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Regenerative interventional treatment of hip and knee aseptic osteonecrosis: evaluation of effectiveness



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ABSTRACT

The incidence and prevalence of aseptic osteonecrosis of the joints remain insufficiently studied in most countries. According to various authors, it occurs in 1.4 – 4.7 % of patients with hip joint pathology. Interventional regenerative technologies are becoming the only alternative to hip and knee replacement in aseptic osteonecrosis today.

THE AIM of the study was to develop a method for treating aseptic osteonecrosis of the hip and knee using regenerative technologies and analyse the results of its application.

MATERIALS AND METHODS. The overall group analysed for treatment outcomes of aseptic osteonecrosis of the hip and knee included 182 patients (262 joints), of whom 102 were men and 80 were women. The mean age of patients was 42.5 ± 20.8 years. A total of 121 patients (187 joints) had aseptic osteonecrosis of the hip and 61 patients (75 joints) had aseptic osteonecrosis of the knee. For patients with aseptic necrosis of the hip the Harris Hip Score, Oxford Hip Score, and VAS were used, while for patients with aseptic osteonecrosis of the knee, the KOOS, Oxford Knee Score, and VAS were applied. The follow-up period in all groups was 12 ± 0.5 months.

RESULTS. A regenerative interventional technique for treating aseptic osteonecrosis of the hip and knee was developed. To improve the technology of intramedullary administration of the biotechnological product, a navigation device was designed. The quality of life indicators in the group that underwent preoperative intra-articular administration of autologous peripheral blood concentrates demonstrated better improvement in pain reduction and joint function compared with the group that underwent core decompression with administration of the mononuclear fraction of bone marrow aspirate alone.

In patients with Ficat stage I, positive functional outcomes and pain reduction were observed as early as three months after treatment. Significant positive results were obtained in all patients of this group 12 months after treatment across all scales. Positive outcomes were also observed in patients with stage II and III, although in stage III the improvement progressed much more slowly.

Analysis of clinical indicators over time using KOOS, OKS and VAS scales, depending on the Ficat stage, revealed that positive dynamics in aseptic osteonecrosis of the knee developed more slowly compared with hip necrosis, but by 12 months the quality of life scores were nearly comparable. The improvement in quality of life, pain relief and joint function was significantly more pronounced in patients with stage I and II.

CONCLUSION. It was established that the two-stage treatment approach (preoperative intra-articular administration of autologous peripheral blood concentrates followed by core decompression and intramedullary administration of the mononuclear fraction of bone marrow aspirate) significantly improves clinical outcomes according to quality of life questionnaires compared with the one-stage treatment group. Analysis of clinical dynamics depending on the Ficat stage demonstrated significant improvement in quality of life, pain relief and joint function in patients with stage I and II 12 months after treatment.

KEY WORDS: hip; knee; aseptic osteonecrosis; regenerative interventional technologies; intramedullary injections

The incidence and prevalence of aseptic necrosis of the joints remain insufficiently studied in most countries. According to various authors, it occurs in 1.4 – 4.7 % of patients with hip pathology. In the United States,

approximately 15,000 new cases of aseptic necrosis are registered annually, and more than 10 % of all hip arthroplasties are performed due to its consequences. In Japan, 2,500 – 3,300 cases of femoral aseptic necrosis

are diagnosed each year, of which 34.7 % are caused by corticosteroid use, 21.8 % result from alcohol abuse, and 37.1 % are attributed to idiopathic mechanisms [1-5]. As for aseptic osteonecrosis of the knee, epidemiological data are virtually absent in the literature; however, based on our observations, the incidence of this condition has increased significantly following the coronavirus pandemic, which requires further investigation.

According to etiological factors, aseptic osteonecrosis is classified into traumatic, which mainly results from high-energy injuries (fractures in the joint region, traumatic dislocations and subluxations), and non-traumatic, which may develop due to prolonged corticosteroid use, exposure to alcohol, drugs and other toxins, ionizing radiation, fat embolism, hematologic diseases (coagulopathies, sickle cell anemia, Gaucher disease), decompression sickness, etc. [6]. In non-traumatic aseptic osteonecrosis, the initial stage is characterized by hypertrophy of bone marrow adipocytes, which leads to impaired blood supply to the epiphysis. In traumatic AN, the disruption is directly caused by the injury itself. Subsequently, both pathogenic variants converge: critical ischemia develops, leading to osteonecrosis. An inflammatory process ensues, resulting in bone resorption and destruction. Regenerative medicine technologies are becoming the only alternative to hip and knee replacement in aseptic osteonecrosis today [7-8].

Regenerative interventional orthopedics is a field that has emerged due to the integration of advances in modern regenerative medicine with imaging techniques [9]. In essence, regenerative interventional technologies (RIT) represent a "bridge" between traditional conservative treatment methods and conventional surgical interventions.

Of course, the use of imaging modalities such as ultrasound and C-arm fluoroscopy had already been relevant in the past. Ultrasound guidance was used for intra-articular administration of hyaluronic acid and corticosteroids, while the C-arm was applied for bone core decompression in aseptic osteonecrosis of various localizations. However, with the rapid development and implementation of regenerative technologies, the scope of ultrasound- and X-ray-guided interventional procedures has expanded significantly.

Owing to advances in ultrasound and radiologic navigation, the capabilities of regenerative interventional technologies have markedly increased. Not only intra-articular administration of biotechnological products has become accessible and relevant, but also targeted delivery into specific intra-articular or periarticular structures [10]. In the hip, injections can be performed into the labrum, ligaments, and muscle attachment sites [11]. In the knee, navigation allows access for injections into the menisci, tendons, ligaments, and muscle attachment sites [12].

Intraosseous administration of biotechnological products has always been important in the treatment of aseptic osteonecrosis, particularly through core decompression of the proximal femur. These intraosseous injection techniques are continuously evolving, being refined, and increasingly applied in aseptic osteonecrosis [13-14], becoming a real alternative to early joint replacement.

THE AIM of the study was to develop regenerative technologies using biotechnological products based on autologous peripheral blood and bone marrow aspirate for the treatment of aseptic necrosis of the hip and knee joints, and to analyze the outcomes of their application.

MATERIALS AND METHODS

The overall study group for analyzing treatment outcomes of aseptic necrosis of the hip and knee joints consisted of 182 patients (262 joints), including 102 men and 80 women. The mean age of the patients was 42.5 ± 20.8 years. A total of 121 patients (187 joints) had aseptic osteonecrosis of the hip, and 61 patients (75 joints) had aseptic osteonecrosis of the knee. The mean age of patients with hip aseptic osteonecrosis was 40.4 ± 18.7 years, while the mean age of patients with knee aseptic osteonecrosis was 51.2 ± 9.3 years.

Among men, 80 patients were treated for aseptic osteonecrosis of the hip (34 with unilateral involvement and 46 with bilateral involvement), and 22 were treated for aseptic osteonecrosis of the knee (19 with unilateral involvement and 3 with bilateral involvement).

Among female patients, 41 were treated for aseptic osteonecrosis of the hip (21 with unilateral involvement and 20 with bilateral involvement), and 39 were treated for aseptic osteonecrosis of the knee (28 with unilateral involvement and 11 with bilateral involvement). **Table 1** presents the distribution of patients with aseptic osteonecrosis of the hip and knee according to age, sex, and localization of the pathological process.

Table 1. Distribution of patients with aseptic necrosis of the hip and knee joints by age, sex, and localization of the pathological process.

Parameter	Characteristics	Total	Hip joint	Knee joint
Age	Years	42.5 ± 20.8	40.4 ± 18.7	51.2 ± 9.3
Sex	Male	102	80 (126 joints)	22 (25 joints)
	Female	80	41 (61 joints)	39 (50 joints)
Follow-up	Months	12 ± 0.5	12 ± 0.5	12 ± 0.5

The treatment outcomes were analyzed according to the stage of aseptic osteonecrosis based on the Ficat classification [15-16]. For patients with aseptic necrosis of the hip the Harris Hip Score, Oxford Hip Score, and VAS were used, while for patients with aseptic osteonecrosis of the knee, the KOOS, Oxford Knee Score, and VAS were applied [17]. The distribution of patients is presented in **Table 2**.

Table 2. Distribution of patients with aseptic osteonecrosis of the hip and knee according to the Ficat stage (patients/joints).

Ficat stage	Hip joint	Knee joint
1	43/68	26/37
2	51/76	21/24
3	27/43	14/14

The analysis was conducted according to the type of regenerative interventional technologies applied. In Group 1, patients underwent core decompression of the proximal femur (for aseptic osteonecrosis of the hip) or distal femur (for aseptic osteonecrosis of the knee), followed by administration of 5 ml of the mononuclear fraction of bone marrow aspirate (single-stage treatment).

In Group 2, the first stage involved preoperative preparation through intra-articular administration of autologous platelet lysate, aimed at influencing the articular cartilage. Patients with hip joint aseptic osteonecrosis received 3 mL of the biotechnological product, while those with knee aseptic osteonecrosis received 4 mL. Injections were administered once weekly for a total of 6 sessions. The second stage consisted of core decompression with administration of 5 ml of the mononuclear fraction of bone marrow aspirate (two-stage treatment). The distribution of patients in the groups is presented in **Table 3**.

Table 3. Distribution of patients with aseptic osteonecrosis of the hip and knee according to the type of RIT (Group 1 – single-stage treatment, Group 2 – two-stage treatment).

RIT variant	Single-stage treatment	Two-stage treatment
Hip (patients/joints)	60/85	61/102
Knee (patients/joints)	29/29	32/46

For patients with aseptic osteonecrosis of the hip, treatment outcomes were analyzed using the HOOS, OHS, and VAS scales. Correspondingly, for patients with aseptic osteonecrosis of the knee, the KOOS, OKS, and VAS scales were applied. Assessments were performed before treat-

ment and at 3, 6, and 12 months after treatment. The mean follow-up period across all analysis groups was 12 ± 0.5 months.

STATISTICAL ANALYSIS. Numerical values of the studied parameters were processed using descriptive statistical methods in MS Excel (Microsoft, USA) and are presented as mean \pm standard deviation. The parametric Fisher F-test was used as the criterion of significance after performing the Shapiro–Wilk test for normality. Differences were considered statistically significant at $p < 0.05$.

RESULTS AND DISCUSSION

A method for treating aseptic osteonecrosis of the hip and knee using regenerative technologies with biotechnological products based on autologous peripheral blood and bone marrow aspirate was proposed, consisting of the following stages. During the surgical procedure on the hip joint, the patient was positioned supine. The hip joint was visualized using a C-arm, and a lateral incision of up to 2 cm on the femur was performed (Fig. 1).

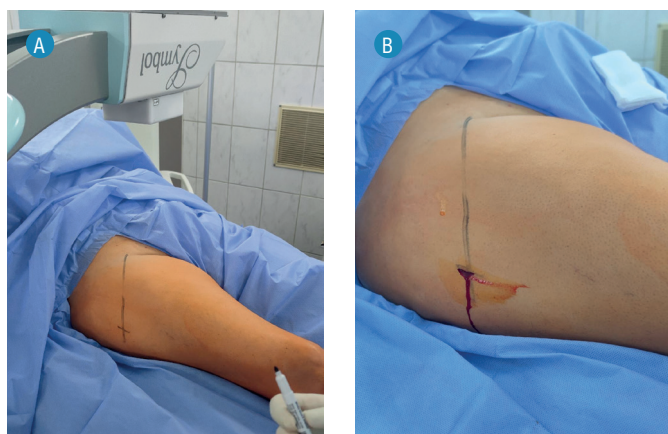


Fig. 1. Photographs of the stages of intramedullary administration of biotechnological products in aseptic osteonecrosis of the femoral head: A – radiologic navigation; B – percutaneous access.

The next stage involved placing a guide pin at the site of proximal femur core decompression and adjusting its trajectory in both the antero-posterior and lateral projections (Fig. 2).

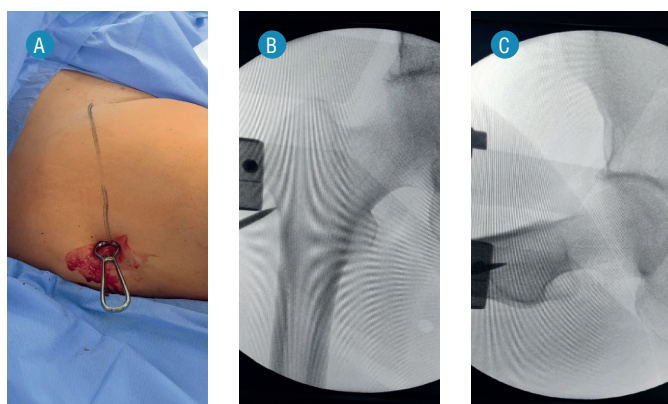


Fig. 2. Photographs of navigation during proximal femur core decompression in aseptic osteonecrosis of the femoral head: A – placement of the guide pin to determine the trajectory of the core decompression; B – radiologic control of the core decompression direction in the anteroposterior projection; C – radiologic control of the core decompression direction in the lateral projection.

A method for administering the biotechnological product was proposed, involving the use of a custom-designed navigator for guiding the guide pin, drill, and trocar during core decompression.

The navigator consists of a handle and a working part. The handle is connected to the working part via a threaded joint. The proximal end of the working part is cylindrical, transitioning into a grooved blade at an obtuse angle relative to the axis of the handle, with the blade having a sharpened distal tip.

The presence of a grooved blade with a sharpened distal end allows the navigator to be inserted into the bone canal without obstruction and eliminates the need for radiologic control during trocar placement. Designing the grooved blade at an obtuse angle relative to the handle axis maximizes its adaptation to the anatomical features of the targeted area, particularly the proximal femur. Furthermore, the navigator can be used in patients with varying anthropometric characteristics. Fig. 3 presents a schematic of the navigator in the lateral projection.

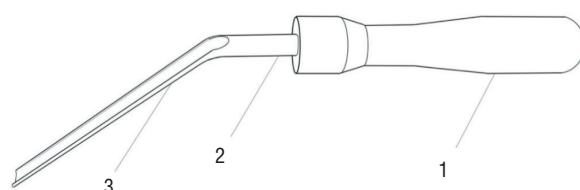


Fig. 3. Schematic of the navigator for guiding the hollow drill and trocar during bone core decompression for the administration of biotechnological products, where 1 – handle, 2 – working part, 3 – grooved blade.

During proximal femoral core decompression, the navigator was used at the stages of replacing navigation instruments (guide pin, Kirschner wire, drill, trocar) to create the bone tunnel. The device allowed for sequential replacement of each navigation instrument with the next. The advantages of the navigator include facilitating the surgical procedure by ensuring precise intramedullary administration of regenerative injection products, preventing soft tissue interposition and injury during the procedure. The proposed navigator does not require additional technical equipment and reduces the duration of the surgical intervention.

In the next stage, using the navigator, the guide pin was removed from the created channel, and a Kirschner wire was inserted through the channel to the site of biotechnological product administration. A cannulated drill and the custom-designed navigator were used to guide the wire [18]. The placement of the wire was controlled using a C-arm in antero-posterior and lateral projections (Fig. 4).

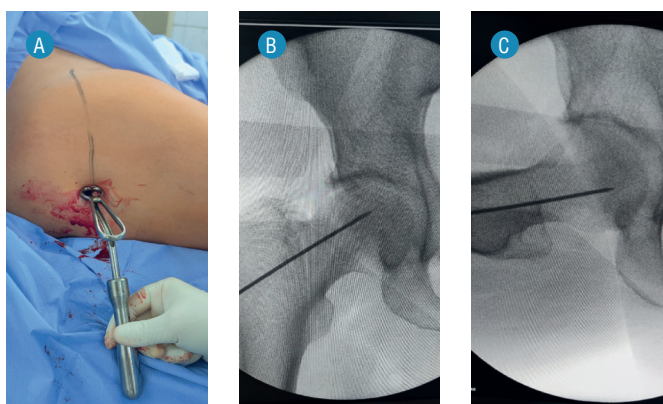


Fig. 4. Photographs of guiding the Kirschner wire to the site of biotechnological product administration in the femoral head: A – using the custom-designed navigator to replace the guide pin with the navigation wire; B – control of wire placement in the anteroposterior projection; C – control of wire placement in the lateral projection.

In the next stage, a 4.5 mm cannulated drill was advanced over the navigation Kirschner wire, creating a channel to the site of biotechnological product administration under C-arm control in anteroposterior and lateral projections (Fig. 5).

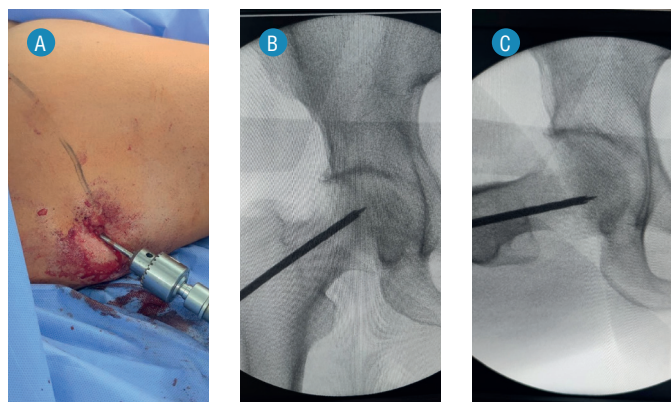


Fig. 5. Photographs of bone channel creation for biotechnological product administration: A – creation of a bone channel for biotechnological product administration in the subchondral region of the femoral head; B – control of bone channel creation in the anteroposterior projection; C – control of bone channel creation in the lateral projection.

After creating the bone channel, the drill was replaced with an 8G trocar for intramedullary manipulations. A three-component Luer Lock syringe filled with the biotechnological product was connected to the trocar, and the product was administered under C-arm guidance. After administration, 0.9 % sodium chloride solution was introduced through the trocar to flush the remaining biotechnological product from the walls of the trocar into the pathological area of the femoral head and to ensure fixation of the product within the site (Fig. 6).



Fig. 6. Photographs of biotechnological product administration through the trocar and subsequent 0.9 % sodium chloride solution injection to flush the remaining product from the walls of the trocar into the pathological area of the femoral head.

For intramedullary administration of biotechnological products into the knee, depending on the location of the lesion, core decompression of the bone was performed sequentially from the lateral or medial surface of the distal third of the femur or the proximal third of the tibia using a Kirschner wire, a cannulated drill, and an 8G trocar for intramedullary manipulations. The custom-designed method of biotechnological product administration using the navigator for the guide pin, the drill, and the troakar during core decompression, described above, was applied.

As an example, intramedullary administration of the mononuclear fraction of bone marrow aspirate was performed in aseptic necrosis of the lateral femoral condyle. The injection was performed from the side of the healthy bone, in this case from the medial femoral condyle. Fig. 7 presents the stage of access and selection of the direction for creating the intramedullary channel using the guide pin.

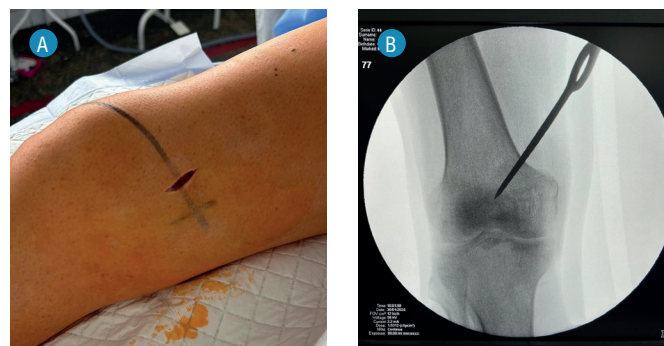


Fig. 7. Photographs of access (A) and guide pin placement (B) for creating an intramedullary channel in a patient with aseptic osteonecrosis of the lateral femoral condyle.

Subsequently, the guide pin was replaced with a navigation Kirschner wire, which was advanced using a cannulated drill and the custom-designed navigator to the site of biotechnological product administration. The placement of the wire was controlled using a C-arm in anteroposterior and lateral projections (Fig. 8).

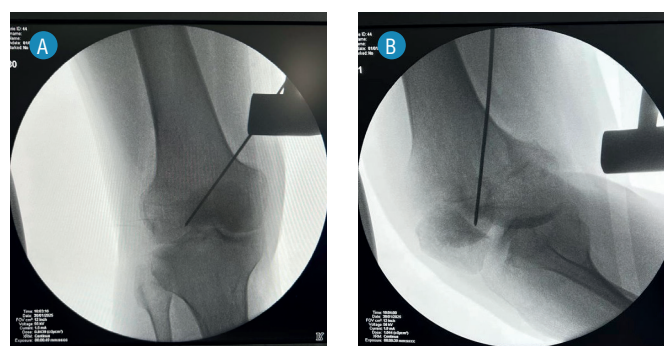


Fig. 8. Photographs of controlling the navigation Kirschner wire placement into the pathological area of the lateral femoral condyle in anteroposterior (A) and lateral (B) projections.

The next stage involved reaming the intramedullary channel over the wire using a 4.5 mm cannulated drill, with guidance and control using the C-arm in anteroposterior and lateral projections (Fig. 9).

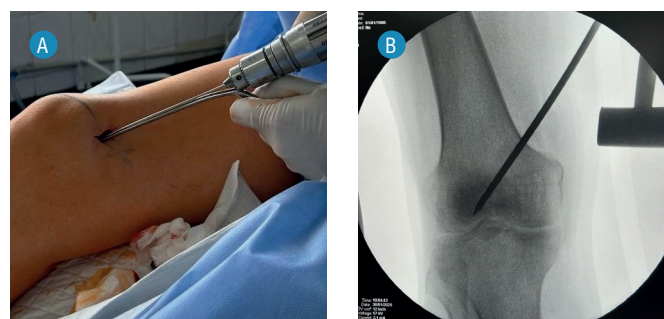


Fig. 9. Photographs of intramedullary channel creation to the area of aseptic osteonecrosis of the lateral femoral condyle (A) and C-arm control (B).

The drill was then replaced with an 8G trocar for intramedullary manipulations. A three-component Luer Lock syringe filled with the biotechnological product was connected to the trocar, and the product was administered under C-arm guidance (Fig. 10).

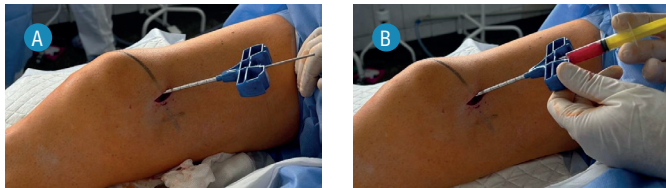


Fig. 10. Photographs of trocar placement over the navigation wire (A) and biotechnological product administration (B).

After the administration of the biotechnological product, 0.9 % sodium chloride solution was introduced through the trocar to flush the remaining product from the walls of the trocar into the pathological area of the femoral head and to ensure fixation of the product within the site.

The dynamics of clinical indicators during follow-up were analyzed in patients with aseptic necrosis of the hip (Table 4) and knee (Table 5) joints using the HOOS and KOOS scales, respectively, depending on the variant of regenerative interventional technology (RIT) applied: in Group 1 (core decompression of the proximal femoral shaft or femoral condyle with administration of the mononuclear fraction of bone marrow aspirate) and in Group 2 (preoperative preparation via intra-articular administration of autologous peripheral blood concentrates followed by core decompression of the proximal femoral shaft or femoral condyle with administration of the mononuclear fraction of bone marrow aspirate).

Table 4. Dynamics of clinical indicators in patients with aseptic osteonecrosis of the hip at follow-up according to the HOOS scale, depending on the follow-up period and RIT variant, Mean ± SD.

HOOS	Group	Follow-up period							
		Pre-treatment		3 months		6 months		12 months	
		1	2	1	2	1	2	1	2
Overall score, %		28.5 ± 11.4	28.2 ± 10.9	40.2 ± 10.6	42.7 ± 10.2	50.6 ± 10.1*	60.4 ± 10.5*#	62.6 ± 14.8*	71.7 ± 11.9*#
Pain score, %		35.8 ± 8.4	36.3 ± 8.1	54.2 ± 7.9*	59.1 ± 8.2*	61.4 ± 7.8*	73.2 ± 6.9*#	69.8 ± 13.9*	81.6 ± 11.1*#
Symptoms score, %		34.9 ± 12.6	33.8 ± 12.1	52.8 ± 12.8*	53.6 ± 11.9*	62.9 ± 10.7*	65.2 ± 13.8*	69.4 ± 14.9*	73.8 ± 10.9*
Joint function score, %		36.5 ± 10.6	36.8 ± 9.8	42.3 ± 8.7	45.6 ± 7.3	54.1 ± 8.5*	63.8 ± 7.1*	65.9 ± 15.1*	77.1 ± 12.4*#
Ability to perform activities, %		15.7 ± 12.4	14.9 ± 11.7	25.8 ± 11.9	26.7 ± 11.5	32.8 ± 12.1*	43.1 ± 11.9*#	49.3 ± 17.1*	55.2 ± 14.8*
Quality of life, %		19.8 ± 13.2	19.5 ± 12.8	25.9 ± 11.7	28.1 ± 12.3	41.9 ± 11.5*	55.4 ± 12.8*#	58.7 ± 13.2*	70.7 ± 10.1*#

Notes: * – p < 0.05 compared to pre-treatment values; # – p < 0.05 compared to Group 1.

Table 5. Dynamics of clinical indicators in patients with aseptic osteonecrosis of the knee at follow-up according to the KOOS scale, depending on the follow-up period and RIT variant, Mean ± SD.

KOOS	Group	Follow-up period							
		Pre-treatment		3 months		6 months		12 months	
		1	2	1	2	1	2	1	2
Overall score, %		27.4 ± 11.2	27.2 ± 10.7	39.7 ± 10.2*	41.4 ± 9.9*	48.8 ± 9.5*	59.1 ± 10.1*#	61.4 ± 12.9*	70.5 ± 12.4*#
Pain score, %		34.6 ± 8.1	35.8 ± 7.9	52.1 ± 8.4*	58.6 ± 9.0*	60.2 ± 8.1*	71.8 ± 7.2*#	68.6 ± 13.2*	80.8 ± 11.3*#
Symptoms score, %		34.1 ± 12.8	33.2 ± 12.4	52.4 ± 12.6*	52.8 ± 12.1*	62.4 ± 11.2*	64.6 ± 13.2*	68.8 ± 15.1*	73.2 ± 11.2
Joint function score, %		35.9 ± 10.8	36.1 ± 10.4	41.8 ± 9.1	45.2 ± 7.8	53.8 ± 8.8*	63.2 ± 7.6*#	65.4 ± 14.8*	76.4 ± 12.6*#
Ability to perform activities, %		15.4 ± 12.8	14.8 ± 12.2	25.4 ± 12.1	26.1 ± 11.9	32.2 ± 12.6*	42.6 ± 12.6*#	48.6 ± 16.8*	54.7 ± 15.1*
Quality of life, %		19.6 ± 12.9	19.2 ± 12.6	25.7 ± 11.8	27.6 ± 12.1	41.4 ± 11.2	55.1 ± 12.4*#	58.2 ± 12.9	70.2 ± 10.4*#

Notes: * – p < 0.05 compared to pre-treatment values; # – p < 0.05 compared to Group 1.

The dynamics of treatment outcomes were evaluated in patients with aseptic osteonecrosis of the hip (Table 6) and knee (Table 7) depending on the RIT variant using the OHS and OKS scales, respectively.

Table 6. Dynamics of clinical indicators in patients with aseptic osteonecrosis of the hip at follow-up according to the OHS scale, depending on the follow-up period and RIT variant, Mean ± SD.

Follow-up period	Group 1	Group 2
Pre-treatment	15 ± 3.2	13 ± 3.7
3 months	24 ± 2.8	26 ± 3.0*
6 months	31 ± 3.1*	35 ± 3.3*
12 months	30 ± 3.4*	37 ± 3.9*#

Notes: Group 1 – core decompression with administration of the mononuclear fraction of bone marrow aspirate; Group 2 – preoperative preparation via intra-articular administration of autologous peripheral blood concentrates.

* – p < 0.05 compared to pre-treatment values; # – p < 0.05 compared to Group 1.

Table 7. Dynamics of clinical indicators in patients with aseptic necrosis of the knee joint at follow-up according to the OKS scale, depending on the follow-up period and RIT variant. Mean ± SD.

Follow-up period	Group 1	Group 2
Pre-treatment	14.6 ± 3.4	12.7 ± 3.2
3 months	23.2 ± 3.2	25.4 ± 2.8*
6 months	30.6 ± 3.4*	34.1 ± 3.4*
12 months	29.2 ± 3.6*	36.8 ± 4.4*#

Notes: Group 1 – core decompression with administration of the mononuclear fraction of bone marrow aspirate; Group 2 – preoperative preparation via intra-articular administration of autologous peripheral blood concentrates.

* – p < 0.05 compared to pre-treatment values; # – p < 0.05 compared to Group 1.

The dynamics of treatment outcomes were evaluated in patients with aseptic osteonecrosis of the hip (Table 8) and knee (Table 9) depending on the RIT variant using the VAS scale.

Table 8. Dynamics of clinical indicators in patients with aseptic osteonecrosis of the hip at follow-up according to the VAS scale, depending on the RIT variant, Mean \pm SD.

Follow-up period	Group 1	Group 2
Pre-treatment	9.1 \pm 0.4	9.3 \pm 0.5
3 months	6.4 \pm 0.9	5.9 \pm 0.7*
6 months	5.6 \pm 1.1*	3.9 \pm 0.8*
12 months	4.5 \pm 1.0*	2.5 \pm 0.9**

Notes: Group 1 – core decompression with administration of the bone marrow aspirate mononuclear fraction; Group 2 – preoperative preparation by intra-articular injection of autologous peripheral blood concentrates.

* – $p < 0.05$ compared to pre-treatment values; # – $p < 0.05$ compared to Group 1.

Table 9. Dynamics of clinical indicators in patients with aseptic osteonecrosis of the knee at follow-up stages according to the VAS depending on the variant of regenerative interventional technologies (RIT), Mean \pm SD.

Follow-up period	Group 1	Group 2
Pre-treatment	9.3 \pm 0.3	9.5 \pm 0.4
3 months	6.6 \pm 1.1	6.2 \pm 0.9*
6 months	5.9 \pm 1.2*	4.2 \pm 1.0*
12 months	4.8 \pm 0.8*	2.8 \pm 0.8*#

Notes: Group 1 – patients who underwent core decompression of the femoral condyle with administration of the bone marrow aspirate mononuclear fraction; Group 2 – patients who received preoperative preparation via intra-articular injection of autologous peripheral blood concentrates followed by core decompression of the femoral condyle with administration of the bone marrow aspirate mononuclear fraction.

* – $p < 0.05$ compared to pre-treatment values; # – $p < 0.05$ compared to Group 1.

Table 10. Dynamics of clinical parameters in patients with aseptic osteonecrosis of the femoral head at different stages of the disease according to Ficat, assessed at follow-up using the Harris Hip Score, OHS, and VAS, Mean \pm SD.

	Follow-up period				p*
	Pre-treatment	3 months	6 months	12 months	
Ficat 1					
Harris, points	67.1 \pm 8.3	79.1 \pm 7.7	81.4 \pm 6.9	90.5 \pm 5.8	$p < 0.01$
OHS, points	22.4 \pm 3.7	32.1 \pm 6.4	36.3 \pm 4.7	42.4 \pm 5.7	$p < 0.01$
VAS, cm	7.9 \pm 1.3	3.7 \pm 1.9	2.9 \pm 1.4	2.0 \pm 1.2	$p < 0.01$
Ficat 2					
Harris, points	65.5 \pm 7.4	72.5 \pm 5.4	79.1 \pm 4.9	85.5 \pm 6.4	$p < 0.05$
OHS, points	17.8 \pm 3.4	26.2 \pm 5.1	31.8 \pm 4.4	37.1 \pm 6.4	$p < 0.01$
VAS, cm	9.4 \pm 0.6	4.7 \pm 2.1	3.8 \pm 1.6	2.8 \pm 1.8	$p < 0.01$
Ficat 3					
Harris, points	58.2 \pm 5.8	60.1 \pm 6.7	73.8 \pm 5.4	81.3 \pm 7.1	$p < 0.05$
OHS, points	14.2 \pm 6.1	23.1 \pm 8.7	26.8 \pm 6.6	26.4 \pm 7.3	$p < 0.05$
VAS, cm	9.7 \pm 0.3	7.2 \pm 2.1	6.5 \pm 1.9	4.8 \pm 2.5	$p < 0.05$

Notes: * – statistically significant differences when comparing the 12-month follow-up values with baseline.

Table 11. Dynamics of clinical outcomes in patients with aseptic osteonecrosis of the knee at different stages of the disease according to the Ficat classification, assessed using the KOOS, OKS, and VAS scales, Mean \pm SD.

	Follow-up period				p*
	Pre-treatment	3 months	6 months	12 months	
Ficat 1					
KOOS, points	29.1 \pm 8.4	43.9 \pm 8.7	62.4 \pm 7.9	73.1 \pm 9.8	$p < 0.01$
OKS, points	24.8 \pm 8.5	29.3 \pm 7.1	35.6 \pm 6.7	39.8 \pm 8.2	$p < 0.01$
VAS, cm	7.6 \pm 1.4	3.5 \pm 1.8	2.8 \pm 1.6	1.3 \pm 0.6	$p < 0.01$
Ficat 2					
KOOS, points	27.9 \pm 7.8	41.7 \pm 8.4	49.1 \pm 7.9	67.5 \pm 9.4	$p < 0.05$
OKS, points	18.8 \pm 8.1	25.2 \pm 8.1	30.4 \pm 7.4	35.2 \pm 7.2	$p < 0.01$
VAS, cm	9.4 \pm 0.6	4.7 \pm 2.1	3.8 \pm 1.6	2.8 \pm 1.8	$p < 0.01$
Ficat 3					
KOOS, points	25.2 \pm 8.8	36.4 \pm 10.7	43.8 \pm 9.4	54.3 \pm 12.1	$p < 0.05$
OKS, points	12.8 \pm 5.9	21.9 \pm 8.9	25.8 \pm 7.1	24.9 \pm 6.8	$p < 0.05$
VAS, cm	9.6 \pm 0.4	7.9 \pm 2.9	6.8 \pm 2.4	5.3 \pm 2.8	$p < 0.05$

Notes: * – statistically significant differences when comparing the 12-month post-treatment values with baseline data.

As can be seen from the analysis of the results, patients' quality of life improved significantly in both groups, in cases of aseptic necrosis of both the hip and the knee, starting from the 6th month according to the HOOS and KOOS scales. According to the OHS, OKS, and VAS scales, in group 1, quality of life improved significantly from the 6th month after treatment, whereas in group 2, improvements were observed as early as the 3rd month.

In group 2, where preoperative preparation was performed by intra-articular administration of autologous peripheral blood concentrates followed by core decompression with the injection of the mononuclear fraction of bone marrow aspirate, quality of life scores on all scales were significantly higher at 12 months after treatment compared to group 1, where just core decompression with injection of the mononuclear fraction of bone marrow aspirate was performed ($p < 0.05$). This was observed both in patients with aseptic osteonecrosis of the hip and the knee.

The next step was to assess the dynamics of clinical outcomes during follow-up depending on the stage of disease according to Ficat. The results of quality of life assessment in patients with aseptic osteonecrosis of the femoral head are presented in **Table 10**.

Thus, in patients with femoral head avascular osteonecrosis at Ficat stage I, positive functional outcomes and a reduction in pain were achieved as early as 3 months after treatment ($p < 0.05$). Statistically significant improvements across all assessed scales were observed in all patients in this group after 12 months. Positive outcomes were also recorded in patients at stages II and III of the disease. The analysis of treatment dynamics in patients with avascular osteonecrosis of the knee is presented in **Table 11**.

A more pronounced improvement in quality of life, as well as stronger analgesic and functional effects, was observed in patients with Ficat stage 1 and 2 disease ($p < 0.01$) at 12 months after treatment, compared with patients with stage 3 disease at the same time point.

Below are examples of MRI dynamics in patients with aseptic osteonecrosis of the hip and knee following regenerative interventional treatments. **Fig. 11** shows MRI images of the hip joints of a 35-year-old female patient with avascular osteonecrosis of the left femoral head, Ficat stage II, prior to surgical intervention.

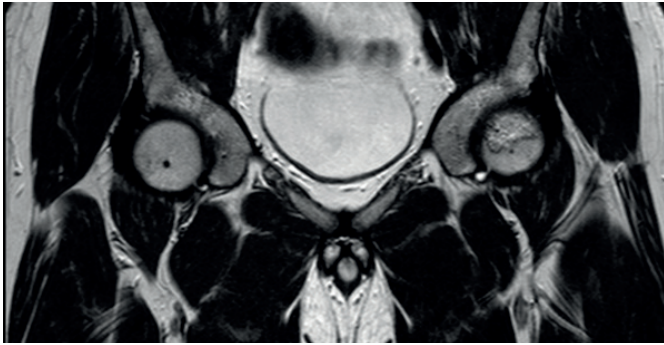


Fig. 11. MRI of the hips of patient L., 35 years old, with aseptic osteonecrosis of the left femoral head, Ficat stage II, before treatment.

Fig. 12 shows the patient's MRI scans 6 months after treatment, which included six intra-articular injections of autologous platelet lysate administered once weekly, followed by intraosseous administration of autologous bone marrow aspirate mononuclear fraction. A reduction in the aseptic necrosis lesion of the left femoral head is observed. On follow-up MRI at 12 months after treatment, an almost complete resolution of the necrotic lesion is noted (**Fig. 12B**).

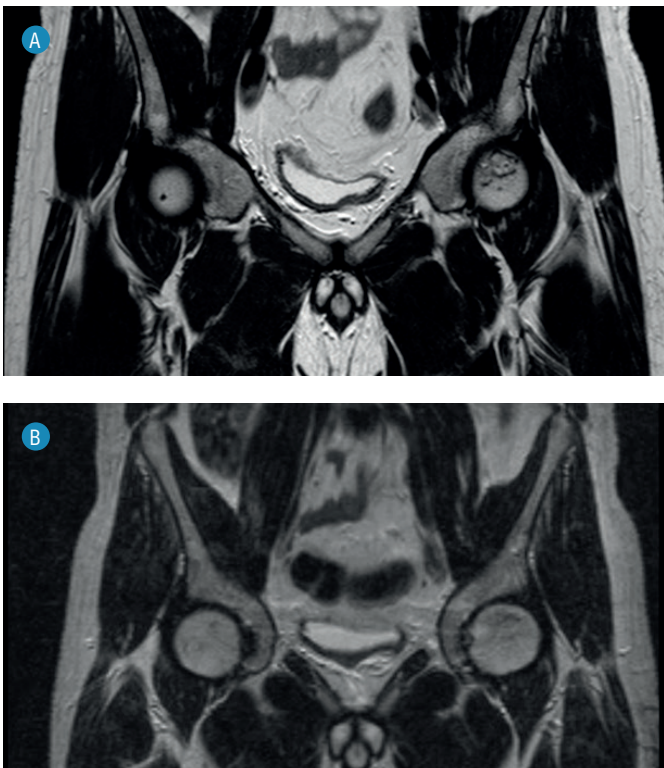


Fig. 12. MRI of the hips of patient L., 35 years old with aseptic osteonecrosis of the left femoral head at 6 months (A) and 12 months (B) after treatment using regenerative interventional technologies (details in the text).

We present MRI findings illustrating the clinical dynamics in a 52-year-old female patient with aseptic osteonecrosis of the medial femoral condyle, Ficat stage I (**Fig. 13**).

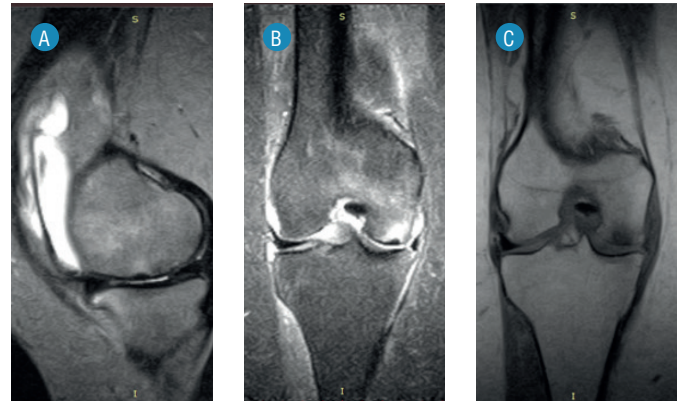


Fig. 13. MRI of the right knee of patient B., 52 years old, with aseptic osteonecrosis of the medial femoral condyle, Ficat stage I, before treatment with regenerative technologies.

The patient underwent six intra-articular injections of autologous platelet lysate administered once weekly, followed by intraosseous administration of autologous bone marrow aspirate mononuclear fraction. **Fig. 14** shows MRI changes 12 months after treatment, demonstrating an almost complete resolution of the necrotic lesion.

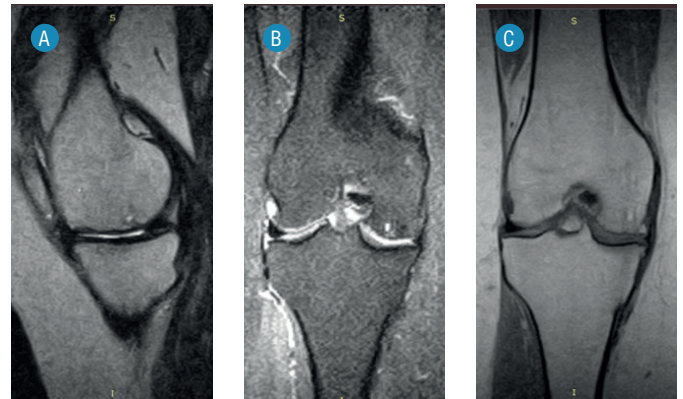


Fig. 14. MRI of the right knee of a 52-year-old female patient with aseptic osteonecrosis of the medial femoral condyle, Ficat stage I, 12 months after treatment with regenerative interventional technologies (details in the text).

Fig. 15 presents the MRI of patient M., 23 years old, with aseptic osteonecrosis of the left femoral head, Ficat stage I, before treatment.

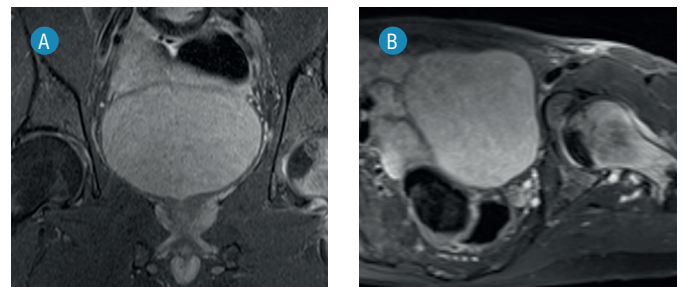


Fig. 15. MRI of the hips of a 23-year-old male patient with aseptic osteonecrosis of the left femoral head, Ficat stage I, before treatment (details in the text).

The patient initially received six intra-articular injections of autologous platelet lysate, followed by core decompression of the proximal segment of the left femur with subchondral administration of the mononuclear fraction of bone marrow aspirate. **Fig. 16** shows the follow-up MRI results obtained 12 months after treatment.

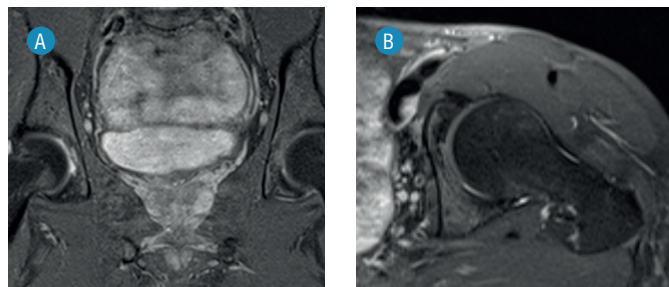


Fig. 16. MRI of the hips of patient M., 23 years old, with aseptic osteonecrosis of the left femoral head, Ficat stage I, 12 months after treatment using regenerative interventional technologies (details in the text).

Fig. 17 shows the MRI of a 34-year-old female patient with aseptic osteonecrosis of the lateral femoral condyle, Ficat stage II, before treatment.

Fig. 18 shows the MRI findings of this patient 12 months after completing the course of treatment with regenerative interventional technologies, which included six intra-articular injections of autologous platelet lysate administered once weekly, followed by core decompression of the lateral femoral condyle with administration of the mononuclear fraction of autologous bone marrow aspirate into the area of aseptic osteonecrosis. The follow-up MRI demonstrates an almost complete resolution of the necrotic lesion 12 months after treatment.



Fig. 17. MRI of the left knee of a 34-year-old female patient with aseptic osteonecrosis of the lateral femoral condyle, Ficat stage II, before treatment (details in the text).

Aseptic osteonecrosis is a severe joint pathology and one of the most common indications leading to joint replacement surgery [19]. Numerous conservative and surgical treatment modalities for aseptic osteonecrosis have been described in the literature [20]. Regenerative technologies hold a key position in determining the treatment strategy for these patients. The most widely used approaches include platelet-rich plasma therapy [21–26] and various applications of stem cells, ranging from transplantation of native autologous bone marrow [27–28] and its mononuclear fraction [29–31] to cultured autologous mesenchymal stem cells derived from bone marrow [32–35] or adipose tissue [36], as well as combinations of different biotechnological products [37].

The majority of published studies report positive clinical outcomes following the use of regenerative technologies, including reduction of pain, improvement in patients' quality of life, and MRI-based evidence of decreased necrotic lesion size. Our results are consistent with these findings for both hip and knee aseptic osteonecrosis. The rate and magnitude of the therapeutic response were influenced, among other factors, by the Ficat stage of the disease. When treatment was initiated at stage I, both the speed and extent of clinical improvement were greater compared with patients treated at stage II or III ($p < 0.01$). Remodeling of the necrotic lesion in this group also occurred more rapidly.

It should be noted that currently available publications on the treatment of aseptic osteonecrosis of the hip and knee describe bone core decompression followed by intramedullary administration of bone-marrow-derived biotechnological products as the sole therapeutic approach [38–40]. For the first time, we performed a comparative analysis between a group of patients who underwent core decompression with subsequent injection of the mononuclear fraction of bone marrow aspirate, and a group of patients who first received intra-articular injections of autologous peripheral blood concentrates. A significant improvement in quality of life indicators and a reduction in pain intensity 12 months after treatment were observed in the second group compared with the first ($p < 0.05$).

In view of the above, regenerative interventional technologies represent a promising alternative to conventional treatment methods for avascular necrosis of major joints and, in most cases, may help prevent the need for total joint replacement.



Fig. 18. MRI of the left knee of a 34-year-old female patient with aseptic osteonecrosis of the lateral femoral condyle, Ficat stage II, 12 months after treatment with regenerative interventional technologies (details in the text).

CONCLUSION

1. The analysis of treatment outcomes in patients with aseptic osteonecrosis of the hip and the knee demonstrated that two-stage therapy – namely, preoperative preparation via intra-articular injections of autologous peripheral blood concentrates followed by core decompression and intramedullary administration of the mononuclear fraction of bone marrow aspirate – significantly improves clinical outcomes according to quality of life questionnaires compared with patients who underwent single-stage treatment.

2. Analysis of the dynamics of clinical indicators during follow-up, according to quality of life questionnaires and stratified by disease stage according to Ficat, revealed significant improvements in quality of life, analgesic effect, and joint function in patients with stage 1 and stage 2 disease at 12 months after treatment.

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Методика лікування асептичного некрозу кульшового та колінного суглобів за допомогою регенеративних інтервенційних технологій та оцінка її ефективності



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РЕЗЮМЕ

Частота та поширеність асептичного некрозу суглобів у більшості країн вивчені недостатньо. За даними різних авторів, він зустрічається у 1,4 - 4,7 % пацієнтів з патологією кульшового суглоба. Єдиною альтернативою ендопротезування суглобів при асептичному некрозі сьогодні стають інтервенційні технології регенеративної медицини.

МЕТОЮ ДОСЛІДЖЕННЯ була розробка методики лікування асептичного некрозу кульшового та колінного суглобів за допомогою регенеративних технологій та аналіз результатів її застосування.

МАТЕРІАЛ І МЕТОДИ. Групу аналізу лікування асептичного некрозу кульшового та колінного суглобів склали 182 пацієнта (262 суглоба), серед яких 102 чоловіки та 80 жінок. Середній вік хворих становив $42,5 \pm 20,8$ роки. У 121 пацієнта (187 суглобів) був асептичний некроз кульшових суглобів, у 61 пацієнта (75 суглобів) – некроз колінного суглоба. Для пацієнтів з некрозом кульшового суглоба використовували шкалу Harris Hip Score, Oxford Hip Score та VAS, тоді як для пацієнтів з остеонекрозом коліна – шкалу KOOS, Oxford Knee Score та VAS. Середній строк спостереження склав $12 \pm 0,5$ місяців.

РЕЗУЛЬТАТИ. Розроблено регенеративну інтервенційну методику лікування асептичного некрозу кульшового та колінного суглобів, а також навігатор для покращення технології внутрішньокісткового введення біотехнологічного продукту. Показники якості життя пацієнтів з попереднім внутрішньосуглобовим введенням аутологічних концентратів периферичної крові продемонстрували кращу динаміку щодо зменшення больового синдрому та покращення функції суглоба, ніж у групі, де проводилася виключно тунелізація з введенням моноклеарної фракції аспірату кісткового мозку.

У пацієнтів з асептичним некрозом головки стегнової кістки при 1-й стадії за Ficat вдалося отримати позитивні функціональні результати та зменшення больового синдрому вже через 3 місяці після лікування. Отримали достовірно позитивні результати в усіх пацієнтів зазначеної групи через 12 місяців після лікування за усіма шкалами. Також позитивні результати отримали у пацієнтів при 2-й та 3-й стадії, але при 3-й стадії позитивна динаміка мала значно повільніший прогрес.

При аналізі клінічних показників за шкалами KOOS, OKS та VAS, залежно від стадії захворювання за Ficat, встановлено, що позитивна динаміка при асептичному некрозі колінного суглоба, порівняно з асептичним некрозом кульшового суглоба, проявляється більш повільно, але через 12 місяців показники якості життя практично співставні. Більш достовірним є покращення якості життя та функції суглоба, а також знеболюючий ефект у пацієнтів з 1-ю та 2-ю стадією за Ficat.

ВИСНОВОК. Встановлено, що двохетапне лікування (передопераційна підготовка шляхом внутрішньосуглобового введення аутологічних концентратів периферичної крові з подальшою тунелізацією та внутрішньокістковим введенням моноклеарної фракції аспірату кісткового мозку) достовірно покращує клінічні результати згідно опитувальників якості життя порівняно з пацієнтами, яким проводили одноетапне лікування. За результатами аналізу динаміки клінічних показників залежно від стадії захворювання за Ficat встановлено достовірні показники покращення якості життя, а також знеболювальний ефект та покращення функції суглоба у пацієнтів з 1-ю та 2-ю стадією захворювання через 12 місяців після лікування.

КЛЮЧОВІ СЛОВА: кульшовий суглоб; колінний суглоб; асептичний некроз; регенеративні інтервенційні технології; внутрішньокісткові ін'єкції