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Dear colleagues,

You are invited to read the final in 2023 issue of our journal.

The Clinical Studies section opens with the work of a team of authors from Samara (Semenkin et al.), which presents the principles of surgical treatment of delayed carpal tunnel syndrome (DCTS) in malunited fractures of the distal metaepiphysis of the radius (DMR). Having studied the results of treating 33 patients, the authors came to a conclusion that corrective osteotomy and osteosynthesis with a palmar locking plate is a reliable and effective method of treatment in malunion of the radius. In moderate and severe DCTS, combined with intermediate and predominantly dorsal DMR deformity, the best results can be achieved by open release of the carpal tunnel from a separate limited approach. In mild DCTS, as well as in predominantly palmar DMR deformity, decompression of the median nerve can be performed from the main extended approach to the radial flexor of the wrist.

The results of intramedullary osteosynthesis in re-fractures of the forearm bones in children that depend on the time of their occurrence are presented in the publication by the authors from Uzbekistan Kosimov AA and Khodzhanov IYu. Their analysis of treatment outcomes in 48 children showed that the success of repeated healing depends on the stage of bone regeneration at the time of forearm re-fracture occurrence. In the early stage of repeated fracture, the regeneration process is more advanced.

The problem of primary and revision hip arthroplasty associated with acetabular defect is the subject of the work by Udintseva et al. (Yekaterinburg, Kurgan). Based on the analysis of the treatment results of 93 patients, the authors conclude that long-term and painless functioning of a hip joint implant in acetabular defects is possible along with restoration of the spherical shape of the acetabulum and the joint rotation center in the true acetabular region, in adequate replenishment of bone tissue deficiency and reliable primary fixation of the cup with provision of conditions for secondary stabilization due to osseointegration. Acetabular defects are diverse in their anatomical manifestations. This fact creates certain difficulties in choosing pelvic components, augments, and methods of their fixation to the pelvic bone.

Results of intraoperative alpha-defensin express test used in 105 patients at the second stage of revision hip arthroplasty are demonstrated in the work of Murylev et al. (Moscow, Istanbul). The authors note that the test demonstrated 96.39 % specificity, 89.52 % accuracy and 63.64 % sensitivity. It has high diagnostic value in the intraoperative verification of reinfection in patients with an installed hip spacer, allowing timely correction of treatment tactics. Cases of "dry tap", synovial fluid material that does not meet the requirements for performing the test and weakly virulent coagulase-negative microflora, including as part of microbial associations, are limitations of in use of alpha-defensin express test.

Clinical results of impregnating a silver-containing preparation in an antimicrobial spacer for treatment of periprosthetic hip joint infection are presented in the work of the authors from St. Petersburg (Bozhkova et al.). The obtained results of the study showed that in the debridement stage of a two-stage treatment for chronic PJI of the hip joint caused by gram-positive bacteria, the antimicrobial spacer with highly dispersed silver showed high efficiency; however, further development of new combinations for impregnation of bone cement is required in order to expand the spectrum of antimicrobial activity of spacers.

The results of minimally invasive decompression and bone autoplasty in combination with autologous bone marrow concentrate (ABMC) in the treatment of 86 patients with aseptic osteonecrosis of the femoral head are presented in the work of Naida et al. (Moscow, Volgograd, Cheboksary). The authors note that the technique of minimally invasive decompression and bone

autoplasty in combination with ABMC is an effective method of treatment at precollapse stages of ANFH that improves the quality of life of patients, but does not achieve regression of structural changes in the bone.

Lychagin et al. (Moscow) discuss the problem of kinematic alignment in robotic total knee arthroplasty. Based on the data obtained during the treatment of 47 patients, the authors state that a personalized approach to total knee arthroplasty using an active robotic unit allows for effective kinematic alignment of the lower limb axis with an accuracy of up to 2° in 87.3 % of patients.

The optimal method of lateral lengthening osteotomy of the calcaneus based on a tomographic study of the feet in 250 patients is presented in the work of Gudi et al. (Novosibirsk). The results of the study showed that the Hintermann method of osteotomy of the calcaneus can be successfully applied in the Russian population with fewer complications, in particular, a lower number of injuries to the articular facets of the subtalar joint.

Theoretical studies are presented in this issue by three publications.

The effect of transphyseal intramedullary rod on the formation of distraction regenerate of the tibia and its subsequent growth in lambs was studied Kononovich et al. (Kurgan). The authors observed that pronounced periosteal osteogenesis and additional stabilization of the position of bone fragments in the conditions of a transphyseal rigid titanium rod contribute to a faster formation and maturation of bone regenerate. There were neither signs of the elongated segment spontaneous growth inhibition nor signs of epiphysiodesis at the level of the transphyseal implant. The central location of the transphyseal rod relative to the plane of the growth zone and the area of its cross-section of less than 5 % of the physis area can be considered conditions under which epiphysiodesis does not develop.

The release of antibiotics from materials for post-osteomyelitic bone defect filling was studied by authors from Kurgan (Stogov et al.). A comparative *in vitro* analysis of the kinetics of the release of cefotaxime, vancomycin and meropenem from two materials was conducted: based on polyurethane polymers (RK series) and based on polymethyl methacrylate (PMMA series). The results obtained by the authors showed that the duration of the release of the studied antibiotics in effective concentrations from the material based on polyurethane polymers is longer than from the material based on PMMA.

Bayan Jabr Hussein and Ban A. Ghani (Iraq) studied the distribution of osteocalcin during the healing of bone injuries by topical application of collagen and beta-tricalcium phosphate in rats. Based on the data obtained, the authors revealed that the combination of collagen with β-TCP showed the greatest efficiency in accelerating bone healing and increased osteogenic capacity due to increased immunoreactivity of osteocalcin.

The New Technologies section presents the publication by Skrebtsov et al. (Moscow). The authors developed an original model of a hemiendoprosthesis of the first metatarsophalangeal joint and a method for its installation in the treatment of hallux rigidus stage 3–4. The authors demonstrate a clinical case of treating a 74-year-old patient with stage 3 osteoarthritis of the first metatarsophalangeal joint and state that hemiarthroplasty of the first metatarsophalangeal joint with an implant made of zirconium ceramics of the original model has shown effectiveness in treating patients with hallux rigidus stage 3–4. The technique may be a good alternative to arthrodesis of this joint.

Two literature reviews that conclude the issue are devoted to current trends in the treatment of patients with degenerative lumbar spinal stenosis using direct lateral spondylodesis with indirect decompression of the spinal cord roots (Isakov et al., Novosibirsk) and patients with stenosing ligamentitis of the fingers (Kotelnikov et al., Samara).

On behalf of the editorial board, I congratulate the readers of our journal on the New Year and wish them happiness and professional success.

A.V. Burtsev, MD
Chief Editor of Genij Ortopedii

Original Articles

New technologies

Literature reviews

Anniversaries

Оригинальные статьи

Новые технологии

Обзоры литературы

Юбилеи

Original article
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Principles of surgical treatment of delayed carpal tunnel syndrome in malunion of the distal metaepiphysis of the radius

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Abstract

Introduction Delayed carpal tunnel syndrome (DCTS) in patients with malunited fracture of the distal metaepiphysis of the radius (DMR) develops from several weeks to months after the injury. The main treatment method for these patients is corrective osteotomy and fixation of the radius bone. However, the necessity and methods of median nerve decompression still remain controversial.

Purpose To evaluate long-term results of surgical treatment of patients with a malunited distal radius fractures and concurrent delayed carpal tunnel syndrome, depending on the method of median nerve decompression, and to develop a treatment concept.

Methods The results of treatment were studied in 33 patients (30 women and three men, average age 54.6 years) with malunited DMR fracture complicated by DCTS. All patients underwent corrective osteotomy of the distal radius and osteosynthesis with a volar locking plate. Open carpal tunnel release (OCTR) was performed in the first group of patients through a separate limited surgical approach (n = 19), while decompression of the median nerve was carried out through an extended flexor carpi radialis (EFCR) approach in the second group (n = 14). Patients were evaluated clinically (wrist range of motion, hand strength, VAS pain level, DASH score), radiographically, and electromyographically before surgery and one year after it. DCTS severity and DR deformity were compared.

Results After the operation, patients in both groups showed improvement in clinical, radiographic and ENMG parameters. The average union time was 12 weeks. Better results were achieved in the first group: the hand grip strength increased significantly, as did daily activity and the amplitude of the M-response of the short muscle abducting the thumb. The most significant changes were observed in moderate and severe DCTS cases, as well as in the intermediate and predominantly dorsal DR deformity.

Discussion The questions about the advisability of simultaneous decompression of the median nerve in patients with OCTR and the nature of the corresponding approaches do not have a clear answer. Most authors believe that it is sufficient to perform only corrective osteotomy and osteosynthesis. Our study showed the importance of a differentiated approach to solving this problem.

Conclusions Corrective osteotomy and volar locking plate osteosynthesis in carpal tunnel release are reliable and effective treatments for malunited DMR fractures with concurrent delayed carpal tunnel syndrome. The best results were obtained after open carpal tunnel release from a separate limited approach in patients with moderate and severe deformity of the distal metaepiphysis of the radius, combined with “intermediate” and “predominantly dorsal deformity. In mild DCTS cases, as well as in cases of predominantly palmar DMR deformity, decompression of the median nerve can be performed from the main EFCR approach.

Keywords: distal radius fracture, malunion, osteotomy, delayed carpal tunnel syndrome, carpal tunnel release, limited open approach, extended flexor carpi radialis approach, median nerve

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INTRODUCTION

Malunion of fractures of the distal metaepiphysis of the radius (DMR) may involve soft tissue structures passing through the carpal tunnel in the regeneration process [1]. In this case, the median nerve, which is subject to compression, suffers particularly, what predisposes to the formation of carpal tunnel syndrome (CTS). Based on the time of its development, CTS is divided into acute, appearing within a few hours and days after the fracture (5.4–8.6 %), subacute or transient (4 % of cases), and delayed or chronic that occurs several weeks or months after the injury (0.5–22 %) [2, 3].

Delayed CTS (DCTS) develops during consolidation of the radius fragments and, in most cases, in their malunion [4–10]. According to Stewart et al., at 3 months after the fracture, the incidence of DCTS reaches 17 %, and 6 months later, 12 % [11]. The immediate causes of DCTS are a decrease in the volume of the carpal tunnel space, residual dorsal or palmar displacement of the distal fragment, edema, tenosynovitis, prolonged immobilization of the hand in the Cotton-Loder position, and excessive bone callus size [12–17].

Questions about the indications for decompression of the median nerve in case of DMR malunion and the preferred methods of its implementation remain open [18, 19]. Considering these questions from a systemic perspective, it is possible to conditionally distinguish two types of surgical approaches used for the purpose of prompt elimination of the DCTS.

The first type of approach is through a longitudinal incision in the lower third of the forearm along its anterior surface, which is 3 cm long, with an angular deviation to the radial side in the projection of the palmar folds of the wrist, through the tendon of the radial flexor of the hand, cutting off the external leaves of the retinaculum flexorum. This type of approach was first described by Weber et al. [20] and was used by the authors only for decompression of the median nerve. This approach was later adapted by Gwathmay et al. [21] for prophylactic decompression of the median nerve with simultaneous osteosynthesis of the DMR by prolongation of the skin incision to 7–8 cm. A similar approach, distinguished by a length of 8–10 cm, but used only for operations on the DMR, was also used by Orbay et al. [22]. To generally designate approaches of this type that are performed only for the purpose of decompression of the median nerve, we, with some conventionality, used the term EFCR approach (Extended Flexor Carpi Radialis Approach) [23], which is well known among hand surgery specialists. Thus, approaches of the first type involve performing one incision, but to achieve two goals: to release the median nerve and for reconstructive intervention on the DMR.

The second type is combined approaches, which involve two incisions: the first for decompression of the median nerve in the palmar surface of the wrist, which is known among hand surgeons as the OCTR approach (Open Carpal Tunnel Release) [24], and the second for corrective osteotomy and osteosynthesis of the DMR in the lower third of the forearm. Thus, approaches of the second type involve two differently localized incisions, each with its own specific purpose.

In this study, we examined the effectiveness of both types of approaches in order to determine the therapeutic potential of each of them and the possibility of their differentiated use for different DCTS severity and different inclination of the articular surface of the DMR in case of a malunited fracture.

Purpose To evaluate long-term results of surgical treatment of patients with a malunited distal radius fracture and concurrent delayed carpal tunnel syndrome, depending on the method of median nerve decompression, and to develop a treatment concept.

MATERIALS AND METHODS

In the period from 01.01.2006 to 31.12.2022, we followed 33 patients (30 women and three men) aged 36 to 71 years (mean 54.6 years) with malunion of the DMR associated with DCTS. The time from injury to surgery ranged from 3 to 16 months (mean 4.8 months).

Study characteristics: a prospective, randomized, controlled in parallel groups, multicenter study. The subject of the study is DCTS that developed as a result of a malunion of the DMR fracture. The object of the study is patients suffering from DCTS due to malunion of the DMR fracture. Inclusion criterion: malunion of the DMR in the patient with clinical signs of DCTS. Exclusion criteria were concomitant diabetes mellitus, severe osteoporosis, and fixed wrist displacement.

The primary endpoint of the study was to evaluate the effectiveness of surgical treatment of DCTS using a combined surgical approach, including an incision in the lower third of the forearm to correct a malunited fracture and osteosynthesis of the DMR, and a mini-incision on the palmar surface of the wrist for decompression of the median nerve, epineurotomy and neurolysis (OCTR approach); the development of recommendations for differentiated surgical treatment based on DCTS severity and the magnitude of the palmar tilt of the articular surface of the radius.

Secondary endpoints of the study were clinical parameters (pain intensity during exercise, total range of active wrist movements, hand grip strength, daily activities), radiographic parameters (radio-ulnar angle, palmar tilt of the articular surface of the radius, radio-ulnar index), and ENMG parameters (amplitude of the M-response of the abductor pollicis brevis muscle, distal latency of the motor fibers of the median nerve, motor conduction velocity along the motor fibers of the median nerve, conduction velocity along the sensory fibers of the median nerve).

All patients were divided into two clinical groups randomly. Group 1included 19 patients who were treated with a combined approach: from the first mini-incision on the palmar surface of the wrist, decompression of the median nerve was performed by dissecting the transverse carpal ligament, epineurotomy and neurolysis (OCTR approach), and from the second incision in the lower third of the forearm, corrective osteotomy and osteosynthesis of the DMR were performed. Group 2 included 14 patients who were treated with an approach from only one incision in the lower third of the forearm, through which corrective osteotomy, osteosynthesis of the DMR and decompression of the median nerve were performed (EFCR approach) without epineurotomy and neurolysis.

The clinical groups were comparable in terms of age, type of DMR fracture, DCTS severity, the magnitude of the palmar tilt of the articular surface of the radius, and the timing of reconstructive surgery (Table 1).

Table 1

Characteristics of patients in the study groups

Parameters		Clinical groups				*p*
		1 (*n* = 19)		2 (*n* = 14)		
		n	%	*n*	%	
Age (years)	Up to 50	5	26.3	4	28.6	> 0.05
	51–60	11	57.9	6	42.8	> 0.05
	Over 60	3	15.8	4	28.6	> 0.05
Fracture type	Type A	10	52.6	7	50.0	> 0.05
	Type B	3	15.8	2	14.3	> 0.05
	Type C	6	31.6	5	35.7	> 0.05
Terms of reconstructive surgery after trauma	< 6 months	14	73.6	9	64.3	> 0.05
	6 < 12 months	4	21.0	5	35.7	> 0.05
	⩾ 12 months	1	5.4	–		> 0.05
DCTS severity	Mild	12	63.2	5	35.7	> 0.05
	Moderate	2	10.5	4	28.6	> 0.05
	Severe	5	26.3	5	35.7	> 0.05
Palmar tilt of the articular surface of the radius (PT)	PT ⩾ (+)11°	1	5.3	4	28.6	> 0.05
	PT = from (+)10° to (–)10°	7	36.8	4	28.6	> 0.05
	PT ⩽ (–)11°	11	57.9	6	42.8	> 0.05

The indications for surgery were complaints of pain in the hand, mainly at night, a feeling of numbness in the first, second and third fingers of the hand, deformity and pain in the wrist under load, decreased hand strength, and limited mobility in the wrist joint. Moreover, we studied the changes in radiographic parameters: a deficit in the palmar tilt of the articular surface of the radius of more than 20°, radial inclination of less than 10°, an increase in the ulnar variance of more than 2 mm, and an intra-articular displacement of more than 2 mm. Contraindications to corrective osteotomy were uncompensated diabetes mellitus, severe osteoporosis, and fixed displacements in the wrist.

Preoperative planning was based on radiographs of the wrist joints in standard views, anteroposterior and sagittal. Computed tomography was performed on CT systems Toshiba Aquillion 32 and Philips Brilliance 190 P (Netherlands) in the spiral scanning mode with a reconstructed slice thickness of 0.5 mm and a reconstruction step of 0.3 mm. The magnitude of the displacement of DMR fragments in millimeters and degrees was measured, the level of osteotomy, shape and size of the bone defect were determined.

The effectiveness of surgical treatment was assessed according to the following criteria:

— clinical findings

- Pain intensity under load in VAS;
- Total range of active motion (TRAM) in the wrist;
- Grip strength (GS);
- Daily activity in DASH score;

— radiographic findings:

- Radial inclination (RI) angle;
- Palmar tilt (PT) of the radius articular surface;
- Shortening of the radius relative the ulna;
- Ulnar variance (UV);

— ENMG findings:

- compound muscle action potential (CMAP, mV);
- Distal motor latency (DML, ms);
- Motor conduction velocity (MCV, m/s) and sensory conduction velocity (SCV, m/s) in the median nerve fibers

All the parameters were studied before the intervention and one year after it.

The OCTS severity was determined according to Żyluk et al. [25]. Based on the magnitude of the M-response amplitude of the abductor pollicis brevis muscle (CMAP), patients with mild (> 4 mV), moderate (4–2 mV), and severe (< 2 mV) OCTS were identified.

Based on the PT value, all patients were conditionally divided into those with predominantly palmar deformity (PT ⩾ (+) 11°), intermediate (PT (+)10° — (–)10°), and predominantly dorsal (PT ⩽ (–)11°) DMR deformity.

The IBM SPSS Statistics package (USA license No. 5725-A54) was used for statistical analysis. Descriptive statistics are presented as mean and standard deviation (M ± SD). The Kruskal – Wallis analysis of variance, Mann – Whitney criteria, and Wilcoxon paired test were used in the work.

Surgical technique

The intervention was performed under general anesthesia and regional tourniquet, placing the upper limb in the supination position on a radiolucent side table. In the patients of the first group, open decompression of the median nerve was performed using a limited open approach (OCTR approach). For this purpose, a Z-shaped incision 3.5–4 cm long was made on the palmar surface of the wrist.

The skin and tissue were dissected at the level of the ulnar part of the carpal tunnel, and the palmar aponeurosis was dissected on its radial side. The incision line of the transverse palmar ligament was drawn obliquely from the dorsoradial to the palmar-ulnar side of the tunnel. The median nerve and its motor branch were mobilized, epineurotomy and neurolysis were performed. The palmar aponeurosis and skin were sutured. Next, through the incision in the lower third of the forearm along its palmar-radial surface, corrective osteotomy and DMR osteosynthesis were performedaccording to Orbay et al. [22] (Fig. 1).

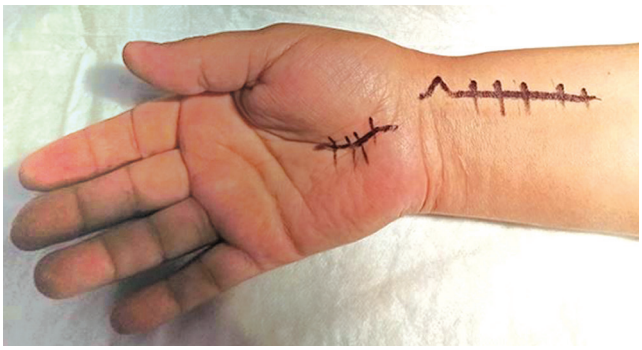


Fig. 1 Planning of incisions for open decompression of the median nerve in the wrist, corrective osteotomy and DMR osteosynthesis

In the patients of the second group, decompression of the median nerve was performed using an approach to the forearm, simultaneously performing corrective osteotomy and osteosynthesis according to Gwathmay et al. [21]. For this purpose, a 7–8 cm long linear incision was made on its palmar-radial surface in the lower third in the projection of the tendon of the radial flexor carpi radialis and extended distally like a Z-shaped curve by 7–10 mm (EFCR approach) (Fig. 2 a). Then, along the tendon of the radial flexor carpi radialis, the superficial flexor retinaculum was mobilized and dissected. The palmar branch of the radial artery was ligated and transected, or retracted to the side. The tendon of the radial flexor carpi radialis was retracted radially, and the deep ligament was dissected. After the ulnar abduction of the tendon of the long flexor of the thumb, the superficial and deep sheets of the transverse carpal ligament were finally dissected from the tubercle of the scaphoid bone and from the trapezium bone (Fig. 2 b). To approach the radius, the quadratus pronator muscle was cut off from the bone in the lateral and distal parts and abducted to the ulnar side. The tendon of the brachioradialis muscle was dissected in a Z-shape. This made the deformed surface of the radius accessible.

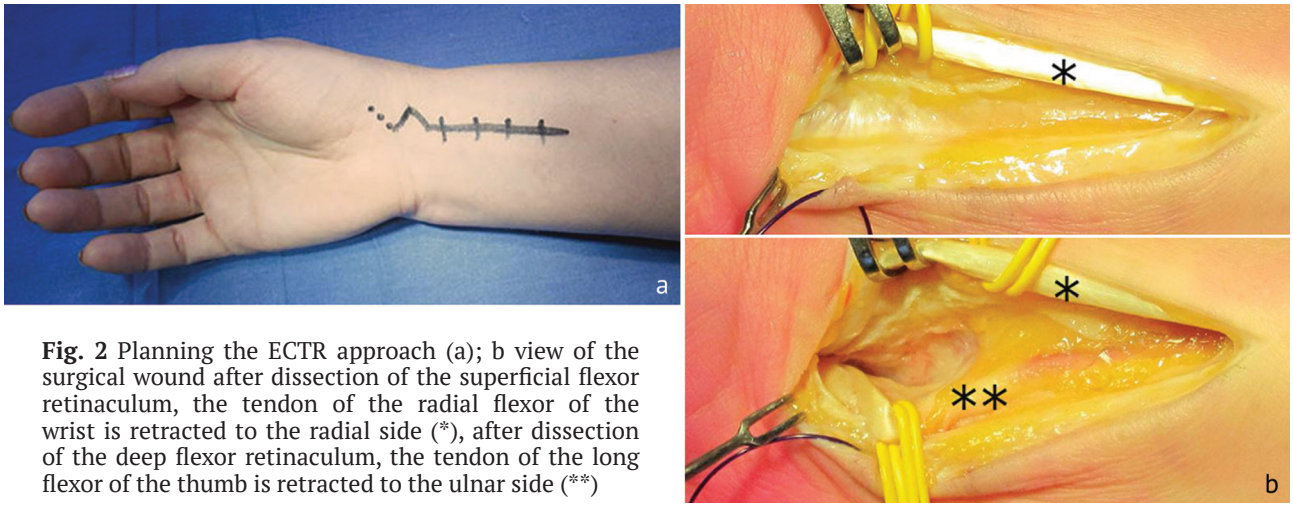


Fig. 2 Planning the ECTR approach (a); b view of the surgical wound after dissection of the superficial flexor retinaculum, the tendon of the radial flexor of the wrist is retracted to the radial side (*), after dissection of the deep flexor retinaculum, the tendon of the long flexor of the thumb is retracted to the ulnar side (**)

In the patients with predominantly dorsal deviation of the distal fragment of the radius (n = 17), an additional dorsal mini-incision up to 4 cm in size was made for complete mobilization and retention of the distal fragment of the radius [26]. The proximal part of the extensor retinaculum was dissected in a Z-shape, and the flaps were moved apart. Using precision surgical technique, the fibrous bone canals of the extensors were identified in the periosteal bone callus. The first, second, third, and fourth canals were dissected; and the extensor tendons were moved apart. Particular attention was paid to preserving the tendon of the long extensor of the thumb.

In accordance with the preoperative planning, osteotomy of the radius was performed under the control of an operating stenoscope, alternately using both the palmar and dorsal incisions. Direct reduction of bone fragments was performed, restoring normal anatomical DMR relationship. The bone defect was filled with autogenous bone or synthetic osteoplastic material based on β-3 calcium phosphate. A plate of a personalized size was placed on the volar surface of the radius so that it did not protrude beyond the distal and volar edges of the DMR "watershed line". Locking and cortical screws were installed under the control of an operating stenoscope (Fig. 3). Continuity of the brachioradialis tendon, the integrity of the pronator quadratus and the extensor retinaculum were restored. The tendon of the extensor pollicis longus was left in the subcutaneous tissue. The wounds were sutured layer by layer, active drainage was placed.

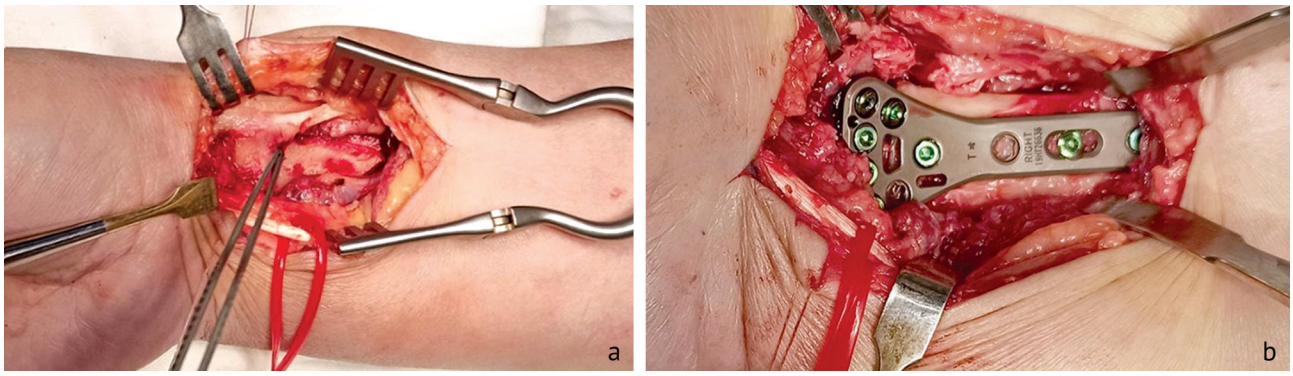


Fig. 3 View of the surgical wound: a before corrective osteotomy; b after osteotomy with a palmar plate placed

Immobilization was performed with a removable palmar plaster splint in the functional position of the wrist for 2–3 weeks. A removable orthosis was used in the following four weeks. Therapeutic exercises for the fingers of the hand began on the second postoperative day. Active rehabilitation treatment was initiated at 5–6 weeks after the operation. Full loading was allowed after consolidation of bone fragments, but not earlier than 12 weeks after the operation.

All patients signed informed consent; the study was approved by the Bioethics Committee at Samara State Medical University (protocol dated 03.05.2024 No. 285).

RESULTS

Due to the treatment provided, all patients had their DMR deformity completely corrected or significantly reduced. Bone fragment healing was observed on average at 12 weeks.

Moreover, clinical parameters significantly improved. Thus, the intensity of pain under load (VAS) decreased by 66 %, the total range of active motion in the wrist joint (TRAM) increased by an average of 43 %, the hand grip strength (GS) increased by 82 %, and daily activity (DASH-score) improved by 58 % (Table 2).

The radiographic changes were positive. The radial inclination (RI) angle increased by 75 %, palmar tilt (PT) improved by 144 %, and the ulnar variance (UV) decreased by 73 % (Table 2).

The changes in ENMG parameters were also characterized by positive dynamics. The increase in the amplitude of the M-response (CMAP) reached 78 %, the decrease in distal motor latency (DML) was 27 %, the velocity of the motor response (MCV) increased by 19 %, and the velocity of the sensory response (SCV) increased by 47 % (Table 2).

Thus, all 11 parameters significantly improved in all patients one year after the operation.

The values of the parameters in the clinical groups studied before the operation were similar. However, after one year all the parameters in the first group changed more significantly than in the second group. Thus, the hand grip strength (GS) in patients of the first group increased

to (74.37 ± 13.52) %, and in the second only to (60.43 ± 16.15) %. Daily activity (DASH-score) in the first group reached (15.06 ± 6.38) points, and in the second (20.82 ± 7.17) points. The amplitude of the M-response of the short muscle abducting the pollicis (CMAP) in the first group increased to (7.53 ± 2.08) mV, and in the second only to (5.48 ± 2.58) mV (Table 3). The changes in these criteria were reliable.

Table 2

Clinical, radiographic and ENMG characteristics of patients in both groups, M ± m

Parameter	Before surgery (*n* = 33)	One year after surgery (*n* = 33)	*P*
VAS, points	4.97 ± 1.66	1.68 ± 0.80	< 0.001
TRAM, %	57.05 ± 12.15	81.76 ± 7.46	< 0.001
GS, %	37.58 ± 16.52	68.45 ± 16.05	< 0.001
DASH-score, points	41.83 ± 8.74	17.50 ± 7.22	< 0.001
RI, °	12.26 ± 5.15	21.50 ± 4.36	< 0.001
PT, °	–9.49 ± 18.58	4.19 ± 5.06	< 0.001
UV, mm	4.38 ± 2.34	1.20 ± 1.98	< 0.001
CMAP, mV	3.75 ± 2.37	6.66 ± 2.49	< 0.001
DML, m/sec	5.66 ± 1.86	4.10 ± 0.73	< 0.001
MCV, m/sec	45.53 ± 10.08	54.28 ± 6.76	< 0.001
SCV, m/sec	30.19 ± 15.01	44.29 ± 10.83	< 0.001

Table 3

Clinical, radiographic and ENMG characteristics of patients one year after surgery, M ± m

Parameter	Group 1 (*n* = 19)	Group 2 (*n* = 14)	*p*
VAS, points	1.62 ± 0.76	1.77 ± 0.86	0.883
TRAM, %	82.11 ± 6.92	81.29 ± 8.38	0.798
GS, %	74.37 ± 13.52	60.43 ± 16.15	0.010
DASH-score, points	15.06 ± 6.38	20.82 ± 7.17	0.038
RI, °	21.45 ± 4.66	21.57 ± 4.07	0.715
PT, °	4.59 ± 4.91	3.64 ± 5.39	0.826
UV, mm	1.21 ± 2.39	1.18 ± 1.34	0.698
CMAP, mV	7.53 ± 2.08	5.48 ± 2.58	0.023
DML, m/sec	3.91 ± 0.74	4.36 ± 0.65	0.065
MCV, m/sec	56.63 ± 3.56	51.11 ± 8.73	0.061
SCV, m/sec	46.98 ± 8.36	40.64 ± 12.93	0.140

The comparing of all 11 indicators based on the severity of DCTS found that one year after the operation, in its mild grade (*n* = 17), there were no reliable changes in the groups. On the contrary, in moderate and severe DCTS (*n* = 16), significant changes were revealed in the values of several indicators. Thus, one year after the operation, the power of grip strength (GS) of the hand in patients of the first group increased to (70.29 ± 18.78) %, and in the second only to (51.89 ± 10.86) %. Daily living activities (DASH questionnaire) in the patients of the first group compared to the second improved better, amounting to (15.51 ± 8.45) and (25.00 ± 4.45) points, respectively. The amplitude of the M-response (CMAP) in the first group reached (5.53 ± 1.98) mV, and in the second only (3.86 ± 1.11) mV. The value of sensory conduction velocity (SCV) in the first group also exceeded the similar indicator in the second group, amounting to (43.43 ± 7.39) m/s and (32.89 ± 8.82) m/s, respectively (Table 4). The changes in these parameters were reliable.

Table 4

Clinical, radiographic and ENMG characteristics of patients with moderate and severe OCTS one year after surgery, M ± m

Parameter	Group 1 (*n* = 7)	Group 2 (*n* = 9)	*p*
VAS, points	1.80 ± 1.05	1.98 ± 0.78	0.957
TRAM, %	80.71 ± 8.42	78.89 ± 9.64	0.671
GS, %	70.29 ± 18.78	51.89 ± 10.86	0.026
DASH-score, points	15.51 ± 8.45	25.00 ± 4.45	0.015
RI, °	23.47 ± 4.43	22.56 ± 4.33	0.594
PT, °	5.00 ± 4.62	5.22 ± 5.49	0.789
UV, mm	0.86 ± 1.68	1.50 ± 1.17	0.449
CMAP, mV	5.53 ± 1.98	3.86 ± 1.11	0.034
DML, m/sec	4.24 ± 0.87	4.61 ± 0.57	0.395
MCV, m/sec	55.19 ± 4.65	47.89 ± 9.33	0.095
SCV, m/sec	43.43 ± 7.39	32.89 ± 8.82	0.029

Our findings show that in mild DCTS, decompression of the median nerve with its epineurotomy and neurolysis via the OCTR approach is inappropriate. Such an approach provides tangible results only in moderate and severe DCTS. In mild DCTS, a positive result can be achieved via the EFCR approach.

The comparison of the changes in the parameters between the groups based on the severity of the DMR deformity found that in predominantly palmar deformity (*n* = 5) there were no reliable changes between the groups. However, in intermediate deformity (*n* = 11), significant differences in the magnitude of several parameters was revealed. Thus, the amplitude of the M-response in the first group increased to (8.80 ± 1.17) mV, while in the second only to (4.40 ± 2.13) mV. The distal latency of the motor fibers of the median nerve (DML) in the first group decreased to (3.87 ± 0.39) m/sec, and in the second to (4.53 ± 0.26) m/sec. The velocity of the motor response also improved. In the first group it increased to (57.16 ± 1.68) m/sec, and in the second one to (43.63 ± 9.59) m/sec (Table 5).

Similarly, in predominantly dorsal deformity (n = 17), significant improvement was noted in several parameters. Thus, the total range of active movements (TRAM) in the wrist joint in the first group increased to (29.64 ± 9.74) % while in the second one only to (14.17 ± 5.95) %. The hand grip strength (GS) showed values of (37.60 ± 10.96) % and (18.47 ± 6.91) %, respectively. Daily activities (DASH questionnaire) also improved, (18.27 ± 4.44) points in the first group and (29.67 ± 7.26) points in the second (Table 5).

Table 5

Clinical, radiographic and ENMG characteristics of patients with intermediate and predominantly dorsal DMR deformity" one year after surgery, M ± m

Parameter	Group 1 (*n* = 7)	Group 2 (*n* = 4)	*P*
Intermediate deformity, PT from (+)10° to (–) 10°			
VAS,points	1.50 ± 0.76	1.53 ± 0.68	0.846
TRAM, %	85.57 ± 5.94	84.25 ± 11.44	0.568
GS, %	75.57 ± 10.45	59.50 ± 14.82	0.071
DASH-score, points	12.67 ± 5.06	19.63 ± 7.27	0.131
RI, °	19.91 ± 5.80	20.75 ± 6.75	0.635
PT, °	4.46 ± 3.14	6.25 ± 3.20	0.340
UV, mm	0.36 ± 1.60	1.00 ± 0.82	0.625
CMAP, mV	8.80 ± 1.17	4.40 ± 2.13	0.013
DML, m/sec	3.87 ± 0.39	4.53 ± 0.26	0.007
MCV, m/sec	57.16 ± 1.68	43.63 ± 9.59	0.008
SCV, m/sec	45.97 ± 5.96	37.00 ± 14.54	0.129

Table 5 (continued)

Clinical, radiographic and ENMG characteristics of patients with intermediate and predominantly dorsal DMR deformity" one year after surgery, M ± m

Parameters	Group 1 (*n* = 11)	Group 2 (*n* = 6)	*P*
Predominantly dorsal deformity, PT ⩽ (–)11°			
VAS, points	1.69 ± 0.83	1.95 ± 1.15	0.575
TRAM, %	29.64 ± 9.74	14.17 ± 5.95	0.006
GS, %	37.60 ± 10.96	18.47 ± 6.91	0.004
DASH-score, points	18.27 ± 4.44	29.67 ± 7.26	0.007
RI, °	22.24 ± 4.03	21.00 ± 1.55	0.225
PT, °	4.18 ± 5.86	–0.17 ± 4.62	0.189
UV, mm	1.68 ± 2.81	1.58 ± 0.97	0.612
CMAP, mV	6.59 ± 2.15	5.93 ± 2.91	0.763
DML, m/sec	3.98 ± 0.93	4.40 ± 0.65	0.391
MCV, m/sec	56.71 ± 4.34	52.83 ± 8.40	0.410
SCV, m/sec	46.45 ± 9.30	41.67 ± 16.48	0.650

The above findings indicate that in patients with predominantly palmar DMR deformity, decompression of the median nerve with its epineurotomy and neurolysis through the OCTR approach is inappropriate. It is quite sufficient to perform decompression through the EFCR approach, not performing epineurotomy and neurolysis.

Complications Two patients in the first group developed a dense and painful postoperative scar at 2 and 3 months after the operation, and three patients developed pillar pain. These symptoms disappeared during the postoperative treatment and did not bother them one year later. One patient in the second group developed transient irritation of the superficial branch of the median nerve. Neither surgical wound suppuration nor migration of screws was observed. There were no repeated operations.

Case presentation Female patient H., 58 years old, was admitted two months after the injury with the diagnosis: malunion of the right DMR fracture (according to the AO/ASIF classification, type A 3.2) and DCTS. Upon admission, she complained of wrist deformity, pain and limited mobility in the right wrist, decreased sensitivity in fingers I–II–III, and decreased hand strength. Objective findings were: the total range of active movements in the right wrist joint compared to the contralateral limb was 64 %, and the strength of the rough grip of the hand was 35 %. The pain intensity (VAS) under load reached 4.7 points. Radiographs showed angular volar displacement of the cortical plate of the distal fragment of the radial bone, a decrease in the radioulnar angle (UV) to 12.3°, an increase in the dorsal tilt of the articular surface of the radius in the sagittal plane to –4°, and 4-mm shortening of the radius (Fig. 4). ENMG of the upper limbs revealed a decrease in the M-response of the median nerve at the right wrist (APB-CMAP), as well as a decrease in the conduction velocity along the sensory fibers of the median nerve (SCV) (Fig. 5). According to the classification

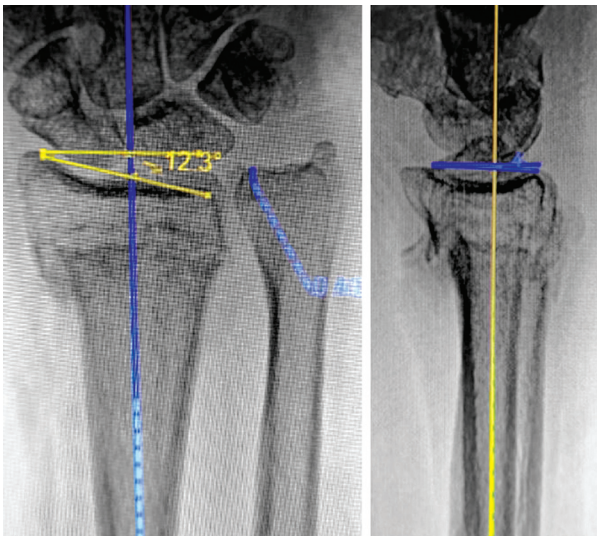


Fig. 4 Radiographs of the right wrist before surgery: decrease in the radioulnar angle (PI), palmar tilt and increase in the radioulnar index (UV)

of Żyluk et al. [25], a pronounced DCTS severity was diagnosed. The function of the right upper limb according to the DASH-score was 45.8 points (poor).

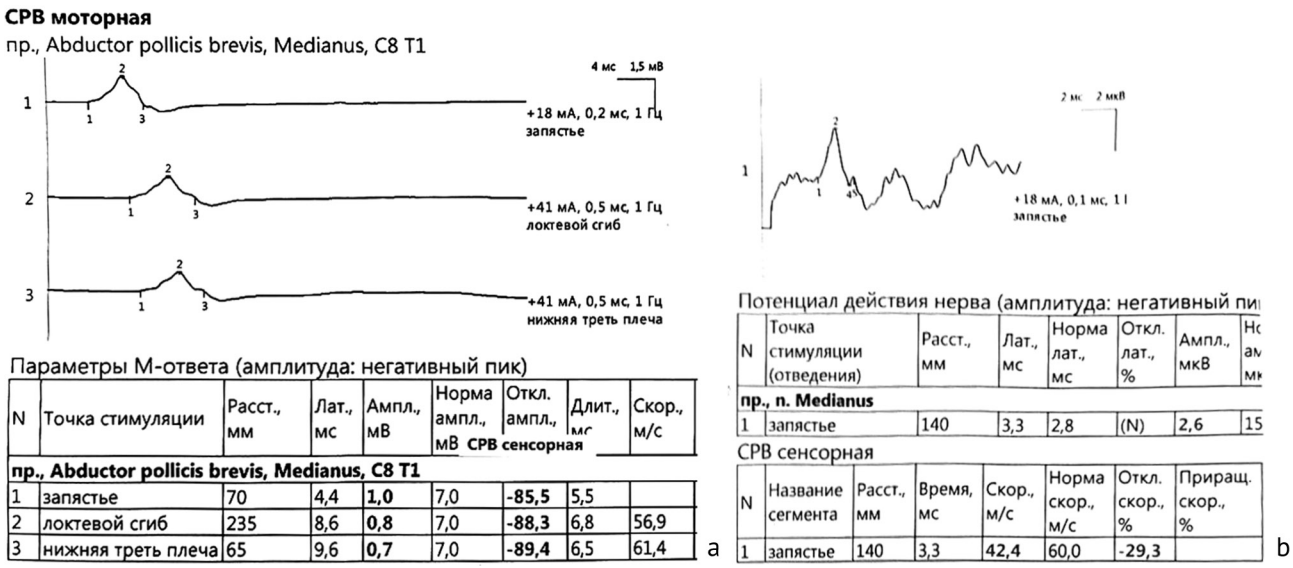


Fig. 5 ENMG parameters before surgery: a decreased M-response of the median nerve on the right wrist (APB-CMAP); b decreased conduction velocity along the sensory fibers of the median nerve on the right wrist (SCV)

In a planned manner, open decompression of the median nerve with epineurotomy and lateral neurolysis was performed from a separate limited approach on the palmar surface of the right wrist (Fig. 6 a). Next, extra-articular open-angle corrective osteotomy and DMR osteosynthesis were performed from the palmar approach on the forearm (Fig. 6 b). Results of osteotomy and DMR osteosynthesis were: the deformity was corrected, the bone fragments were fixed in a satisfactory position (Fig. 7).

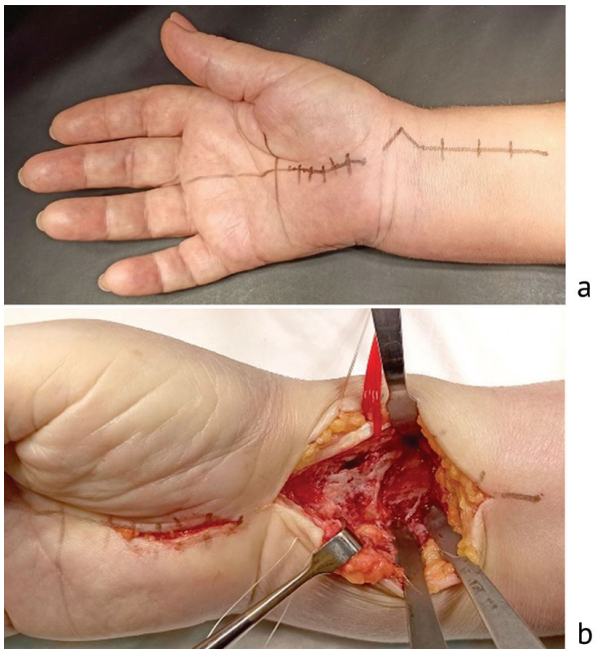


Fig. 6 View of the right forearm and hand on the operating table: a surgical approach marks; b view of the wound on the palmar surface of the wrist after open decompression of the median nerve and access to the distal radius for osteotomy and osteosynthesis

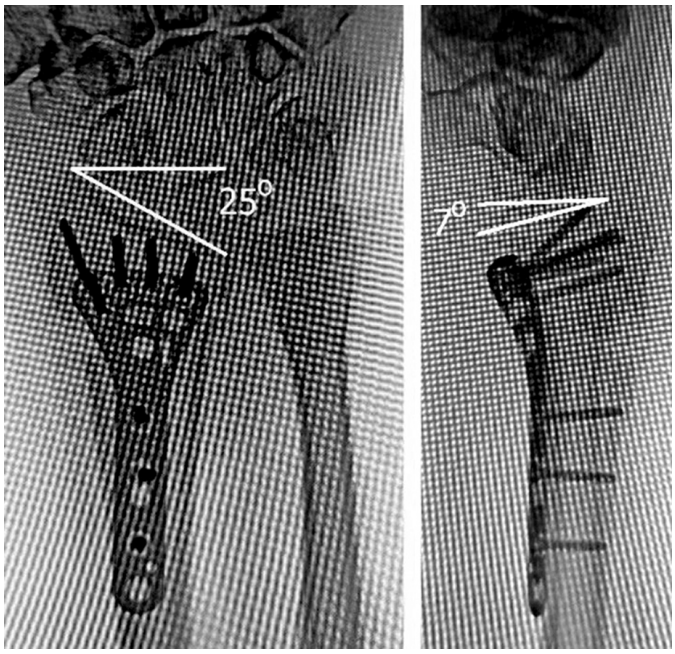


Fig. 7 Radiographs of the right wrist joint after surgery: correct relationships of the articular surfaces and the length of the forearm bones have been restored

The patient was examined one year later. She was satisfied with the result of the operation, complaining of periodic aching pain in the wrist joint only after heavy load (VAS, 2.8 points). The DMR is not deformed (Fig. 8), the total range of active movements in the right wrist joint compared to the contralateral limb is 91 % (Fig. 9), the strength of rough grip of the hand is 84 % (Fig. 10). ENMG showed restoration of the M-response, conduction velocity along motor and sensory fibers, distal motor latency normalization (Fig. 11). The indicators of daily activities (DASH-score) were 7.5 points, which corresponded to an excellent result.

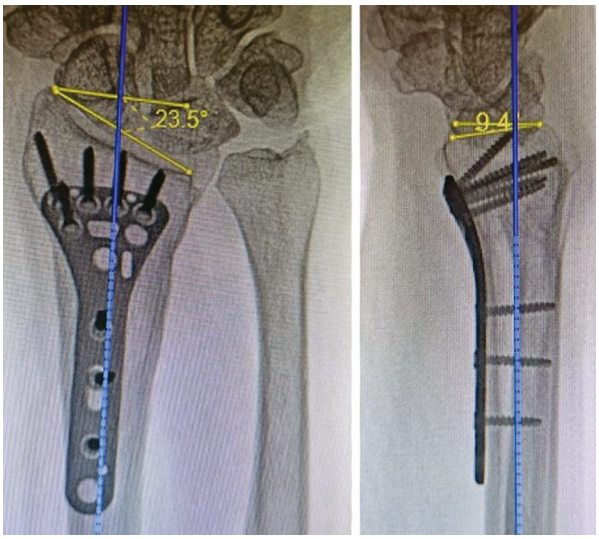


Fig. 8 DMR radiographs one year after the intervention

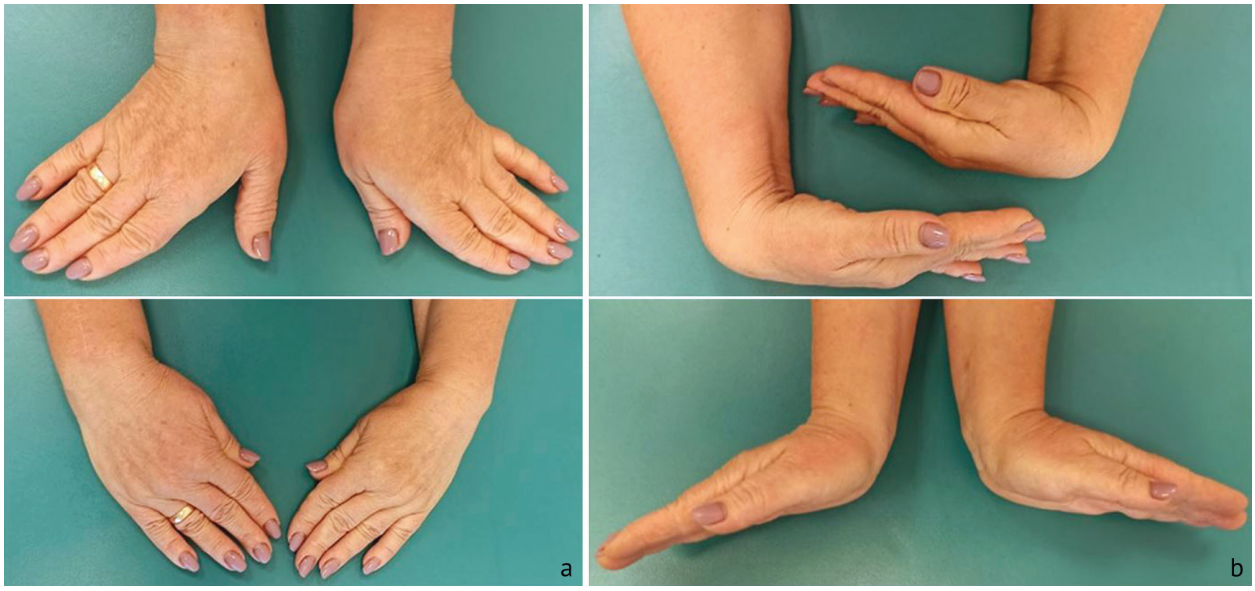


Fig. 9 Range of active movements in the wrist joint one year after surgery: *a* ulnar and radial abduction of the wrist; *b* flexion and extension of the wrist

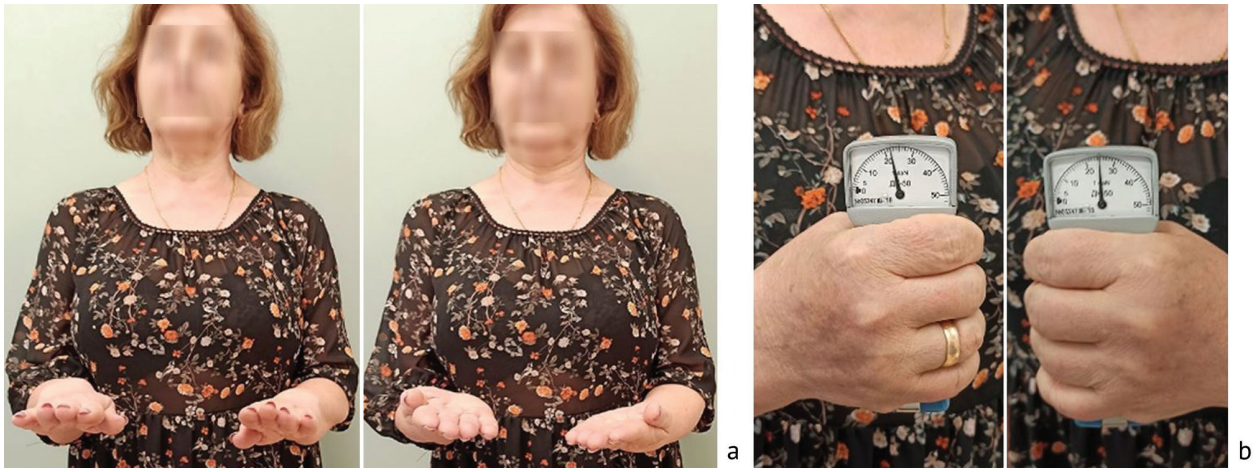
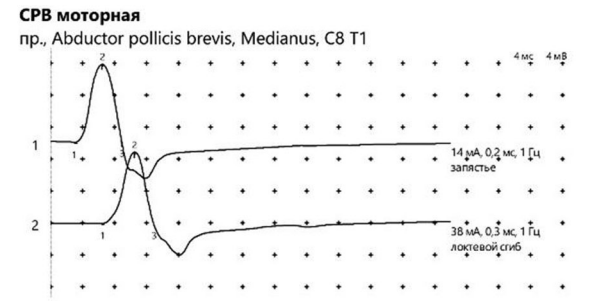


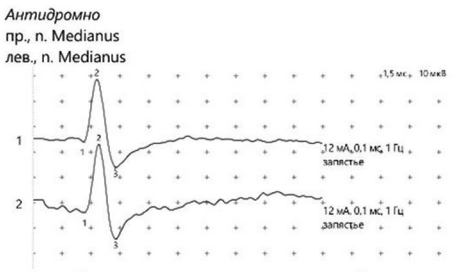
Fig. 10 Range of active movements in the wrist joint one year after surgery: *a* pronation and supination of the forearms; *b* measurement of the rough grip strength of the hands



Параметры М-ответа (амплитуда: негативный пик)

N	Точка стимуляции	Расст., мм	Лат., мс	Ампл., мВ	Норма ампл., мВ	Откл. ампл., %	Длит., мс	Скор., м/с
пр., Abductor pollicis brevis, Medianus, C8 T1								
1	запястье	55	3,0	9,7	7,0 (3,5-12,0)	(N)	5,9	
2	локтевой сгиб	210	6,5	8,9	7,0 (3,5-12,0)	(N)	6,4	60,3

a



Потенциал действия нерва (амплитуда: негативный пик, площадь: расчетный пик)

N	Точка стимуляции (отведения)	Расст., мм	Лат., мс	Норма лат., мс	Откл. лат., %	Ампл., мкВ	Норма ампл., мкВ	Откл. ампл., %	Скор., м/с
пр., n. Medianus									
1	запястье	130	2,6	2,8 (2,3-3,3)	(N)	24,5	15,0 (5,0-30,0)	(N)	50,8
лев., n. Medianus									
2	запястье	140	2,6	2,8 (2,3-3,3)	(N)	26,9	15,0 (5,0-30,0)	(N)	53,0

b

Fig. 11 ENMG parameters one year after surgery: a normalization of the M-response and conduction velocity along the motor fibers of the median nerve on the right wrist; b improvement of conduction velocity along the sensory fibers of the median nerve

DISCUSSION

The assertion of most hand surgeons that malunion of DMR fractures contributes to the development of DCTS and that the only way to eliminate or reduce the manifestations of this complication is surgical is beyond doubt. However, the question of the preferred approaches for corrective osteotomy and decompression of the median nerve does not have a clear answer.

Thus, Watanabe et al. convincingly proved that in DMR fractures, the displacement of the distal fragment together with the wrist significantly changes the anatomical relationships of the structures of the carpal canal, thereby causing morphological and functional disorders in the median nerve. According to the authors, DCTS almost always developed within 6 weeks to 6 months in dorsal displacement of the center of the head of the capitate bone by 1 cm or more from the palmar cortical plate of the radius. Therefore, the authors recommended paying special attention to these patients even in the acute period of injury and take adequate measures to prevent it [16].

Kim et al. examined 216 elderly patients with malunion of the DMR fracture and diagnosed DCTS in only 12 % of patients at least 6 weeks after the fracture. Independent predictors of this complication were radiographic criteria of the volar tilt (VT) and tear drop angle (TDA). Their multivariate logistic regression analysis found that for each degree of decrease in the volar tilt angle and tear drop angle, the probability of developing DCTS increased by 12 and 24 %, respectively [27]. In our patients, the volar tilt angle ranged from (+)28° to (–)45°. Moreover, all of them had both clinical and ENMG signs of DCTS.

Bourque et al. found that the removal of the plaster cast 6–8 weeks after injury caused paresthesia in the area innervated by the median nerve in 20 %, and after another week in 26 % of patients. However, ENMG performed at the same time did not detect signs of focal demyelination of the median nerve or “axon loss” in none of them [28].

In our 33 patients, nerve conduction disorders were recorded in all patients with ENMG study performed upon admission for surgical treatment. In 10 patients (30.3 %), ENMG changes corresponded to a severe grade, in 6 patients (18.2 %) to a moderate grade, and in the remaining 17 patients (51.5 %) to mild DCTS.

Stewart et al. found that in 235 patients with fractures of the DMF, aged 66 years on average, and treated conservatively, the rate of DCTS at 3 months after injury was 17 %, and 12 % 6 months later. The authors explained the relatively low DCTS rate by avoiding excessive flexion of the wrist when applying an immobilization plaster cast in the acute period of injury. Due to the developed DCTS, 8 patients (3.4 %) required surgical treatment. All of them underwent a standard decompression of the median nerve, with an incision at the level of the carpal tunnel (n = 7) and extended technique with another incision at the level of the fracture (n = 1). The PI of the articular surface of the DMR in them was ⩾ (+)12.6°. At the same time, patients with an inclination angle ⩽ (+)7° did not have DCTS symptoms [11]. This study clearly showed that DCTS does not develop in all patients with malunion of DMR fractures.

According to Kwasny et al., it is sufficient to perform isolated opening wedge osteotomy and osteosynthesis without median nerve release in malunion of DMR fracture complicated by DCTS in order to eliminate tension and compression of the median nerve. After such an operation, night pain stopped in 12 patients within 2 days, and tactile and pain sensitivity in the fingers was restored within 2 months. One patient required an additional operation, open decompression of the median nerve, which was performed 6 months after the first one. It should be noted that all patients were diagnosed with pronounced predominantly dorsal deformity of the articular surface of the radius in the sagittal plane ranging from (–)17° to (–)47°. The authors noted a direct proportional relationship between the duration of the clinical DCTS picture from the moment of its onset to surgery and the fair clinical results of restoration of the function of the median nerve [18].

Megerle et al. performed only corrective osteotomy with DMR osteosynthesis without additional intervention for decompression of the median nerve in 30 patients with malunion of the DMLC fracture accompanied by DCTS. Of these, clinical manifestations of DCTS before surgery were present in 7 patients (23.3 %), and ENMG disorders were present in 19 (63.3 %). In the late period, pain relief and improved sensitivity in the fingers were recorded in 10 patients (33.3 %). ENMG signs of improvement were revealed in 6 patients (20.0 %), and ENMG signs of normalization of nerve conduction were found in 4 patients (13.3 %). The authors concluded that corrective osteotomy is a self-sufficient treatment measure that effectively relieves the DCTS signs, and decompression of the median nerve in the carpal tunnel is indicated only in cases of DCTS that occurs before the injury and is associated with other causes, but not with a DMR fracture [19]. In our study, there were no patients with DCTS that occurred before the DMR fracture. In all of them, this complication developed in the late period, and reconstructive surgeries were performed within 3–13 months after the injury.

We believe that in the presence of clinical findings of DCTS, decompression of the median nerve, along with corrective osteotomy of the radius, is an indicated and even mandatory surgical intervention, regardless of DCTS severity. Moreover, chronic compression of the median nerve, in our opinion, requires not only the elimination of the DMR deformity and decompression of the nerve, but also its mobilization, and in moderate and severe DCTS - epineurotomy and neurolysis. In the present study, we noted a significant improvement in clinical, radiographic and ENMG characteristics in patients of both clinical groups, but to a greater extent in patients of the first group, who additionally underwent epineurotomy and neurolysis from a separate limited approach on the palmar surface of the wrist (OCTR approach).

Odumala et al. surgically treated 69 patients with DMR fractures without concomitant clinical DCTS and found that with simultaneous prophylactic decompression of the median nerve, complications such as its dysfunction developed in 38 % of patients. At the same time, in patients who did not undergo prophylactic decompression, the frequency of such complications was almost two times lower, amounting to 18 %. Thus, the authors stated that preventive decompression of the median nerve is inappropriate [29].

Niver et al. also believe that preventive release of the carpal tunnel during fracture fixation is inappropriate. The exception is patients who already had signs of CTS unrelated to trauma before the fracture. If decompression of the median nerve is still necessary, it should be performed through an incision along the tendon of the radial flexor carpi radialis or through a separate incision [30].

In our study, we used a separate Z-shaped incision with a total length of up to 4 cm for decompression of the median nerve in patients of the first group. We did not find a similar description in the available literature on the problem of DCTS. In its essence, this is a variant of the OCTR approach. What was important for us was that it allowed us to effectively perform not only decompression, but also epineurotomy and neurolysis, virtually eliminating the conflict with the motor and palmar sensory branches of the median nerve.

Weber et al. used an approach through the tendon of the radial flexor carpi radialis (a variant of the EFCR approach) to decompress the median nerve, which allowed them to sufficiently visualize the carpal tunnel without an auxiliary incision, significantly reduce the intensity of postoperative pain, and almost eliminate the incidence of postoperative complications. The authors claim that their method was effective in 91 % of clinical cases in terms of relieving DCTS symptoms [20].

Nevertheless, critics of this approach believe that its most frequent complication is damage to the motor branch of the median nerve. Therefore, Pensy et al. conducted a cadaveric study and found that the reverse motor branch of the median nerve most often passes 11 mm below the distal edge of the transverse ligament of the wrist. According to the authors, this parameter should be considered and will ensure safe dissection of the ligament, minimizing the likelihood of iatrogenic damage to the motor branch of the median nerve [31].

Gwathmey et al. performed DMR osteosynthesis in the acute period of injury and simultaneously performed preventive decompression of the median nerve in 65 patients (mean age, 48 years). To do this, the authors used an approach that allowed them to perform both osteosynthesis and dissection of the transverse carpal ligament along the radial side from a single skin incision, i.e. prophylactic decompression (a variant of the EFCR approach). According to them, this approach did not involve skin incision extension and its transition to the wrist. At the same time, it allowed avoiding direct contact with the median nerve. All patients had no signs of CTS before the operation. In the postoperative period, two developed late neuropathy of the median nerve, which did not require surgical correction. However, no one experienced complications associated with damage to the sensory or motor branches of the median nerve, or damage to the tendons [21].

Tannan et al. performed osteosynthesis with palmar plates in 27 patients with acute DMR fractures that did not have signs of acute CTS in a prospective study. For this purpose, the EFCR approach was used in 15 patients (the first group), with simultaneous preventive decompression of the median nerve, and the traditional Henry (VH) approach along the anterior surface of the forearm, which involves only DMR osteosynthesis was used in 12 patients (the second group). In both groups, a significant improvement in the function of the upper limb and an increase in the grip strength of the hand were noted. However, in the first group, statistically significant improvement was achieved after 1.5 months, and in the second after 3 months after surgery. The authors concluded that it is advisable to simultaneously perform osteosynthesis and prophylactic release of the median nerve with the preferred use of the EFCR approach [23].

The results of our study indicate that the EFCR approach should be recommended for patients with mild DCTS and predominantly palmar DMR deformity, when there is no need for nerve mobilization, epineurotomy, and neurolysis. In patients with moderate and severe DCTS, as well as with intermediate and predominantly dorsal DMR deformity, the OCTR approach is most appropriate. An appropriate limited incision on the palmar surface of the wrist allows for minimally traumatic and at the same time maximally effective decompression, epineurotomy, and neurolysis, prevents the formation of a linear constricting scar in the area of the palmar crease of the wrist, and minimizes the risk of damage to the superficial palmar branch of the median nerve.

CONCLUSION

Corrective osteotomy and simultaneous decompression of the median nerve in patients with malunited DMR fractures and developed DCTS is an effective and reliable method of surgical correction of the resulting complication.

In mild DCTS, as well as in cases of predominantly palmar DMR deformity, it is advisable to perform decompression of the median nerve through the EFCR approach, which involves an incision in the lower third of the forearm.

In moderate and severe DCTS, as well as in intermediate and predominantly dorsal DMR deformity, decompression of the median nerve should be performed through the OCTR approach, which involves a separate limited incision on the palmar surface of the wrist.

In most patients, regardless of the DCTS severity, corrective osteotomy and osteosynthesis of the distal metaepiphysis of the radius are best performed through an incision in the lower third of the forearm along its anterior surface. However, in patients with predominantly dorsal deformity, it is advisable to use an additional mini-incision on the dorsal surface of the forearm, which enables o reduce and ensure strong fixation of bone fragments as correctly as possible.

Conflict of interests *The authors confirm that they have no conflict of interest. .*
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Intramedullary osteosynthesis for pediatric forearm re-fractures depending on the time of occurrence

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Abstract

Background Tactical and technical errors in repair of pediatric forearm fractures can be associated with various complications including refractures. There are many questions regarding diagnosis (osteoreparation at the time of the occurrence) and in surgical treatment.

The **objective** was to improve outcomes of pediatic forearm refractures treated with intramedullary osteosynthesis considering a osteoreparation period and the time of the occurrence.

Material and methods There were 48 children with forearm refractures treated in the clinic between 2010 and 2020. The patients were divided into two groups. Patients of group 1 ($n = 25$) were treated with intramedullary osteosynthesis neglecting the regenerative process and the timing of refracture relative to the primary fracture. Patients of group 2 ($n = 23$) sustained a recurrent fracture at 6 months of early osteoregeneration with developing callosity. Re-fracture occurred in 19 (76.0 %) patients of group 1 including six children (24 %) with two or greater occurrences. Recurrence was observed in 16 (69.6 %) cases of group 2 including seven patients (30.4 %) who sustained more than two fractures.

Results The timing of re-fractures, immobilization and gradual removal of fixation components can facilitate improved short- and long-term results of surgical treatment and prevent complications that were evident in 22 (95.6%) children of group 2 with good results observed at 6 months.

Discussion The calluses were replete with blood vessels indicating the normal regeneration for fractures that occurred at 6 months of the initial fracture. No vessels in the callus were seen after 6 months due to resorption of the bundles and poor fracture healing.

Conclusion The outcome of re-consolidation would be dependent on the stage of bone regeneration at the time of forearm refracture. The regeneration process was more effective in the early stage of re-fracture.

Keywords: repeated fracture, refracture, forearm, surgical treatment, intramedullary osteosynthesis, children

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INTRODUCTION

Pediatric forearm fractures are common and account for 43.6 % [1–4] of trauma cases. With new trends in repair of pediatric forearm fractures, the frequency of repeated forearm fractures is high and ranges between 4 and 21.3 % [1, 2, 5–10]. There are opposing opinions regarding the principles of pediatric treatment of repeated forearm fractures. Conservative treatment is commonly used for this cohort of patients [11–13]. The treatment strategy can be dissociated with the morphology of the fractures, and the problem remains poorly understood [14–17]. This causes poor treatment results and leads to various complications [18–20]. Intramedullary (IM) nailing can be associated with complications including inadequate fracture healing (0.7–0.9 % of cases), nonunion (2.2–3.8 %), delayed bone healing (5.1–7. 8 %) and recurrent fractures (2.1–2.3 %) [1, 6, 7, 19, 20].

The **objective** was to compare the results of IM nailing in children with forearm re-fractures at different times of the occurrence during osteoreparation.

MATERIAL AND METHODS

Forty-eight patients with forearm re-fractures were reviewed between 2010 and 2020 at the Scientific and Practical Medical Center of Traumatology and Orthopaedics, Republic of Uzbekistan. The patients aged 3 to 18 years with the mean age of (9.75 ± 0.28) years. All therapeutic and diagnostic measures in children were carried out in the presence of parents with the documented consent. The patients were divided into two groups. Patients of group 1 (n = 25) were treated with IM osteosynthesis neglecting the regenerative process and the timing of refracture relative to the primary fracture. Patients of group 2 (n = 23) sustained a recurrent fracture at 6 months of early osteoregeneration with developing callosity. Re-fracture occurred in 19 (76.0 %) patients of group 1 including six children (24 %) with two or greater occurrences. Recurrence was observed in 16 (69.6 %) cases of group 2 including seven patients (30.4 %) who sustained more than two fractures (Table 1). Clinical assessment of consolidation and functional status, and radiological assessment of the pathological site were produced for the patients.

Table 1

Distribution of patients by type, number and location of re-fractures

Type and location of the fracture	Number of patients			
	Group 1, n = 25		Group 2, n = 23	
	abs.	%	abs.	%
Original fracture pattern				
Transverse fracture	12	48.0	16	69.6
Oblique-transverse fracture	13	52.0	7	30.4
Number of re-fractures				
one	19	76.0	15	65.2
More than one	6	24.0	8	34.8
Re-fracture location				
Upper third	3	12.0	7	30.5
Mid third	12	48.0	11	47.8
Lower third	10	40.0	5	21.7

The secondary fracture line coincided with the line of the primary fracture in all patients. Patients of both groups underwent surgical treatment using open intramedullary antegrade osteosynthesis. Closed osteosynthesis was not performed due to the fact that the medullary canal was closed by endosteal callus and prevented the passage of the wire. Re-fractures occurred within 2 to 4 months of the primary fracture in the majority of cases, in 32.0 % of cases of group 1 and in 56.5 % of cases in group 2 (Table 2).

Table 2

Distribution of patients according to the timing of re-fractures depending on the ongoing osteoreparation relative to the first fracture

Groups	2 months		2 to 4 months		4 to 6 months		6 to 12 months		More than 12 months	
	abs.	%	абс.	%	абс.	%	абс.	%	абс.	%
Group 1, *n* = 25	3	12.0	8	32.0	7	28.0	5	20.0	2	8.0
Group 2, *n* = 23	4	17.4	13	56.5	6	26.1	–		–	

We have developed an algorithm of surgical strategy for pediatric forearm re-fractures with regard to the timing of their occurrence relative to the primary fracture, location and fracture pattern, and displacement.

Re-fracture of 2–4 months was characterized by a normal fusion process, sufficient blood supply at the site of the periosteal callus. A re-fracture in the phase of callus resorption was accompanied by delayed healing or nonunion.

Indications for intramedullary osteosynthesis with Kirschner wires included:

— child aged 9 years and younger;

— a re-fracture occurred within three months;

— periosteal and paraosseous callus at the re-fracture site seen in an X-ray or MSCT image;

— displacement by 1/3 of the bone diameter and length, a deformity measuring more than 10°.

Indications for intramedullary osteosynthesis with Kirschner wires and Ilizarov external fixation:

— child's age over 9 years;

— a forearm re-fracture occurring during consolidation of the primary fracture within 6 months;

— periosteal, paraosseous and endosteal callus detected at the site of re-fracture on an X-ray or MSCT image;

— displaced bone at the re-fracture site.

Contraindications for intramedullary osteosynthesis with Kirschner wires and Ilizarov external fixation:

— open fracture and cntaminated wound of the soft tissues;

— a second fracture of the forearm bones occurred during consolidation of the primary fracture for more than six months;

— resorption of periosteal and paraosseous calluses and the presence of an endosteal callus at the re-fracture site seen in the X-ray or MSCT image;

— no bone displacement.

Surgical treatment of forearm re-fractures was produced in two stages with regard to the fracture pattern using IM osteosynthesis. The first stage included IM osteosynthesis with wires and application of a plaster cast with pediatric procedures performed under general anesthesia. Periosteal and paraosseous calluses were not removed intraoperatively. At 6 months of control radiography wires could be removed and segmental plaster casts applied for two weeks with bone fused, to improve medullary circulation and create conditions for endosteal callosity. The results were rated as “good” with 3 scores, “fair” with 2 scores and “poor” with 1 score. The results were based on

clinical, radiological, and functional aspects of the injured limb. The scoring allowed visual evaluation of the outcomes and comparison with a qualitative assessment, which we did for the first time. The assessment criteria of the results of treatment that we developed were used for the "Program for assessing the results of treatment for pediatric re-fractures" registered with the Intellectual Property Agency of the Republic of Uzbekistan (No. DGU 04277 dated March 1, 2017). Linear methods were used for statistical analysis. Arithmetic means, standard errors of arithmetic means, and standard deviations were calculated. A comparative analysis of the significant differences between the study groups was produced using the Student's t test. Differences were considered significant with the level of significant differences being $p<0.05$ (95 % confidence level) in individual parameters in the groups. Statistical calculations were produced using Excel-2013 built-in statistical functions.

RESULTS

Neither fair nor poor results were noted at a short (Table 3) or long term (Table 4) in the groups of children with re-fractures within 4 months of the primary fracture.

Table 3

Short-term results

Time frame for re-fracture, months	Group 1 (n = 25)						Group 2 (n = 23)					
	good		fair		poor		good		fair		poor	
	abs.	%	abs.	%	abs.	%	abs.	%	abs.	%	abs.	%
До 2	3	12.0	–	–	–	–	4	17.4	–	–	–	–
2–4	8	32.0	–	–	–	–	13	65.5	–	–	–	–
4–6	4	16.0	3	12.0	–	–	4	17.4	2	8.7	–	–
6–12	1	4.0	3	12.0	1	4.0	–		–	–	–	–
Over 12	–	–	–	–	2	8.0	–	–	–	–	–	–
Total	16	64.0	6	24.0	3	12.0	21	91.3	2	8.7	–	–

Table 4

Long-term results

Time frame for re-fracture, months	Group 1 (n = 25)						Group 2 (n = 23)					
	good		fair		poor		good		fair		poor	
	abs.	%	abs.	%	abs.	%	abs.	%	abs.	%	abs.	%
До 2	3	12.0	–		–		4	17.5	–		–	–
2–4	8	32.0	–		–		13	56.5	–		–	–
4–6	6	24.0	1	4.0	–		5	21.7	1	4.3	–	–
6–12	3	12.0	1	4.0	1	4.0	–		–		–	–
Over 12	1	4.0	–		1	4.0	–		–		–	–
Total	21	84.0	2	8.0	2	8.0	22	95.7	1	4.3	–	–

Note: presented are 1-year outcomes of re-fractures that occurred at different times after the first fracture

No poor results at short and long terms were reported for re-fractures that occurred at 4 to 6 months. In the immediate period for periods of more than 6 months. the result in Three patients of group 1 showed a poor result at a short term within a period of more than 6 months due to pathological periosteal and paraosseous callosity seen radiographically and on MSCT images with the callus being partially sclerotic at the ends of the broken bone. A fair result at a long term was observed in one patient of group 2 who developed very slow bone fusion at the re-fracture site that led to prolonged immobilization and contractures in adjacent joints. The same picture was observed in the period of 6

to 12 months with a fair result seen in 3 patients of group 1 at a short term. Radiographs and MSCT images showed sclerotic periosteal and paraosseous calluses at the top of the bone fragments at the re-fracture site with the dissolving endosteal callus. Despite the strong bone fixation, a slow healing process was observed in the patients treated with intramedullary osteosynthesis and resultant contractures. Joint contractures were completely eliminated in two patients at a long term. The range of motion in the joints was limited to 60° in one patient and rated as fair. A poor result in the group of children was observed due to bone sclerosis and resorption of callus at a short- and long-term period, in 1 case each (due to non-union of a secondary fracture). For repeated fractures that occurred at 12 months of the primary fracture, a poor result was noted in 2 patients at a short term with sclerotic re-fractured bone ends seen on MSCT images indicating bone restoration. This period was the stage of callus resorption and bone formation. Blood circulation at the re-fracture site appeared as an unusual process causing high complication rate in re-fractures observed during this period. These patients underwent repeated surgical treatment (resection of the incomplete area) with the outcome rated as good at a long term in one case and with no changes in the 'poor' rating in the other case.

Fair and poor results were not seen in children of group 2 with re-fractures occurred within 4 months of the primary fracture. The patients had adequate periosteal and paraosseous calluses visualized on MSCT and radiographs. Re-fractures that occurred at 4 to 6 months of the primary fracture osteoreparation were assessed as fair in two cases at a short term due to joint contracture. One child developed a good joint function completely restored at a long term, and another case demonstrated a fair result due to the remaining contracture in the joints. No osteoreparation of the primary refracture was observed in the group at 6 months. A comparative analysis of treatment outcomes in both groups showed that bone healing after a second fracture was dependent on the callosity which was caused by refractory conditions during the primary consolidation. Clinical, functional and radiological scores showed significantly better results at a short (91.3 % vs. 64 %) and at a long term (95.6 % vs. 84 %) in group 1 with use of intramedullary wires (Table 5).

Table 5

Results of intramedullary osteosynthesis of pediatric forearm refractures in the control and treatment groups at a short (up to 1 year) and long term (more than 1 year)

Group 1					
Clinical and radiological criteria		Re-fractures (*n* = 19)		Two and more fractrures (*n* = 6)	
		Short-term results	Long-term results	Short-term results	Long-term results
Clinical score		2.52 ± 0,16	2.89 ± 0.07	2.16 ± 0.4	2.3 ± 0.36
Radiological score		2.52 ± 0,14	2.84 ± 0.11	1.83 ± 0.4	2.33 ± 0.42
Functionality	Flexion in the wrist				
	dorsal,°	31.3 ± 1.79	69.2 ± 1.39	45.0 ± 10.4	74.2 ± 5.08
	palmar,°	26.3 ± 1.75	63.15 ± 1.4	37.5 ± 7.74	68.3 ± 4.02
	ROM,°	57.6 ± 3.43	131.8 ± 2.3	82.5 ± 17.8	144.2 ± 8.34
	Flexion / extension in the elbow joint				
	flexion, °	80.5 ± 1.57	51.6 ± 1.9	74.2 ± 6.4	50.8 ± 5.25
	extension, °	144.4 ± 3.08	164.7 ± 3.004	143.3 ± 6.69	164.2 ± 6.1
	ROM °	63.9 ± 4.4	113.1 ± 3.8	69.2 ± 10.8	113.3 ± 9.6
Immobilization period (days)		61.4 ± 1.02		61.3 ± 1.77	
Range of individual values		54–67		55–68	

Table 3 (continued)

Results of intramedullary osteosynthesis of pediatric forearm refractures
in the control and treatment groups at a short (up to 1 year) and long term (more than 1 year)

Group 2			
Clinical and radiological criteria		Re-fracture (*n* = 16); Two and more fractrures (*n* = 7)	
		Short-term results	Long-term results
Clinical score		2.7 ± 0.15	3
Radiological score		2.9 ± 0.1	3
P		< 0.001	
Functionality	Flexion in the wrist		
	dorsal,º	64.5 ± 3.02	81.0 ± 1.45
	palmar,º	70.0 ± 2.35	85.0 ± 1.4
	ROM,º	134.5 ± 5.2	166 ± 2.33
	Flexion / extension in the elbow joint		
	flexion, º	44.0 ± 1.94	37.5 ± 0.83
	extension, º	173 ± 2.001	180
	ROM º	129 ± 3.48*	142.5 ± 0.8
P		< 0.001; < 0.0001*	
Immobilization period (days)		57.0 ± 1.49	
Range of individual values		52–61	

Note: * — *P* < 0.0001 relative to the results in the control group.

Clinical instance

A 12-year-old patient K.D. sustained an injury 11/2 years ago falling on his arm while playing with friends, as reported in the medical history and told by his parents. On admission he was diagnosed with closed displaced fracture of the mid shaft of the left forearm. The fracture was reduced under local anesthesia and a plaster splint applied. The patient was treated as an outpatient and immobilization lasted for 1 month. The child sustained the second fracture from a fall at 6 months. A plaster cast was applied at a local clinic and the patient was followed up as an outpatient. Immobilization lasted for 40 days, consolidation was achieved clinically and radiologically. The third injury occurred from falling on the arm stumbling over at school and was hospitalized in the pediatric trauma department. The radiograph showed a residual angular displacement after the primary fracture; re-fracture occurred as a result of changes in bone physics. The paraosseous and periosteal callosity dissolved, and the endosteal callus was not fully formed. The regenerate bone appeared as the Kaplan 5th morphological and 4th clinical stages indicating resorption of paraosseous and periosteal callosity with the endosteal callus formed. Reduction was performed and the control radiograph showed poor bone re-alignment followed by intramedullary osteosynthesis of the left forearm bones. Intramedullary wires were removed after 21/2 months of surgery that resulted in limited motion in the elbow joint. The regeneration appeared as 4 morphological and 3–4 clinical phases. The periosteal and paraosseous callosity completely restored with developing endosteal callus indicating restoration of the bone strength and immobilization removed. Rehabilitation for the patient continued over the next 2 months and resulted in elbow functionality restored.

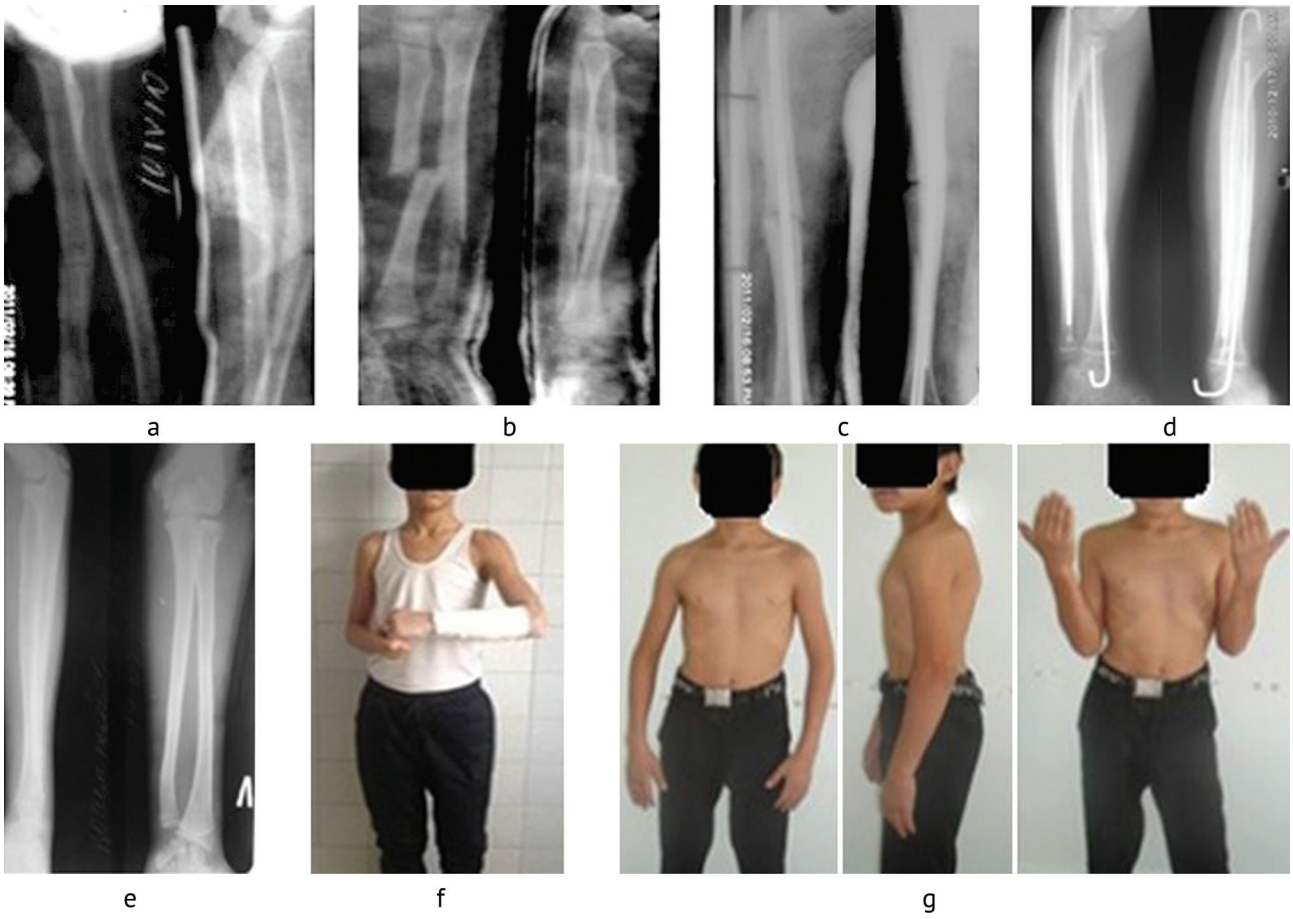

Fig. 1 Radiographs showing (*a*) primary fracture; (*b*) re-fracture; (*c*) re-fracture following intramedullary osteosynthesis; (*d*) bone regeneration at a month; (*e*) bone regeneration at 9 months of surgery. Photo of the patient showing (*f*) appearance of the patient with a segmental plaster cast applied; (*g*) functionality of the joint

DISCUSSION

Flexible intramedullary nailing (FIN) is reported as the method of choice for the surgical treatment of pediatric forearm re-fractures [11, 13]. FIN has important advantages of minimal invasiveness, stable fixation, the possibility of early limb function, good cosmetic results, low risk of complications [4], shorter inpatient period and more rapid return to everyday life. Intramedullary osteosynthesis with a wire is difficult to perform in a closed manner for a re-fracture case due to the closure of the bone marrow canal providing no opportunity for stability during bone reduction. Thin wires can be used for re-fractured bones with a narrow medullary canal [10], but wires with a smaller diameter can cause a bone re-fracture or instability of the fracture during surgical treatment [7]. Wires with a larger diameter were suggested [3]. Wires with a diameter 2/3 of the diameter of the medullary canal were used in closed reduction. They believed that fractures treated with FIN can be associated with bone re-fractures. FIN is recommended to be used for 10–12 months to minimize the risk of re-fractures [12, 16]. Re-fractures can occur with wires, therefore, there is little benefit from leaving the wires longer for complete fracture healing. Pinning can be associated with skin perforation, requiring additional intervention, subcutaneous hematoma and joint contracture, incomplete elimination of diastasis between bone fragments at the fracture site, and limited forearm rotation [2, 8, 11, 19].

Morphological examination of re-fractures and primary fractures were experimentally conducted in laboratory animals [15]. A re-fracture occurred in the early period of consolidation with the callosity of the primary fracture heals well in the callus and in the cortex of the

involved bone due to good blood circulation. The risk of complications in the form of impaired consolidation can be reduced. A re-fracture occurring in the late period of healing of the primary fracture, i.e. during the callus resorption heals longer due to deteriorated blood circulation at the site [15]. Intramedullary osteosynthesis used for re-fractured forearm bones in children can lead to various complications including delayed consolidation, nonunion, pseudarthrosis and contractures of adjacent joints the morphology of the fracture is neglected. The timing of the primary fracture is essential for a good outcome of a pediatric re-fracture. If a re-fracture occurs in the late stages of healing of the primary fracture, the calluses can dissolve and the bone would have a pathological structure. Callosity in the phase of completely healed primary fracture is important for a positive effect on osteoreparation with a re-fracture. Therefore, staged surgical treatment of pediatric forearm refractures using intramedullary osteosynthesis during this period considering the regeneration and stages of callus formation facilitates good results and reduced complication rate. The regeneration of a primary fracture occurs in several stages that are essential for repair of pediatric forearm re-fractures. Taking into account the morphological and radiological manifestations of the callosity are important for achieving good outcomes at the time of re-injury.

CONCLUSION

Surgical treatment of patients with re-fractures and periosteal and paraosseous callosity suggests their preservation in early 3-month re-fractures relative to the first fracture. Intramedullary osteosynthesis used to repair pediatric forearm re-fractures at an early stage provides tension at the fracture site and allows bone consolidation to be achieved at a short term. A balanced approach to the choice of surgical treatment considering the stage of callus formation, staged removal of fixation components can significantly reduce immobilization period and help avoid poor results and complications, and reduce fair outcomes by 2.2 times compared to the comparison group. A differentiated approach to intramedullary osteosynthesis used to repair re-fractures considering the stage of osteoreparation and the timing of the occurrence relative to the first fracture can improve surgical results at the short and long terms.

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Compensation of acetabular defects in primary and revision hip arthroplasty

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Abstract

Introduction Total hip arthroplasty in defects of the acetabulum is a complex type of surgical intervention, and the search for optimal implants and bone substituting materials to restore the integrity of the acetabulum is one of the current problems.

The **aim** of the work was to analyze the results of primary and revision hip arthroplasty with compensation of acetabulum defects.

Materials and methods The study material consisted of 93 patients with primary (65) and revision (28) total hip arthroplasty in the presence of bone defects of the acetabulum of varying severity. To systematize primary defects, the classification of the American Association of Orthopedic Surgeons (AAOS, 2017) was used; for defects in revision surgeries, the classification of W.G. Paprosky (1994) was used. Clinical, radiological, and statistical study methods were used. The results of managing bone defects of the acetabulum with various methods of compensation were studied. The Harris Hip Score (HHS), 1969, was used to assess the function of the involved joints.

Results Depending on the type of acetabular defects, an algorithm was developed for choosing a bone grafting method for acetabular defects and implanting the cup. The best results were observed for cases of a combination of resorbable and non-resorbable bone graft materials and cementless fixation of the pelvic component. A clinical example of three consecutive revision interventions on one hip joint in a patient with bilateral dysplastic coxarthrosis is presented.

Discussion The most widely used method of bone grafting in primary arthroplasty is plastic surgery with autologous chips from the femoral head. In significant bone tissue loss, one of the plastic surgery options is a structural auto- or allograft, the use of which allows restoring the rotation center and forming a bone support for possible future revisions; poor results with this method are caused by allograft lysis. In revision arthroplasty on the hip joint in large defects, plastic surgery of the defect is performed with crushed or structural allograft bone. An antiprotrusion constructs or cups made of trabecular metal are installed; in instability of the pelvic ring, osteosynthesis of the posterior column is required. Trabecular metal structures feachuring high porosity and adhesion to bone and the elastic modulus close to bone tissue provide conditions for optimal primary and secondary fixation of the component.

Conclusion Long-term and painless functioning of the hip joint after arthroplasty performed for acetabular defects is possible with restoration of the spherical shape of the acetabulum and the center of joint rotation in the true acetabulum, adequate elimination of bone tissue loss, reliable primary fixation of the cup with provision of conditions due to restoration and osteointegration. Acetabular defects are diverse in their anatomical manifestations, which create difficulties in choosing pelvic components, augments, and the method of their fixation to the pelvic bone. Based on the type of the acetabular defect, an algorithm has been developed for choosing a method for acetabular bone defect filling and implanting a cup.

Keywords: hip joint arthroplasty, bone defect of the acetabulum, osteosubstitution material, bone grafting

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INTRODUCTION

Hip joint arthroplasty in the presence of acetabular defects is a complex type of surgical intervention. The search for optimal designs and bone substituting materials to restore the integrity of the acetabulum has been currently one of the pressing issues in traumatology and orthopaedics. Defects in the acetabulum are typical of congenital dysplasia, systemic connective tissue diseases, and pelvic bone fractures. Bone defects may be formed due to implant instability, after resection of bone tumors, and also may result from previous periacetabular osteotomies [1].

The choice of methods for filling acetabular defects is determined by the quantity and quality of the bone tissue in the site, the integrity of the acetabular columns, and the stability of the pelvic ring. In primary arthroplasty, small defects are filled with non-structural autografts from the resected femoral head or allograft chips. Large defects require massive supporting grafts, for which structural allograft bone, xenograft bone, or artificial bone substituting materials (calcium phosphate ceramics, metal and titanium augments) are suitable [2, 3]. In some cases, bone cement is used to fill defects; however, most researchers describe the negative effect of cement on bone tissue, provide data on a large number of late complications and arthroplasty failures [4].

The main goal of filling an extensive defect of the acetabulum is to restore the integrity of the bone structure of the acetabulum, its hemispherical shape and the center of rotation of the hip joint to ensure primary stable implantation of the acetabular component [5].

Since the end of the last century, reinforcing and antiprotrusion rings with support on the lateral edges of the acetabulum (Müller, Ochsner, Gans, Burch-Schneider, Beznosko and other rings) have been used to manage defects of the acetabulum in both primary and revision arthroplasty. The most known is the reinforcing support ring, which was developed by M. Müller in 1977. Regularly, the size of the rings corresponds to the acetabulum; they are made of sheet metal, have bent edges for support and multiple holes for screws for attachment to the pelvic bone. To improve the osteointegrative qualities, the acetabular part of the ring can have a porous coating. The Burch – Schneider support ring is intended for defects that cannot be covered by the Müller ring. The use of Müller and Burch – Schneider support rings involves the initial filling of the defect with autogenous bone or allograft bone, and a support structure is installed press-fit on top of the bone graft. A standard cement cup is cemented into the support ring [6].

According to Schatzker et al., satisfactory results were obtained over a follow-up period of one to three years after twenty-five hip replacement surgeries (20 with Müller support ring, 5 with Burch – Schneider). It confirms the logic of their use in the treatment of patients with acetabular defects [7]. Currently, trabecular metal augments are increasingly used, as well as customized three-flange support structures, which are manufactured using computer modeling in cases of extensive defects and discontinuity of the acetabulum [8]. The results obtained by Kovalenko et al. show that acetabular reconstruction using the above-described techniques requires considering the individual anatomical features of the patient in providing surgical approach and implantation technology, otherwise the implant cannot be installed. Moreover, the first experience of customized implants was not always successful, and the rates of poor results remained high [9].

Purpose To analyze the results of primary and revision hip arthroplasty with compensation of acetabulum defects.

MATERIALS AND METHODS

The work was carried out within the framework of the state assignment 124020700095-4 FGBOU Ural State Medical University of the Ministry of Health of the Russian Federation for 2024–2026. The study was conducted in compliance with the ethical principles of the Helsinki Declaration and approved by the institutional ethics committee of the Ural State Medical University (protocol of 10.22.21 No. 9). All patients gave informed voluntary consent to participate in the study. The study design is presented in Figure 1.

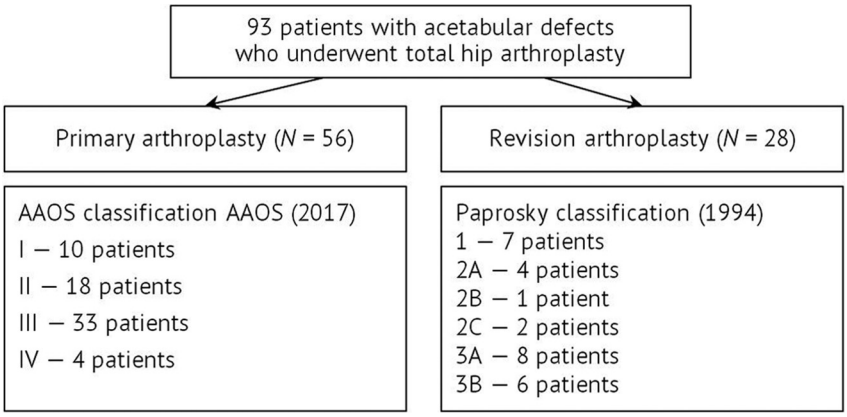

Fig. 1 Study design

The study material was 93 patients with primary and revision total hip arthroplasty in the presence of bone defects of the acetabulum of varying severity.

Primary arthroplasty was performed in 65 patients (21 men, 44 women), of which 26 patients were treated at the State Autonomous Healthcare Institution of the Sverdlovsk Region Regional Clinical Hospital No. 1, Yekaterinburg (Regional Clinical Hospital No. 1); 39 patients at the Ilizarov National Medical Research Center of Traumatology and Orthopaedics, Kurgan (Ilizarov Center). The average age of patients at primary arthroplasty was (56 ± 1.4) years.

Cementless arthroplasty was performed in 49 patients; cemented prostheses were installed in 16 patients. The following implant systems were used: Aesculap (*n* = 19), Smith&Nephew (*n* = 13), De Puy (*n* = 21), Zimmer (*n* = 12).

Revision arthroplasty was performed in 28 patients (2 men, 26 women), of which 19 patients were treated at the Regional Clinical Hospital No. 1; 9 at the Ilizarov Center. The average age of patients was (61.0 ± 2.4) years.

Cementless revision arthroplasty was performed in 12 patients, and cemented one in 16 patients. The ollowing systems were installed: Aesculap (*n* = 6), Smith&Nephew (*n* = 5), De Puy (*n* = 11), Zimmer (*n* = 6).

Age, social status and disability grade are presented in Table 1.

Table 1

Patients' age and social status

Категории		Primary arthroplasty (*n* = 65)		Revision arthroplasty (*n* = 28)	
		Number of patients	%	Number of patients	%
Age, years	18–44	11	17	3	10
	45–59	28	43	10	36
	60–74	23	35	11	40
	over 74	3	5	4	14
Social status	working	27	42	7	25
	Not working	10	15	2	7
	Not working pensioners	28	43	19	68
Disability	None	42	64	17	61
	Grade 3	14	22	6	21
	Grade 2	8	12	4	14
	Grade 1	1	2	1	4

Primary arthroplasty in the revision group of patients had been previously performed at the Regional Clinical Hospital No. 1 in four cases; at the Ilizarov Center in one case. The remaining 23 patients were initially treated at trauma hospitals of the Sverdlovsk and Kurgan regions.

To systematize primary defects, the classification of the American Association of Orthopedic Surgeons (AAOS, 2017) [10] was used due to its simplicity and the possibility of preoperative planning of bone grafting options. According to the AAOS classification, four types of acetabular defects are distinguished: type I is a segmental bone defect in the superior, anterior, or posterior part of the acetabulum; type II is a cavitary defect (bone cavity) in the superior, anterior, or posterior part of the acetabulum; type III is a combined segmental-cavitary defect; type IV is an obvious or hidden rupture of the pelvic ring [10].

The types of defects in patients with primary hip arthroplasty depending on the etiology of osteoarthritis (OA) according to the AAOS classification (2017) are presented in Table 2. The leading cause of acetabular defects in cases of primary arthroplasty was hip dysplasia. In 36 patients, dysplasia corresponded to Crow type II–III, in two cases to type IV [11, 12, 13]. The developing neoarthrosis at the level of the upper edge of the acetabulum and cranial displacement of the femoral head in Crow dysplasia II–III [11] led to the formation of defects in the roof of the acetabulum, corresponding to types II and III according to the AAOS classification (2017).

In systemic diseases of connective tissue (RA, systemic lupus erythematosus), due to porous bone tissue, a protrusive deformation of the acetabulum was formed with a medial displacement of the center of rotation of the joint, which led to the a defect in the bone tissue of the acetabulum in its central parts [14, 15].

Table 2

Types of defects in patients with primary THA depending on the etiology of OA according to the AAOS classification (2017)

Type of defects	I		II		III		IV		Total	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Hip dysplasia	–		12	67	24	73	2	50	38	58
Systemic diseases of the connective tissue	9	90	6	33	7	21	–		22	34
Trauma	1	10	–		2	6	2	50	5	8
Total	10	100	18	100	33	33	4	100	65	100

Post-traumatic deformities of the acetabulum result from of injuries — fracture-dislocations of the hip joint. Tikhilov et al. divide post-traumatic deformities of the acetabulum into three groups of patients: 1) patients with fractures of the acetabulum bottom with a slight displacement of fragments or after osteosynthesis of the posterior parts; 2) patients after a fracture of the posterior part of the acetabulum with a defect in the area of the posterior wall and / or roof of the acetabulum of varying length; 3) patients with a complete violation of the anatomy of the acetabulum resulting from a defect in the posterior wall, roof, or from malunion of bone fragments [16]. In the first group it is possible to perform primary standard implantation of a cementless cup, while in the second and third groups, bone grafting, augments and revision support rings are required for implantation of the pelvic component. The most common post-traumatic defects of the acetabulum are in the posterior-superior part and are combined with subluxation of the hip and persistent flexion-adduction contracture. The acetabulum looks oval and elongated, the posterior wall is destroyed, and the head of the femur is displaced backwards and upwards.

To systematize revision defects, the Paprosky classification [17] was used. This classification reflects in detail the anatomical location of the defect and allows choosing the optimal method for replenishing bone tissue deficiency during preoperative planning, and considers technical difficulties during the intervention. According to the classification of W.G. Paprosky, there are

3 types of acetabular defects. Type 1 defect involves the presence of single or multiple bone cysts, the total volume of which does not exceed 10 mm^3. Subtype 2A is a superomedial cavitary defect; 2B defects are segmental superolateral defects, when bone loss does not exceed 1/3 of the acetabulum circumference; 2C is a defect of the medial wall of the acetabulum; 3A defect is a superolateral migration of the acetabulum or "up and out", intact medial support (lateral to the Kohler line) and lysis is observed in the ischial bone area; 3B defect is a superomedial migration or “up and in”, there is no medial and superior support (rupture of the Kohler line), pronounced lysis of the ischium (less than 15 mm above the superior obturator line), complete destruction of the “teardrop figure”; type 4 defect is an obvious or hidden rupture of the pelvic ring.

The types of defects according to the classification of W.G. Paprosky in patients with revision hip replacement depending on the initial disease/injury before primary arthroplasty are presented in Table 3.

Table 3

Types of defects according to the classification of W.G. Paprosky in patients with revision hip replacement depending on the underlying disease/injury before primary arthroplasty

Types of defects	1		2A		2B		2C		3A		3B		Total	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Trauma	4	57	1	25	1	100	1	50	4	50	1	20	12	43
Systemic diseases of the connective tissue	1	14	2	50	–		1	50	2	25	3	50	9	32
Hip dysplasia	2	29	1	25	–		–		2	25	2	30	7	25
Total	7	100	4	100	1	100	2	100	8	100	6	100	28	100

In patients with revision arthroplasty, the leading reason for performing primary arthroplasty was previous trauma. Of 28 cases of revision arthroplasty, early instability (up to 5 years after primary arthroplasty) developed in 15 patients (54%), late instability (after more than 5 years) in 13 (46%).

Study methods

Clinical The mid-term values of hip joint function were assessed using the Harris scale [16]: 90 points or more were considered an excellent result; 80–89 points — a good result; 70–79 points — a fair result; 69 points or less — a poor result.

Radiological The plain radiograph of the pelvis was assessed in a direct view, and the affected hip joint with the femur in direct and lateral views.

The computed tomography method was used to clarify the grade of acetabulum bone loss according to the AAOS classification for primary arthroplasty, and Paprosky classification was used for revision arthroplasty.

Statistical method The Statistica 8.0 analysis package was used in the study. Descriptive statistics data are presented as M ± SD; where M is the mean value, SD is the standard deviation.

RESULTS

Information on the methods of bone grafting and midterm results are presented in Table 4.

Based on the analysis of Table 4, it can be noted that in primary arthroplasty, type I defects were filled with bone cement in two cases, which is quite acceptable for cemented arthroplasty which was performed in these two cases; in eight cases (three cementless prostheses and five cemented ones), the defects were filled with bone chips from the resected femoral head.

Table 4

Methods of bone defect management in primary arthroplasty based on the type of defect according to the AAOS classification and HHS results

Method of defect compensation / functional outcome		Excellent		Good		Fair		Poor		Total	
		⩾ 90 points		80–89 points		70–79 points		⩽ 69 points			
		n	%	*n*	%	*n*	%	*n*	%	*n*	%
I type (4 ± 2)*	Bone autograft from femoral head	1	10.0	3	11.0	2	10.0	2	25.0	8	12.3
	Bone cement	1	10.0	1	4.0	–		–		2	3.1
II type (7 ± 2)*	Non-structural femoral head autograft	–		2	7.0	2	10.0	1	12.5	5	7.7
	Structural autograft from the femoral head, fixed with screws	2	20.0	6	21.0	3	15.0	2	25.0	13	20.0
III type (4 ± 3)*	Non-structural femoral head autograft	2	20.0	3	11.0	4	20.0	–		9	13.8
	Structural autograft from the femoral head, fixed with screws	2	20.0	8	30.0	7	35.0	2	25.0	19	29.2
	Big size cup	1	10.0	–		1	5.0	–		2	3.1
	Titanium mesh	–		1	4.0	–		–		1	1.5
	Metal support structure (Muller ring)	–		–		–		1	12.5	1	1.5
	Autograft from the femoral head + titanium mesh	–		1	4.0	–		–		1	1.5
IV type (6 ± 1)*	Structural autograft from the femoral head, fixed with screws	1	10.0	1	4.0	1	5.0	–		3	4.6
	Muller ring	–		1	4.0	–		–		1	1.5
Total		10	100	27	100	20	100	8	100	65	100

Note: *— average term after the intervention (years)

In type II, structural and non-structural autografts were used, which yielded good functional results. Of those, three implants were cemented and 15 were cementless. In this type of defect, only three poor results were noted, associated with premature lysis of the graft; in one of those cases, a cementless technique was used and two implants were cemented.

The greatest variety of defect compensation techniques was used for type III. For this type of defect, five were cemented fixation implants: two in combination with a structural autograft were fixed with screws, with good and fair results; one had a titanium mesh as a supporting structure with autoplasty of the defect; one cemented implant was installed with defect plasty with autobone chips and resulted in fair outcome; a failure was observed in the case of installing a cemented implant with a Muller supporting ring. In the remaining 28 cases of type III defect, cementless implants were installed. The best results were onserved with the use of structural autografts additionally fixed with screws.

Defects of type IV in primary arthroplasty were encountered in three cases and were compensated by massive structural autografts fixed with several screws to the pelvic bone, which provided good results; all three were cementless. A cemented implant was installed in one case together with a Muller ring, a fair result was obtained.

Methods of bone defect compensation in revision arthroplasty and assessment of hip joint function with HHS are presented in Table 5.

Table 5

Methods of bone defect management in revision arthroplasty based on the type of defect according to Paprosky classification and HHS results

Method of defect compensation / functional outcome		Excellent		Good		Fair		Poor		Total	
		⩾ 90 points		80–89 points		70–79 points		⩽ 69 points			
		n	%	*n*	%	*n*	%	*n*	%	*n*	%
1 type (3 ± 2)*	Bone cement	–		1	16.7	2	14.3	1	20.0	4	14.3
	Big size cup	–		–		3	21.4	–		3	10.7
2A type (4 ± 1)*	Impaction with allograft	–		–		2	14.3	–		2	7.1
	Bone cement	–		–		–		2	40.0	2	7.1
2B type 2*	Bone cement	–		–		1	7.1	–		1	3.6
2C type (6 ± 3)*	Bone cement	–		–		1	7.1	1	20.0	2	7.1
3A type (3 ± 3)*	Allograft	–		–		1	7.1	–		1	3.6
	Muller ring	–		1	16.7	1	7.1			2	7.1
	Iliac wing autograft	–		–		1	7.1	–		1	3.6
	Iliac wing autograft + mesh + screws	1	33.3	–		–		–		1	3.6
	Allograft+screws	1	33.3	1	16.7	–		–		2	7.1
	Allograft + mesh + screws	1	33.3	–		–		–		1	3.6
3B type (4 ± 2)*	Allograft	–		1	16.7	–		–		1	3.6
	Bone cement	–		–		1	7.1	–		1	3.6
	Iliac wing autograft + Muller ring	–		–		1	7.1	–		1	3.6
	Tantalum augment + autograft	–		1	16.7	–		–		1	3.6
	Big size cup	–		–		–		1	20.0	1	3.6
	Muller ring	–		1	16.7	–		–		1	3.6
Total		10	100	27	100	20	100	8	100	65	100

Note: *— average term after the intervention (years)

According to the data presented in Table 5, in revision operations to fill type 1 defects, from a total of seven patients four cases (57%) had cemented arthroplasty and the defects were filled with bone cement. If bigger diameter cups was used, cementless fixation was performed.

In four patients with defect type 2A, cemented technique was used in two cases, the defects were filled with cement. In two cases, impaction bone grafting with subsequent cementless fixation of the cup was used. In 2B (one patient) and 2C (two patients) defects, cemented fixation of the cup was used in all cases. No other bone substituting materials except cement were used. One defect type 2C compensation was a failure.

In Type 3A defects (eight patients), the cementless technique was used together with auto- and allografts fixed with press-fit, as well as with auto- and allografts fixed with screws. In the remaining cases, the cemented technique was used.

Cementless arthroplasty for type 3B defects (six patients in total) was used in three patients: together with autogenous bone, fixed press-fit, big-diameter cup and metal supporting structure. Cemented fixation was used in three patients: with a Muller ring, with a supporting structure made of tantalum and in one case the defect was filled only with cement with a fair result.

Based on the type of acetabular defect according to Paprosky classification (for revision) and AAOS (for primary AP), we developed an algorithm for choosing the method of managing the bone defect of the acetabulum and implanting the cup (Table 6) [18].

Table 6

Method of cup implantation based on the type of bone defect of the acetabulum

Type of defects (AAOS, Paprosky)	Method of cup implantation
Defects type I and II AAOS Type I and IIA Paprosky	It is possible to perform reimplantation of a hemispherical cup with a cementless press-fit fixation into the true acetabular region, bone grafting with auto- or allochips in osteolysis foci
Type III AAOS Defects IIB, IIC, IIIA Paprosky	It is possible to reimplant a hemispherical cup with a cementless press-fit fixation into the true acetabular region. To compensate for the segmental defect of the coating in the area of the roof of the acetabulum over 30% of the cup area and the medial defect in the bottom area, bone auto- and allografts, porous metal augments are used. It is possible to use acetabular components of a special oval shape. In case of pronounced medial defects, it is possible to use reinforcement of the defect with a titanium mesh fixed to the rim of the acetabulum with 2-3 screws, before this the defect is necessarily filled with autobone, allobone or artificial bone osubstituting material; a hemispherical cup with a cement type of fixation is implanted into the titanium mesh. It is possible to use big-sized Jumbo-cups with auto- or alloplasty of the defect
Defects IV AAOS Defects III B Paprosky	It is necessary to use Müller reinforcing rings or Bursch-Schneider antiprotrusion rings with defect repair in the true acetabulum with massive structural auto- or allografts, titanium augments; hemispherical cups with cement fixation are implanted into the support ring. It is possible to use bilobed or oblong cups with additional fixation with screws (distraction method for achieving stability), defect repair using modular titanium/ceramic inserts or a massive structural allograft. It is possible to use customized pelvic components manufactured with 3D model data.
Defects IV, V AAOS Defects with disrupted pelvic ring	Osteosynthesis of the anterior and posterior columns using reconstructive plates in combination with the Bursch-Schneider antiprotrusion ring (flanges for the ischial and ilium bones), plastic surgery of defects using massive structural allografts, a cup with cement fixation is implanted into the ring. It is possible to use bilobed or oblong cups with additional fixation with screws (distraction method for achieving stability). Arthrodesis, pelvic support osteotomy

We present the following case report as a clinical example of performing three consecutive revisions of the pelvic component within five years after the primary arthroplasty.

Patient A. with bilateral dysplastic coxarthrosis stage III, Crow IV subluxations of the hips referred to the clinic at the age of 55 years with complaints of persistent pain in the hip joints (more on the left), limited movement, and lameness (Fig. 2).

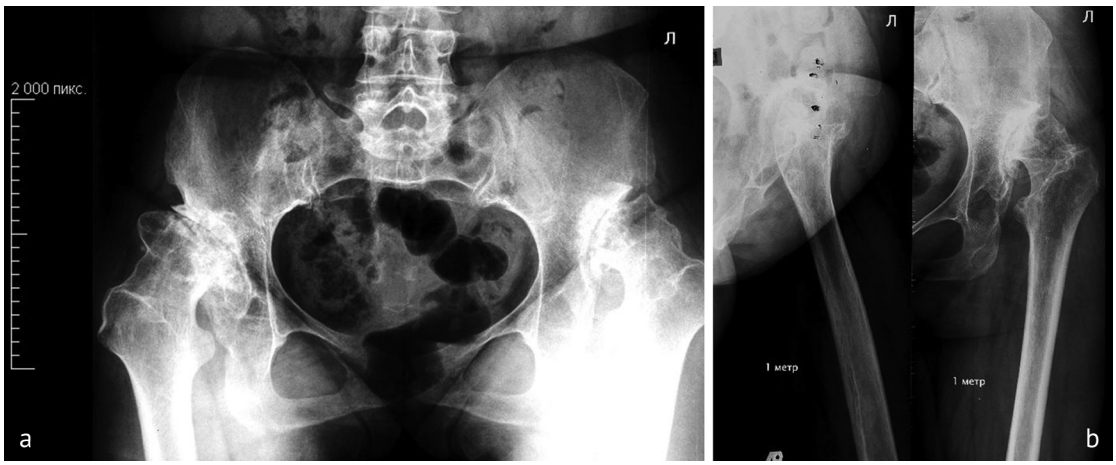

Fig. 2 Plain radiograph of the pelvis in a direct projection (*a*) and the left hip joint (*b*) in lateral and direct views before surgery. Bilateral dysplastic coxarthrosis stage III, Crow IV subluxations of the hips: the heads are displaced cranially, are located above the acetabular region, a deficiency of bone tissue is visualized in the area of the anterior, posterior edge and roof of the true acetabulum of the right and left hip joints. Defects of the bone tissue of the acetabulum correspond to type III AAOS

Case history Congenital bilateral hip dislocation was detected at the age of 3.5 years, for which she was treated conservatively using traction and staged plaster casts, but the dislocations were not reduced. At the age of 30 years, she started feeling pain in the hip joints. After visiting the clinic and undergoing a comprehensive examination, hip joint arthroplasty was indicated (Fig. 2).

In November 2009, the left hip joint was replaced with a cementless Smith&Nephew system with acetabular roof plasty using an autograft from the resected femoral head. The acetabular bone tissue defect III AAOS was adequately compensated. The early postoperative period was uneventful. However, four months later, pain in the area of the joint reappeared, and radiographs revealed probable signs of pelvic component instability: pronounced areas of bone tissue enlightenment (lysis) at the border of the cup and the pelvic bone in the II and III acetabular zones De Lee and Charnley (Fig. 3 a). Six months after the primary implantation on 05.05.2010, revision arthroplasty of the left hip joint was performed due to early instability of the cementless cup. A cement fixation cup was installed, signs of instability of which appeared 16 months after the repeated revision: an enlarged oval-shaped cavity with a crescent-shaped enlightenment in its lower sections was visualized, the pelvic component was located in its cranial section, a 3A Paprosky defect was diagnosed (Fig. 3 b).

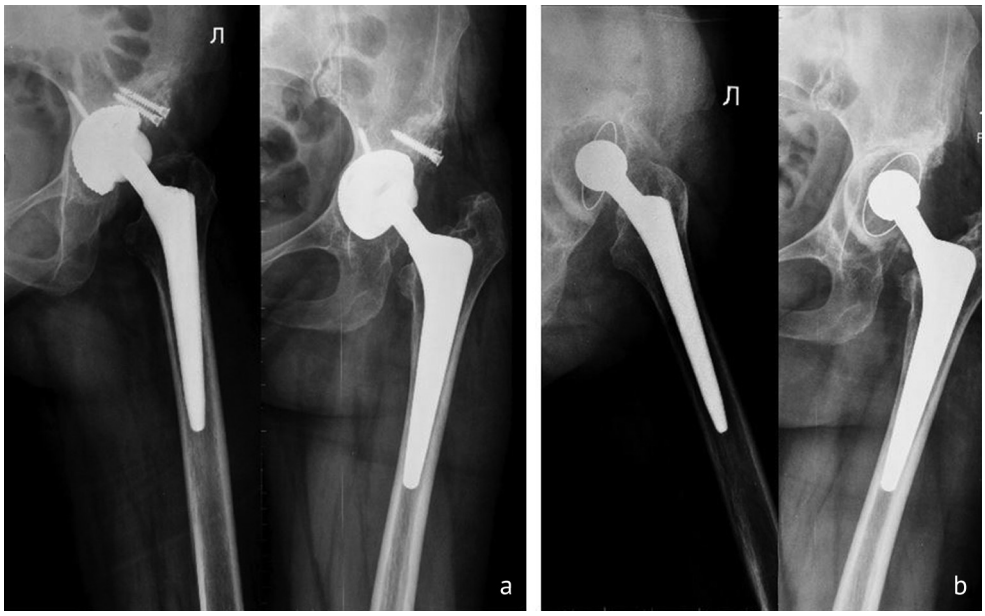

Fig. 3 Radiographs of the left hip joint in lateral and frontal views: *a* 6 months after primary arthroplasty (signs of instability of the cementless pelvic component); *b* 6 months after revision arthroplasty with replacement of the cup with a cemented system (instability of the cemented pelvic component)

On 19.05.2010, between repeated revisions of the left hip joint (before the development of repeated instability of the already cemented pelvic component), primary cementless arthroplasty of the right hip joint was performed using the Smith&Nephew system with impaction grafting using bone chips from the resected femoral head (Fig. 4 a). In September 2011, the second revision intervention was performed to replace the unstable cemented pelvic component: bone grafting using allochips was performed and a Müller support ring was installed with the pelvic component implanted into it using cement; the femoral component remained stable (Fig. 4).

Three years after the second revision, the patient felt pain in the left hip joint and groin, with irradiation to the thigh and knee joint. In February 2015, the third revision of the left hip joint was performed. Intra-operatively, instability of the Müller support structure was detected, which was removed along with the remnants of the cement. Some technical difficulties arose when releasing the screw head grooves from the bone cement. A defect of the anterior wall and a significant defect of the acetabular dome (3B Paprosky) were detected.

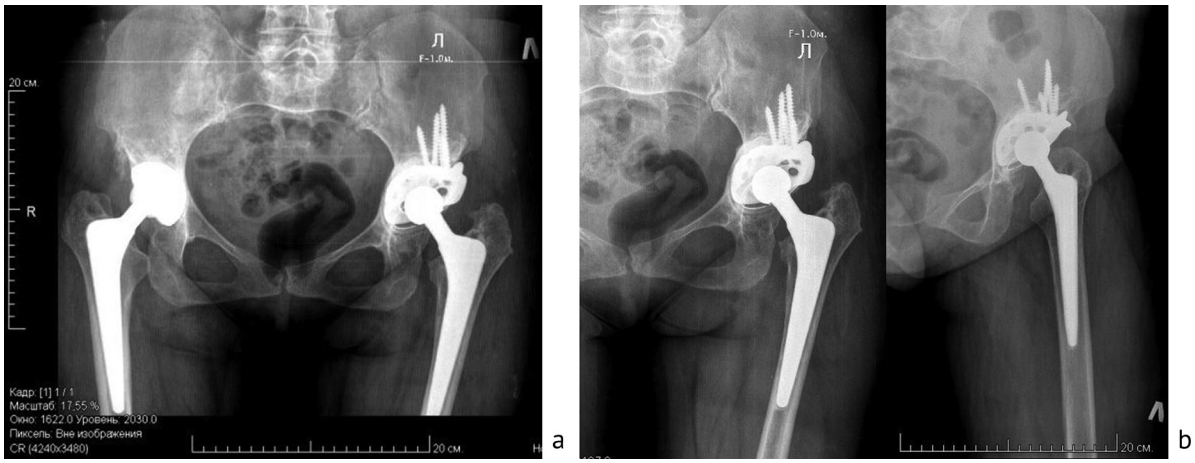

Fig. 4 Radiographs of the pelvis (*a*) and left hip joint in lateral and frontal views (*b*) after primary arthroplasty of the right hip joint and the second revision intervention on the left hip joint to replace the unstable cemented pelvic component and install a Muller support ring

The acetabulum was processed in turn with 40- to 50-mm cutters and bone spoons until bleeding occurred. A 50-mm Zimmer tantalum augment, 15 mm high, was installed in the area of the acetabular dome defect and fixed with two 6.5 × 35 mm and 6.5 × 30 mm screws. Next, the acetabulum was processed with 51- and 52-mm cutters centering in the true acetabular region, and the thinned bottom of the acetabulum was covered with bone chips (from the cutters after processing). A 52-mm Zimmer Trabecular Metal press-fit cup was stably installed. The cup was fixed with three 6.5 × 35 mm (1) and 6.5 × 20 mm (2) cancellous screws. The stem remained stable. A metal head + 4 mm (L) Smith&Nephew was installed. After reduction, the joint was stable, and the length of the legs was equal. In the radiographs, the position of all implant components is biomechanically correct (Fig. 5).

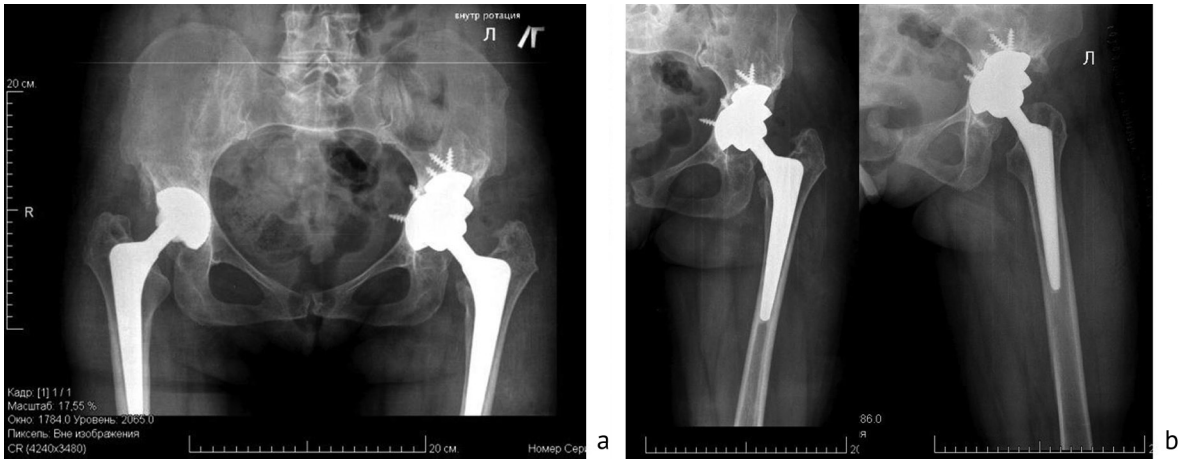

Fig. 5 Radiographs of the pelvis (a) and left hip joint in the direct and lateral views (b) after the third revision intervention on the left hip joint to replace the unstable Mueller support ring, fill the bone defect in the area of the acetabular dome with a tantalum augment from Zimmer and a cementless 52-mm cup Zimmer Trabecular Metal press-fit. The defect of the acetabulum, 3B Paprosky, was filled

At the time of this study (2024), 9 years passed since the third revision surgery to replace the pelvic component. The patient walks with a cane, has no complaints, no lameness, and uses public transport. The need for painkillers is episodical, after prolonged physical activity. The limb is in the correct position. The range of motion in the hip joints is restored. The functional HHS result is good (85 points).

DISCUSSION

Analyzing the above clinical case as a series of revision failures, it should be noted that initially the patient had a complex bilateral pathology of the hip joints with the formation of neoarthrosis of both supra-acetabular areas and high Crow grade III–IV subluxation of the femurs due to pronounced

degenerative changes in the joints and surrounding muscles. Despite the fact that during the primary arthroplasty of the left hip joint the method of compensation of the bone defect in the area of the dome with an autograft from the resected femoral head was correctly chosen and the cup was installed biomechanically correctly in the true acetabulum, its early instability developed after six months.

Obviously, the main role in the development of early instability of the pelvic component was played by overloading of the joint due to the fact that patients almost immediately and unconsciously load the replaced joint, which no longer hurts, compared to the non-operated one. Even such a short time of increased loading on the endoprosthesis in the early postoperative period resulted in pain syndrome and instability of the pelvic component as secondary stabilization of the component through osseointegration did not occur due to increased loading. In bilateral severe joint pathology, it is advisable to operate on both joints in one surgical session or with a time interval of no more than 2-4 weeks [19, 20].

During the first revision, the cementless cup was replaced with a cemented one. However, the acetabulum had already been altered (AAOS type III defect), enlarged in longitudinal size, and there was no adequate covering of the expanded acetabulum by the pelvic component. The cup was installed in the upper sections of the acetabulum above the true acetabulum, and the lower sector of the implantation site remained unfilled with the component itself, bone, or cement. Therefore, instability of the pelvic component developed already 16 months after the revision. A second revision intervention was required with the installation of a Müller support ring and bone grafting with allochips. The Müller ring was also installed in the upper sections of the acetabulum, above the true acetabulum. This fact led to asymmetric loading on the pelvic bones (overload of the left hip joint) and the development of instability of the supporting structure. Both in the first and in the second revision, when bone deficiency was still moderate (Type 3A Paprosky), it was possible to use a large-diameter pelvic component, a Jumbo-cup. The use of a bigger cup provides lateralization and a slight caudal displacement of the rotation center of the hip joint. The biomechanics of the joint, therefore, approaches the normal one, while the contact area of the Jumbo-cup with the bone bed is large enough, which allows us to hope for successful secondary stabilization due to osseointegration and a good outcome.

Removal of the unstable Müller support ring, its fixing screws, and bone cement during the third revision further enlarged the bone deficit in the acetabulum area to the point of an extensive defect in the acetabular dome and its anterior rim (Paprosky type 3B defect).

During the third revision, the Paprosky type 3B bone defect in the acetabular dome area was compensated for with a Zimmer tantalum augment, a 52-mm Zimmer Trabecular Metal cementless cup, implanted press-fit into the true acetabular area. Adequate compensation of the defect, the correct choice of the augment and cup size, and its biomechanically correct positioning in the true acetabulum achieved its stable position and a good long-term result. Thus, it should be noted that it is important to fully compensate for the defects of the acetabulum to ensure the stability of the prosthesis and the ability to implant the cup into the true acetabulum to restore the correct anatomical relationships in the joint.

Currently, there are various options for implanting a pelvic component in case of acetabular bone tissue loss: installation of a standard full-profile cup with cementless fixation in the true acetabulum with bone grafting of the defect; installation of a cup in the true acetabulum with its partial non-coverage and grafting with bone chips; installation of the cup in a more vertical position; installation of a cup with a shift in the rotation center above the true acetabulum region in the preserved bone in the dome region; installation of a cemented cup into supporting and antiprotrusion structures. In all these options, it is possible to use structural autobone from the resected femoral head, massive structural allografts, bone auto- and allochips, artificial bone substituting materials made of titanium and ceramics, as well as their combinations.

The analysis of data reported by domestic and foreign researchers shows that the most widely used method of filling defects in primary arthroplasty remains plastic surgery with bone chips from the autologous femoral head. Such plastic surgery recreates the sphericity of the socket well and, if osseointegration is successful, provides mechanical support for the cup along its entire length and long-term functioning of the endoprosthesis. However, the volume of bone material is very limited and does not allow for filling an extensive defect. If revascularization fails, the autobone can lyse over time leading to loss of stability [21]. Crushed bone allografts are also widely used for plastic surgery of small defects, complementing any technique. Sometimes they are used as an independent augmentation method, impaction bone plastic surgery. Usually, a cementless press-fit cup is used, less often a cemented cup. The surface of the pelvic component in this case has little contact with the patient's bone, while contact with the donor allograft bone can approach 100% [2].

In large bone tissue defects (Paprosky type 2B, 3A, 3B), one of the options for plastic surgery is the use of structural auto- or allografts, which allow restoring the rotation center and bone support for possible future revisions. Poor results with this method are due to the lysis of the allograft bone, if its revascularization does not occur over time [20]. The long-term viability of the allograft bone with the preservation of its support characteristics remains controversial [22, 23].

The cemented cup was widely used in the first hip arthroplasty operations, especially in revision interventions. However, the results in the medium and long terms turned out to be poor. Therefore, at present, preference is given to pelvic components of cementless fixation in primary arthroplasty. If cement fixation is necessary, the thickness of the cement mantle should be minimal. The deficiency in the thickness of the medial wall under the cement mantle should be compensated by impaction bone grafting [4, 24, 25].

In revision interventions on the hip joint, one should consider severe osteoporosis, cicatricial changes in the capsule, and weakness of the surrounding muscles. Removal of the implant requires additional physical effort and is associated with the risk of periprosthetic fractures, as well as an increase in the length and depth of bone tissue defects in the area of the implantation bed [26]. One of the options for revision replacement of the pelvic component in moderate bone loss is the use of large-sized Jumbo-cups. However, if the acetabulum rims are insufficient, this method is unacceptable. A negative aspect of Jumbo-cup implantation is that the large component, being at the same time a supporting structure covering the defect, limits the possibilities of pelvic bone regeneration [15].

In large Paprosky 2B, 2C, 3A, 3B defects, plastic surgery with crushed or structural allobone is performed, an antiprotrusion ring or cups made of trabecular metal with press-fit fixation and screws are implanted. Then a plastic cup is installed in the metal cup or ring with cement; in pelvic ring instability, osteosynthesis of the posterior column is required. According to the studies of Tikhilov et al., the use of an antiprotrusion support ring allows creating support for the pelvic component, transferring the load to the remaining areas of the ilium and ischium. Implantation of the support ring is supplemented by bone alloplasty with a structural or crushed graft, implantation of a cup made of trabecular metal, osteosynthesis of the posterior column [27, 28].

In recent years, components made of highly porous materials, in particular trabecular metal, have become increasingly widespread. They can be used for both simple revisions and more complex cases, including osteoporosis, severe bone defects and pelvic ring disruption [29]. High porosity and adhesion to bone, elastic modulus close to bone tissue in trabecular metal structures provide conditions for optimal primary and secondary fixation of the component, while additional holes can be made with a high-speed drill in any area of such a component for fixation with screws to the pelvic bone. To achieve acceptable primary stability, bone coverage of the structure can be less than 50% [30, 31].

Positive treatment outcomes and long-term functioning of the prosthesis is possible to achieve only with a comprehensive approach to defect plastic surgery. AAOS defects I and II and Paprosky type 1 and 2A defects allow impaction bone grafting with resorbable non-structural grafts. AAOS defects

III and IV and Paprosky defects 2B, 2C, 3A, 3B require the use of structural grafts with additional fixation. It is preferable to use combined bone grafting, including non-resorbable and resorbable materials.

Pelvic components with cementless fixation, which demonstrate good survival after many years of functioning, are certainly promising for both primary and revision arthroplasty [32].

CONCLUSION

Hip joint arthroplasty (primary or revision) performed in the presence of a bone defect of the acetabulum is a complex surgical intervention, the technical aspects of which have not been finally resolved. Anatomical manifestations of acetabular defects are diverse and create certain difficulties in choosing pelvic components, augments, and methods of their fixation to the pelvic bone. Long-term and painless functioning of the hip joint implants used for acetabulum defects is ensured if the spherical shape of the acetabulum is restored and the center of the joint rotation is in the true acetabulum, bone tissue deficiency is adequately replenished, and reliable primary fixation of the cup provides conditions for secondary stabilization of the component due to its osseointegration.

The algorithm developed for choosing a method of filling a bone defect of the acetabulum and implanting a cup allows a practicing physician to adequately assess his experience, surgical skills and the capacity of the clinical institution in providing complex reconstructive surgeries on the hip joint.

Significant difficulties in surgical treatment of patients with acetabulum defects are due to the insufficient legislative base in the field of using customized designs, new materials and techniques for replenishing bone deficiency.

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Results of the intraoperative alpha defensin lateral flow test in the second stage of revision hip arthroplasty

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Abstract

Background Alpha defensin lateral flow (ADLF) test is a current accurate tool for detecting/excluding periprosthetic joint infection (PJI); however, its usage in patients with a hip joint spacer has not yet been fully studied.

The **purpose** of the study was to determine the diagnostic parameters (accuracy, specificity, sensitivity, AUC) of the alpha-defensin lateral flow test as part of the reinfection verification in patients with a hip joint spacer in the second stage of revision hip arthroplasty (RHA).

Material and methods In a prospective study the effectiveness of the intraoperative use of ADLF test was evaluated in 105 patients with hip joint spacers during the 2nd stage of revision hip arthroplasty (RHA). The standard microbiological examination of intraoperative samples of tissues and synovial fluid was accepted as the gold standard for re-infection diagnosis.

Results The growth of microflora according to the results of intraoperative microbiological examination was detected in 24 (23 %) cases. The discrepancy in the results of intraoperative microbiological examination and the results of the ADLF test was found in 10 (11 %) cases. False positive and false negative cases were identified. ADLF test demonstrated 96.39 % specificity, 89.52 % accuracy and 63.64 % sensitivity. The AUC index was 0.8.

Discussion ADLF test has good diagnostic indicators for the verification of PJI in patients after hip replacement. The use of ADLF test in patients with a hip joint spacer who continue antibacterial therapy allows the test to be performed in the 2nd stage of RHA. However, the results of ADLF test in patients during the 2nd stage of RHA show that additional studies are required.

Conclusion The ADLF test, despite the divergent data from scientific publications, demonstrates high diagnostic value for intraoperative verification of reinfection in patients with a hip joint spacer, allowing timely correction of treatment tactics. "Dry tap", bloody synovial fluid, as well as weakly virulent coagulase-negative microflora, including in microbial associations, are limitations of the ADLF test application.

Keywords: periprosthetic joint infection (PJI), diagnosis of hip joint reinfection, intraoperative aspiration of synovial fluid of the hip joint, hip joint spacer, revision hip arthroplasty, alpha defensin lateral flow test (ADLF)

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INTRODUCTION

Total hip arthroplasty, being the “operation of the 21st century” [1], can significantly improve the quality of life of patients suffering from late stages of osteoarthritis [2]. Growing obesity rates and increasing life expectancy contribute to the growth of musculoskeletal diseases [3, 4]. As a result, the number of primary arthroplasties of large joints and the associated number of potential complications has been growing [5]. Periprosthetic joint infection (PJI) is one of the leading complications after joint arthroplasty in terms of incidence, destructiveness and cost of treatment [6, 7]. Timely and accurate diagnosis of periprosthetic infection of the hip joint allows for the most rational choice of treatment tactics and a reduction in the risk of potentially adverse consequences [8].

The "gold standard" for treating patients with chronic periprosthetic joint infection is two-stage revision hip arthroplasty (RHA), which involves removing the hip implant components, debridement, and installation of a spacer impregnated with antibacterial drugs at the first stage. After the infection process has been stopped, the wound has healed, and laboratory parameters have returned to normal, the second stage of RHA is performed, which involves removing the spacer, debridement, and re-implantation of components [9]. In any case, the authors report high rates of reinfection after the second RHA stage [10, 11]. In this regard, perioperative diagnosis to exclude reinfection during the second stage of RHA is an extremely important task. There are various algorithms for diagnosing PJI, such as ICM, WAIOT, EBJIS; each of them has good diagnostic value [12]. However, these algorithms to make a decision on performing the second revision stage have limited significance [13]. In the absence of a generally accepted preoperative diagnostic algorithm before performing the second stage of RHA, the use of various synovial intraoperative express tests becomes relevant, allowing exclusion or detection of reinfection and, if necessary, and changes in the treatment tactics.

Alpha-defensin lateral flow (ADLF) test is one of the most current, rapid, sensitive and specific tests that allow for effective verification of PJI, even in the context of ongoing antibacterial therapy [14, 15, 16]. Moreover, the updated ICM 2018 algorithm has added the determination of alpha-defensin proteins in synovial fluid as a “minor criterion” for diagnosing PJI [17]. However, there is currently insufficient data on how effective ADLF test is in detecting reinfection after spacer placement [18]. There is an opinion that the characteristics of local immunity after first-stage RHA operations, as well as the very presence of an installed spacer impregnated with antibacterial drugs, contribute to a decrease in the prognostic significance of using various serum and, especially, synovial biomarkers in order to exclude reinfection [19]. Available data on the assessment of ADLF test diagnostic parameters in the context of perioperative diagnosis of reinfection during the second stage of revision hip arthroplasty in patients with an installed hip spacer vary significantly [20, 21, 22, 23].

The **purpose** of the study was to determine the diagnostic parameters (accuracy, specificity, sensitivity, AUC) of the alpha-defensin lateral flow test as part of reinfection verification in patients with a hip joint spacer in the second stage of revision hip arthroplasty (RHA).

MATERIALS AND METHODS

A total of 135 patients took part in a prospective study conducted in 2019–2024 at the Orthopaedic Department of the Botkin City Clinical Hospital.

Inclusion criteria:

— a hip spacer installed for the first time due to periprosthetic infection;

— no clinical signs of an infectious process in the area of the planned operation (no fistula, local hyperemia, hyperthermia);

— consent to perform the second stage of revision arthroplasty;

— written informed consent to participate in the study.

Non-inclusion criteria:

— active infectious process with the presence of a fistula in the hip joint area, local hyperemia, hyperthermia;

— patients with a previous Girdleston operation ("hanging hip") for periprosthetic infection;

— objective contraindications to revision surgery due to somatic or mental status;

— presence of HIV infection;

— patients with repeated spacer implantation.

Exclusion from the study:

— the patient develops a fistula in the area of the hip joint;

— the patient refuses surgery and does not want to participate in the study;

— reinfection is detected during preoperative diagnostic examination;

— the patient dies before the second stage of RHA is performed.

The study assessed the diagnostic parameters of intraoperative alpha-defensin lateral flow test in patients with an installed hip spacer during the second stage of RHA.

The average age of patients was 64 years (42–78 years). Most patients included in the study were women (n = 67; 63 %), while 38 patients (37 %) were men. The average time to the second stage of RHA was 45 weeks (19–69).

All 135 (100 %) patients admitted for the second stage of RHA were pre-examined to exclude reinfection in the hip joint. As part of the pre-operative exclusion of reinfection, serum biomarkers (ESR, CRP, leukocyte count in the general blood test, interleukin-6) were analyzed and pre-operative aspiration of synovial fluid of the examined hip joint was performed with subsequent microbiological analysis of the aspirate.

During preoperative examination, 26 (19 %) cases of microflora growth were detected (according to the results of preoperative microbiological testing during preoperative synovial fluid aspiration). The situation was interpreted as reinfection. Those patients were excluded from the study and referred for repeated sanitation and hip joint spacer change.

There were also 4 (3 %) cases of fistula developed in the area of the involved hip joint detected before the second stage of RHA. The situation was interpreted as the fistula form of reinfection. Those patients were also excluded from the study and referred for debridement and hip joint spacer change (Fig. 1).

According to preoperative diagnostic examination, reinfection was excluded in 105 (78 %) patients. All 105 patients admitted for the second RHA stage were required to cease the intake of antibacterial drugs at least 14 days before the date of the planned operation (the so-called "antibacterial holidays").

The second RHA stage included removal of the spacer, sanitation and reimplantation of revision components. In all patients, peri-implant tissue samples were taken from the joint cavity and from under the removed spacer components (from 3 to 6 samples) upon approach to the joint and after explantation of the spacer. The samples were then subjected to microbiological analysis with a cultivation period of 14 days and mandatory determination of sensitivity to antibacterial drugs in case microorganism growth was detected.

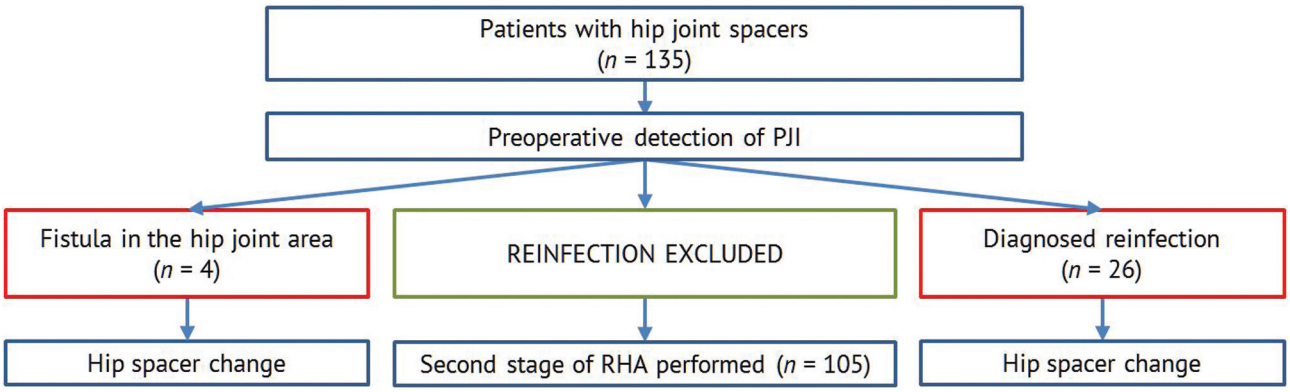

Fig. 1 Diagram of study design

At the stage of approaching to the spacer before opening the fascia, synovial fluid was aspirated in all patients for further microbiological examination. Cultivation was performed on the PEDS PLUS nutrient medium and continued 14 days. If there was a sufficient volume of synovial fluid (at least 5 ml) without visible traces of blood and/or other impurities, an express test for alpha-defensin was performed for the purpose of intraoperative verification of reinfection.

Intraoperative administration of antibacterial drugs was performed only after sampling of peri-implant tissues and synovial fluid. If the operation lasted for 2–4 hours or more, an additional dose of antibacterial drugs was administered in accordance with clinical recommendations (depending on the drug administered) [24].

In the absence of synovial fluid during intraoperative aspiration ("dry joint"), the patient was prescribed a course of two-component empirical antibacterial therapy until the results of the intraoperative microbiological study of peri-implant tissue samples were obtained. In the absence of microflora growth according to the results of the intraoperative microbiological study, the course of antibacterial therapy was canceled in the second stage of revision arthroplasty.

The results of intraoperative microbiological analysis of peri-implant tissue samples and synovial fluid during the second RHA stage were used as references, on the basis of which the results of intraoperative verification of reinfection using the alpha-defensin express test were assessed and analyzed.

The implementation of the alpha-defensin express test and the interpretation of the results obtained were in accordance with the manufacturer's instructions (Fig. 2).

The intensity of the control line and the test strip result on the device may vary. Any solid reddish-pink line is considered a line, regardless of intensity or size. Test results should not be interpreted after 20 minutes.

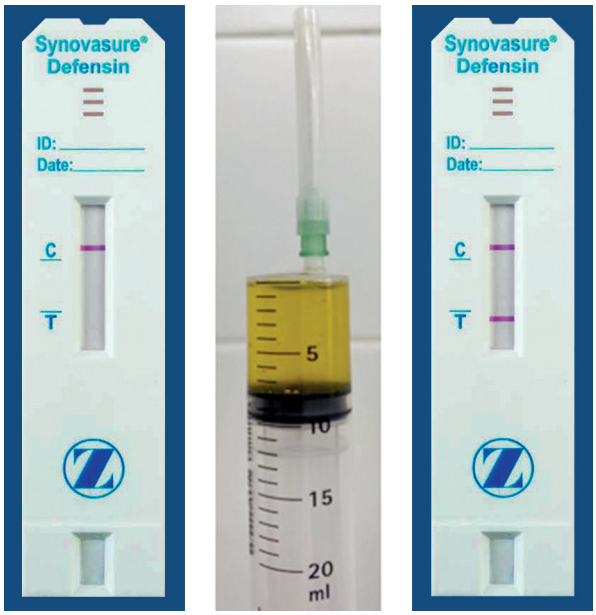

Fig. 2 Illustration of the results of the alpha-defensin express test: left — negative result; center — sample of the synovial fluid used, right — positive result [1]

[1] https://www.zimmerbiomet.com/content/dam/zb-corporate/en/products/specialties/diagnostics/synovasure-alpha-defensin-lateral-flow-test/1314.2-GLBL-en-Synovasure-Reference-Guide.pdf

A *negative result* for alpha defensin means only the presence of a reddish-pink control line (C) on the device without the appearance of a result on the test strip (T) after 10 min. The presence of a control line indicates that the test was performed correctly.

A *positive (non-negative) result* for alpha defensin is the appearance of a reddish-pink control line (C) on the device and a reddish-pink line on the test strip (T). The presence of the control line indicates that the test was performed correctly.

Invalid test Before interpreting the results, it is checked whether the control line marked "C" has appeared on the device. If the control line does not appear, the test strip does not appear completely, or the background does not become clear, the test is considered invalid and the results cannot be used. The test should be repeated with a new device. For retesting, use the previously prepared dilution vial. The retest should be performed within 4 hours.

In case of a positive result, the patient was prescribed a course of two-component empirical antibacterial therapy until the results of a intraoperative microbiological study were obtained. If there was growth of the patient's microflora, the patient was prescribed antibacterial based on the sensitivity data of the identified microorganism.

The study was conducted in accordance with the "Rules of Clinical Practice in the Russian Federation" (Order of the Ministry of Health of the Russian Federation dated June 19, 2003, No. 266), the ethical principles of the Helsinki Declaration (World Medical Association Declaration “Ethical Principles for Medical Research Involving Human Participants”, 2013) and with the approved by the ethics committee at the First Sechenov Moscow State Medical University (protocol dated January 20, 2022, No. 01-22).

Microsoft Office Excel was used to collect, process and systematize the information. Student's T-test was used to determine the statistical significance of the data. Differences at a significance level of $p < 0.05$ were considered statistically significant. The data were also analyzed using MedCalc 13.2.2 (MedCalc Software bv, Ostend, Belgium) to conduct ROC analysis and determine the sensitivity, AUC, specificity and accuracy of the alpha-defensin express test of intraoperative verification of reinfection in patients with a hip spacer.

RESULTS

According to the results of microbiological examination of intraoperative peri-implant tissue samples and synovial fluid at the second stage of revision hip arthroplasty, 24 cases (23 %) of microflora growth were identified (Fig. 3).

The following data were obtained regarding the results of intraoperative verification of reinfection using the alpha-defensin express test: out of 105 patients who underwent revision surgery, the effectiveness of this test could be assessed in 86 (82 %) cases (Fig. 4).

In 3 (3 %) patients, synovial fluid with a high content of associated blood was obtained by intraoperative aspiration. In the remaining 16 (15 %) patients, no synovial fluid could be obtained by intraoperative synovial fluid aspiration (“dry tapt”). This fact indicates that it was impossible to assess the effectiveness of any synovial biomarkers in 18 % of cases (Fig. 4).

The diagnostic indicators of the alpha-defensin lateral flow express test in cases of sufficient synovial fluid material without foreign impurities are presented in the diagram (Fig. 5).

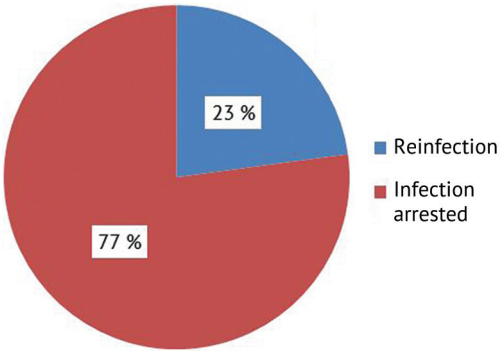

Fig. 3 Results of intraoperative microbiological examination of peri-implant tissue samples and synovial fluid

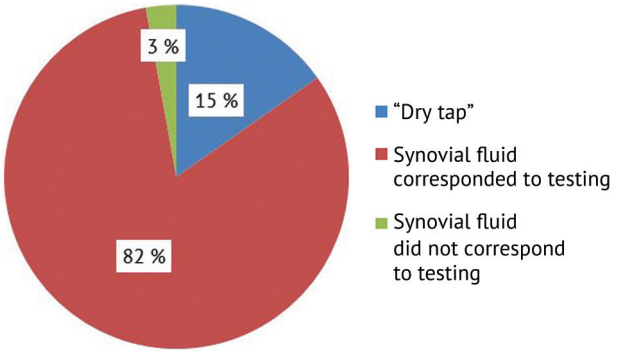

Fig. 4 Distribution of patients according to intraoperatively obtained aspirate

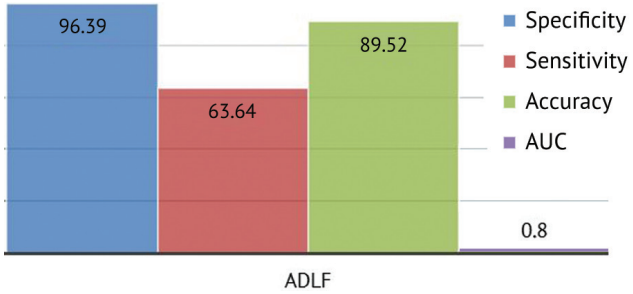

Fig. 5 Diagnostic indicators of intraoperative use of alpha-defensin express test in patients with an installed hip joint spacer

According to the results of the intraoperative microbiological examination of peri-implant tissue and synovial fluid samples, 65 (76 %) true negative and 11 (13 %) true positive results of the ADLF test were obtained.

Also, there were 10 (11 %) cases in which a discrepancy was observed between the results of the intraoperative ADLF test and the microbiological examination of intraoperative peri-implant tissue and synovial fluid samples: false negative result in 7 cases (7 %), false positive result in 3 cases (4 %).

No statistically significant differences were found in the analysis of the obtained results of the microbiological examination of intraoperative peri-implant tissue and synovial fluid samples when compared with the results of the intraoperative alpha-defensin express test ($p \geqslant 0.05$).

DISCUSSION

A study devoted to the specific effects of articulating spacers on peri-implant tissues revealed that spacers made of PMMA promote an immunomodulatory effect on the synovial membrane and tissues surrounding the implant. The membrane formed at the spacer-bone contact is induced by various immune cells (due to cement abrasion, formation of cement debris, and migration of cellular immunity components) [29]. It is important to understand that antibacterial drugs impregnated in the spacer are released into the synovial fluid and contribute to false-negative results of microbiological testing [30].

The duration of antibacterial release from the spacer is quite debatable. In this regard, the accuracy of synovial biomarkers in the aspirated synovial fluid in patients with an installed spacer may differ at different time-points. Thus, Boelch et al. demonstrated that the local concentration of antibacterial drugs may remain elevated for more than 6 weeks from the time of surgery. The authors state

that the findings were obtained in an *in vitro* experiment, and that in *in vivo* situations the duration of antibiotic release may differ [31]. Based on the above, the presence of an elevated concentration of immune cells and antibacterial drugs in the joint cavity may contribute to false results of reinfection diagnosis in synovial fluid studies.

Despite the abundance of various serum and synovial markers of periprosthetic joint infection, the diagnostic accuracy of synovial tests exceeds serum biomarkers [25]. However, synovial fluid cannot be obtained by pre/intraoperative aspiration in all cases. Therefore, it is impossible to evaluate the effectiveness of any synovial biomarkers for the purpose of verifying PJI/reinfection in about a third of cases [26, 27]. In our study, the number of cases in which ADLF test was not performed due to the absence/extremely scarce amount of synovial fluid or due to the fact that it did not meet the criteria for ADLF test during intraoperative aspiration was 18 %.

The high efficiency of the alpha-defensin test for verification of periprosthetic infection in large joints has been proven [28, 29, 30, 31, 32]. In turn, there are few publications evaluating the diagnostic potential of the alpha-defensin express test in the context of excluding/confirming reinfection in patients with an installed hip spacer.

Carender et al. evaluated the diagnostic value of preoperative use of alpha-defensin express test in patients with installed spacers in knee and hip joints before performing the second stage of revision arthroplasty [22]. The authors demonstrated data on high specificity (96 %) with 0 % sensitivity of the method, indicating that the alpha-defensin test did not increase the efficiency of preoperative exclusion of reinfection when added to the generally accepted synovial and serological markers of infection detection [22].

In other studies, the authors found high diagnostic rates of the alpha-defensin express test before performing revision arthroplasty [21, 33]. In the study by Frangiamore et al., the specificity and sensitivity rates of the method were 97 % and 67 %, respectively [33]. Stone et al. also reported high specificity (92 %) with less significant sensitivity (50 %) rates using the alpha-defensin express test in patients with an installed spacer before performing the second stage of revision arthroplasty [21].

The authors draw attention to two false-negative results of the alpha-defensin express test, noting the growth of *Cutibacterium acnes* in one case and the detection of the growth of two different coagulase-negative staphylococci (microbial association) in the second case [21].

It should be emphasized that neither Stone et al. nor Frangiamore et al. indicated the number of "dry tap" in their works, and therefore the true indicators of the effectiveness of the alpha-defensin test in patients with an installed spacer in those publications remain unclear [21, 33].

Our study also revealed seven cases of false-negative results of the alpha-defensin rapid test, associated with the growth of various weakly virulent coagulase-negative microorganisms in 5 cases (71 %) and in 2 cases (29 %) with the detection of various microbial associations. The false-negative results of the ADLF test that we obtained are consistent with the causes of false-negative results in other studies [21, 34, 35].

The false-positive results of the alpha-defensin test (3 cases, 4 %) obtained in our study are most likely associated with the use of fluid that did not fully meet the criteria for performing the test: the synovial fluid obtained by intraoperative aspiration contained a hemorrhagic component (Fig. 6).

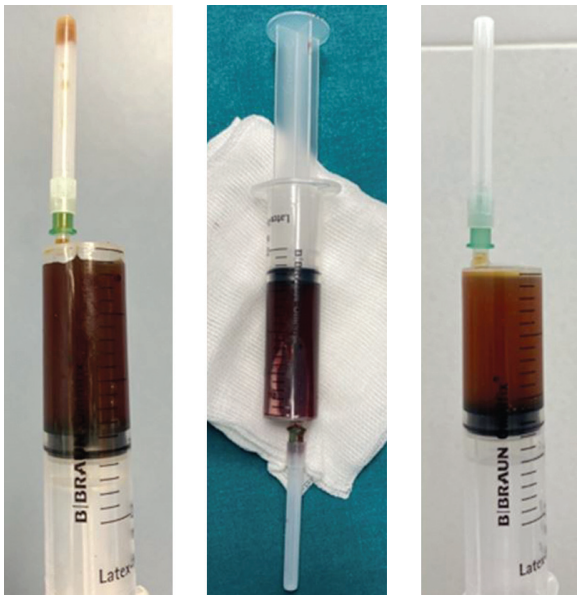

Fig. 6 Intraoperatively obtained samples of synovial fluid with a hemorrhagic component

Some publications report the successful use of alpha defensin test for synovial fluid containing blood admixture, in contrast to the use of test strips for determining leukocyte esterase [36, 37]. However, the authors did not specify the volume of dilution/blood admixture in those tests.

The instructions for use provide a conclusion on the high diagnostic value of alpha-defensin express test, but there is a note that the indicators are relevant to using synovial fluid samples, excluding samples with blood dilution > 20 % [2]. In this regard, the probability of obtaining false positive results of alpha-defensin test for using synovial fluid with more than 20 % blood dilution is not excluded.

According to the results of our study, the diagnostic accuracy rates of intraoperative use of ADLf test in the context of reinfection verification in patients with an installed hip spacer were 96.39 % for specificity and 63.64 % for the sensitivity of the method, which is similar to the results of similar studies [21, 33].

Shahi et al. claim that such a diagnostic tool for periprosthetic joint infection as alpha-defensin had a higher specificity and provided better screening for PJI in patients continuing to take antibacterial drugs than serum ESR, CRP, determination of PMN in synovial fluid, and even microbiological testing [16]. However, the study was conducted before revision surgery, and it is not possible to evaluate the effectiveness of this tool in patients with an installed spacer. In turn, Owens et al. noted that the routine use of such a synovial biomarker as alpha-defensin before performing the second stage of RHA may be unjustified [38].

Treatment of PJI is a complex task that requires a multidisciplinary approach and an experienced team of specialists, including a clinical pharmacologist [39]. Despite the fact that there is currently no single protocol for prescribing antibacterial therapy in the second stage of revision arthroplasty, it is important to understand that antibiotics should be selected based on the patient's somatic condition (kidney function, liver function, cardiovascular system), taking into account possible allergic reactions to a particular antibacterial drug, as well as the results of microorganism sensitivity according to the microbiological study conducted during the first stage of RHA. Patients admitted for the second stage of RHA are preliminarily examined, reinfection/relapse of PJI should be excluded. Such patients are recognized as "reconvalescents" for PJI. Therefore, it is relevant to use preventive, rather than therapeutic regimens and dosages when prescribing antibacterial drugs.

[2] https://www.zimmerbiomet.eu/en/products/synovasure-alpha-defensin-lateral-flow-test#overview

Different medical centers use different empirical schemes that are based on the characteristics of the species spectrum of pathogens causing PJI and local treatment protocols [40]. Most often, various combinations or monotherapy with antibacterial drugs of such groups as third-generation cephalosporins, glycopeptides, lincosamides, fluoroquinolones [41], as well as broad-spectrum beta-lactams [42] are used.

In intraoperative verification of reinfection/relapse of PJI from the samples of peri-implant tissues from the joint cavity and from under spacer components removed, as well as a sample of synovial fluid, followed by ADLF test (if SF meets the test performance criteria), a prophylactic dose of one of the antibacterial drugs was administered for two days in case of a negative ADLF result. If a positive ADLF result was obtained, two antibacterial drugs were administered intraoperatively (as part of the initial empirical therapy) until the results of the intraoperative microbiological study were obtained, followed by a transition to targeted prolonged antibacterial therapy, based on the sensitivity data.

CONCLUSION

Like all synovial biomarkers, ADLF test is ineffective in "dry tap". The test also demonstrates limited results if synovial fluid with a pronounced hemorrhagic component is used and in the presence of weakly virulent coagulase-negative microflora and/or microbial associations.

Alpha-defensin lateral flow test demonstrated high rates of diagnostic accuracy, specificity and AUC in patients with a hip spacer at the second stage of RHA. ADLF test is a good additional intraoperative express test, allowing, if necessary, correction of treatment tactics. Despite conflicting data from scientific publications, the use of ADLF test allows for effective verification of reinfection and is a good tool for confirming successful eradication of hip joint infection.

Conflict of interest *Not declared.*

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Clinical results of using a silver-containing preparation as part of an antimicrobial spacer in the treatment of periprosthetic hip joint infection

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Abstract

Introduction Periprosthetic infection (PPI) is one of the most serious complications of primary arthroplasty. Its rates range between 1.1 and 2 %. This study presents a comparative analysis of the results of the sanitizing stage of two-stage treatment of patients with chronic PPI of the hip joint (HJ) using an antimicrobial spacer impregnated with highly dispersed silver and without its impregnation.

Purpose To conduct a comparative analysis of the clinical efficacy of using HD-Ag for impregnation of an antimicrobial spacer in patients with chronic PPI HJ during the sanitizing stage.

Materials and methods A retrospective study is based on the analysis of the treatment outcomes of 223 patients with PPI HJ with antimicrobial spacers implanted during the sanitizing stage. Two groups of patients were formed based on the impregnation of bone cement with only an antibiotic or its combination with HD-Ag, group 1 (n = 112) and group 2 (n = 111), respectively. The evaluation of the treatment outcomes at a follow-up period of at least 2 years was carried out in accordance with the modified Delphi criteria. The reliability of differences in quantitative parameters between the groups was analyzed using nonparametric Mann – Whitney test, whereas Fisher test was used to analyze relative indicators. The differences were considered significant at $p < 0.05$.

Results The spectrum of pathogens was comparable in both groups. The recurrence rate in groups 1 and 2 was 23.2 % and 17.1 %, respectively ($p > 0.05$), while for monobacterial infection caused by gram-positive bacteria it was significantly lower in group 2 ($p = 0.012$).

Discussion As reported, the recurrence rate of periprosthetic infection varies from 8 to 40 %, depending on the nature of the infectious process and the type of pathogen. In the group with the use of HD-Ag as part of an antimicrobial spacer, the effectiveness of the sanitizing stage was 82.9 % and in the comparison group it was 76.8 %. However, a subanalysis of the effect of the etiology of PPIs on treatment results showed that the use of AM-spacer with a combination of silver and vancomycin led to a statistically significant reduction in the risk of recurrence in patients with monobacterial infection caused by gram-positive pathogens and provided arrest of infection in 89.7 % of cases.

Conclusion In the sanitizing stage of two-stage treatment of chronic peri-implant hip infection caused by gram-positive bacteria, the antimicrobial cement spacer impregnated with highly dispersed silver showed high efficiency. However, further development of new combinations for bone cement impregnation is required to expand the spectrum of antimicrobial activity of the spacers.

Keywords: peri-implant infection, periprosthetic infection, antimicrobial spacer, highly dispersed silver, bone cement impregnation

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INTRODUCTION

Currently, joint replacement (JR) is an effective method for treating a number of diseases and injuries of the hip joint, which in some cases has no alternative. Over the years of widespread use of this intervention in practical medicine, implant designs, surgical techniques, and perioperative pharmacological support of patients have been significantly improved, and resulted in excellent anatomical and functional results in the majority of cases. One of the rare but most severe complications of this surgical intervention is periprosthetic infection, the rates of which vary from 1.1 % after primary JR due to osteoarthritis to 2 % after hip replacement (HR) due to a femoral neck fracture [1]. Revision surgeries result in the development of an infectious complication in 7–15 % of cases [2, 3, 4], and currently, according to domestic and foreign authors, infection is one of the main causes of revision joint replacement [5, 6, 7].

Two-stage revision JR is still the operation of choice in most cases of chronic PPI of the hip joint [8]. A recently published meta-analysis analyzed 46 publications with the outcomes of two-stage treatment of 5,009 patients with infections in the hip joint [9]. On average, the recurrence rate of the infectious process was 8.35 %, while in seven studies included in this analysis, the PPI recurrence was diagnosed in more than 15 % of cases: from 16.7 % in the first two years after the second stage [10] to 27 % during a five-year follow-up in the study of Theil et al [11]. The implantation of any type of spacer may result in complications such as recurrence of the infectious process, dislocation, fracture or migration of the spacer, fracture of the femur [12, 13]. Moreover, one of the most significant risk factors for treatment failure was the detection of bacterial growth from the joint during the second stage of treatment [14].

Apparently, one of the reasons for failure to eradicate pathogens in the area of the infection focus may be an ineffective local depot of antibiotics in an antimicrobial spacer (AMS) at the first stage of revision. Despite the fact that the procedure of bone cement impregnation with various antibacterial drugs is currently routine, according to various authors, the release of antibiotics mainly occurs from the outer layer of cement which is 100 μm thick [15] and continues during the first 24–48 hours after which the elution of drugs slows down and does not achieve effective local concentrations to fight against microbial pathogens [16, 17]. Once the antimicrobial activity of bone cement (BC) ceases, the spacer becomes a foreign body on which bacterial cells can adhere with the subsequent formation of biofilms, which can lead to a relapse of the infectious process [18].

Thus, new approaches are needed to improve the efficiency of local AB-therapy by developing methods to expand the spectrum and increase the duration of the antimicrobial activity of cement spacers. One such method may be additional impregnation of AMS with preparations containing metal ions, in particular, silver ions [RU 2 707 734 C1, RU 2 754 075 C1]. An *in vitro* study found that impregnation of bone cement with vancomycin and highly dispersed silver (HD-Ag) contributes to a significant prolongation of sample's antimicrobial activity (up to 34 days), which effectively prevented the formation of microbial biofilms on their surface during the entire period of AB release [19]. However, the clinical efficacy of this combination of antimicrobial drugs has not been assessed.

Purpose To conduct a comparative analysis of the clinical efficacy of the sanitizing stage using HD-Ag for additional impregnation of an antimicrobial spacer in patients with chronic PPI HJ.

MATERIALS AND METHODS

The study is retrospective and is based on the analysis of the results of 223 patients that underwent treatment for chronic PPI of the hip joint at the Department of Purulent Surgery in the period from 2014 throughout 2018. The study included all patients with PPI of the hip joint who, during the specified period, underwent the first stage of a two-stage treatment of hip joint PPI with the implantation of an antimicrobial spacer (AMS) made of bone cement based on polymethyl

methacrylate (PPMA) and from whom the material was collected for bacteriological examination before surgery (aspirates, tissue biopsies) and/or intra-operatively (tissue biopsies and removed implants).

The patients were divided into two groups. In one of the groups, a highly dispersed silver (HD-Ag) preparation (Poviargol, Technolog LLC, Russia) was used for bone cement impregnation. Group 1 included 112 patients treated in 2014–2016, who, during the two-stage treatment of PPI of the hip joint, had an AMS implanted which was based on gentamicin-containing bone cements made of PMMA, additionally impregnated with vancomycin, during the first (sanitizing) stage. Group 2 included 111 patients treated from 2016 to 2018 with AMS impregnated with ancomycin and a silver preparation.

Steps of the sanitizing phase of the two-stage treatment of hip PPI were skin incision along the lateral surface of the thigh with subsequent anterolateral approach to the hip joint; excision of scars in the joint cavity; removal of the femoral and acetabular components of the endoprosthesis or spacer; treatment of the acetabulum with cutters until blood dew; abundant washing of the wound with antiseptic solutions; installation of a cement spacer and drainage; suturing of the wound.

The study assessed the patient's gender, age, duration of the infectious process at the time of the index surgery, white blood cell count, CRP and ESR levels in the blood upon admission and 5–7 days after surgery, type of pathogen, and correspondence of the microbiological examination results (culture and PCR diagnostics) of pre- and intra-operative samples. Patient treatment outcomes were assessed according to the modified Delphi criteria [20]. A satisfactory outcome was defined as the absence of signs of PPI recurrence after the second stage of treatment (reimplantation) or "life with a spacer" without the development of signs of an infectious and inflammatory process for two years after the sanitizing stage. An unfavorable outcome was a relapse of infection after a sanitizing operation or after reimplantation, as well as a death due to the generalization of the infectious process during the follow-up period.

Records, systematization of primary data and visualization of the obtained results were performed in Microsoft Office Excel spreadsheets. Statistical analysis was performed using the Past 4 software system. To describe quantitative indicators, a test for normal distribution was performed. With a normal distribution, the mean value and standard deviation were used to describe the parameter. For distribution different from the normal, the median (Me), and the lower (Q1) and upper (Q3) quartiles (25–75 % ICI) as measures of dispersion were used. The reliability of differences in quantitative parameters (age, duration of the infectious process, number of sanitizing operations at the time of the index operation) between the groups was analyzed using the nonparametric Mann-Whitney test. Fisher's test was used to analyze relative indicators. Differences between the groups were considered statistically significant at $p < 0.05$.

RESULTS

The groups of the study were comparable in terms of age and gender. In groups 1 and 2, the average age of patients was 58 years (CI95 % 53–63) and 60 years (CI95 % 55–65), respectively; the proportion of men was 48.2 % and 51.5 %; The proportion of patients with a history of sanitizing operations in group 1 was slightly higher than in group 2: 22.1 % and 14.4 %, respectively ($p = 0.098$); however, the average duration of the infectious process did not differ significantly in the compared groups ($p = 0.560$).

The groups were comparable in terms of the level of blood inflammation markers (CRP, ESR) and the number of leukocytes at the time of admission of patients to the hospital (Table 1). However, in the group of impregnated silver preparation, more pronounced dynamics of ESR normalization were observed in comparison with the preoperative level ($p = 0.003$) and compared with group 1 ($p = 0.005$).

Table 1

Dynamics of laboratory tests in the groups

Inflammation markers	At admission		*P* value	Before discharge		*P* value
	Group1	Group 2		Group 1	Group 2	
leucocytes, 10^9/l, Me (MIC)	7.8 (6.4–9.4)	7.6 (6–9.3)	0.325	7.2 (5.5–8.2)	6.1 (4.9–8.1)	0.623
CRP, mg/ml, Me (MIC)	25.9 (11.2–44.8)	23.8 (9.3–42.8)	0.203	19.2 (12–31.6)	13.8 (7.2–23.4)	0.339
ESR, mg/ml, Me (MIC)	50 (28–75.5)	51 (27–68)	0.533	47 (34–67.7)	*35 (14–50)	**0.005**

Note: * significantly different from the initial level at admission (p = 0.003)

Analysis of the results of bacteriological tests of intra-operative material showed that positive growth of microorganisms was obtained in 96.4 and 98.2 % of cases ($p = 0.415$), respectively, in groups 1 and 2, while the etiology of PPI was polymicrobial in 27.6 % (31 out of 112 cases) and 18.9 % (21 out of 111 cases) ($p = 0.122$).

The species spectrum of pathogens causing PPI of the hip joint was comparable in the groups (Table 2). The leading pathogens were staphylococci (*S. aureus, S. epidermidis* and other coagulase-negative staphylococci) that comprised 63 % and 56.3 % of the total, respectively in groups 1 and 2. The isolation rates of methicillin-resistant strains was 32.1 % (36 of 112) and 31.5 % (35 of 111) of cases ($p = 0{,}922$). Among gram-negative pathogens in both groups, non-fermenting bacteria (*Pseudomonas aeruginosa* and *Acinetobacter spp*.) were more frequent than *Enterobacteriaceae*.

Table 2

Bacterial spectrum in the groups

Возбудители	Group 1 (*n* = 112)		Group 2 (*n* = 111)		*P* value
	N	%	*N*	%	
S. epidermidis	46	32.2	39	29.3	0.610
S. aureus	37	25.9	32	24.0	0.729
Enterococcus spp.	12	8.4	20	15.0	0.073
Non-fermenting bacteria (*P. aeruginosa* and *Acinetobacter spp*.)	8	5.6	10	7.5	0.627
Other CoNS	7	4.9	4	3.0	0.424
Streptococcus spp.	10	7	6	4.5	0.379
fem. Enterobacteriace	7	4.9	4	3.0	0.424
Propionibacterium spp.	5	3.5	3	2.2	0.540
Corynebacterium spp.	3	2.1	2	1.5	0.712
Candida	2	1.1	0		0.172
Other	6	4.2	13	9.8	0.107
Total	143	100	133	100	

Note: other CoNS — coagulase-negative staphylococci except *S. Epidermidis*; N — number of patients in the groups

It was established that the results of microbiological tests of pre- and intra-operative materials completely coincided only in 47.3 % (53 of 112) and 56.7 % (63 of 111) of cases, respectively, in groups 1 and 2 (Fig. 1).

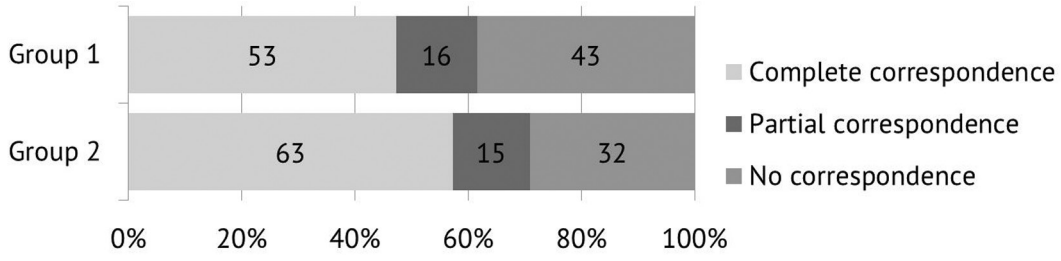

Fig. 1 Correspondence of the results of microbiological examination of pre- and intraoperative biomaterial samples

The analysis of treatment outcomes showed that the recurrence rate in Group 1 was 1.7 times higher than in group 2, 23.2 % (26 of 112) and 17.1 % (19 of 111) of cases, respectively ($p = 0.257$). At the same time, in patients with monobacterial PPI caused by gram-positive bacteria when AMS was impregnated with the silver preparation, relapses of the infectious process were diagnosed almost two times less frequently ($p = 0.012$) than in the comparison group (Table 3).

Таблица 3

Frequency of recurrent infection depending on the etiology of PPI at the time of index surgery

Infection etiology	Group 1			Group 2			*P* value
	Total	Recurrence		Total	Recurrence		
		N	%		*N*	%	
Монобактериальная Гр+	69	18	26.1	78	8	10.3	**0.012**
Монобактериальная Гр–	8	1	12.5	10	4	40	0.196
Полибактериальная	31	7	22.6	21	7	33.3	0.345

Re-implatation arthroplasty was performed in 73.2 % (82 of 112) and 73.0 % (81 of 111) of patients in groups 1 and 2, respectively. The average period between stages was 8.4 months. At the time of the survey, no information was found on the development of recurrent infection after the second stage. The rest of the patients preferred "life with a spacer" or are in the waiting list for hospitalization to undergo the second stage of treatment.

DISCUSSION

The installation of an antimicrobial spacer at the sanitizing stage of a two-stage revision has two main goals: to increase the effectiveness of systemic antibacterial therapy by creating a local depot of antibiotics in the bone cement and to maintain the anatomical relationship in the joint by filling in tissue defects after the removal of the endoprosthesis components [21]. An ideal spacer should ensure long-term elution of the antimicrobial drug in an effective concentration to stop the infection and prevent the selection and spread of multiresistant bacterial strains [22].

There are many known factors that influence the pharmacokinetic properties of antimicrobial spacers *in vivo*, including differences in the brand of bone cement used, the method of mixing it, the addition of one or a combination of two or more antibiotics, their dose and/or ratio, the duration of spacer implantation, etc. [22]. Despite the fact that the duration of the antimicrobial activity of bone cement has been well studied *in vitro* [16, 23] one cannot directly extrapolate the findings to the clinical situation. At the same time, the number of publications reporting on the elution of antibiotics *in vivo* is limited, and they are characterized by significant discrepancies in the results of determining the maximum concentration of the drug and the duration of its release from the cement [22]. Therefore, in our study, we took the proportion of patients with no signs of infection within two years after the debridement operation as the clinical efficacy of PPI treatment.

The overall effectiveness of treating chronic PPI of the hip joint in the analyzed sample of patients within a two-year follow-up was 79.3 %. It should be noted that the data on the effectiveness of chronic peri-implant infection arrest in the hip joint area in the scientific literature vary greatly. Thus, Petis et al report that the proportion of patients with hip joint PPI arrest was 90 % at 1-year follow-up after revision surgery and 86 % after 5 years [24]. In another study, the authors observed the absence of signs of an infection for two years in 83.3 % of patients [10]. However, it is known that the risk of relapse after sanitizing surgery for PPI of the hip and knee joints significantly depends on the pathogen and is 25–67 % [21, 25, 26]. One of the most significant predictors of treatment failure is considered to be the involvement of gram-negative bacteria and microbial associations in the etiology of PPI, that result in poor outcomes in almost half of the cases [27, 28, 29].

In our study, gram-negative bacteria were isolated in 15.4 % of patients, and in 21.8 % of cases, PPI was caused by microbial associations, which generally corresponds to the reported data of scientific publications. The rates of gram-negative bacteria in the spectrum of PPI pathogens vary from 11.3 to 60.0 % as found by different authors [30, 31, 32]; the incidence of polymicrobial infection ranges from 25 to 45 % of cases [20, 33]. In our cohort of patients, relapses with the participation of gram-negative pathogens in the etiology of the infectious process in the first two years after the sanitizing operation developed 1.5 times more frequently than with PPI caused by gram-positive bacteria, and 1.4 times more frequently in the case of microbial associations than with monobacterial infection. One of the reasons for this may be the low efficiency of antimicrobial spacers impregnated with vancomycin, a drug active only against gram-positive bacteria. The discrepancy (partial or complete) between the results of microbiological examination of pre- and intraoperatively collected materials that we identified indicates the impossibility of impregnating bone cement with an antibiotic with etiotropic action in 47.5 % of cases.

In the group using the HD-Ag preparation as part of the antimicrobial spacer in our study, the efficiency of the sanitizing stage was 82.9 %, and 76.8 % in the comparison group. However, a subanalysis of the effect of the PPI etiology on the treatment results showed that the use of an AM spacer with a combination of a silver preparation and vancomycin led to a statistically significant decrease in the risk of relapse in patients with monobacterial infection caused by gram-positive pathogens (OR 0.840; CI 95 % 0.735–0.960), and provided the arrest of infection in 89.7 % of cases. However, this combination did not have a positive effect in the subgroups with PPI caused by gram-negative bacteria and microbial associations.

Silver nanoparticles are known to have an antibacterial effect, but the mechanism of their action on bacteria is not specific, and therefore they act almost equally on gram-positive and gram-negative bacteria [34]. It is reported that silver nanoparticles penetrate into the cell and bind to cell structures [35], act on DNA, preventing the proliferation of bacterial cells, and also destroy the cytoplasmic membrane and lead to the death of bacteria [36]. To date, a number of studies have shown that combinations of nanosilver with antibiotics increase the activity of the latter against strains with multiple drug resistance [37, 38]. Previously, we showed that poviargol contributed to the preservation of the antimicrobial activity of bone cement samples for up to 34 days and prevented the formation of microbial biofilms on them. Apparently, this is what is associated with the greater effectiveness of the complex treatment of patients with chronic PPI of the hip joint caused by gram-positive bacteria. In our opinion, this result may be a consequence of both a longer release of the antimicrobial drug from the bone cement due to an increase in its porosity, and the presence of a synergistic effect of vancomycin and the drug HD-Ag in relation to the inhibition of biofilm formation, proven in a study by other authors [39]. It is possible that the effect of poviargol on microorganisms at the cellular level is also due to the more pronounced dynamics of ESR normalization ($p = 0.005$) and the tendency to a greater decrease in CRP ($p > 0.05$) in the group with bone cement spacers impregnated with the silver drug.

It is important to remember that impregnation of bone cement with additional preparations affects the mechanical and physical properties of the antimicrobial spacer. We previously showed that adding vancomycin or its combination with 2.5 wt. % silver to bone cement did not lead to any deterioration in the mechanical properties of bone cement under bending and compression. A further increase in the silver content to 10 wt. % worsened the strength and elasticity under bending, but did not significantly affect the mechanical properties under compression and significantly increased the antimicrobial activity of the samples [40]. In our opinion, at the sanitizing stage, a decrease in the strength of the spacer is a largely positive factor, since it allows the spacer to be removed without any particular technical difficulties at the stage of reimplantation. However, this limits the use of the combination for permanent fixation.

It is also worth noting that in our study, no cases of reaction of the silver preparation with surrounding tissues, cases of argyria or other adverse events were detected.

CONCLUSION

Impregnation of bone cement based on polymethyl methacrylate with a combination of vancomycin and a highly dispersed silver preparation demonstrated significant clinical efficacy in arrest of periprosthetic hip joint infection caused by gram-positive bacteria (*Staphylococcus spp., Streptococcus spp., Enterococcus spp., etc*.). However, the absence of a significant clinical effect in a subgroup of patients with infection caused by gram-negative pathogens and microbial associations, as well as a significant proportion of cases where the final microbiological diagnosis is established only based on the results of a study of intra-operatively collected materials, indicate the need to develop new combinations for impregnation of bone cement in order to expand the spectrum of antimicrobial activity of spacers.

Conflict of interests *The authors read and approved the final version of the manuscript. All authors agree to be accountable for all aspects of the work to ensure that any potential questions related to the accuracy or reliability of any part of the work are appropriately reviewed and resolved.*

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Ethical statement *All manipulations involving human participants in the study were in accordance with the ethical standards of the institutional and/or national scientific ethics committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.*

Informed consent *Not required for this type of study.*

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Results of minimally invasive core decompression and autologous bone grafting in combination with autologous bone marrow aspirate concentrate in the treatment of patients with aseptic osteonecrosis of the femoral head

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Abstract

Introduction Currently, limb salvage methods have been used for the treatment of aseptic osteonecrosis of the femoral head (ANFH), but their use does not always avoid joint replacement in the later stages of the disease. The combination of core decompression and autologous bone grafting with autologous bone marrow aspirate concentrate (BMAC) in the treatment of patients with ANFH could improve their quality of life, delay joint replacement, or, in some cases, avoid it completely.

Purpose To evaluate the results of surgical treatment of patients with ANFH using minimally invasive core decompression and autologous bone grafting in combination with BMAC, develop an algorithm for choosing a method of surgical treatment based on the extent of damage to the femoral head and the stage of the disease.

Material and methods A pilot multicenter study included 86 patients diagnosed with ANFH. All patients underwent minimally invasive core decompression in combination with autologous bone grafting and BMAC. Results were analyzed 3, 6, 12 months after surgery.

Discussion Due to the fact that the presented study included mainly patients with post-Covid and steroid-induced osteonecrosis, and did not include patients with the first stage of the disease, the percentage of positive treatment results was slightly lower compared to other similar studies.

Results Within 3 to 6 months after surgery, 21 patients (24 %) required joint replacement; among the remaining 65 patients (76 %), there was a significant improvement in the condition and quality of life that was confirmed by instrumental studies and functional assessment.

Conclusion The technique of minimally invasive core decompression and autologous bone grafting in combination with BMAC is an effective method of treatment patients with pre-collapse ANFH stages, might improve their quality of life but does not allow regression of structural changes in the bone.

Keywords: osteonecrosis, femoral head, core decompression, bone grafting, bone marrow aspirate concentrate

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INTRODUCTION

Aseptic osteonecrosis is a multifactorial degenerative disease characterized by impaired microcirculation in a certain bone tissue area, leading to the death of osteocytes, demineralization, resorption, as well as changes in the trabecular architecture of the bone resulting in secondary osteoarthritis of the adjacent joint [1, 2].

In general, to date there is no single epidemiological report on the incidence of this pathology among the general population. However, in a number of countries, screening is periodically carried out to identify and assess the prevalence of the above-mentioned disease in the population. According to statistics, in the USA, from 300 thousand to 600 thousand cases are affected by aseptic necrosis of the femoral head (ANFH) in the general population. From 10 thousand to 20 thousand new cases of the disease are registered annually. These numbers correlate with the results of studies conducted in other countries. Thus, a screening analysis of the Japanese population showed an incidence rate of 1.9 per 100 thousand, and in the UK from 1.4 to 3.0 per 100 thousand. It is worth noting that the majority of patients suffering from this pathology are young and working-age people who have high demands on joint function [3, 4, 5].

Currently, the pathogenesis of ANFH remains incompletely understood, but it has been established that one of the etiological factors of the disease is long-term use of glucocorticosteroids (GCS), which has become widespread during the COVID-19 pandemic. The use of GCS has become an effective method for treating moderate forms of the disease and for relieving acute respiratory syndrome, what has saved the lives of many patients [6, 7]. The high therapeutic potential of these drugs in relation to COVID-19 is explained by their ability to significantly suppress the expression of major pro-inflammatory mediators such as IL-1, IL-6, TNF-α, IFN-γ to hinder the development of a "cytokine storm" and help prevent acute respiratory distress syndrome [8, 9, 10]. However, it has been proven that long-term hormonal therapy leads to serious side effects, one of which is ANFH [11, 12, 13, 14].

Moreover, it is now reliably known that the new coronavirus infection may lead to the development of osteonecrosis even without the administration of GCS due to disseminated coagulopathy and occlusions of the small vascular bed [7, 11, 12].

Speaking about the ANFN pathogenesis, it is also necessary to note the ongoing structural changes in bone tissue that prevent its independent regeneration. The explanation lies in the a sclerotic plate formed by osteocytes during osteonecrosis, which separates the necrotic area from the healthy bone and hinders vascular invasion into the pathological focus, as a result of which its further revascularization becomes impossible [3, 15, 16, 17].

Since the 1960s, limb saving methods of treating ANFH have been widely used in orthopaedic practice, such as decompression of the necrotic lesion, vascularized and non-vascularized bone grafting [18, 19, 20]. These methods of surgical treatment are used at precollapse stages of osteonecrosis, but, unfortunately, they do not always achieve the desired result and could not postpone joint replacement for a long time or help avoid it [21, 22, 23, 24, 25].

In current traumatology and orthopaedics, studying the possibilities of orthobiological products is of great importance, one of which is autologous bone marrow apirate concentrate (BMAC). The high regenerative potential of mesenchymal stromal cells (MSCs) was appreciated by the French scientist P. Hernigou, who was the first to use BMAC for the treatment of aseptic osteonecrosis [26].

The hypothesis of our study was based on the idea of possible improvement of treatment results in patients with ANFH by combining a traditional surgical technique of necrotic lesion decompression and bone autografting with a modern BMAC orthobiological product [22, 27, 28, 29, 30].

The **purpose** of the work was to evaluate the results of surgical treatment of patients with ANFH by the method of minimally invasive decompression and bone autografting in combination with BMAC, as well as to develop an algorithm for choosing a surgical method based on the volume of the femoral head lesion and the stage of the disease.

MATERIALS AND METHODS

A pilot multicenter prospective non-randomized study was conducted from 2021 to 2023 at the Center for Traumatology and Orthopaedics of the Burdenko Main Military Clinical Hospital (Moscow), Volgograd State Medical University (Volgograd), and the Federal Center for Traumatology, Orthopфedics, and Joint Arthroplasty (Cheboksary).

The clinical study complied with the requirements set forth in the Declaration of Helsinki. The study was approved by the institutional ethics committee (registration number: IRB 00005839 IORG 0004900 (OHRP)). Patients voluntarily gave written informed consent to participate in the study and publish its results.

A total of 93 patients underwent treatment with the technique described. According to the inclusion and exclusion criteria, the study involved 86 patients diagnosed with ANFH: 64 men, 22 women in the average age of (40.1 ± 6.7) years, body mass index (28.2 ± 3.8), disease duration (6.2 ± 4.1) months. Unilateral process was observed in 23 patients and bilateral in 63; the volume of femoral head damage ranged from 15 to 60 %. A confirmed diagnosis of COVID-19 preceding the manifestation of pain was in 73 cases (84.9 %); 61 patients (70.9 %) underwent glucocorticosteroid therapy, the total dosage of which was (406 ± 28) mg in dexamethasone equivalent.

The diagnosis was established based on complaints, anamnesis and data from instrumental methods (X-rays, CT, MRI). MRI study detected signs of aseptic necrosis. On T2-weighted images, a perifocal zone of heterogeneous hyperintensive signal was visualized due to edema and bone marrow ischemia in the femoral head area. On T1-weighted images, the above-mentioned areas had a hypointensive signal and corresponded to an osteonecrotic lesion.

To assess the clinical and functional state of the hip joint and the results of treatment, the following evaluation systems were used: modified Harris Hip Score, Lequesne index (limitation of life activities), UCLA Activity Score, Eq-5d (quality of life questionnaire), visual analog scale for pain (VAS), subjective assessment of quality of life (0 to 100 %).

Inclusion criteria were:

— Association Research Circulation Osseuos (ARCO) ANFH stage 1–2;

— MRI findings of areas of trabecular edema in the femoral head area;

— Pain intensity not lower than 6 VAS points.

The study excluded patients over 60 years of age, HIV-infected patients, carriers of antigens to hepatitis B and C viruses, as well as individuals with blood and/or bone marrow diseases, with concomitant pathologies of internal organs in the decompensation stage, and subjects with a history of malignant oncological diseases. Also, the exclusion criteria were the presence of an acute inflammatory process; intra- and (or) peri-articular GCS injections, hyaluronic acid preparations or other orthobiological products within 6 months before the initial examination.

All patients underwent minimally invasive decompression and bone autografting of the femoral head in combination with ABMC.

The treatment results were interpreted 3, 6 and 12 months after the operation. At follow-ups, the dynamics of pathological changes were assessed studying MRI findings, determining the size of the osteonecrotic lesion and trabecular edema of the femoral head, its sphericity, as well as the presence of signs of secondary osteoarthritis.

The main criterion for failure in the treatment of this pathology was the need for hip arthroplasty in patients selected for the study. Moreover, the final result was considered poor if collapse of the articular surface of the femoral head or significant signs of secondary osteoarthritis based on radiological diagnostic methods were detected. Objectively, the outcome of the study was assessed as poor if HHS was 70 points and lower.

Statistical processing of the results was carried out using mathematical statistics methods, using the Excel 2019 for Windows.

Analysis of parameters with a normal distribution of values was carried out using the Student t-test. In turn, nonparametric quantitative features were analyzed using the Friedman criterion. The results obtained were compared with the tabular values at the selected level of statistical significance $p < 0.001$.

The research centers used different methods for obtaining BMAC. Clinics in Moscow and Cheboksary used the automated closed system Angel® System (Arthrex, USA). At the clinical base of the department of traumatology, orthopaedics and military field surgery in Volgograd, BMAC was obtained by centrifuging the aspirate in YCELLBIO tubes (Korea). In this regard, a preliminary laboratory study was conducted to select optimal centrifugation modes, determine the qualitative and quantitative characteristics of orthobiological products.

Evaluation of qualitative and quantitative characteristics of orthobiological products

Bone marrow aspirate from 22 patients was studied in the laboratories of the Burdenko Main Military Clinical Hospital, Volgograd State Medical University and Volgograd Medical Research Center. BMAC was obtained using the automated closed system Angel® System (Arthrex, USA) at a hematocrit of 15, as well as the centrifugation method in YCELLBIO tubes (Korea) at a speed of 2400 rpm for 10 min.

Flow cytometry and a cell analyzer were used to study the characteristics of the aspirate and supernatant. The samples were layered on Ficoll-Paque Plus (Sweden) with a density gradient of 1.077 g/ml, separated, and a fraction with "pure" mononuclear cells was isolated. Flow cytometry was used for immunophenotyping and determining the concentration of MSCs in the resulting sample, using antibodies to marker co-receptors: CD73, CD105, CD90. A cell analyzer was used to count the number of erythrocytes, platelets, leukocytes, and lymphocytes.

According to the data obtained, the above-mentioned methods provided the increase in the number of MSCs and platelets in the concentrate by 6–9 and 10–12 times, respectively, compared to native aspirate, and the orthobiological products obtained by automated means and by centrifugation in special test tubes had similar qualitative and quantitative characteristics.

Surgical technique

Collection of bone marrow aspirate After the surgical field had been treated and with the patient in the supine position on an orthopedic table (Fig. 1) under spinal anesthesia, the first step was to perforate the cortical layer in the area of the anterosuperior iliac wing spine using an 11G aspiration trocar. The tip of the aspirator was immersed in the bone with rotational movements to a depth of 2 to 7 cm. Next, using a syringe, an aspirate was collected in a volume

of 90 to 160 ml (Fig. 2). Moreover, during bone marrow aspiration, the direction of the trocar tip in the thickness of the spongy bone changed in order to minimize the entry of the patient's peripheral blood into the syringe and achieve the maximum concentration of blast cells in the aspirate.

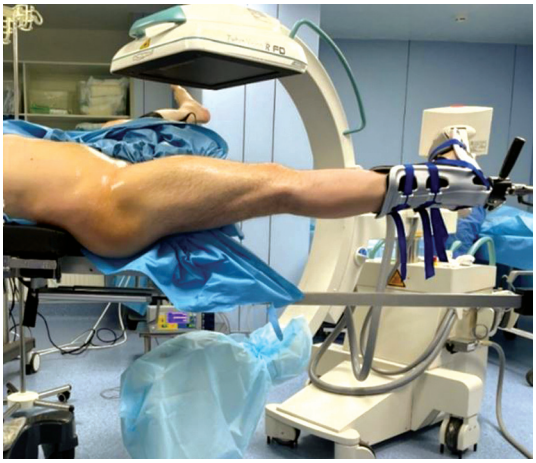

Fig. 1 Patient's position on the orthopaedic table

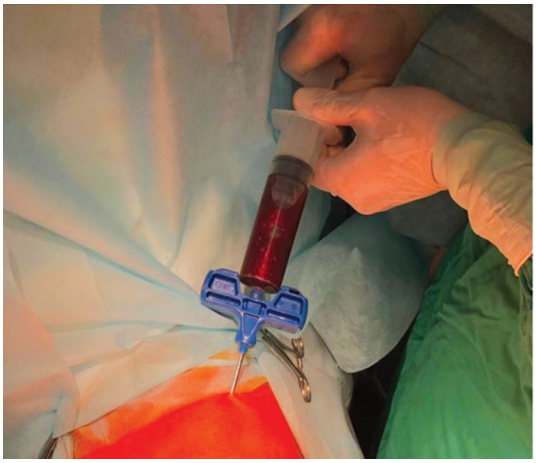

Fig. 2 Aspiration of bone marrow from the iliac crest

BMAC production In the clinics of the Burdenko Main Military Clinical Hospital and the Federal Center for Traumatology and Orthopaedics, bone marrow aspirate was placed in an automated closed system Angel® System (Arthrex, USA) together with 15 ml of anticoagulant (heparin 5000 U), then centrifuged with a hematocrit parameter of 15.

At the clinical base of the Volgograd State Medical University, bone marrow aspirate was distributed into YCELLBIO tubes (Korea) together with an anticoagulant (heparin 5000 U) at a ratio of 1.5 ml of anticoagulant per 13.5 ml of bone marrow aspirate in each tube, then they were centrifuged at 2400 rpm for 10 min according to the original method (RU Patent No. 2763250) [39]. After separation, the fraction with a high MSC content was centered in the narrow neck of the tube and extracted using a syringe (Fig. 3). Then, a bone autograft was collected from the iliac wing in a volume of about 18 cm^3, which was crushed into fragments using bone rongeurs and mixed with the previously produced BMAC (Fig. 4).

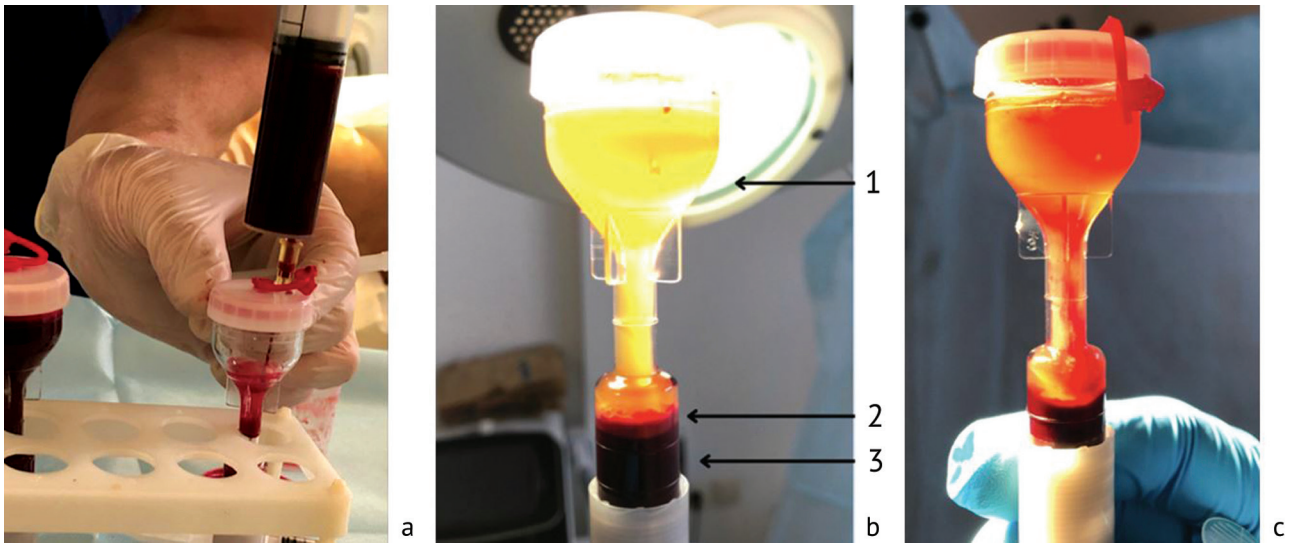

Fig. 3 Placing the aspirate into YCELLBIO tubes (*a*); separation into fractions (1 — plasma, 2 — fraction with a high content of MSCs, 3 — erythrocyte mass (*b*); centering the bone marrow concentrate in the neck of the tube by rotating the rotary cap (c)

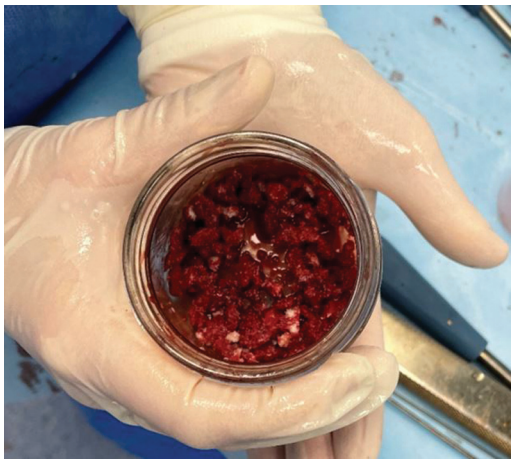

Fig. 4 Crushed autogenous bone mixed with BMAC

Decompression and autogenous bone grafting of osteonecrotic lesions Without changing the patient's position on the operating table, a 2.3-mm diameter Kirschner wire was percutaneously inserted along the lateral surface of the thigh, distal to the greater trochanter, into the center of the osteonecrotic lesion that localizes in the anterosuperior sector of the femoral head. The positioning of the guide wire was controlled with an image intensifier in the direct and axial projections.

At the site of wire insertion, a 2–3 cm long surgical approach was performed. Next, a 10-mm diameter cannulated drill was installed along the wire and drilling was performed along the femoral neck to the affected area, removing necrotic masses and surrounding areas of osteosclerosis as completely as possible (Fig. 5).

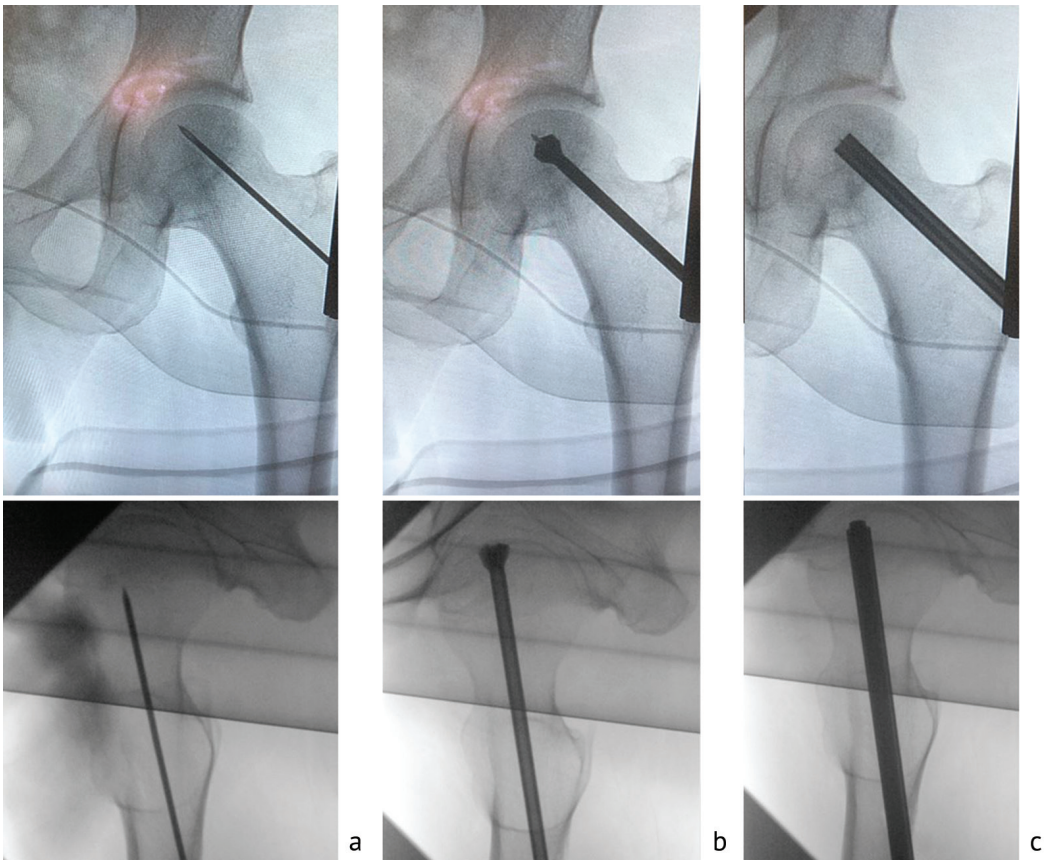

Fig. 5 Stages of bone grafting of the osteonecrotic focus in the femoral head: *a* insertion of a wire into the area of the necrotic focus; *b* reaming with a cannulated drill; *c* insertion of an instrument for bone grafting

After removing the drill, a hollow 9-mm diameter guide was inserted into the resulting canal. Next, under the EOP control, the crushed bone autograft, pre-mixed with BMAC, was impacted into the target zone of the femoral head by doses (Fig. 6). The wound was sutured layer by layer.

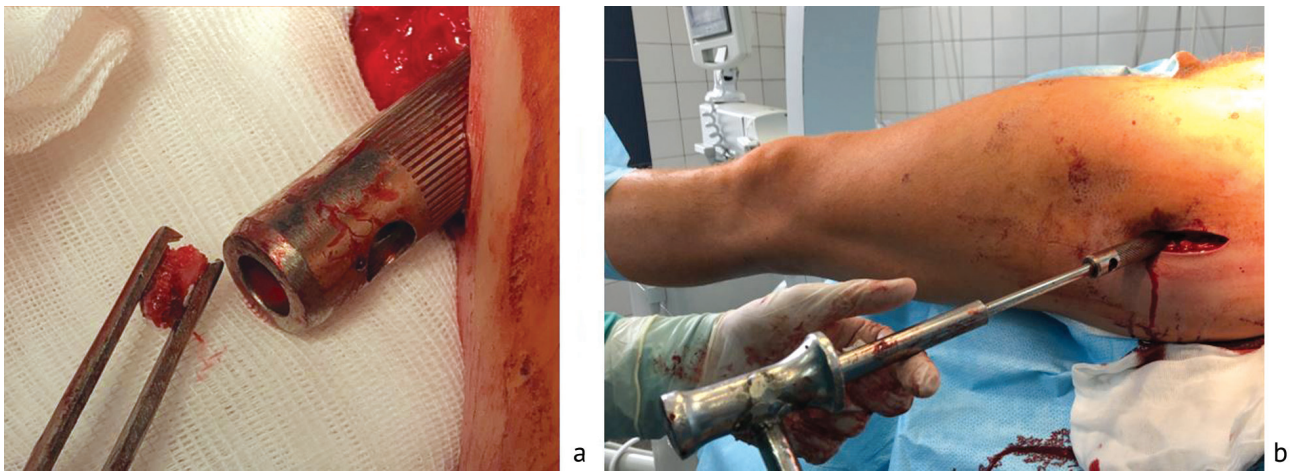

Fig. 6 Introduction of crushed bone autograft with BMAC into the osteonecrosis lesion: a dosed loading through a hollow bone conductor; *b* impaction

Postoperative patient's care On the first day after the operation, all patients underwent radiography of the affected joint (Fig. 7).

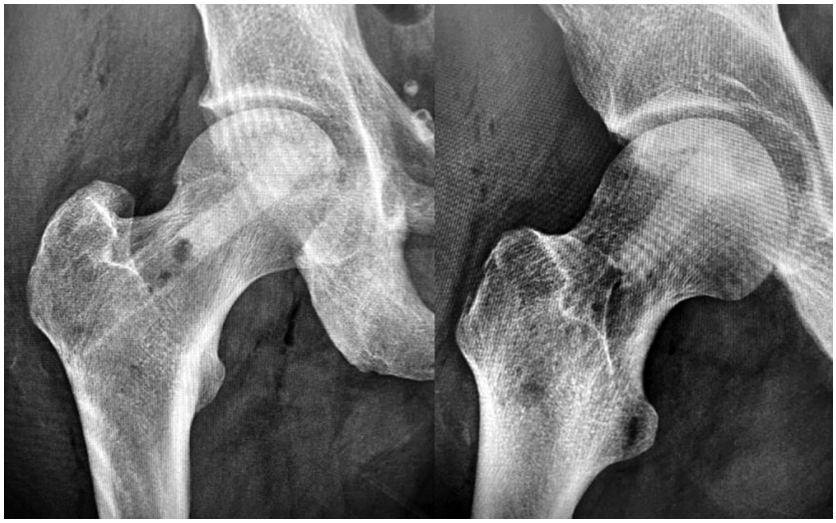

Fig. 7 Postoperative radiograph of patient B., 33 years old, which clearly shows the column of bone autograft impacted into the osteonecrosis zone

During the first 4 weeks, axial load on the operated limb was completely excluded. After one month, patients were allowed a dosed load on the leg of 20 % of body weight that gradually increased to full load over 4 weeks. All subjects were prescribed drug therapy in accordance with current recommendations for the treatment of ANFH [1]. The treatment regimen included calcium and vitamin D preparations intake for 3 months, bisphosphonates, anticoagulants for 1 month, and after their cessation antiaggregants for 2 months.

RESULTS

Six months after the surgical treatment, 21 patients (24 %) required joint replacement due to persistent pain and poor clinical and functional state (Fig. 8). According to MRI, the osteonecrotic lesion in this group of subjects occupied more than 30 % of the femoral head in the preoperative

period and was accompanied by pronounced trabecular edema, which corresponded to ARCO stage IIC. In the postoperative period, 16 (76.2 %) of those patients had collapse of the articular surface of the femoral head, 5 (23.8 %) continued to complain of pain (more than 6 VAS points) and impaired lower limb function, as a result of which the overall quality of life of the patients significantly decreased. As there was no possibility to objectively assess such patients according to clinical and functional systems, the results of their survey were excluded during statistical data processing.

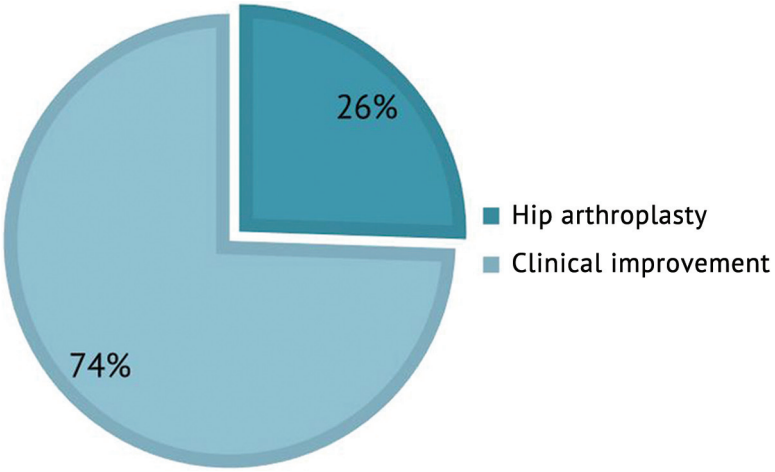

Fig. 8 Proportion of patients who achieved clinical improvement after decompression autoplasty with BMAC and who underwent hip arthroplasty

The obtained average values of the functional state of the hip joint of the remaining 65 patients, assessed with six evaluation systems in the postoperative period, were significantly higher than before the surgical intervention, and the identified differences were not only reliable, but also highly significant ($p < 0.001$).

VAS evaluation of the treatment results in that group of patients who did not require joint arthroplasty showed decrease in the pain level from (6.9 ± 1.4) to (2.4 ± 1.4) points 3 months after surgery. Within 3 to 6 months of follow-up, the pain intensity index remained unchanged and was (2.3 ± 1.3) points, and by 12 months it had smoothly decreased to (1.7 ± 0.5) points.

The modified HHS showed an improvement in the hip joint function in all 65 patients who underwent decompression and bone autografting with BMAC, and whose treatment results were included in the statistical processing of the data. Three months after the operation, the average value reached 76 points, and the result was assessed as fair. After 12 months of follow-up, the indicator increased to 83 points, which corresponded to a good clinical and functional state of the joint.

The assessment of Lequesne life activities restrictions also showed a gradual improvement in such indicators as pain and discomfort, walking distance, and daily activities from “significant” limitation before the operation to “mild” limitation one year after the treatment.

Similar findings were obtained with the UCLA Activity Score. Patients noted a significant increase in motor activity over time. A small increase in indicators at the first time-points was explained by a fairly long rehabilitation period, but by one year from the date of the operation, a significant improvement in functional results was recorded.

Analysis of the patients' quality of life based on a subjective 100-point scale, as well as the Eq-5d questionnaire, showed positive dynamics in mobility, self-care, everyday activity, pain and discomfort, anxiety and depression. According to respondents, their quality of life was estimated at 60 % in the preoperative period, and a year after treatment increased to 85 % (Table 1).

Table 1

Results of the patients' survey at studied observation time-points

Evaluation system	Before intervention	3–6 months after intervention	9–12 months after intervention
VAS	6.9	2.4	1.7
Modified Harris Hip Score	66.6 (poor)	76.6 (fair)	83.6 (good)
Lequesne index (limitation of life activities)	12.8 (marked)	5.5 (moderate)	3.2 (mild)
UCLA Activity Score	2.4	3.6	7.9
Eq-5d (quality of life questionnaire)	10.8	9.1	7.8
Subjective evaluation of quality of life (0–100 %)	60 %	80 %	85 %

In order to assess the morphological changes in the autograft, a histological study of the resected femoral head of one of the patients who underwent joint arthroplasty surgery was performed. The preserved preoperative MRI data allowed us to compare the MRI picture, the visual characteristics of the sawn macropreparation and the results of the histological study.

The comparison of the volume of the femoral head lesion visible on the macropreparation and the volume of the autograft impacted into the osteonecrosis zone revealed that the entire osteonecrotic bone tissue focus was not replaced with the technique applied. The results of the histological study showed that there was no complete restructuring of the autograft. The microscopic picture of the micropreparation corresponded to aseptic bone necrosis with the presence of the fragments of spongy bone tissue, partially lysed bone trabeculae, fibrous foci with inclusions of fatty tissue in the intertrabecular space (Fig. 9).

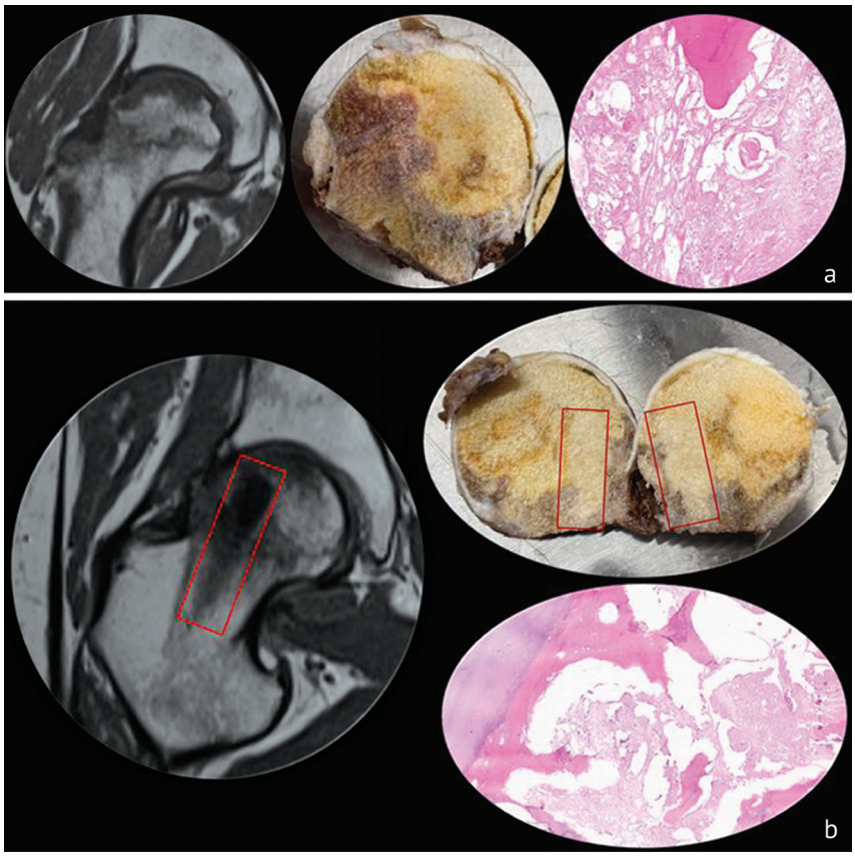

Fig. 9 MRI image, macropreparation and histological image of the femoral head sections in patient K., 43 years old: *a* section without bone grafting areas; *b* section with a column of bone autograft (red rectangle)

One year after the surgical treatment, after comparing the clinical and radiographic findings in the group of 65 patients who did not need joint replacement, 10 cases showed a collapse of the femoral head, 15 cases showed no structural changes in bone tissue, and 40 cases showed regression of trabecular edema of the femoral head and neck despite a good clinical outcome (Fig. 10, 11).

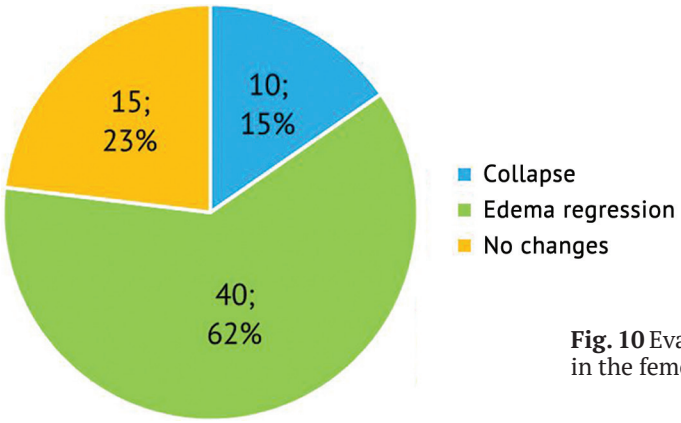

Fig. 10 Evaluation of structural changes in the femoral head based on MRI

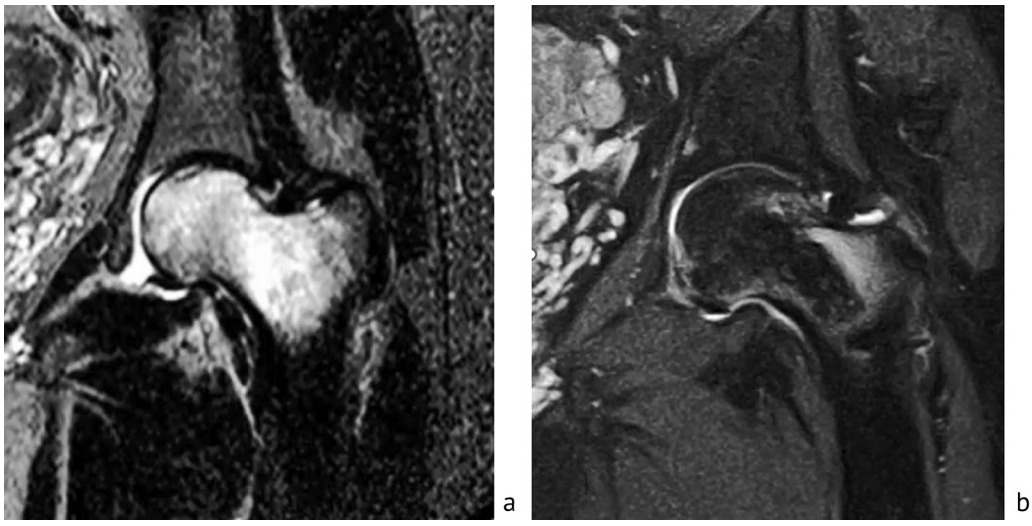

Fig. 11 MRI image of the hip joint of patient T., 45 years old, with ANFH: a before surgery; b 6 months after treatment

During the surgical treatment and subsequent observation, one complication (0.86 %) was detected, neuropathy of the external cutaneous nerve of the thigh, which probably occurred as a result of nerve trauma during the collection of bone autograft from the iliac crest. Paresthesia resolved 6 months after the surgery without drug therapy.

DISCUSSION

Our pilot multicenter prospective non-randomized study demonstrated the effectiveness of minimally invasive decompression and bone autografting combined with BMAC in the treatment of patients with ANFH. Most patients showed a decrease in pain, an improvement in the functional state of the hip joint and overall quality of life at all follow-up time-points.

The surgical treatment tactics used in the study provided arrest of disease progression and prevented the collapse of the femoral head in 55 patients (63.9 %). However, it was not possible to achieve a noticeable regression of pathological structural changes. According to the results obtained, the undertaken minimally invasive surgical intervention allowed 76 % of patients to avoid hip arthroplasty within 12 months of observation.

Decompression of the osteonecrotic lesion proposed by P. Ficat and J. Arlet is a generally accepted technique used over the past decades [31]. It is believed that this surgical intervention may eliminate bone marrow edema and excessive intraosseous pressure, improve local perfusion of bone tissue and create conditions for revascularization of the affected area [26, 30]. Unfortunately, in most cases, the use of core decompression only does not allow for a comprehensive effect on the main links in the ANFH pathogenesis and to obtain the desired treatment result by applying this method. Moreover, according to some researchers, classical core decompression to create a tunnel which is 8–10 mm in diameter without bone grafting, may deprive the subchondral bone of support and provoke its collapse [22, 23, 35]. Due to the high percentage of poor outcomes, independent researchers have attempted to improve organ salvage methods for treating ANFH [32]. The basic concept is to modernize decompression by combining it with various types of vascularized and non-vascularized grafts, as well as applying various synthetic materials [3, 22, 24, 27, 28].

In 1996, Mont et al. reviewed 42 studies to compare the effectiveness of decompression of the osteonecrotic focus and non-operative treatment tactics for patients with ANFH; the treatment results of 2025 people were analyzed. In the group of decompression (n = 1206), the rate of satisfied patients ranged from 53 to 63 %. In the control group (n = 819) of a conservative treatment method, only 22 % of patients achieved positive results [21].

In 2008, Seyler et al. analyzed the treatment results of 33 patients (39 hip joints) with ANFH stages II and III according to the classification of P. Ficat and J. Arlet (1980). All subjects underwent decompression of the osteonecrotic lesion in combination with impaction of a non-vascularized autograft. After 36 months, 26 (67 %) of the 39 hip joints did not require hip arthroplasty; the authors considered the treatment results of their patients successful [33].

In 2023, a group of Indian scientists led by H. Singh performed decompression with autoplasty with a cancellous graft in 20 patients with ANFH stage I and II according to the classification of P. Ficat and J. Arlet (1980). Ninety percent of the subjects were young people aged 20 to 40 years. After 6 months, the authors diagnosed the development of secondary osteoarthritis or signs of osteonecrosis progression to stage III or IV of the disease in 30 % of patients [34].

High rates of poor outcomes of limb preserving surgeries for ANFH were caused mainly by incomplete regeneration of the area of aseptic bone necrosis and directed the search for new approaches to improve treatment results towards regenerative medicine [18, 21, 29, 30].

Autologous bone marrow aspirate and concentrate (ABMC) are among the basic orthobiological products. The mechanism of their action has not been sufficiently studied, but the mesenchymal stromal cells they contain with their paracrine effect and the ability to differentiate along the osteogenic pathway, numerous growth factors, cytokines, and biologically active molecules suggest the potential for using these products to stimulate reparative processes in various types of connective tissue. Experimental studies and the few clinical studies on the use of orthobiological products in the treatment of musculoskeletal diseases and injuries show very encouraging results [22, 26, 27, 28, 36, 37, 40, 41]. As for aseptic necrosis itself, the stimulating effect of ABMC on vascular proliferation has an undoubted pathogenetic significance. Secretion of growth factors in BMAC such as VEGF and PDGF contributes to angiogenesis and reduces ischemia of the affected bone area. Along with this, the anti-apoptotic and immunomodulatory effects of BMAC, achieved by inhibiting TNF-α, as well as IL-1, IL-6, IL-12 and other inflammatory mediators, prevent disease progression and further destruction of the joint [22, 28, 37].

The possibility of core decompression in combination with BMAC introduction was first reported by Hernigou et al. based on the results of a prospective study involving 534 patients with aseptic necrosis of the femoral head stage I and II according to the Steinber classification [38]. The follow-up period ranged from 8 to 18 years (13 years on average). Throughout the study follow-up, 94 patients required

joint replacement, which is 17 % of the total number. In patients who did not require joint replacement (n = 400), an improvement in the clinical and functional state was found according to the Harris scale (70 points before surgery, 88 points in the postoperative period). The authors noted a direct dependence of the treatment results on the number of progenitor cells administered with the concentrate [26]. The latter was logically consistent with the known fact of a significant decrease in the number of osteoblasts and MSCs in bone tissue during ANFH progression that explains the decrease in the ability of bone tissue to osteogenesis and replacement of the necrotic focus with "living" bone [2, 3, 15, 16].

Some comparative clinical studies showed the advantages of BMAC as an adjunct to conventional surgical treatment. Thus, in a prospective double-blind randomized study by Wang et al., including 45 patients (53 hip joints) diagnosed with ANFH stages I–III, the functional results of decompression of the necrotic lesion combined with bone autografting and BMAC administration after 24 months of observation were significantly better than those in patients who underwent decompression alone. Moreover, in the comparison group, the authors observed MRI signs of disease progression in 33.3 % of cases, and hip arthroplasty was performed in 4 patients. In the main group of patients, negative dynamics were noted in only 8 % of cases, while 2 patients with stage III ANFH required joint arthroplasty [35].

In 2020, Zhang et al. conducted a systematic meta-analysis to evaluate the efficacy of osteonecrotic lesion decompression in combination with BMAC. The work included 16 clinical studies, 7 of which were randomized. The total number of participants was 1051. Patients in the main group (n = 583) underwent decompression in combination with cell therapy, and in the comparison group (n = 468) only femoral head decompression was used. The results were assessed over 24 months based on the VAS and Harris scales, as well as the patients' need for total joint arthroplasty. According to the final results, the evaluation scores were higher in the group where osteonecrotic lesion decompression was combined with the use of an autologous bone marrow aspirate product. After the treatment, hip replacement was required in 22.5 % and 43.3 % of patients in groups 1 and 2, respectively [36]. In general, according to the systematic review by Zhang et al. and a number of other case studies in recent years, positive outcomes of surgical treatment using decompression in combination with BMAC at precollapse stages of the disease can be achieved in 70–90 % of cases, which is 20 % higher compared to using decompression alone, without bone marrow concentrate [21, 33, 34, 35, 36].

The aim of our study was to evaluate the impact of minimally invasive decompression, bone autografting combined with BMAC on hip function and quality of life in patients with ANFH, as well as on pathological structural changes occurring in the femoral head.

According to the data obtained, we achieved successful treatment outcomes in 76 % of cases. Due to the fact that the presented study mainly included patients with post-COVID and steroid-induced osteonecrosis, and there were no subjects with the first stage of the disease, the rate of positive treatment results was slightly lower compared to other similar studies. It also cannot be ruled out that the stage of the disease might have been determined incorrectly in some patients. The reason for this was the high intensity of bone marrow edema on MR images, as a result of which the symptoms of subchondral bone tissue lysis might have remained undetected. Meanwhile, it is these changes that are identified as the "crescent symptom" and are considered a pathognomonic sign of stage IIIA according to the ARCO classification, in which organ salvage treatment methods are recognized as ineffective in most cases [25, 26, 28, 30, 35].

Along with the uncontroversial need to consider the staging of ANFH for choosing treatment tactics, our work also confirmed the no lesser importance of assessing the extent of the femoral head lesion. In patients with stage II and a lesion volume of up to 30 %, the need for hip replacement after minimally invasive decompression in combination with bone autografting combined with BMAC was relatively low. For patients with stages IIIB and IV, hip arthroplasty remains the optimal solution, since in their cases the likelihood of secondary osteoarthritis remains extremely high [18, 21, 29, 30, 35, 38].

The limitations of our study were a relatively small sample size, the absence of a control group and patients with the first stage of the disease. Moreover, the follow-up was short, and the clinical and functional systems of evaluation were mainly based on the subjective opinion of the respondents.

CONCLUSION

The study showed the effectiveness of minimally invasive decompression and bone autografting combined with BMAC in the treatment of patients with ANFH. In most cases, a decrease in the level of pain, improvement in the functional state of the hip joint and quality of life of patients at all follow-up points of the study were observed. However, no noticeable regression of pathological structural changes in the bone tissue was revealed. To obtain more objective data on the effectiveness of BMAC in the surgical treatment of ANFH, it is necessary to conduct a study with a larger sample of patients and a control group, as well as an analysis of long-term treatment results.

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

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Ethical statement *The study was approved by institutional ethics committee (registration number: IRB 00005839 IORG 0004900 (OHRP)).*

Informed consent *Patients gave voluntary written informed consent to participate in the study and publish its results.*

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Kinematic alignment in robotic total knee arthroplasty

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Abstract

Introduction There are two main concepts of total knee arthroplasty: mechanical and anatomical alignment of the lower limb axis. Howell et al. (2013) proposed the concept of kinematic alignment, the main idea of which is to preserve the level of the joint line and the axis of the lower limb that patients had before the onset of osteoarthritis. Initially, kinematic alignment was proposed to be performed with individual guides based on the results of CT/MRI scans but they took a long time to manufacture, were difficult to install, broke down, and were quite expensive. Introduction of robotic orthopaedic systems into clinical practice enabled to plan and perform bone resection with high accuracy, to install the components of the implant system according to the necessary concept thus providing new opportunities for the application of kinematic alignment, which was the purpose of our study.

Objective To study the possibilities of a robotic surgical system in performing restricted kinematic alignment in total knee arthroplasty (TKA).

Materials and methods A prospective single-center study was conducted in 47 patients (12 men and 35 women) with knee osteoarthritis in Kellgren – Lawrence grades 3–4, an average age of 65.87 ± 7.4 years, an average BMI of 31.3 ± 4.7, median HKA angle of 175°, median LDFA of 87°, median MPTA of 87°. The patients underwent robotic total knee arthroplasty (RoTKA) with the method of restricted kinematic alignment.

Results On the control whole-leg radiographs, the average HKA angle after surgery was 176° ± 1.5°. In 42.6 % of cases, the deviation from the plan was within ± 1°, the deviation ± 2° in 44.7 % of cases, and in the remaining 12.7 % of cases the deviation was negative.

Discussion In the literature, we did not find the results of radiographic evaluation of the HKA angle in the coronal view before and after robotic total knee arthroplasty and their comparison with the results of preoperative planning using the kinematic alignment method of the limb axis. The results we obtained show high accuracy of the implementation of the preoperative plan.

Conclusion A personalized approach to TKA with application of an autonomous robotic system effectively provides kinematic alignment of the axis of the lower limb with an accuracy of up to 2° in 87.3 % of patients.

Keywords: knee joint, robot, restricted kinematic alignment, robotic total knee arthroplasty

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INTRODUCTION

The anatomy and biomechanics of a healthy knee joint are constantly being studied and are individually variable. Pathological changes increase the difficulty of orientation in the surgical wound and have an impact on the results of knee arthroplasty [1–6].

At the beginning of total knee arthroplasty (TKR) introduction in the 1970s, the accuracy of the instruments was low and errors during implantation were frequent, so the main efforts were directed at improving the accuracy of implant placement, while reproduction of normal knee biomechanics was the second task [7].

Historically, two main concepts of total knee arthroplasty have been practiced for a long time: mechanical and anatomical techniques of lower limb axis alignment. The basis for the concept of mechanical alignment of the lower limb axis was laid by Inshall et al. and implied restoration o the neutral frontal mechanical axis of the limb and position of the knee joint line parallel to the horizon that improved load distribution on the tibial component and reduced its wear. Based on this concept, instruments were designed and an operating technique was developed [8–10]. The competing technique of Hungerford et al. was based on the concept of anatomical alignment of the limb axis, while the mechanical axis of the limb was also restored to neutral, but the joint line was located within 3º of varus deviation to the mechanical axis of the limb, thus improving knee biomechanics [9, 11, 12].

The philosophy of mechanical alignment is based on the precision of bone resection and the elimination of ligament imbalance by releasing the ligamentous apparatus, which allowed for an increase in the service life of the implants. In anatomical alignment, the ligament balance does not require an extended release, but the difficulty of performing bone resection with a varus angle of 3º resulted in more pronounced deformations, which affected the wear of the implant components and prevented the widespread use of the anatomical alignment technique [12].

A systematic review of studies on gait analysis of patients after TKA undertaken McClelland et al, demonstrated significant kinematic differences compared to normal gait [13]. A study by Bellemans et al. showed that 32 % of men and 17 % of women have constitutional varus of the knee joint of 3º [14]. According to Almaawi et al., the anatomical parameters in 4,884 patients with osteoarthritis during TKR planning varied and that the HKA (Hip-Knee-Ankle) was > 3° in 40 %, > 5° in 19 %, and > 10° in 3 % of patients. Therefore, reconstruction of the neutral mechanical axis in these patients required significant bone resection, caused soft tissue imbalance and problems with joint line orientation, which led to significant changes in knee joint kinematics [3].

Based on these studies, Howell et al. proposed the concept of kinematic alignment, the main idea of which is to maintain the level of the joint line and the axis of the lower limb that patients had before the onset of osteoarthritis [9, 10, 15].

Initially, it was proposed to perform kinematic alignment based on the results of CT/MRI scanning using personalized guides [16, 17]. However, the guides took a long time to manufacture (10–14 days), were difficult to install, broke, and were quite expensive. The use of standard instrumentation does not allow for reliable bone resection for kinematic alignment; the use of computer navigation allows visualization of the limb axis, but does not guarantee the accuracy of the resection, and a special instrumentation or customized implants are very expensive [15].

The introduction of robotic orthopaedic systems into clinical practice allows for planning and performing bone resection with high precision, installing components according to the chosen concept, and provides new opportunities for the use of kinematic alignment [18–23].

The **purpose** of the work was to evaluate the effectiveness of a robotic surgical system in performing restricted kinematic alignment in TKA.

MATERIALS AND METHODS

A prospective single-center study of 47 patients with gonarthrosis was conducted in 2023 at the Clinic of Traumatology, Orthopaedics and Joint Pathology of the University Clinical Hospital No. 1, Department of Traumatology, Orthopaedics and Disaster Surgery of the Sechenov Medical University.

Criteria for inclusion of patients in the study were:

— patients over 18 years old;

— diagnosis of gonarthrosis grade 3–4 according to the Kellgren – Lawrence classification;

— written informed consent for performing TKA according to the proposed technique.

Criteria for noninclusion of patients in the study were:

— risk of anesthesia in physical status greater than ASA 3;

— body mass index (BMI) more than 45 kg/m^2;

— knee joint deformity (varus > 10°);

— valgus deformity of the knee joint;

— extension contracture of the knee joint up to 90°;

— presence of a metal implant on the affected side;

— patients who underwent total arthroplasty of the contralateral knee joint using the mechanical alignment method.

Criteria for exclusion of patients from the study were:

— patient's refusal to continue participating in the study;

— patient's failure to comply with the prescribed regimen.

The study was approved by the institutional ethics committee of Sechenov University (protocol dated 08.12.22 No. 25-22) and registered on ClinicalTrials.gov (ID: NCT05750784). Informed consent from patients to participate in the study was obtained before inclusion in the study.

The study assessed the HKA angle, lateral distal femoral angle (LDFA) and medial proximal tibial angle (MPTA) before and after surgery, which were measured by radiologists together with trauma orthopaedic surgeons in the RadiAnt DICOM Viewer program and were introduced into the database.

Statistical processing of the clinical material was performed using IBM SPSS Statistics 23 (SPSS Inc., Chicago, IL): data grouping, calculation of intensive and extensive indicators, determination of the mean error of relative values, determination of normal distribution using the Shapiro – Wilk criterion. For truly numerical variables (age, BMI, mechanical axis, LDBU, MPTU), frequency histograms and values of statistical parameters were calculated, including the arithmetic mean (M), standard deviation (σ), statistical error of the mean (m), minimum and maximum values, and median (Me). To analyze changes in the parameters over time with a normal distribution before and after surgery, the paired Student's t-test was used, and with an abnormal distribution, the Wilcoxon test. Differences were considered reliable (statistically significant) at $p < 0.05$.

According to the inclusion and exclusion criteria, 47 patients (12 men and 35 women) were enrolled in the clinical study using the continuous sampling method (Fig. 1 a). The affected side was left in 21 and right in 26 patients (Fig. 1 b).

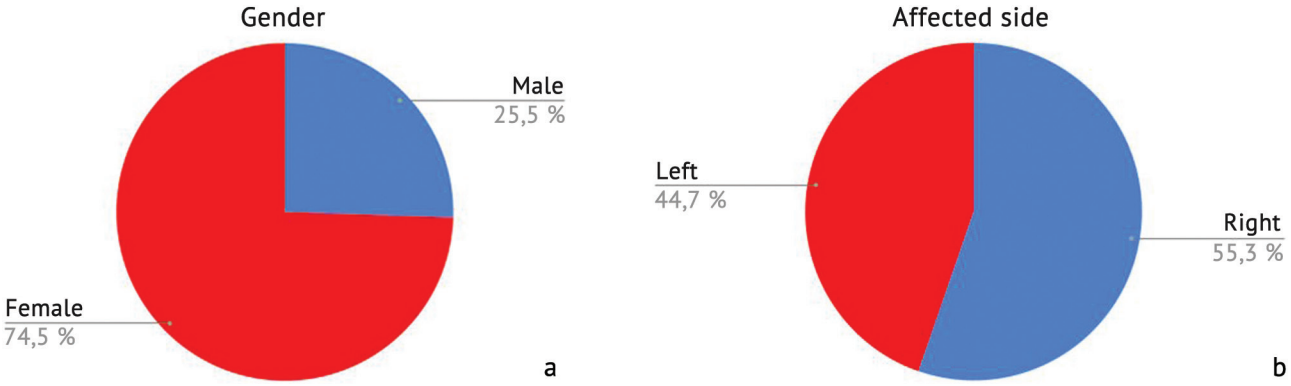

Fig. 1 Distributions of patients according to: *a*) gender; *b*) side affected

The mean age of patients was (65.87 ± 7.4) years (Shapiro – Wilk test, $p = 0.307$), the mean BMI was (31.3 ± 4.7) kg/m^2 ($p = 0.099$). The median HKA angle before surgery was 175° (min. — 170°; max. — 178°) ($p = 0.093$). The median LDFA before surgery was 87° (min. — 83°; max. — 90°) ($p = 0.002$), the median MPTA before surgery was 87° (min. — 83°; max. — 90°) ($p = 0.006$) (Table 1).

Table 1

Parameters studied

Parameter	Mean value	*p*
Age (years)	65.87 ± 7.4	0.307
BMI (kg/m^2)	31.3 ± 4.7	0.099
HKA (°)	175* (min — 170; max — 178)	0.093
LDFA (°)	87* (min — 83; max — 90)	0.002
MPTA (°)	87* (min — 83; max — 90)	0.006

* — median

Analyzing data by age, BMI and mechanical axis, the distribution was normal; the LDFA and MPTA data are assessed as different from the normal distribution (Fig. 2).

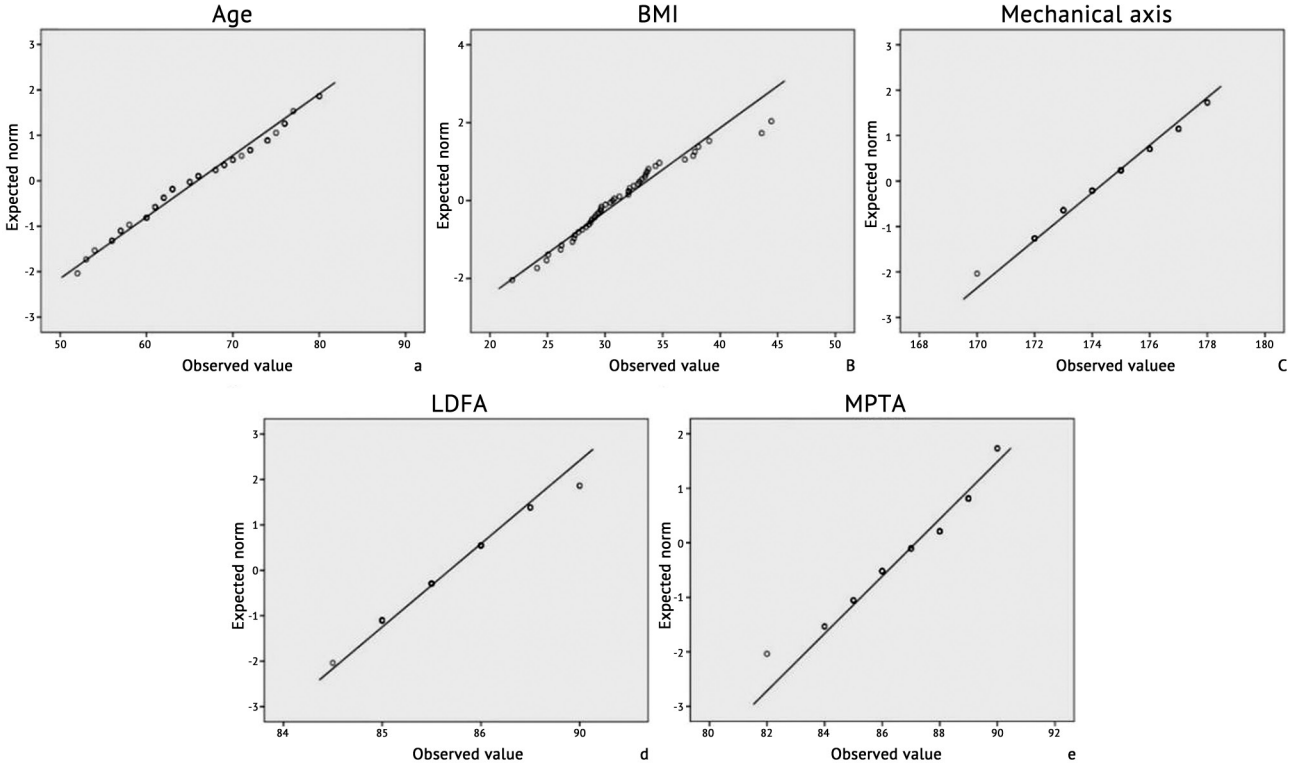

Fig. 2 Data distribution diagrams: *a* age; *b* BMI; *c* mechanical axis; *d* LDFA; *e* MPTA

Technique

To achieve the aim of the study, the autonomous robotic system T-Solution One® (THINK Surgical, Inc., USA) was used. The robotic total knee arthroplasty (RoTKA) technology consisted of three stages: CT examination of the lower extremities, preoperative planning in the TPLAN system, and surgery using the TCAT system.

CT examination was performed with the patient lying on his back with a calibration rod fixed to the affected limb; the results of the study were recorded on a compact disc [21].

The compact disc with the data was loaded into the TPLAN planning system for segmentation of CT slices with subsequent creation of a 3D model of the patient's lower limb. During planning, the TPLAN system allowed choosing a mechanical or a kinematic type of alignment. The unique feature of the TPLAN system is that when choosing the kinematic alignment technique during preoperative planning, it automatically installs the components of the endoprosthetic implant based on the anatomical features of the patient, but allows the surgeon to adjust the position of the implant (Fig. 3).

The planned HKA angle is 177°, as before the state of gonarthrosis developed, the inclination of the knee joint line relative to the horizon is up to 5°. The intact contralateral joint served as a sample. The axis of the lower limb, kinematic axes, such as the supracondylar and longitudinal axis of the tibia, were determined automatically during planning after marking the anatomical structures (head and epicondyles of the femur, centers of the plateau and distal articular surface of the tibia). The patellar axis was not determined, since the patella is not included in the anatomical landmarks in computer planning. The joint line was not measured, but obtained as a result of resection, which leads to an HKA angle of 177°. In mechanical alignment, the planned HKA angle was 180°, the knee joint slope angle was 0°. The plan was approved by the surgeon, and it was recorded on a CD (Fig. 4).

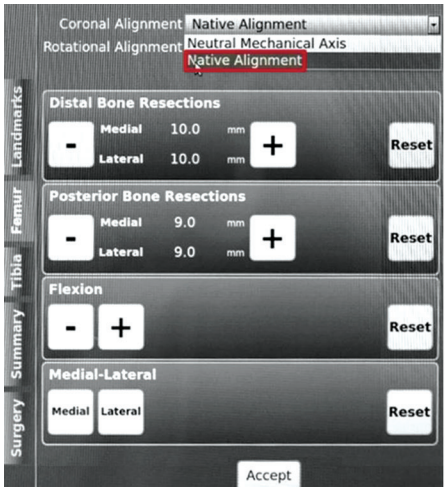

Fig. 3 TPLAN monitor by planning

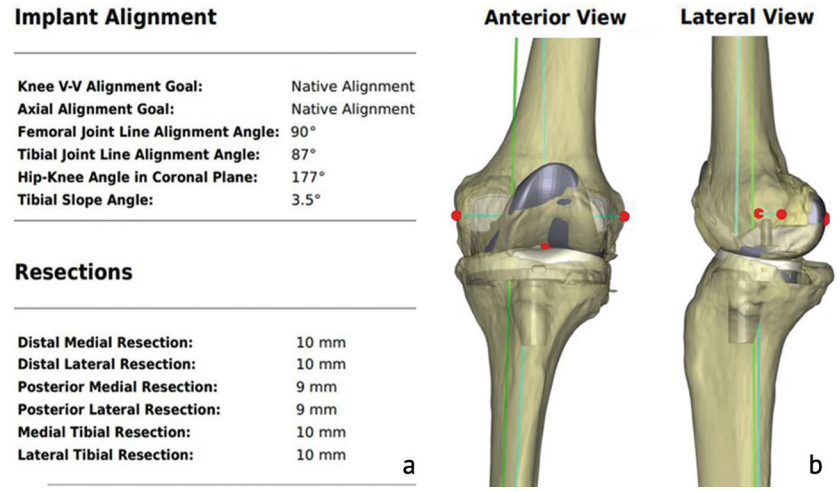

Fig. 4 Preoperative plan: *a* angles of implant placement and bone resection levels; *b* implant placement on the 3D model of the left knee joint

The CD with the approved plan was loaded into the TCAT system. RoTKA was performed using the restricted kinematic alignment technique with the aids of the T-Solution One® autonomous robotic orthopaedic system (THINK Surgical, Inc., USA) under spinal anesthesia without the use of a pneumatic tourniquet, performing a medial parapatellar approach with an outward dislocation of the patella. RoTKA stages: fixation of the lower limb in the leg holder at a flexion angle of 90–100°, surgical approach, fixation of the robot to the patient's limb, digitalization of the knee joint, resection of the articular surfaces of the bones, dismantling of the robot fixators, patellar processing, fitting, assessment of the range of motion, stability of the ligamentous apparatus, implantation of the components and wound suturing (Fig. 5).

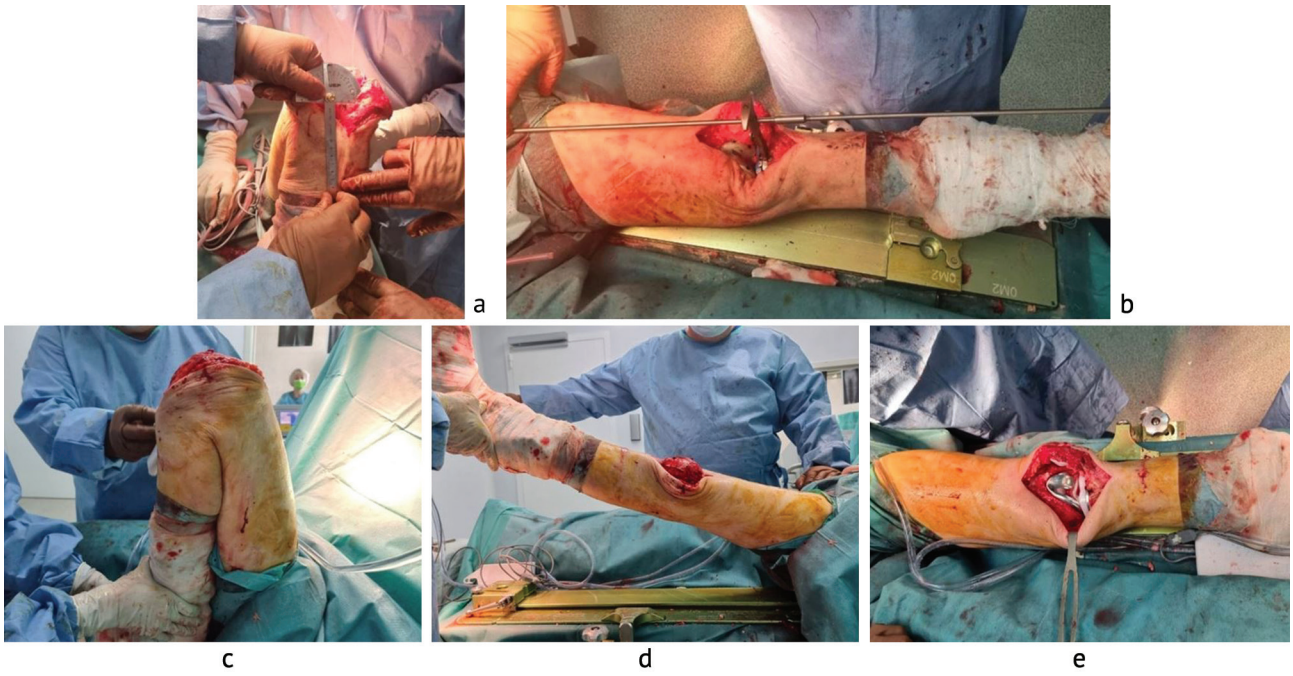

Fig. 5 Intraoperative procedures of RoTKA stages: *a* control of the tibial component position; *b* assessment of the mechanical axis; *c* assessment of flexion; *d* assessment of extension; *e* view of the installed implant

All patients underwent TKA with with the Zimmer® Persona implants, which currently have the largest size range, a minimum step of insert thickness of 1 mm, a type of containment with retaining of the posterior cruciate ligament with a fixed insert. Femoral components: standard or narrow, with a cemented fixation of the knee joint implant. Patellar plasty was not performed, only removal of osteophytes and circular denervation.

RESULTS

In the early postoperative period, on the third day, whole lower limb radiography was performed, after which a comparison was made with the preoperative whole-limb radiographs (Fig. 6).

The results of the analysis are presented in Table 2. On the control whole-leg radiographs, the average HKA angle after the operation was (176 ± 1.5)° (paired t-test, $p > 0.01$). In 42.6 % of cases, the deviation from the plan was within ± 1°, in 44.7 % of cases the deviation was ± 2°, in the remaining 12.7 % of cases there was a deviation in the negative direction: from –5° to –3° (Figs. 7, 8). The average value of LDFA and MPTA after the operation was 88° ($p > 0.01$, Wilcoxon test).

Table 2

Analysis of the results before and after the TKA

Value	Before intervention (min/max)	After intervention (min/ max)	*p*
HKA (°)	175 (170/178)	176 (172/179)	< 0.01*
LDFA (°)	87 (83/90)	88 (86/90)	< 0.01**
MPTA (°)	87 (83/90)	88 (84/90)	< 0.01**

Note: * — paired t-test; ** — Wilcoxon test

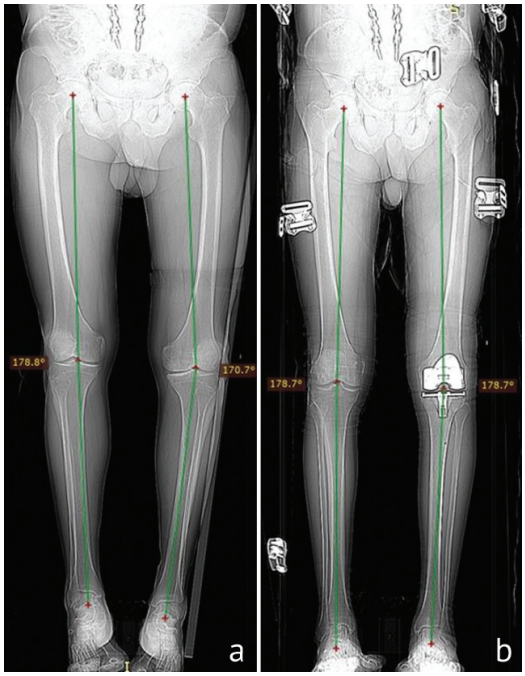

Fig. 6 Whole leg radiographs: *a* before surgery (HKA angle — 170°); *b* after surgery (HKA angle — 178°)

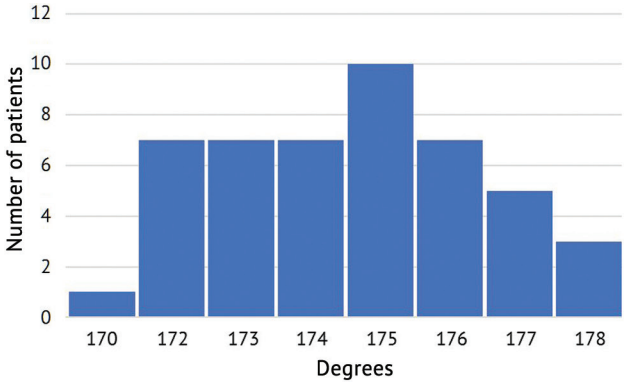

Fig. 7 Histogram of patients' distribution by mean HKA before surgery

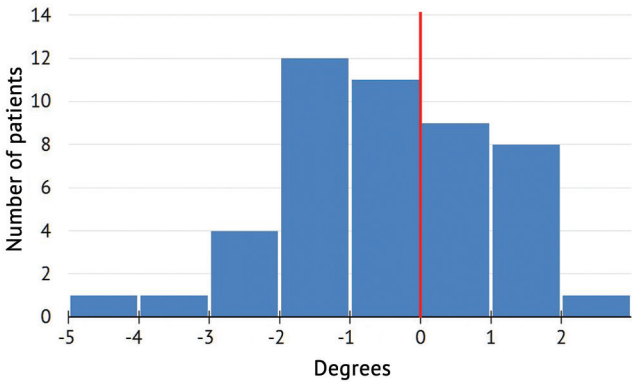

Fig. 8 Histogram of the distribution of the HKA angle deviations from the plan after surgery (red line – planned value 177°)

DISCUSSION

Thus, we obtained the post-surgery HKA angle value of (176.0 ± 1.5)° with statistical insignificance of the paired t-test < 0.01, that is, within ± 2°, deviations from the planned value of 177° were in 87.3 % of patients, and only in 12.7 % of cases the deviation was more than 2°, which is undoubtedly an excellent result.

Massé et al. described a personalized alignment technique, the main goal of which was to reproduce the pre-arthritis tension of the knee ligaments with the aids of a semi-active ROSA Knee system robot and Zimmer Persona implants, using an insert with a Medial Congruent (MC) type of connection, with which the authors implemented a personalized alignment method [24]. However, in their study, the authors do not provide the results of measuring the angles of the limb axis after surgery, limiting themselves to the results of functional scales.

Binfeng et al's meta-analysis conducted a comparison between mechanical (553 cases) and kinematic (559 cases) types of alignment, where functional results were significantly better in terms of WOMAC, KSS scales and range of motion in the kinematic alignment group, but no difference was recorded in terms of radiological indicators (HKA, LDFA and MPTA) [25].

In a study of gait parameters in patients after TKA, Vendittoli et al. showed that patients who underwent surgery using the kinematic alignment technique were closer in their gait patterns to the control group than patients with mechanical alignment of the limb axis [26].

In a retrospective study by Ollivier et al., in which 200 patients were divided into three groups (before surgery with varus, neutral and valgus deformities) and underwent RoTKA using a semi-active robotic MAKO® system (Stryker) according to the kinematic alignment technique. The conclusion was that with kinematic alignment, the femoral component is located in an excessive valgus position and internal rotation in the valgus group and to a lesser extent in the neutral axis group of the knee joint compared to functional alignment [27].

Aflatooni et al. came to the conclusion that functional alignment is a compromise between the mechanical and kinematic alignments that eliminates constitutional varus/valgus deformity, provides flexion up to 90° and avoids ligament damage, but the goal remains the stability and long-term survival of the functioning implant [28].

Morrisey et al. compared RoTKA using the semi-active robotic system VELYS™ (DePuy Synthes, Warsaw, USA) by the kinematic alignment method with the traditional mechanical alignment technique. There were no obvious differences in functional results, including pain, 6 weeks after

surgery. After 6 months, patients who underwent RoTKA had a greater range of motion in the knee joint than those in the second group [29].

Kafelov et al. compared two groups of patients (200 cases): patients in one group underwent RoTKA with functional positioning, while in the second group the manual TKA technique with kinematic alignment was used. In the RoTKA group, the scores of the FJS-12 questionnaire were much higher than in the manual technique group [30].

Huber et al. in a retrospective analysis of the use of the semi-active robotic system MAKO® (Stryker) showed that only in 44 % of patients the kinematic alignment technique could be applied and achieve good clinical results [31].

In the available literature, we did not find the results of radiographic study of the hip-knee-ankle angle in the coronal view before and after robotic total knee arthroplasty and their comparison with the results of preoperative planning using the method of kinematic alignment of the limb axis. The results we obtained show high accuracy of the implementation of the preoperative plan.

CONCLUSION

The use of an autonomous robotic system in TKA provides effective kinematic alignment of the lower limb axis with an accuracy of ± 2° in 87.3 % of patients.

Conflict of interests *The authors declare that they do not have conflict of interest.*

Funding *The study was not sponsored.*

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The optimal method of lateral lengthening osteotomy of the calcaneus: CT study in the Russian population

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Abstract

Introduction In the current professional literature, lengthening of the lateral column is considered to be one of the most effective and pathogenetically sound joint salvage methods for correction of plano-valgus deformity of the foot. The most widely used osteotomies in clinical practice are those of Evans and Hintermann. However, the articular facets of the subtalar joint are at risk of damage due to the variety of their number, shapes and location in different nationalities.

The **purpose** of the work was to reveal the anatomical variants of the structure of the articular facets of the subtalar joint in the Russian population in order to determine the optimal method of lateral lengthening osteotomy of the calcaneus, based on personal characteristics.

Material and methods The results of multispiral computed tomography (MSCT) of the feet of 250 patients were analyzed on the basis of the Tsivyan Novosibirsk Research Institute of Traumatology and Orthopedics. After applying the exclusion criteria, the final sample consisted of 150 patients. 3D modeling of their calcaneal bones with visualization of articular facets of the subtalar joint was performed on a workstation using the syngo.via–Siemens Viewer program. Patients were systematized according to the classification of P. Bunning and C. Barnett (1965). On 3D models of calcaneal bones, the distance between the anterior and middle, as well as between the middle and posterior articular facets was measured.

Results The anterior and middle articular facets of the subtalar joint were separated (type A) in 40.7 % (61 feet), the remaining 59.3 % (89 feet) had fused anterior and middle facets (type B). Fully fused anterior, middle and posterior facets (type C) were not found. The average distance between the anterior and middle articular facets was 4.2 ± 0.08 mm, and the average distance between the middle and posterior facets was 5.3 ± 0.0027 mm.

Discussion Articular facets of type B prevailed in the Russian population. Evans osteotomy will damage them 100 % of the cases. Hintermann osteotomy decreases the chance of their damage. However, the distance between the facets is very small, visualization during osteotomy is difficult, what can lead to damage to the subtalar joint. Thus, the development of a new method for determining and controlling the level of calcaneal osteotomy that would exclude joint damage is an urgent problem for further research.

Conclusion Hintermann's lateral lengthening osteotomy of the calcaneus may be successfully applied in the Russian population with the least complications in the postoperative period and less damage to the articular facets of the subtalar joint.

Keywords: lateral lengthening osteotomy, articular facets of the subtalar joint, plano-valgus deformity of the foot

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INTRODUCTION

Acquired flatfoot is characterized by a decrease in the height of the arch of the foot, valgus deformity of the posterior part and abduction of the anterior part [1]. The prevalence of the disease is 26.6–60.0 %; it is one of the most common reasons for visiting an orthopaedist [2, 3]. Among the existing surgical methods for treating abducted flat-valgus deformity of the foot, lateral lengthening osteotomy of the calcaneus is one of the most effective joint-sparing operations [4–6]. The method of performing lengthening osteotomy of the calcaneus between the anterior and middle articular facets of the subtalar joint was first proposed by D. Evans in 1975 [7]. Initially, Evans performed this variant of osteotomy of the calcaneus in children with valgus foot deformity, which resulted from hypercorrection of clubfoot, but, observing the high efficiency of the operation, began to use it to correct flatfoot in adolescents. Classically, the Evans osteotomy is performed 1.5 cm proximal to the calcaneocuboid joint and parallel to it [7]. The operation had good clinical results and became widely popular among surgeons; over time, it began to be used not only in children but also in adults with forefoot abduction, valgus deformity of the calcaneus, and dorsolateral peritalar subluxation [8]. However, despite good clinical and radiographic results, complications in the postoperative period included insufficient correction, nonunion, arthrosis of the subtalar joint, subluxation of the calcaneocuboid joint, damage to the sural nerve, peroneal tendons, and infection of the surgical site [8–11]. In his work, Evans did not consider the variability of the subtalar joint structure and, according to the data obtained after 13 years of observation of his operated patients, only 17 of 23 had good and very good results [10]. The remaining 6 patients had complications in the late postoperative period. Three patients continued to experience pain during exercise, but it did not interfere with sports and their normal lifestyle; osteoarthrosis of the talonavicular joint was noted. Three other patients showed clinical and radiographic regression of the treatment results as valgus of the hindfoot persisted, and osteoarthrosis of the subtalar joint and other joints, except the calcaneocuboid, developed. In order to reduce postoperative complications and the risk of damage to the subtalar joint, V. Mosca [12] modified the Evans osteotomy in 1995. In his variant, a bone raspatory was first inserted into the subtalar joint between the anterior and middle articular facets to determine their location and then an osteotomy was performed at a certain interval at a level of 1.5–2 cm posterior to the calcaneocuboid joint. However, this method had shortcomings associated with the need to open the capsule of the subtalar joint, as well as difficulties in determining the acceptable interval for osteotomy during surgery due to limited surgical visibility, which makes the creation of a new effective method for determining and monitoring the level and direction of osteotomy a significant issue in improving the results of lateral lengthening osteotomy of the calcaneus.

The first study of the structures at risk during the Evans operation was conducted by R. Raines and M. Brage in 1998 [9]. They concluded that the ideal osteotomy level to prevent damage to the anterior and middle articular facets of the subtalar joint is 10 mm proximal to the calcaneocuboid joint. Nevertheless, Hyer et al. [13] determined that the average distance between the calcaneus and middle articular facets is 3.9 mm and recommended the optimal osteotomy level at 1.1–1.5 cm (1.3 cm on average) posterior to the calcaneocuboid joint. However, Bussewitz et al. [14] reported that with a saw entry point at a level of 1.3 cm posterior to the calcaneocuboid joint, the articular facets of the subtalar joint and the support of the talus are at risk. The lack of consensus among researchers on the level and direction of osteotomy might be due to significant individual anatomical variability. In order to protect the anterior and middle articular facets of the subtalar joint, Hintermann et al. [15] proposed in 1999 a new version of lateral extension osteotomy of the calcaneus, the line of which runs along the anterior border of the posterior articular facet of the subtalar joint. The described surgical treatment methods according to Evans and Hintermann show excellent clinical and radiographic results [16].

The morphology of the articular facets of the subtalar joint in European, African and Indian populations was first studied by P. Bunning and C. Barnett [17] in 1965, and the first classification was proposed. Later, studies were conducted in many countries, and a variety of classification options were published. Thus, Madhavi et al. [18] expanded the classification of P. Bunning and C. Barnett in 2008, and proposed six types of articular facets of the subtalar joint. They identified different variants of fusion of the anterior and middle articular facets, including a type where the anterior facet is completely absent. However, such a detailed approach to describing significant variability does not make it easier for surgeons to choose a method of surgical treatment that would not damage the articular facets of the subtalar joint. Due to significant differences in the anatomical structure of the subtalar joint region in people of different nationalities and the variable approach of researchers to systematization of data, a single classification has not yet been adopted [13, 17, 19–26]. However, none of the studies presented to date on studying the anatomical features of the subtalar joint and their relationship with the risk of damage to the articular facets during lateral lengthening osteotomy of the calcaneus have assessed the population of Russia. Consequently, the optimal method of surgical treatment of abducted flat-valgus foot deformity in the population of the Russian Federation still remains uncertain.

The **purpose** of the work was to show the anatomical variants of the structure of the articular facets of the subtalar joint in the Russian population in order to determine the optimal method of lateral lengthening osteotomy of the calcaneus, based on personal characteristics.

MATERIALS AND METHODS

An analysis of MSCT scans of 250 patients (92 (36.8 %) men and 158 (63.2 %) women) taken between October 2023 and March 2024 at the Tsivyan Research Institute of Traumatology and Orthopedics was conducted. The average age of patients was (45 ± 19) years. Patients with recent and old calcaneus fractures, severe degenerative lesions of the subtalar joint, a history of surgical interventions in the subtalar joint area and metal implants in the calcaneal area were excluded from the sample, since in such cases it was not possible to visualize the articular facets of the subtalar joint with reliable accuracy after 3D reconstruction of the image and its manual processing. The final sample consisted of 150 individuals (66 men (44 %), 84 (56 %) women) in the average age of (46 ± 16) years.

In each studied patient, individual features of the articular facets of the subtalar joint were assessed on 3D models of the calcaneus based on MSCT of the feet at the CT workstation. Before assessment, 3D models of the calcaneus underwent a certain processing algorithm. Processing began with loading a standard MSCT study of the foot in Dicom format on the CT workstation (Fig. 1 a). Next, 3D reconstruction of the foot was performed in bone mode using the syngo.via — SiemensViewer program (Fig. 1, b). Using the Punch tool, all bones except the calcaneus were removed. Artifacts from soft tissues were also removed (Fig. 1 c). Then, the high-resolution Cinematic VRT mode was switched and the remaining artifacts were cut out (Fig. 1 d). The 3D model of the calcaneus was aligned. All the manipulations resulted in a fully prepared 3D model (Fig. 1 d). The Distanceline tool was then used to calculate the facet spacing in milimeters. The measurement was performed by setting two points at the narrowest site between the subtalar joint facets and automatically calculating the length of the resulting segment between them. For calcaneus with type A facets, the distance from the posterior edge of the anterior facet to the anterior edge of the middle facet was measured at the narrowest point between them (Fig. 2). For types A and B, the width from the posterior edge of the middle facet to the anterior edge of the posterior facet was additionally measured at the narrowest point between them (Fig. 3).

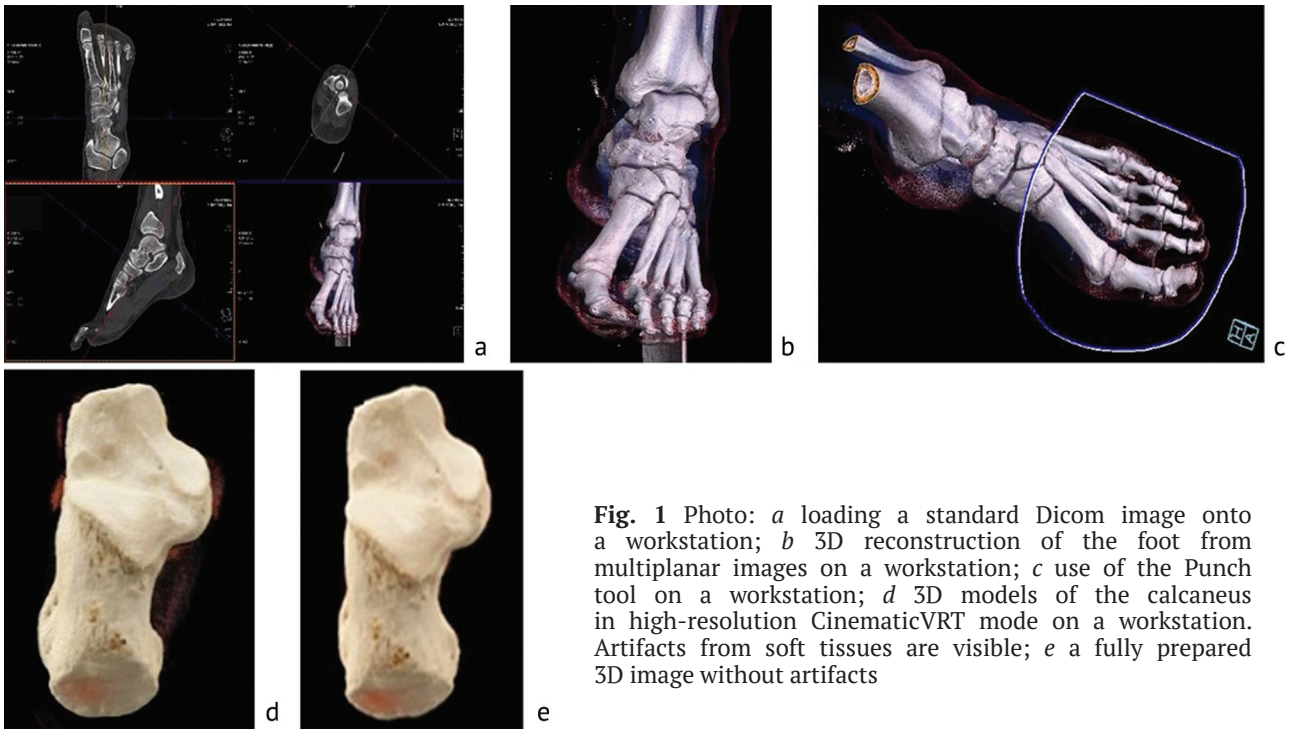

Fig. 1 Photo: *a* loading a standard Dicom image onto a workstation; *b* 3D reconstruction of the foot from multiplanar images on a workstation; *c* use of the Punch tool on a workstation; *d* 3D models of the calcaneus in high-resolution CinematicVRT mode on a workstation. Artifacts from soft tissues are visible; *e* a fully prepared 3D image without artifacts

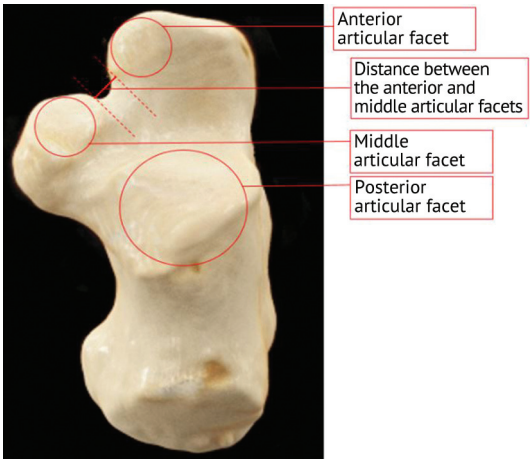

Fig. 2 Technique for measuring the distance between the anterior and middle articular facets in type A subtalar joint using the Distanceline tool

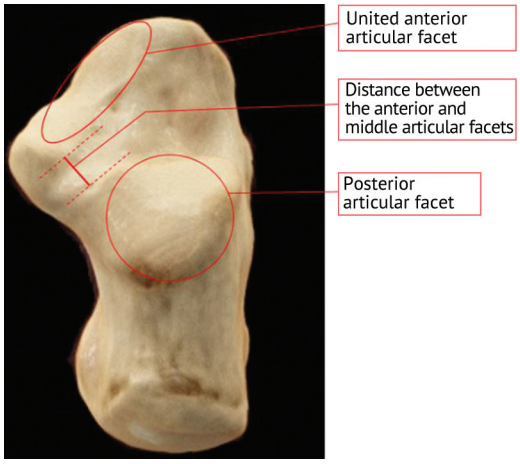

Fig. 3 Technique for measuring the distance between the middle and posterior articular facets in type B subtalar joint structure

The patients were grouped according to the classification of P. Bunning and C. Barnett [17]:

— Type A: there are three articular facets on the surface of the calcaneus, the anterior and the middle ones are separated from each other;

— Type B: there are two articular facets on the surface of the calcaneus, the anterior and the middle ones connected to each other;

— Type C: there is one articular facet on the surface of the calcaneus, since all three are fused together.

The obtained data were summarized in a table. For all the obtained measurements, the ratio between men and women in each group, their percentage in the entire sample, the average age and standard deviation for each of the given values, as well as the standard deviation for the spaces between facets measured in millimeters were calculated. All calculations were performed using the spss21 program.

RESULTS

According to the classification of P. Bunning and C. Barnett, 61 (40.7 %) patients (34 (55.7 %) women and 27 (44.3 %) men; average age (42.9 ± 14) years) were classified as type A (Fig. 4). 89 (59.3 %) patients (50 (56.2 %) women, 39 (43.8 %) men; average age (48.1 ± 21.3) years) were classified as type B (Fig. 5). There were no patients with type C in the study.

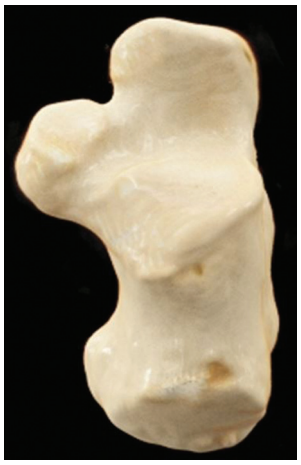

Fig. 4 Photo of a 3D model of the calcaneus of patient A.: separated articular facets, type A according to the classification of P. Bunning and C. Burnett

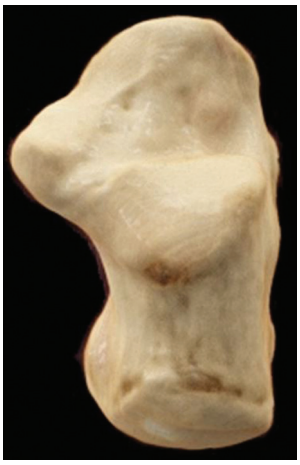

Fig. 5 Photo of a 3D model of the calcaneus of patient B.: fused articular facets, type B according to the classification of P. Bunning and C. Burnett

According to measurements, the average distance at the narrowest point between the anterior and middle articular facets of the subtalar joint was (4.20 ± 0.08) mm in type A individuals. The average distance between the middle and posterior facets in types A and B was (5.3 ± 0.0027) mm.

DISCUSSION

The types of articular facets of the subtalar joint have been studied in different nationalities, living in America [13], Africa [17], Japan [20], Korea [21], India [17, 22], Egypt [23], Spain [24], Turkey [25], China [26], Russia [27]. Despite the differences in the classifications used, in most studies, the proportion of separated anterior and middle articular facets of the subtalar joint varied from 30 to 40 % in different countries; fused articular facets are the most common. Type A predominantly was detected only in the population of Belgium [19] and Great Britain [17], (61 % and 67 %, respectively). The variability of the subtalar joint structure in the Russian population was studied in 2014 by Bayroshevskaya et al. [27]. They conducted an autopsy study of 57 feet in the subjects of the age range from 20 to 70 years and presented their own classification, based on which fused anterior and middle articular facets of the subtalar joint were found in 26 (45.61 %) cases, all separated articular facets accounted for 26 (45.61 %) cases, in 4 (7.02 %) cases the anterior facet was absent, and completely fused all three articular facets were found in one (1.76 %) case. According to their findings, fused anterior and middle facets as well as separated anterior and middle articular facets had the same incidence of occurrence.

Our study found that type B articular facets of the subtalar joint according to the classification of P. Bunning and C. Burnett are dominant in the Russian population (59.3 %). Accordingly, the fused articular facet would be damaged in 100 % of cases if Evans osteotomy is performed in such patients. Moreover, according to our results, the average distance between the anterior and middle articular facets is only (4.20 ± 0.08) mm in the group with type A. However, the thickness of the oscillating saw blade used to perform osteotomy ranges from 0.5 to 1.47 mm, and intraoperative visualization of the articular facets of the subtalar joint is extremely difficult. Currently, there is no method to accurately determine and monitor the level and direction of osteotomy. Accordingly, performing an operation in a safe space not damaging the subtalar joint is a difficult task.

In regard to the above-mentioned difficulties arising during surgery, popularization of the use of MSCT with 3D modeling at the stage of preparation for surgical intervention would allow visualization of the articular facets of the subtalar joint, determination of their type and choice of the method of performing the operation, as well as calculation of the level and angle of the osteotomy direction based on individual features of the anatomical structure, as a result of which the risk of damage to the subtalar joint will be reduced [28]. Thus, it is necessary to create a new method of effective and safe intraoperative determination and control of the level and direction of osteotomy using the data that are calculated with computer modeling for each patient during preoperative planning considering the type of articular facets of the subtalar joint. Such an approach to preoperative preparation would help to avoid damage to the subtalar joint and, accordingly, improve the results of surgical treatment.

The methods proposed by Evans and Hintermann of lateral lengthening osteotomy of the calcaneus were compared with each other by different authors. The anatomical structures at risk during surgery were analyzed by Ettinger et al. [29]. The researchers report that the Hintermann method is the best option in terms of potential damage to the articular facets of the subtalar joint and leads to rare complications such as degenerative changes in the calcaneocuboid joint [30]. Thus, Xu et al. [16] report that with the application of grafts of the same length and thickness, the corrective ability of the Hintermann operation is higher, but the characteristics of the contact stress in the surrounding joints are more abnormal. At the same time, the pressure in the calcaneocuboid joint during the Evans osteotomy did not increase as compared to the pressure in the same joint of the deformed foot [31]. Also Ettinger et al. [29] reported that the anterior and middle facets of the subtalar joint remain intact in 100.0 % and 85.7 % of cases, respectively, if the Hintermann procedureis used. In contrast, in the Evans procedure, they remain intact in only 42.9 % of cases for the anterior and 71.4 % of cases for the middle facet. The posterior facet of the subtalar joint is intact in all cases [29]. Several studies focused on the outcomes of the Evans and Hintermann procedures, which showed good clinical and radiographic results [16]. Overall, with a lower risk to the subtalar and calcaneocuboid joints but similar clinical outcomes, the Hintermann procedure appears to be the best alternative to the Evans procedure for the population of the Russian Federation.

We recognize that our study had a number of limitations. Firstly, the sample included not only patients with abducted flat-valgus foot deformity, but also those with other diagnoses (except for calcaneal fractures, any previous surgical interventions in the subtalar joint area and severe degenerative changes in the subtalar joint). Secondly, the size of our sample (150 feet) cannot fully reflect the diversity among the large population of Russia. Thirdly, the study was conducted using 3D CT reconstruction methods, which do not visualize articular cartilage; measurements were taken between bone structures that have different shapes and heights, what in controversial cases could lead to inaccuracies.

CONCLUSION

The anatomy of the subtalar joint has significant personal differences in the Russian population. Fused anterior and middle articular facets of the subtalar joint were found in more than half of the examined patients. Thus, the Evans osteotomy in this group of patients will always result in damage to the subtalar joint. In separated anterior and middle articular facets, the average distance between them was only 4.2 mm. Due to the fact that the facets are inaccessible for visualization during the operation, and the average saw blade thickness is 1 mm, it is an impossible task to blindly target the approachable space interval. Thus, the Hintermann operation may be more preferable in the Russian population; however the safe window for performing the osteotomy is only 5.3 mm.

Conflict of interests *None.*

Funding source *There was no external funding in this study.*

Ethical approval *The study was approved by the institutional ethics committee of the Tsivyan Novosibirsk Research Institute of Traumatology and Orthopaedics of the Ministry of Health of the Russian Federation (protocol No. 01-18/4853 dated July 11, 2024) and was conducted in accordance with the ethical standards developed in accordance with the Declaration of Helsinki of the World Medical Association.*

Informed consent *The patients gave voluntary written informed consent for inclusion in the study.*

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Impact of transphyseal intramedullary nailing on tibial distraction regenerate and subsequent tibial growth in sheep: an experimental study

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Abstract

Introduction In lengthening of limbs in children, the combination of elastic intramedullary reinforcement and external fixation has advantages over standard techniques, but requires the removal of elastic nails and does not provide the possibility of their locking, that could significantly reduce the period of external fixation.

The **purpose** of the work was to study the features of tibial distraction regenerate formation and residual growth of the lengthened segment in lambs under the conditions of external fixation combined with a transphyseal rigid titanium rod.

Materials and methods *In vivo* experiments were performed on lambs (n = 7) during their growth period. In the control group, the right tibia was lengthened using transosseous distraction osteosynthesis for 28 days. In the study group, the segment was additionally reinforced with an intramedullary rigid rod. The following were measured in radiographs: the height of the distraction gap between the fragments, the transverse dimensions of the distraction regenerate, the height of the bone sections of the regenerate and the growth zone, the length of the tibia; the anatomical angles of the proximal articular end of the tibia. To determine the intrinsic growth dynamics of the segment under lengthening, the size of the distraction regenerate was subtracted from the length of the tibia.

Results In the main group, the transverse dimensions of the distraction regenerate were larger, and the height of the growth zone was smaller than in the control group. Consolidation of the regenerate in the main group occurred after 30 days, and in the control group 60 days after the cessation of lengthening. No slowdown in the longitudinal growth of the elongated segment was noted compared to the contralateral one, the orientation angles of the inclination of the proximal articular surfaces did not change.

Discussion Transphyseal implants should be located centrally to reduce the risk of epiphysiodesis, their area should not exceed 7 % of the growth zone. These conditions were met in the study. The reduction in the time of distraction regenerate corticalization and early termination of external fixation was associated with pronounced periosteal osteogenesis and increased bone fragments stability. The location of the rod in the growth plate does not lead to epiphysiodesis and does not interfere with normal growth of the segment.

Conclusion Pronounced periosteal osteogenesis and additional stabilization of the bone fragments with a transphyseal rigid titanium rod contribute to the faster bone regenerate formation and maturation. There are no signs of inhibition of spontaneous growth of the segment under lengthening and radiographic signs of epiphysiodesis at the transphyseal level. The central location of the transphyseal rod relative to the growth zone plane and its cross-sectional area of less than 5 % of the physis area can be considered conditions under which epiphysiodesis does not develop.

Keywords: intramedullary nail, limb lengthening, discrepancy, physis

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INRODUCTION

It is recommended to perform limb lengthening in children in early childhood if magnitude of shortening is significant and there are associated deformities as well as when parents insist [1, 2]. Lengthening with classical techniques requires external fixation for a prolonged period, that is associated with both an increased risk of complications and a psychological burden on the patient and his/her family [3, 4]. The use of fully implantable lengthening intramedullary nails in children is impossible due to the small diameter of the bone and open growth zones [5]. The use of elastic intramedullary reinforcement has shown its advantages: reduced time of wearing the external fixation device (EFD), decreased incidence of complications, the possibility of using the technique in small diameters of the bone marrow canal [6, 7]. However, this method implies an additional operation to remove the elastic rods [8]. Moreover, elastic titanium rods are not capable to perform locked osteosynthesis, which theoretically would speed up the removal of the EFD. Our recent experimental studies have shown that a transphyseal titanium rigid rod with its threaded parts in the epiphyses and a smooth part at the level of the growth zones in the metaphyses and in the diaphyseal parts of the tibia under experimental conditions does not lead to a slowdown in the growth of the lengthened segment [9].

The **purpose** of the work was to study the features of tibial distraction regenerate formation and residual growth of the lengthened segment in lambs under the conditions of external fixation combined with a transphyseal rigid titanium rod.

MATERIALS AND METHODS

Study design

A prospective, randomized, controlled, monocentric in vivo experimental study was performed in two groups of lambs during their growth period: a control one (n = 3) and a study one (n = 5). All animals underwent lengthening of the right tibia with the method of transosseous distraction osteosynthesis at a distraction rate of 1.0 mm/day in 4 steps for 28 days. In the study group, the segment was additionally reinforced with an intramedullary rigid rod. The pre-distraction period was 7 days.

Inclusion criteria

The experiment involved clinically healthy sheep of both sexes, who had a tibial medullary canal diameter of at least 5 mm and a biological age ranging from 4.5 to 5 months (inclusion criteria). The exclusion criteria were: death of animals or pathological conditions not related to the experimental conditions.

Experiment time-points

Before the start of the experiment, the following study time-points for control were determined: immediately before the surgical intervention; end of the lengthening period; 30 days of fixation after the end of the lengthening period; end of fixation with the EFD; 30 days after the end of EFD fixation.

Description of surgical intervention

Surgical interventions were performed in the operating room by one surgical team. The Ilizarov apparatus, consisting of four supports forming two subsystems, proximal and distal (Fig. 1 a), was mounted on the right shin of the animals in the control group. The subsystems were connected to each other with threaded rods with the possibility of subsequent longitudinal distraction along them. Transverse osteotomy of the tibial diaphysis was performed through a longitudinal incision of the soft tissues using a Gigli saw. Sutures were applied to the soft tissues upon completion of osteotomy.

In the animals of the study group, two supports were mounted, proximal and distal. Before performing the osteotomy, the tibia was reinforced with an intramedullary rigid titanium rod (Ti6AI4V alloy) (Fig. 1 b).

The rod diameter (4.5 mm or 5.0 mm) depended on the diameter of the medullary canal. The rod was selected so that the diameter of the canal in the narrowest part exceeded the rod diameter by 2–3 mm. The medullary canal was not drilled. The length of the rod was determined for each animal individually. The rod was installed through the parapatellar approach. In the intercondylar space of the tibia, a cannulated drill was used along a guide pin at slow speed to drill a canal in the proximal epiphysis, passing to the medullary canal. A rigid rod was inserted through this canal, its threaded part was screwed under X-ray control. The height of the threaded part did not exceed the height of the epiphysis and did not enter the growth cartilage zone. The diameter of the threaded part of the rod was 11 mm. Through a longitudinal incision of soft tissues, a transverse osteotomy of the diaphysis of the tibia was performed using a Gigli saw, followed by layer-by-layer suturing of the wound.

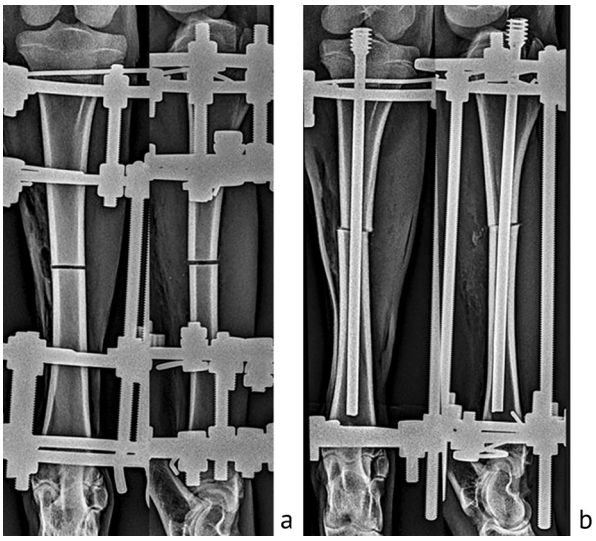

Fig. 1 Radiographs taken on the day of intervention: *a* control case; *b* study group case

All animals were administered ketoprofen intramuscular injections (50 mg/ml) of 0.5 ml per day for 5 days after surgery. The skin around the wires and sutures were treated with a 3 % hydrogen peroxide solution.

All animals underwent radiography of the experimental and contralateral segment using a Premium VET X-ray system (TOSHIBA (Rotanode) Model E7239. N: 10G749, Japan) and a digital radiography system supplied with a CANON CXDI-401C COMPACT flat-panel detector (Canon Inc. Medical Equipment Group, Japan).

The animals were kept in vivarium conditions 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 34088-2017 "Guidelines for the Care and Maintenance of Laboratory Animals. Rules for the Maintenance and Maintenance of Farm Animals". 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 were observed.

Main outcome measures

To determine the characteristics of the distraction bone regenerate, the structure of its shadows, its shape, zones, the presence and expressiveness of the middle zone of enlightenment (growth zone) were studied in radiographs.

For quantitative assessment, the height of the gap between bone fragments (cm), the transverse dimensions of the distraction bone regenerate, the height of its bone sections and the height of its growth zone (cm) were measured in digital X-ray images.

Additionally, the features of segment growth under the created conditions and the formation of the proximal articular end were studied. For this purpose, the length of the tibiae in the lateral projection (cm), the mechanical medial proximal tibial angle (mMPTA), and the mechanical posteroir proximal tibial angle (mPPTA) were measured. The intrinsic growth dynamics of the segment under lengthening were calculated by subtracting the value of the distraction regenerate from the length of the tibia.

Statistical analysis was performed using the AtteStat version 13.1 for Excel spreadsheets (2016, 16.0.5278.1000). Descriptive statistics methods were used: mean values (M) and standard deviation (SD). Comparative studies were performed using the Mann – Whitney test. Differences were considered statistically significant at $p \leqslant 0.05$.

RESULTS

The entire periods of distraction, fixation and the period after removal of the EFA were fully completed in seven animals. In one case of the main study group, premature bone consolidation occurred in the second week of distraction, which forced us to exclude this case from the study analysis.

The results of osteometry of all lambs' tibiae before the experiment did not reveal a reliable difference ($p = 0.7$) between the length of the experimental and intact segments. In the control group, these indicators were (20.07 ± 0.3) cm and (20.03 ± 0.31) cm, and in the main study group (19.81 ± 1.05) cm and (19.83 ± 1.05) cm, respectively.

The evaluation of the radiographic features of the distraction regenerate determined that by the end of the lengthening period, the contours of the fragment ends in the animals of the control group were smooth and clear. The gap between the bone fragments averaged (3.1 ± 0.1) cm, (12.3 ± 1.8) %. Shadows of the distraction bone regenerate with a longitudinally striated structure and zonal formation were determined in its cavity. Regularly, the height of the proximal bone section of the regenerate ((1.74 ± 0.29) cm) was greater than the height of the distal bone section ((0.9 ± 0.21) cm) by more than 90 %. The length of the middle zone of enlightenment varied from 0.41 cm to 1.68 cm, and averaged (0.85 ± 0.35) cm. Its values were 27.42 % of the gap height. The regenerate growth zone was bridged by the shadows of bone trabeculae in some areas. The transverse dimensions of the regenerate exceeded the diameter of the ends of the fragments by more than 35 %. Their values were in the range from 1.61 cm to 2.36 cm and averaged (1.87 ± 0.27) cm (the diameter of the bone was (1.36 ± 0.1) cm).

By the 30th day of fixation, the contours of the fragment ends in the animals of the main study group became less clear in comparison with the previous period of examination. The shadows of the bone regenerate acquired a homogeneous structure. Its bone sections (proximal and distal) merged with each other in some areas. The diameter of the regenerate in the projection of the growth zone was (1.99 ± 0.4) cm. The growth zone was represented by separate areas of enlightenment or was in the form of a zigzag line. Its height sharply decreased in relation to the previous time-point and averaged (0.25 ± 0.14) cm.

Under the conditions created in the main study group, the formation of a weight-bearing bone regenerate occurred by the 60th day of fixation after the termination of the lengthening period. At this time-point, the contours of the ends of the fragments became even less clear. The zonal structure of the newly formed bone distraction regenerate completely disappeared. It was represented by continuous homogeneous shadows. The growth zone was most often revealed in the projection of the peripheral part of the regenerate in the form of single areas of enlightenment on one or both sides. A thin cortical plate continued development.

In that period during the clinical test, neither pathological mobility nor pain in the lengthening area was detected, which allowed removal of the Ilizarov apparatus.

Thirty days after the Ilizarov apparatus removal, the contours of the fragment ends were blurred. The newly formed section of the diaphysis had uniform shadows. Its height did not change in comparison with that at the end of lengthening, and the transverse dimensions averaged (1.83 ± 0.16) cm. Signs of the formation of the medullary canal were present.

The radiographic dynamics of the distraction bone regenerate formation in the animals of the control group is presented in Fig. 2.

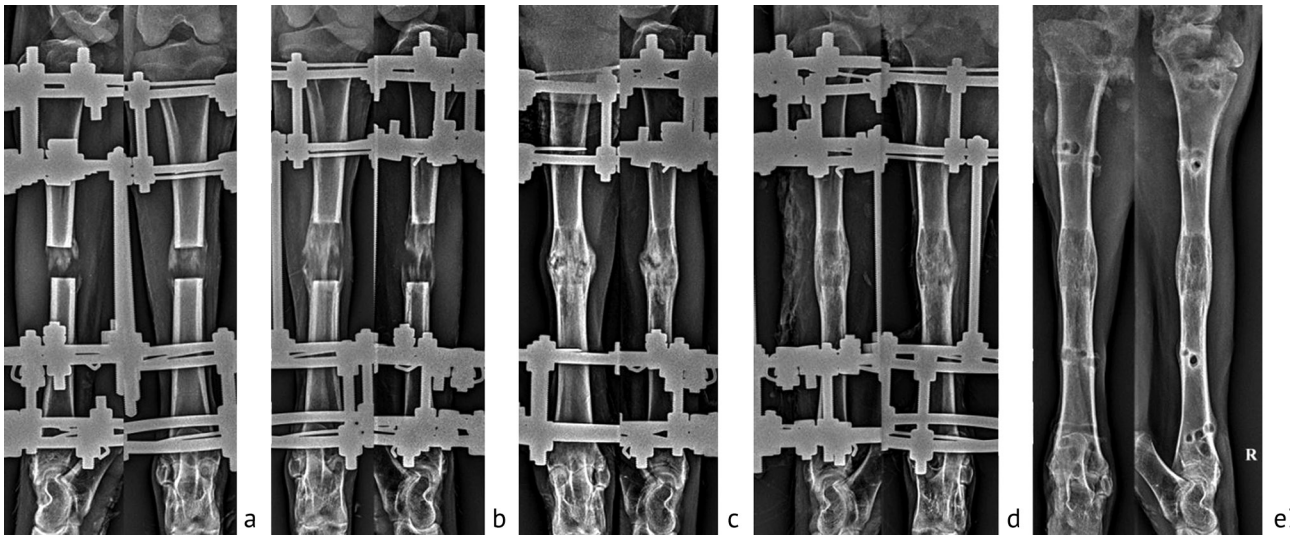

Fig. 2 Radiographs of the tibia during lengthening with the classical technique, control group: *a* 14 days of distraction; *b* 28 days of distraction (end of lengthening); *c* 30 days of fixation period; *d* 60 days of fixation period, bone union, day of EFD removal; *e* 30 days after dismantling the external fixation device

The evaluation of the radiographic characteristics of the distraction regenerate in the animals of the main study group showed that the gap between the bone fragments at the end of distraction averaged (2.75 ± 0.14) cm, (12.1 ± 1.5) %. In the gap cavity, shadows of the bone distraction regenerate of zonal structure were determined. The transverse dimensions of the regenerate averaged (2.32 ± 0.38) cm and exceeded the diameter of the maternal bone by 51.6 %. The height of the proximal bone section of the regenerate varied from 0.75 to 2.75 cm and averaged (1.56 ± 0.69) cm. The length of the distal section, as in the control group, was smaller. Its values corresponded to (0.94 ± 0.97) cm (from 0.44 cm to 1.26 cm). The growth zone, (0.54 ± 0.22) cm high, was most often determined in the periphery. It was usually bridged by shadows of bone trabeculae of a longitudinally striated structure, more pronounced than in the control group.

After 30 days of fixation following the end of the lengthening procedure, the contours of the fragment ends were poorly defined on radiographs. The distraction bone regenerate lost its zonal structure. Its transverse dimensions averaged (2.38 ± 0.42) cm. The shadows of the bone sections of the regenerate were of a uniform longitudinally striated structure and merged with each other. The growth zone had small isolated areas of enlightenment, and averaged (0.43 ± 0.2) cm. A thin cortical plate started formation along the periphery.

In the animals of the main study group, fixation with the Ilizarov apparatus was stopped at that time-point based on the results of the clinical test and radiographic findings.

Following 30 days after dismantling the EFD, the axis of the elongated segment on the radiographs was correct. The contours of the ends of the fragments were not defined. The shadows of the newly formed distraction bone regenerate were partially compacted in comparison with the previous time-point of the experiment. Its transverse dimensions slightly decreased and were (2.14 ± 0.14) cm. A continuous cortical plate was formed on all sides. A single continuous bone marrow canal was formed along the rod.

The radiographic dynamics of the distraction bone regenerate formation in the animals of the main study group is presented in Fig. 3.

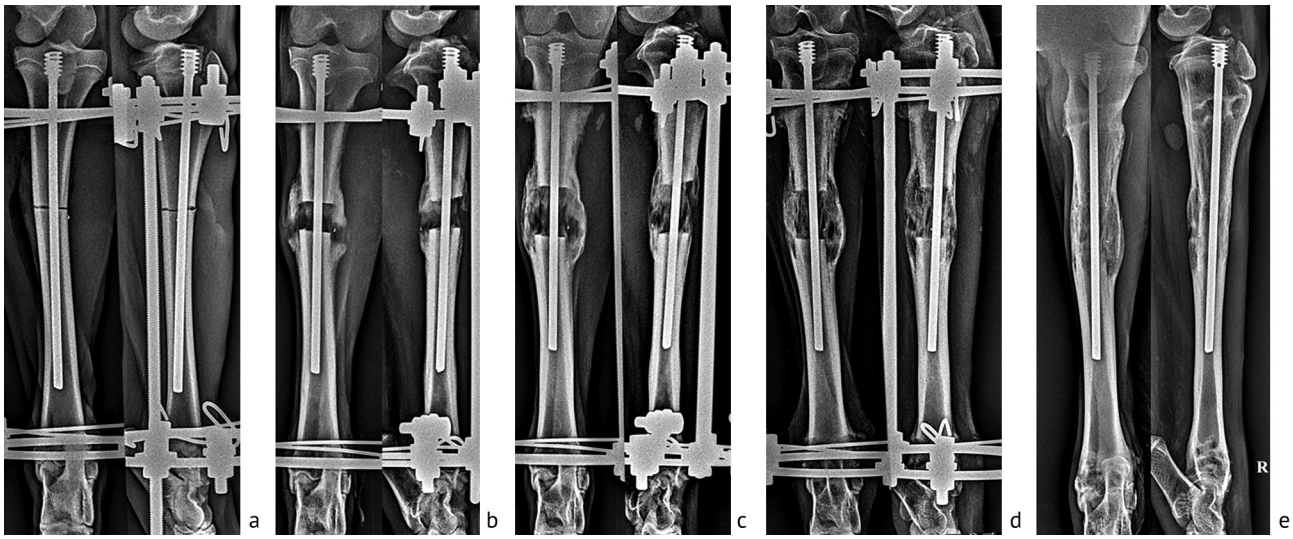

Fig. 2 Radiographs of the tibia during lengthening over the titanium rod, main study group: *a* day of surgery; *b* 14 days of distraction; *c* 28 days of distraction (end of lengthening); *d* 30 days of fixation period, bone union, day of EFD removal; *e* 30 days after dismantling the external fixation device

The measurements showed that the area of damage to the growth plate averaged (4.08 ± 0.32) %. The length of the tibiae due to spontaneous growth (subtracting the height of the distraction regenerate) following 60 days after the end of the fixation period is presented in Table 1.

Table 1

Length of the operated and intact tibiae 60 days after the end of the fixation period

Groups	Intact tibia; cm	Operated tibia; cm	Significance
Classical lengthening (control)	20.9 ± 0.32	21.54 ± 0.19	$P = 0.045$
Lengthening over the titanium rod (study)	21.14 ± 0.41	21.31 ± 0.23	$P = 0.274$

Thus, no disorders in the longitudinal growth of the lengthened tibiae were detected in comparison with the intact contralateral ones.

There was no difference in the values of the radiographic angles of inclination of the proximal articular surfaces of the MPTA ($p = 0.51$) and PPTA ($p = 0.03$) either immediately before surgery or subsequently at different time-points in both groups in comparison with the contralateral (intact) limb (Table 2).

Table 2

Radiographic anatomical angles of the proximal articular end of the tibia

Parameter	Intact tibia		Experimental tibia	
	Before surgery	30 days after EFD removal	Before surgery	30 days after EFD removal
Control group				
mMPTA; °	91.65 ± 0.50	95.02 ± 2.25	91.15 ± 1.78	94.01 ± 2.08
mPPTA; °	62.47 ± 3.02	65.07 ± 1.97	64.55 ± 5.83	71.1 ± 1.08
Study group				
mMPTA; °	92.4 ± 1.35	92.4 ± 1.39	92.35 ± 3.02	92.5 ± 1.22
mPPTA; °	65.7 ± 1.36	69.6 ± 3.1	66.92 ± 4.17	70.3 ± 0.92

It should also be noted that none of the animals that underwent lengthening over the rod experienced its blockage in the medullary canal during distraction, nor did the threaded portion lose fixation in the proximal epiphysis of the tibia.

DISCUSSION

In pediatric orthopaedics and traumatology, the issue of the long-term presence of transphyseal implants has been most actively discussed in three areas: surgical treatment of fractures of long bones involving damage to growth zones, reconstruction of the anterior cruciate ligament of the knee joint before closure of the growth zones, as well as reconstruction and/or preventive transphyseal reinforcement in bone tissue pathology accompanied by decreased bone strength [10–16].

In experimental surgery, various models are used to determine the effect of injuries and implants on the function and structure of the growth plate and articular cartilage of the knee joint. In most cases, studies are conducted on lambs, rabbits, and piglets [17–20]. It is recognized that the model of operations on the knee joint and the growth plate area of lambs is more suitable for translating the experimental results into clinical practice [21]. Trials of testing pathological features and effectiveness of the principles of new surgical methods on an experimental model have remained mandatory in evidence-based medicine [22].

The incidence of physeal injuries was nealy 20 % in paediatric limb fractures [23]. One third of such injuries results in epiphysiodesis zones [24]. In traumatological practice, the opinions of authors on the effect of transphyseal pins during fixation of small fragments in osteoepiphysiolysis on the function of physis and the formation of limited epiphysiodesis are contradictory. Thus, Horn et al. described partial epiphysiodesis and the development of angular deformity in the treatment of fractures in children [25]. In turn, Yung et al. and Langenhan et al. did not find any effect of transphyseal straight Kirschner wires on the subsequent growth of the operated limb [11, 12]. Garrett et al. [26] did not reveal statistical correlations between diafixation of distal epiphysiolysis and osteoepiphysiolysis of the femur and the incidence of epiphysiodesis either, while the severity of injury and the type of fracture according to the Salter-Harris classification had a reliable effect. In the context of eliminating the consequences of injuries in growth zones by resection of epiphysiodesis areas, experimental studies played a role, showing the absence of physeal bone bridge formation between the epiphysis and metaphysis in the case of filling the resection zone with autologous cartilage tissue [20]. Bone bridging was observed in all cases at the site of the removed growth cartilage after filling the zones with fatty tissue or leaving them empty. The importance of slowing down the resorption of transphyseal material and its inert properties for preventing formation of epiphysiodesis zones was demonstrated in the work of South Korean researchers: microarc oxidation of thin implants made of Mg-Ca-Zn alloys slowed down resorption in the physis zone and excluded the formation of bone bridging between the epiphysis and metaphysis [27].

There is an opinion that for reconstruction of the anterior cruciate ligament of the knee joint in children, anatomical reconstruction is possible only with transphyseal formation of canals and location of autoimplants [28, 29]. However, this method of performing the operation increases the risk of shortening and valgus deformity due to traumatization of the growth zones [14, 15]. Experimental studies of the methods of anterior cruciate ligament reconstruction revealed factors that reduce the risks of epiphysiodesis: the central location of the canals in the growth zones, their small diameter (5 mm) and the location of biologically inert material (autologous tendon grafts). In a larger diameter of the canals (8 mm), their posterolateral localization and lack of filling with tendons led to the formation of epiphysiodesis in lambs [30]. The importance of the tendon grafts introduced in the drilled transphyseal canal to prevent epiphysiodesis was also confirmed experimentally [31].

The question of the impacts of transphyseal implants on limb growth during reconstructive surgeries on limb bones used in clinical practice for treating children with genetic diseases has not yet been answered due to both the lack of methods for predicting spontaneous growth in such pathologies and the low relevance of this problem until recently [32–34].

It is in the field of reconstructive orthopaedics that experimental studies are the vanguard of scientific research, rather than following in the wake of expanding indications for established clinical technologies. Thus, studying the extent of damage and the duration of diafixation with any material, Mäkelä et al. [35] were able to show that the transphyseal location of straight steel pins with a diameter of 2 mm for less than 12 weeks did not cause the development of growth dysfunction, but after 12 to 24 weeks, epiphysiodesis and shortening of the segment were observed. The pins of 3.2–3.5 mm diameter pins that occupied 7 % of the growth zone area inevitably led to epiphysiodesis and shortening. This critical damage area (7–9 %) of the growth zone was confirmed by another study, but the location in the canal of autologous tendon graft enabled to avoid the formation of bony fusion [31]. In our own study, the 6 % damage of the physis area with transphyseal steel pins and long-term placement of implants *in situ* (for 25 weeks), led to a loss of 5.4 % of residual growth, and in a combination of reinforcement and osteotomy, to a loss of 9.5 % of residual growth of the reinforced tibia [36]. It is important to note that the telescopic transphyseal implants (sliding one inside the other), made of titanium alloys and introduced into the tibia centrally relative to the geometry of the growth zones and without additional bone osteotomies, did not lead to inhibition of the physis function [9]. Of importance in this discussion are the results of an experimental study of retrograde insertion of a massive titanium rod into the femur of piglets for 8 weeks (without additional osteotomy) that did not lead to inhibition of longitudinal growth [37]. That work was aimed at substantiating the possibility of using fully implantable electromagnetic rods in children for limb lengthening, but the authors acknowledge that experimental studies should be continued to study the effect of transphyseal implants on growth function in the context of surgical segment lengthening.

Thus, to reduce the risks of epiphysiodesis, transphyseal implants that can be potentially used in reconstructive orthopaedics should have inert properties with respect to surrounding tissues, be non-resorbable (or with a long resorption period), be located centrally, and not exceed an area of 7 % of the growth zone.

In our experimental series, titanium transphyseal rods were used, the method of application of which met the above criteria, with the exception that they were a component of a combined limb lengthening technique.

The results of the experimental series showed not only the possibility of such lengthening but also a faster maturation and consolidation of the distraction regenerate in the conditions of a thin rigid rod compared to the standard technique. We see two explanations for this phenomenon: a pronounced periosteal reaction and increased stability of bone fragments [38–42]. Our study confirmed the advantage of lengthening with intramedullary implants, in this case with a rigid intramedullary rod with possibility blocking. In all the cases of the experimental lengthening using the combined technique, bone consolidation with full corticalization of the distraction regenerate was achieved within 30 days of fixation.

As for the effect of a permanent transphyseal rod on growth, a promising result is the absence of growth inhibition of the elongated segment and, especially, the absence of epiphysiodesis. No statistically significant difference in the length of the intact and elongated (subtracting the height of diastasis) segment was found.

The limitation of this study for the clinical interpretation of the results is its experimental nature, as well as the magnitude of relative elongation within 13 %. Another limitation is the small number of animals used in the experiment. In subsequent research, it is planned to increase the number of cases in each of the groups.

Nevertheless, it is obvious that compliance with proven requirements for transphyseal implants and under elongation conditions provides avoiding a negative impact on the function of the involved growth zone.

CONCLUSION

Experimental lengthening of the tibia under the conditions of external fixation combined with transphyseal rigid titanium rod has been achieved. Pronounced periosteal osteogenesis and additional stabilization of bone fragments contribute to faster formation and maturation of bone regenerate compared to the classical lengthening technique. There are no signs of inhibition of spontaneous growth of the lengthened segment and no radiographic signs of epiphysiodesis at the level of the transphyseal part of implant The central location of the transphyseal rod relative to the plane of the growth zone and its cross-sectional area of less than 5 % of the physis area can be considered conditions under which epiphysiodesis does not develop during experimental limb lengthening.

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

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Release of antibiotics from the materials for post-osteomyelitic bone defect filling

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Abstract

Introduction The search for materials for bone defect filling that would provide a release of antibiotics in therapeutic levels over a long period is a pressing issue in the treatment of patients with osteomyelitis.

The **purpose** of the work was to compare the kinetics of antibiotic release from materials based on polyurethane polymers for filling post-osteomyelitic bone defects.

Materials and methods A comparative *in vitro* analysis of the kinetic release of cefotaxime, vancomycin, and meropenem from two materials was performed: one was based on polyurethane polymers (RK series) and the other on polymethyl methacrylate (PMMA series). In each series, antibiotics were added to the original materials in three proportions: polymer/ antibiotic — 10:1 (group 1); 10:0.5 (group 2), and 10:0.25 (group 3). The samples were incubated in 10 ml of saline at 37 °C. The incubation solution was changed daily during the first week, and then once a week. Six samples were incubated in each group.

Results It was revealed that the volume of eluted cefotaxime in the PMMA series was higher than in the RK series for all antibiotic concentrations. In turn, for vancomycin and meropenem, it was observed only for group 1 samples. For groups 0.5 and 0.25, a larger volume of released antibiotics was noted in the RK series than in the PMMA series. It was found that in the RK series, the release of vancomycin and cefotaxime in an effective (therapeutic) concentration was more prolonged. In the RK series, there was prolonged release of effective concentrations but in a smaller volume of released antibiotic than in the PMMA series.

Discussion Each material showed its own antibiotic elution profile and each of them may have its own indications. The RK-based material has advantages in terms of the duration of antibiotic elution in therapeutic doses.

Conclusion The release of the studied antibiotics in effective concentrations from the material based on polyurethane polymers is longer than from the PMMA-based material.

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

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INTRODUCTION

Currently, various materials impregnated with antibiotics are widely used to fill in bone defects formed after removal of osteomyelitic foci [1, 2]. This allows for the most effective suppression of the local infectious process, thereby decreasing dependence on systemic antibiotics [3–5]. The main material used for these purposes is polymethyl methacrylate (PMMA) (the so-called bone cement) [6]. The experience of using PMMA as an antibiotic carrier revealed a number of shortcomings in solving the problems of osteomyelitis arrest. In particular, the key shortcoming is the kinetics of antibiotic release from the material as most of it is released within the first day after implantation. Thus, the risk of reinfection may arise in the later period and also there is a toxic load on the patient's organism. An additional negative factor is the difficulty of removing this material [7, 8]. These circumstances support the relevance of searching the main material (carrier) for filling bone defects, which would provide release of antibiotics in therapeutic volumes over a long period [9–11]. In this regard, the domestically developed material *Rekost* (RZN 2014/1646, state registration date 03.07.2014, indefinite) [12] based on polyurethane polymers [13] seems a promising material for solving such problems.

The **purpose** of the work was to compare the kinetics of antibiotic release from materials based on polyurethane polymers for filling post-osteomyelitic bone defects.

MATERIALS AND METHODS

The study is an *in vitro* comparative analysis of the kinetics of release of three antibiotics (cefotaxime, vancomycin, meropenem) from two materials: *Rekost* (RK) based on polyurethane polymers (Nizhny Novgorod, RZN 2014/1646 dated 03.07.2014, indefinitely) (series RK) and bone cement (RU No FSZ 2012/11622 dated 19.03.2012, indefinitely) based on polymethyl methacrylate (series PMMA).

The tested materials (according to the instructions) were used in the shape of cylinders, 7 mm high and 4 mm in diameter. Antibiotics were added to the initial material in three proportions:

1) polymer/ antibiotic — 10:1 (group 1 in each series);

2) polymer/ antibiotic — 10:0.5 (group 0.5 in each series);

3) polymer/ antibiotic — 10:0.25 (group 0.25 in each series).

The cylinders were incubated in 10 ml of physiological solution at 37 °C. The incubation solution was changed daily during the first week, and then once a week. Six samples were incubated in each group. Samples without antibiotics were also incubated (control).

In each sample of the incubation solution, the concentration of the tested antibiotics was determined spectrophotometrically relative to the standard calibration curve by absorption intensity: cefotaxime at 243 nm, vancomycin at 280 nm, meropenem at 298 nm. For calculating the concentration of the experimental samples, the extinction values in the samples of the control material (without antibiotics) were subtracted. Incubation was stopped when trace amounts were noted in the samples over two weeks.

In parallel, the median and interquartile ranges were calculated. The reliability of differences between the groups was assessed using the Wilcoxon W-test for independent samples.

The studies were carried out considering the recommendations specified in GOST ISO 10993-13-2016 "Medical devices. Evaluation of the biological effect of medical devices. Part 13. Identification and quantification of degradation products of polymeric medical devices."

The work was carried out in the format of an *in vitro* study without the use of biomaterials, so an ethical approval was not required.

RESULTS

The results of the cefotaxime release kinetics showed that the antibiotic released from the PMMA series samples was maximal during the first day of the experiment for all concentrations: 25–40 % (Fig. 1). The cefotaxime release from the RK series samples during this period was about 10 %. In subsequent observation periods, the antibiotic release from the RK series samples was, on average, higher than in the PMMA series.

In the PMMA series, the release of vancomycin in the first day of the experiment was also maximal for all concentrations during the entire observation period and significantly exceeded the values of the RK series (Fig. 2). However, in subsequent periods of the experiment, the antibiotic release from the RK series samples was more significant relative to the PMMA series, especially in the 0.25 group.

The release of meropenem in the first day of the experiment in the PMMA series of group 1 was significantly higher than the values of the similar RK series (Fig. 3). In the 0.5 group, the release kinetics in the RK series during the first week of the experiment was identical to that in the PMMA series, and in subsequent periods it even exceeded the release level in the PMMA series. In the 0.25 group, the antibiotic release from the RK series samples was higher relative to the PMMA series at all observation time-points.

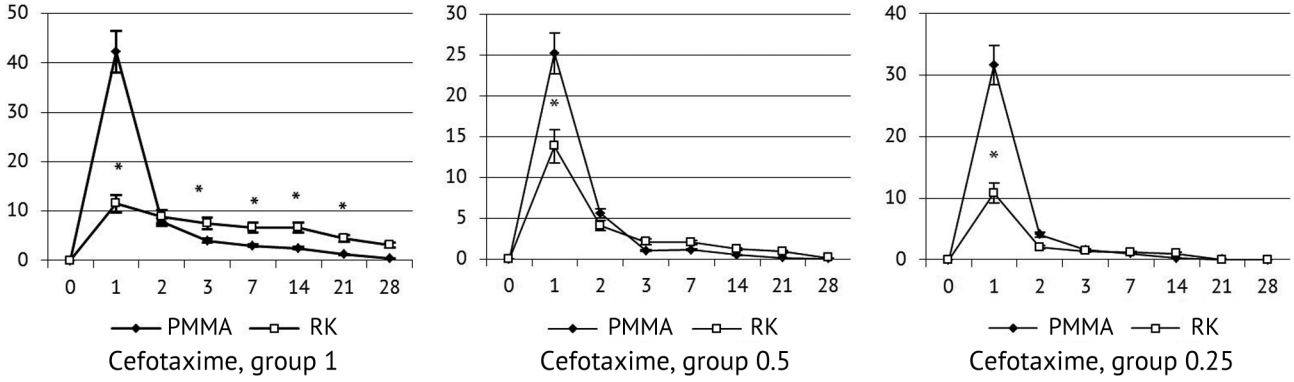

Fig. 1 Dynamics of cefotaxime release (% of the total of the impregnated antibiotic) from the tested materials (Me, interquartile range). * — reliability of differences between series at $p < 0.05$. On the abscissa axis — day of incubation

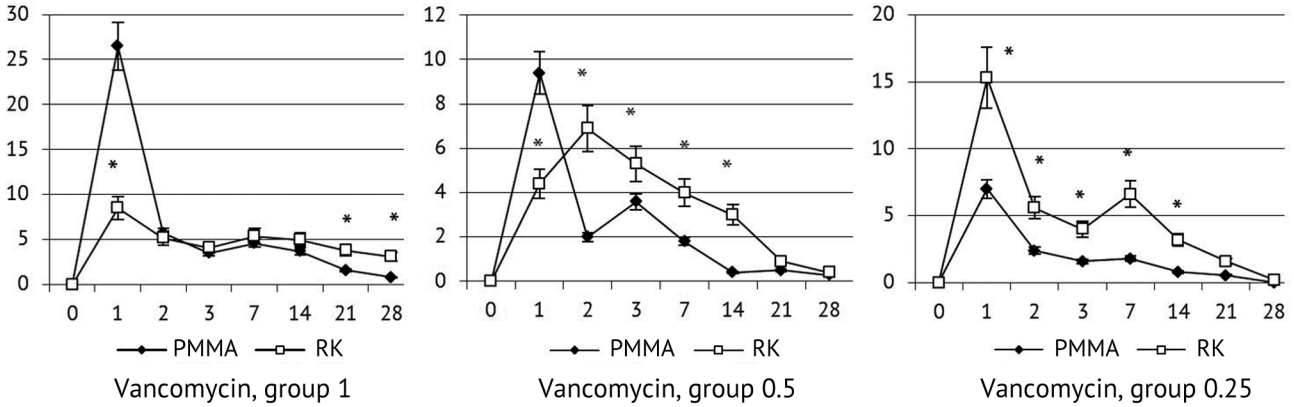

Fig. 2 Dynamics of vancomycin release (% of the total of the impregnated antibiotic) from the tested materials (Me, interquartile range). * — reliability of differences between series at $p < 0.05$. On the abscissa axis — day of incubation

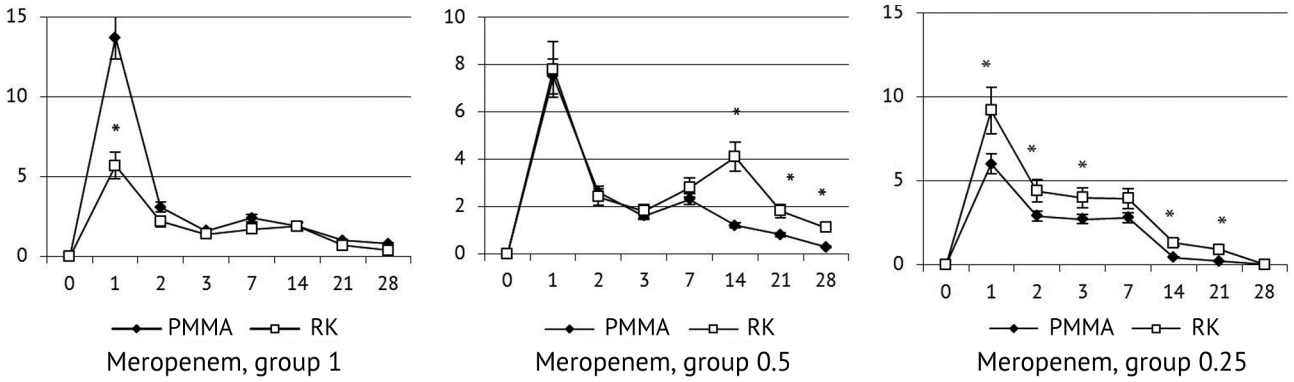

Fig. 3 Dynamics of meropenem release (% of the total of the impregnated antibiotic) from the tested materials (Me, interquartile range). * — reliability of differences between series at $p < 0.05$. On the abscissa axis — day of incubation

The summarized results of the release kinetics of the studied antibiotics in different concentrations from PPMA and RK materials are shown in Table 1. It was found that the total duration of antibiotic release (L) decreased with a decrease in their content in the samples. The total duration of vancomycin and meropenem release was the same for the PMMA and RK groups. For cefotaxime in groups 1 and 0.5, the antibiotic was released from the RK series material for a longer time. However, the total volume (Vo,) of cefotaxime released from PMMA was higher than from RK at all concentrations. For vancomycin and meropenem, the total release from PMMA was in group 1, while in groups 0.5 and group 0.25, a larger volume was released from the RK series material. For all series, the maximum released volume of antibiotics (Max) was noted after the first day of incubation.

Table 1

General results of the kinetics of antibiotic release in different concentrations from PPMA and RK materials (Median)

Antibiotic	Group	L, days PMMA/RK	V_O, % PMMA/RK	Max, days (%) PMMA/RK
Cefotaxime	1	56/70	69.2/48.2	1(52.2)/1(11.5)
	0.5	21/28	30.6/25.5	1(25.2)/1(13.8)
	0.25	14/14	39.7/15.8	1(31.6)/1(10.8)
Vancomycin	1	42/42	52.1/49.5	1(26.5)/1(8.5)
	0.5	35/35	20.8/30.1	1(9.4)/1(4.4)
	0.25	21/21	13.8/33.6	1(7.0)/1(14.7)
Meropenem	1	42/42	25.8/14.3	1(13.7)/1(5.7)
	0.5	28/28	16.5/21.5	1(7.5)/1(7.7)
	0.25	14/14	15.3/23.4	1(5.9)/1(9.1)

Notes: L — duration of antibiotic release; Vo — total volume of released antibiotic (%) relative to the total of the impregnated antibiotic; Max — observation term (days) of maximum volume of the released antibiotic and (brackets) the percentage of this released antibiotic relative to the total impregnated antibiotic

Thus, we have shown that the volumes of released antibiotics depend both on their concentration in the material and on the nature of the material itself. To assess the probable clinical applications of the findings obtained, we compared the amounts of eluted antibiotic with the values of minimum inhibitory concentration (MIC) for the main classes of microorganisms. The MIC values are taken from the "European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for the interpretation of MIC values and zone diameters of inhibition. Version 13.0, 2023" (https://amrnet.crie.ru/upload/iblock/4c9/od4c56ltfmoaatnvk6d8i1n1r4mg1cj8/v_13.0_Breakpoint_Tables_RU_Translation.pdf). According to the references for cefotaxime and meroponem in relation

to *Staphylococcus spp*. the MIC is 4 mg/L, for vancomycin relative to *Staphylococcus spp*. — 2 mg/L, in relation to *Enterococcus spp*. — 4 mg/L, for meroponem relative to *Pseudomonas spp*. — 2 mg/L.

Table 2

Terms of maintaining the level of antibiotics above the MIC values for different microorganisms in eluates from the studied materials

Antibiotic	Groups	*Staphylococcus spp.*, PMMA/RK	*Enterococcus spp.*, PMMA/RK	*Pseudomonas spp.*, PMMA/RK
Cefotaxime	1	7/56	–	–
	0.5	3/7	–	–
	0.25	2/1	–	–
Vancomycin	1	35/42	14/42	–
	0.5	3/21	1/7	–
	0.25	3/14	1/7	–
Meropenem	1	14/14	–	35/21
	0.5	2/2	–	14/21
	0.25	1/1	–	7/7

It was found that the concentration of cefotaxime exceeding the MIC for *Staphylococcus spp*. in the eluate from the RK series samples was maintained longer than for the PMMA series samples in groups 1 and 0.5, lasting 56 and 7 days, respectively (Table 2). In the 0.25 group samples, the concentration of cefotaxime exceeding the MIC was observed in the eluate only during the first two days of incubation in the PMMA series and the first day in the RK series. The concentration of vancomycin in the eluate higher than the MIC for *Staphylococcus spp*. and *Enterococcus spp*. from the samples in the RK series was maintained longer than in the PMMA series in all studied groups. The concentration of meropenem was higher than the MIC in relation to *Staphylococcus spp*. in the eluate from the RK and PMMC series samples was maintained for the same period. In relation to *Pseudomonas spp*. the MIC was higher in the RK series samples in groups 1 and 0.5 and was maintained longer compared to the PMMA series.

DISCUSSION

The findings allow us to conclude that the volumes of released antibiotics and, accordingly, the duration of maintaining the MIC in the eluates are determined by their concentration in the original material and the type of the carrier. It was shown that the volume of eluted cefotaxime from the PMMA series material was higher than that from the RK series material at all antibiotic concentrations. In turn, for vancomycin and meropenem, this was observed only for samples in group 1. For group 0.5 and group 0.25, a larger volume of released antibiotics was noted in the RK series than in the PMMA series. Assessing such an important parameter as the duration of maintaining the antibiotic level in the eluates above the MIC values, it became obvious that in the RK series, the release of vancomycin and cefotaxime in an effective (therapeutic) concentration was more prolonged. Moreover, an additional criterion in favor of RK is the fact that prolonged maintenance of effective concentrations occurred in smaller volumes of released antibiotic, which reduces the toxic load.

Our findings for the PMMA series are in good agreement with the data reported by other authors [14]. However, the elution indices of the carriers proposed as analogues of PMMA differ significantly. Thus, the antibiotic delivery systems being under development, where calcium phosphate materials act as carriers, have quite variable characteristics in terms of elution duration. In particular, by varying the composition of this material, researchers achieve the duration of antibiotic release in therapeutic volumes (above the MIC values) from one [15] to 18–34 days [16, 17].

The use of artificial polymers, in particular polylactic and polyglycolic acid copolymer (PLGA) as a carrier, appears quite promising due to the fact that the material is degradable, has sufficient mechanical strength and can be used to create 3D models of the defect [18]. However, the available studies demonstrate that the release of antibiotics from this material occurs mainly within the first two days [19, 20].

In terms of biodegradability, it is worth noting the materials of natural origin. Thus, almost a complete release of clindamycin or gentamicin from a hydrogel of human collagen occurred within 18 hours [21]. The use of chitosan as a carrier increases the duration of elution, but its speed depended on the nature of the antibiotic: cefotaxime released within 3 days, gentamicin and lincomycin within 15 days [22].

Attempts to increase the duration of antibiotic elution in therapeutic doses led researchers to develop materials of combined composition. Thus, the material based on collagen and hydroxyapatite showed vancomycin elution within 28 days [23], ciprofloxacin elution from a hydrogel based on carboxymethyl-resistant starch and polyacrylic acid released for 3 days [24], ampicillin elution from chitosan/starch nanocomposites occurred within 24 hours [25].

New potential carriers are also being developed: nanocomposite hydrogels from polyacrylamide/dextran containing carbon quantum dots [26], hydrogels based on aspartic acid/acrylamide [27], ion-containing carriers [28], molecularly imprinted polymers, which are synthetic receptors [29].

In general, the majority of current studies are the works in which an attempt to obtain materials with characteristics of prolonged release of antibiotics was the search for optimal chemical compositions. Therefore, a group of new materials that allow regulation of release kinetics by changing the physicochemical parameters of the carrier looks quite interesting. Thus, a group of authors demonstrated the possibility of regulating the rate of antibiotic elution from oxide nanotubes by modifying the sizes of those nanotubes [30]. Carriers have been proposed in which the release of antibiotics is regulated by an alternating magnetic field [31]. A hydrogel has been developed, the rate of release of antibiotics from which depends on the pH of the medium and the presence of free radicals in it [32].

The presented above shows that each material has its own antibiotic elution profile and each of them may have its own indications related to the need for either prolonged elution of the active substance (chronic process) or, conversely, the need to create a "shock" concentration in a local volume (acute process). However, most of the materials used and being developed have limitations on the duration of antibiotic elution in effective concentrations. In this regard, it can be stated that the RK-based material has advantages in terms of the duration of antibiotic elution in therapeutic doses. According to this criterion, RK corresponds to similar materials being developed that are based on calcium phosphate.

In general, based on the study, the RK material appears quite promising as a carrier of antibiotics in the management of bone defects. Moreover, the possibility of achieving a dose of the released antibiotic higher than the MIC values at lower concentrations of drugs in the material will allow impregnating several active drugs into the material to increase the effectiveness of antibiotic therapy. Such studies are available in the literature [33].

Undoubtedly, the design of our study has limitations. In particular, the model of the experiments conducted should be confirmed by further studies on living objects.

CONCLUSION

Thus, the duration of release of studied antibiotics in effective concentrations from the material based on polyurethane polymers is longer than from the material based on PMMA. These characteristics of the studied product seem promising for prevention of infection in management of post-osteomyelitic bone defects.

Conflict of interests *None.*

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Localization of osteocalcin in bone healing treated by local application of collagen and beta-tricalcium phosphate in rats

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Abstract

Introduction Bone repair is a complex and multifaceted process that generally happens naturally unless complicated by situations such as substantial bone defects. The bone healing process is typically divided into three stages: inflammation, repair, and remodeling. Beta-tricalcium phosphate (β-TCP) renowned for its abundant reserves of calcium and phosphorus, easily assimilated by the body. Its exceptional biocompatibility assists in the formation of an absorbable interlinked structure at the injury site, contributing to the advancement of the healing process.

Purpose This study aimed to estimate the effects of a scaffold of collagen/β-tricalcium phosphate (Coll/β-TCP) on bone construction to evaluate its latent usage as a bone auxiliary to repair bone defects.

Material and Methods The experiment was performed on 20 adult male albino rats. Four holes were surgically created on each animal, two in each femur; two holes were treated separately with Coll or β-TCP, one hole with their combination. The untreated hole served as a control. Animals were scarified after two- and four-week treatment periods (10 rats for each). Immunohistochemical analysis of bone marrow stromal cells, osteocytes, osteoblasts and osteoclasts using polyclonal antibodies to osteocalcin was performed.

Result Immunohistochemical results discovered strong positive expression of osteocalcin in bone healing in the group of combined treatment (β-TCP and collagen) as compared to other groups. Highly significant differences were seen between the combination of collagen with β-TCP and the control group at both time-points of the experiment.

Discussion The marker osteocalcin is unique to osteoblasts, specifically to osteoblasts that are actively forming new osteoid or remodeling bone. The obtained findings showed that mean values of osteocalcin expression were greater in the experimental groups than in the control group.

Conclusion The combination of collagen with β-TCP showed the greatest efficacy in accelerating bone healing and increasing osteogenic capacity due to increased osteocalcin immunoreactivity.

Keywords: bone defect, collagen, β-TCP, osteocalcin

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INTRODUCTION

Bone repair is a complex and multifaceted process that generally happens naturally unless complicated by situations such as substantial bone defects. The bone healing process is typically divided into three stages: inflammation, repair, and remodeling [1]. However, the system of healing of bone defect is time intense, and generation of original bone takes place gradually as a result of the size of defects or unbalanced biomechanical possessions, uncomplimentary environment of wound, suboptimal surgical preparation, metabolic aspects, hormones, nutrition, and functional stress [2]. The two primary tissue compartments that make up a bone are called trabecular bone (also known as cancellous or spongy bone) and cortical bone (also known as thick or compact bone). The structural makeup of bone is a combination of inorganic substances like hydroxyapatite and whitlockite with organic collagen nanoparticles [3]. With hydroxyapatite (HA) and within the collagen matrix, there is an existing bone material called whitlockite. It plays a vital role via earlier stages of bone development. It is present in short-range order and is difficult to identify in the bone, when compared to HA mineral that cover 80 % of the bone inorganic phase. It has similar structural analogy with β-tricalcium phosphate (β-TCP), however detailed structural and crystallographic analyses of bone have shown that β-TCP is merely a synthetic analog of bone whitlockite, having the same crystalline structure whereas different chemically. Whitlockite contain magnesium at Ca(IV), Ca(V) positions, and HPO_4^{2-} on a threefold axis in a rhombohedral crystal lattice. Its bio-compatibility, functionality, negative surface charge, mechanical strength, and stability in physiological solvents make it an ideal bone substitute as compared to hydroxyapatite (HA) and β-TCP [4].

Beta-tricalcium phosphate (β-TCP) also called bone ash is a tertiary calcium phosphate [$Ca_3(PO_4)_2$], renowned for its abundant reserves of calcium and phosphorus, easily assimilated by the body. Its exceptional biocompatibility assists in the formation of an absorbable interlinked structure at the injury site, contributing to the advancement of the healing process [5]. β-TCP is widely acknowledged for its ability to support new bone growth and induce bone formation, making it a highly effective material in managing bone defects in orthopedic and maxillofacial surgery [6]. It facilitates the process of bone renewal and gradually disintegrates inside the body, paving the way for the development of new bone tissue, thereby ensuring the effective repair of the injury [7]. Collagen (Coll), a crucial protein naturally synthesized in the body, serves as the primary structural component in the skin, tendons, and bones. Renowned for its favorable biocompatibility and minimal immune response, collagen has been extensively researched for its potential applications in various biomedical products, including cosmetics and pharmaceuticals [8]. Collagen, a reliable biomaterial, has been widely utilized in tissue manufacturing and clinical contexts, serving as an essential component in dental compounds, regeneration of skin templates, and biodegradable conditions. Its usefulness extends to various medical fields, including cardiovascular operation, plastic surgery, orthopedics, urology, neurology, and ophthalmology [9]. When employed as a scaffold, collagen not only provides a structural foundation for cells to adhere to and proliferate, but also impacts cellular activity. Studies have confirmed that collagen-based biomaterials effectively facilitate bone regeneration when inserted into bone defectiveness [10]. Collagen sponge promotes wound healing by allowing blood vessels and fibroblasts from the surrounding tissue to infiltrate the sponge inside and form granulation tissue. Furthermore, the collagen sponge device is required for the healing of dental extraction sockets [11]. Osteocalcin (OCN) serves as an exclusive protein in bones, serving as an indicator of fully developed osteoblast function. This protein acting a crucial role in the process of bone restructuring, the creation of novel bone tissue, and the strengthening of bone minerals [12]. Naturally pro-osteoblastic, or bone-building, osteoblasts secrete osteocalcin and it is believed to have a role in the regulation of the body metabolism. Moreover, calcium ion homeostasis and bone mineralization are related to it [13]. Osteocalcin is a helpful indicator of bone turnover that is especially beneficial for patients who are receiving treatment for bone disease [14]. Serum osteocalcin levels are an indicator of osteoblast activity and bone turnover. Osteoblasts secrete OCN, which has a strong affinity for the bone hydroxyapatite matrix [15]. The primary sources of OCN are chondrocytes, cementoblasts, odontoblasts, mature osteoblasts, and osteocytes. OCN is essential for bone mineralization [16].

Identification of bone marrow mesenchymal stromal cells (BMSCs), firstly by Frieden in 1976 [17], as peri-cytes comprising the hematopoietic niche, which are a group of heterogeneous cells composed of multi-potent stem cells, involving osteo-chondral and adipocyte progenitors [18]. They are forming immunomodulatory ability with niche, which of great clinical significance and are widely explored in biological engineering and the treatment of autoimmune disorders [19, 20]. BMSCs have limited applications because of less well-defined [21], however the traditional RNA sequencing can only obtain the average data of cells, which fail to reflecting cellular heterogeneity [22]. Recently, by lineage tracing and single-cell sequencing, many new subgroups of BMSCs and their roles in normal physiological and pathological conditions have been clarified [17].

Purpose This study aimed to estimate the effects of a scaffold of collagen/β- tricalcium phosphate (Coll/β-TCP) on bone construction to evaluate its latent usage as a bone auxiliary to repair the defects of bone.

MATERIALS AND METHODS

Study design

Twenty adult male albino rats weighing approximately 250–350 g and aged 3–4 months were used in this study. Rats were given an intramuscular injection, with a dosage of 50 mg ketamine hydrochloride per 1 ml per kilogram of body weight, combined with 2 % xylazine at a rate of 0.2 ml per kilogram of body weight. Sterile conditions were maintained during the surgical procedure by making an incision on the skin and underlying fascia. Then, reflection was performed to expose the rat femurs. Intrabony holes approximately 3 mm in depth and 2 mm in width were induced in both femurs of each animal (Fig. 1), with intermittent drilling and constant cooling with normal saline using a micro engine that was set at a rotary speed of 2500 rpm. The operation sites were washed with normal saline to remove debris. Then they were subdivided into:

1. Group A (control group); 20 holes were left untreated for spontaneous healing.
2. Group B; 20 holes were filled with collagen.
3. Group C; 20 holes were filled with β-TCP.
4. Group D (20 holes) were filled with combination of Coll and β-TCP material in a ratio of 1:1.

Finally, animals were sacrificed by administering an excessive amount of anesthesia, two and four weeks after surgery (10 rats for each healing interval).

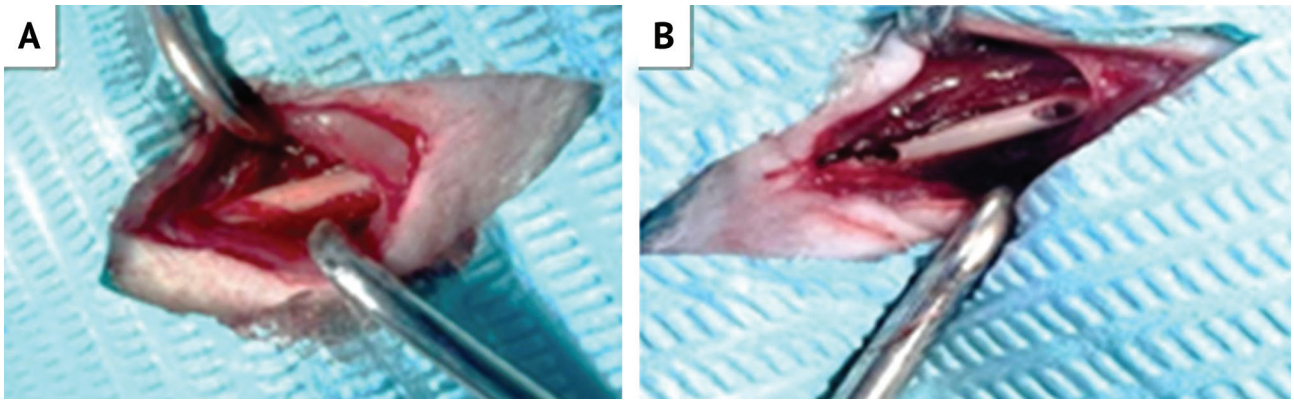

Fig. 1 A: Exposure of rat femur; B: Holes prepared

Immunohistochemical preparation

Collected bone specimens were fixed for 24 hours using 10 % freshly made formalin; then the process of decalcification was done by using 10 % formic acid for 2–3 days; afterwards, they were embedded in paraffin wax. A microtome that operated automatically divided the blocks for serial slices of 4 μm, which were positioned on charged slide. After immunohistochemical staining, osteocalcin localization by bone cells and bone marrow stromal cells (BMSCs) was analyzed for all collected bone specimens at 2- and 4-weeks.

Statistical analysis

Descriptive analysis of mean, standard deviation (SD), minimum (Min), and maximum (Max) values of the immunoreactive score (IRS) of OCN by bone cells (OB, OC, and OCL) and bone marrow stromal cells (BMSC) at 2- and 4-week duration was done for all investigated groups. Immunohistochemical scoring of OCN. Employing an objective lens with a power of ×40, the procedure was carried out, taking into account scoring systems were used as follows. To estimate the immunostaining of the antibodies, positively stained cells were calculated at 5 representative fields (×40) for 2- and 4-weeks periods of healing. Within the chosen fields, the percentage of cells that tested positive for OCN was scored and evaluated visually. Calculation of the ratio of stained cells to the total cell count and multiplying it by 100 offers an approximation of the percentage of cells that display positive staining. The scores were: 0 (no stain), 1 (< 25 %), 2 (25–50 %), 3 (> 51–80 %), 4 (> 80 %) stained cells in two sections and scoring the intensity of stain as: 0 (no clear stain), 1 (mild stain), 2 (moderate stain), 3 (intense stain) and calculating the immunoreactive score (IRS), which is obtained by multiplying the of positive cells (0–4) by the staining intensity score, has a range of {0–12} [23].

RESULTS

Immunohistochemical results for expression of osteocalcin after 2 and 4 weeks

Two weeks

Immunohistochemical localization of ocsteocalcin in the control group showed strong positive expression in osteoblasts, osteocytes and negative staining is evident within the bone (Fig. 2, A). Moderate positive expression of immunohistochemical localization of osteocalcin in collagen group was shown in osteoblasts and osteocytes (Fig. 2, B). In the β-tricalcium phosphate group, immunohistochemical localization of osteocalcin revealed positive expression in osteoblasts, osteocytes and bone marrow stromal cells, with negative expression seen in trabecular bone (Fig. 2, C). Positive immunohistochemical localization of osteocalcin in bone section postoperatively in the combination group was detected in osteocytes and osteoblasts, while trabecular bone had a negative expression (Fig. 2, D).

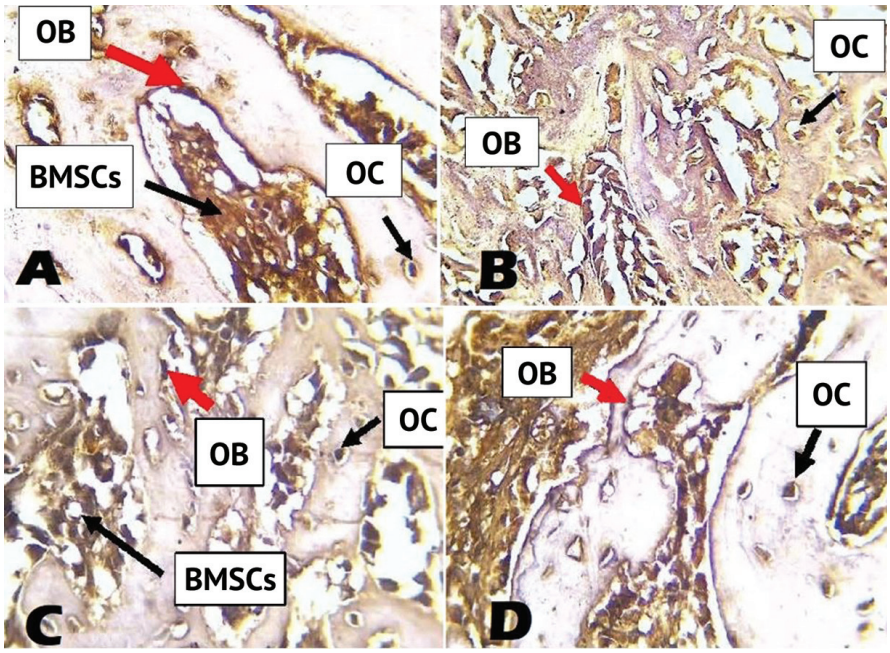

Fig. 2 A: View of the control group after 2 weeks shows positive localization of osteocalcin in osteoblasts (OB), osteocytes (OC) and bone marrow stromal cells (BMSCs); B: Collagen group shows positive expression of OCN after 2 weeks in OBs and OCs; C: Positive localization of osteocalcin in the β-TCP group after 2 weeks is seen in OBs, OCs and BMSCs; D: View of combination group after 2 weeks shows a strong positive expression of osteocalcin in OCs and OBs. (DAB stain with counter stain hematoxylin ×40)

Four weeks

Immunohistochemical localization of osteocalcin antibody in bone sections of the control group showed positive expression in bone marrow stromal cells, osteoblasts, osteocytes; bone was negatively stained (Fig. 3, A). The collagen group revealed positive expression of osteocalcin seen in osteocytes and osteoblasts, negative expression noticed in bone (Fig. 3, B). Positive expression of osteocalcin seen in osteoblasts, osteocytes, bone was negatively stained in β-TCP group (Fig. 3, C). Immunohistochemical localization of osteocalcin in the combination group shows positive expression in osteoblasts and osteocytes (Fig. 3, D).

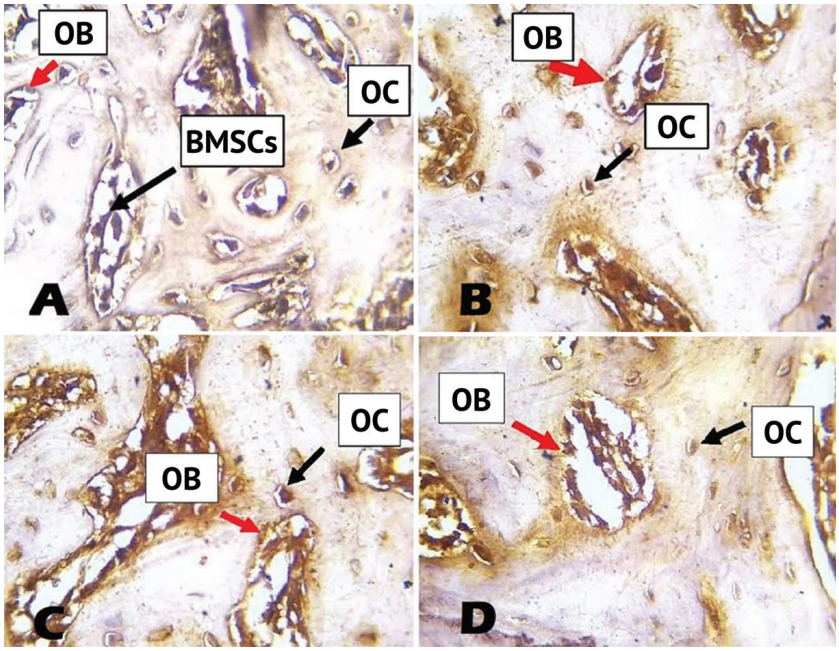

Fig. 3 A: View of the control group after 4 weeks shows strong positive expression of osteocalcin in osteocytes (OC), osteoblasts (OB), bone marrow stromal cells (BMSC); B: View of the collagen group after 4 weeks shows strong positive expression of osteocalcin in OCs and OBs; C: View of the β-TCP group after 4 weeks shows a strong positive expression of osteocalcin in OCs and OBs; D: View of the combination group after 4 weeks shows positive expression of osteocalcin in OCs and OBs. (DAB stain with counter stain hematoxylin × 40)

Descriptive data analysis for percentages of positively expressed bone cells for OCN in the studied groups at 2 and 4 weeks

The descriptive data of mean, SD, minimum and maximum values of the immunoreactive score (IRS) for expression of OCN by bone cells (osteoblasts, osteocytes, osteoclast) and bone marrow stromal cells at 2 and 4 weeks in all studied groups are illustrated in Table 1 and Figure 4.

Table1

Descriptive mean values of IRS of OCN in bone cells and BMSC in the studied groups at 2 and 4 weeks

Variable	Duration	A(Control) group				B (Collagen) group				C (β-TCP) group				D Collagen/ β-TCP (combination) group			
		Mean	SD	Min.	Max.	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.	Mean	SD	Min.	Max.
Osteoblasts	2 weeks	4.2	0.7	2	5.8	5.1	1.2	3.3	6.2	6	1	3.5	8	8.6	0.9	6.5	10.5
	4 weeks	3.1	0.8	0	4.3	4	0.8	0.8	5.5	5.1	0.6	3.8	7	6	0.7	3	8.8
Osteocytes	2 weeks	2.8	1.2	0	4	3.9	1.1	0	5	4	1.1	1	5.8	5.5	1	4	6.8
	4 weeks	4.5	1.7	1.3	5.3	5.9	1.7	3.5	8	7.1	1.3	3	8	8.2	0.7	6.5	10
Osteoclasts	2 weeks	1	0.6	0	1.5	0.6	1.1	0	3	0.4	0.6	0	1.5	0.2	0.6	0	0.8
	4 weeks	0.45	0.1	0	0.6	0.33	0.05	0	0.5	0.06	0.05	0	0.1	0.04	0.05	0	0.09
BMSCs	2 weeks	5.5	1.8	4	8.3	6.8	1.7	4	8.3	8.2	1.2	4	9.8	9.1	1.3	6	11.5
	4 weeks	4.2	1	3	5.3	4.8	1.4	1.8	5.9	5.9	1.2	1.5	6.5	6.2	1.1	3	8.3

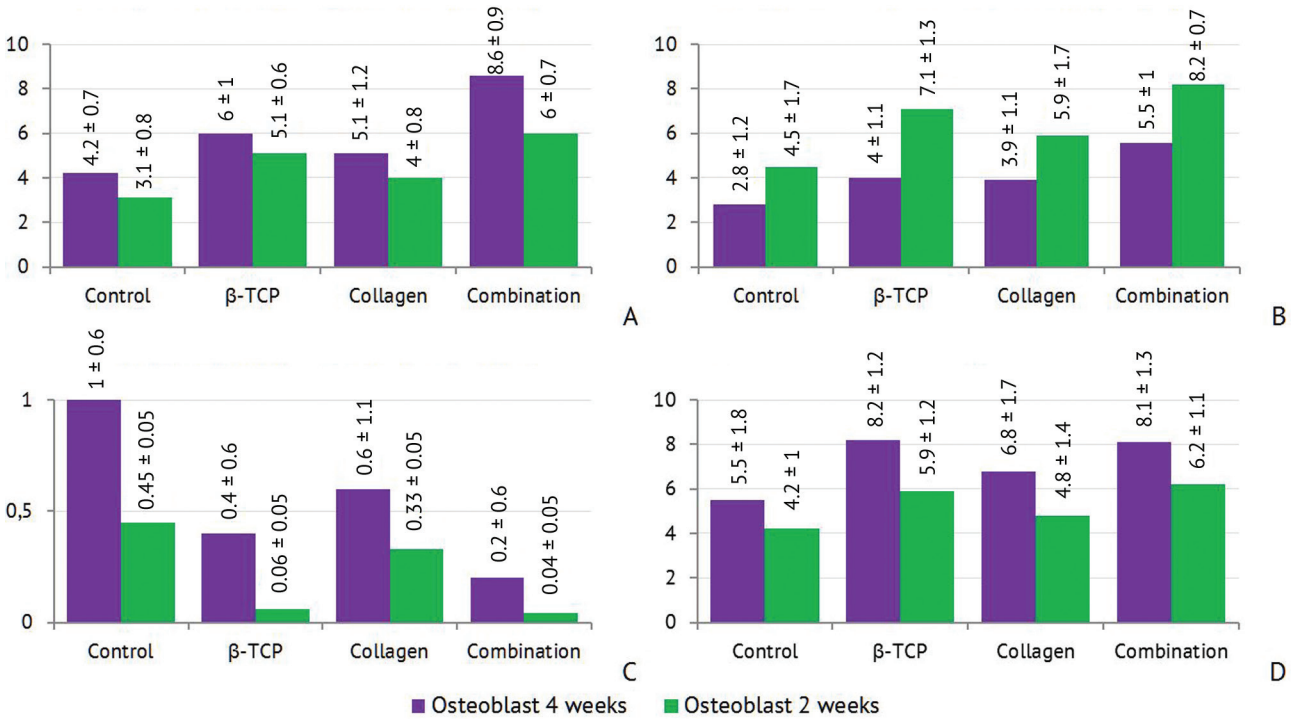

Fig. 4 A: Mean value of IRS for OCN in OB after 2- and 4-weeks healing intervals; B: Mean value of IRS for OCN in OC after 2- and 4-weeks healing intervals; C: Mean value of IRS for OCN in OC after 2- and 4-weeks healing intervals; D: Mean value of IRS for OCN in BMSCs after 2- and 4-weeks healing intervals

The mean value of IRS of osteocalcin by OB, OC and BMSCs decreased with time in all studied groups, the highest values were detected in the combination group at both time-points. Regarding OCs, increase in mean values of IRS of osteocalcin was seen in all groups and highest values were noticed after 4 weeks in the combination group.

Group comparison for bone cells after 2 and 4 weeks

The group comparison of IRS expression of OCN for bone cells (OB, OC, OCL) and BMSCs illustrated in Table 2 using ANOVA test, a highly significant difference was found between all investigated groups at 2 and 4 weeks.

Table 2

Group comparison for bone cells and BMSCs for OCN expression at 2 and 4 weeks

Variable	Duration	Group comparison	
		F test	*P* value
Osteoblasts	2 weeks	6.256	0.000**
	4 weeks	6.025	0.000**
Osteocytes	2 weeks	4.873	0.003**
	4 weeks	5.719	0.000**
Osteoclasts	2 weeks	5.767	0.000**
	4 weeks	5.016	0.000**
BMSCs	2 weeks	6.124	0.000**

**Highly significant result

DISCUSSION

When there is a loss of bone substance, it is referred to as a bone defect. This can be caused by a variety of congenital disorders, infections, degenerative diseases, trauma, bone tumors, and infections [24]. Bone reconstruction involves the reconfiguration of various bone cells to maintain bone strength and regulate mineral balance in response to environmental adjustments. This complex procedure can be categorized into four phases: initiation, maintenance, reversal, and growth through absorption, carried out by osteoclasts and osteoblasts, respectively [25].

The marker osteocalcin is unique to osteoblasts, specifically to osteoblasts that are actively forming new osteoid or remodeling bone. The obtained findings showed that mean values of IRS of osteocalcin expression were greater in the experimental groups than in the control group, except for OCL where values were greater in the control group at both time-points and that at 2 weeks they were greater than at 4 weeks. This coincides with Alpan et al. study [26] that showed an early detection of strong positive expression for osteocalcin recorded as new bone matrix and the surrounding region of the resorptive lacunae suggesting active bone matrix production.

Mean values of IRS elevated with the time in osteocytes and this phenomena is in line with Sananta et al. study [27] that found that the mean value of positive expression for osteocalcin in osteoblasts reduced, whereas for osteocytes raised at 4 weeks of healing duration in a bony defect in experimental rats.

Immunohistochemical findings for IRS of osteocalcin monoclonal antibodies positive expression was detected in bone cells and BMSCs in both groups with high significant difference which is similar to Al-Molla et al. study [28] that mentioned osteocalcin expression was strongly positive in the active mitotic osteoblast and progenitor cells in amelogenin and amelogenin-propolis coated implants and negative expression in an uncoated group at one-week interval.

Moreover, the immunohistochemical findings seem to be as same as the conclusions of the survey where the bone defect was treated with Eucommia ulmoides [29].

Bone defects treated with Coll/β-TCP combination have upward mean values of IRS of OCN expression which may indicate an elevating in osteoblasts activity in the early period of bone healing which was noticed at 2 weeks. These were supported by Abeas and Al-Azawy [30] who reported that the experimental group dental cells and their progenitors expressed a strong immunoreaction for osteocalcin, which is crucial for promoting and speeding up bone formation and regeneration through raising the activity of osteogenic cells which is an essential role in the orthodontic treatment.

The findings supported that the osteocalcin-positive osteoblasts and osteocytes indicated greater bone tissue maturity which was significant in the experimental group treated with alendronate as an anti-resorptive drug [31]. Moreover, it was found that immunohistochemical analysis of osteocalcin expression at the bone-implant site showed active osteoblasts scattered during an early bone deposition suggesting that OCN appears to play a part in the early phases of bone formation and that OCN regulates osteoblast activity and acts as a chemotactic agent for osteoclasts [32].

CONCLUSION

The combination of collagen with β-TCP promotes and accelerates the bone defect healing process through raised osteocalcin expression.

Conflict of interest *Not declared.*

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Ethical Approval *This work was approved and received a permission from the Ethical Reviewer Board Committee of College of Dentistry, University of Baghdad (No. 429721 in 27 Dec 2021).*

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Original first metatarsophalangeal hemiarthroplasty and installation technique in treatment of grade 3–4 hallux rigidus

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Abstract

Introduction Arthrodesis is the "gold standard" for the treatment of stage 3–4 osteoarthritis of the first metatarsophalangeal (MTP) joint. However, restricted movements in the joint can lead to changes in the biomechanics of the foot overloading the adjacent joints and are accompanied by decreased activity which is important for younger patients. The available implants of the first MTP joint have some disadvantages and an original hemiarthroplasty of the first MTP joint was developed.

The **objective** was to demonstrate an original technique of hemiarthroplasty of the first MTP joint and installation to treat stage 3–4 hallux rigidus.

Material and methods The hemiendoprosthesis is made of zirconium ceramics. The head of the hemiendoprosthesis is made with a low profile. The cross-section of the stem has a four-bladed shape to ensure rotational stability of the implant. The hemiendoprosthesis can be placed using specially designed instruments. A case of a 74-year-old patient diagnosed with stage 3 osteoarthritis of the first MTP joint is reported.

Results AOFAS Hallux scored 28 and 95, VAS scored 9 and 0 and FFI scored 112 and 6 preoperatively and at 24 months, respectively. The range of motion in the joint (extension/flexion) measured 0°–0°–5° preoperatively and 60°–0°–15° at 24 months. The dynamic pedobarography indicated to the physiological distribution of pressure in the foot being restored postoperatively.

Discussion The first implants offered to replace first MTP joint were made of silicone and metal alloys and total joint arthroplasty was associated with significant resection of bone tissue; cases of endoprosthetic instability were reported. Hemiarthroplasty appeared to be a sparing technique. However, implants made of metal alloys could have an aggressive effect on the opposite articular surface. Hemiarthroplasty of the first MTP joint using a zirconium ceramic implant could minimize the risk of the complications.

Conclusion Hemiarthroplasty of the first MTP joint using an original zirconium ceramic implant was shown to be effective for patients with stage 3–4 hallux rigidus. The technique reported can be a good alternative to arthrodesis of MTP joint.

Keywords: osteoarthritis, rigid finger, hemiarthroplasty, zirconium ceramics

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INTRODUCTION

Hallux rigidus is a condition that is characterized by degenerative changes in the first metatarsophalangeal (MTP) joint, pain and limited range of motion (ROM) in the joint. Joint-saving techniques are used for surgical treatment of patients grade 1–2 osteoarthritis to ensure good results. Fusion of the first metatarsophalangeal joint is the best option for cases of advanced osteoarthritis [1]. Despite its widespread use and low cost, the treatment can be associated with progressive overload osteoarthritis of adjacent joints including the interphalangeal joint, poor outcomes in younger patients, some limited activities. Surgical interventions aimed at preserving movements in the joint are essential to avoid the adverse events. Original hemiarthroplasty of the first MTP joint using a ceramic implant was developed [2].

The **objective** was to demonstrate an original technique of hemiarthroplasty of the first MTP joint and installation to treat stage 3–4 hallux rigidus.

MATERIAL AND METHODS

Description of the hemiendoprosthetic implant

The hemiendoprosthesis is made of yttrium-stabilized zirconium ceramics. This material has the best coefficient of friction and wetting, is characterized by high strength and crack resistance, is the most gentle to the articular cartilage, bioinert and has the property of osseointegration [3–6].

The implant consists of a head and a stem. The hemiendoprosthetic head is made as a sphere and is close to the anatomical shape of the head of the first metatarsal. The articulating surface is smooth with roughness of Ra ~ 0.02 μm corresponding to the roughness class 13 and provides optimal characteristics of the ceramic-cartilage friction pair and high functionality over a long period of time. The low profile of the hemiendoprosthetic head allows for minimal resection of the affected portion of the head of the first metatarsal to ensure implant stability and preserve bone mass for revision interventions in case of a complication. There are longitudinal and transverse grooves on the back side of the implant head designed to increase the contact area and accelerate osseointegration.

The implant stem has a four-blade shape to ensure stable fixation of the hemiendoprosthesis in the metaphysis of the first metatarsal due to the press-fit and an increased contact area at the implant-bone interface. The stem roughness is Ra ~ 1.5–2.5 μm to promote optimal ingrowth, a strong and reliable connection between the implant and body tissues. The shape of the hemiendoprosthetic stem allows for maximum rotational stability of the implant and minimizes the bone defect with a canal forming in the metaphysis of the metatarsal. The size range of the hemiendoprosthesis is presented in four options, allowing surgical intervention to be performed with different diameters of the plane of the bone sawing of the head.

Surgical procedure

The patient is in supine position. The surgical field is treated with antiseptic solutions three times. An arthrotomy of the first MTP joint is performed using a medial approach. An oscillatory saw is used to resect osteochondral exostoses and perform soft tissue release of the first MTP joint and sesamoid hammock. The affected area of the articular surface of the head of the first metatarsal is resected with an original sawing block (Fig. 1).

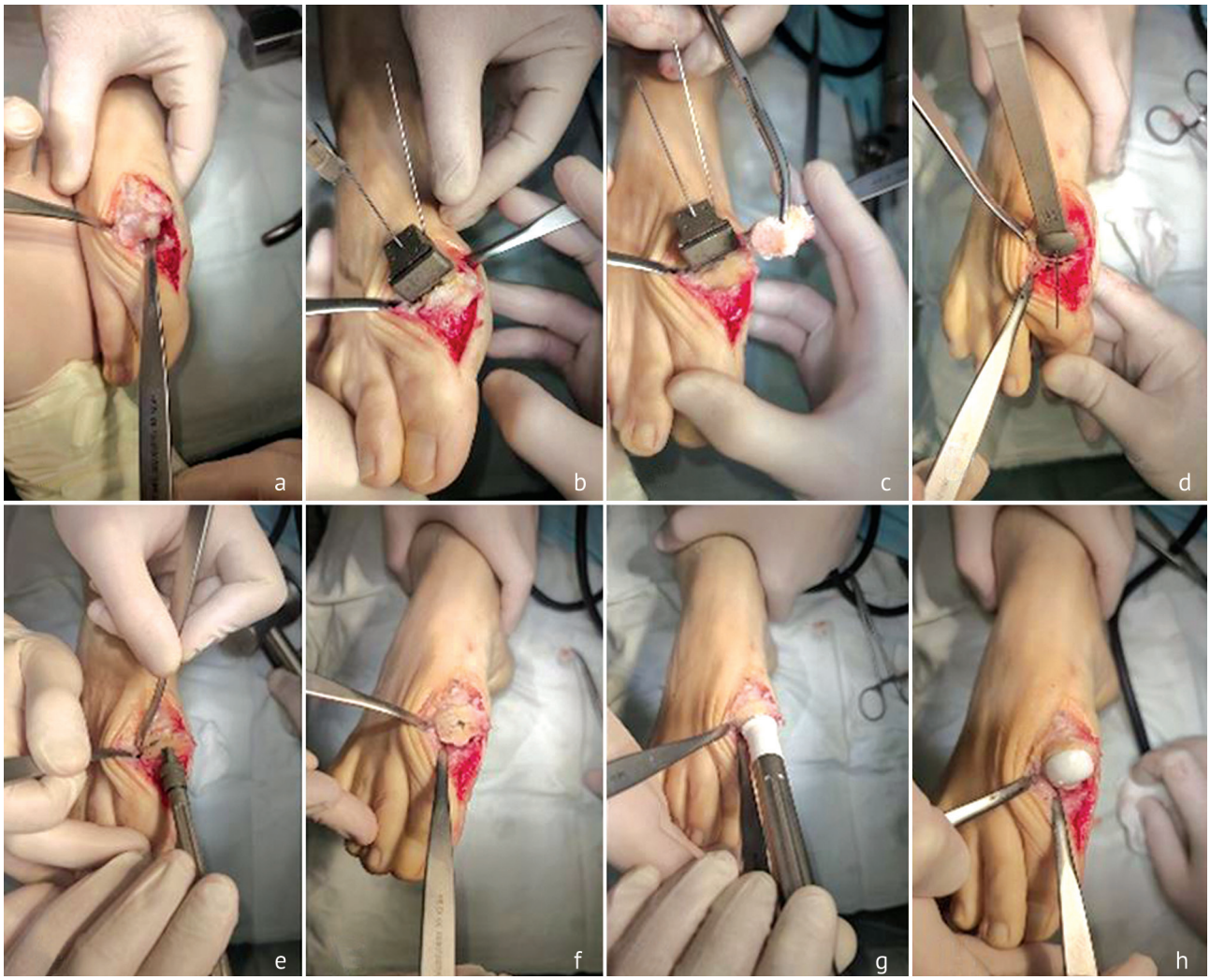

Fig. 1 Intraoperative photos showing (a) intraoperative assessment of the articular cartilage, (b) use of a sawing template, (c) resection of the articular surface, (d) determination of the implant size using a test template, (e, f) preparation of the canal with a compactor, (g) installation of a hemiendoprosthesis, (h) hemiendoprosthesis placed

Amount of the head resected is essential. Based on experience with the surgical procedures, resection to the cancellous bone tissue supplied with blood can be recommended. Installation of a hemiendoprosthesis into the sclerotic head of the first metatarsal can result in cracking during the formation of the channel for the stem and worse osseointegration of the implant.

A test template of the original model is placed on the osteotomy plane of the metatarsal to assess the required size of the hemiendoprosthesis, the expected ROM in the joint and the adequate metatarsal shortening.

If greater shortening of the metatarsal bone is necessary, the sawing block is moved proximally and additional resection of bone tissue is produced to achieve the ROM as required. The intraoperative ROM is deemed as a sufficient ROM in the MPT joint with extension/flexion measuring 60°–0°–15°. Then a guide pin is passed through the guide in the test template. The canal for the hemiendoprosthetic stem is prepared along using compactors of two sizes (starting and finishing). The implant is placed press-fit using the original impactor and the ROM in the joint is re-assessed. The wound is treated with antiseptic solutions and sutured in layers, and an aseptic bandage applied.

Clinical instance

A 74-year-old patient reported pain in the projection of the first MTP joint of the right foot, which intensified during physical activity, and limited ROM in the joint. The patient considered himself sick for many years, reported negative dynamics in his condition. he complained of constant pain for the last two years. He denied any history of injuries to the right foot. Previously, the patient had undergone courses of conservative anti-inflammatory therapy and used custom orthopaedic insoles with no improvement noted.

A physical examination revealed pronounced hard tissue formations in the projection of the first MTP joint of the right foot. Palpation of the joint was painful. He had severely limited and painful movements in the MTP joint. Preoperative ROM in the first MTP joint measured extension/flexion of 0°–0°–5°. AP view of both feet showed pronounced osteochondral exostoses in the projection of the joint, a significantly narrowed joint space and subchondral sclerosis.

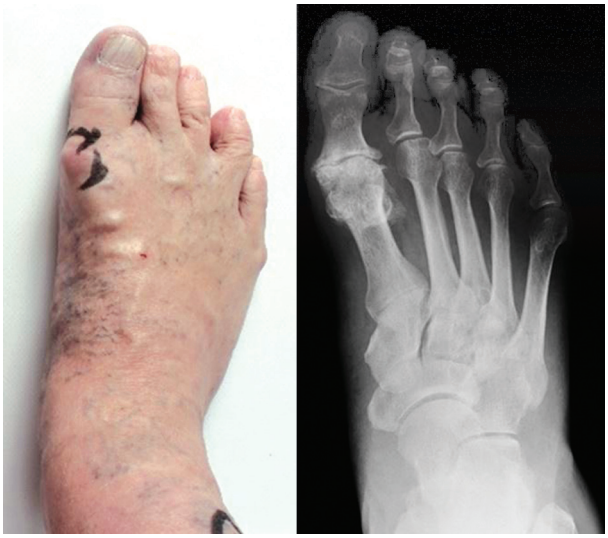

Fig 2 Preoperative photograph and radiography of the right foot showing pronounced osteochondral exostoses in the projection of the first MTP joint; narrowing and distorted joint space, subchondral sclerosis seen radiographically

Preoperative AOFAS Hallux scored 28, VAS scored 9, and Foot Function Index (FFI) scored 112 points.

Dynamic pedobarography indicated a pathological distribution of pressure at the gait and a decrease in maximum pressure and force in the hindfoot. A significant increase in the maximum pressure and force in the forefoot, high values of the maximum pressure under the heads of the 4th and 5th metatarsals were recorded (Fig. 3).

The patient was diagnosed with stage 3 osteoarthritis of the first MTP joint of the right foot.

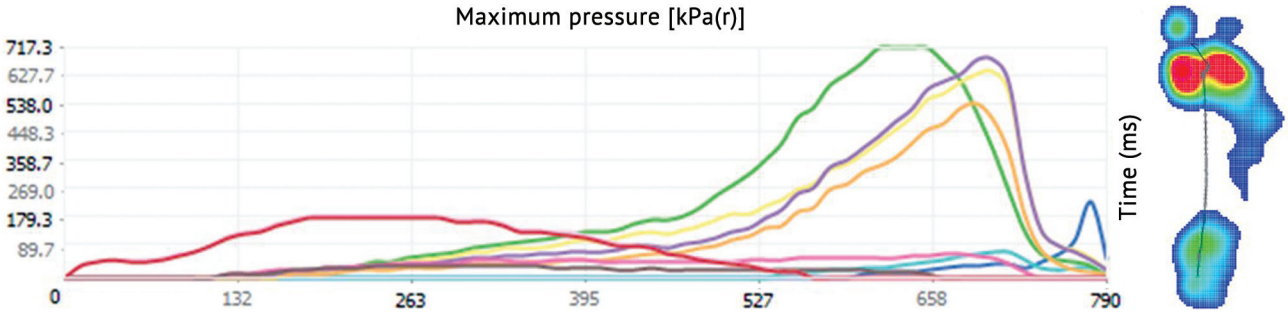

Fig. 3 Preoperative dynamic pedobarography showing a significant increase in maximum pressure in the forefoot. Green indexing — first metatarsal — 714 kPa, yellow indexing — second metatarsal — 586 kPa, purple indexing — third metatarsal — 617 kPa, orange indexing — fourth metatarsal — 499 kPa

RESULTS

The treatment options including arthrodesis of the first MTP joint were discussed with the patient. However, the patient chose the treatment aimed at preserving the motion in the affected joint.

Surgical intervention included hemiarthroplasty of the first MTP joint of the right foot using the technique described above. The patient was encouraged to ambulate early after the surgery and exercise the operated MTP joint the next postoperative day. He was allowed to walk using a Barock shoe for 1 month. The postoperative period was uneventful. The patient had no complaints at the time of a follow-up examination at 24 months.

Postoperative scars showed no signs of inflammation (Fig. 4). Palpation in the projection of the joint was painless. The ROM in the first MTP joint measured extension/flexion of 60°–0°–15° (Fig. 5). The AOFAS Hallux scored 95, the VAS scored 0 and the FFI scored 6.

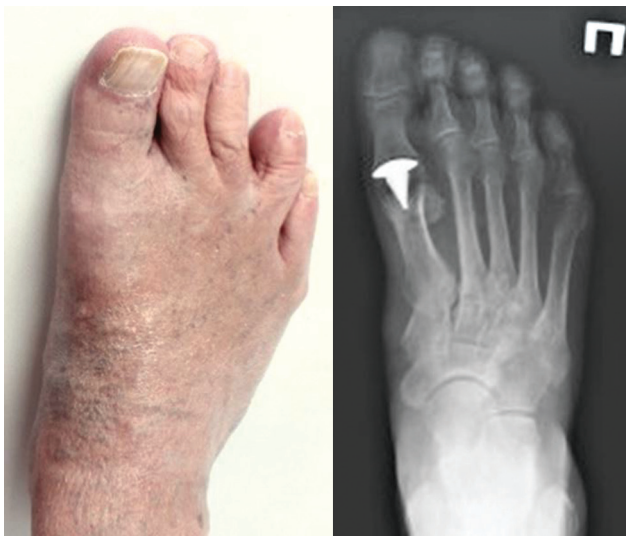

Fig. 4 Photograph and radiograph of the foot at 24 months showing the realigned first toe; no radiological signs of implant instability seen

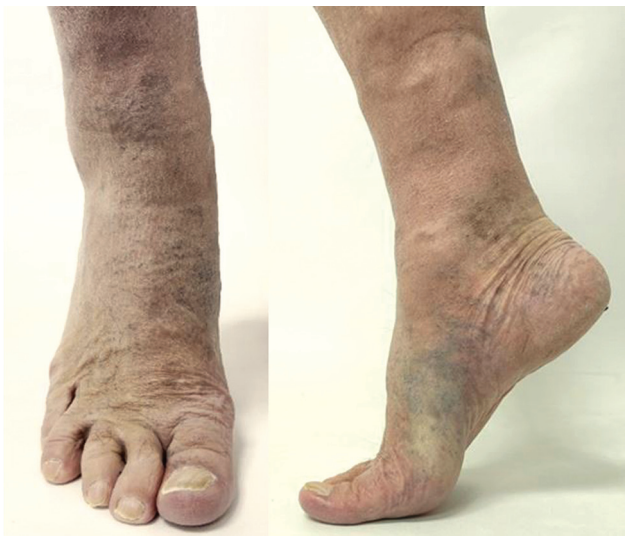

Fig. 5 The ROM in the first MTP joint at 24 months measured extension/flexion 60°–0°–15°

Dynamic pedobarography produced at 24 months showed changes in the patient's gait as compared to the baseline. There was an increase in maximum pressure and force in the hindfoot and a decrease in contact time and maximum pressure in the midfoot. The RMI index allowed us to conclude that the physiological distribution of pressure in the foot restored in the postoperative period [7] (Fig. 6).

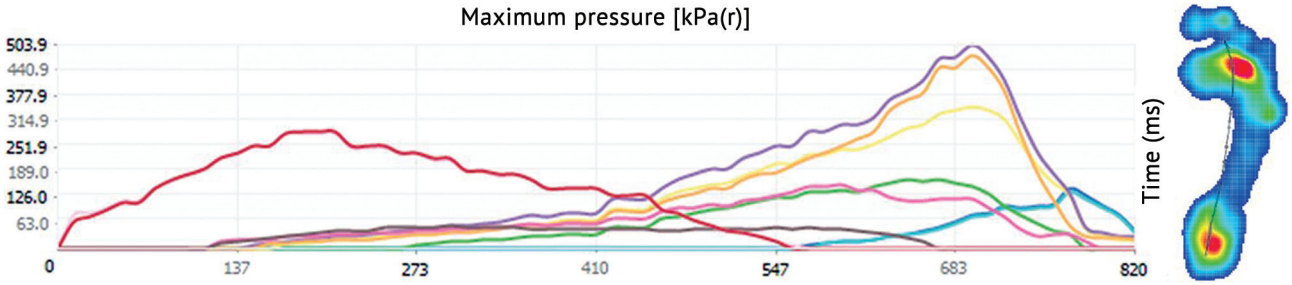

Fig. 6 Dynamic pedobarography performed at 24 months indicated an increase in maximum pressure in the hindfoot and a decrease in maximum pressure in the forefoot. Green Indexing — First Metatarsal — 184 kPa, Yellow Indexing — Second Metatarsal — 356 kPa, Purple Indexing — Third Metatarsal — 503 kPa, Orange Indexing — Fourth Metatarsal — 477 kPa

DISCUSSION

There is a wide range of implants on the market that differ in philosophy, assembly and structure [8]. The total arthroplasty of the first MTP joint is a conventional and one of the first options offered for joint replacement [8]. The first and second generations of the total arthroplasty include silicone implants that provide satisfactory long-term results despite a fairly high complication rate [9]. Implants of later generations are made of metal alloys and other materials [10]. The MTP1 joint replacement using the *ToeFit Plus* system is one of the treatment alternatives. The prosthesis is composed of a tapered, threaded, conical titanium core, which avoids any need for cement. On the metatarsal side, a cobalt chrome metatarsal head is tapped into the titanium core and to accommodate the proximal phalanx, a polyethylene phalangeal plate is clipped to the core. Short-term and long-term results show the effectiveness of the system [11, 12].The ceramic toe implant made of zirconium oxide can be used for MTP1 joint replacement. The ceramic prosthesis offers less reliable outcomes than the "gold standard" arthrodesis and caution is advised regarding its use for osteoarthritis of the first MTP joint. More studies including larger number of patients with longer follow-up are needed to evaluate the long-term results of the ceramic prosthesis for MPJ replacements [13].

Total arthroplasty of the first MTP joint is associated with resection of a significant amount of bone tissue. With unstable proximal component of the prosthesis, this may necessitate complex osteoplastic surgical interventions aimed at replacing the bone defect of the first metatarsal bone. A high incidence of instability of the distal component of the implant is reported [11]. The complication can occur with hemi-prostheses used at the base of the proximal phalanx of the first toe. A significant injury to the articular cartilage on the metatarsal head can result in a poor outcome with this type of hemi-prosthesis [14].

Hemiarthroplasty of the metatarsal head is another treatment option for hallux rigidus. The treatment is more pathogenetically substantiated with the articular surface of the metatarsal head being degenerative in osteoarthritis of the first metatarsophalangeal joint [15]. Another advantage of articular surface replacement is the ability to perform decompression in the joint due to gradual shortening of the metatarsal head bone which is used in other surgical techniques [16, 17]. HemiCAP is a common implant of this type and is available in several generations. The results with the implant are described in the literature [18].

The aggressive effect of titanium on the opposite articular surface is a disadvantage with the implant. Galambor et al. reported the results of histological studies performed during two revision surgeries after hemiarthroplasty of the main phalanx of the first toe using titanium implants due to instability [19]. The authors reported metallosis which indicated destruction of the implant.

There is also evidence in the literature about pronounced changes in the opposite articular surface due to wear caused by the aggressive effect of the metal implant on the cartilage [14]. We have been performing hemiarthroplasty of the first MTP joint with a ceramic implant since 2021. During this period, more than 40 surgical interventions were performed for patients with stage 3–4 hallux rigidus. An invention patent was received for this technology [2].

Preoperative dynamic pedobarography indicated antalgic gait and aimed at reduction of the ROM including extension in the first MTP joint in the sagittal plane. Restricted extension in the first MTP joint causes an increase in maximum forefoot pressure under the first metatarsal head and the heads of the lesser rays. These changes correspond to a “low-gear” roll, which occurs through the oblique axis connecting the second and fifth metatarsals [20]. According to the author, the roll is more energy-consuming, since the winch mechanism is not activated. Postoperative dynamic pedobarography performed at the time of examination at 24 months show an increase in maximum pressure in the hindfoot and a decrease in this parameter in the forefoot.

Restoration of the foot kinematics during the treatment of advanced hallux rigidus is still an unresolved issue. Cheilectomy is recommended for early disease to restore the natural roll of the foot [21]. The physiological roll of the foot cannot be restore in advanced stages of the disease. The main goal is to reduce resistance in the first metatarsal joint during forefoot roll. In this case, the maximum pressure under the head of the first metatarsal decreases, a relatively high load on the minor rays remains, and the load vector of the foot lateralizes. These changes are observed regardless of the treatment method, are compensated by the body and do not cause discomfort or pain in the postoperative period [22, 23, 24].

A succession of correction of the concomitant forefoot deformity and hemiarthroplasty of the head of the first metatarsal bone is important. In our opinion, the best results can be achieved in stages: anatomical realignment and deformity correction are to be produced first, and the affected articular surface can be replaced as the second step. This is justified by different approaches to postoperative rehabilitation. A protective regime for the forefoot is to be observed in the case of osteotomies. Isolated hemiarthroplasty allows for early ambulation and early exercising. The practice described allows you to achieve the best clinical results.

CONCLUSION

Hemiarthroplasty of the first metatarsophalangeal joint using a ceramic implant of an original design was shown to be an effective and reproducible surgical treatment of patients with stage 3–4 hallux rigidus. The functional results indicated the technique as a good alternative to arthrodesis of the first MTP joint.

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Review article
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Direct lateral interbody fusion with indirect decompression of the spinal roots in patients with degenerative lumbar spinal stenosis

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Abstract

Introduction Degenerative spine conditions involve the gradual loss of normal structure of the spine among the population and remain a common form of work-limiting health condition in 80 % of the population. The demand for surgical interventions will remain high in an aging population to improve quality of life. Lumbar spinal decompression and stabilization are produced using ventral, posterior and lateral approaches. Lateral lumbar interbody fusion (LLIF) is used for treatment of degenerative lumbar stenosis having advantages over surgical interventions from other approaches.

The **objective** was to determine the prospects of LLIF as an independent decompressive and stabilizing surgical intervention using literature data.

Material and methods This article presents generalized information from Russian and foreign publications on LLIF with indirect decompression of the lumbar nerve roots. The original literature search was conducted on key resources including Scientific Electronic Library (www.elibrary.ru), the National Library of Medicine (www.pubmed.org) and Scopus using keywords: direct lateral interbody fusion, indirect decompression of the spinal nerve roots, predictors, lateral lumbar interbody fusion, direct lumbar interbody fusion, extreme lumbar interbody fusion, indirect decompression. The review included 60 articles published between 1998 and 2023 inclusive.

Results and discussion After performing LLIF, some patients experience indirect decompression of the spinal nerve roots to prevent epidural fibrosis, injury to the dura mater and spinal nerve roots. Identifying a model of patients with degenerative spinal stenosis who can undergo LLIF as an independent decompressive-stabilizing surgical intervention without additional instrumentation can improve the effectiveness of surgical treatment.

Conclusion LLIF was shown to be an effective method for indirect decompression of spinal nerve roots at the intervertebral foramina. Indirect decompression of the spinal nerve roots in the spinal canal may fail and the choice of a LLIF candidate (a single surgical intervention) remains open.

Keywords: degenerative spinal stenosis, direct lateral fusion, indirect decompression, predictors of indirect decompression

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INTRODUCTION

Spinal degenerative diseases are associated with morbidity, pain and disability in the population of developed countries affecting 80 % of the working population according to the World Health Organization (WHO). About 266 million individuals (3.63 %) worldwide are diagnosed with lumbar degenerative diseases yearly [1].

The increase in the average age of the population and high requirements for quality of life are cause for development of surgical treatments of patients with degenerative spine diseases [2]. Modern diagnostic equipment, innovative technical solutions in the field of minimally invasive spine surgery, anesthesia options facilitate surgical care to patients for whom spinal surgery was previously unavailable due to high risks of complications [3]. Reducing the morbidity of surgical interventions is essential for surgical communities [4].

Decompressive minimally invasive interventions with preservation of the supporting spinal structures are less traumatic in comparison with decompressive-stabilizing operations, and some cases require fixation of the spinal motion segment. Decompressive and stabilizing surgical interventions can be performed using ventral (ALIF\OLIF), posterior (PLIF\TLIF) and lateral (LLIF) approaches. Each of the accesses can be performed using MIS technology. With LLIF, some complications encountered with PLIF\TLIF and OLIF\ALIF can be eliminated, and LLIF can be considered a minimally invasive standalone decompressive-stabilizing surgical intervention if indirect decompression can be produced in some cohorts of patients with interbody implant placed and no need for additional fixation of the SMS. The objective was to determine, based on literature data, the prospects for performing LLIF as an independent decompressive and stabilizing surgical intervention.

The **objective** was to determine the prospects of LLIF as a standalone decompressive and stabilizing surgical intervention using literature data.

MATERIAL AND METHODS

The article presents generalized information from Russian and foreign publications on direct lateral spinal fusion with indirect decompression of the spinal cord roots in the lumbar spine, the history of the development of the method, its capabilities in the treatment of patients with degenerative spinal diseases, and differences from other approaches to the lumbar spine.

The original literature search was conducted on key resources including Scientific Electronic Library (www.elibrary.ru), the National Library of Medicine (www.pubmed.org) and Scopus using keywords and phrases: direct lateral spinal fusion (direct lumbar interbody fusion, lateral lumbar interbody fusion, extreme lumbar interbody fusion), indirect spinal decompression, predictors of indirect decompression. The review included 60 articles published between 1998 and 2023 inclusive.

Inclusion criteria:

— full-text scientific articles, abstracts of scientific conferences and dissertations reporting surgical treatments of patients with degenerative spinal stenosis;

— full-text scientific papers on direct lateral fusion and its capabilities in achieving indirect decompression of the spinal cord roots, comparison of direct lateral fusion with other methods of fusion;

— full-text scientific papers reporting the nature and rate of complications after LLIF including comparison with other methods of spinal fusion.

Exclusion criteria included scientific articles that had no information on the treatment of patients with degenerative spinal diseases. Overall, 60 scientific papers were selected for the literature review, of which 6 (10 %) reported by Russian authors and 54 (90 %) by foreign contributors.

RESULTS AND DISCUSSION

Degenerative spinal stenosis

Degenerative spinal stenosis is associated with progressive pathological changes in the spine leading to a decrease in reserve spaces for neurovascular formations in the spinal canal and intervertebral foramina, and can cause compression of the spinal cord root with neurogenic intermittent claudication and/or radicular syndrome [5]. Pathomorphological substrates for compression of the spinal cord roots include hypertrophied facet joints, hypertrophied ligamentum flavum, osteophytes and intracanal synovial cysts of the facet joints. Degenerative spinal stenosis can be localized to the spinal canal, lateral recesses and intervertebral foramina.

Surgical treatment of degenerative spinal stenosis

Degenerative diseases account for 59.9–71.4 % of surgical interventions in spine surgery [6]. Decompressive, decompressive-stabilizing, decompressive-corrective and decompressive-plastic surgical interventions are used to treat patients with degenerative spinal stenosis using open surgical techniques and minimally invasive procedures. Today, the surgeon has the opportunity to perform surgical interventions on the lumbar spine using different approaches: LLIF, ALIF, OLIF, PLIF, TLIF. Technical solutions in the field of surgical visualization and power equipment allow maximum preservation of the supporting structures of the spine during decompression of the spinal cord roots and can eliminate the need for spinal fusion in some cases [4].

There is a group of patients with unstable spinal motion segment of the spine who require spinal fusion, and decompression of the spinal cord roots if combined with degenerative spinal stenosis. Indirect decompression of the spinal cord roots may occur if spinal fusion is produced using ventral approaches for the patients especially in cases of the dynamic compression [7]. The surgical interventions are minimally invasive and can ensure long-term preservation of treatment results.

There are no strict standards in fixation of the spinal motion segment, surgical access and decompression of the spinal cord roots and the selection of the surgical method would depend on the decision of the surgeon [8].

Direct lateral fusion

In 2006, Ozgur et al. reported a spinal fusion technique with an access to the intervertebral discs of the lumbar spine without endoscopic equipment and posterior traction of the psoas [9]. The method was a modernized retroperitoneal approach to the lumbar spine anterior to the psoas, described by McAfee et al. in 1998, and access through the psoas with use of endoscopic equipment reported by Pimenta in 2001 [10, 11]. Direct lateral spinal fusion is termed in modern literature as LLIF (lateral lumbar interbody fusion), DLIF (direct lumbar interbody fusion), XLIF\ELIF (extreme lateral lumbar interbody fusion). Direct lateral spinal fusion is more common, and there is an increase in scientific publications on the topic over time [12]. Direct lateral fusion is normally performed at the levels L2–L3, L3–L4 and occasionally at L1–L2, L4–L5 levels. The L4–L5 segment may be inaccessible due to the high position of the iliac crests, and the lower ribs may make access to the L1–L2 intervertebral disc difficult.

Such complications as retrograde ejaculation, injury to major vessels, ureter, peritoneum, intestines, venous or arterial thromboembolism are not common with LLIF compared to ALIF\OLIF,

and the preserved anterior and posterior longitudinal ligaments do not allow the implant to migrate anteriorly and posteriorly [13, 14, 15].

LLIF can be the most practical surgical intervention for patients with excess body weight, does not increase the risk of complications with direct lateral fusion [16] and allows easier performance. Previous surgical interventions in the lumbar spine with use of ventral or posterior approaches faclitate LLIF for treatment at the adjacent level [17, 18] to avoid scars and a long transpedicular system [19]. Indirect decompression of the spinal cord roots helps to avoid microsurgical decompression of the spinal cord roots providing shorter operation time and reducing the risk of injury to the dura mater and spinal cord roots. The advantages of ventral approaches include the parameters of interbody implants with a larger supporting surface area than implants for PLIF\TLIF [20]. Implants for LLIF are wider than those used for OLIF\ALIF with the cortical edges of the vertebral endplates being most resistant to subsidence of interbody implants [21–24], thereby the risk of implant subsidence in LLIF is not greater without additional transpedicular fixation [25, 26].

Indirect decompression

Indirect decompression of the spinal cord roots with spinal fusions produced using ventral approaches is often described in the scientific literature. Indirect decompression can be interpreted as a clinical result in the form of regression of compression syndromes of the spinal cord roots after surgery, and secondarily as an increased size of the intervertebral foramina, lateral recess or spinal canal seen with neuroimaging. Indirect decompression of the spinal cord roots in the intervertebral foramina after ventral spinal fusion is reported [9, 10, 11, 19, 27, 28], and indirect decompression of the spinal cord roots in the spinal canal is less predictable, with severe stenosis, in particular.

An increased size of the intervertebral foramina can be identified with intraoperative radiographs. An increased reserve space for the spinal roots is difficult to visualize intraoperatively in case of degenerative spinal canal stenosis and a successful LLIF as a decompression surgical intervention can be identified with ambulation. LLIF as the only surgical intervention can be unreliable for decompression of the spinal roots in the spinal canal and stabilization of SMS. LLIF is commonly used as the first stage of surgery to stabilize and/or correct the spinal balance. The second stage involves microsurgical decompression of the spinal cord roots and transpedicular fixation of the SMS. Neurosurgeons are interested in indirect decompression of the spinal cord roots with the effect being similar to microsurgical decompression with no contact with the dura mater during repeated surgical intervetions [29].

The mechanism of indirect decompression of the spinal cord roots relies on the restored height of the intervertebral disc, increasing the height of the intervertebral foramina and stretching the posterior longitudinal and flaval ligaments [30–41]. An increased reserve space for the spinal cord roots in the spinal canal can be observed at two years of LLIF due to hypotrophied ligamentum flavum and rigid fixation of the SMS [42–44].

Maximum preservation of the anatomical integrity of the SMS with LLIF, in comparison with ALIF\OLIF, preservation of the anterior and posterior longitudinal ligaments, a greater portion of the fibrous ring contribute to the stability of the segment creating conditions to avoid anterior and posterior migration of the cage [45]. This is the main reason for strict selection of patients for indirect decompression of the spinal cord roots in the spinal canal after LLIF in comparison with ALIF\OLIF, because the limited possibility of a higher interbody implantation can lead to an insufficient increase in the volume of the spinal canal.

With possibilities of indirect decompression of the spinal cord roots in the spinal canal it should be noted that Schizas grade D spinal canal stenosis has less potential for indirect decompression with direct lateral spinal fusion, however, there are results of surgical interventions with no need of direct decompression [46] reducing the volume of surgical intervention.

Modern scientific publications focus on indirect decompression of the spinal cord roots in the intervertebral foramina [12, 47, 48]. Studies that focus on indirect decompression of the spinal cord roots in the spinal canal and identification of the predictors have low reliability [49, 50, 51]. Other series do not report a particular group of patients with degenerative spinal stenosis and the effectiveness of indirect decompression of the spinal cord roots [52–54]. There are publications reporting patients with Schizas grade C and D spinal stenosis being excluded from the study [55]. There are publications reporting the effectiveness of indirect decompression using different surgical approaches (LLIF, OLIF, ALIF) [29]. It is difficult to identify a model of a patient with degenerative spinal stenosis in whom clinically effective indirect decompression can be predicted after LLIF.

Patients with Roussouly type 3 sagittal profile of the spine can be treated with indirect decompression [56], and spinal canal stenosis caused by ossified posterior longitudinal and flaval ligaments cannot be treated with LLIF for the purpose of indirect decompression of the spinal cord roots [45].

Indirect decompression of the spinal cord roots using ALIF and OLIF can be predicted in most cases preoperatively due to the knowledge of the capabilities with the methods. If direct decompression is necessary, the approaches allow microsurgical decompression of the spinal cord roots through the interbody space after total discectomy, and the surgical procedure can be produced in one stage.

Indirect decompression failure (IDF) after lateral lumbar interbody fusion is reported as absence of indirect decompression scheduled preoperatively, mainly in the spinal canal after direct lateral interbody fusion [57]. This outcome of surgical intervention results from insufficient knowledge of indirect decompression of the spinal cord roots in the spinal canal performing direct lateral spinal fusion.

MIS LLIF allows for indirect decompression of the spinal cord roots at the intervertebral foramina being equivalent to MIS TLIF and ALIF [46]. In the absence of a bone fusion with the involved SMS, there is a high probability of increased disc height due to interbody implantation, which leads to an increase in the height and area of the intervertebral foramina on both sides, regardless of the side for the surgical approach [45]. The effectiveness of indirect decompression of the spinal cord roots in the intervertebral foramina after LLIF does not depend on the position of the interbody implant, whereas the likelihood of indirect decompression of the spinal cord roots is higher in the spinal canal with the dorsal position of the implant [46]. This is a complicating factor in planning indirect decompression of the spinal cord roots in the spinal canal with correction of the sagittal balance with the sagittal profile, position of the interbody implant to be restored in the anterior third of the interbody space. Subsidence of the interbody implant has a lesser effect on the loss of indirect decompression in the intervertebral foramina than in the spinal canal [12].

With the formation of severe spinal canal stenosis, compensatory capabilities allow many patients manage without medical help for a long time due to the absence of clinical manifestations of the disease [58]. Indirect decompression of the spinal cord roots with a slight increase in the volume of the spinal canal at the level of degenerative stenosis evidenced with neuroimaging can be effective in relief of clinical manifestations of compression of the spinal cord roots.

Complications associated with LLIF

Iatrogenic lumbar plexus injury is a common complication early postop after LLIF [59]. The manifestations include weakness of the hip flexors in 24 % of cases, decreased sensitivity along the anterior surface of the femur in 38 % and paresis of the abdominal muscles in 1.8 %. Other complications associated with LLIF include vascular injury (0.1 %), intestinal injury (0.08 %) and interbody implant subsidence (14 %) [60].

Common events associated with surgical access through the psoas include weakness of the psoas, pain or decreased sensitivity along the anterior femur resulting from the surgical approach that can be resolved within two weeks to one year with conservative treatment [12].

Treatment of degenerative spinal stenosis and stabilization of the SMS can be produced with LLIF and indirect decompression of the spinal roots and transcutaneous transpedicular fixation (or without it) in some cases.

Confidence is required for LLIF as the only decompressive-stabilizing surgical procedure bringing an effect in relieving spinal root compression in the spinal canal. Predictors of indirect decompression of the spinal cord roots in the spinal canal with degenerative stenosis are to be identified for LLIF. Patients with Schizas grade D spinal stenosis cannot be excluded from studies in search for predictors of indirect decompression and the ability of LLIF to achieve it. A slight increase in the volume of the spinal canal will be sufficient to relieve clinical manifestations of compression of the spinal cord roots.

With rigid fixation of the SMS, the thickness of the hypertrophied ligamentum flavum decreases. Therefore, LLIF can be considered as the only decompressive-stabilizing surgical intervention with indirect decompression of the spinal cord roots and volume of the spinal canal can be followed up using MRI and MSCT of the lumbar spine.

The approach can improve the effectiveness of surgical treatment of patients with degenerative spinal stenosis in the lumbar spine, and more often use the LLIF can be employed as the only decompressive-stabilizing minimally invasive surgical intervention for particular cohort of patients to reduce surgical stages of treatment, operation time, blood loss and the morbidity with overall surgical treatment.

CONCLUSION

LLIF is a method of surgical intervention on the lumbar spine, which appeared as an effective minimally invasive surgical intervention for stabilization, correction of deformity in the SMS providing indirect decompression of the spinal roots in the intervertebral foramina.

Direct lateral fusion is not commonly used as the only surgical intervention on the SMS for decompression and stabilization due to little knowledge in indirect decompression of the spinal roots in the spinal canal with degenerative stenosis.

Identification of predictors of indirect decompression of the spinal cord roots in the spinal canal will improve the efficiency of surgical treatment of patients using the LLIF.

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Stenosing tenosynovitis

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Abstract

Introduction Stenosing tenosynovitis or trigger finger is a common cause of hand disability. With the 174-year history of the condition, treatment strategy and new minimally invasive surgical approaches are essential for researchers around the world.

The **objective** was to determine the current treatment options of the stenosing tenosynovitis using the Russian and foreign literature.

Material and methods The original literature search was conducted on key resources including Scientific Electronic Library (www.elibrary.ru), the National Library of Medicine (www.pubmed.org) and MedLine. Seventy contributions were identified published for the last 10 years.

Results and discussion Treatment of stenosing ligamentitis can be initiated depending on the stage of the disease, the duration, relapses or complications, comorbidities. Conservative orthopaedic treatment includes joint immobilization and/or corticosteroid injections. Although percutaneous dissection of the annular ligament is minimally invasive and has advantages of less tissue trauma, shorter recovery time, absence of painful scars open ligamentotomy can help to minimize complications and relapses of the disease.

Conclusion Conservative treatment of trigger finger is effective in 47 to 93 % and surgical procedures are practical in 94–99 %. Surgical treatment can be employed with failure of conservative treatment and has been shown to be effective and with a low rate of complications and relapses.

Keywords: stenosing tenosynovitis, Nott's disease, annular ligament

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INTRODUCTION

Stenosing ligamentitis (SL) (“snapping finger”, Knott’s disease) is a common disease of the fingers, which is caused by injury to the tendon-ligamentous apparatus leading to impaired motor function [1]. Snapping finger can be described as the sensation or sound of crackling within the affected finger during movement [2]. The disease was first described by the French surgeon Alfred Nott in 1850 [2, 3] and is characterized by a typical “snapping” of the finger or fingers at maximum flexion, limited movements, pain at the base of the fingers when pressing, and morning stiffness of movements in the hand [4]. SL can lead to an impaired hand function and grip strength. As the disease progresses, the patient's quality of life may change [5, 6].

The **objective** was to determine the current treatment options of the stenosing tenosynovitis using the Russian and foreign literature.

MATERIAL AND METHODS

The original literature search was conducted on key resources including Scientific Electronic Library (www.elibrary.ru), the National Library of Medicine (www.pubmed.org) and MedLine using keywords in Russian and in English: stenosing ligamentitis, incidence of pathology, conservative therapy, operative treatment, long-term results, complications.

Inclusion criteria:

— full-text scientific articles reporting fundamental information about stenosing ligamentitis (etiology, pathomorphology, classification);

— full-text scientific publications containing modern information on treatment methods (conservative and surgical) of SL;

— full-text scientific articles reporting the results of multicenter cohort studies, specific clinical examples of the treatment of SL, complications and long-term results of therapy.

Exclusion criteria included abstracts of scientific conferences, articles without a full-text version, publications that did not fully meet the inclusion criteria.

Seventy contributions including 59 foreign and 11 Russian publications brought out for the last 10 years were identified.

RESULTS

Etiology of the disease Several causes of trigger finger have been described in the literature, although the exact etiology has not been identified. Possible causes include repetitive, monotonous finger movements and local trauma [7]. There are associations between trigger finger and an occupation that requires prolonged grasping and bending of the arm, such as the use of scissors or hand tools [7–10]. Knott's disease can be caused by deforming arthrosis of the finger joints, tenosynovitis of the flexor tendons and other inflammatory diseases of the hand [11]. SL can develop with systemic diseases: diabetes mellitus, gout or rheumatoid arthritis [12]. The condition can be caused by monotonous hand movements (typing on a keyboard, driving a car); regular, intense stress on the fingers; inflammatory process localized in the hand; injuries and damages; hereditary predisposition; atherosclerosis; thyroid diseases; constant compression of the ligaments; physical labor associated with a load on the hands [13, 14]. Although the natural history of SL is not fully understood, McKee et al. reported 52 % of patients symptom free at 8 months in a cohort of 348 cases without any treatment [15]. According to statistics, SL occurs in 2–3 % of the population, being common in females aged 40 and older [16]. The condition often occurs in children [17]. SL primarily affects the ring (44 %) and the thumb (26 %) fingers; middle finger is involved in 20 %; little finger, in 7 %; index finger, in 3 % of cases [18].

Pathomorphology In SL, inflammation and hypertrophy of the annular ligament result in gradual restriction of the flexor excursion [19, 20]. The biomechanical basis for the effective functioning of the hand tendons is provided by a system consisting of annular and cruciform pulleys in each finger, which serve to maximize the force produced by the flexor tendon and the efficiency of movement (Fig. 1) [19].

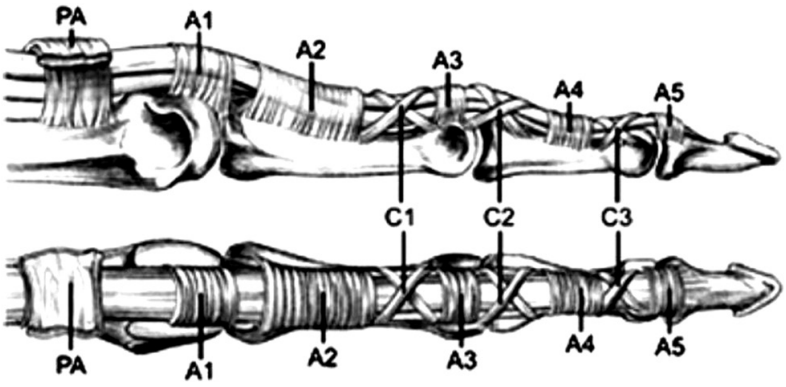

Fig. 1 Diagram of the osteofibrous canal showing (A) ring-shaped pulleys (A1–A5); (C) cruciform pulleys (C1–C3); (PA) palmar aponeurosis

The first annular trochlea (A1) on the metacarpal head is the commonly affected trochlea in LS, and cases have been reported in the second and third annular trochleas (A2 and A3), as well as in the palmar aponeurosis [19]. Due to the location, the A1 pulley is exposed to the highest forces and pressure gradients during normal and power grips. Knott's disease is characterized by thickening of the tendon sheath and A1 ligament, nodules on the tendon and narrowed lumen leading to disruption of the connection between the tendon and its sheath at the level of the metacarpal head.

Classification There are four degrees of severity of SL as graded by Green [11] (Table 1)

Table 1

SL graded by D.P. Green

Stage		Clinical manifestations
I (initial)		Patient-reported pain, pinching, tenderness over A1 pulley
II (active)		Fixation during finger extension on physical examination
III (passive)	III A	Correcting pinched fingers using passive finger extension
	III B	Loss of active flexion
IV (contracture)		Pinching with fixed flexion contracture of the proximal interphalangeal joint

Patients may experience painless clicking or stiffness of the affected finger in the early stages of the disease (stage I) [21]. As the disease progresses, painful pinching or locking of the finger occurs and may require passive extension of the unaffected hand (stage II). On examination, the joints of the affected finger are not swollen or erythematous, despite complaints of pain. With snap finger, a thick and painful A1 pulley can be palpated distal to the transverse palmar crease, which distinguishes it from other hand diseases (rheumatoid arthritis, gout, etc.). The presence of the “painful nodule” and absence of previous trauma confirm the suspicion of stage III SL. Patients with advanced stage of the disease (grade IV) deliberately try to avoid active use of the finger, which leads to the development of a fixed contracture of the proximal interphalangeal joint [21].

Treatment of stenosing ligamentitis The most effective treatment for Knott’s disease is still a matter of debate [23, 24, 25, 26]. A variety of techniques can be used in medical practice depending on the grade of the condition and conservative therapy is applied first [27].

Conservative treatment SL can be primarily treated with non-steroidal anti-inflammatory drugs for pain relief, immobilization of the metacarpophalangeal joint, corticosteroid injections, physical therapy and massage [25, 28, 29].

Immobilization of the metacarpophalangeal joint Splinting is aimed at preventing friction caused by the flexor tendon moving through the affected A1 pulley until the inflammation is controlled [29]. Splinting is a suitable treatment option for patients who refuse corticosteroid injections [30]. The method is less effective in patients with severe triggers or long duration of symptoms. In this case, a variety of tires can be used including custom-made ring tires, tires made of thermoplastic, metal, or ready-made tires (Fig. 2) [29].

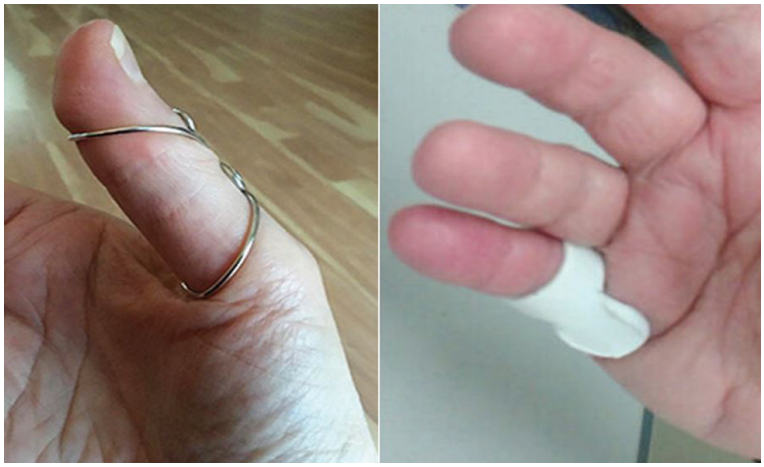

Fig. 2 Options for splinting fingers [29]

The finger should be splinted for 6 weeks or longer if inflammation persists. Lunsford et al. recommended immobilization of the joint for 6–10 weeks, with treatment success rates ranging between 47 % and 93 % [27]. As pain and inflammation decrease, the patient can self-splint at night and gradually resume normal hand activities [29]. Some patients may require up to 6 months. Based on the European HANDGUIDE study, it was concluded that there is no optimal orthopedic regimen, and the duration of treatment should be individualized depending on the duration of symptoms, severity and preference of each patient [22].

Corticosteroid injections Treatment of trigger finger by steroid injection was described as early as 1953 by Howard [30]. Some authors reported high effectiveness (up to 93 %) in the initial stages of SL in the absence of concomitant endocrinological diseases, with the disease lasting less than 6 months and one affected finger [31, 32, 33, 34]. Many researchers emphasize that the Knott's disease lasting more than 6 months is associated with chondroid metaplasia of the A1 ligament and conservative therapy cannot be effective [32, 33]. The available literature shows the effectiveness of the therapy ranging between 49 % and 93 % after the first injection [32, 34]. Castellanos et al. reported the long-term effectiveness of corticosteroid therapy at 69 % (follow-up duration was 8 years, 71 patients were included in the study) [35].

The injection is traditionally given directly into the sheath [36]. There are reports of effective extrasynovial injection reducing the risk of tendon injury (Fig. 3) [29].

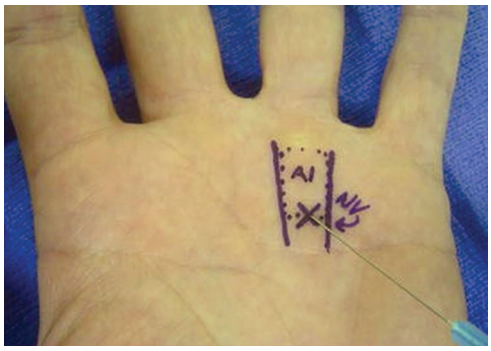

Fig. 3 Steroids injected in the A1 pulley; NV of the neurovascular bundle

Polat et al. reported effective corticosteroid therapy in 43 patients; injections were ultrasound guided [37]. The authors reported the high effectiveness of glucocorticosteroid injections combined with joint immobilization. Shultz et al. reported a prospective study of 99 trigger finger cases and patients with multiple involved fingers were 5.8 times more likely to have no resolution of symptoms compared with those with a single affected finger [38].

Physical therapy and massage include:

— ultrasound effect on the inflamed tendon and vagina to reduce inflammation and scar adhesions;

— friction massage of tendons to address adhesions, nodules and swelling;

— passive range of motion in the metacarpal and interphalangeal joints;

— passive internal and external stretching of the hand and wrist [29].

Ferrara et al. recommended the use of external shock wave therapy (ESWT) with a frequency of 15 Hz and a flow density of 0.1 to 3 bar [39]. ESWT was an effective and safe therapy for the conservative treatment of SL: it seemed to reduce pain and trigger severity and to improve functional level and quality of life.it significantly relieves pain, improves the functional level and quality of life.

Surgical treatment With ineffective conservative treatment and blockades, late stages of the disease, surgical intervention with dissection of the A1 annular ligament at the base of the finger can be recommended [40–43].

The Knott's disease can be surgically treated with:

1) open procedure using a small skin incision, suturing and subsequent dressings (under local anesthesia, the orthopedic surgeon cuts the A1 annular ligament, which limits the movement of the tendon) [44, 45];
2) a minimally invasive method using small skin punctures with a needle, without sutures or bandages [46, 47].

Open surgery is the "gold standard" for the treatment of SL as it allows for a more thorough examination of the surgical site, is highly effective (effectiveness approaches 100 %) and has a low complication rate [48]. There are many techniques for open surgical treatment of SL [49, 50, 51].

Kosiyatrakul and Luenam reported the following surgical technique [52]. The patient's hand is placed in the supinator position, the thumb is positioned in the radial abduction. The incision line is planned before local anesthesia is injected. The radial groove is located between the A1 pulley and the radial sesamoid bone. The flexor pollicis longus and proximal phalanx of the thumb are identified by palpation and marked with a marker (Fig. 4). The skin is infiltrated with 3–4 ml of 1 % lidocaine without epinephrine and a tourniquet is placed around the shoulder. A skin incision is made along the intended line. With incision in the deep dermal layer of the skin, gentle blunt dissection is used to identify the radial digital nerve in the subcutaneous layer. The A1 ligament is cut with a scalpel along its radial edge (Fig. 5). The skin is sutured with 4–0 nylon stitches.

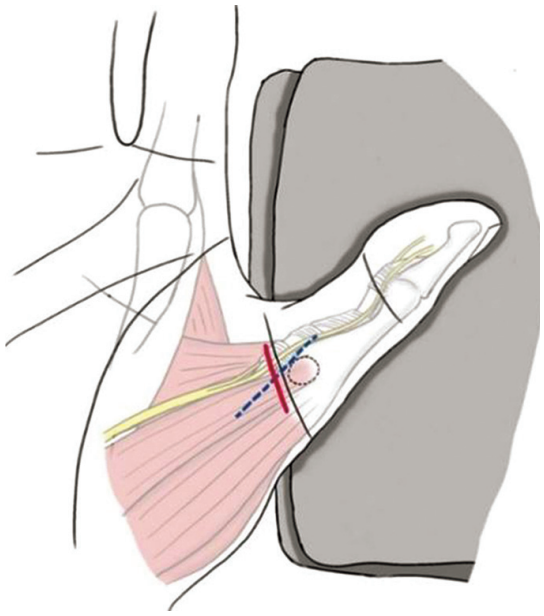

Fig. 4 Illustration of the skin incision (red line), radial sulcus (dashed blue line), and radial sesamoid (dashed black line) [52]

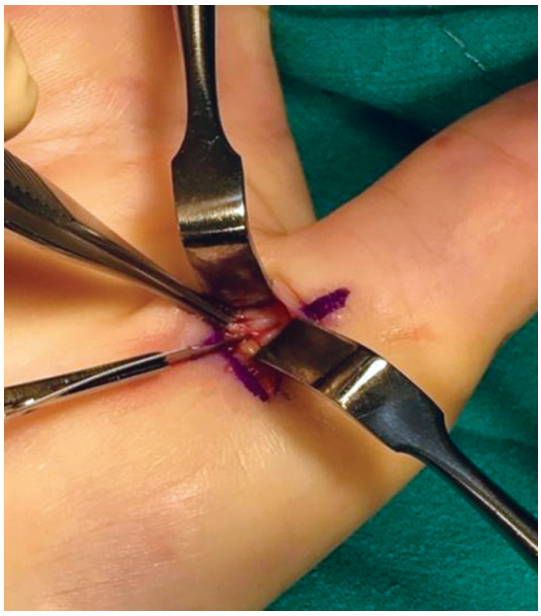

Fig. 5 Dissection of the A1 pulley of the thumb along the radial edge [52]

Open intervention on the A1 pulley can be associated with minor and major complications [53, 54]. Minor complications (pain at the scar, at the A1 pulley and a slight lag in extension) do not require surgical treatment. Major complications cause significant hand dysfunction including persistent or recurrent triggering, flexor tendon strain, and digital nerve injury [55].

The radial digital nerve is the most vulnerable structure during release of the A1 pulley of the thumb [56]. The nerve can be damaged if the skin incision is too deep. Anatomical studies have shown that the nerve is located at a depth of 1.29–2.19 mm in the skin. Once the deepest dermal layer of skin has been incised, careful blunt dissection should be performed to identify and protect the radial digital nerve [56].

Koopman et al. performed a retrospective study of 3428 patients who underwent open surgery for trigger finger and reported that 16 % of patients experienced complications and 2 % required surgical treatment [57].

Federer et al. reported a significantly higher complication rate (26.3 % vs. 13.0 %) in patients with diabetes compared with patients without diabetes, which was associated with a significantly higher rate of limited postoperative range of motion in patients with endocrinological pathology [58].

Percutaneous annular ligament intervention is widely covered in the literature, with success rates approaching 95 % [59, 60]. Percutaneous release of the A1 pulley was first performed in 1958 by Lorthioir [61]. Eastwood et al. called it an outpatient procedure back in 1992, showing 94 % success rate [62]. With this intervention, the metacarpophalangeal joint is hyperextended with the palm facing upward, thereby stretching the A1 pulley and displacing the neurovascular structures dorsally. After injection of lidocaine to relieve pain, the needle is inserted through the skin into the A1 pulley. It is then moved to cut the pulley proximal and distal to the injection site [60].

Zhigalo et al. developed a new minimally invasive method for subcutaneous dissection of the A1 ligament using special small-diameter needles (0.6–1.2 mm) [63, 64]. The technique was applied for 215 patients, excellent to good results were obtained in most cases (70 % and 20.3 %, respectively); fair outcomes were seen in 7.5 % and poor results with recurrence were observed in 2.2 % of cases [63].

Chinese researchers Pan et al. reported the effectiveness of ultrasound-guided percutaneous release of A1 pulley by using a needle knife in 21 patients [65], obtaining an effect with a single intervention.

Xie et al. randomized 76 patients to open or percutaneous surgery and found no difference in finger range of motion or symptom recurrence [60]. However, some authors reported an increased risk of incomplete release, scarring, nerve damage, and recurrence [66]. Aksoy and Sir suggested that percutaneous decompression is an intervention performed blindly, and can be associated with a damage to the digital nerve (hypoesthesia), recurrence, painful scar and tendon rupture [66].

Despite the high effectiveness of surgical treatment of SL, which has been identified by many authors, there are publications reporting persistent pain syndrome in long-term studies of patients. Thus, Langer et al. reported moderate or severe pain in 37 % of cases at one year of the intervention [67].

However, not only surgical intervention is fraught with consequences. Oh et al. reported an unusual case of flexor digitorum profundus rupture after a single corticosteroid injection in a 57-year-old male golfer [68]. There were other reports of similar complications [69, 70].

DISCUSSION

Stenosing ligamentitis is a common cause of hand disability and is often encountered in practice of experts; however, the choice of the optimal treatment is still a matter of debate. Conservative

treatment is indicated for grades I–III of the disease. Corticosteroid injections can reduce the thickness of the A1 pulley and are considered first-line therapy. However, many authors report low effectiveness of hormonal therapy (43–57 %) [16, 19, 27, 28, 30, 34, 38]. Corticosteroid injections should be offered to all patients before surgery, regardless of comorbidities [12, 41]. Individual orthopedic splints can reduce pain, but require long-term immobilization of the joint. Success rates with orthosis range from 50 % to 93 %, with less than 50 % success rates for the thumb involvement [22, 29]. However, literature review including randomized cohort studies shows a lack of convincing evidence of high-level effectiveness [4, 14, 15].

Most authors report the preferred surgical treatment [6, 26, 40, 41, 43, 60, 66]. Surgical treatment of SL should not be performed within three months after corticosteroid injection [19, 27]. According to many researchers, effectiveness rates are comparable with open treatment and percutaneous release [24, 27, 42, 52, 57, 60]. The percutaneous release is considered a less invasive procedure, but there is a risk of iatrogenic damage to the radial digital nerve [36, 46, 61, 62, 63]. Although the open procedure is the preferred option according to many authors, it is associated with a risk of infection at a short term and the formation of scar tissue, however, it has higher success rates reported in retrospective long-term studies [1, 45, 52, 53]. In addition to that, the method allows surgeons to identify a rare case of atraumatic rupture of the deep digital flexor tendon [27].

We believe that treatment for Knott's disease should be tailored. Each treatment option has its own benefits, risks, and limitations. These issues should be discussed with the patient before making an informed decision. We agree that treatment should begin with conservative methods for grades I–III SL. Surgical methods have higher success rates, but should be used after failed conservative therapy, for recurrent condition and stage IV of the disease (Fig. 6).

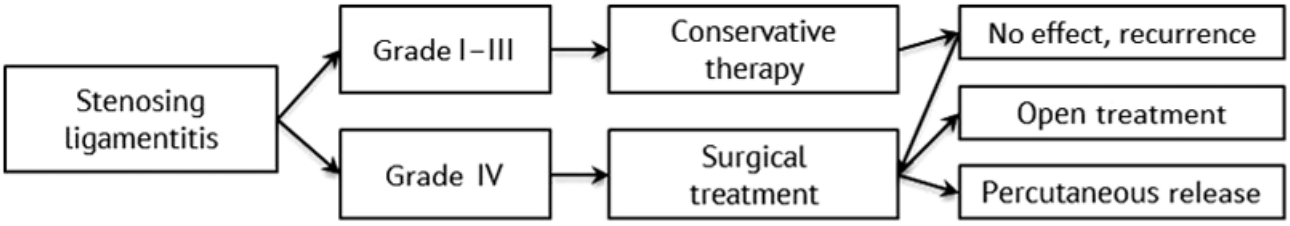

Fig. 6 Treatment algorithm for stenosing ligamentitis

Further study of the etiology, pathogenesis and pathomorphology of LS will help develop new methods of therapy. New minimally invasive methods are essential for treatment of Knott's disease.

CONCLUSION

Analysis of current literature has shown that most cases of trigger finger can be effectively managed without surgery with conservative measures with corticosteroid injections and/or orthopedic immobilization of the metacarpophalangeal or proximal interphalangeal joint.

Open surgery or percutaneous release are indicated for relapse after or failed conservative treatment or initially in cases lasting > 6 months. Open trigger finger release is an elective surgical procedure that serves as the gold standard treatment for trigger digits and is associated with minimal complications.

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Shlykov Igor Leonidovich (60th birthday anniversary)

Igor Leonidovich Shlykov, Director of the Ural Chaklin Institute of Traumatology and Orthopaedics, Chief Specialist in Trauma- and Orthopaedics of the Ministry of Health of the Sverdlovsk Region, Doctor of Medical Sciences, Honored Doctor of the Russian Federation, Excellence Healthcare Worker of the Russian Federation, celebrated his 60th birthday on August 14, 2024.

Igor Leonidovich graduated from the medical faculty of the Sverdlovsk State Medical Institute in 1987, and was assigned to the Ural Research Institute of Traumatology and Orthopaedics, where he worked his way up from a junior to a senior researcher.

In 2004, Igor Leonidovich successfully defended his candidate of medical sciences dissertation "Surgical treatment of patients with consequences of pelvic ring injuries". In 2005 he was appointed head of a trauma department. He was the first to organize a trauma department at the Regional Psychoneurological Hospital for War Veterans, which became one of the largest in the Sverdlovsk Region.

In 2008, Igor Leonidovich was appointed director of the Ural Research Institute of Traumatology and Orthopaedics.

In 2010, he defended his doctor of medical sciences dissertation entitled "System of diagnostic measures and complex treatment of patients with pelvic bone fractures".

For his significant contribution to the development of methods for surgical treatment of the pelvis, Igor Leonidovich became a laureate of the High Medical Technologies Foundation (Kurgan) for a series of works entitled "Improving technologies of transosseous osteosynthesis for pelvic injuries and their consequences" in 2010.

With the participation of I.L. Shlykov, new methods of diagnosis and treatment were developed, new devices for surgical interventions in orthopaedic and trauma patients were proposed; high-tech minimally invasive technologies of intramedullary osteosynthesis for fractures of upper and lower extremity bones, pseudoarthrosis, bone deformities, periprosthetic fractures were developed; serial production of intramedullary nails for osteosynthesis of the femur and tibia was organized. Under his leadership, changes in the hemostasis system, optimal medication regimes of blood loss reduction and correction of anemia in arthroplasty of large joints were studied; fundamental research was conducted on the use of hyperbaric oxygenation modes in immobilization osteoporosis, as well as on the creation of bioimplants based on porous nanocoated titanium, which have passed preclinical trials and are ready for registration in the Register of Medical Devices.

To implement new medical technologies and developments, scientific and practical conferences, master classes, demonstration operations, seminars, congresses of trauma- and orthopaedic surgeons of the Urals Federal District were held with the direct participation of Igor Leonidovich. The achievements of the Institute are regularly presented at specialized medical exhibitions.

On the initiative of I.L. Shlykov, the journal *Vestnik of Traumatology and Orthopaedics named after V.D. Chaklin* (2009) was launched, and the Chaklin Readings were organized. Since 2008, I.L. Shlykov is chief traumatologist of the Ministry of Health of the Sverdlovsk Region.

With his participation, the work to improve the organization of providing care to the injured, standards for providing care, national clinical recommendations, and hospitalization algorithms are being developed; assessment parameters are analyzed; methodological basis for the establishment of inter-municipal trauma centers and the preparation of instructional materials has been provided.

Igor Leonidovich is a member of the editorial board of the journal *Traumatology and Orthopaedics of Russia*; he is the author of 12 monographs, 250 scientific papers, and has received 35 patents for inventions.

In 2022, I.L. Shlykov was awarded the title of Honored Doctor of the Russian Federation.

He was also awarded with the Letter of Appreciation from the President of the Russian Federation, the Excellence Healthcare Worker badge, the Certificates of Honor of the Legislative Assembly of the Sverdlovsk Region, the Ministry of Health of the Sverdlovsk Region, the Main Directorate of Internal Affairs of the Sverdlovsk Region, the Head of the Administration of the Leninsky District of Yekaterinburg, and letters of acknowledgment from various ministries and departments. For his significant contribution to the development of traumatology and orthopaedics in the Sverdlovsk Region and the city of Yekaterinburg, he was awarded the V.N. Tatishchev and G.V. De Gennin Prize, and the Certificate of Honor of the Healthcare Committee of the State Duma of the Federal Assembly of the Russian Federation.

The staff of the Ural Research Institute of Traumatology and Orthopaedics and the editorial board of the journal Genij Ortopedii sincerely wish the jubilee further creative success, health and prosperity.

Kutepov Sergey Mikhailovich (75th birthday anniversary)

On October 21, 2024, the **outstanding orthopaedic surgeon of the Ural School of Trauma- and Orthopaedic Surgeons, Sergey Mikhailovich Kutepov**, Corresponding Member of the Russian Academy of Sciences, Honored Doctor of the Russian Federation, Doctor of Medical Sciences, Professor, member of the editorial board of the journal "Genij Ortopedii", **turned 75 years old**.

Sergey Mikhailovich was born on October 21, 1949 in Donetsk. In 1973, he graduated from the Sverdlovsk State Medical Institute, specializing in "General Medicine". From 1973 to 1982, he was a clinical resident and assistant at the Department of Hospital Surgery, Faculty of Medicine of Sverdlovsk Medical Institute. In 1982, he defended his PhD thesis on "The Use of Thoracoscopy in Some Types of Chest Trauma". From 1982 to 1986, he worked as chief doctor at City Trauma Hospital No. 36.

Later, for 15 years, he headed the Ural Chaklin Research Institute of Traumatology and Orthopaedics, and was the scientific director of the emergency trauma clinic of this institute. During 15 years of work, under the guidance of Sergey Mikhailovich Kutepov, 8 doctoral and 20 candidate dissertations were defended, 82 patents were obtained, and more than 50 methodological recommendations and manuals for doctors were published.

Main scientific achievements of Prof. S.M. Kutepov:

- An apparatus for osteosynthesis of pelvic bone fractures was developed.
- A compression-distraction apparatus for hip pathology was proposed.
- A method for treating pubic symphysis ruptures was developed.
- A method for predicting the course of consolidation in transosseous osteosynthesis was substantiated.
- A method for inflammation process diagnosis was proposed.
- A method for a personalized magnetic therapy regimen in the treatment of pelvic bone fractures was developed.
- A utility model of an intervertebral disc implant was designed.

With his participation, new technologies for treating patients with pelvic bone injuries were developed and implemented in medical institutions in Russia and abroad.

In 1996, S.M. Kutepov defended his doctoral dissertation on the topic "Guided transosseous osteosynthesis in the treatment of pelvic bone fractures". In 2000, he was awarded the academic title of professor. In 2016, he was elected a Corresponding Member of the Russian Academy of Sciences.

In 2005, Sergey Mikhailovich was appointed acting rector of the Ural State Medical Academy. He was elected rector of USMA in May 2006 and until 1 March 2018, he successfully headed the only medical university in the Middle Urals, combining the work of the rector with the head of the Department of Traumatology of the Faculty of Advanced Training and Preventive Medicine, which he organized.

Currently, his main scientific interests are related to development and application of new biocomposite materials, minimally invasive surgical treatment methods in traumatology and orthopaedics. Sergey Mikhailovich is the chief researcher of the Institute of Traumatology of the Central Scientific Research Laboratory and the President of the Federal State Budgetary Educational Institution of Higher Education "Ural Medical University" of the Ministry of Health of the Russian Federation.

He is the author of over 200 scientific papers, including ten monographs. He holds about 20 patents for inventions. Seven candidate and doctoral dissertations were defended under his supervision.

He has honorary diplomas from the Ministry of Health of the Russian Federation, the Governor and the Government of the Sverdlovsk Region. He was awarded the USSR state award, the medal "For the Development of Virgin and Fallow Lands", the badges "Excellent Healthcare Worker of the Russian Federation", "For Services to the Sverdlovsk Region" of the 3rd degree.

He was awarded the international Ertsmaker award in the nomination "For the wisdom and flexibility of management policy" within the framework of the program "The Man Who Defines the Face of the Planet".

It is difficult to overestimate the importance of Sergey Mikhailovich's long-term work for the benefit of the population of the Middle Urals. He not only preserved the Ural School of trauma- and orthopaedic surgeons during the difficult years of perestroika, but also raised a generation of remarkable doctors, enthusiasts of their work.

In honor of his anniversary, the administration and staff of the Ural Chaklin Institute of Traumatology and Orthopaedics, the Federal State Budgetary Educational Institution of Higher Education Ural Medical University of the Ministry of Health of the Russian Federation, the Department of Traumatology and Orthopaedics, the Institute of Traumatology of the Central Scientific Research Laboratory and the editorial board of the journal Genij Ortopedii would like to wish Sergey Mikhailovich good health, creative longevity, happiness and joy in the company of his family and friends!

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