient to participate in the study, previous surgical interventions on the lateral ligamentous complex, a history of fractures at the level of the ankle joint, osteochondral defect of the talus

Exclusion criteria: refusal to provide the necessary information about health status and medical history, unwillingness to continue participation in the study at any stage of the study

Description of eligibility criteria: The patient sample was formed based on the presence of a primary inversion injury of the ankle joint, a subjective feeling of instability, as well as on the basis of instrumental studies and functional tests performed confirming damage to the lateral ligamentous complex of the ankle joint.

Statistical analysis

The obtained data were introduced into tables using Microsoft Excel, allowing for editing and processing. Jamovi (version 2.3.28) and PAST (version 4.03) were used for statistical processing.

Psychometric assessment

The evaluation of the psychometric properties of the Russian-language version of the KAFS questionnaire was carried out on the basis of the international principles of COSMIN (Consensus-based Standards for the Selection of Health Status Measurement Instruments) [21].

Cronbach's α coefficient is a statistical indicator that helps assess the internal consistency between all questionnaire items and the questionnaire as a whole. It does not prove unidimensionality or evaluate other types of reliability, but rather indicates how well all items measure the same characteristic. This coefficient is calculated automatically using software packages and does not require manual calculation. The Cronbach's α coefficient in the range of 0.7 to 0.9 is considered high and indicates excellent consistency across all items in assessing the overall construct [22].

Construct validity was assessed by correlation analysis with the AOFAS-AHS questionnaire using the Spearman criterion. Construct validity shows how well a set of indicators reflects a concept. Test-retest reliability was calculated using the Intraclass Correlation Coefficient (ICC) [22]. The Standard error of the measurement (SEM) was calculated using the formula: $SEM = SD \times \sqrt{(1 - ICC)}$. The minimal detectable change (MDC) was determined with the formula: $MDC = 1.96 \times SEM \times \sqrt{2}$. Ceiling and floor effects were defined as the proportion of patients who

scored the maximum or minimum value for the final score. Values lower than 15% are considered low for ceiling and floor effects.

Hypothesis planning

Construct validity is the extent to which a questionnaire measures the theoretical construct it was designed to measure. One of the most powerful ways to assess construct validity is to examine relationships with other variables. Our study utilized a comparison method with AOFAS-AHS questionnaire scores based on pre-formulated hypotheses about the strength of the expected correlations [20]. Spearman's correlation coefficient is used to test these hypotheses, as the data are more stable to deviations from a normal distribution [23].

RESULTS

Cross-cultural adaptation meant ensuring that the translated questionnaire was not only linguistically accurate but also conceptually and semantically equivalent to the original, as well as simple and understandable to patients. We needed to ensure data comparability and guarantee that the instrument was reliable and valid for use in the new culture.

All 60 patients included in the study completed the entire study. The average KAFS score was 36.3 (minimum 26; maximum 72) out of a possible 100. All patients were interviewed in person by a trauma/orthopedic specialist. They were provided with information on how to correctly complete the questionnaire, resulting in a 100% completion rate. None of the patients included in the study reported any difficulties in completing the printed version of the questionnaire. The average time to complete the questionnaire was 3.1 minutes.

The distribution of scores for the Russian-language version of the KAFS questionnaire revealed no significant ceiling or floor effects (0 points and 100 points), critical indicators of the quality of a measuring instrument, demonstrating the questionnaire's good discriminatory ability, high sensitivity, and suitability for measuring ankle function in patients with varying degrees of pathology severity.

Internal consistency

The Russian-language version of the KAFS questionnaire demonstrated high internal consistency, confirming that this ankle function assessment tool is comprehensive and consistent in measuring the required property. The Cronbach's α coefficient was 0.826. This calculation was based on the initial completion of the printed version of the questionnaire and included 60 patients at the preoperative stage in a state of complete clinical rest.

Reliability

The test-retest analysis helped us assess the stability of measurement results over time. The Russian-language version of the KAFS questionnaire demonstrated good test-retest reliability in 39 patients who repeated the printed version of the KAFS questionnaire within 7-14 days of the initial survey in their clinical condition unchanged prior to surgery. The intraclass correlation coefficient (ICC) for the total score was 0.720, indicating good reproducibility and stability of questionnaire results obtained by the repeated completion.

To assess measurement accuracy, the standard error of measurement (SEM) was calculated and found to be 2.89 points. The minimally significant difference (MDC) of 7.95 points confirms the high accuracy and reliability of this questionnaire.

Construct validity

To assess construct validity, we developed five pre-defined hypotheses regarding correlation strength. The indicators were assessed using Spearman's rank correlation coefficients. All five hypotheses (100%) were confirmed (Table 1), demonstrating high construct validity for the Russian-language version of the KAFS [21].

Table 1

Hypothesis testing to determine the construct validity of the translated version of the questionnaire

Compared scales/domains	Hypothesis	Expected ρ
KAFS and AOFAS-AHS: activity	Direct correlation	⩾ 0.5
KAFS and AOFAS-AHS: instability	Direct correlation	⩾ 0.5
KAFS and AOFAS-AHS: pain/discomfort	Direct correlation	⩾ 0.5
KAFS and AOFAS-AHS: use of additional support means	Direct correlation	⩾ 0.4
KAFS and AOFAS-AHS: selfservice	Direct correlation	⩾ 0.4

DISCUSSION

Chronic ankle instability is currently a pressing issue due to its prevalence among physically active and working individuals. Currently, there is no scale that is specific for this condition and useful during diagnosis and postoperative follow-up. Physicians use a variety of scales that do not fully reflect the patient's subjective sensations and are not specific for assessing the subjective sensations of patients with chronic lateral ankle instability. The international literature shows that authors actively use the KAFS scale for diagnosing chronic ankle instability and postoperative follow-up, considering it the most specific for this condition [24–28]. This study, in accordance with international criteria, translated, cross-culturally adapted, and validated the Russian-language version of the KAFS on a sample of patients with chronic lateral ankle instability. The obtained results prove the high psychometric characteristics of this scale.

CONCLUSION

The KAFS questionnaire demonstrated high sensitivity and specificity in assessing ankle joint function. Unlike the AOFAS-AHS questionnaire, which combines objective and subjective parameters, the KAFS questionnaire focuses on patient perceptions, making it particularly valuable for assessing quality of life and the patient's perception of ankle stability.

The KAFS questionnaire is a valid and reliable tool for assessing ankle function in patients with chronic lateral ankle instability. The application of the KAFS in clinical practice allows for a more accurate assessment of the effectiveness of treatment and the level of joint function recovery in patients with chronic lateral ankle instability, considering patient's subjective perceptions.

Conflict of interests *The authors declare that there is no conflict of interests..*

Source of funding *The study was not sponsored.*

Ethical approval *Ethical approval of the study protocol was not conducted.*

Informed consent *All patients signed an informed consent form to participate in the study.*

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Information about the authors:

Tatiana N. Kubrina — orthopaedic surgeon, post-graduate student, Kubrina_1998@mail.ru, https://orcid.org/0009-0000-3309-2560;

Evgenii P. Sorokin — Candidate of Medical Sciences, orthopaedic surgeon, Head of Department, Assistant Professor, sorokinortoped@gmail.com, https://orcid.org/0000-0002-9948-9015;

Ekaterina A. Pashkova — Candidate of Medical Sciences, orthopaedic surgeon, Junior researcher, caterinapashkova@yandex.ru, https://orcid.org/0000-0003-3198-9985;

Nikita S. Konovalchuk — Candidate of Medical Sciences, orthopaedic surgeon, Junior researcher, konovalchuk91@gmail.com, https://orcid.org/0000-0002-2762-816X;

Ksenia A. Demianova — orthopaedic surgeon, ortodem@yandex.ru, https://orcid.org/0000-0002-2239-2792;

Yulia P. Faustova — orthopaedic surgeon, post-graduate student, fausjulie99@mail.ru, https://orcid.org/0009-0000-2779-7564;

Petr M. Preobrazhenskii — Candidate of Medical Sciences, orthopaedic surgeon, Junior researcher, pedrro@yandex.ru,

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Application of platelet-rich plasma in compensating bone defects with ceramic Implants

I.P. Antropova, E.A. Volokitina✉, K.A. Timofeev, R.A. Trufanenko, S.M. Kutepov, L.G. Polushina

Ural State Medical University, Ekaterinburg, Russian Federation

Corresponding author: Elena A. Volokitina, Volokitina_elena@rambler.ru

Abstract

Introduction The use of ceramic materials is a promising approach to bone defect repair. Various orthobiological agents are used to improve their properties and enhance their regenerative potential.

The **aim** of this study was to determine the efficacy of platelet-rich plasma in repairing bone defects with yttria-doped zirconia ceramic implants.

Materials and Methods Bioceramic samples were zirconium dioxide. The ceramic implants measured 0.15 × 0.15 × 1.00 cm. Male Chinchilla rabbits were used in the experiment: Group 1 (n = 10) included animals that underwent bilateral metaphyseal bone defect filling with implantation of ceramic augments; Group 2 (n = 10) included animals that underwent bone defect repair without implantation. Platelet-rich plasma (PRP) was injected into the bone defect in the right femur of rabbits in both groups; PRP was not injected into the defect in the left femur. Blood samples were collected preoperatively and at the end of the experiment, four and eight weeks after surgery. Key blood parameters, including C-reactive protein, and platelet-derived growth factor (PDGF) in PRP were determined. To assess the effect of PRP on the dynamics of osteogenesis, a comparative histological analysis of the tissue structure in the simulated bone defect area was conducted.

Results No significant differences were found between the groups in key parameters of leukocytes, erythrocytes, and platelets, or C-reactive protein levels, either preoperatively or eight weeks after surgery. The concentration of PDGF in the injected PRP did not differ significantly between the groups. Histological analysis showed that injection of PRP increased the number of regenerating bone trabeculae and reduced the number and size of fibrotic foci and osteochondral callus in both groups.

Discussion Autologous PRP has previously been shown to be a simple and effective way to enhance bone regeneration due to the release of multiple growth factors by platelets, which regulate key biological processes, including angiogenesis, inflammation resolution, and tissue regeneration. Our study aimed to investigate whether platelet-rich plasma enhances the osteogenic potential of zirconia ceramic implants in bone defect repair. Our results confirm that PRP, with a platelet concentration of 800 × 10^9/L to 1200 × 10^9/L, a white blood cell count of 4–7 %, and a red blood cell count of no more than 1 % of the baseline blood count, may be a useful tool for bone regeneration.

Conclusion The use of PRP is effective in compensating bone defects using zirconia ceramic implants. However, further rigorous clinical studies are needed to integrate PRP-based methods into evidence-based medical practice.

Keywords: bone tissue, defect repair, implant, zirconium ceramics, platelet-rich plasma, osseointegration, experiment

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INTRODUCTION

Bone defect repair is a key objective in modern traumatology and orthopedics. Every year, the number of injuries, degenerative diseases, and oncological pathologies involving bone tissue and requiring surgical treatment and, in some cases, defect repair continue to grow. The number of surgical interventions for intra-articular and comminuted fractures with bone defects is increasing every year [1, 2, 3].

Various osteoplastic materials are used to compensate bone defects. Autografts are considered the "gold standard," but their use is associated with potential complications, both at the donor site and at the site of defect 4]. The use of allografts and xenografts also has significant drawbacks [5]. A shortage of natural sources, coupled with the growing demand for implants, has stimulated the search for and development of artificial materials for osteoplasty.

One promising area for bone defect repair is the use of ceramic materials. The broad range of properties of bioceramics and their good compatibility with human tissue make this material potentially suitable for solving a wide range of problems in traumatology and orthopedics [6]. Yttria-stabilized zirconia dioxide bioceramics occupy an important place. This material exhibits exceptional mechanical properties and biocompatibility, and does not cause cytotoxic effects or allergic reactions in surrounding tissues [7, 8].

Due to their physicochemical properties, bioceramics used for bone plasty primarily exhibit osteoconductive properties [9]. To improve the properties of osteoplastic materials and enhance their regenerative potential, various orthobiological preparations are used [10]. Particular attention has been paid in recent years to platelet-based biopreparations [11]. It has been noted that the use of platelet-rich plasma (PRP) not only improves the proliferation of mesenchymal stem cells [12], but also promotes their osteogenic differentiation [13]. Studies show that the use of PRP in combination with ceramic or composite implants can promote osteoinduction [14] and significantly improve treatment outcomes [15]. The results of the combined use of PRP therapy with bone plasty materials are considered promising [16]. At the same time, it was noted that, despite the additional advantages of combining ceramic osteosubstituting materials with platelet-based orthobiological products, further experimental and clinical studies are needed.

The **aim** of this study was to determine the efficacy of platelet-rich plasma in repairing bone defects with yttrium-doped zirconium dioxide ceramic implants.

MATERIALS AND METHODS

Experimental animals

Experimental animals were male chinchilla rabbits kept in the vivarium of the Ural State Medical University at a temperature of 23–25 °C, with a 12-hour day/night lighting cycle, and with access to food and water ad libitum. All experiments were carried out in accordance with the Good Laboratory Practice Rules (Order of the Ministry of Health of the Russian Federation No. 199n dated 01.04.2016), State Standards (GOST 33215-2014, GOST 33216-2014 "Guidelines for the care and maintenance of laboratory animals"), and the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (ETS No. 123, Strasbourg, 18 March 1986 with the appendix dated 15.06.2006). The studies were approved by the institutional ethics committee of the Federal State Budgetary Educational Institution of Higher Education Ural State Medical University of the Ministry of Health of the Russian Federation (protocol No. 4 dated 26.05.23).

All rabbits were divided into two groups: group 1 (n = 10) included animals that underwent modeling of bilateral metaphyseal bone defects in their femurs with implantation of ceramic augments; group 2 (n = 10) included animals that also underwent modeling of bilateral metaphyseal bone defects in their femurs but did not undergo implantation of ceramic augments. Rabbits in both groups received PRP injections into the bone defect in the right femur; PRP was not injected into the defect in the left femur.

Surgical modeling of a bone defect in the distal metaphysis of the femur

To model a bone defect, the experimental animal was placed on their side, the hind limb was treated with antiseptic solutions, and the surgical field was covered with sterile surgical drapes. A 1-cm longitudinal skin incision was made along the lateral surface of the lower third of the thigh in the projection of the femur. Soft tissue along the approach was separated using a blunt dissection. A bone defect was created in the distal metaphysis of the femur parallel to the articular surface of the knee using a 2.0-mm Kirschner wire. The bone defect was modeled bilaterally. PRP was injected into the bone defect in the right limb; no PRP was injected into the bone defect in the left limb.

In group 1, ceramic augments (0.15 × 0.15 × 1 cm) were implanted into the bone defects of both femurs. In group 2, ceramic augments were not implanted into the bone defects of either femur. The wound was sutured layer by layer, the skin was treated with an antiseptic, and an aseptic dressing was applied. In each group, five animals were sacrificed four weeks after surgery, and five animals were sacrificed eight weeks after surgery.

Material for bone defects compensation

Bioceramic implants made of zirconium dioxide (ZrO_2) doped with yttrium oxide (Y_2O_3, 5 wt %) were obtained at the Institute of High-Temperature Electrochemistry, Ural Branch of the Russian Academy of Sciences. The material has closed porosity, with a pore volume fraction of approximately 15 %. Pores range in size from 1–2 to 30 μm and have complex shapes. The ceramic implants measured 0.15 × 0.15 × 1 cm (Fig. 1).

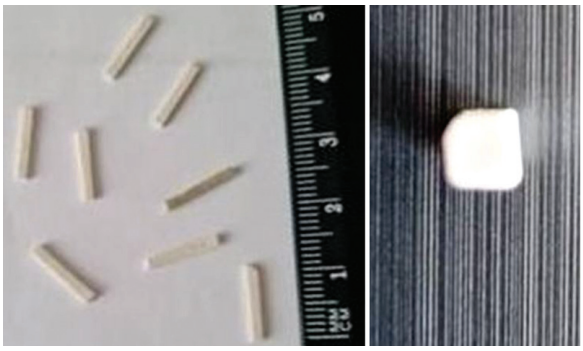

Fig. 1 Ceramic implants made of yttrium oxide-doped zirconium dioxide and a cross-section of the implant

Preparation of plasma, serum, PRP

The procedure for collecting blood in both groups was carried out before surgery and at withdrawal from the experiment four and eight weeks after surgery.

Blood was collected from the marginal vein of the rabbit ear:

— in tubes with EDTA-K2 (ethylenediaminetetraacetate potassium) to determine hematological parameters;

— in tubes without anticoagulant to obtain serum, which was then was frozen and stored at –80 °C until enzyme-linked immunosorbent assay (ELISA);

— in tubes with 3.2 % sodium citrate in a 9:1 ratio.

To obtain PRP, blood with sodium citrate was centrifuged for 7 minutes at 1500 rpm. The resulting plasma was aspirated with a sterile insulin syringe, 200 µl was placed in an Eppendorf tube for platelet count determination using a Cell-70 hematology analyzer (Biocode-Hygel, France) and subsequent freezing. The remaining PRP (1 ml) was injected into the metaphyseal defect of the right femur.

Laboratory tests

Laboratory studies were conducted at the Central Scientific Research Laboratory of the Ural State Medical University. Basic blood parameters were determined using a Cell-70 automated hematology analyzer (Biocode-Hygel, France). Platelet-derived growth factor (PDGF subunit A, rabbit) was determined after the PRP freeze-thaw procedure using ELISA kits (Cloud-Clone Corp., China). C-reactive protein (CRP, rabbit, Cloud-Clone Corp) and osteocalcin (Osteocalcin, rabbit, Cloud-Clone Corp) were also determined using ELISA. The analysis was performed using a system including a Termo Scirntific Multiskan GO plate enzyme immunoassay analyzer (Japan); a Thermo Scientific Wellwash washer (Japan), and an Elmi ST-3L shaker-thermostat (Latvia).

Histological study

After the animal was sacrificed, block-like samples of bone tissue were collected from the distal femoral metaphyses and fixed by immersion in 10 % buffered formaldehyde at room temperature for at least seven days. Following fixation, the samples were decalcified for 48 hours in a solution of hydrochloric (11.5 ± 0.5 %) and formic (5.8 ± 0.3 %) acids, which was replaced every 24 hours. The decalcified samples were sectioned at the bone defect site to form 2- to 4-mm-thick plates. The resulting plates were dehydrated in graded ethanol and embedded in paraffin to form blocks. The paraffin blocks were then sectioned to 3- to 4-µm-thick sections, and the material was stained with hematoxylin and eosin. Ceramic implants were removed during the excision of samples for histological examination after decalcification. Histological sections were prepared using a CUT 4062 mechanical rotary microtome. Histological and morphometric studies were performed using an Olympus CX-31 microscope and an Olympus DP27 camera. The degree of fibrosis, the presence and severity of osteochondral callus, and regenerating bone trabeculae were assessed, and the presence of inflammatory infiltrate was determined.

Statistical protesting of the findings

Variation statistics were used using Statistica 10 software. The Mann-Whitney test was used to compare the groups. A $p < 0.05$ level was considered statistically significant. Data are presented as median [interquartile range].

RESULTS

To assess the impact of the implanted ceramic material on the overall health of the experimental animals, general hematological parameters were determined dynamically (before and after surgery). A complete blood count (Table 1) revealed no significant differences in the key white blood cell, red blood cell, and platelet counts between groups 1 and 2, either before or after surgery.

The analysis of the inflammatory marker C-reactive protein preoperatively showed no significant differences between the groups (Fig. 2). However, four weeks after surgery, CRP levels were significantly higher in the animals of group 1 than in group 2, which could be related to both the body's response to the implant and the implantation technique. Eight weeks after surgery, no differences in inflammatory marker levels were found between the groups.

The concentration of osteogenesis marker osteocalcin four weeks after surgery was significantly higher in group 2. However, after eight weeks, significantly higher osteocalcin levels were observed in group 1 (Fig. 3). These data indicate changes in the dynamics of osteogenesis in the animals with ceramic implant compared to the animals in the control group.

Table 1

Basic hematological parameters before and after modeling of bone defect in rabbits

Параметры и группы		Median [interquartile range]		
		Baseline (*n* = 10)	4 weeks (*n* = 5)	8 weeks (*n* = 5)
Leukocytes (WBC), ×10⁹/l	Group 1	11.4 [10.3; 12.4]	7.8 [7.5; 8.1]	9.4 [9.3; 9.7]
	Group 2	10.4 [9.3; 10.6]	8.2 [7.8; 8.4]	8.5 [7.4; 9.6]
	p	0.109	0.095	0.413
Erythrocytes (RBC), ×10¹²/l	Group 1	5.72 [5.50; 6.10]	6.06 [5.76; 6.23]	5.82 [5.74; 5.84]
	Group 2	6.08 [5.65; 6.23]	5.24 [5.19; 5.51]	5.56 [5.38; 5.97]
	p	0.193	0.056	0.286
Hemoglobin (HGB), (g/l)	Group 1	130 [122; 135]	130 [126; 138]	130 [129; 130]
	Group 2	135 [128; 139]	120 [117; 126]	125 [118; 132]
	p	0.193	0.151	0.556
Hematocrit (HCT), %	Group 1	37.5 [35.8; 38.6]	39.0 [37.0; 39.8]	37.3 [37.0; 37.5]
	Group 2	39.6 [36.7; 40.4]	35.9 [34.8; 38.1]	36.9 [35.1; 38.3]
	p	0.109	0.151	0.730
Platelets (PLT), ×10⁹/l	Group 1	211 [199; 243]	216 [202; 223]	239 [234; 244]
	Group 2	212 [176; 231]	239 [217; 280]	235 [181; 290]
	p	0.669	0.413	0.730
Mean platelets volume (MPV), fl	Group 1	3.7 [3.4; 4.1]	4.1 [3.6; 4.2]	3.5 [3.4; 3.5]
	Group 2	3.4 [3.3; 3.9]	3.8 [3.7; 3.9]	3.8 [3.3; 4.8]
	p	0.417	0.548	0.413
Relative width of platelet distribution by volume PDW	Group 1	19.0 [18.2; 19.9]	19.9 [19.3; 20.7]	17.7 [17.5; 18.3]
	Group 2	18.4 [17.8; 19.0]	19.3 [18.4; 19.3]	18.4 [17.6; 19.0]
	p	0.270	0.310	0.730
Band neutrophils, ×10⁹/l	Group 1	0.21 [0.11; 0.28]	0.22 [0.08; 0.24]	0.19 [0.19; 0.22]
	Group 2	0.09 [0.00; 0.28]	0.11 [0.08; 0.17]	0.26 [0.17; 0.34]
	p	0.364	0.310	0.556
Segmented neutrophils, ×10⁹/l	Group 1	3.30 [2.71; 4.72]	3.55 [2.35; 4.56]	2.88 [2.59; 3.35]
	Group 2	2.88 [2.60; 4.49]	2.81 [2.77; 3.10]	2.85 [2.33; 3.56]
	p	0.475	0.690	0.905
Eosinophils, ×10⁹/l	Group 1	0.32 [0.14; 0.56]	0.13 [0.08; 0.21]	0.09 [0.07; 0.12]
	Group 2	0.20 [0.12; 0.32]	0.25 [0.17; 0.31]	0.12 [0.08; 0.24]
	p	0.613	0.343	0.730
Basophils, ×10⁹/l	Group 1	0.0 [0.0; 0.0]	0.0 [0.0; 0.0]	0.0 [0.0; 0.0]
	Group 2	0.0 [0.0; 0.1]	0.0 [0.0; 0.0]	0.0 [0.0; 0.0]
	p	0.161	0.690	0.556
Lymphocytes, (LYM), ×10⁹/l	Group 1	7.21 [4.62; 7.78]	3.31 [2.64; 4.11]	5.95 [5.12; 6.91]
	Group 2	6.90 [5.58; 7.06]	4.16 [3.90; 4.37]	5.05 [.22; 5.46]
	p	0.475	0.343	0.286
Monocytes (MON), ×10⁹/l	Group 1	0.33 [0.22; 0.79]	0.41[0.30; 0.44]	0.28 [0.23; 0.29]
	Group 2	0.31 [0.20; 0.36]	0.64 [0.46; 0.83]	0.24 [0.15; 0.32]
	p	0.315	0.151	0.730

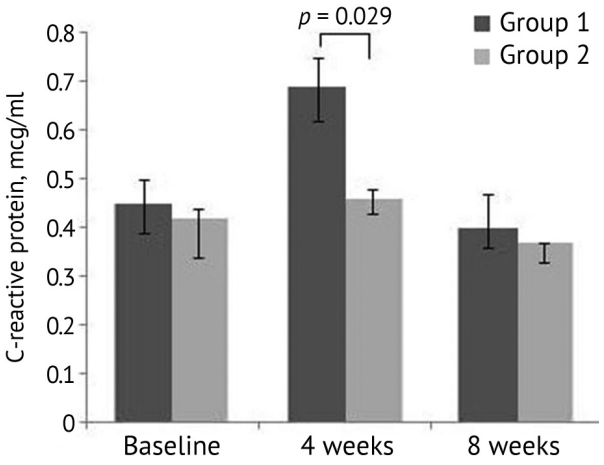

Fig. 2. C-reactive protein levels before and after modeling a bone defect in rabbits that received ceramic implants (group 1) and in the rabbits without implantation (group 2). The results are presented as median and interquartile range

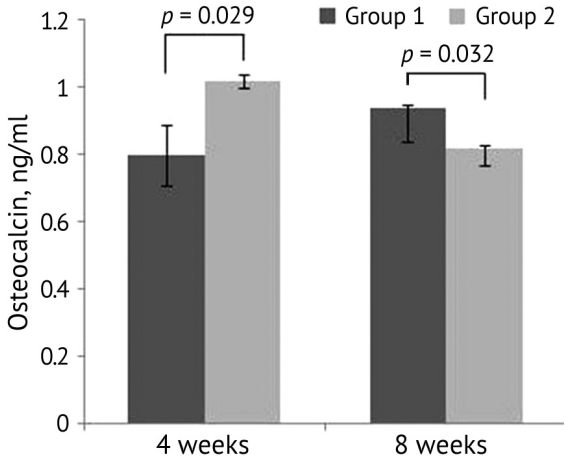

Fig. 3 Osteocalcin concentration after modeling a bone defect in rabbits that received ceramic implants (group 1) and in rabbits without implantation (group 2). The results are presented as median and interquartile range

The resulting PRP was characterized using parameters such as platelet, leukocyte, and erythrocyte concentrations (Table 2). The relative leukocyte count did not exceed 5–8 %, and the erythrocyte count did not exceed 1 % of the baseline blood levels of these cells. The concentration of PDGF, a growth factor released during platelet activation, also showed no significant differences between groups 1 and group 2. Relative to the baseline blood level, the platelet count in the PRP was increased fourfold, and the mean platelet volume was increased 1.4-fold (Fig. 4).

Table 2

Indices of PRP injected in the rabbits of the study groups

Parameters	Median [interquartile range]		
	Group 1	Group 2	*p*
Platelets (PLT), $\times 10^9$/l	846 [837; 1204]	808 [790; 1110]	0.310
Mean platelet volume (MPV), fl	5.0 [5.0; 5.1]	4.8 [4.3; 5.0]	0.421
Leukocytes (WBC), $\times 10^9$/l	0.50 [0.40; 0.70]	0.70 [0.60; 0.90]	0.310
Erythrocytes (RBC), $\times 10^{12}$/l	0.04 [0.03; 0.04]	0.04 [0.04; 0.05]	0.421
PDGF, ng/ml	1.89 [1.88; 2.18]	1.78 [1.75; 2.14]	0.364

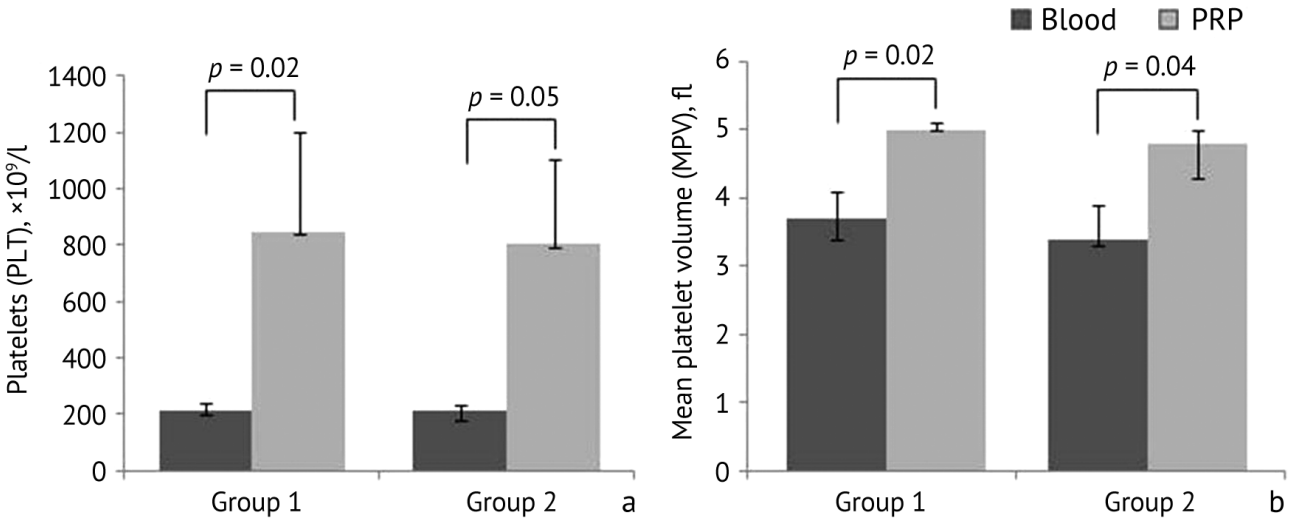

Fig. 4 Comparison of platelet levels (a) and mean platelet volume (b) in blood and PRP obtained from it in the rabbits of the studied groups. The results are presented as median and interquartile range

To assess the effect of PRP on the dynamics of osteogenesis during surgical modeling of a bone defect in the area of the distal metaphysis of the rabbit's femur, a comparative analysis of the histological structure of tissues in the area of the bone defect modeling was carried out.

Histological analysis revealed that four weeks after surgery, large foci of fibrosis (Fig. 5a) and foci of incomplete secondary osteogenesis (Fig. 5b) were observed in the microscopic specimens of group 2 (without implantation) with modeling of the defect without PRP administration. In the case of PRP administration, regenerating bone trabeculae were observed, indicating more effective regeneration under the conditions of the platelet-derived product injection (Fig. 5c).

In group 1 (with ceramic implants), a more active reparative process was also observed with PRP injection into the defect area. However, unlike group 2 and regardless of PRP use, inflammation was observed in the peri-implant area (Fig. 5g). The inflammation may be related to both the reaction to the implant and the implantation technique.

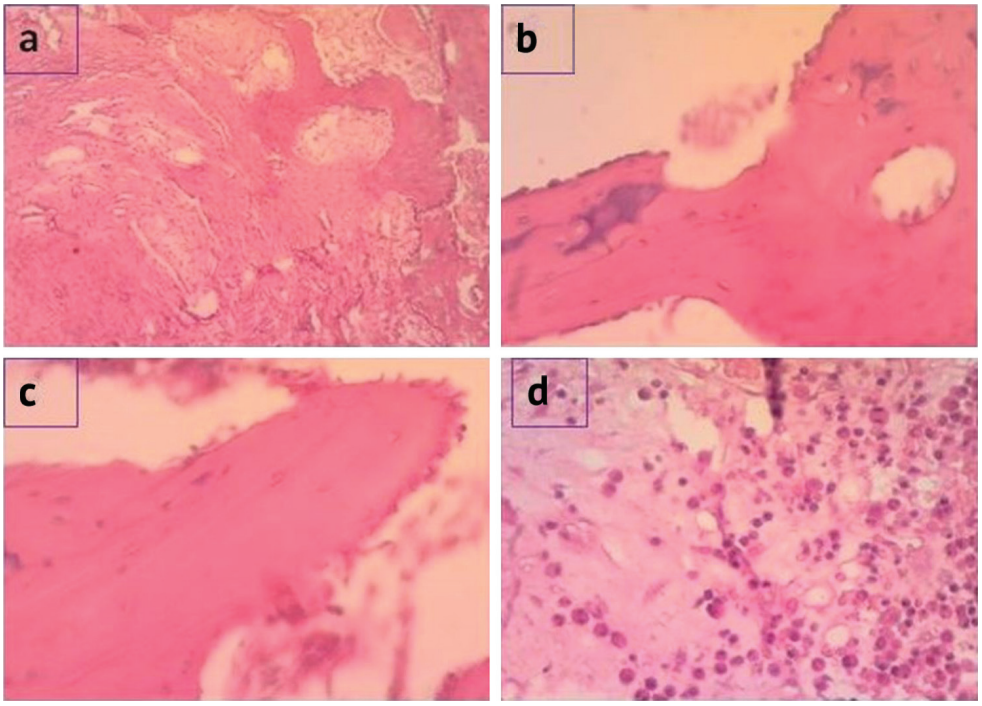

Fig. 5 Features of the histological structure of tissues in the area of modeling a bone defect in rabbits 4 weeks after surgery: (a) a large focus of fibrosis in the animals without implantation and without PRP, ×40, G-E; (b) a small focus of incomplete secondary osteogenesis in animals without implantation, without PRP, ×100, G-E; (c) regenerating bone trabecula, animals with implantation, with PRP, ×100, G-E; (d) inflammation in the implant area, animals with implantation, with PRP, ×100, G-E

Eight weeks after surgery without PRP administration, bone tissue micropreparations from the animals in both groups showed signs of incomplete reparative bone regeneration, including secondary (enchondral) osteogenesis and areas of fibrosis. However, the use of PRP promoted more effective reparative regeneration in both the group that did not undergo bone defect augmentation and the group that received the implant. Regenerating bone trabeculae were detected in both groups. Table 3 presents the comparative results for PRP use in groups 1 and group 2.

Thus, the use of PRP increased the number of regenerating bone trabeculae in both groups 1 and group 2. The use of the platelet-derived product also resulted in a decrease in the number and size of fibrotic foci and osteochondral callus in both groups. The signs of inflammation in the histological samples are likely related to the body's response to the insertion of the artificial implant; the influence of the implantation technique could be ruled out either. However, it should

be noted that by the eighth postoperative week, the level of the biochemical inflammation marker C-reactive protein in the group of animals that received implantation did not differ significantly from the group of animals that did not.

Table 3

Comparison in regard to PRP use in groups

	Focuses			
	Group 1		Group 2	
	PRP (–)	PRP (+)	PRP (–)	PRP (+)
Fibrosis	Multiple large	Solitary small	multiple small, solitary large	Solitary small
Osseo-cartilaginous callus	Multiple small, solitary large	Solitary small	multiple small, solitary large	Solitary small
Regenerating bone trabeculae	Single	Multiple	Not dtected	multiple
Inflammatory infiltration	+	+	–	–

Note: **fibrosis**: *solitary* — no more than one focus in three fields of view at ×40; *small* — fewer than 1 field of view at ×100; *multiple* — two or more focuses in three fields of view at ×40; *large* — more than 1 field of view at ×100. **Osseo-cartilaginous callus**: *solitary* — not more than 1 focus in three fields of view at ×40; *small* — fewer than 1 field of view at ×200; *multiple* — two or more focuses in three fields of view at ×40; *large* — more than one field of view at ×200. **Regenerating bone trabeculae**: *solitary*— not more than three regenerating trabeculae in a sample; *multiple* — more than three regenerating trabeculae in a sample

DISCUSSION

The desire to find optimal treatment strategies for patients with bone injuries has led to the study of the potential use of PRP to accelerate fracture healing [17], since platelet-rich plasma is a cost-effective autologous preparation containing a wide range of growth factors, cytokines, and adhesion molecules [18].

Direct injection of PRP into the injured area provides a high concentration of growth factors at the site of injury, which promotes tissue repair, reduces inflammation, and accelerates the regenerative process [19]. The use of platelet-rich plasma in surgical procedures can be combined with the use of bone grafts; this approach is aimed at optimizing the integration of osteosubstituting materials and at increasing the effectiveness of reparative regeneration [19]. Currently, the efficacy and safety of PRP have been demonstrated in a large number of medical studies [20]. However, the regenerative effects of PRP used along with artificial, particularly ceramic, implants have not yet been fully elucidated [21].

It is known that the effectiveness of PRP depends on the donor's health [22]. A clinical blood test can reflect the general health. Our study showed that the introduction of zirconium dioxide implants to the animals included in the study did not significantly affect red blood cell, white blood cell, or platelet counts during the postoperative period.

Yttria-stabilized zirconia-based bioceramics, in addition to exceptional mechanical properties, also exhibit biocompatibility and do not cause cytotoxic effects or allergic reactions in surrounding tissues [23, 24]. In our study, a highly sensitive analysis of C-reactive protein concentrations revealed that implantation increased the level of this inflammatory marker in rabbits relative to animals that did not receive the implant. However, given that no differences in C-reactive protein levels were detected between the groups by the end of the follow-up, it can be concluded that this reaction was associated not with the physicochemical properties of the ceramic material, but with the body's response to the implant and the surgical technique.

We previously showed that the rate of human fibroblast proliferation in the presence of bioceramic samples is slower than in controls during the initial stages of cell culture growth [25]. In the present study, we used osteocalcin to assess osteogenesis, which is released by osteoblasts

during osteosynthesis and is used as an informative marker of bone formation [26]. We found that the application of the implant slows down the osteogenesis process in the early postoperative period, which can be explained by adaptation processes to the introduction of an artificial bone substitute material.

The PRP obtained in this study was characterized in terms of cell composition and the concentration of platelet-derived growth factor released from alpha granules upon activation. Platelet count is one of the main parameters routinely assessed during PRP preparation, as it is believed to be related to the concentration of biologically active components in the platelet product. Although a clear correlation between platelet count in PRP and clinical response is currently not supported [27], the recommended platelet count in PRP ranges from 800×109 до 1200×109/L [21, 28]. In our study, the platelet count in PRP in both groups complied with these recommendations.

Recent studies have shown that mean platelet volume can be a useful parameter. A higher MPV indicates a higher concentration of bioactive molecules [29]. We found that the MPV in our PRP was significantly higher than that in rabbit whole blood. This may be due to the plasma preparation technique. We observed this finding in both groups of the animals studied.

Leukocytes perform numerous biological functions that typically promote and initiate inflammation. Leukocyte levels should be measured and reported by describing PRP preparation [30]. The benefit of including leukocytes in PRP is controversial, but the release of beneficial cytokines by leukocytes is considered a positive factor, especially in cases where an initial pro-inflammatory process is necessary [31]. At the same time, the presence of erythrocytes in PRP is considered undesirable [32]. In our study, a small number of leukocytes (4–7 % of the initial level) was retained in the PRP product, and the residual number of erythrocytes did not exceed 1 % of their initial content in the blood.

Platelet alpha granules, release numerous growth factors being activated, including platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF), epidermal growth factor (EGF), and insulin-like growth factors (IGF-1 and IGF-2). These factors control key biological processes, including angiogenesis induction, inflammation resolution, and tissue regeneration [33]. The level of growth factors in PRP, and consequently its quality, can be determined after the freeze-thaw procedure [34]. We applied this method with subsequent determination of PDGF; the level of platelet-derived growth factor was similar in the PRP products of the studied groups. The work of Pulcini et al. found a direct correlation between the platelet count and the PDGF-AA isoform, but not with the -BB and -AB isoforms. We did not find a correlation between the platelet count and PDGF [21]. This can be explained by the fact that we determined the A subunit, which is present in both the PDGF-AA and PDGF-AB isoforms.

The use of PRP to improve bone tissue regeneration during bone defect reconstruction is varied. In particular, the use of autologous PRP is a simple and effective way to ensure osteoinduction and improve bone regeneration in bone grafting and tissue-engineered bone reconstructions [35, 36].

Our study aimed to investigate whether platelet-rich plasma enhances the osteogenic potential of zirconia ceramic implants in the restoration of bone defects. Histological evaluation of the effectiveness of using PRP for osteogenesis correction in a surgically modeled bone defect in the distal metaphysis of rabbits' femurs was performed four and eight weeks after surgery. The previous study of Saginova et al. showed that the PRP-and-bone graft complex improves bone tissue restoration in a bone defect at the initial stages of bone regeneration [37]. Oktaş et al. also found that the use of PRP can play a role in accelerating fracture healing and eliminating nonunion at very early stages in the restoration of bone defects [38]. Our data are consistent with those studies; we also showed that four weeks after the implantation of the ceramic material a more active reparation process was observed after PRP injection into the defect area. At a later date, eight weeks

after surgery, we found that the use of PRP not only increased the number of regenerating bone trabeculae, but also reduced the number and size of fibrous foci and osteochondral callus.

Platelet concentrates are known to have the ability to control the inflammatory environment due to their anti-inflammatory properties [39]. However, the analysis of histological samples in our study did not find significant reduction in inflammatory infiltration in peri-implant tissue following PRP injection.

Platelet-rich plasma is a useful adjunct in the context of bone reparative regeneration due to its benefits which include stimulation of cell responses, acceleration of tissue repair, and potentially enhanced rehabilitation. However, further rigorous clinical studies are needed to integrate PRP-based methods into evidence-based medical practice. Such studies could deepen our understanding of PRP's role in regenerative medicine and facilitate effective treatment for patients with injuries and musculoskeletal disorders.

CONCLUSION

The use of platelet-rich plasma is effective in compensation of bone defects with ceramic implants made of yttrium oxide-doped zirconium dioxide.

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Information about futhors:

Irina P. Antropova — Doctor of Biological Sciences, Leading Researcher, aip.hemolab@mail.ru, https://orcid.org/0000-0002-9957-2505;

Elena A. Volokitina — Doctor of Medical Sciences, Professor, Head of Department, Leading Researcher, volokitina_elena@rambler.ru, https://orcid.org/0000-0001-5994-8558;

Kirill A. Timofeev — Postgraduate Student, orthopaedic surgeon, kirilltimofeev64166@gmail.com, https://orcid.org/0000-0003-2208-7154;

Roman A. Trufanenko — Assistant Professor, rtrufanenko@gmail.com, https://orcid.org/0000-0002-9978-4807;

Sergey M. Kutepov — Corresponding Member of the Russian Academy of Sciences, Professor, Doctor of Medical Sciences, Head of the Institute of Traumatology at the Central Research Laboratory, kcm@usma.ru, https://orcid.org/0000-0002-3069-8150;

Larisa G. Polushina — Candidate of Medical Sciences, Senior Researcher, polushina-larisa@bk.ru, https://orcid.org/0000-0002-4921-7222.

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In vivo biological testing of titanium alloys with added rare earth elements to assess their possible use in medical products

A.S. Anokhin[1], N.A. Kononovich[1,2]✉, A.L. Shastov[2], E.N. Gorbach[2], E.A. Ermakova[1], A.A. Kirsankin[1], M.S. Chuvikina[1], A.S. Lukyanov[1], S.S. Strelnikova[1], I.V. Shipitsyna[2], E.A. Kireeva[2], N.V. Tushina[2]

[1] Baykov Institute of Metallurgy and Materials Science, Moscow, Russian Federation
[2] Ilizarov National Medical Research Centre for Traumatology and Orthopedics, Kurgan, Russian Federation

Corresponding author: Natalia A. Kononovich, n.a.kononovich@mail.ru

Abstract

Introduction Medical implants for treating injuries and orthopedic diseases are often made of titanium and its alloys. Their physicochemical properties, including corrosion inhibition, can be improved by adding rare earth elements.

The **aim** of this study was to evaluate the safety of new materials based on the titanium alloy Ti6Al7Nb doped with yttrium, lanthanum, and cerium using an experimental *in vivo* subcutaneous implantation model.

Materials and Methods Male Wistar rats were subcutaneously implanted with titanium and titanium alloy samples: VT1-00 (control, $n = 10$); Ti6Al7Nb0.3Y (group 1, $n = 12$); Ti6Al7Nb0.3La (group 2, $n = 12$); Ti6Al7Nb0.3Ce (group 3, $n = 12$). The experiment lasted 28 days. The animals' general condition and behavioral responses were assessed, and the implantation area was visually marked. Body weight, body temperature, and local temperature at the implantation site were recorded. Hematological and biochemical blood tests were performed, and internal organs and peri-implant tissue condition were anatomically assessed.

Results In all groups, general condition, behavioral responses, body weight, body temperature, and peri-implant tissue temperature were normal, and skin wound healing occurred by primary intention. A positive effect of the rare earth elements studied was observed on reparative processes during skin wound healing. In the control group and group 1, organs retained normal size, color, and anatomical structure. In group 1, red blood cell counts were slightly elevated, along with increased concentrations of low- and medium-molecular-weight substances. In groups 2 and 3, changes in the anatomical characteristics of the liver, kidneys, and spleen were determined. Serum AST and LDH levels increased, C-reactive protein levels decreased, the proportion of neutrophils increased, and the lymphocyte count decreased. Glucose levels decreased in group 2, while glucose and urea levels increased in group 3.

Discussion Subcutaneous implantation of yttrium (Y), lanthanum (La), and cerium (Ce) at 0.3 % wt. each in titanium alloys of Ti6Al7Nb composition for one month had no negative impact on the general condition, thermoregulation, cardiovascular system, or reproductive organs of male rats. The titanium alloy doped with yttrium (Y) had a compensatory toxic effect on the body. Titanium alloys doped with lanthanum (La) and cerium (Ce) exhibited hepatotoxic and nephrotoxic effects and impaired spleen function. The results obtained are consistent with existing literature data.

Conclusion Under the conditions created, yttrium-doped materials and control samples can be considered safe. Materials doped with lanthanum and cerium raise concerns when implanted *in vivo*, requiring a longer-term study using histological methods.

Keywords: traumatology and orthopedics, implant, titanium alloy, corrosion, yttrium, lanthanum, cerium, *in vivo* experiment, medical product safety

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INTRODUCTION

It is known that some conventional metal alloys used in the manufacture of implantable medical product, including those in additive manufacturing, have a number of shortcomings that can negatively impact treatment outcomes, particularly in patients with musculoskeletal disorders. This is typically due to the physicochemical properties of the materials themselves, whose elastic modulus (Young's modulus) often significantly exceeds that of bone tissue [1–3]. Under such conditions, in prolonged implantation, bone loss occurs at the interface between the implant surface and the bone, leading to fixation instability, the elimination of which requires repeated surgery. A number of elements included in metal alloys have a toxic effect on surrounding tissues and the body as a whole. To prevent such effects, materials must have increased corrosion resistance [4–6].

Currently, research is being conducted to improve the mechanical properties of titanium and its alloys, in particular. They are most frequently used in the manufacture of medical products, including those intended for traumatology and orthopedics [3, 7, 8]. One method for enhancing mechanical properties, wear resistance, and corrosion resistance is alloying such materials with rare earth elements (REEs). Thus, the addition of a small amount of yttrium or cerium (0.3 wt. %) reduces the elastic modulus and improves plasticity. The corrosion rate is reduced by the addition of lanthanum, cerium, yttrium, or neodymium. While low concentrations of rare earth metals often improve the characteristics of alloys, higher weight fractions of these elements can negatively influence porosity, tensile strength, tensile toughness, and other properties [9–11].

Contemporary materials used for the manufacture of medical products, in addition to improved mechanical properties, must possess biocompatible, bioactive, and antibacterial properties [12–16]. Some metals, including rare earth metals, can exhibit antimicrobial activity, which expands the possibilities and justifies their use in the development of new medical alloys [17–19].

Despite the broad potential for using rare earth elements to improve the physicochemical and mechanical properties of alloys intended for the subsequent manufacture of medical devices, their safety has not been sufficiently studied and requires additional comprehensive investigation.

The **aim** of this study was to evaluate the safety of new materials based on the titanium alloy Ti6Al7Nb alloyed with yttrium, lanthanum, and cerium using an experimental *in vivo* subcutaneous implantation model.

MATERIALS AND METHODS

Eight-month-old male Wistar rats with an average body weight of 473.3 ± 74.03 g were used. All animals underwent subcutaneous implantation of test samples of the studied materials in the spine area under operating conditions. The samples were cylindrical, 10.0 mm in diameter, and 1.0 mm thick. The rare earth element content in the samples of the study groups was 0.3 wt. %.

Four groups of experiments (one control and three study ones) were performed *in vivo*:

— control group — samples made of titanium VT1-00 (n = 10);

— study group 1 — samples made of Ti6Al7Nb0.3Y (n = 12);

— study group 2 — samples made of Ti6Al7Nb0.3La (n = 12);

— study group 3 — samples made of Ti6Al7Nb0.3Ce (n = 12).

The procedure was performed in an operating room under general anesthesia adapted to the animals' weight (Rometar 2 % 1–2 mg/kg (Bioveta, Czech Republic); Zoletil 100 10–15 mg/kg (Virbac Sante Animale, France)). After surgery, the animals were placed in cages for two animals. Postoperative analgesia was achieved with Analgin (Biosintez, OJSC, Russia) administered subcutaneously at a dose

of 30–50 mg/kg twice daily for three days. The recommended temperature regime (24–26 °C) was maintained in the rat vivarium throughout the experiment. The animals were kept on a standard balanced diet with free access to water.

To assess the safety of the test materials using *in vivo* testing methods, the animals' body weight (g), overall body temperature (°C), and local body temperature at the implantation site (°C) were recorded immediately before the experiment and at seven, 14, 21, and 28 days postoperatively. The values obtained before surgery were used as the reference values.

At the same time-points, the animals' appearance, behavioral responses, intensity and pattern of motor activity, condition of their hair and skin, and the color of their mucous membranes were examined. A visual assessment of the soft tissues in the implantation area was performed.

The studies were conducted in the morning before the first feeding. After 28 days of the experiment, six animals from each group, randomly selected, were euthanized by decapitation to collect blood for hematological and biochemical analysis. Next, anatomical specimens were collected, and autopsies were performed to remove internal organs. When conducting preclinical studies, especially those aimed at identifying toxic effects, measuring the weight of internal organs and calculating their mass coefficients relative to body weight are mandatory. Analysis of these parameters allows for the detection of the target organ by the toxic agent. Therefore, after removal of the internal organs, they were weighed and their mass coefficients were calculated.

The condition of the tissues around the implant was visually assessed, as well as the location, color, and shape of the internal organs in the chest and abdominal cavities. The remaining animals (four in the control group and six in each experimental group) were retained for long-term study.

For histological study, skin fragments were collected from the implantation area, fixed in 10 % neutral formalin, and embedded in paraffin. Histological sections were prepared using a sled microtome (Reichard, Germany) and then stained with hematoxylin and eosin. Digital images of the histological specimens were obtained by scanning them at a resolution of 40x using a PANNORAMIC Midi II BF scanning microscope for laboratory research (3DHISTECH Ltd., Hungary). The thickness of the epidermis and dermis as well as the area and length of the scar were measured using PANNORAMIC Viewer, version 2.4 (3DHISTECH Ltd., Hungary). The numerical density of derivatives and vessels in the scar area was determined in the field of view of the histological specimen image at a magnification of ×400 and then proportionally recalculated per 1 mm^2.

In hematological tests, the cell composition of the peripheral blood was determined using standard cell counting techniques in a Goryaev chamber. The counts of leukocytes, erythrocytes, and platelets, as well as the relative numbers of neutrophils, eosinophils, monocytes, and lymphocytes, were determined in the rats' peripheral blood. The white blood cell count was determined in Romanovsky-Giemsa-stained blood smears under immersion at magnification ×100.

The concentration of total protein, urea, creatinine, glucose, C-reactive protein (CRP), as well as the activity of aminotransferases (ALT, AST) and lactate dehydrogenase (LDH) were determined in the blood serum of experimental animals. Biochemical studies were performed on an automatic biochemical analyzer Hitachi/BM 902 (F. Hoffmann-La Roche Ltd., Italy), using reagent kits from Vital Diagnostics, Vector-Best, BioSystems (Russia). The level of endogenous intoxication was assessed by the content of low- and medium-molecular-weight substances (LMMW) in the blood serum, among which the percentage of the catabolic pool (Cat. %) was calculated, equal to the sum of decay products recorded in the wavelength range of 238–258 nm. The content of LMMW was determined using the method of Malakhova [20].

Animal body weight was recorded using a TV A electronic scales. A POCKET SCALE MH-100 portable electronic scales (100 g/0.01 g) was used to weigh internal organs. Body temperature was measured using a DT-622 electronic thermometer, and local body temperature was measured using a Uni-T Uti320e infrared thermal imager (Fig. 1).

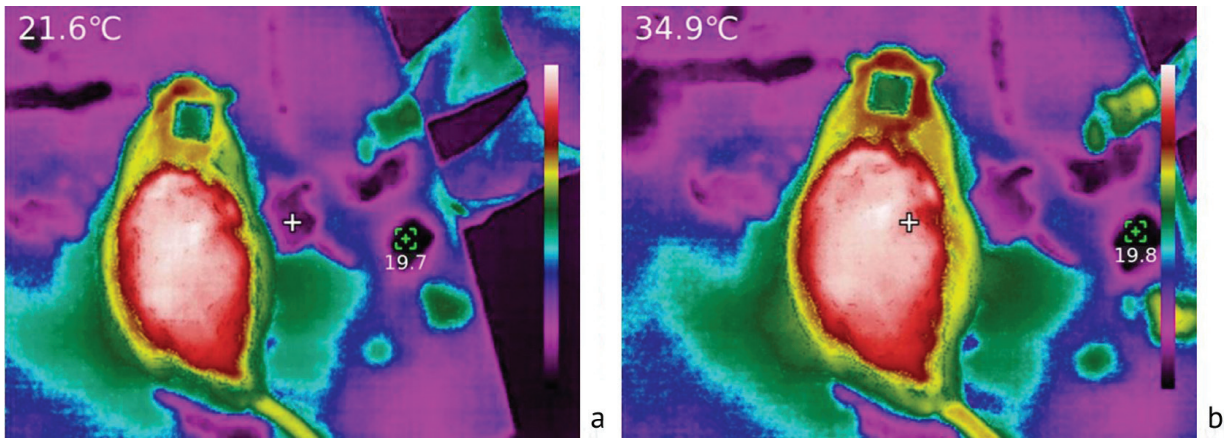

Fig. 1 Thermogram of the spinal area of the experimental animal: (a) immediately before the thermal imaging examination; (b) during the thermal imaging examination (the cross marks the area of implantation of the test sample from which the data was collected; in the upper left corner is the temperature value of the integumentary tissues of the implantation area of the test sample)

The obtained quantitative data were subjected to statistical analysis. Statistical analysis was performed using the AtteStat version 13.1 add-in for Excel spreadsheets (2016, 16.0.5278.1000). Descriptive statistics were used to determine the median and interquartile range (Me, Q1–Q3). The Wilcoxon test was used to compare the dynamics of changes within a one group (dependent samples). The Kruskal-Wallis test was used to compare indicators between the study groups and the control group (independent samples). Differences were considered statistically significant at $p < 0.05$.

The animals were cared for in accordance with the requirements of GOST R 33044-2014 "Principles of Good Laboratory Practice", GOST 33215-2014 "Guidelines for the Care and Maintenance of Laboratory Animals. Rules for the Equipment of Premises and Organization of Procedures", GOST 33216-2014 "Guidelines for the Care and Maintenance of Laboratory Animals. Rules for the Care and Maintenance of Laboratory Rodents and Rabbits". The experiments were carried out in accordance with the requirements of the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes and Directive 2010/63/EU of the European Parliament and of the Council of the European Union of 22.09.2010 on the protection of animals used for scientific purposes. The study was approved by the Ethics Committee of the IMET RAS (Protocol No. 1 of 15.02.2024).

RESULTS

Throughout the experiment, the general condition of the animals in all groups was satisfactory. No deaths were recorded. Neither deviations in food or water consumption, nor any infectious or neurological complications were observed. Skin and hair condition, as well as mucous membrane coloration, were unchanged. Animal behavior and general condition were consistent with the expected clinical picture. At rest and during movement, the animals assumed a natural physiological position.

In none of the groups at different time-points of the experiment there were no significant changes in body weight in relation to the initial values.

In all groups, at all time-points of the experiment, a significant decrease in overall body temperature was recorded compared to preoperative values. No significant differences were found between the groups.

The analysis of local body temperature dynamics at the implantation site of the test samples revealed that after seven days of the experiment, this parameter significantly decreased in the control group and group 1 compared to baseline values by 1.6°C ($p = 0.0002$; $p = 0.01$, respectively). During this period, local temperature in group 2 was significantly higher than in the other groups by 0.9–1.2 °C ($p < 0.05$). Subsequently, this parameter was significantly lower than baseline values in all groups, but no differences were found within or between groups.

The dynamics of changes in body weight, general body temperature and local tissue temperature in the area of implantation of test samples are presented in Table 1.

Table 1

Changes in body weight, general and local body temperature, Me (Q1–Q3)

Groups	Experiment stages				
	0 days (norm)	7 days	14 days	21 days	28 days
Body weight, g					
Control	412 (390–434)	404 (388–439)	393 (378–439)	394 (382–452)	398 (386–398)
1	440 (417–461)	435.5 (426–479)	440 (411–427)	429 (409–435,5)	424 (410–434)
2	523 (446–574)	528 (348–540)	542 (496–558)	560 (514–584)	556 (526–574)
3	552 (507–591)	565 (485–582)	564 (499–584)	577 (502–588)	560 (510–592)
General body temperature, °C					
Control	37.3 (37.2–37.6)	**36.35 (36.3–36.7)**	**36.65 (36.2–37)**	**36.5 (36.3–36.5)**	**36.2 (35.8–36,.2)**
1	37.1 (36.65–37.55)	**36.35 (36.15–36.65)**	**36.4 (36.2–36.35)**	**36.3 (36.05–36.35)**	**36.5 (36.1–36.5)**
2	37.7 (37.55–37.95)	**36.65 (36.4–36.75)**	**36.5 (36.4–36.5)**	**36.65 (36.4–36.9)**	**36.8 (36.6–37)**
3	37.2 (37.1–37.35)	**36.6 (36.45–36.8)**	**36.5 (36.25–36.95)**	**36.6 (36.4–36.8)**	**36.7 (36.5–36.8)**
Local body temperature, °C					
Control	34.1 (34–34.3)	**32.5 (32.1–32.9)**	**32 (31.2–32)**	**33 (32–33)**	**32.5 (31.8–32.5)**
1	33.75(33.05–34.2)	**32.1 (31.35–33.1)**	**32.6 (32.15–32.4)**	**32.1 (31.65–32.1)**	**32.8 (32.1–32.8)**
2	34.95 (34.05–35)	34.2* (33.55–34.85)	**32.0 (31–32.8)**	**32.5 (32–33.8)**	**33.0 (32.2–33.2)**
3	34.0(33.8–34.2)	33.3(32.3–34.1)	**32.55 (32.05–33.3)**	**32.9 (31.95–33.1)**	**32.7 (31.55–33.45)**

Notes: **bold typed** are values that differ statistically from the preoperational ones (0 days) at $p < 0.05$; * are differences of the parameter with the control, study group 1 and study group 3 at $p < 0.05$.

The postoperative wound at the site of implantation of the tested specimen healed by primary intention in all experiment groups. No hematomas, abscesses, or other pathological changes in the skin were observed at any stage of the experiment. During anatomical preparation, no local signs of inflammation were visually observed in the area of contact between the test specimens and the adjacent soft tissue.

In the control group (BT1-00), skin wound healing after implantation occurred by primary intention, under a scab. Seven days later, a brown "crust" was visible on the surface of the skin wound. No swelling of the surrounding tissues or hemorrhages in the adjacent intact skin tissues was observed. After 14 days, complete or almost complete desquamation of the scab occurred. Epithelization of the wound surface was observed. After 21 days, a normotrophic linear scar with signs of remodeling was observed in the area of skin damage. Suture marks were visible. After 28 days, an even greater restructuring of the scar tissue into normotrophic tissue occurred. The scar in the healing area had a linear shape and was hardly visualized. Dissection of the skin flap around the implanted sample provoked the formation of a fairly dense fibrous capsule (Fig. 2a). No signs of significant edema, hemorrhage, ulceration, or necrosis were detected in the fibrous capsule tissue. Minor thickening and compaction of the subcutaneous and superficial muscular fascia were detected.

In Group 1 (Ti6Al7Nb0.3Y), healing occurred under a scab. However, unlike in the control group, complete wound epithelialization had not occurred after 14 days, with the scab partially peeling off. During this period, slight swelling of the tissues surrounding the skin wound was observed, manifested by a mound-shaped protrusion of tissue around the healing skin wound above the general horizontal skin surface. However, by the 21st day, a filiform linear scar had formed, which by the 28th day was virtually invisible (Fig. 2b). The surrounding tissues showed no visual changes. A thin, transparent connective tissue capsule formed around the implant (Fig. 2b). No reactions of the surrounding tissues to the implant were observed. The fascia were not thickened, translucent, and organotypic.

After seven days of the experiment, in Group 2 (Ti6Al7Nb0.3La), the skin wound surface was covered with a tan-colored scab. Labium-like swelling of the skin wound edges was noted, which persisted through the 14th day of observation. No changes in the color of the skin adjacent to the wound were visible. No significant localized edema was detected. By the 14th day, the scab did not sloughed off and covered the entire wound surface. By the 21st day, wound epithelialization occurred, and the scab was no longer detectable. The formation of thin epithelium at the site of skin injury was confirmed by the intense pink color of the linear scar that had formed by this time. The scar was structurally hypotrophic. After 28 days, the scar was hardly visible at external examination. A translucent fibrous tissue was formed around the subcutaneous implant. The fascial tissue surrounding the implant lost its transparency, became denser and significantly thicker, and acquired a whitish-flesh-colored appearance and a slight opacity (Fig. 1c).

In Group 3 (Ti6Al7Nb0.3Ce), similarly to the other groups, wound healing occurred under the scab by primary intention. By the seventh day of the experiment, the wound edges were tightly closed, and the scab, unlike in the other series, was already beginning to peel off. No wound discharge was observed, as in the other groups. By the 14th day,

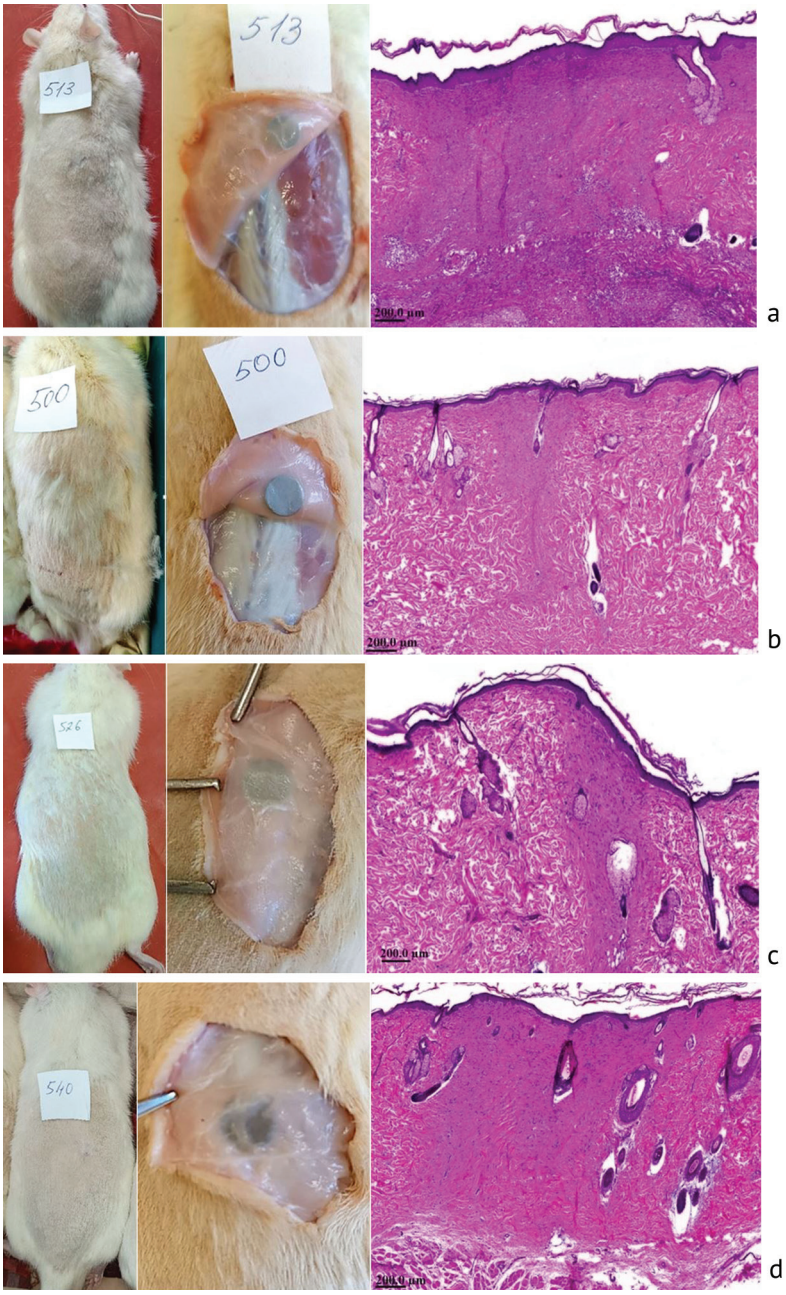

Fig. 2 The condition of the tissues in the implantation area after 28 days of the experiment: (a) control group (VT1-00); (b) group 1 (Ti6AL7Nb0.3Y); (c) group 2 (Ti6AL7Nb0.3La); (d) group 3 (Ti6AL7Nb0.3Ce). The left column: the appearance of the implantation area; the middle column: the condition of the tissues in the peri-implantation area; the right column: the histostructural organization of the skin scar, stained with hematoxylin and eosin, magnification — 50×

the wound was largely epithelialized, although some of the scab remained. The wound tissue did not protrude above the skin surface. No significant swelling, hemorrhage, or tissue necrosis was observed. After 21 days, a hypotrophic scar with labium-like protrusions along the wound edges was formed. After 28 days, the scar became less noticeable, while its hypotrophic nature persisted. The implant was surrounded by a dense, opaque, and fairly thick fibrous capsule at its periphery, becoming thinner, more transparent, and more heterogeneous in the central areas above the implant surface. The surrounding tissues were fairly dense, opaque, and flesh-white in color, with fatty inclusions (Fig. 1d).

Histologically, by the 28th day of the experiment, the formation of a skin regenerate (scar) was observed in the area of the skin wound in both the treatment and control groups that was covered externally by a full-thickness epidermis (Fig. 2a–d, right column). The differences consisted in the fact that in the treatment groups, the cells of the spinous layer were usually arranged in a single row, while in the control group they were in two or even three rows. This was reflected in the thickness of the epidermis, the thickness of which in group 1 was significantly lower than in the control group by 37.4 %, and in groups 2 and 3 — by 49.3 % and 47.3 %, respectively (Table 2). The dermis in the control group (Fig. 2a, right) and group 3 (Fig. 2d, right) was represented predominantly by densely packed fibrous connective tissue (mainly fibrous), the fibers of which lay in different directions. Increased cellularity was observed in group 3. Granulation areas were noted in the control group. Scar length in these groups was greatest compared to groups 1 and 2, exceeding by an average of three times (Table 2). The scar area in the control group was three times greater than in group 3 and nine times greater than in groups 1 and 2. The minimal content of scar tissue was characteristic of the study groups 1 and 2. Dermal thickness in the animals of the control group did not differ significantly from that in group 1, while in groups 2 and 3 it was significantly lower than in the control group.

Table 2

Histological parameters of skin regenerate in the damaged area on the 28th day after implantation of the material, Me (Q1–Q3)

Parameters	Experimental groups			
	Control	Group 1	Group 2	Group 3
Epidermal thickness h, μm	98.8 (96.7–101.4)	**62.1 (61.3–70.4)**	**50.1 (47.1–52.6)**	**52.1 (47–54.7)**
Dermis thickness h, μm	1870.6 (1856.6–1868.3)	1876.8 (1758.3–1876.8)	**1272.95 (1171.5–1345.1)**	**1553.45 (1505.1–1555.7)**
Scar length L, μm	1789 (1776–1801)	**558.1 (501.3 –600.9)**	**549 (538.6–593.3)**	**1431.5 (1228.1–1626.5)**
Scar area S, mm^2	5.4 (4.9–5.6)	**0.553 (0.531–0.584)**	**0.631 (0.579–0.649)**	**1.8 (1.6–1.9)**
Numerical density of NAder derivative, units/mm^2	4.75 (4.1–6.2)	**7.2 (4.3–9.1)**	**7.4 (5.8–8.3)**	**15.6 (16.4–17.03)**
Numerical density of vessels NAsos, units/mm^2	59.02 (29.51–59.02)	59.03 (44.26–73.7)	59.02 (29.52–59.01)	59 (29.63–59.6)

Note: **bold typed** are values that differ statistically from the control group (at $p < 0.05$).

The skin regenerates of the control group contained a few hair follicles and sebaceous glands. Their numbers were significantly higher in the regenerates of animals from the experimental groups: by 51.6 % and 55.8 % in groups 1 and 2, respectively, and by 2.28 times in group 3. The density of vessels in the skin regenerates of all groups was similar.

In all groups, including the control group, low leukocyte counts were recorded on the 28th day of the experiment compared to the physiological norm for animals. In group 1, the erythrocyte count significantly increased compared to the results obtained in the control group. Platelet counts in both the study and control groups were within normal limits (Table 3). The blood profile was lymphocytic. The leukogram values in the control group varied within the normal range. In the leukocyte formulas of groups 2 and 3, the number of lymphocytes and neutrophils was significantly different from the values of the control group (Table 3).

Table 3

Hematological parameters of the blood of experimental animals on the 28th day after implantation of the material,Me (Q1–Q3)

Parameter	Reference interval	Control	Group 1	Group 2	Group 3
Erythrocytes, 10^{12}/l	5.5–11.0	6.6 (6.4–6.8)	**7.4 (6.9–7.6)**	5.7 (5.5–6.5)	7.0 (6.4–7.5)
Leukocytes, 10^9/l	8.0–23.0	5.0 (4.7–5.4)	5.2 (4.5–6.2)	5.4 (5.0–5.5)	5.7 (5.0–6.0)
Platelets, 10^9/l	200–600	430.0 (420.1–490.0)	425.5 (412.5–447.5)	475.5 (425.0–550.0)	475.0 (369.0–675.0)
NEU, %	20–35	29 (28–30)	34 (29–38)	**44 (42–45)**	**44 (34–50)**
LYM, %	55–75	65 (64–68)	57 (52–65)	**50 (48–52)**	**49 (44–55)**
MON, %	1–5	5 (4–6)	6 (4–6)	3 (3–5)	4 (3–6)
EOS, %	1–5	1 (1–4)	3.5 (2–4.5)	3 (2–3)	3 (3–4)
BAS , %	0–1	0 (0–0)	0.5 (0–0.5)	0 (0–0)	0 (0–0.5)

Note: values **in bold** are significantly different from the values of the control group animals (at $p < 0.05$), NEU — neutrophils, LYM — lymphocytes, MON — monocytes, EOS — eosinophils, BAS — basophils.

The results of the biochemical study of the blood serum (Table 4) showed that 28 days after implantation, the level of endogenous intoxication products (EIPPs) in rats of group 1 was significantly ($p = 0.05$) elevated compared to the animals of the control group. The level of catabolism products in the animals of the study groups did not differ from the control. In groups 2 and 3, the CRP level compared to the control was significantly lower ($p = 0.03$; $p = 0.04$). This indicates that the acute response to the implantation of these materials was lower than that of the control material. A significant change in liver damage markers (AST and LDH) was recorded in rats of group 2 ($p = 0.05$) and group 3 ($p = 0.03$) compared to the control. Moreover, a more significant increase in the activity of these enzymes was noted in the rats of group 3. In animals of this group, a statistically significant ($p = 0.02$) increase in the level of urea in the blood was also noted, as a sign of a nephrotoxic effect. By this time, animals in group 2 showed a significant decrease in blood glucose levels ($p = 0.05$) relative to the animals in the control group.

Table 4

Biochemical parameters of blood serum of experimental animals on the 28th day after implantation of the material, Me (Q1–Q3)

Parameters	Control	Group 1	Group 2	Group 3
Total protein, g/l	67 (64–68)	67 (65–68)	64 (64–68)	67 (62–67)
CRP, μg/L	7.3 (6.2–8.3)	6.7 (5.0–7.9)	**2.0 (1.9–3.9)**	**3.5 (2.7–4.3)**
ALT, units/L	67 (58–71)	69 (59–85)	87 (70–91)	85 (70–105)
AST, units/L	121 (117–149)	142 (130–155)	**160 (153–195)**	**158 (155–180)**
LDH, units/L	1061 (987–1645)	1547 (1418–2002)	**2371 (2230–3045)**	**2974 (2485–3333)**
Urea, mmol/l	4.8 (4.6–5.1)	4.9 (4.8–5.1)	4.9 (4.8–5.6)	**6.8 (6.6–7.1)**
Creatinine, μmol/l	56 (53–56)	60 (56–61)	49 (48–55)	51 (50–54)
Glucose, mmol/l	21.6 (19.6–23.0)	21.7 (18.9–24.3)	**16.7 (16.6–16.9)**	22.5 (21.2–23.7)
Low and middle molecular weight substances, units of optical density	7.44 (6.94–7.60)	**8.48 (7.95–11.18)**	8.22 (7.70–8.27)	7.60 (7.45–8.28)
Cat. %	16.6 (16.4–18.9)	20.6 (15.6–26.2)	15.7 (15.2–16.4)	16.7 (15.7–17.1)

Note: **bold typed** are values that differ statistically from control group (at $p < 0.05$).

The autopsy showed that the internal organs were anatomically arranged in all animals. No significant differences were found between the groups in heart and testicle weight, their color or shape. In group 1, the weight and anatomical characteristics of the liver, spleen, and kidneys were consistent with those of the controls. Macroscopically, liver changes were observed in groups 2 and 3, characterized by smoothed edges and a more saturated brown color. Three of six animals in group 2 euthanized during this period and four of six animals in group 3 had hepatomegaly. Kidney changes were visually detected in these groups: they lacked the typical bean-shaped form

(they were closer to oval), had a more watery structure, and their weight was significantly greater than in the controls ($p = 0.02$). Significant differences in spleen weight ($p = 0.01$) were also observed compared to the same parameter for this organ in the control group. In some cases, visual edema was detected in the center of the organ while maintaining the anatomy of the edges. The weights of the major internal organs are presented in Table 5.

Table 5

Weight of the main internal organs, Me (Q1–Q3)

Groups	Organs (g/% of total body weight)				
	Heart	Liver	Spleen	Kidneys	Testicles
Control	1.75 / 0.45 (1.69–1.79 / 0.42–0.48)	18.86 / 3.76 (17.68–20.83 / 3.44–4.35)	1.03 / 0.26 (0.99–1.09 / 0.25–0.28)	2.45 / 0.66 (2.26–2.56 / 0.61–0.67)	2.59 / 0.66 (2.54–2.71 / 0.64–0.74)
Group 1	1.95 / 0.46 (1.9–1.97 / 0.43–0.47)	19.21 / 4.21 (17.77–25.88 / 3.67–5.5)	1.23 / 0.28 (1.08–1.33 / 0.24–0.32)	2.53 / 0.61 (2.32–2.88 / 0.57–0.65)	2.74 / 0.63 (2.54–2.93 / 0.59–0.68)
Group 2	2.36 / 0.45 (1.94–2.16 / 0.41–0.43)	**22.73 / 4.32 (18.17–21.27 / 4.17–4.25)**	**1.55 / 0.33 (1.36–1.5 / 0.29–0.31)**	**2.68 / 0.55 (2.45–3.24 / 0.52–0.57)**	3.31 / 0.66 (2.89–3.54 / 0.58–0.7)
Group 3	2.49 / 0.45 (2.22–2.56 / 0.43–0.49)	**23.27 / 4.04 (17.02–20.81 / 3.98–4.03)**	**1.68 / 0.32 (1.48–1.86 / 0.29–0.35)**	**2.99 / 0.55 (2.57–3.47 / 0.51–0.61)**	3.19 / 0.6 (3.11–3.5 / 0.57–0.66)

Note: bold typed are values that differ statistically from the control group (at $p < 0.05$).

DISCUSSION

Currently, active research is underway to improve the physicochemical properties of metals, particularly those intended for the manufacture of medical implantable orthopedic products [16, 21, 22]. Ensuring their safety and efficacy requires *in vitro* studies, including mechanical tests to assess corrosion resistance, wear resistance, elasticity, and other characteristics. An important step is testing new alloys *in vivo* using intravital and postmortem methods. They allow for determination of biocompatibility with surrounding tissues, evaluation of the immune response, cytotoxicity, and other possible reactions of a living organism in response to interaction with new materials.

The primary objective of the *in vivo* study was to evaluate the safety of new materials based on titanium alloy doped with rare earth elements such as yttrium, lanthanum, and cerium. The Ti6Al7Nb titanium alloy contained 0.3 wt. % of each of these elements. The test system consisted of mature, clinically healthy male Wistar rats in which the test materials were implanted subcutaneously. The animals were studied for 28 days.

Throughout the experiment, no disturbances in thermoregulation were observed in any of the experimental animals, as evidenced by the absence of significant fluctuations in general and local body temperature in the control and study groups under identical housing conditions. Feed and water intake were also unchanged. Motor and behavioral responses were maintained. No animal deaths were recorded.

In all groups, skin wound healing at the implantation site occurred by primary intention, under a scab. Earlier skin scar formation was observed in group 3 animals with cerium-doped samples. In these animals, scab desquamation was observed by the seventh day of the experiment, whereas in the other groups, the scab covered the entire wound surface by thas time. Histological examination revealed a threefold reduction in scar tissue compared to the control group at the skin wound site by the 28th day of the experiment, indicating the effect of cerium on accelerating the organotypic remodeling of scar tissue. Cerium also demonstrated a positive effect on the formation of skin derivatives at the site of injury. Some authors obtained similar results in *in vivo* experiments on male Wistar rats with topical application of cerium oxide nanoparticles in a water-soluble hydrogel to a skin wound. In those studies, complete wound healing with the formation of a sufficiently

strong scar connection with a favorable cosmetic effect was determined as early as the sixth day of the experiment [23]. According to other data, exposure to nanodispersed cerium dioxide activated marginal epithelialization of an experimental burn wound in rats [24]. This effect may be due to the fact that cerium nanoparticles can act as direct antioxidants, limiting the amount of reactive oxygen species necessary for cell death, particularly in nerve cells [25].

Several studies showed that long-term oral administration of cerium nitrate does not have a toxic effect on reproductive function in female laboratory rats. However, behavioral responses, body weight, and uterine weight were unchanged in the breeding stock [26]. In the study presented on male rats in group 3 (samples with cerium) after 28 days, we also observed no changes in behavioral responses, and body weight and testicular mass ratio did not change significantly compared to the control group.

In our study, hematological and biochemical parameters in the control group (VT6) and group 1 (samples with yttrium) were closest to the normal ones. Group 1 showed a statistically significant (but clinically insignificant) increase in red blood cell counts, as well as an increase in the concentration of low- and medium-molecular-weight substances. Blood tests findings were fully consistent with the anatomical findings. Animals in those groups showed no hepatomegaly or changes in the kidneys or spleen. The organs retained normal size, color, and structure. This indicates that the yttrium-doped alloy has a toxic effect that the body is able to compensate for.

Subcutaneous implantation of titanium alloy samples doped with lanthanum (group 2) and cerium (group 3) revealed signs of toxic effects on the liver, kidneys, and spleen. In most cases, the hepatotoxic effect manifested itself as hepatomegaly, changes in liver color and shape, and a sharp increase in AST and LDH in the serum (especially in group 3). In group 2, the decreased glucose levels could also be a consequence of impaired liver metabolism, which, combined with the aforementioned signs, indicated an even more pronounced hepatotoxic effect than in group 3.

Nephrotoxic manifestations in the animals of groups 2 and 3 were characterized by changes in the anatomical shape and structure of kidneys, reflected in the weight of these organs, which increased compared to the control group implanted with VT1 titanium alloy was implanted. Apparently, the negative impact on the kidneys was more pronounced in group 3, as its animals showed statistically significant elevation in blood glucose and urea levels—key markers of impaired renal nitrogen excretion. As noted above, autopsy confirmed this fact, in addition to changes in the shape and structure of these organs, as well as a significant increase in their weight compared to other groups.

The toxic effect on the spleen in animals of groups 2 and 3 was characterized by a significant increase in its weight and organ mass coefficient, combined with swelling.

In groups 2 and 3, compared to the control group, the decrease in C-reactive protein levels can be explained by general suppression of the immune system or the specific effect of lanthanum and cerium ions on the synthesis of acute-phase proteins, which does not negate the presence of toxic damage. Significant changes in the white blood cell count were recorded in those groups: a significant increase in the proportion of neutrophils and a decrease in lymphocytes. This shift is characteristic of a chronic inflammatory process or toxic stress, indicating a systemic response to the implanted material. Signs of toxic chronic inflammation in the kidneys, pancreas, and testicles of white male rats, which arose due to the inhalation of a substance containing, in particular, lanthanum, were seen by other authors [27]. The literature also contains information about the toxic effects of lanthanum on the function of liver, kidneys, and spleen; negative effects on the immune system and bones were noted [28].

It is evident that implantation of yttrium-doped experimental samples (group 1) also caused a minor toxic effect, characterized by increased levels of endogenous intoxication products. However, this effect can be considered compensated for, as it did not manifest itself in visceral organ dysfunction.

Subcutaneous implantation of lanthanum- and yttrium-containing alloys revealed a significant effect on the restructuring of scar tissue toward organotypic restoration. Yttrium in the implanted material promoted normotrophic scar formation, while lanthanum promoted hypotrophic scar formation.

CONCLUSION

The analysis of the study results showed that within one month of implantation in a living organism:

— titanium alloys of Ti6Al7Nb, **doped with yttrium, lanthanum, or cerium** at 0.3 wt. %, have no noticeable negative impact on the cardiovascular system and reproductive organs, do not disrupt thermoregulation processes, and promote reparative processes in skin wounds;

— titanium alloys of Ti6Al7Nb, **doped with yttrium** 0.3 wt. %, contribute to the manifestation of signs of endogenous intoxication without causing organ damage;

— titanium alloys i6Al7Nb, **doped with lanthanum** at 0.3 wt. %, have a pronounced hepatotoxic effect, a nephrotoxic effect, and impair the function of the spleen;

— titanium alloys Ti6Al7Nb, **doped with cerium** at 0.3 wt. %, have a pronounced nephrotoxic effect, a hepatotoxic effect, and impair the function of the spleen.

The results obtained should be considered in developing new materials intended for the manufacture of medical products.

Conflict of interests *Not declared*

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Information about the authors:

Alexander S. Anokhin — Candidate of Technical Sciences, Senior Researcher, aanokhin@imet.ac.ru, https://orcid.org/0000-0002-2847-1651;

Natalia A. Kononovich — Candidate of Veterinary Sciences, Leading Research Fellow, n.a.kononovich@mail.ru, https://orcid.org/0000-0002-5990-8908;

Alexander L. Shastov — Candidate of Medical Sciences, Senior Researcher, alshastov@yandex.ru, https://orcid.org/0000-0001-7434-1404;

Elena N. Gorbach — Candidate of Biological Sciences, Leading Researcher, gorbach.e@mail.ru, https://orcid.org/0000-0002-9516-7481;

Elena A. Ermakova — Research Fellow, eadrshina@imet.ac.ru, https://orcid.org/0000-0003-1376-1004;

Andrey A. Kirsankin — Candidate of Physical and Mathematical Sciences, Senior Researcher, akirsankin@imet.ac.ru, https://orcid.org/0000-0002-9206-7805;

Maria S. Chuvikina — Junior Research Fellow, mchuvikina@imet.ac.ru, https://orcid.org/0000-0002-3124-5356;

Alexander S. Lukianov — Research Engineer. alukyanov@imet.ac.ru; https://orcid.org/0009-0002-8770-909X;

Svetlana S. Strelnikova — Candidate of Technical Sciences, Leading Researcher, sstrelnikova@imet.ac.ru;

Irina V. Shipitsyna — Candidate of Biological Sciences, Leading Researcher, ivschimik@mail.ru, https://orcid.org/0000-0001-5791-1989;

Elena A. Kireeva — Candidate of Biological Sciences, Leading Researcher, ea_tkachuk@mail.ru, https://orcid.org/0000-0002-1006-5217;

Natalya V. Tushina — Candidate of Biological Sciences, Senior Researcher, ntushina76@mail.ru, https://orcid.org/0000-0002-1322-608X.

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Elution of vancomycin and meropenem and their combinations from various bone cement materials

M.V. Stogov✉, A.L. Shastov, E.A. Kireeva, N.V. Tushina

Ilizarov National Medical Research Center of Traumatology and Orthopedics, Kurgan, Russian Federation

Corresponding author: Maksim V. Stogov, stogo_off@list.ru

Abstract

Introduction Saturation of bone defect filling materials with antibacterial agents is used for the treatment of patients with infectious bone complications and for their prevention.

The **purpose** of the work was to evaluate the elution rate of vancomycin and meropenem from bone cements based on polymethyl methacrylate and polyurethane polymers impregnated into the material in their combination.

Materials and methods In an *in vitro* study, a comparative analysis of the kinetics of vancomycin and meropenem release from two materials was performed that were based on polyurethane polymers (PU series) and polymethyl methacrylate (PMMA series). Antibiotics were added to the materials before their polymerization in the following proportions: group 1 — polymer : antibiotic 10 g : 1 g (0.5 g vancomycin + 0.5 g meropenem); group 2 — polymer : antibiotic 10 g : 0.5 g (0.25 g vancomycin + 0.25 g meropenem). Samples loaded with one antibiotic were used as a control: group 1v — polymer : antibiotic 10 g : vancomycin 0.5 g; group 1m — polymer : antibiotic 10 g : meropenem 0.5 g; group 2v — polymer: antibiotic 10 g: vancomycin 0.25 g; group 2m — polymer: antibiotic 10 g: meropenem 0.25 g.

Results Vancomycin elution from both PMMA- and PU-based materials loaded with a vancomycin+meropenem was greater in final volume and longer in time than from materials containing vancomycin alone. Conversely, meropenem release from PMMA and PU loaded with a vancomycin + meropenem mixture was less in volume than from the materials containing meropenem alone.

Discussion The use of a vancomycin-meropenem complex in bone cements reveals the following feature: meropenem promotes the release of vancomycin from the studied materials, while the elution of meropenem itself is reduced.

Conclusion Combining antibiotics for impregnation into materials for bone defect filling has an impact on the kinetics of antibiotics release, unlike the release kinetics of an antibiotic loaded into the material as monotherapy.

Keywords: osteomyelitis, bone defect, bone cement, antibiotics, elution kinetics

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INTRODUCTION

Currently, the effective practice of saturating the materials for filling bone cavities and defects (the so-called bone cement) with various antibiotics is widely used for the prevention and complex treatment of patients with periprosthetic infection and osteomyelitis [1–3]. The principle of this approach is a gradual release of an antibiotic from the material to achieve a more effective local therapeutic concentration of antibiotics than with their parenteral administration, as well as to reduce the toxic effect of antibiotics on the body [4–6]. The technology of using bone cement with antibiotics has proven to be quite effective in primary joint arthroplasty for the prevention of deep infections [7]. Therefore, the addition of antibiotics to bone cements has become a fairly routine practice. The expansion of using this technology in practice is associated with a wide range of different antibiotics [8–10]. An additional stimulus for the development of this field is a prognostically negative situation due to the increase in the number of isolated strains in osteomyelitis, the growth of their resistance to antibiotics, as well as the increase in the proportion of microorganism associations in patients with chronic osteomyelitis [11–13]. The solution to these problems may be associated with both an expansion of the range of materials used to fill in defects [14–16], and with the use of a complex of antibiotics that are tropic to both gram-positive and gram-negative flora [17].

The **purpose** of the work was to evaluate the elution rate of vancomycin and meropenem from bone cement materials based on polymethyl methacrylate and polyurethane polymers that were impregnated alone and in their combination.

MATERIAL AND METHODS

The *in vitro* study compared the kinetics of the release of vancomycin and meropenem (both antibiotics produced by Promomed LLC, Russia) from two materials:

— Rekost, a polyurethane-based polymer material (Nizhny Novgorod, RZN 2014/1646 dated July 3, 2014, unlimited) (PU series);

— bone cement (RU No. FSZ 2012/11622 dated March 19, 2012, unlimited) based on polymethyl methacrylate (PMMA series).

The test materials (according to their instructions for use) were shaped into cylinders 7 mm high and 4 mm wide. Antibiotics were added to the materials before polymerization in the following proportions:

— group 1 — polymer: antibiotic 10 g: 1 g (0.5 g vancomycin + 0.5 g meropenem);

— group 2 — polymer: antibiotic 10g: 0.5g (0.25 g vancomycin + 0.25 g meropenem);

For control, samples loaded with one antibiotic were used:

— group 1v — polymer: antibiotic 10 g: 0.5 g vancomycin;

— group 1m — polymer: antibiotic 10 g: 0.5 g meropenem;

— group 2v — polymer: antibiotic 10 g: 0.25 g vancomycin;

— group 2m — polymer: antibiotic 10 g: 0.25 g meropenem.

The cylinders were incubated in 10 ml of saline in an incubator at 37 °C. The incubation solution (eluate) was changed daily during the first week and once a week thereafter. Six samples were incubated in each group. Samples without antibiotics (zero control) were also incubated in parallel.

In each sample of the incubation solution, the concentration of the tested antibiotics was determined spectrophotometrically against a standard calibration curve using absorbance intensity: vancomycin at 280 nm, meropenem at 298 nm. For calculating the concentrations of the test samples, the extinction values of the zero control samples (without antibiotics) were subtracted. Incubation was stopped when trace amounts of antibiotics were detected in the samples over a two-week period.

The studies were conducted according to the recommendations outlined in GOST ISO 10993-13-2016 "Medical devices. Biological evaluation of medical devices. Part 13. Identification and quantification of degradation products of polymeric medical devices".

The median and interquartile range (Q1–Q3) were calculated in parallel studies. The significance of differences between groups was assessed using the Wilcoxon signed-rank test for independent samples.

The work was carried out *in vitro* without the participation of animals or humans, so the approval of the ethics board was not required.

RESULTS

The dynamics of vancomycin release from PMMA and PU materials impregnated with the vancomycin-meropenem combination in a ratio of 0.5 + 0.5 g (group 1) were virtually identical, with the maximum release of antibiotics after the first day of incubation (Fig. 1). Moreover, the volume of vancomycin released from the PU-based material saturated with the antibiotic complex was higher than from the same material impregnated with vancomycin alone (group 1v). With an antibiotic content of 0.25 + 0.25 g (group 2), vancomycin release was higher in the PMMA series, while vancomycin elution from the PU-based material in group 2v was significantly higher than in group 2.

The release of meropenem from PMMA- and PU-based materials saturated with a vancomycin-meropenem mixture in a ratio of 0.5:0.5 g (group 1) was virtually identical. However, the total volume of meropenem eluted from both materials saturated with the antibiotic mixture was 1.5–2.0 times lower than from the materials loaded with meropenem alone (Fig. 2). In group 2, meropenem release was higher in the PMMA series, while in group 2, it was higher in the PU-based series. Overall, it is worth noting that the volumes of meropenem eluted from both materials containing the antibiotic mixture were significantly lower than from materials loaded with the single drug.

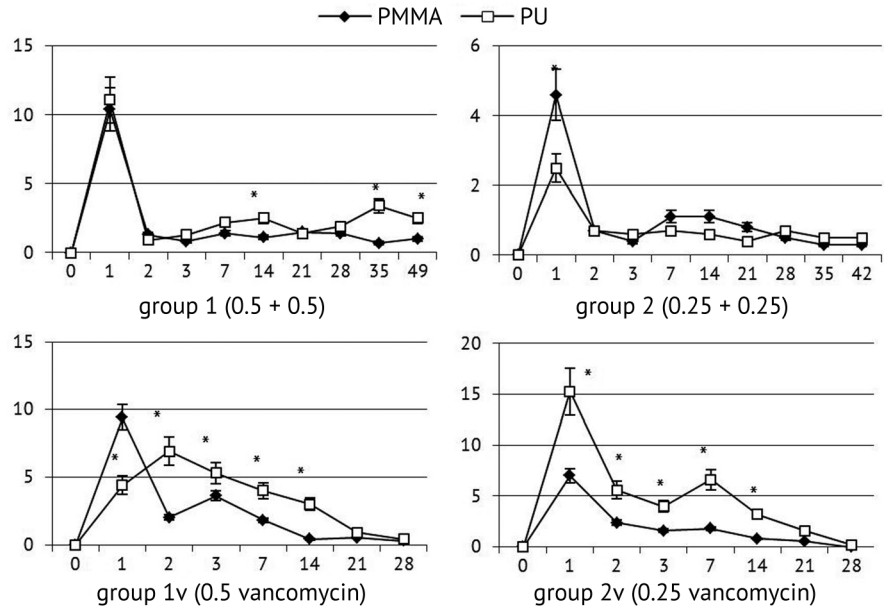

Fig. 1 Dynamics of vancomycin release (% of the total mass of the impregnated antibiotic) from the tested materials (Me, interquartile range); * — significance of differences between series at $p < 0.05$. The abscissa axis shows the day of incubation

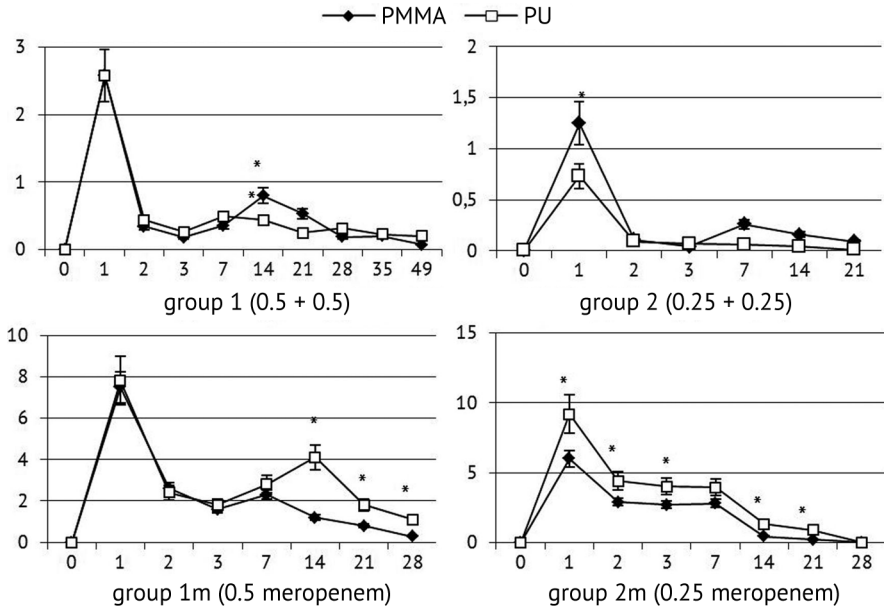

Fig. 2 Dynamics of meropenem release (% of the total mass of the impregnated antibiotic) from the test materials (Me, interquartile range); * — significance of differences between series at $p < 0.05$. The abscissa axis shows the day of incubation

PMMA PU meropenem oup 1m Group 2m

Overall, the overall elution characteristics of vancomycin and meropenem from the tested materials with a mixture of these antibiotics in equal weight ratios differed from the release of them if added in the monovariant (Table 1). Vancomycin elution from both PMMA and PU materials loaded with a vancomycin+meropenem mixture was greater in final volume and lasted longer than from the materials containing vancomycin alone. Conversely, the release of meropenem from PMMA and PU loaded with a vancomycin+meropenem mixture was less in volume than from the materials containing meropenem alone.

Table 1

General results of the release kinetics of antibiotics at different concentrations from PPMA and PU materials (median)

Antibiotic	Group	*L*, days	V_O, %	*Max*, days (%)
		PMMA/PU		
Ванкомицин	1v (mono 0.5)	35/35	20.8/30.1	1(9.4)/1(4.4)
	1 (mixture 0.5)	77/63	45.7#/64.4*#	1(10.4)/1(11.1)
	2v (mono 0.25)	21/21	13.8/33.6*	1(7.0)/1(14.7)
	2 (mixture 0.25)	42/42	42.0#/32.9	1(18.3)/1(10.0)
Меропенем	1m (mono 0.5)	28/28	16.5/21.5	1(7.5)/1(7.7)
	1 (mixture 0.5)	56/56	11.6#/12.5#	1(5.2)/1(5,2)
	2 m (mono 0.25)	14/14	15.3/23.4	1(5,9)/1(9,1)
	2 (mixture 0.25)	21/14	8.1#/4.0*#	1(5.0)/1(2.9)

Note: *L* — duration of antibiotic release; V_O — total volume of released antibiotic in % relative the impregnated total volume; *Max* — term of observation (days) when the maximum release was noted and it percentage (in brackets) relative the total of impregnated antibiotics; * — differences between PMMA and PU significant at $p < 0.05$; # — significant differences from the group of monotherapy at $p < 0.05$

DISCUSSION

The results of this study demonstrate that the release kinetics of vancomycin and meropenem that are loaded into post-osteomyelitic defect filling materials and added as their mixture in an equal weight ratio differed from the release kinetics if the material was loaded with a single antibiotic. Specifically, vanocomycin release from both studied materials loaded as a vancomycin + meropenem

mixture was greater than from the materials containing vancomycin alone. Vancomycin release from the PU-based material was more effective than from the PMMA-based material. Conversely, meropenem release from both studied materials loaded as a vancomycin + meropenem mixture was less effective than from the materials loaded with meropenem alone.

Existing literature data are primarily devoted to the elution of antibiotic monopreparations impregnated in PMMA-based bone cement [8–10]. We found only one study that examined the elution of the antibiotic mixture we studied. It was noted that the elution of vancomycin from acrylic cement was independent of the presence of meropenem [18]. Those results are similar to our data, so it can be concluded that the use of a vancomycin-meropenem combination in bone cements exhibits the following feature: one antibiotic (meropenem) promotes the release of the other (vancomycin), while the elution of meropenem itself is reduced.

In general, almost all similar studies of the kinetics of the release of various combinations of antibiotics added to bone cements note a common rule: a combination of antibiotics in materials for filling infected bone defects changes the release characteristics of all the antibacterial components included in the composition, both enhancing and weakening their elution [19, 20]. It was shown that a synergistic effect is observed with a combination of gentamicin and vancomycin: the elution of both antibiotics increases when loaded together into bone cement [21]. With a combination of tobramycin and vancomycin, the release of vancomycin increases compared to the release of vancomycin in its pure form [22]. Enhancement/weakening of the elution of several antibiotics were also described for combinations consisting of three antibiotics (cefazolin, gentamicin, vancomycin) [23].

The dose-dependent features of antibiotic elution according to the results of our study are as follows: for both materials used, a direct relationship was observed between the initial concentration of impregnated antibiotics and the volumes of their elution; thereby the dose/elution relationship was nonlinear, which is also consistent with literature data [24].

The kinetics of antibiotic release depending on the initial mass ratio of the combined antibiotics in the cement has been poorly studied, although the general pattern remains the same here: an increase in the proportion of a single antibiotic can change (increase or decrease) the kinetic profile of another antibiotic [25].

Moreover, the kinetics of antibiotic elution, as shown by our studies and literature data, can be influenced by the composition of the material used to fill bone defects [26, 27] and its viscosity [28].

Therefore, in general, it can be concluded that each antibiotic combination and each cement brand exhibits a unique antibiotic release profile [24]. These circumstances significantly complicate the selection of material and antibiotic combination in practice. Considering that the antibiotic kinetic profile is also determined by the cement composition, the choice of material and antibiotics used in real-life practice can present significant challenges and carry significant risks that the antibacterial efficacy of antibiotic-impregnated bone cements for the management of post-osteomyelitic defects will be lower than expected. Therefore, at this stage, the most feasible approach is to test a bone cement sample with antibiotics for efficacy parameters (elution and antibacterial sensitivity) in an *in vitro* study before clinical use to ensure that the antibiotic combination is suitable for the selected cement [24].

To increase the elution of antibiotics from bone cements, approaches associated with additional modification of the material through its chemical modification, the use of various reinforcing elements, and saturation of the material with antimicrobial drugs that are not antibiotics can be used [29–32].

CONCLUSION

Mixing several antibiotics impregnated in the materials for bone defect repair, such as those based on polymethyl methacrylate and polyurethane polymers, has an impact on the rate of antibiotic elution, as opposed to the release rate of the antibiotic if loaded into the material alone. Specifically, meropenem combined with vancomycin increases the rate of vancomycin release.

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Information about the authors:

Maksim V. Stogov — Doctor of Biological Sciences, Associate Professor, Head of Department, stogo_off@list.ru, https://orcid.org/0000-0001-8516-8571;

Alexander L. Shastov — Candidate of Medical Sciences, orthopaedic surgeon, Senior Researcher, alshastov@yandex.ru, https://orcid.org/0000-0001-7434-1404;

Elena A. Kireeva — Candidate of Biological Sciences, Leading Researcher, ea_tkachuk@mail.ru, https://orcid.org/0000-0002-1006-5217;

Natalia V. Tushina — Candidate of Biological Sciences, Senior Researcher, ntushina76@mail.ru, https://orcid.org/0000-0002-1322-608X.

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Features of adjacent joint structures remodeling after prosthetic application of a tibial calcium-phosphate coated implant

T.A. Stupina[1]✉, A.A. Emanov[1], V.P. Kuznetsov[1,2]

[1] Ilizarov National Medical Research Centre for Traumatology and Orthopedics, Kurgan, Russian Federation
[2] Ural Federal University named after the First President of Russia B.N. Yeltsin, Ekaterinburg, Russian Federation

Corresponding author: Tatyana A. Stupina, StupinaSTA@mail.ru

Abstract

Introduction Studying the reorganization of adjacent joint components due to prosthesis application and identifying predictors of arthrosis are key factors to successful functional restoration of a prosthetic limb.

The **aim** of this study was to evaluate the structural reorganization of the basic joint components after prosthetic application of a calcium phosphate-coated implant at long term.

Materials and Methods The study was conducted on five intact and six experimental mongrel male dogs, aged 1.8 ± 0.5 years and weighing 19.0 ± 1.2 kg. A tibial stump was modeled at the level of the upper third of the diaphysis. A Ti6Al4V calcium-phosphate coated implant was used 2.5 months later. The study was conducted at six and 12 months after prosthesis application. Histomorphometry of the synovial membrane and osteochondral component of the tibial plateau was performed on semithin and paraffin sections using an AxioScope.A1 microscope with Zenblue software (CarlZeissMicroImagingGmbH, Germany).

Results Mild synovitis detected at six months (hyperplasia of the integumentary layer, predominance of macrophage-like synoviocytes, plasma cells, and mast cells) was reversible in 70 % of cases at 12 months. Signs of impaired synovial blood supply were recorded. Articular cartilage changes according to the OARSI scale corresponded to grades 0–1 at six months and grades 1–2 at 12 months (in one case, synovial pannus). Basophilic line abnormalities were noted: vessel density (number of vessels per unit of visual field analyzed) was (0.35 ± 0.02) at six months and (0.30 ± 0.02) at 12 months. Differences between time points were statistically insignificant, $p = 0.736$. Subchondral bone plate thickness was significantly ($p = 0.0105$) lower than in the control. At 12 months, the median subchondral bone plate thickness was 33 % higher than the one in the control animals, and the bone index was 31 % higher; differences were statistically significant. Active osteoblasts that were lining bone trabeculae were noted at all stages; fuchsinophilic structures predominated in the bone matrix when stained with Masson's method.

Discussion The histological signs of inflammation and impaired blood supply to the synovial membrane, thinning of the articular cartilage, and invasion of the synovial pannus into the superficial zone and vessels into the deep cartilage zone were prognostic markers of osteoarthritis.

Conclusion Structural changes in the osteochondral component of the tibial plateau one year after application of a tibial calcium phosphate-coated implant were consistent with the initial stage of osteoarthritis. Mild non-infectious synovitis was reversible. The use of calcium phosphate-coated implants promoted the activation of reparative osteogenesis and mineralization of the bone matrix in the subchondral zone.

Keywords: exoprosthetics, calcium phosphate-coated implant, synovial membrane, osteochondral component, morphometry

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INTRODUCTION

Osteointegrative exoprosthetics of limbs is an advanced technology for the restoration of lost limbs by integrating a metal implant with the bone tissue of the stump, thus providing a stable and functional connection [1, 2, 3, 4]. The advantages of this method include improved functionality and quality of life of patients, sensory feedback (osteoperception and osteoproprioception), long-term function and elimination of problems associated with traditional socket prostheses (skin irritation, poor fit, high incidence of bone and/or soft tissue pain, allergic reactions, decreased function and further deterioration in quality of life) [5, 6, 7, 8, 9].

Current research on improving the osteointegrative properties of implants is aimed at increasing the efficiency of bone tissue bonding with the implant by modifying its surface (microtexturing, nanostructured and biologically active coatings), stimulating osteogenesis (electrical stimulation, use of drugs that stimulate mineralization) [10, 11, 12, 13].

It was established that calcium-phosphate coated implants have high biocompatibility and accelerate the process of osseointegration [14, 15].

Animal studies showed that in the adjacent joint, six months after tibial prosthesis application with a PressFit implant, structural changes in the articular cartilage corresponded to grade 0–1 according to the Osteoarthritis Association for the Study of Osteoarthritis (OARSI) classification [16]. Structural changes in the subchondral zone corresponded to stage 0 according to the classification of Aho et al. [17] what indicates “very early signs of osteoarthritis” [18]. When calcium phosphate-coated implants were installed in the overlying joint, the processes of subchondral bone resorption and articular cartilage thinning were expressed to a lesser extent compared to uncoated implants [19].

In patients with limb amputation, a common complication after prosthetic fiting is contractures and arthrosis in the adjacent joint, which arise due to factors such as increased stress on the joint, impaired biomechanics, prolonged joint immobility, muscle weakness, and the body's inflammatory response to implants [20, 21].

Disorders in the normal joint biomechanics and the presence of infection foci which may develop after prosthesis application [5] are among the main causes of synovitis development.

Studying the features of the structural reorganization of the components of the joint adjacent to the prosthesis and identifying predictors of arthrosis are the key to successful restoration of the function of the prosthetic limb and long-term service life of the prosthesis.

The **aim** of this study was to evaluate the structural reorganization of the basic joint components after prosthetic application of a calcium phosphate-coated implant at long term.

MATERIAL AND METHODS

Study design

The study was performed on 11 mongrel dogs (males) aged (1.8 ± 0.5) years, with a body weight of (19.0 ± 1.2) kg. A tibial stump at the level of the upper third of the diaphysis was modeled in experimental animals (n = 6). After 2.5 months, a calcium-phosphate coated implant made of Ti6Al4V alloy was applied (Patent for Utility Model of the Russian Federation No. 194912, [23]). Next, using the Ilizarov apparatus and a special device (Patent of the Russian Federation No. 185647, [24]), the implant was fixed and compression was applied to the bone (F_{load} = 20 N) for 35 days after the surgery, after which an exoprosthesis was fitted. The time-points of the follow-ups were six and 12 months after prosthesis application.

Study objects were synovial membrane, articular cartilage and subchondral bone of the tibial plateau.

As a control group, the synovial membrane, articular cartilage and subchondral zone of the tibial plateau of five intact dogs were examined.

Ethical statement

The study was conducted in accordance with the European Convention (ETS No. 123) for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes and state standards (GOST 33044-2014). The study was approved by the institutional ethics board (protocol dated November 29, 2024, No. 1(76)).

Euthanasia

Euthanasia was performed after muscle relaxation with a solution of 1 % diphenhydramine (0.02 mg/kg) and 2 % rometar (5 mg/kg) by administering a lethal dose of barbiturates.

Histological methods of study

For histomorphometric analysis, the knee joint was opened, fragments of the synovial membrane were excised, and articular cartilage samples with underlying subchondral bone were excised from weight-bearing areas of the tibial plateau. The excised osteochondral blocks were fixed in 10 % neutral formalin and then decalcified in a mixture of formic and hydrochloric acids (a standard gentle decalcification protocol was used, which does not significantly affect the tinctorial properties of the bone matrix). Subsequent paraffin embedding of the osteochondral blocks was performed in a HISTOSAFE™ INFILTRA™ vacuum tissue embedding apparatus (ErgoProduction LLC, Russia). Sections 5–7 μm thick from paraffin blocks were prepared on a Thermo Scientific HM 450 microtome (USA), stained with hematoxylin and eosin; to identify the degree of mineralization of the bone matrix, a special three-color staining method according to Masson was used [25].

To analyze angiogenesis, an immunohistochemical study was performed to determine the presence of the CD34 marker (rabbit monoclonal antibodies to CD34 [EP373Y]) (Abcam, UK). To visualize the reaction, a reagent kit for the immunohistochemical detection of HRP/DAB (ab236469 — Rabbit-specific HRP/DAB Detection IHC Detection Kit-Micropolymer, Abcam, UK) was used. All stages of the reaction were carried out according to the protocol of the antibody manufacturer. Sections were counterstained with hematoxylin.

Synovial membrane samples were dehydrated after aldehyde-osmium fixation and embedded in a two-component epoxy resin. Semithin (0.5–1.0 μm) sections (4–8 mm^2) were prepared on a Nova ultramicrotome (LKB, Sweden) and stained with methylene blue and basic fuchsin.

The study at the light-optical level was carried out using an AxioScope.A1 microscope with an AxioCam digital camera (CarlZeissMicroImagingGmbH, Germany).

Histomorphometry using Zenblue software (CarlZeissMicroImagingGmbH, Germany) was used to determine the following parameters in the articular cartilage: thickness of uncalcified cartilage ($h_{uncal.cr}$, μm) and thickness of calcified cartilage ($h_{cal.cr}$, μm). In the deep zone of uncalcified cartilage, the vessel occurrence was assessed (the ratio of the sum of vessels in the visual fields to the number of all analyzed visual fields). An average of 20 fields was analyzed in each animal at a magnification of 400×. In the subchondral zone, the thickness (height) of subchondral bone plate (h_{CtTh}, μm) was determined, and the bone index was calculated as the ratio of the thickness of trabeculae (TbTh, μm) to the width of the intertrabecular spaces (ItTh, μm).

The severity of structural changes in the articular cartilage was assessed according to the OARSI histological classification [16], structural changes in the subchondral zone were assessed according to the classification of Aho et al. [17], and the severity of the inflammatory process in the synovial membrane was assessed according to the scale of Krenn et al. [26].

Statistical methods

Quantitative data were processed in a Microsoft Excel spreadsheet. The Kolmogorov test was used to assess the sample distribution type. The measure of central tendency of the parameters is

presented as the median and quartiles, minimum and maximum values (Me ($p25$–$p75$) [min–max]), and as the mean and standard error of the mean (M ± m). The Mann – Whitney test was used to analyze differences between the compared groups, and the Barnard test was used for frequency indicators; differences were considered significant at $p < 0.05$ (AtteStat software, version 9.3.1).

RESULTS

Structural reorganization of the synovial membrane

After six months of the experiment, synovial cells in the synovial membrane in the inner layer were arranged in one to three layers, with macrophage-like synoviocytes predominating. Those cells had an ovoid nucleus, cytoplasmic outgrowths, and basophilic cytoplasm containing numerous granules and vacuoles (Fig. 1a). Collagen fibers predominated in the superficial collagen-elastic layer, the cellularity was moderately increased, and plasma cells and mast cell clusters were recorded along with fibrocytes and fibroblasts (Fig. 1b). Vessels with thickened walls due to smooth muscle cell hypertrophy were seen in the deep collagen-elastic layer; in some vessels, swollen endothelial cell nuclei blocked the intravascular space (Fig. 1c).

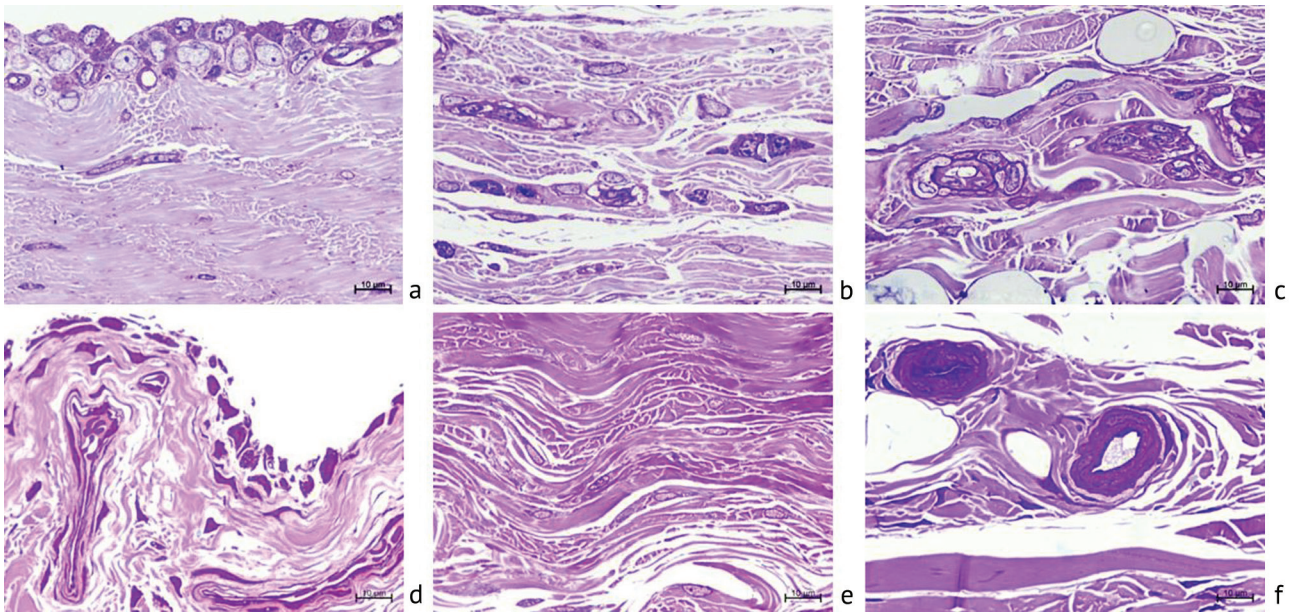

Fig. 1 Synovial membrane of the knee joint at the experiment time points: (a, b, c) six months; (d, e, f) 12 months. Macrophage-like synoviocytes (a) and destructively altered synoviocytes (d) predominate in the inner layer. In the upper collagen-elastic layer there are fibroblasts, fibrocytes, mast and plasma cells (b), fibrocytes (e). Changes in vessels in the deep collagen-elastic layer (c, f). Semi-thin sections; stained with methylene blue and basic fuchsin; magnification ×1000

After 12 months of the experiment, areas of thickening of the inner layer were noted, in which synovial cells were arranged in three to four layers, the majority of synoviocytes showing signs of destruction, an abnormal shape, and pyknotic nuclei (Fig. 1d). In the superficial collagen-elastic layer, normal cellularity and singly located fibroblasts and fibrocytes were preserved (Fig. 1e), and an increase in optical voids between the fibers was noted. In the deep collagen-elastic layer, vessels had thickened walls and stenosis (Fig. 1f).

Structural reorganization of articular cartilage

The articular cartilage of the tibial condyles in the experiment, as in the control group, retained its zonal structure, with all cartilage zones clearly defined. In the superficial zone, after six months of the experiment, most observations showed a decrease in the proportion of the cellular component and an increase in the proportion of acellular areas, along with a disruption of the homogeneity

of the intercellular substance (Fig. 2b). After 12 months of the experiment, one of three observations showed synovial pannus invasion into the superficial zone of the cartilage, with empty cellular lacunae (Fig. 2c).

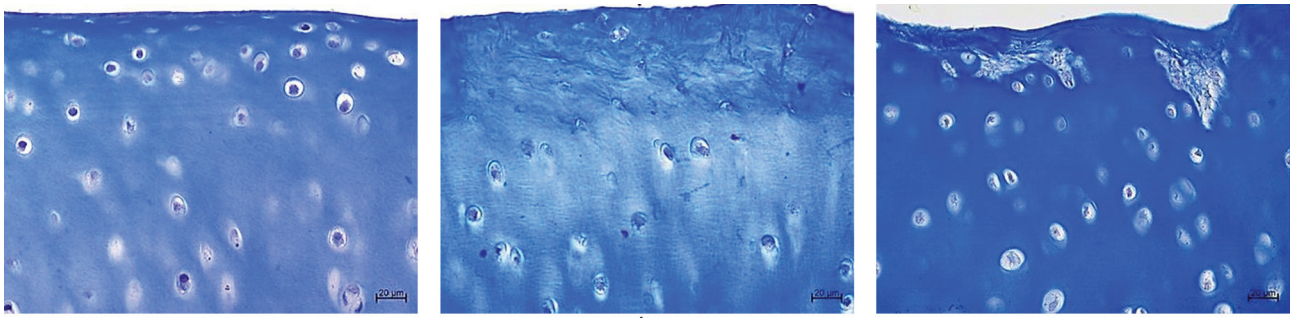

Fig. 2 Superficial and part of the intermediate zone of the lateral condyle of the tibia: (a) control (intact norm); (b) six months of the experiment, unmasking of collagen fibers, acellular fields in the superficial and intermediate zones; (c) 12 months of the experiment, ingrowth of the synovial pannus. Paraffin sections, stained with the three-color method according to Masson. Magnification ×400

Throughout the experiment, cytoarchitecture was preserved in the intermediate and deep zones, with cell-free fields and some cells exhibiting signs of chondroptosis. Areas of discontinuity of the basophilic line and vascular and bone marrow pannus invasion into the deep zone of non-calcified cartilage were recorded (Fig. 3). The frequency of vessel occurrence in the deep zone after six months of the experiment was (0.35 ± 0.02) and (0.30 ± 0.02) after 12 months; the differences were statistically insignificant (p = 0.736).

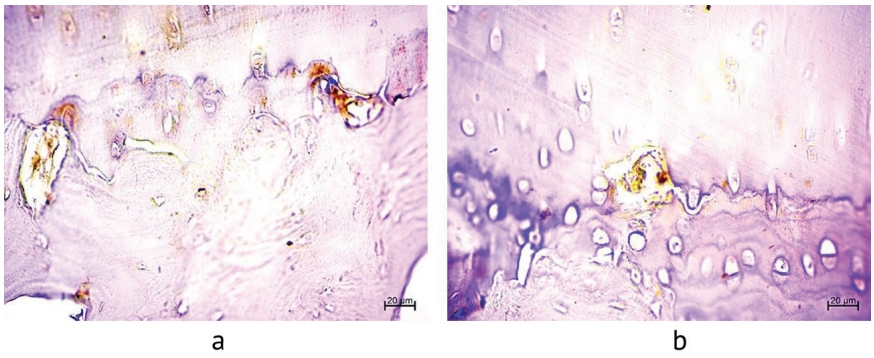

Fig. 3 CD34 expression in vessel endothelium (brown sediment). Disruption of basophilic line continuity, vascular invasion into the deep zone of cartilage: (a) six months of the experiment; (b) 12 months of the experiment. Paraffin sections. Magnification ×400

Structural reorganization of the subchondral zone

In intact animals (control group), the subchondral bone plate was of uneven thickness and continuous; fuchsinophilic structures predominated in the bone matrix when stained with the Masson three-color method (Fig. 4a). In the experimental series, the thickness of the subchondral bone plate varied; thinning areas were more common at six months of the experiment, while thickened areas were more common at 12 months. Staining with the Masson three-color method showed a decrease in the proportion of fuchsinophilic structures after six months (Fig. 4b), and after 12 months the proportion of fuchsinophilic structures increased again (Fig. 4c), indirectly indicating increased bone matrix mineralization.

Throughout the experiment, areas of the subchondral bone plate lined with active osteoblasts producing the main substance were recorded (Fig. 4 b, c).

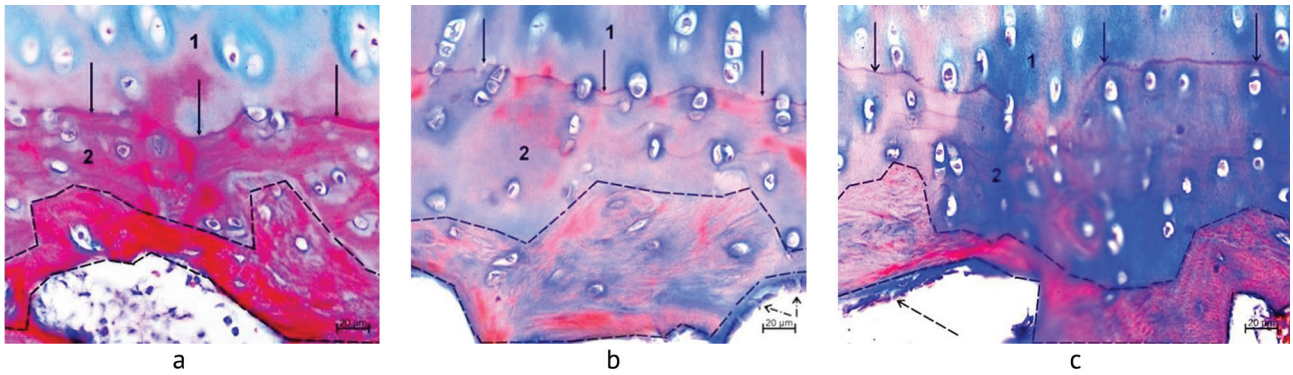

Fig. 4 Contact of calcified cartilage with the subchondral bone plate: (a) control; (b) six months of the experiment; (c) 12 months of the experiment. Designations: 1 — deep zone of non-calcified cartilage; 2 — calcified cartilage; dotted line — borders of the subchondral bone plate; solid arrows — basophilic line; dotted arrows — osteoblasts. Paraffin sections. Staining by the three-color method according to Masson. Magnification ×400

At all stages of the experiment, signs of reparative osteogenesis were observed in the subchondral trabecular bone: active osteoblasts lining the surfaces of bone trabeculae (Fig. 5). The bone trabecular network was sparse, and the trabecular surfaces were partially lined with osteoblasts (Fig. 5a). Staining with the Masson three-color method revealed that the bone trabecular matrix was predominantly red (Fig. 5b). The bone trabeculae and subchondral bone plate were thickened (Fig. 5c). Osteoblasts were present on the surface of the bone trabeculae (Fig. 5d).

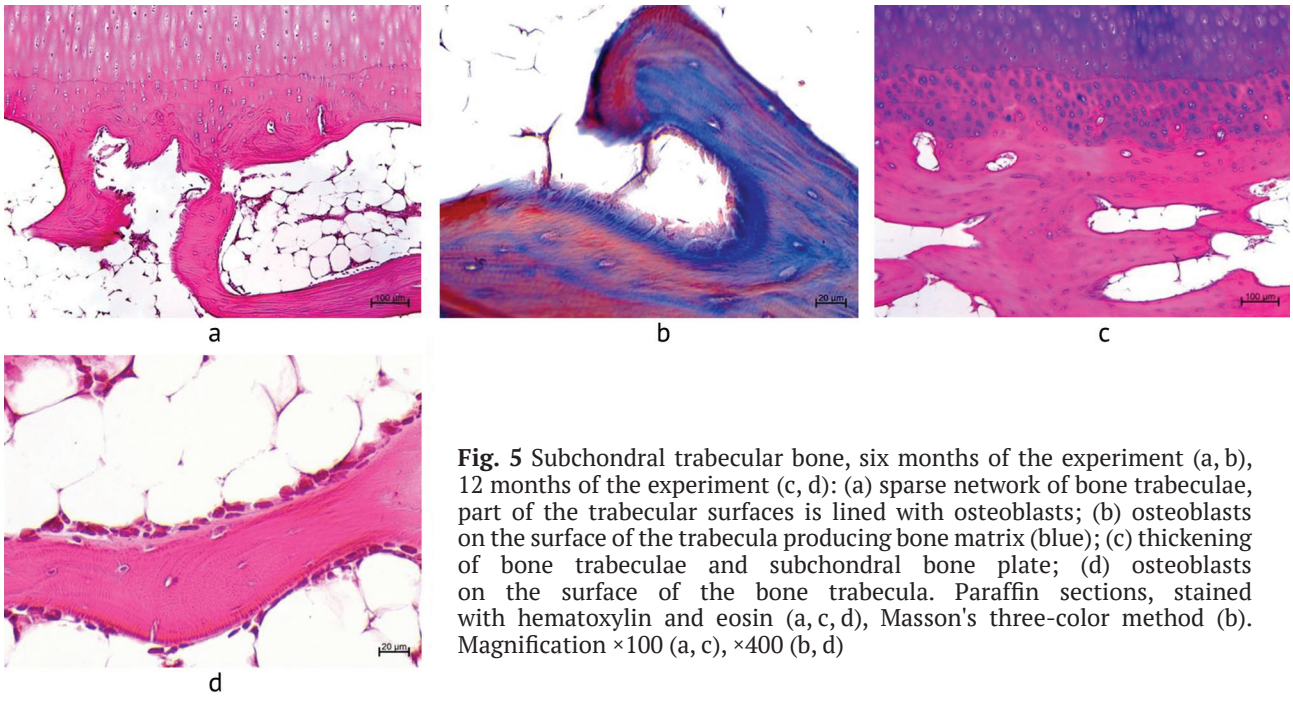

Fig. 5 Subchondral trabecular bone, six months of the experiment (a, b), 12 months of the experiment (c, d): (a) sparse network of bone trabeculae, part of the trabecular surfaces is lined with osteoblasts; (b) osteoblasts on the surface of the trabecula producing bone matrix (blue); (c) thickening of bone trabeculae and subchondral bone plate; (d) osteoblasts on the surface of the bone trabecula. Paraffin sections, stained with hematoxylin and eosin (a, c, d), Masson's three-color method (b). Magnification ×100 (a, c), ×400 (b, d)

Histomorphometric analysis after six months of the experiment did not reveal any significant differences in the values of the thickness parameters of non-calcified and calcified cartilage relative to the control group; a statistically significant decrease in the thickness of the subchondral bone plate was noted, and differences in the values of the bone index in the subchondral trabecular bone were at the level of a statistical tendency (Table 1).

After 12 months of the experiment, a statistically significant decrease in non-calcified cartilage thickness and an increase in calcified cartilage thickness, indicating a statistical tendency, were recorded when compared with the control group. In the subchondral zone, the median subchondral bone plate thickness was 33 % greater than in the control group, and the median bone index

in the subchondral trabecular bone was 31 % greater. Differences from the control group were a statistical tendency while the differences between the experimental time points were statistically significant (Table 1).

Table 1

Histomorphometric characteristics of articular cartilage and subchondral zone of the tibia at the experimental time points and in control rabbits (Me (Q1; Q3) [min–max])

Parameters	Findings		
	Control group	6 months	12 months
Thickness (height) of uncalcified cartilage ($h_{uncal.cr}$, μm)	1.28 (1.21; 1.33) [1.16–1.66]	1.24 (1.18; 1.32) [1.15–1.79] p = 0.5823	1.15 (1.09; 1.18) [1.01–1.24] **p = 0.0013; p^1 = 0.0045**
Thickness of calcified cartilage ($h_{cal.cr}$, μm)	125.93 (104.68; 135.66) [95.98–173.84]	120.34 (105.43; 129.24) [75.36–189.76] p = 0.9081	154.46 (132.39; 155.83) [89.14–190.83] p = 0.0576; p^1 = 0.1552
Subchondral bone plate thickness (h_{CtTh}, μm)	144.11 (87.55; 205.31) [60.92–223.87]	97.44 (87.97; 172.96) [60.92–167.86] **p = 0.0105**	195.21 (125.77; 216.51) [69.52–284.78] p = 0.1293; **p^1 = 0.0068**
Trabecula thickness (TbTh, μm)	156.47 (81.95; 234.91) [28.23–281.94]	112.91 (70.35; 140.54) [56.82–195.12] p = 0.2801	189.69 (163.06; 195.93) [64.36–436.09] p = 0.0556; **p^1 = 0.0113**
Intertrabecular space width (ItTh, μm)	267.09 (175.78; 311.26) [105.65–729.22]	312.69 (176.28; 402.02) [54.13–718.13] p = 0.9181	216.58 (160.04; 230.24) [62.92–429.26] p = 0.0552; p^1 = 0.0598
TbTh / ItTh	0.69 (0.31; 0.75) [0.26–2.66]	0.56 (0.25; 0.73) [0.14–1.97] p = 0.3284	0.91 (0.48; 0.82) [0.27–2.82] p = 0.0571; **p^1 = 0.0261**

Note: p — level of significance of differences when compared with the control, p^1 — level of significance of differences between the time points of the experiment according to the Mann – Whitney criterion, $p \leqslant 0{,}05$. Statistically significant differences are highlighted in bold, differences at the level of statistical tendency are in italics.

Morphological assessment of the synovial membrane according to the scale of Krenn et al. [26] indicated mild synovitis in all animals after six months of the experiment and in 30 % of cases after 12 months of the experiment (in 70 % of cases, synovitis was not detected). Structural changes in the articular cartilage according to the OARSI scale [16] after six months of the experiment corresponded to grade 1 in most cases (30 % — grade 0), after 12 months in 70 % of cases it was grade 1, and in 30 % grade 2. Structural changes in the subchondral zone according to the scale of Aho et al. [17] after six months of the experiment corresponded to grade 0 of "very early changes", when subchondral sclerosis is absent, and the subchondral bone plate is thinned. After 12 months of the experiment, an increase in the median thickness of the subchondral bone plate and an increase in the volume of trabecular bone indicated focal subchondral sclerosis and corresponded to grade 1 (Table 2).

Table 2

Analysis of the results of the assessment of structural changes in joint components at the stages of the experiment

N	Experiment stage	Results		
		Krenn et al., points	OARSI, grade	Aho et al., grade
1	6 months	2	0	0
2	6 months	2	1	0
3	6 months	3	1	0
4	12 months	2	2	1
5	12 months	1	1	1
6	12 months	1	1	1

DISCUSSION

The study conducted provided a comprehensive assessment of the structural reorganization of the main components of the joint after application of a calcium-phosphate coated implant to the adjacent limb segment in the late stages of prosthesis fitting.

According to current concepts, the initial changes in osteoarthritis, arising from macro- or microdamage, occur at the molecular level and activate pathological adaptive restorative responses, including pro-inflammatory pathways of the immune system [27]. It is known that the synovial environment in osteoarthritis is characterized by hyperplasia of the synovial membrane, the formation of synovial pannus, an increase in the representation of macrophage-like synoviocytes, and increased infiltration of immune cells. M1-polarized macrophages and activated fibroblast-like synoviocytes and fibroblasts produce pro-inflammatory cytokines, which, in turn, are responsible for increased synthesis and expression of matrix metalloproteinases that destroy articular cartilage [28, 29]. Simultaneously with changes in the cartilage, structural changes are recorded in the underlying subchondral zone, sclerosis of the subchondral bone, extensive remodeling of trabeculae, the formation of foci of necrosis and osteophytes in the marginal areas of the joint [30].

This study demonstrated that mild synovitis was detected in the adjacent joint in most cases at six months after prosthesis application. This synovitis was characterized by hyperplasia of the integumentary layer, an increased proportion of macrophage-like synovial cells, and the presence of plasma and mast cells in the subsynovial layer. Histological signs of impaired synovial blood supply (narrowing of the microvascular lumen) were recorded throughout the experiment. Mild synovitis, detected at six months, was reversible in most cases after 12 months (it persisted in one case and was accompanied by synovial pannus invasion into the superficial zone of the articular cartilage).

Histological signs of inflammation of the synovial membrane under these experimental conditions are characteristic of non-infectious synovitis [26] and may be caused by damage to nerve fibers and/or disruption of joint biomechanics.

The study of the biomechanical factors of knee osteoarthritis by Esposito et al. showed that patients with transtibial amputation have an increased risk of developing this disease [31].

Inflammation and impaired blood supply to the synovial membrane have a negative impact on the structure of articular cartilage through several mechanisms, including the release of inflammatory mediators, impaired transport of nutrients and the removal of metabolic products through diffusion [32].

Throughout the experiment, ingrowth of vessel from the subchondral zone into the deep zone of non-calcified cartilage was observed. The penetration of blood vessels into cartilage is a pathological process that can lead to its destruction and replacement with fibrous and/or bone tissue. Anti-angiogenic factors produced by chondrocytes help prevent this process. It was established that the severity of articular cartilage damage correlates with the number of newly formed blood vessels [33, 34].

Histomorphometrically, a statistically significant decrease in non-calcified cartilage thickness values relative to the control group was recorded by the end of the experiment, while calcified cartilage thickness values were significantly greater. In the subchondral zone, morphometric parameters varied widely both in the control group and throughout the experiment. By the end of the experiment, the median values for the subchondral bone plate thickness and subchondral trabecular bone index parameters were greater than those in the control group. The observed difference in subchondral bone plate thickness and subchondral zone bone index compared to the control group is not statistically significant, but tends to be significant ($p < 0.1$), requiring further studies with a larger sample size to confirm or refute this tendency.

Staining with the three-color method according to Masson detected that fuchsinophilic structures predominated in the subchondral bone plate and subchondral trabecular bone; the surfaces of the bone trabeculae were lined with active osteoblasts, which indirectly indicated the positive effect of the calcium phosphate coating of the implant on the processes of reparative osteogenesis and mineralization of the bone matrix.

Subchondral sclerosis in osteoarthritis is the result of compensatory and adaptive reactions in response to decreased mineralization of the bone matrix, aimed at maintaining the structure of hyaline cartilage under mechanical load and preventing its further destruction [35, 36]. The key factor in osteoarthritis is not subchondral sclerosis itself, but increased bone tissue remodeling and decreased mineralization of the bone matrix [35, 37]. The histological signs of inflammation and impaired blood supply to the synovial membrane, invasion of the synovial pannus into the superficial zone of cartilage, thinning of the articular cartilage, and penetration of blood vessels into the deep zone of non-calcified cartilage from the subchondral zone identified in this study are prognostic histological markers of osteoarthritis.

The obtained knowledge about the structural reorganization of the main components of the joint adjacent to the prosthesis in the late stages after prosthetic application is of great importance for the development of an optimal therapeutic strategy aimed at slowing the progression of osteoarthritis.

CONCLUSION

Structural changes in the osteochondral component of the tibial plateau one year after application of a tibial calcium phosphate-coated implant were consistent with the initial stage of osteoarthritis. Mild non-infectious synovitis was reversible. The use of calcium phosphate-coated implants promoted the activation of reparative osteogenesis and mineralization of the bone matrix in the subchondral zone.

Conflict of interests *Not declared*

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Information about the authors:

Tatyana A. Stupina — Doctor of Biological Sciences, Leading Researcher, StupinaSTA@mail.ru, https://orcid.org/0000-0003-3434-0372;

Andrey A. Emanov — Candidate of Veterinary Sciences, Leading Researcher, a_eman@list.ru, https://orcid.org/0000-0003-2890-3597;

Viktor P. Kuznetsov — Doctor of Technical Sciences, Professor, Head of Laboratory, wpkuzn@mail.ru, https://orcid.org/0000-0001-8949-6345.

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Gradual correction of nail deformity with adjustable tension: a new technique using steel wire and elastic components

D.O. Rozov

RoziRoz Beauty Salon, Apatin, Serbia

✉ Dmitry O. Rozov, droziroz@gmail.com

Abstract

Introduction Nail deformity is a common condition in podiatry, affecting 15–20 % of the population at different stages of their life. The disorder can cause chronic pain with a greater risk of infectious complications and significant limitations in activities of daily living. Minimally invasive and affordable solutions are needed for the problem. The key difference between the technique proposed and similar approaches lies in a rigid wire to be replaced with elastic components to allow adjustable gradual nail tensioning and stable fixation.

The **objective** was to determine the effectiveness of a minimally invasive technique using a steel wire combined with elements of elastic orthodontic chains made of medical polyurethane (elastofors) or nickel-titanium metal alloy in the form of nitinol springs to provide adjustable gradula tension for nail deformity correction.

Material and methods The method suggests creating customized corrective systems based on a steel wire and a selected active element. The systems are secured to the nail with hooks, ensuring constant, controlled tension. The study included patients with various types of nail deformities, excluding those with acute inflammatory processes. Standard orthonyxia instruments and elastic elements (Elastofors and nickel-titanium springs) were used. Results were assessed by measuring the nail width and tension force every two weeks for two months.

Results and discussion The technique demonstrated high efficacy in correcting different types of nail deformities, with the nail width increasing from 2 mm to 4.1 mm over eight weeks. The technique is minimally invasive and causes no discomfort to patients. Elastic elements provide a gentle and comfortable pressure on the nail without affecting the patient's ability to function or perform daily activities. The technique is universal and applicable to different types of deformities. Prospects for further research might include introduction of adhesive platforms for uniform pressure distribution; the study of alternative alloys (titanium-molybdenum, cobalt-chromium) and optimization of wire-free Elastofors fixation.

Conclusion The technique was shown to be effective in the nail deformity correction, combining minimal invasiveness, adaptability and aesthetics. The results offer potential for implementation in clinical practice with an emphasis on personalized treatment.

Keywords: orthonyxia, nail deformity, ingrown toenail, correction systems, podology, Elastoforce, nitinol

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INTRODUCTION

Deformity of the nail plate including onychocryptosis, onychogryphosis and transverse/longitudinal curvature are among most common pathologies in podiatry, affecting 15-20 % of the population at different periods of life [1]. The disorder can cause chronic pain with a greater risk of infectious complications and significant limitations in activities of daily living [2]. In addition to a variety of conservative treatments for correcting ingrown nails (tamponade, orthonyxia with staples) and surgical techniques (resection with matrix phenolization), there are minimally invasive and affordable solutions [2, 3]. This is due to the high recurrence rate (up to 70 % with conservative treatment) and postoperative complications [3].

Orthonyxia, a non-surgical correction of nail deformities is a promising method with use of mechanical systems. Correction of ingrown nails using metal braces dates back to the mid-20th century. One brace that has maintained its significance since the 1940s is the Ross-Fraser brace. However, documentary evidence of the authorship and date of creation is limited, as patent records and publications from that period do not contain direct references to Ross Fraser. Modern sources often attribute popularization of the method to the work of podiatrists in the 1960^{s} and 1970^{s}. Modern techniques, such as 3TO (three-component point orthonyxia), are based on a combination of support elements and wires to create targeted tension [4].

The key difference between the technique proposed and similar approaches lies in a rigid wire to be replaced with elastic components to allow adjustable gradual nail tensioning and stable fixation.

The **objective** was to determine the effectiveness of a minimally invasive technique using a steel wire combined with elements of elastic orthodontic chains made of medical polyurethane (elastofors) or nickel-titanium metal alloy in the form of nitinol springs to provide adjustable gradual tension for nail deformity correction.

MATERIAL AND METHODS

The study included six female patients aged 40 to 60 years, with deformity of the nail plate and a degree of ingrowth no higher than the Mozena grade I [5].

Inclusion criteria included presence of nail plate curvatures, absence of contraindications to orthonyxia.

Exclusion criteria included acute inflammatory processes in the nail bed (paronychia, felon), active onychomycosis, systemic diseases (e.g., diabetes mellitus with signs of diabetic foot).

All patients were informed about the objectives and methods of the study and gave written consent for publication of the results.

Tools and materials used

— Steel wire with a diameter of 0.4 mm as the basic fixing element to ensure the construct stability;

— Wire working tools:

  • wire cutters for cutting and adjusting a length;

  • round-nose pliers for loops and bends;

  • needle holder for precise installation of elements;

— Adhesive materials:

  • adhesive — to prepare the surface of the nail plate prior to applying the composite;

- light-curing viscous flow composite for fixation of active elements;
- polymerization lamp (wavelength 420–480 nm) for composite activation;

— Preparing the nail plate:

- pedicure clippers;
- diamond-coated cutter.

Active element

Elastofors (chain) and closed springs made of nickel-titanium alloy were active elements used with the method. The materials were chosen due to their proven effectiveness in orthodontics and availability [6, 7, 8]. The parameters selected for the springs were the diameter of 0.3556 mm (0.014 in), length varied from 3 to 4 mm depending on the individual needs of the patient.

The use of elastic elements ensured a smooth and controlled effect on the nail plate, minimizing the risk of trauma and overcorrection. A podiatrist selected the specific type of active element based on the individual nail deformity and the correction force required.

Attachment principle Both corrective systems are attached to the lateral edges of the nail plate using hooks made of steel wire. The design ensures even load distribution at the attachment points due to the symmetrical arrangement of the elements and the use of elastic elements.

The principle of corrective action Correction is achieved through the combined action of a lever and an elastic element. The lever mechanism, created by a curved wire, enhances the targeted action, while the elastic component (Elastofors/Nitinol spring) provides gradual and adaptive tension as the nail plate changes.

The principle of controlled force on the nail plate before the corrective system is placed The force applied to the nail plate can be adjusted by the podiatrist during installation of the corrective system through controlled tensioning of the flexible elements. Tensioning force can be measured using a dental dynamometer.

Placement of correction system

Steel wire forming two hooks was used to create the corrective system. The hooks were secured under the nail plate on both sides, with the wire length and bending angle adjusted to create a lever mechanism. At the point of force application, an additional link was formed on each wire to securely attach the active element (Fig. 1). The free ends of the wire were minimized to prevent excessive tension and possible damage to the nail plate during the application of the active element.

The elastofors tension force was adjusted by selecting the required number of chain links and using multiple layers of elastofors to achieve the desired tension force with a short active element length. For the springs, the tension force was adjusted by varying the length, diameter, and the tension force applied during the placement. Maintaining a balance was crucial: excessive tension could have led to reverse deformity of the nail or its separation from the nail bed.

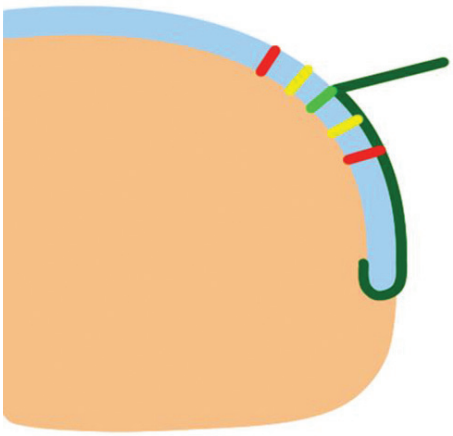

Fig. 1 A diagram showing the points of optimal force applied with a steel hook being placed

The junction between the active element and the steel wire was secured with a small amount of light-curing composite material to ensure the stability of the construct. The protruding wire elements were carefully trimmed and sanded to improve patient comfort. The complete installation of one corrective system, including nail plate preparation, took an average of 15 minutes. It is recommended to inspect and reinstall the system every four weeks to monitor the effectiveness of the correction and make any necessary adjustments.

Tensile force was measured from the first fixation point of the active element to the second using a dental dynamometer. Since the instrument readings are expressed in grams, the obtained values were converted to newtons using the formula $F = m \cdot g$, where m is the mass in kilograms (1 g = 0.001 kg) and g is the acceleration due to gravity (≈ 9.81 m/s²). Nail plate width was measured from ridge to ridge using a caliper with an electronic display.

RESULTS

Treatment results were assessed every two weeks after the installation of the corrective systems (Table 1). The corrective system was replaced with a new one every four weeks.

Table 1

Dynamics of changes in nail plate width and correction parameters

Patient	Toe	Nail width, mm					Active element		Tensile force, N	
		baseline	2 weeks	4 weeks	6 weeks	8 weeks	baseline	2 weeks	baseline	2 weeks
No. 1	Left first	15	16	16	17	17	Spring 0.014 inch 3 mm	Spring 0.014 inch 3 mm	3.434	3.434
	Right first	14	15.5	15.5	16	16	Spring 0.014 inch 3 mm	Spring 0.014 inch 3 mm	2.943	4.415
No. 2	Left first	14	15.5	15.5	16.5	17	Elastofors, two layers, two cells	Elastofors, two layers, two cells	1.962	2.943
No. 3	Left first	14	17	17	18.1	18.1	Spring 0.014 inch 3 mm	Elastofors, one layer, two cells	3.924	2.943
No. 4	Left first	15.5	17.9	18	19.5	19.5	Spring 0.014 inch 4 mm	Spring 0.014 inch 3 mm	4.905	4.905
	Right first	16	17.5	17.6	19	19	Spring 0.014 inch 3 mm	Elastofors, two layers, two cells	3.924	2.453
No. 5	Left first	14	14.5	14.5	16	16	Spring 0.014 inch 4 mm	Spring 0.014 inch 3 mm	4.415	4.905
	Right first	14,5	15	15	16	16	Titanium thread 0.014 inch	Titanium thread 0.014 inch		
No. 6	Left first	14	15	15	17	17	Elastofors, two layers, two cells	Elastofors, two layers, two cells	3.924	3.434
	Right first	13	14.5	14.5	16.8	16.9	Elastofors, three layers, two cells	Elastofors, two layers, two cells	2.453	3.434

For patient No. 5, Ni-Ti wire was used on the right first toe as part of a control protocol for dynamics in nail plate correction compared to the standard Ni-Ti wire correction technique. Tension was not recorded.

Dynamics in correction

All patients experienced an increase in nail plate width from 1.5 to 4.1 mm over two months, which was associated with deformity correction and restoration of the physiological shape.

Better improvement was observed in patients using nitinol springs (patients No. 1, No. 3, and No. 4), with a width increased to 4.5 mm (Figs. 2, 3, 4).

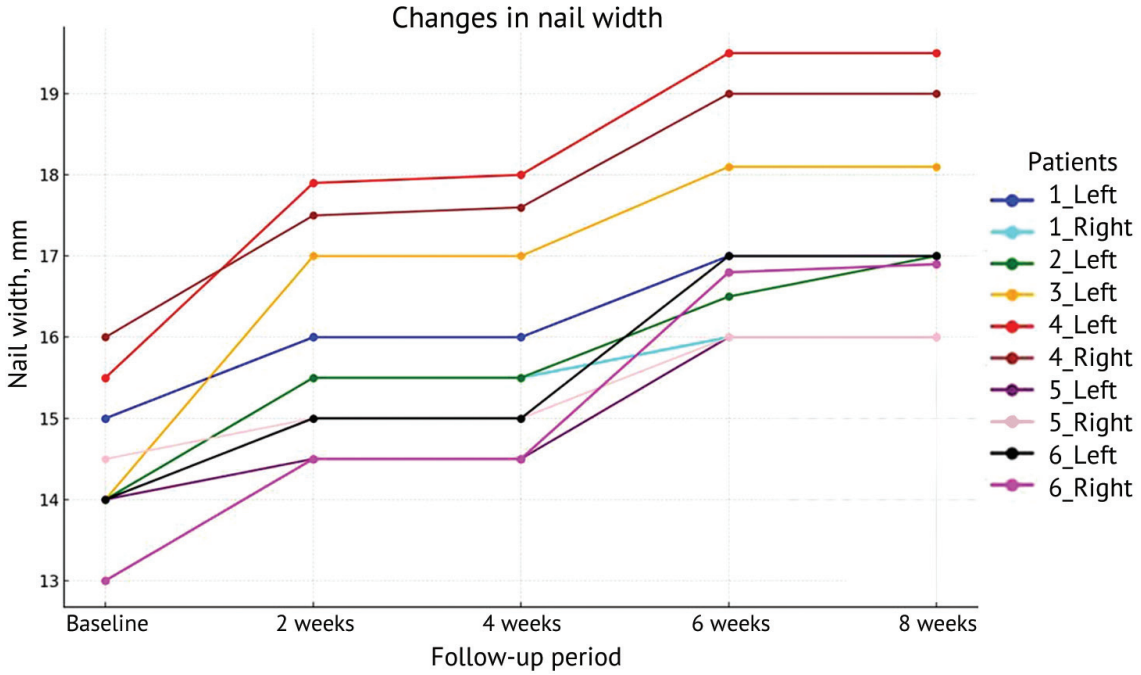

Fig. 2 Graph of nail width changes in patients

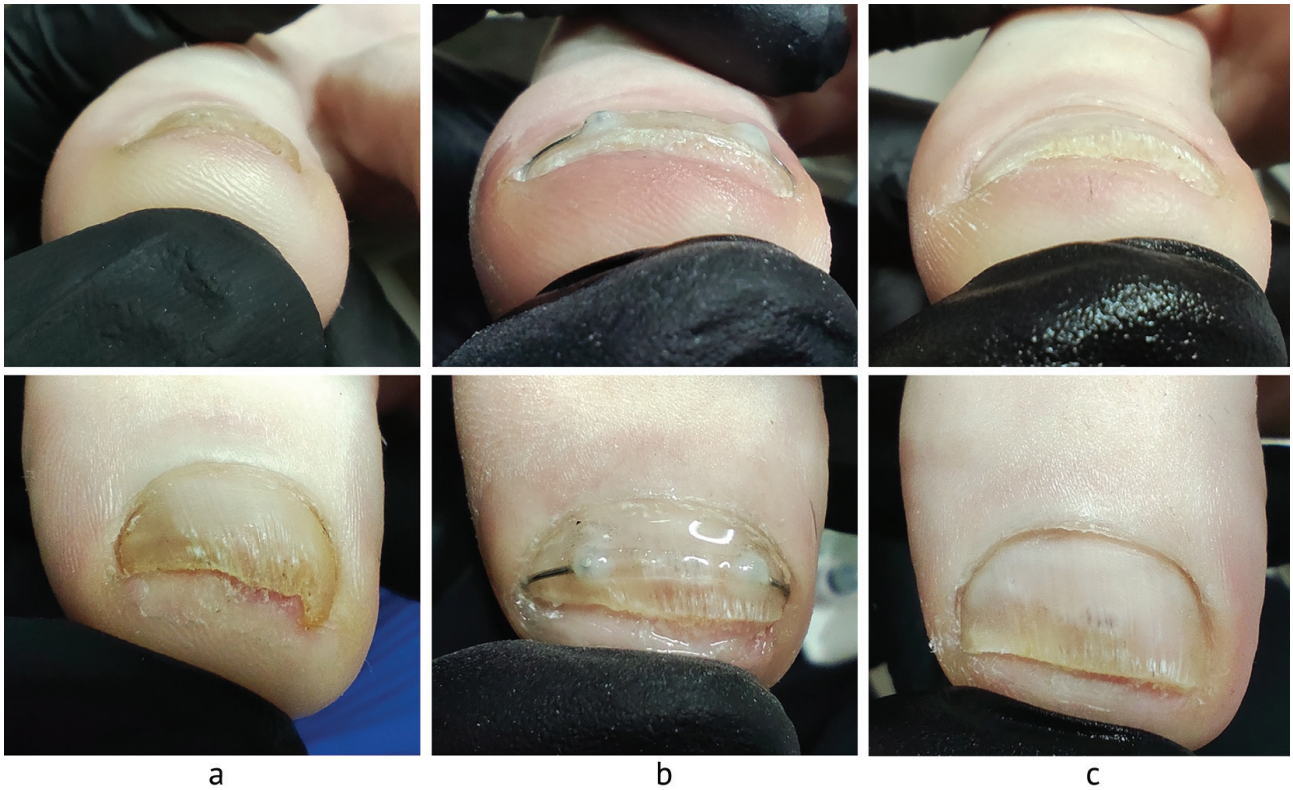

Fig. 3 Photo of the left first toe of patient No. 3, the active element "elastofors", dynamics: (a) at the baseline; (b) at four weeks; (c) at eight weeks

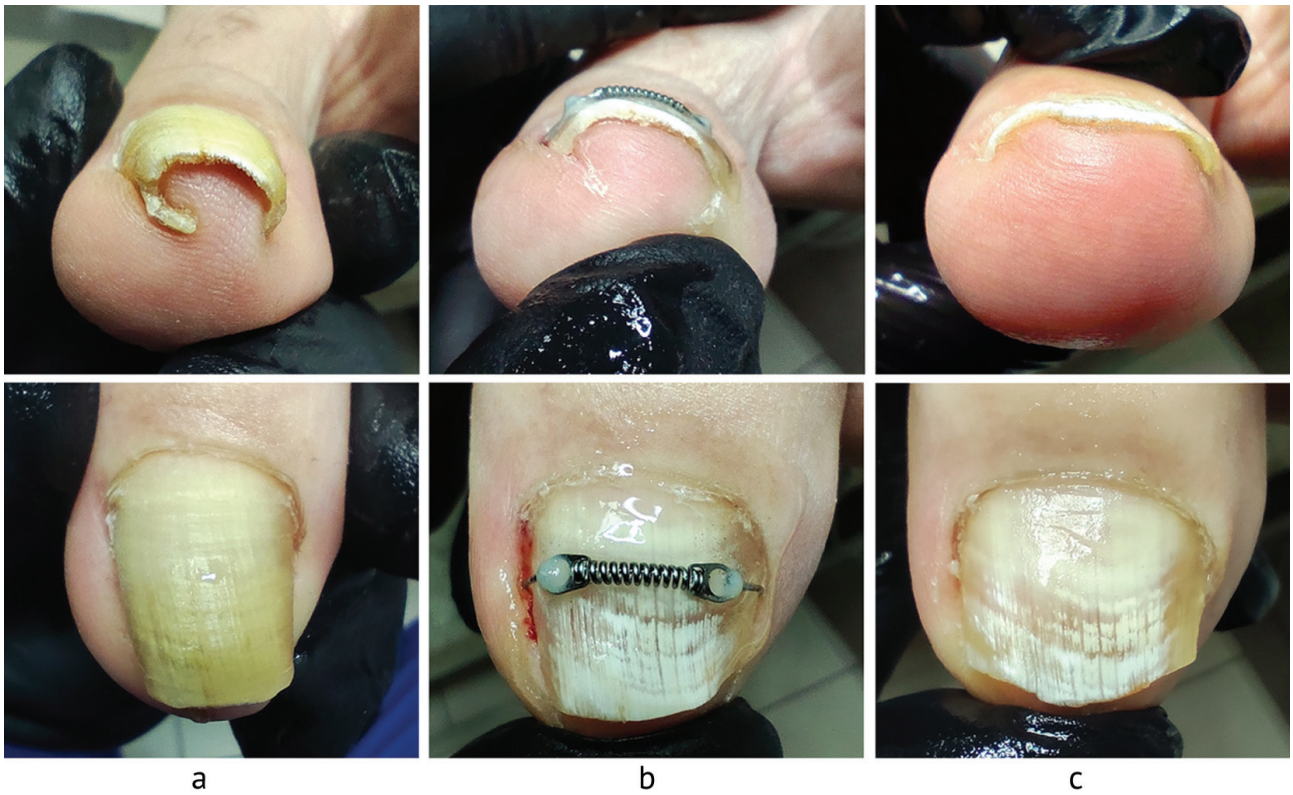

Fig. 4 Photo of the left first toe of patient No. 4, the active element "elastofors", dynamics: (a) at the baseline; (b) at four weeks; (c) at eight weeks

Using active elements

Elastic elements such as "elastofors" were used for thin and fragile nail plates to allow for precise adjustment of the tension force. The material was applied in two or more layers if needed, allowing for variable tension. Closed springs were used to correct more severe deformities, allowing for significant corrective force.

DISCUSSION

The findings indicated the effectiveness of the method developed for correcting nail plate deformities using elastic elements (Elastofors, Nitinol springs). The approach combined the advantages of traditional orthonyxia and innovative materials, providing a personalized effect on the nail plate. A comparative analysis of key aspects is presented below, based on current scientific research.

Advantages of the method offered:

— Highly effective for various types of deformities. The technique demonstrates a reduction in the recurrence rate, which is consistent with the results of the study by Wang and Huang [9], in which the use of nail correction staples resulted in a successful outcome in 89 % of cases. An important advantage is the adaptability of the system to the anatomy to minimize the risk of complications typical of surgical methods [3].

— Possibility of precise adjustment of tension force. The use of nitinol springs and elastofors as active elements correlates with the trend towards individualization of treatment, described in the study by Pelant et al. [10], in which the combination of materials increased the adaptability of correction. Unlike standard braces, such as Podofix, in which the tension force is fixed by the design, the proposed technique allows for adjustment of force by varying the length of the springs and elastofors layers. This is consistent with the recommendations of Dressler et al., in which

72 % of dermatologists reported the need for flexible force adjustment for complex cases [11]. Unlike rigid constructs, elastic elements can reduce the risk of overcorrection, which is critical for patients with thinning nail plates.

— The combination of two types of staples improved stable nail growth, as reported by Wang et al. [12].

— The absence of discomfort is confirmed by data on 94 % satisfaction of patients treated with non-invasive correction methods [13]. Transparent Elastophore and small size of the systems ensured aesthetics, which was critical for compliance with therapy [14].

— No need for additional instruments. The technique is accessible to all specialists familiar with most popular orthonyxia brace techniques (Fraser, ZTO, ORA) without the need to purchase specialized instrumentation. A significant advantage of the approach includes elimination of the need for expensive investments in new technical equipment, which fundamentally distinguishes it from the UniBrace system, which utilizes a unique instrumentation system [15].

Prospects for the development of the methodology

— Improved fixation. The introduction of adhesive platforms similar to those used in dermatological patches will allow for a more even distribution of pressure, reducing the risk of composite detachment [16].

— Optimization of the Elastofors immobilization technique for nail correction. The development of an alternative approach to Elastofors fixation, eliminating the use of steel wire, could form the basis for an innovative correction protocol on arbitrary areas of the nail plate. The method involves a controlled, gradual effect with the ability to precisely calibrate the gentle mechanical action on the nail tissue, which helps minimize trauma and improve the effectiveness of the therapeutic intervention.

— Use of alternative alloys in active elements:

• titanium-molybdenum alloys — high biocompatibility and corrosion resistance [17];

• cobalt-chromium alloys — increased strength for the correction of hypertrophic deformities [18].

CONCLUSION

The technique allows for precise adjustment of the force applied to the nail plate on each side. This is achieved by adjusting both the lever angle and the tension level of the active element in each specific correction system.

Eliminating the need for complex wire manipulation significantly reduces the time required to manufacture a custom-made correction system. The high elasticity and versatility of the active elements allow the developed systems to be used to correct various types of nail plate deformities.

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

Ethical approval *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 as revised in 2013.*

Informed consent *All patients were informed about the aims and methods of the study and provided written consent to participate and publish the results.*

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Information about the author:

Dmitrij O. Rozov — Podologist, droziroz@gmail.com, https://orcid.org/0009-0002-2648-0754.

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Role of olecranon osteosynthesis types and approaches in surgical treatment of patients with distal humerus fractures: a systematic review

T.E. Prokopovich[1], A.E. Medvedchikov[1,2], E.A. Anastasieva[1]✉, I.A. Kyrilova[1]

[1] Tsivyan Novosibirsk Research Institute of Traumatology and Orthopaedics, Novosibirsk, Russian Federation

[2] Clinical Hospital MD Group Michurinsky, Moscow, Russian Federation

Corresponding author: Evgeniya A. Anastasieva, evgeniya.anastasieva@gmail.com

Abstract

Introduction Distal humerus fractures account for about 2 % of all fractures, with annual fracture incidence up to 5.7–8.3 cases per 100,000 population. In this regard, optimal surgical treatment methods continue to be sought. Despite the widespread use of olecranon osteotomy to approach the humerus, the choice of an osteotomy type and fixator for an artificial fracture consolidation remains with the surgeon. This paper systematizes the available literature related to types of osteotomies, types of fixators, and characteristics of complications.

Purpose To evaluate the results of performing olecranon osteotomy to approach the humeral trochlea in the treatment of distal humerus fractures, to determine the optimal type of approach, type of osteotomy and type of fixators for an artificial olecranon fracture in the surgical treatment of distal humerus fractures.

Material and methods The search for publications was carried out in the PubMed, Google Scholar, eLibrary databases for the period from 2020 to 2025. Studies that described olecranon osteotomy in the surgical treatment of distal humerus fractures (DHFs) were selected. After evaluating 595 articles, 18 studies with a total sample size of 640 patients were included in the systematic review according to the PRISMA criteria.

Results and discussion The results of the review are: the overall incidence of delayed consolidation was 5 out of 112 cases (4.46 %), pseudarthrosis developed in 24 out of 416 (5.76 %), and metal implant broke in 10 out of 150 (6.6 %). Development of surgical site infection in the early postoperative period was described in 37 out of 473 (7.82 %). Metal implants were removed in the postoperative period in 55 out of 297 cases (18.51 %). The incidence was calculated based on the available data for each described complication.

Conclusion The results of olecranon osteotomy used to approach to the humeral trochlea in distal humerus fracture treatment have been evaluated. Based on the results of this systematic review, it is impossible to indicate the optimal approach, type of osteotomy and type of fixation due to the limited data. However, given the available statistics, it is possible to assume the advantage of the Tension Band Wiring (TBW) method. Therefore, the issue of conducting experimental and prospective studies remains open.

Keywords: elbow joint, olecranon, olecranon osteotomy, distal humerus intra-articular fractures, humerus fracture

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INTRODUCTION

Distal humeral fractures (DHFs) account for approximately 2 % of all fractures, with a high incidence rate of up to 5.7–8.3 cases per 100,000 population per year [1, 2]. DHFs typically have a bimodal distribution: they occur either in young males due to high-energy injuries or in older women due to low-energy injuries [1].

Successful surgical fixation of DHFs is challenging. Numerous factors must be considered in selecting the best surgical strategy for open reduction and internal fixation (ORIF). Over the past 25 years, surgical outcomes in the management of DHFs have improved significantly. The principles formulated by the AO-ASIF (Arbeitsgemeinschaft für Osteosynthesefragen — Association for the Study of Internal Osteosynthesis) group include anatomical reduction of the articular surface and rigid internal fixation, ensuring rapid healing and early rehabilitation [3]. Furthermore, over the past two decades, a better understanding of elbow anatomy has emerged and surgical approaches have been refined [4–11]; innovative fixation devices have become available, and the rehabilitation protocols developed by the AO have evolved. Precontoured locking plates for the posterior and medial columns, as well as for fixation of artificial olecranon fractures, are new and effective means of fixation, especially if fractures are associated with osteoporosis [12].

However, olecranon osteotomy may result in damage to articular cartilage, thus increasing the risk of complications such as postoperative osteoarthritis [13–16]. To minimize its impact on the articular surface of the elbow, it is recommended to perform the osteotomy within the permissible zone, the proximal ulna fossa. The authors describe this area as a bare area [17, 18], which serves as a suitable site for olecranon osteotomy. However, its anatomical narrowness creates difficulties in performing the osteotomy correctly. Wang et al in their study on cadavers described 39 elbow joints. The bare area was measured, and the following data were obtained: the average width was 0.53 cm (range: 0.13–0.97 cm), and the average distance from the insertion of the distal triceps tendon to the area was 2.1 cm (range: 1.4–2.5 cm) [19]. Hakl et al obtained the height of the bare area equal to (4.92 ± 0.81) mm. Moreover, the insertion site of the distal triceps tendon was found to be wide and allowed for different attachment options to the olecranon, which could lead to inaccurate positioning of the osteotomy instrument when used as a landmark [20]. This led to the search for a method to improve the accuracy of osteotomies in this area.

For olecranon osteotomy, the standard approach is to perform a chevron osteotomy and fixation of the artificial fracture with Kirschner wires and a tensioned wire or tape, or an intramedullary screw with or without a washer. Transverse osteotomy is easier to perform and causes minimal bone damage compared to chevron osteotomy. Biomechanical studies demonstrated comparable stability of transverse and chevron osteotomies [21], but the effect of osteotomies on the area to reduce cartilage damage remains unknown. Anatomical and biomechanical studies focusing on the morphological characteristics of the bare area are currently not sufficient and lack a reliable description of the precise anatomical landmarks for the initiation and termination of olecranon osteotomy. However, there are numerous variants of olecranon osteotomy with a wide range of fixation types: chevron osteotomy, transverse or oblique osteotomy, L-shaped osteotomy, SCOOT osteotomy (step-cut olecranon osteotomy) [22]. Moreover, there is still interest among researchers in structuring the complication profile.

Purpose To evaluate the results of performing olecranon osteotomy to approach the humeral trochleain the distal humerus.

MATERIAL AND METHODS

Data sources

A search for relevant publications was conducted in the electronic databases eLIBRARY, PubMed, and Google Scholar for the period from 2020 to 2025. A total of 595 full-text publications were

identified based on the keywords after removing duplicates. After screening according to PRISMA criteria, 36 publications were selected, 18 of which did not contain the required quantitative data. A systematic review and quantitative analysis included 18 publications [23].

Selection of studies and data extraction

Inclusion criteria:

— age 18 years or older;
— olecranon osteotomy for a distal humerus fracture;
— fixation of the artificial fracture with various types of fixators.

Exclusion criteria:

— case reports;
— biomechanical studies;
— pediatric studies and patients under 18 years of age;
— isolated olecranon fractures;
— studies conducted on cadaveric material.

The exclusion criterion was the lack of data on treated patients.

The sampling algorithm according to the PRISMA criteria for the subsequent systematic review is presented in Figure 1. The data were analyzed and presented descriptively.

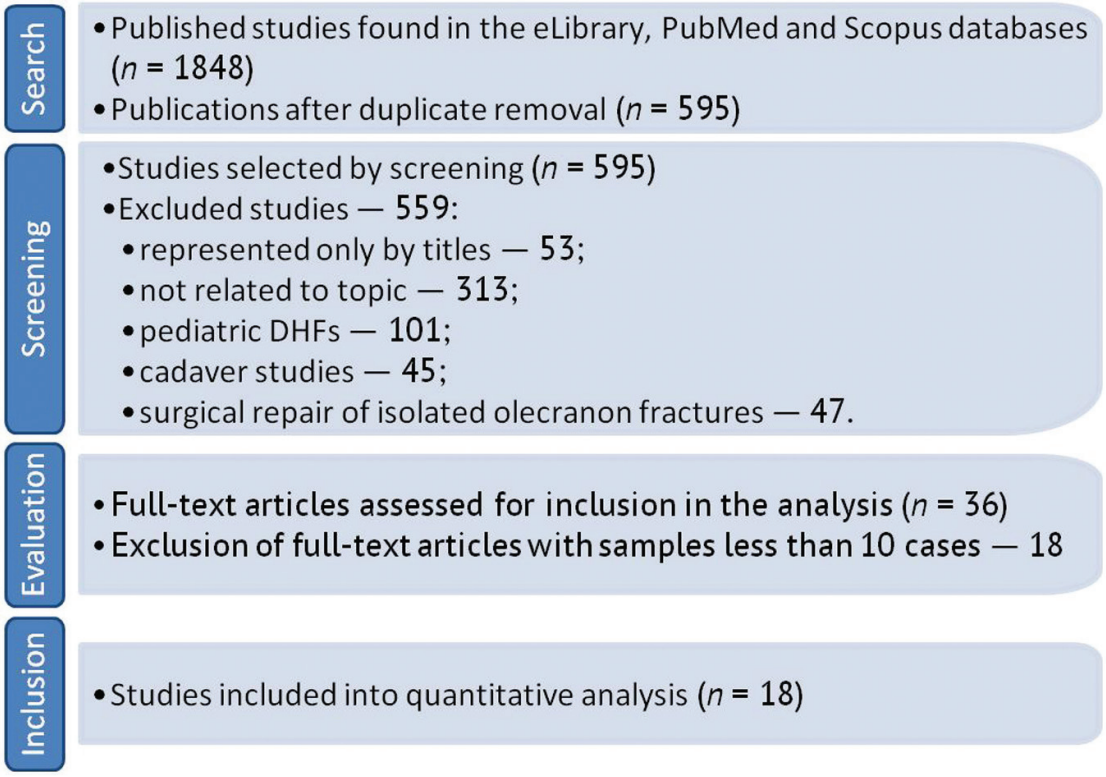

Fig. 1 Flowchart of the search and staged selection of publications for a systematic review

RESULTS AND DISCUSSION

Based on the data from all studies included in the systematic review, 640 clinical cases were reported in which the authors performed olecranon osteotomy (Table 1). The mean age of patients was (46.18 ± 8.5) years. One study did not specify the age of the study population [24]. Patient gender was reported in 14 studies, with men accounting for (51.4 ± 12.2) %.

Tabl 1

Distribution of data obtained by literature analysis for the period from 2020 to 2025

Source	LE	Number of patients (n)	OT	Fixation type	DC		PS		Break or migration		MI removal		SSI		MA, лет	M, %	F, %	FP, mo
					n	%	*n*	%	*n*	%	*n*	%	*n*	%				
Haglin JM et al, 2021 [24]	IV	48	III	TBW — 27, plate — 21	2	4.17	2	4.17	N/A		3	6.25	1	2.08	N/A	N/A	N/A	21
Zhou M et al, 2024 [25]	IV	73	II	TBW	N/A		N/A		N/A		N/A		N/A		40	60	40	37
Somerson JS et al, 2022 [26]	III	43	III — 41, II — 2	TBW, plate, screw & TBW, screw	N/A		2	4.65	N/A		N/A		9	20.93	59	61	39	17
Weber M.B. et al, 2022 [27]	III	14	III — 13, II — 2	TBW — 2, plate — 5, screw & TBW — 7	N/A		5	35.71	N/A		N/A		0	0.00	58	47	53	10
Cañete San Pastor P. et al, 2021 [28]	IV	26	III	screw	2	7.69	1	3.85	N/A		8	30.77	1	3.85	54.8	N/A	N/A	12
Phadnis J.S. et al, 2020 [29]	IV	30	III	TBW — 8, plate — 5, suture — 17	N/A		1/17 (suture)	3.33	N/A		1 (plate), 3 (TBW)	13.33	N/A		55	N/A	N/A	12
Kellam P.J. et al, 2024 [30]	IV	38	III	mini plate	N/A		0	0.00	N/A		3	7.89	N/A		50	42	58	10
Sinkler M.A. et al, 2025 [31]	III	36	III	TBW, plate, screw & TBW, screw	N/A		7	19.44	3	8.33	N/A		1	2.78	58	44	56	12
Wilson E.S. et al, 2021 [32]	III	64	III	N/A	N/A		0	0.00	N/A		3	4.69	9	14.06	45	41	59	13
Ailani R. et al, 2024 [33]	IV	20	III	TBW	N/A		N/A		5	25,00	N/A		2	10.00	37.5	55	45	12
Meldrum A. et al, 2021 [34]	IV	91	III	TBW — 63, plate — 18, screw & TBW — 1, screw — 9	N/A		2/63 (TBW), 1/18 (plate)	8.73	N/A		34	37.36	3	3.30	55.1	41	59	74
Jamoh K. et al, 2022 [35]	IV	30	III	TBW	N/A		N/A		1	3.33	N/A		8/	26.67	38.1	N/A	N/A	12
Ding J. et al, 2022 [37]	IV	27	III, II	screw & TBW	N/A		N/A		0	0.00	N/A		0	0.00	51.4	41	59	16
Ansari M.F. et al, 2020 [38]	IV	28	III	TBW	1	3.57	1	3.57	N/A		N/A		3	10.71	37.5	64	36	46
Yıldız V. et al, 2021 [39]	III	37	III	screw & TBW — 20, plate — 8, nail — 9	N/A		2	5.41	1	2.70	N/A		1	2.70	37	51	49	44
Butala R.R. et al, 2022 [40]	IV	15	III	TBW	N/A		N/A		N/A		N/A		N/A		44.6	53	47	6
Kumar D. et al, 2024 [41]	IV	10	III	TBW	0	0.00	0	0.00	N/A		N/A		N/A		36	60	40	13
Song Z.F. et al, 2025 [42]	IV	10	III	TBW	N/A		N/A		N/A		N/A		N/A		51.4	60	40	40

Notes: LE — level of evidence; OT — type of osteotomy; DC — delayed consolidation; PS — pseudoarthrosis; MI — metal implant; SSI — surgical site infection; MA — mean age; FP — follow-up period; TBW — tension band wiring; plate; screw; screw and TBW — screw with tension band wiring method; nail; suture; MP — mini plates; M — male; F — female; CO- chevron osteotomy; TO - transverse osteotomy; N/A — no data.

The follow-up period was 22.56 ± 17.7 months (range 1.5–74.4). Seventeen studies included 536 patients who underwent chevron osteotomy, and one study described 73 cases of transverse osteotomy [25]. Two studies reported transverse or chevron osteotomies in 57 patients, but did not specify the number of osteotomies [26, 27].

The most commonly used fixation method was tension band fixation using Kirschner wires and metal loop wiring: 286 patients in 11 articles. The next most frequently used method was fixation of the artificial fracture with a plate and screws: 95 patients in five articles. A cancellous screw along with the tension band wire method was used in 55 patients in four articles. Cañete San Pastor et al. used olecranon fixation with a 6.5 mm screw [28].

Over the past five years, only one study described successful fixation of an artificial fracture with a bone suture in 17 cases [29]. In one study, the authors reported 38 successful cases using 2.7 mm miniplates [30]. In the remaining articles, the authors included groups of patients with several types of fixation. In three studies, 143 patients were not distributed by type and method of fixation [26, 31, 32]. The incidence of complications after olecranon osteotomy for distal humerus fractures is shown in Figure 2.

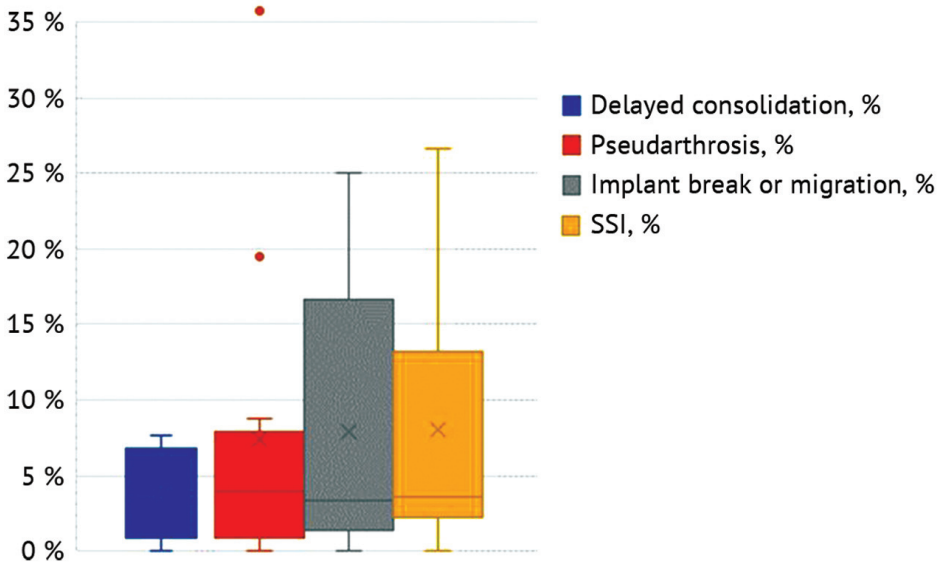

Fig. 2 Incidence of complications after olecranon osteotomy In DHFs (SSI — surgical site infection)

In 112 patients from four studies analyzed, there were five (4.46 %) cases of delayed olecranon consolidation after its osteotomy. The highest rate was described in the article by Cañete San Pastor et al.: two cases out of 26 patients (7.69 %) [28]. In 24 (5.76 %) cases out of 416, pseudarthrosis of an artificial olecranon fracture developed. Weber et al. reported pseudarthrosis in five (35.71 %) out of 15 patients [27], and Sinkler et al. [31] found pseudarthrosis in seven cases (19.44 %) out of 36.

In 10 out of 150 cases (6.6 %), fractures of the fixing metal or its migration into soft tissues occurred. Ailani et al. described repeated interventions due to implant failure in five patients (25.0 %) out of 20 [33].

In the late postoperative period, after complete consolidation of the artificial olecranon fracture, metal implants were removed in 55 (18.51 %) of 297 cases. Meldrum et al. removed metal structures in more than a third of cases, i.e., 34 (37.36 %) of 91 cases [34].

Wound infection in the early postoperative period developed in 37 (7.82 %) out of 473 cases; Jamoh et al. identified eight cases (26.67 %) out of 30 in their study [35], and a similarly high rate was reported by Somerson et al., i.e., 20.93 % (9 out of 43 cases) [26].

According to the literature, chevron osteotomy of the olecranon was used much more frequently, with better clinical outcomes than transverse osteotomy. Most studies used an oscillating saw to perform chevron osteotomy, cutting the bone only to three-quarters of its depth. An osteotome was used to complete the osteotomy, thereby avoiding damage to the articular cartilage and creating a relief surface for improved consolidation of the artificial fracture. The increased surface area of the cut bone ends in chevron osteotomy promotes effective apposition of the fragments, thus enhancing the rotational and translational stability of the artificial fracture.

Somerson et al. reported on the performance of two transverse osteotomies with delayed consolidation of fragments [26]. Weber et al. recorded five cases of pseudarthrosis after performing chevron and transverse osteotomies, but did not indicate which type of osteotomy they were obtained with [27]. In each study with mixed osteotomy techniques, it was concluded that chevron osteotomy is more reliable and yields better results [36].

Among the types and methods of fixation, the tension band wiring method alone and in combination with a single cancellous screw (with or without a washer) was used more frequently than other fixation devices.

The results of fixation of the artificial fracture site with plates and screws showed differences between studies. Five different types of plates or methods of their use were presented in 92 patients. Kellam et al. used 2.7 mm miniplates, resulting in implant removal in three (7.89 %) of 38 patients [30]. Phadnis et al. performed fixation of an artificial fracture with a bone suture; in a study of 30 patients, only one case of pseudarthrosis and four cases of subsequent implant removal were noted [29]. Cañete San Pastor et al. used a cancellous screw to fix the artificial fracture in 26 patients. It resulted in two cases of delayed consolidation and one case nonunion; the fixator was removed in the late postoperative period on a planned basis in eight patients [28].

The postoperative rehabilitation protocol in all analyzed studies included a short (up to 14 days) period of immobilization of the upper limb using a splint or cast. The range of motion exercises were initiated between the first and seventh days after surgery. Most studies prescribed wearing an orthosis after cast removal, while others did not use supportive means.

Limitation of the study

This systematic review has several limitations. As the study was designed as a descriptive one, we pooled similar groups to calculate incidence rates to demonstrate the trends. These results should be interpreted with caution (Fig. 3). A larger sample size would likely have yielded more reliable estimates.

We excluded biomechanical studies and studies involving patients diagnosed with an isolated olecranon fracture who did not undergo osteotomy to access the humeral trochlea for a olecranon fracture. Biomechanical studies provide valuable information unavailable in patient cohort studies, but our goal in this review was to evaluate clinical outcomes. We also observed heterogeneity between the groups. Thus, when using the tension band wiring technique (wiring loop and Kirschner wires), different plate types were grouped together.

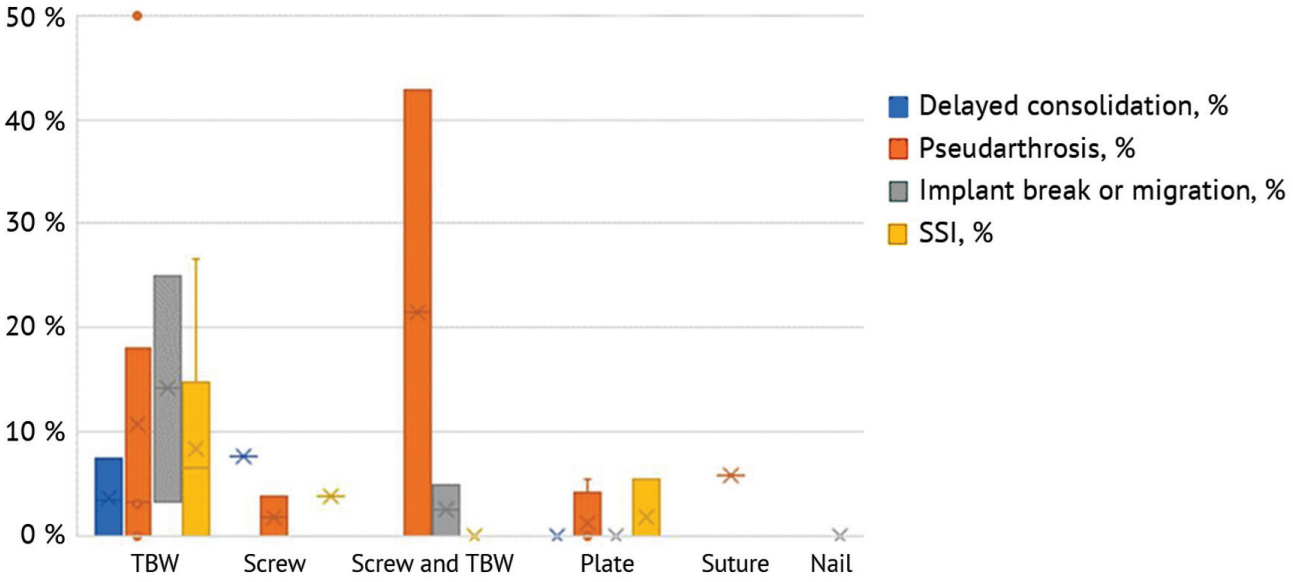

Fig. 3 Comparative diagram of complications based on the use of various techniques according to literature data for 2020–2025 (SSI — surgical site infection)

We were limited by the calculation information provided in each study. Patients were excluded from the review if it was unclear how to classify them.

CONCLUSION

Despite the frequent use and reproducibility of the general fixation methods in artificial fractures, the results of olecranon osteotomy used to approach to the humeral trochlea in distal humeral fractures remain poor. Based on the results of this systematic review, it is impossible to indicate the optimal approach, type of osteotomy and type of fixation due to the limited data. Therefore, the issue of conducting experimental and prospective studies remains open.

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Information about the authors:

Timofey E. Prokopovich — Clinical Resident, timp2354@gmail.com, https://orcid.org/0009-0003-8687-0866;

Artem E. Medvedchikov — Candidate of Medical Sciences, research associate, orthopaedic surgeon, medikea@mail.ru, https://orcid.org/0000-0002-1271-9026;

Evgeniya A. Anastasieva — Candidate of Medical Sciences, orthopaedic surgeon, evgeniya.anastasieva@gmail.com, https://orcid.org/0000-0002-9329-8373;

Irina A. Kirilova — Doctor of Medical Sciences, Deputy Director for Research, irinakirilova71@mail.ru, https://orcid.org/0000-0003-1911-9741.

Anton Gerasimovich Nazarenko
Corresponding Member of the Russian Academy of Sciences, Doctor of Medical Sciences

Renowned Russian scientist Anton Gerasimovich Nazarenko, Director of the Priorov National Medical Research Center of Traumatology and Orthopedics, Corresponding Member of the Russian Academy of Sciences, and Doctor of Medical Sciences, celebrates his 50th birthday In March 2026.

Anton G. Nazarenko graduated from the Sechenov Moscow Medical Academy, passed residency training in traumatology and orthopedics and neurosurgery, and completed postgraduate training at the Burdenko Neurosurgery Research Institute of the Russian Academy of Medical Sciences. He defended his dissertation for the degree of Candidate of Medical Sciences on the topic: "Development of a Technology for Objective Evaluation of the Efficiency of Surgical Treatment of Degenerative Diseases of the Intervertebral Discs of the Lumbosacral Spine" and his dissertation for the degree of Doctor of Medical Sciences on the topic: "Choosing the Optimal Surgical Tactics for Degenerative Diseases of the Lumbosacral Spine Using an Information-Analytical System and Computer Modeling".

Dr. Anton G. Nazarenko has over 20 years of scientific experience. His primary research focuses on the intersection of clinical medicine (neurosurgery, traumatology, and orthopedics) with applied mathematics, computer science, and artificial intelligence (AI). In 2015, Dr. A.G. Nazarenko was awarded the title of Professor of the Russian Academy of Sciences in Applied Mathematics and Computer Science, and in 2025, the title of Corresponding Member of the Russian Academy of Sciences in Information Technology and Automation.

Prof. A.G. Nazarenko developed a system for quantitative assessment of the severity of degenerative spinal diseases using multidimensional scales and a method for evaluating treatment effectiveness. He was the first in neurosurgery to apply mathematical methods of pattern recognition to predict surgical outcomes with an accuracy of over 90%. His system for interhospital virtual testing of AI models for clinical tasks is a breakthrough in the field of objective evaluation of the AI "maturity". A methodology for automated monitoring of adverse events and analysis of complications in surgery with AI application may improve patient safety. Prof. A.G. Nazarenko currently leads a project, supported by a grant from the Russian Science Foundation, on the use of AI methods for diagnosing wound infections in traumatology and orthopedics. He is the author of 166 scientific publications, including 10 monographs, and co-author of three national guidelines. In 2025, Anton Gerasimovich was awarded the Russian Government Prize in Neurotechnology for the development and implementation of innovative spinal stabilization systems.

Prof. A.G. Nazarenko leads a large-scale work on the development of traumatology and orthopedic services in Russia being the chief freelance trauma- and orthopedic specialist of the Russian Ministry of Health, vice president of the Russian Association of Traumatologists and Orthopedists, and a member of the scientific and practical council of the Russian Ministry of Health.

Anton Gerasimovich devotes much of his efforts to scientific and pedagogical work. He heads the Teaching Department of Traumatology, Orthopedics, and Related Disciplines at the Priorov National Medical Research Center of Traumatology and Orthopedics, and supervises candidate and doctoral dissertations.

Despite an intense administrative work, he continues his active clinical practice as a highly qualified spinal surgeon and performs a full range of operations on the spine and spinal cord.

The editorial board of the journal "Genij Ortopedii" congratulates Anton Gerasimovich Nazarenko on his anniversary and wishes him health, energy to implement his planned projects, the support of like-minded people, and new scientific achievements.

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