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Dear colleagues,

You are welcome to read the third issue of the journal that contains traditional sections and covers a wide range of professional issues not only in traumatology and orthopedics, but also in related disciplines.

Clinical studies are discussed in eight publications.

The analysis of the causes of knee joint revision arthroplasty is presented in the work of authors from Saratov (Girkalo et al.). They studied 361 clinical cases, systematized the etiology of pathological conditions that required revision arthroplasty. The authors identified three main etiological groups: group I of periprosthetic infection; group II of conditions associated with a response to polyethylene wear products (osteolysis); group 3 of biomechanical disorders, which include violations of spatial orientation, improper implant components sizes and all types of instability. The authors believe that the proposed systematization of the causes of revision arthroplasty may help in further research and will be useful in creating a national register of arthroplasty in Russia.

A comparative analysis of the five-year results of using various methods of treating anterior cruciate ligament ruptures in 72 patients is presented in the study of by Pupynina et al. (Orenburg, Moscow). The study results suggested that removal of the injured cruciate ligament with the intact synovium and its replacement with a graft may be unnecessary and is an aggressive approach. Dynamic intraligamentous stabilization in comparison with early ACL repair shows a faster recovery of physical activity in the early period after surgery and fewer relapses of knee instability in the long term.

The results of a multicenter study of applying interstitial electrical stimulation in the treatment of the initial stages of gonarthrosis in elderly and adults were analyzed by Burmatov et al. (Nizhnevartovsk, Tyumen, Kurgan, Yekaterinburg, Omsk). The authors prove the high effectiveness of using IES as an analgesic and anti-inflammatory therapy. The changes in the hydroxyproline content in the studied environments suggest a chondroprotective effect from the therapy used. The IES in the early stages of gonarthrosis eliminates pain, helps reduce the intensity of collagen destruction and restore limb weight-bearing ability.

Sufianov et al. (Moscow, Tyumen, Kurgan) devoted their work to studying MSCT semiotics of the vertebrae in 82 patients with cervical spinal stenosis. The authors stress that in patients with degenerative changes in the spine, the assessment of MSCT density in various structural formations of the vertebrae should be given the greatest importance. First of all, assessing bone density becomes increasingly important as a patient's age grows. Bone quality is critical to treatment success, but it is also part of optimal surgical preparation for spine surgery. The data obtained justify the need to include the MSCT data processing algorithm in the study of the density of vertebral bodies, the vertebral arch, and its thickness to develop a plan for surgical intervention in patients with cervical spinal stenosis, since they allow one to obtain objective data on bone quality.

An alternative method for measuring sagittal balance parameters in patients' sitting and standing positions was proposed by authors from Novosibirsk (Pavlov et al.). The study shows that there is no statistical difference in the values of the angles PI standard in a standing position and PI ischial in a sitting position, which corresponds to objective data and is generally accepted. They present examples of changes in the radiographic parameters of the inclination of the sacrum and the deviation of the ischial tuberosities, reflecting the spatial rotation of the pelvis through the second, ischial axis, which confirms the presence of two axes of rotation of the pelvis depending on the position of the body. The calculations demonstrated the possibility of using alternative indicators of spinal-pelvic relationships (PT ischial, distance of overhang of the sacrum (overhang S1), deviation of the ischial tuberosities), which enable to assess the spatial movements of the pelvis, as well as the ability to predict the spatial position of the acetabulum, which is an important factor influencing the success of treatment in patients with combined pathology of the hip joint and spine.

Features of the kinematics and kinetics of the motor stereotype in children with achondroplasia were analyzed by authors from Kurgan (Dolganova et al.). The authors found statistically significant disorders in locomotor kinetics and kinematics. The first are associated with longitudinal deficits in limb segments and reduced walking speed. The second are not associated with longitudinal deficits, but were manifested in all planes. And, namely, an increase in the maximum forward inclination of the pelvis, flexion position in the hip, knee joints and dorsiflexion of the ankle joint; increased maximum hip abduction angle and varus deformity of the knee joint; increased rotational range of motion of the pelvis.

The Russian-language FADI and FAAM questionnaires to determine foot function before and after surgical treatment were tested by authors from St. Petersburg (Akulaev et al.). Based on the results of the tested questionnaires in the Russian patient population, it was found that they are sensitive to changes in the condition of the foot/ankle joint in patients for whom surgical treatment is indicated. The reliability, validity and informativeness of using the FADI and FAAM questionnaires in patients with foot pathology, including athletes, were demonstrated.

The section is concluded with a pilot study summarizing the experience of early minimally invasive fixation of a rupture of the symphysis pubis with a system of transpedicular screws in 12 patients with combined pelvic trauma in the acute period of the traumatic disease (Petrov et al., St. Petersburg). Having analyzed the outcomes, the authors conclude that the use of bone plates to fix ruptures of the symphysis pubis leads to disorders of its physiological mobility, and the patient's activation in the postoperative period may result in an implant break. Original dynamic plates and wire cerclage are able to avoid this complication. However, those techniques involve significant surgical trauma and blood loss, as well as the risk of postoperative wound infection. Minimally invasive methods of fixation using cannulated screws, systems such as Endobutton, Tight Rope reduce intraoperative trauma and the risk of complications (blood loss, suppuration), but the procedure for their installation is quite complex and lengthy, and for greater stability, external fixation of the pelvic ring is often required. The technique of minimally invasive fixation of the symphysis pubis with a system of transpedicular screws meets current requirements for the treatment of patients with polytrauma and unstable injuries to the pelvic ring and may be successfully used in the acute period of the traumatic disease.

Experimental studies are presented in two works.

The effect of a monoclonal IL-6 blocker on the course of aseptic necrosis of the femoral head in an experiment on 18 rats was studied by authors from Kemerovo (Shabaldin et al.). The data obtained by the authors indicate the important role of inflammation in the regulation of osteodestruction. Inhibition of the biological effect of IL-6 contributed to the suppression of the expression of osteoclastogenesis genes, increased activity of bone metabolism genes and decreased the intensity of osteodestruction and activation of osteoreparation.

An assessment of the long-term results of a single intraoperative electrical neurostimulation after autologous repair of a resection defect of the tibial portion of the sciatic nerve in 30 adult rats was carried out by authors from Kurgan (Shchudlo et al.). Based on the data obtained, the authors conclude that there was a significant increase in the diameters of regenerating nerve fibers in the tibial nerve, as well as the diameters of their axons and the thickness of the myelinated sheaths 4 and 6 months after autoplasty of the tibial portion of the sciatic nerve in the group of animals with a single 40-minute IES of the proximal section of the sciatic nerve indicates the promoting effect of the applied additive effect on regenerative axono- and myelinogenesis. An increase in the lumen and improvement of flow in the endoneurial vessels of the tibial nerve in the series with IES ensured the persistence of the neuroregenerative effect. The functional significance of the effects of a single IES was confirmed by a significantly higher percentage of animals with excellent results in restoring the static functional index.

New technologies for reconstructing fingers using 3D printing are presented in the work of N.M. Alexandrov and I.D. Veshaeva (Nizhny Novgorod). The results of treatment of 5 patients in whom original methods based on 3D technology were used during preoperative planning, reconstruction of the first finger with an osteocutaneous radial flap with axial blood supply, relocation of the stump of the third finger and distraction lengthening of the stumps of the first and second metacarpal bones were retrospectively assessed. All patients achieved consolidation of interpositional bone allografts during distraction lengthening of the stumps of the fingers, stability of the bone base of the finger, organotypic restructuring of the marginal allograft in plastic surgery with an osteocutaneous osteocutaneous radial flap, and a functionally advantageous position of the first finger after transposition of the stump of the third finger. According to th authors, the use of 3D technology in the reconstruction of the fingers using an osteocutaneous radial flap with axial blood supply and the method of distraction of the stumps of the fingers and metacarpal bones improves the results of surgical treatment.

The case reports presented in this issue are cases of treating ankle joint replacement consequences of hematogenous osteomyelitis of the tibia (Zorin et al., St. Petersburg), necrosis of the talus, crusarthrosis, equino-varo-adducted deformity of the foot (Kuznetsov et al., Moscow), ileofemoral thrombosis caused by malposition of the ileosacral screw (Grin et al., Kurgan), juvenile idiopathic scoliosis treated with the use of the 3D corset of the German school (Blandinsky et al., Yaroslavl, St. Petersburg).

On behalf of the journal's editorial board, I congratulate our readers on Medical Worker's Day and wish them all the best and professional success.

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

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Original article
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Analysis of knee arthroplasty revision causes

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Abstract

Introduction Existing discrepancies in knee arthroplasty registries regarding the definition of indications for revision TKA lead to confusion related to the identification of the leading pathology. Many works indicate not only one but several reasons for revision which makes comparison difficult. Therefore, the issue of categorizing indications for revision TKA is a weak point of the available registries and of any large retrospective series. **Purpose** To systematize the etiology of pathological conditions leading to revision knee arthroplasty.

Materials and methods The study included 361 revision knee arthroplasties. A comparative analysis of the etiology of complications of primary arthroplasty was carried out with data from national arthroplasty registries and clinical studies.

Results The main indications for revision knee arthroplasty were infection in 48.2 % of cases (174/361), aseptic implant instability (osteolysis) in 38.2 % (138/361), and instability of the ligamentous apparatus in 4.2 % (15/361). In 98 cases (27.1 %), only one type of complication was identified, and in 263 (85.2 %) more than one. Infection prevailed among early complications (126/234, 54 %) and aseptic loosening (osteolysis) (69/127, 54 %) predominated among late complications.

Discussion In our opinion, the indications for revision arthroplasty can be divided into three main etiological groups: periprosthetic infection (group I); conditions associated with a response to polyethylene wear products (osteolysis) (group 2); and biomechanical disorders, which include spatial malposition, incorrect implant sizes and all types of instability (group 3).

Conclusion Our systematization of revision arthroplasty causes can help in further research and will be useful in creating a national registry of arthroplasties in Russia.

Keywords: knee joint, joint replacement, complications, revision arthroplasty, registry, infection, instability, osteolysis

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INTRODUCTION

Total knee arthroplasty (TKA) is the most common and effective treatment method for patients with advanced knee osteoarthritis (OA). It can relieve pain and improve functional status [1]. However, some patients do not experience improvement due to complications that develop and require repeated surgery on the joint. Revision knee arthroplasty is a complex therapeutic and diagnostic task with an increased risk of complications compared to primary knee arthroplasty [2]. It requires a responsible approach to the indications for revision TKA, which determines the need for a detailed analysis of the reasons for the primary arthroplasty failures. Accurate identification of the leading pathology in the replaced knee joint and targeted elimination of its cause ensures a favorable outcome in the treatment of patients with complications after primary arthroplasty.

A general idea of all the reasons of TKA failures and the absolute indications for revision arthroplasty can be obtained by studying the data from national registries and multicenter studies. However, registry data vary due to the specifics of filling out data forms, analyzing and interpreting the results obtained [3]. Multicenter studies provide a more detailed picture. Nevertheless, their results may also be ambiguous. Dalury et al. stated that the first place among the reasons for revision arthroplasty is implant instability and infection [4], and according to Thiele et al. the leader among the indications for revision is instability of the implant components followed by instability of the ligamentous apparatus while infection takes only the third place [5]. Sharkey et al. reported that polyethylene wear was the most common cause of revision, observed in 19.4 % of all revisions at their institution [6]. However, 10 years later, Sharkey et al. reported that aseptic loosening (39.9 %) surpassed polyethylene wear (3.5 %) [7]. Recently, polyethylene wear has not been considered as an isolated indication for revision arthroplasty since there is an opinion that wear products initiate the development of osteolysis.

The existing discrepancies in knee arthroplasty registries that may determine indications for revision TKA lead to confusion regarding the identification of the leading pathology. Thus, some authors consider pain in the knee joint in the absence of proven presence of other types of complications as a separate indication for revision. However, the cause of this condition may be unspecified infections, instability of the ligamentous apparatus, misalingment of components, or progression of osteoarthritis. Many works indicate not only one but several reasons for revision, what makes comparison difficult. Thus, the issue of categorizing indications for revision TKA is a weak point of the available registries and any large retrospective series.

Purpose of the work was to systematize the etiology of pathological conditions leading to revision knee arthroplasty.

MATERIALS AND METHODS

The study included 361 clinical records in 288 patients who underwent revision arthroplasty between January 2016 and December 2019. The study was conducted at the SSMU Research Institute for TO&N, approved by the local ethics committee (protocol dated 10.04.2018 No. 8), included in the scientific research plan of SSMU (state registration number NIOKTR AAAA-A18-118050890023-7).

As part of the study, we analyzed the etiology of complications that determined the indication for revision TKA, including time after primary TKA; calculated the rates of revision interventions; various demographic data, including age, gender, body mass index (BMI), presence of concomitant pathology; surgical techniques used to perform revision TKA.

We define revision surgery as a new intervention on a previously replaced knee in which one or more components (femoral, tibial, liner, patella) are changed, removed, realigned, or added. Revision surgery may or may not be accompanied by re-implantation of new components during the same surgical session (single-stage revision) or at a later date (multi-stage revision). All procedures of single- and multi-stage treatment due to infection were regarded as one revision. We divided all

revision interventions into first and repeated revisions. A repeated (second) revision was defined as an intervention after the first revision arthroplasty. Procedures in which all components were removed and a cement spacer was placed due to infection were also recorded as a separate revision event. The revisions included surgical procedures with arthrotomy aimed at improving the balance of the soft tissues of the joint (arthrolysis), debridement and irrigation of the joint, sanitation of the joint in case of chronic recurrent hemarthrosis. We also interpreted revisions for failure of unicondylar implants due to progressive arthrosis as a separate revision intervention.

Time to revision was defined as the interval between primary arthroplasty and the first revision, and between the first revision and re-revision. In cases of two-stage revision, we used the date of re-implantation as the end time point of revision. Due to the lack of a consistent and generally accepted categorization of revision periods into early and late in the literature, we adhered to those proposed by Sharkey et al. time intervals: up to two years was early revision, more than two years was late revision [6].

Diagnosis of pathological conditions was carried out as follows. To confirm periprosthetic infection, the criteria of the International Consensus of Joint Infection were used [8]: the presence of a fistula, double detection of the infectious agent during bacteriological examination of punctate synovial fluid of the knee joint and biopsy specimens, leukocytes and neutrophils counts in synovial fluid. X-ray data were used to detect osteolysis in the implant area. To assess the spatial orientation of the components, radiography was taken in a standing position capturing the hip, knee, and ankle joints, and, if necessary, computed tomography (CT) was used. Spatial orientation of the components and failure of the knee joint ligaments was confirmed intra-operatively. Findings were compared with national registries and published studies.

Statistical data processing was carried out using SPSS 21.0. The normality of the distribution of quantitative characteristics was assessed using the Kolmogorov – Smirnov and Shapiro – Wilk methods. Given the non-normal distribution of most quantitative characteristics, nonparametric statistical methods were used. To describe quantitative parameters, median and quartiles were used. Analysis of differences between groups in quantitative characteristics was carried out using the Mann – Whitney U-test. For qualitative characteristics, the Pearson Chi square test was used. Results were considered significant at $p < 0.05$, and two-sided significance was assessed for all criteria.

RESULTS

For the period from 2016 throughout 2019, the SSMU Research Institute for TO&N performed 7,877 knee arthroplasties, of which 7,516 were primary and 361 were revision. Revision interventions accounted for 4.58 % of the total number of arthroplasties. In 175 cases out of 361 (48 %), primary arthroplasty was also performed at SSMU, 186 patients out of 361 (52 %) were referred to our center from other medical institutions. Among all cases of revision knee arthroplasty, the first revision was performed in 64.5 % (233/361). The second revision was completed in 27.7 % (100/361). The third and fourth revisions were performed in 6.4 % (23/361) and 1.4 % (5/361), respectively. According to gender, revision interventions prevailed in women, amounting to 75 % (270/361). Median age was 65 years (59–71; IQR — interquartile range); BMI was 34 (29-37; IQR). In the majority of cases, the indication for primary arthroplasty was osteoarthritis (82 %).

Among the first revisions, 139 operations (59.7 %) occurred after less than two years after the initial implantation. The median was 19 months (IQR: 11–36 months). In 128 cases (35.4 %) two or more revisions were performed on one joint. 74 % (95/128) of all repeated revisions were completed within two years. In terms of age groups, patients aged 65 to 74 years were more likely to undergo revision arthroplasty (43 %), followed by patients aged 55 to 64 years (38 %).

Among the indications for revision, infection was the cause in 48.2 % (174/361) of cases, aseptic instability in 38.2 % (138/361), instability of the ligamentous apparatus in 4.2 %, contracture/arthrofibrosis in 3.9 %, problems with the patella in 1.7 %, periprosthetic fracture in 1.4 %, spatial

maialingment in 1.1 %, wear of the implant in 0.6 %, and other reasons (prolonged wound healing, separation hematomas in three cases) in 0.8 %. One type of complication was revealed in 98 patients (27.1 %), 263 (85.2 %) had more than one type of complication.

Early complications within two years were observed in 234 patients (65 %), late complications two years or more after primary arthroplasty were detected in 127 cases (35 %). The structure of early and late complications is presented in Table 1. Among early complications, infection prevailed in 126 (54 %) cases, and among late complications, aseptic loosening predominated in 69 (54 %) cases.

Table 1

Primary TKA complications and time to revision

Revision cause	Total (n = 361)		Revision time, months					
			Me (IQR)	Early, < 2 years (n = 234)		Late, > 2 years (n = 127)		p*
	abs.	%		abs.	%	abs.	%	
Infection	**174**	**48**	15 (7–27)	**126**	**54**	48	38	**0.004**
Aseptic loosening	**138**	**38**	24 (12–43)	69	30	**69**	**54**	**< 0.001**
Contracture	14	3,9	10 (3–16)	**13**	**5.6**	1	0.8	**0.024**
Ligaments instability	15	4,2	14 (6–19)	12	5.1	3	2.4	0.275
Patella problems	6	1,7	17 (9–32)	4	1.7	2	1.6	0.644
Misalingment	4	1,1	16 (13–44)	3	1.3	1	0.8	0.56
Periprosthetic fracture	5	1,4	13 (10–86)	3	1.3	2	1.6	0.576
Implant wear	2	0,6	26 (18–26)	1	0.4	1	0.8	0.58
Others	3	0,8	5 (1–5)	3	1.3	0	0	0.271

* — χ^2 (Exact Fisher test)

In 149 (64 %) cases, first revisions were performed after primary TKA with posterior stabilization. In 70 cases (30 %), they were done after installation of endoprostheses with preservation of the cruciate ligament. Table 2 presents the characteristics of the revision interventions performed.

Table 2

Characteristics of revision surgeries performed

Revision intervention	All revisions (n = 361)		First revision (n = 233)		Re-revision (n = 128)		p*
	abs.	%	abs.	%	abs.	%	
One-stage revision	130	36	88	37.7	42	32.8	0.378
All components changed	99	76	66	28.3	33	25.7	0.392
Femoral components change	4	3	4	1.7	0	0	
Liner change	11	8	9	3.8	2	1.5	
Liner and tibial component change	3	2	2	0.85	1	0.8	
Tibial component change	13	10	7	3	6	4.7	
Change of unicondylar implant	1	0.3	1	0.4	0	0	0.67
Knee cap replacement	5	1.4	3	1.3	2	1.6	0.581
Two-stage revision	193	53.5	132	56.7	61	47.6	0.101
1 stage: spacer installation	31	16	15	6.4	16	12.5	< 0.001
2 stage: change of spacer for implant	156	81	117	50.2	39	30.4	
Spacer change	6	3	0		6	4.6	
Resection arthroplasty	3	0.8	0		3	2.3	0.044
Revision and sanation (debridement, irrigation)	12	3.3	2	0.9	10	7.8	0.001
Arthrodesis	3	0.8	1	0.4	2	1.6	0.287
Arthrotomy, arthrolysis	14	3.9	6	2.5	8	6.3	0.084
Patella ligament plasty (MPFL reconstruction)	1	0.3	1	0.4	0	0	0.645
Osteosynthesis	5	1.4	2	0.9	3	2.3	0.241

Continuator of the Table 2

Characteristics of revision surgeries performed

Parameters	All revisions (n = 361)	First revision (n = 233)	Re-revision (n = 128)	p*
Time of surgery, min	115 (95–135)	115 (95–135)	110 (75–125)	0.592
Blood loss, ml	200 (200–300)	200 (200–300)	200 (200–300)	0.672
Blood loss along the draining system, ml	300 (200–500)	300 (200–500)	300 (200–500)	0.353
Term of hospital stay, days	8 (7–10)	8 (7–10)	9 (8–13)	0.046
Follow-up, months	26 (11–52)	26 (14–55)	24 (11–42)	0.501

* — calculation of the χ^2 test (Fisher's exact test) and the Mann – Whitney U test.

The first and repeated revisions did not differ significantly when comparing the frequency of one-stage and two-stage interventions. Resection arthroplasty and arthrodesis were performed mainly in re-revision. There was an insignificant increase in the median time between stages of surgical treatment with a two-stage approach in the group of repeated interventions (p = 0.523). Operative time, intraoperative and postoperative blood loss did not differ between the first and second revision groups. The median length of hospital stay for the revision procedure was 8 days (7–10 days); arthrotomy procedures were associated with the longest stay of 12 days (10–14 days) and revision of the patellar component associated with the shortest stay of 3 days (3–5 days).

DISCUSSION

According to national registries and databases, there is an annual increase in the number of revision knee arthroplasties along with an increase in the number of primary knee replacements [9, 10, 11]. In the United States, the number of revision TKAs is predicted to increase by 78–182 % over the next 10 years [10]. Complications after knee arthroplasty are not frequent; however, according to the main arthroplasty registries, they range from 2.0 to 11 %. The Australian registry states the revision rate at the average of 8.6 % over the last 20 years [12]. The English registry reports an average of 6.2 % [13], the North American registry of 8.5 % [14]. The same is observed in Russia. According to the register of Vreden NMRC for TO, an increase in the number of revision arthroplasties was 204 % from 2011 to 2019, while the ratio of primary and revision arthroplasties remained unchanged [15]. At SSMU, the annual revision rate increased slightly from 4.8 % in 2016 to 5.9 % in 2019. The average annual revision rate among all knee arthroplasties for 2016–2019 amounted to 4.6 %.

In our study, the median time between the first operation and revision arthroplasty was 17 months (9–34, IQR). The interval is lower than the data of foreign authors. According to a study by Postler et al., which included 402 observations, the time between primary arthroplasty and the first revision averaged 8.1 years [16]; Sharkey et al. reported a 7-year interval until the first revision [7]; Thiele et al. showed an average time to first revision of 7.9 years in a series of 358 patients [5]. In our opinion, this may be due to the predominance of patients with early complications in our study. Within two years, the first revision was performed in 234 cases, which was 65 %. Our colleagues had early revisions in 76 cases out of 402, which is only 19 % [16].

The structure and correlation of indications for revision arthroplasty in most foreign studies is ambiguous. Thus, according to Sharkey et al., the main reason for revision was polyethylene wear (19.4 %) [6], but 12 years later the data changed, and the leading reason for revision knee arthroplasty was osteolysis (39.9 %) [7]. Thiele et al. identified the following leading indications for revision: osteolysis (21.8 %), ligament instability (21.8 %) and malposition of implant components (20.7 %) [5]. In the Italian and Australian arthroplasty registries, osteolysis as the main indication for revision, accounting for 33 % and 27 %, respectively. The second place as an indication for re-intervention is taken by infection, which accounts for 27 and 23 % of cases,

respectively [17, 12]. Similar results were obtained from the Swiss registry: aseptic loosening and osteolysis were detected in 21.8 % of cases, infection in 14 % [18]. According to the US database, aseptic loosening was also prevalent in the period from 2009 throughout 2013 [19], but in the subsequent US registry (2012–2021), infection was the main reason for revision (28 %) [14].

The structure of complications of primary knee arthroplasty that result in re-intervention, obtained during our study, is presented in Table 1. Among early complications (up to two years after primary knee arthroplasty), infection predominated (54 %), and among late complications, it was aseptic loosening (54 %). The results are similar to other studies. Thus, within a period of up to two years, the most common indications for revision arthroplasty reported are infection and instability of the ligamentous apparatus [5, 7, 16]. The results of studies in which infection is in the first place among the indications for revision demonstrate the prevalence of patients with an increased BMI [20, 21]. Likewise, in our study, among all revisions, interventions in obese patients predominated; the median BMI was 34 kg/m2 (29–37, IQR).

Two-years after primary arthroplasty, the most common indications for revision are osteolysis with instability of implant components and wear of polyethylene [6, 22]. In our study, among the reasons for early revisions following infection are aseptic loosening and osteolysis (30 %), limitation of the range of motion (contracture/arthrofibrosis) (5.6 %), instability of the ligamentous apparatus (5.1 %), problems with the patella (1 .7 %), periprosthetic fractures (1.3 %), malposition of endoprosthetic components (1.3 %) and implant wear (0.4 %). Aseptic loosening and osteolysis, as indications for early revision, were revealed in 30 %.

Among the complications that arose two years or more after primary arthroplasty, the first places were aseptic loosening (54 %) and infection (38 %), followed by instability of the ligamentous apparatus (2.4 %), problems with the patella (1.6 %) and periprosthetic fractures (1.6 %), malposition of endoprosthetic components (0.8 %) and implant wear (0.8 %). These data do not show any discrepancy with the results of previous studies.

It should be noted that continued studies of the etiology of revision knee arthroplasty may be a step towards improving outcomes and reducing the need for repeated revisions in the future. The data we obtained on the rates of revision arthroplasty indicate that the predictions of our foreign colleagues are coming true [23]. We noted an increase in the rate of revision arthroplasties in the structure of operations on the knee joint from 3.1 % in 2017 to 5.9 % in 2019; in absolute terms, there was also an increase up to 116 operations. In our opinion, this is due to the fact that knee replacement surgery is one of the most common in orthopedics and is performed everywhere. At the same time, a significant number of orthopedic surgeons perform less than 50 arthroplasties per year, and the regularity of this procedure performed by the surgeon has an impact on the incidence of complications [24]. In our opinion, this hypothesis requires testing in future studies and it will likely be necessary to determine the minimum threshold of surgical activity of the orthopedic surgeon to successfully complete the learning curve.

Comparing the time interval between primary and revision arthroplasty, we noted a significant difference between our data and the data of foreign studies. Just one and a half years versus seven years reported by Sharkey et al. [7]. This is explained by the significant proportion of early complications in patients in our study. Complications that developed within a period of up to two years were noted in 234 patients (64.8 %), among whom there were predominantly patients with periprosthetic infection (126; 54 %).

Our data coincide with the data of Postler et al. [16]; infection, as the leading indication for revision, was noted by them in 36.3 %, osteolysis in 21.6 % (our data, 48.2 % and 38.2 %, respectively). However, the situation in the national registries of Germany, Norway and New Zealand is

somewhat different, and osteolysis dominates there as the main reason for revision [25, 26, 27]. This may be explained by differences in patient recruitment for studying. Thus, registers take into account all cases of revisions on the territory of the entire state, and these data can be considered quite objective and correct. In the case of studies conducted at large orthopedic centers, the patient population is somewhat different. Due to the high resource intensity [16, 20, 21] and the requirements for the qualifications of medical personnel necessary for the successful treatment of infectious complications, patients with periprosthetic infection from other medical institutions are concentrated in large federal centers. This fact changes the statistics. This is exactly what can be observed in our study and in the study by Postler et al. [16]. It is worth noting that the trend of the North American Health System Registry indicates an increase in infectious complications in the structure of indications for revision arthroplasty, especially with early revision (within the first three months after primary arthroplasty). The comparison of different reasons for revisions revealed an increase in the infection rate from 18.2 % in 2012 [19] to 28.4 % in 2021 [14]. This fact that the North American registry differs from the European and New Zealand national registries suggests that this trend may soon become widespread. In our opinion, this may be due to the worsening somatic status of patients undergoing primary arthroplasty. The results of the studies in which infection takes the first place among the indications for revision demonstrate the dominance of patients with an increased BMI [21]. Likewise, in our study, among all revisions, operations performed on obese patients prevailed. The median BMI was 34 kg/m^2 (29–37, IQR).

Noteworthy is the fact that we found malposition of the implant components in the majority of patients with contractures of the knee joint, signs of instability of the ligamentous apparatus and pain without confirmed osteolysis and infection,. Component misalignment was identified intra-operatively as oversizing or rotational deviations of the femoral and tibial components. These deviations of the endoprosthesis components in most cases manifested themselves clinically in the form of pain and limited range of motion that arose immediately after primary arthroplasty.

The fact is that the main reasons for patient dissatisfaction, which reduces the quality of life, are pain, limited range of motion and joint instability [28]. However, these symptoms can be a manifestation of various conditions and pathological processes. In our study there were eight of these (from infection and aseptic instability to misorientation and pain of unknown etiology). Many conditions have a common nature. Thus, problems with the patella such as instability or pain, as well as contracture or arthrofibrosis, can be a consequence of spatial misorientation of the components of the endoprosthesis [29, 30]. In our opinion, the entire set of indications for revision (complications of primary arthroplasty) can be divided into three main etiological groups: group I of periprosthetic infection; group II are conditions associated with a response to polyethylene wear products (osteolysis); group III are biomechanical disorders, which include spatial malposition, improper size of the endoprosthesis and all types of instability. According to this categorization, we can offer an explanation of the causes of these complications. Thus, the risk of infectious complications is influenced by the patient's condition (obesity, concomitant pathology and immunodeficiency); in the development of osteolysis, an important risk factor is the quality of the materials from which the implant is made. In particular, high molecular weight polyethylene without cross-linked molecules is significantly inferior in wear resistance to polyethylene made using crosslink technology or impregnated with vitamin E. The complications in the group of biomechanical disorders is caused by errors in the surgical technique of performing the operation and depends on the skill of the surgeon and his equipment with high-precision instruments such as computer navigation or personal resector units. All of the above involves carrying out a set of measures to stratify and manage the risks of developing these complications (Table 3).

Table 3

Characteristics of TKA complication groups

Parameters	I group INFECTION	II group OSTEOLYSIS	III group BIOMECHANICAL DISORDERS
Nosological form	Periprosthetic infection	Aseptic instability Osteolysis Implant migration	Contracture Ligamentous instability Patella problems Disbalance of intervals Displacement Malpositioning
Etiology	Agent + patient's condition	Polyethylene product wear	Errors in TKA performance
Risk factors	Concomitant pathology (obesity, immune deficiency, etc)	Implant material quality and design	Surgeon's learning curve, not accurate instrumentation
Prevention measures	Selection and preparation of patients to surgery	Improvement of TKA implant technical characteristics	Increase the accuracy of TKA through the use of "digital assistants" (CT planning, navigation, personal blocks)

Our study has certain limitations. More than half (51 %) of the patients were referred to our center from other medical institutions located in the same or another territorial subject of the Russian Federation. This may distort the structure of complications due to the fact that treatment of periprosthetic infection, as a very resource-intensive section in traumatology and orthopedics, may not be performed in every clinic. This leads to an influx of patients with infectious complications to our center and changes the distribution of complications towards an increase in the infectious ones. Again, patients who had previously been observed in other clinics were not always able to objectively assess their condition, which led to difficulties in establishing the exact timing of the onset of complications after primary arthroplasty. Diagnostic categories for assessing reasons for revisions vary across databases and registries. The issue of categorizing reasons for revision arthroplasty is a weak point in any large retrospective series, and in our study some reasons may have been misclassified into one group or another. In some cases, several indications for revision were seen simultaneously, and it was not possible to establish the root cause of the complication. Therefore, we used a hierarchy of revision reasons to rank cases with more than one cause, which was the majority of patients (85 %). Given the short follow-up period in our study (2-5 years) compared to some other registry data, complications that often occur soon after surgery (infection) are more common than late complications (aseptic loosening). Despite these limitations, we were able to illustrate data on the etiology of revision arthroplasty in a large group of patients. Future research should include examination of risk factors for revision. To ensure the validity and power of such studies, it is necessary to implement a national registry that will allow the assessment of results in a large cohort of patients.

CONCLUSION

The pathological conditions resulting in revision knee artroplaty can be grouped into 1) periprosthetic infection; 2) conditions associated with a response to polyethylene wear products (osteolysis); and 3) biomechanical disorders that include spatial malposition or improper implant size and all types of instability. Our systematization of the causes of revision arthroplasty may help in further research and will be useful in creating a national arthroplasty registry in Russia.

Conflict of interest *None*

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Ethical statement *The study was approved by the local ethics committee of the Federal State Budgetary Educational Institution of Higher Education Razumovsky Saratov State Medical University of the Ministry of Health of Russia (protocol No. 8 of April 10, 2018) and was carried out in accordance with ethical standards developed in accordance with the Declaration of Helsinki of the World Medical Association.*

Informed consent *All study participants signed an informed consent form.*

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Comparative analysis of five-year outcomes of anterior cruciate ligament tears repaired with different techniques

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Abstract

Introduction Primary repair of the anterior cruciate ligament (ACL) torn from the femur and the synovial membrane being intact can be an indication for two competing methods including dynamic intraligamentary stabilization (DIS) as the saving method and resection of the stump and primary autoplasty as a more traumatic option.

The purpose was to evaluate the five-year results of DIS in comparison with early ACL reconstruction of the knee joint.

Material and methods A review and statistical analysis of outcomes of 72 patients with ACL injuries (47 males and 25 females) were performed. The patients aged between 18 and 45 years (30.9 ± 8.5), with the length of time from injury ranging from 3 to 21 days (10.6 ± 5.0) and the Tegner activity score of 5 (1–9; 5.8 ± 0.9) prior to injury. DIS was performed for the first group of patients (n = 39) who arthroscopically were diagnosed with ACL torn off the femur with the synovial membrane preserved. Early ACL repair was performed for the controls (second group, n = 33).

Results VAS scored 1.4 ± 0.8 in group I and 1.9 ± 0.8 in group II at 6 months, p = 0.004. Patient satisfaction scored 8.0 ± 0.8 in group I and 7.4 ± 0.8 in group II at 12 months, p = 0.003. Tegner activity level scored 6.5 ± 0.9 in group I and 6.3 ± 0.8 in group II at 12 months, p = 0.014. The Lysholm knee score measured 91.1 ± 2.2 in group I and 88.6 ± 3.5 in group II at 12 months, p = 0.001. Five-year dynamic observation showed relapses of anterior-medial instability of the knee joint in 10 patients (13.9 %), with 4 patients in group I (10.3 %) and 6 patients in group II (18.2 %).

Discussion Outcomes of proximal ACL tears with intact synovium can be as good as with ACL repair. Removal of the torn cruciate ligament with the synovium being intact and grafting may be an unnecessary and aggressive approach.

Conclusion Dynamic intraligamentous stabilization as compared to early ACL repair shows a faster recovery of physical activity at a short term and less relapses of knee joint instability at a long term

Keywords: anterior cruciate ligament tear, dynamic intraligamentary stabilization, long-term results of ACL reconstruction

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INTRODUCTION

Anterior cruciate ligament (ACL) reconstruction is the gold standard of surgical treatment for anteromedial instability in acute and chronic cases. The outcomes of the operation are nor always practical for the patients, since only 50–65 % of amateur athletes return to their pre-injury level of sports with the overall rate of poor results reaching 10 % [1–3]. There is growing evidence supporting efficacy of early ACL repairs for acute ACL tears [4–7]. Different results of primary ACL repair of ruptures and femoral avulsions were reported with preserved synovium and without fiber disintegration, so the indications for primary ACL repair have not been clearly defined [8–12]. Dynamic intraligamentous stabilization (DIS) is a method based on primary ACL suturing with increased contact force at the suture site using a polyethylene thread fixed to the femur with a button and a spring device in the proximal tibia [13, 14]. The construct protects the suture during healing and allows application of cyclic forces during early rehabilitation with the results being promising for proximal tears (within the proximal third of the ACL), in particular [5, 15]. Early results of these techniques were explored and presented in a number of publications [16–18].

The purpose was to evaluate the five-year results of DIS in comparison with early ACL reconstruction of the knee joint.

MATERIAL AND METHODS

The study was conducted at the Orenburg Regional Clinical Center for Surgery and Traumatology (ORCCST) between 2018 and 2023. Inclusion criteria included age over 18 years, acute injury (within the last 14 days), complete ruptures of the ACL, high level of motor activity prior to injury with the Tegner activity score not less than 5 (1–9). Exclusion criteria included acute or chronic infections, local or general muscle diseases, injury to collateral ligaments and nerves, knee osteoarthritis of any grade, osteoporosis, fractures of the knee and post-traumatic conditions. Professional athletes were not included in the study. If a participant wanted to leave or did not show up for the follow-up examination, he/she was excluded from the study.

Patients admitted to the hospital for an acute closed injury of the knee underwent a radiological examination to rule out bone pathology. Then MRI was performed within 10 days. Patients were offered to participate in the study if a complete ACL injury was detected. Early arthroscopic ACL reconstruction and debridement of other articular injuries were produced. The essence of the study was explained to the patients and they were informed that the final decision would be made during arthroscopic diagnosis of the injuries. The purpose of the study was explained to the patients and they were informed that the final decision can be made during arthroscopic diagnosis of the injuries: DIS could be performed with no contraindications identified. If that was not possible, ACL repair could be offered with hamstring autografts with impaired menisci to be either sutured or resected. All patients signed informed consent, the study was approved by the local expert board (LEK protocol No. 6 dated January 20, 2018).

A total of 77 patients were selected and included in the study, of which 5 (6.5 %) patients were excluded. Statistical analysis was produced for 72 patients (47 males and 25 females) with the mean age of 30.9 ± 8.5 years (range, 18 to 45 years). The left knee was involved in 25 patients, the right side injury was seen in 47 cases (left/right ratio of 1:1.9). The duration of injury in both groups ranged from 3 to 21 days. (10.6 ± 5.0). The mechanism of injury included falls(n = 26; 36.1 %), sports

activities (n = 46; 63.9 % (all amateur athletes)), alpine skiing (n = 16; 22.2 %), football (n = 13; 18.2 %), hockey (n = 6; 8.3 %), athletics (n = 6; 8.3 %), basketball (n = 5; 6.9 %). The mean height was 175.7 ± 8.0 cm, the mean weight measured 71.4 ± 8.1 kg, the mean body mass index (BMI) was 23.6 ± 3.0 kg/m^2, the Tegner activity score was not less than 5 (1–9) before injury with the mean of 5.8 ± 0.9. Comparison of the means between the groups showed no statistically significant differences (Table 1).

Table 1

Patient gender characteristics

Description		Patient			p*
		Group I	Group II	Total	
Quantity	abs.	39	33	72	0.891
	%	47.6	52.4	100	
Gender	M	25	23	47/	0.732
	F	14	10	25	
Involved side	R	25	17	42	0.287
	L	14	16	30	
Age (Me ± SD, years)		30.9 ± 8.2	31.0 ± 8.9	30.9 ± 8.5	0.961
Time from injury to surgery (Me ± SD, days)		10.7 ± 5.2	10.5 ± 4.7	10.6 ± 5.0	0.847
Height (Me ± SD, m)		1.75 ± 0.07	1.74 ± 0.08	1.75 ± 0.08	0.923
Weight (Me ± SD, kg)		71.0 ± 8.2	71.9 ± 8.0	71.4 ± 8.1	0.647
BMI (Me ± SD, kg/m^2)		23.4 ± 2.7	23.8 ± 3.3	23.6 ± 3.0	0.523
Tegner activity score		5.8 ± 0.9	5.9 ± 0.9	5.8 ± 0.9	0.895

*— t-test for equal means of independent samples in groups I and II

Standard knee arthroscopy was performed under spinal anesthesia using a tourniquet and two typical ports to examine ACL stumps. Examination of the ACL and grading a type A or B injury as classified by A. Ateschrang [16], dynamic involved intraligamentary stabilization (DIS) with Ligamys® fixator (Mathys Ltd. Bettlach Switzerland) using a typical technique were performed for the patients [17]. All the necessary diagnostic intra-articular manipulations were produced for Ateschrang type C injury with removal of the ACL stumps. An injury to the menisci (57 cases out of 72; medial: n = 39, lateral: n = 18) suggested a meniscal suture performed in the "red zone" (n = 23); resection of the torn portion was produced in 34 out of 57 cases. A 4 cm long incision was made in the projection of the adductor muscle tendons with a graft isolated, formed using two tendons folded in half (4-bundle autograft). The technique of ACL repair was typical with the femoral canal formed using the anteromedial approach. The femoral end was fixed with bioabsorbable Milagro Advance (DePuy) 6–10 × 23 mm screws and the tibia was fixed with Milagro Advance (DePuy) 6–10 × 30 mm screws [18]. Postoperative rehabilitation was similar for the patients of both groups.

The 100 mm visual analog scale (VAS) score, 10-point patient satisfaction scale (1 means not satisfied, 10 means very satisfied), the Lysholm and Tegner scores were used at 6 and 12 months. The anterior drawer test (ADT) was performed using a KT-1000 arthrometer (MEDmetric, San Diego, CA, USA) at 30° knee flexion annually for 5 years. The result was considered negative if the anterior displacement was no more than 5 mm and the Lachman test being negative in comparison with the normal knee. The measurements were performed three times, the mean was calculated and the result was entered

into the database. Recurrence of the anterior knee instability was considered in case of repeated injury based on clinical examination (with ADT greater than 5 mm in the anteroposterior direction), a positive Lachman test, MRI and the results of surgical arthroscopic treatment with annual examination (ADT greater than 5 mm and positive Lachman test) in the absence of injury.

For statistical analysis, the two-tailed Student's t-test was used for two independent samples with the *p*-value identified with the IBM SPSS Statistics 22 program. The Kaplan – Meier curve was used to determine the treatment failure (recurrence of anterior-medial knee instability) of single tears (DIS) and ACL repair of multiple ruptures. Differences between both groups were tested using the Log Rank (Mantel – Cox) test. A post hoc power analysis considering the sample size and the group difference measured 0.96 at $\alpha = 0.05$. The differences were considered statistically insignificant at $p > 0.05$.

RESULTS

The patients of both groups had pronounced pain early after surgery which necessitated multimodal analgesia. Patients of group I developed less pain at 6 months as compared to patients of group II (group I: 1.4 ± 0.8; group II: 1.9 ± 0.8, p = 0.004). The mean VAS score was similar with the groups at 12 months and later with no statistical difference detected: (1.1 ± 0.8) and (1.3 ± 1.0), $p = 0.340$.

Patient satisfaction scored 7.3 ± 1.3 in group I and 6.4 ± 1.3 in group II at 6 months with $p = 0.006$. Eight (20.5 %) patients scored their condition at 10, which was not noted in the control group. Patient satisfaction scored 8.0 ± 0.8 in group I and 7.4 ± 0.8 in group II at 12 months with $p = 0.003$.

The measurements echoed with the Tegner activity level test and showed decreased statistically significant values at 6 months as compared to preoperative values in both groups. There was a statistically significant difference of 25 % between the groups ($p < 0.001$) at 12 months and the parameters returned to those prior to injury and even higher with the difference being minimal between the groups but statistically significant scoring 6.5 ± 0.9 in group I and 6.3 ± 0.8 in group II at $p = 0.014$.

Lysholm score measured less than 90 in both groups at 6 months (group I: 89.9 ± 3.6; group II:(85.6 ± 4.2, $p = 0.001$) reaching a higher level at 12 months and measuring 91.1 ± 2.2 in the DIS group and 88.6 ± 3.5 in the ACL repair patients with a statistically significant difference at $p = 0.001$ (Table 2).

Table 2

Results of DIS and ACL repair

Показатели	Follow-up period					
	at 6 months			at 12 months		
	Group I ($n = 39$)	Group II ($n = 33$)	p*	Group I ($n = 39$)	Group II ($n = 33$)	p*
VAS	1.4 ± 0.8	1.9 ± 0.8	0.004	1.1 ± 0.8	1.3 ± 1.0	0.340
Patient satisfaction	7.3 ± 1.3	6.4 ± 1.3	0.006	8.0 ± 0.8	7.4 ± 0.8	0.003
Tegner	4.8 ± 1.1	3.6 ± 1.1	0.000	6.5 ± 0.9	6.3 ± 0.8	0.014
Lysholm	89.9 ± 3.6	85.6 ± 4.2	0.000	91.1 ± 2.2	88.6 ± 3.5	0.001
ADT (mm)	2.2 ± 0.9	2.5 ± 1.0	0.268	2.4 ± 0.8	2.6 ± 1.0	0.463

* — t-test for equal means of independent samples in groups I and II

The ADT measured not greater than 2–3 mm at all follow-up periods in both groups with no repeated injuries noted in patients at 12 months. Control examinations and five-year dynamic observation performed once every 12 months during 60 months showed relapses of anterior-medial instability of the knee detected in 10 patients (13.9 %), with four patients in group I (10.3 %). The patients denied re-injury. Six patients of group II developed recurrent anterior-medial knee instability (18.2 %) due to re-injury (n = 4; 12.1 %) and to no-cause in two cases (6.1 %) (Fig. 1).

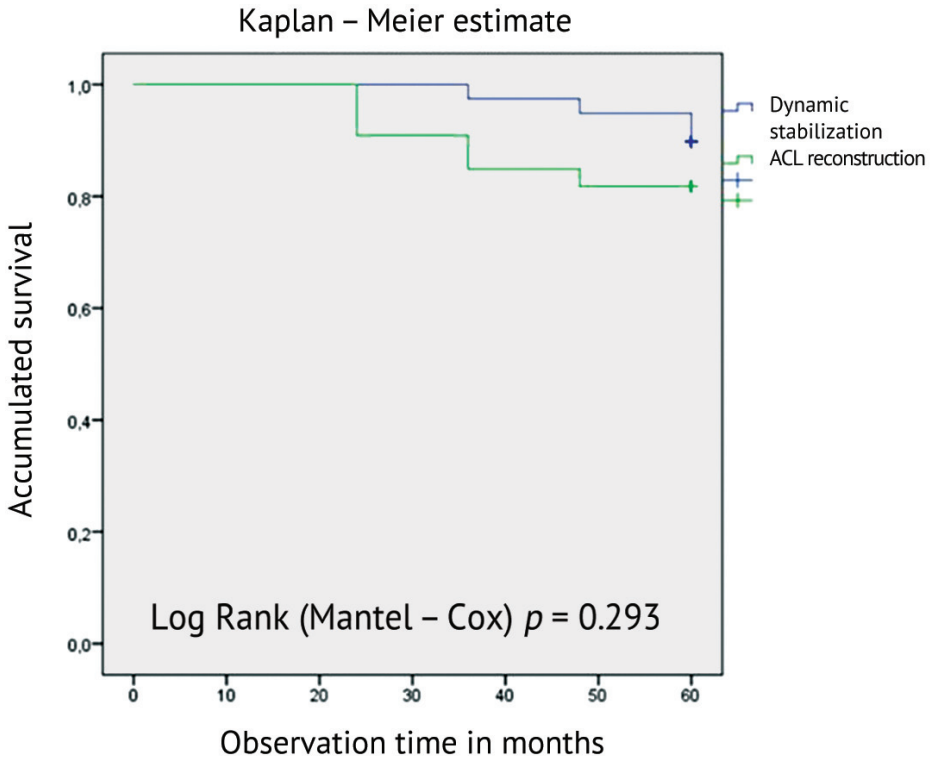

Fig. 1 Kaplan – Meier curve showing significant differences between the groups

Although there was no statistical significance for recurrent knee instability between groups (Log Rank (Mantel – Cox) p = 0.293), the relapse rate was higher in the ACL repair group with spontaneous ruptures without injury being more common in the DIS group.

DISCUSSION

Although a delayed ACL reconstruction approach was a dominant strategy for a long time there has been a renewed interest in the primary ACL suture, which requires discussion and revised indications for surgical interventions for acute ACL ruptures and proximal tears, in particular [8, 9, 15].

However, to justify indications for primary ACL repair, the results must be comparable to the gold standard of ACL repair. Schliemann et al. [11] performed a comparative prospective randomized and reported early functional results and changes in gait pattern after DIS during the first postoperative year. No significant differences between ACL and DIS groups were found for the functional scores (IKDC and Lysholm scales) at any time of the follow-up. [11]. The rate of recurrent instability in this study was 17.7 % within 2.5 years after DIS which was slightly higher compared with other studies.

Kohl et al. reported a re-rupture rate of 6 % and persistent instability in 4 % of 50 patients over two years of follow-up [5]. Henle et al. reported a rupture recurrence rate of 2.9 % and residual instability of 1.1 % [4]. In another study, Henle et al. reported reoperations after ACL reconstructions in 11 % of 96 cases, with a follow-up period of at least two years [14]. Meister et al. reported a relapse rate of 15 % at one year [12]. Osti et al. reported the overall relapse rate of 17.5 % [19]. The results of the series showed the overall failure rate of 17.7 % being higher as compared to ACL repair with the recurrence rate of 3 to 7 % of cases according to a meta-analysis [20].

The asymptomatic course of residual knee instability after ACL repair could be interpreted as a failure and identified as a relapse or a rupture [8, 20, 21, 22]. The condition was caused by the knee instability with the recurrence rate being higher.

Outcomes of DIS suggest that the result of proximal ACL tears with intact synovium may be as good as ACL repair and removal of a torn cruciate ligament with intact synovium and grafting may be an irrelevant and aggressive approach. A prerequisite for a good outcome may be associated with preserved blood supply by the arachnoid periligamentous capillaries in the synovium, which are known to provide blood supply of the ACL [23].

We recognize that the sample size and failure rate in our series were small to provide narrow confidence intervals. However, the cohort size was acceptable to address the primary research question and achieve sufficient power. It should be emphasized that all patients in the group underwent DIS based on an intraoperative decision, which excluded the patient's opinion making the final decision on the surgical method.

Despite these limitations, the results indicate that primary repair of the proximal ACL tears with preserved synovial integrity can be included in the decision-making algorithm for this cohort of patients. However, patient selection is critical. Previous studies have shown a higher risk of recurrence in younger patients — professional athletes, and in patients with a mid-substance ACL injuries [4, 15, 22, 24]. We believe that preservation of the synovial blood supply and the integrity of the ACL proximally torn from the femur can ensure recovery and prevent recurrence.

CONCLUSION

DIS compared with early ACL repair shows a faster recovery of the physical activity at a short term and less relapses of knee instability at a long term.

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

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Ethical review *The study was approved by the local expert board (protocol No. 6 LEK dated January 20, 2018).*

Informed consent *was given by all patients prior to inclusion in this study.*

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Interstitial electrical stimulation for middle-aged, and elderly adults with early stages of knee osteoarthritis

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Abstract

Introduction The adequate, pathogenetically substantiated pain management is essential for treatment of early stages of deforming osteoarthritis of the knee joint. There is a need to explore the effectiveness and mechanisms of modern methods of electrical therapy and their impact on the quality of life due to close cause-and-effect relationship between the pain, inflammatory and destructive components of osteoarthritis (OA) as one of the most common conditions.

The objective was to evaluate the effect of interstitial electrical stimulation (IES) as a monotherapy in the course of conservative treatment of early stages of gonarthrosis based on clinical and biochemical findings.

Materials and methods Radiographic findings, skin electrometry (objective parameters of pain intensity), limb weight-bearing capacity, biochemical parameters of connective tissue matrix degradation in blood serum and 24-hour urine samples, and treatment satisfaction were explored in 43 patients. Patients who received a course of IES were assigned to the treatment group (n = 22) and patients who received standard treatment without IES constituted the control group (n = 21).

Results Electrometric analysis showed a higher effectiveness of pain relief in the treatment group compared to the controls with asymmetry coefficient measuring 3.2 ± 0.31 versus 1.9 ± 0.4 at $p > 0.05$. The weight-bearing scored 3.59 ± 0.34 versus 3.26 ± 0.2 at $p > 0.05$. The treatment group showed shorter treatment length with 13.21 ± 1.2 days versus 18.3 ± 1.2 days in the control group at $p > 0.05$ and a higher degree of satisfaction with outcomes scored 96.2 ± 2.59 in the treatment group versus 86.2 ± 3.17 in the control group. A statistically significant difference ($p > 0.05$) was established in the levels of free and total hydroxyproline characterizing the different intensity of collagen breakdown in the groups at the end of treatment.

Discussion The IES used as an analgesic and anti-inflammatory therapy was shown to be highly effective with changes in the hydroxyproline level in the media suggesting a chondroprotective effect. The analysis and comparison of objective parameters demonstrated high effectiveness of IES in the treatment of early stages of gonarthrosis in middle-aged and elderly adults.

Conclusion The IES used for treatment of early stages of gonarthrosis helps pain reducing the intensity of collagen destruction and improving weight-bearing.

Keywords: osteoarthritis, joint diseases, interstitial electrical stimulation, rehabilitation, gonarthrosis

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INTRODUCTION

Knee osteoarthritis is a degenerative musculoskeletal disease [1] and is diagnosed in nearly 240 million people globally [2]. The prevalence of knee OA is 40–70 % in individuals aged 60 to 70 years with 40 to 65 % of cases being associated with a genetic factor [3]. With the known prevention and treatment measures, the incidence of knee OA is rising and there is an increase in the incidence of arthritis affecting young people that impairs the quality of life in all aspects [4]. Although more effective treatments are available osteoarthritis (OA) is associated with an extremely high economic burden and has an economic impact of 2.5 % of GDP in industrialized countries [5]. There is a search for pathogenetically substantiated methods of treating primary knee OA based on a complex set of biochemical and structural changes that involve all articular components including hyaline cartilage and subchondral bone [6–8]. Different methods for treating the painful and inflammatory components of OA and their combinations including intra-articular injections of blood components, bone marrow and various pharmacological and physiotherapeutic modalities have been shown to be effective. The problem of pain relief in OA is not completely solved and, therefore, is relevant. Bone tissue is rich in osteoreceptors that respond to a decrease in the partial pressure of oxygen in bone vessels, caused by hypoxia and venous stagnation in the subchondral bone [9, 10]. Poor circulation causes chronic bone pain, characteristic of knee OA. It has been proven that the worse the blood supply to the bone, the more intense the pain. Impaired subchondral microcirculation leads to a sharp decrease in the diffusion of essential nutrients into the cartilage matrix. Reduced intraosseous pressure eliminates one of the obstacles to adequate trophism of hyaline cartilage, which is confirmed clinical and biochemical findings. The purpose of the work was to evaluate interstitial electrical stimulation as a monotherapy option in the course of conservative treatment of early knee OA based on clinical and biochemical findings.

MATERIAL AND METHODS

The study included a cohort of patients of both sexes aged 45–65 years ($n = 43$). The clinical examination included a specific assessment of anthropometric parameters and calculation of body mass index (BMI) using the well-known formula:

$$I = \frac{m}{h^2}, \text{ kg/m}^2,$$

where I is body mass index, m is body weight in kilograms, h is height in meters. To rule out obesity, we were guided by body mass index, the presence and severity of concomitant diseases, according to the Clinical Guidelines for the treatment of gonarthrosis (Approved by the Ministry of Health of the Russian Federation on September 3, 2021). The numerical parameter of the comorbidity index (CI) was calculated using the "Environmental Comorbidity Calculator" [11].

Inclusion criteria included:

— a history of an established diagnosis of "knee OA", "arthrosis of the knee joint" (code M17 according to ICD-10);

— disease grade I-II (according to Kellgen-Lawrence) [12];

— one-sided involvement.

Exclusion criteria:

— systemic, allergic, rheumatoid and tumor lesions of joints, aseptic necrosis, obesity grade 1 and over;

— a musculoskeletal pain phenotype being different from mechanical;

— knee surgical interventions;

— kidney pathology;

— diseases of a tumor and endocrine nature;

— Hauser Ambulatory Index of less than 5 [13].

Based on treatment methods, the patients were divided into 2 groups. The control group ($n = 21$) consisted of patients who received treatment including medications, physiotherapy and kinesiotherapy, as featured in the current Order of the Ministry of Health of Russia dated October 27, 2022 No. 706 "On approval of the standard of medical care for adults with gonarthrosis (diagnosis, treatment and dispensary observation)". Individuals who received interstitial electrical stimulation (IES) as monotherapy according to Gerasimov were assigned to the treatment group ($n = 22$). The distribution of the parameters show that the groups are comparable ($p < 0.05$) (Table 1).

Table 1

Characteristics of the patients in the groups

Description		Treatment group	Controls
Male	abs.	10	10
	%	45.5	47.6
Female	abs.	12	11
	%	54.5	52.4
Age (years)		70.00 ± 2.65	69.60 ± 2.93
CI (score)		9.42 ± 0.86	9.73 ± 0.42
BMI (score)		23.85 ± 3.24	23.33 ± 2.3

Note: CI, comorbidity index; BMI, Body Mass Index

The duration of treatment and the number of procedures were individual (from 7 to 21 days) and varied based on the need and condition of the patient. Subjective assessment of the pain intensity was measured with visual analog scale VAS (from 0 to 10 points). Characteristics of pain intensity were determined by skin electrometry according to Gerasimov [14]. The SupportTest original software was used to calculate the lower extremity support ability [15]. The examination was performed with floor scales. The subject stood with one foot on the scales and the other foot on the stand. The scale readings were recorded every 15 seconds within 5 min. The patient's body weight (P) was previously determined on the same scales and was taken as 100 %. The mean P1 was calculated based on the readings of the scales for the leg standing and then the value of the limb's support ability (X) was determined using the formula:

$$X = \frac{P1 \times 100}{P}, \%.$$

The percentage of body weight distribution to the other leg was calculated by subtracting the resulting value from 100 %. The weight-bearing ability of a limb was considered restored if the parameters of the affected limb reached a value of at least (80 ± 10) % of the healthy one. In the absence of impairments and with complete (100 %) restoration of OS, 5 points were awarded; 4, 3 and 2 scored for values of 90, 80 and 70 %, respectively. Markers of cartilage tissue degradation (free and total hydroxyproline) were explored with blood serum and 24-hour urine according to the method offered by Sharaev [16]. Biological material was collected before the treatment and at 45 days of the last procedure or stay in the rehabilitation department. Similar parameters of healthy individuals aged between 45 and 65 years were used as reference values. Satisfaction with treatment was determined according to a personalized assessment of treatment results [17] using the WOMAC (Western Ontario and McMaster University Osteoarthritis Index) scale as the base scale. The research results were processed by nonparametric methods of variation statistics for small samples. Statistical significance of differences was confirmed at $p < 0.05$. The parameters were tested for normality using the Shapiro – Wilk and Tietjen – Moore tests.

RESULTS

Standard radiographs of patients in both groups revealed radiological signs characteristic of the knee OA as described by J. Kallgren and J. Lawrence [12] with a zero value indicating the absence of changes, with a value of I (doubtful degree) showing minor osteophytes. Grade II (minimal) is characterized by clearly defined osteophytes. Minimal narrowing of the joint space (less than 2/3 compared to normal values) was seen in 11 patients with subchondral cysts and minor marginal bone growths noted. No visible changes in bone structure or joint anatomy were detected in 32 cases (Fig. 1).

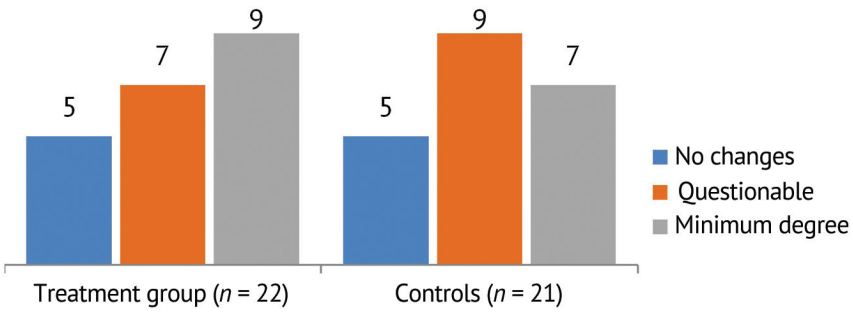

Fig. 1 Distribution of patients according to the Kellgren & Lawrence classification

Objective parameters characterizing the ability to support the limb and the pain were comparable in both groups (Table 1). Preoperative locomotion testing demonstrated impaired ability to support the limb in 70 % of patients in the treatment group and 70 % controls. A comparative analysis of the parameters at a long term revealed a statistically confirmed difference in the values ($p < 0.05$) which indicated a more effective restoration of limb support in the treatment group: (3.59 ± 0.31) versus (3.26 ± 1.2). Preoperative measurements of the skin electrical potential showed presence of pain of varying intensity (from moderate to severe) in the majority of the patients. An objective quantitative measurement of electrical potential in the form of the coefficient of asymmetry (CA) consistently correlated ($r = 0.97$) with similar subjective VAS parameters (Table 2). A clinical and electrometric study confirmed the presence of pain of varying intensity in an equal number of patients, with static and night pain experienced by 55 % ($n = 11$) of patients in the treatment group and 57 % ($n = 11$) of controls. Pain relief was achieved in all patients of the treatment group and in 65 % of controls. Comparison the numerical values of CA at a long term, the presence of mild to moderate pain was established in 15 controls and in 2 patients of the treatment group. The result was confirmed by VAS score. A statistically confirmed difference ($p < 0.05$) was revealed in parameters characterizing the presence and degree of pain intensity at a long term indicating a higher effectiveness of pain therapy in the treatment group.

Table 2

Distribution of anthropometric, locomotor, electrometric and clinical parameters during different periods of treatment

Description	Treatment group ($n = 22$)		Controls ($n = 21$)	
	Pre-op	Post-op	Pre-op	Post-op
VAS (score)	6.7 ± 2.6	0.6 ± 0.02	6.5 ± 2.3	4.6 ± 0,02*
CA (score)	3.2 ± 0.3	1.1 ± 0.1	3.1 ± 0.3	1.9 ± 0,4*
LSA (score)	3.4 ± 0.31	3.59 ± 0.14	3.21 ± 0.2	3,26 ± 0,15*

Note: CA, coefficient of asymmetry; VAS, visual analogue scale; LSA, limb support ability; *, differences between groups are significant at $p \leqslant 0.05$

Similar findings were obtained in biochemical parameters in young healthy individuals aged 30–45 years, who made up the reference group ($n = 20$) and were used as reference values. Preoperative biochemical analysis revealed equally elevated levels of the serum total and free hydroxyproline in both groups ($p > 0.05$). The free hydroxyproline in 24-hour urine tests was

increased, and the values obtained differed from those in the controls indicating increased collagen destruction in both groups (Tables 3, 4).

Table 3

Comparative analysis of biochemical findings in patients' blood serum

Description	Reference group (n = 20)	Treatment group (n = 22)		Controls (n = 21)	
		pre-op	post-op	pre-op	post-op
Total hydroxyproline (mmol/l)	3.28 ± 0.11	3.43 ± 0.08	3.31 ± 0.07*	3.46 ± 0.07	3.06 ± 0.05
Free hydroxyproline (mmol/l)	0.29 ± 0.10	0.25 ± 0.13	0.27 ± 0.06	0.24 ± 0.09	0.28 ± 0.06

Note: *, differences between groups are significant at $p \leqslant 0.05$

Table 4

Biochemistry of 24-hour urine collection from patients of both groups

Description	Reference group (n = 20)	Treatment group (n = 22)		Controls (n = 21)	
		pre-op	post-op	pre-op	post-op
Free hydroxyproline (mmol/l)	0.12 ± 0.01	0.17 ± 0.04	0.12 ± 0.05	0.17 ± 0.02	0.15 ± 0.02*

Note: *, differences between groups are significant at $p \leqslant 0.05$.

A comparative analysis of preoperative and postoperative biochemical parameters measured at a long term of 45.3 ± 1.22 days in the treatment group and at 44.1 ± 1.03 days in the controls revealed statistically significant differences (p > 0.5) indicating improved biochemical parameters of connective tissue metabolism in the treatment group. Personalized assessment of treatment results [17] showed different degrees of treatment satisfaction in the treatment and control groups ($p < 0.05$). The WOMAC score was used as a baseline for assessing knee function [18]. The patients' expectations included pain relief, improved weight-bearing ability, functionality and quality of life. Higher rates of treatment satisfaction were recorded in 95 % of patients in the treatment group and in 55 % of controls. Based on the results of the introductory testing, each group was divided into 2 subgroups (Table 5). The "A" subgroup consisted of patients whose expectations were in the "excellent" range or at the upper limit of the "good" (n = 21). The IE scored ⩾ 85. Subgroup "B" included patients whose expectations were at the lower limit of the "good". The "B" subgroup included patients whose expectations were at the lower limit of the "good". The subgroup consisted mostly of elderly patients with impaired limb support. The IE scored ⩽ 84 in the patients. Analysis of the treatment effectiveness revealed different degrees of treatment satisfaction in patients of the treatment and control groups. The majority of patients in the treatment group were satisfied with outcomes with the intended effect being superior in 25 %. There were less patients in the control group being satisfied with outcomes as compared to those in the treatment group. Two poor outcomes were identified due to low effectiveness of analgesic and anti-inflammatory therapy. Interstitial electrical stimulation and the course of treatment were terminated in the treatment group due to pain relief and the restored limb support. The treatment length differed in the groups measuring 13.21 ± 1.2 days in the treatment group versus 18.3 ± 1.2 days in the control group.

Table 5

Personalized assessment of the results and duration of treatment

Description	Treatment group			Controls		
	A, n = 11	B, n = 6	C, n = 21	A, n = 12	B, n = 7	C, n = 22
IE (score)	91.8 ± 3.8	77.5 ± 6.09*	87.05 ± 8.28	96.2 ± 3.25	85.5 ± 5.68*	92.6 ± 6.59
RO (score)	96.2 ± 3.25	85.5 ± 5.68*	92.6 ± 2.59	89.1 ± 3.68	81.1 ± 2.79	86.21 ± 3.17**
CR (score)	104.9 ± 4.43	110.89 ± 11.3	106.9 ± 7.66	97.9 ± 5.97	106.9 ± 5.15	101.24 ± 7.1
Treatment length (day)	8.2 ± 1.2	11.3 ± 2.2	13.21 ± 1.2	10.2 ± 2.3	13.5 ± 3.4	18.3 ± 1.2**

Note: A, a group of patients with expectations in the "excellent" range or at the upper limit of the "good"; B, patients whose expectations are at the lower limit of the "good"; C, a group of patients with expectations of "excellent" and "good"; IE, intended effect; RO, result obtained; CR, cumulative result; *differences between A and B subgroups are significant at $p \leqslant 0.05$; **, differences between C subgroups of the treatment and control groups are significant at $p \leqslant 0.05$.

DISCUSSION

Early stages of OA are characterized by chronic bone pain of varying intensity and accompanied by characteristic changes in the biomechanical and strength bone properties caused by restructuring and changed quality. Our own clinical observations, confirmed by literature data, indicated the most intense pain being localized in the bradytrophic zones of the bones forming the knee joint (tibial metaphysis) [1, 4]. In addition to pain relief IES can help to restore local microcirculation of the bone and cartilage tissue in the early stages of OA [19]. The previous polarographic and rheographic findings showed a significantly accelerated latent period of oxygen delivery and utilization in bone tissue after a course of electrical stimulation. Restoration of microcirculation and vascularization enhances the activity of energy metabolism processes leading to the elimination of local foci of aseptic inflammation of the bone and restoration of the piezoelectric and biochemical properties [19]. The specificity of markers of degradation and synthesis of cartilage tissue and subchondral bone as the main pathogenetic links of OA is reported [20] with the relationship between structural disorders of the hyaline cartilage and systemic manifestations of the inflammatory response to various (including preclinical) stages of the disease explored [22, 23]. The destruction of collagen fibers is accompanied by an increased excretion of hydroxyproline and an increased content in the blood serum. Hydroxyproline tested in blood serum and urine is a product of collagen breakdown with the free fraction of GP being considered as a marker of destruction, and the bound fraction being a marker of connective tissue metabolic activity [23–26]. A decrease in the total and free hydroxyproline in the blood serum and daily urine was observed in patients of the treatment group after a course of interstitial electrical stimulation suggesting a more active inhibition of the processes of collagen breakdown and restoration of the metabolic activity of connective tissue in this cohort of patients [27, 29]. The biochemical markers we explored had low specificity and high diagnostic significance being an indirect sign of inhibition of collagen breakdown. However, changes in biochemical markers in combination with clinical and electrometric findings suggested a chondroprotective effect of interstitial electrical stimulation with a high degree of probability.

CONCLUSION

IES used for early stages of knee OA can help pain relief reducing the intensity of collagen destruction and improving weight-bearing capacity. Interstitial electrical stimulation is an effective, pathogenetically substantiated method of treating patients with knee OA accompanied by chronic pain.

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Ethical Approval *The local ethics committee decided that the IES method has been introduced into routine clinical practice, has a 15-year period of use, and does not require approval by the local ethics committee for use. Permission to use medical technology "Treatment of pain syndromes of the spine and joints with interstitial electrical stimulation" was issued by the Federal Service for Surveillance in Healthcare and Social Development, FS 210/379 dated 10.26.10. The Vector-MS device used has been in serial production since 2003, registration certificate No. RZN 2013/1050 dated 14.08.13.*

Written ***informed consent*** *for the participation in the research project was obtained from the subject's parent/ legally acceptable representative.*

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MSCT-semiotics of vertebrae in patients with cervical spine stenosis

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Abstract

Introduction The number of surgical interventions on the cervical spine for stenosis has been constantly increasing. This fact proves that there is a need for careful preoperative preparation that would consider the complexity of the intervention and the age of the patients.

Purpose To substantiate the need to include the MSCT data processing algorithm of bone tissue density of vertebral bodies and arches to assess their quality for planning osteoplastic decompressive laminoplasty in patients with cervical spine stenosis due to degenerative changes.

Material and methods This single-center retrospective study investigated qualitative and quantitative characteristics of the spine with radiography and multislice computed tomography (MSCT) in 82 patients with degenerative diseases of the cervical spine and associated spinal canal stenosis (CSS).

Results and discussion The data obtained indicate a tendency for the total density of the cervical vertebrae to increase from C3 to C5 and to decrease caudally, with minimal density in C7 without signs of osteoporosis. A similar trend is characteristic of trabecular bone. The density of the osteon layer of the vertebral arch cortex differs significantly from the density of the outer and inner plates. The total density of the compact layer of the vertebral arch cortex exceeds 785.15 ± 38.4 HU.

Conclusion The data obtained justify the need to include the study of the density of vertebral bodies, vertebral arches, and its thickness in the MSCT data processing algorithm to develop a plan for surgical intervention in patients with cervical spine stenosis in order to obtain objective data on the quality of the bone.

Keywords: spine, cervical spine, stenosis, semiotics, MSCT

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INTRODUCTION

Current imaging techniques provide excellent anatomical images of the cervical spine. The choice among them depends on the clinical scenario and therapeutic alternatives. Polypositional radiography remains a fundamental method, as it allows assessment of the spinal axis, the size and changes of the vertebrae and the subsequent follow-up after treatment, being an economically available and imaging-based examination [1, 2, 3]. The role of MRI has increased significantly and allows visualization of soft tissue formations of the spine, including intervertebral discs, ligaments, the spinal cord, in particular, its mobility, which is extremely important for patients with cervical spinal stenosis (CSS), complicated by myelopathy [2, 4, 5, 6, 7, 8]. Of no less importance is multislice computed tomography (MSCT) in the study of dystrophic changes in the spine due to its high spatial resolution and unique ability to qualitatively and quantitatively assess the condition of the vertebrae, both before treatment and at its various stages [2, 9, 10]. A complex of radiological diagnostic methods is often used in CSS patients to assess the results of treatment [2, 11].

Examination of the anatomy of vertebrae, their architectonics, and density parameters is extremely important for deciding the choice of treatment method for any type of surgical intervention on the spine, including the management of cervical spinal stenosis. Evaluation of bone quality is critical to treatment success in many cases, but it is also part of optimal surgical preparation for spine surgery [12, 13].

First of all, the issue is about assessing the condition of the bone for introduction of implants in different types of transpedicular fixation and other methods of metal osteosynthesis in order to prevent various complications associated with malposition of screws or other structures, failure of metal structures. Much consideration should be paid to patients with pronounced degenerative alterations in density indicators (HU) [14, 15, 16].

Bone density, as an important factor of strength, is determined by various methods, but the most common and universal is MSCT using standardized Hounsfield units (HU), providing a reliable assessment of bone density, improving diagnostic performance [10, 18, 19]. The study of anatomy, architectonics, and vertebral density is carried out using separate methods or in a complex manner, as in the study of Schröder et al., who used micro-CT and MSCT [12]. A histomorphometric study ("gold standard" for studying bone quality) was applied in the work of Grote et al. to assess trabecular bone density [20]. In MSCT studies, cancellous bone density in HU is determined for vertebrae C2–C7 on each sagittal, coronal and axial CT image, the results of computed tomography of the cervical spine (CS) provide reliable information regardless of the measurement plane, age or gender, and degeneration severity [21].

According to Q. Zaidi et al. and Leonova et al., the greatest importance should be given to assessing the density of various structural formations of the vertebrae according to MSCT data in patients with degenerative changes of the spine [15, 22].

The literature sources mentioned above that determined vertebral bone quality based on bone density according to MSCT data studies only some indicators and parameters of the vertebral body and mainly the local density of cancellous bone was measured. However, it is important to know the condition of all structural formations of the vertebra, especially if the laminoplasty method is applied, where the most important anatomical zones for the surgeon are the vertebral arches and facet joints, being the main objects to which the plates are fixed.

Purpose To substantiate the need to include the MSCT data processing algorithm of bone tissue density of vertebral bodies and arches to assess their quality for planning osteoplastic decompressive laminoplasty in patients with cervical spine stenosis due to degenerative changes

MATERIAL AND METHODS

A single-center retrospective study was carried out at the neurosurgical department No. 3 of the Federal Center for Neurosurgery (Tyumen). Qualitative and quantitative characteristics of the spine were studied using radiography and MSCT in 82 patients with degenerative diseases of the cervical spine with spinal canal stenosis.

Level of evidence: IV.

Clinical and statistical characteristics of patients

In the sample there was prevalence of males (86.6 %) aged from 56 to 75 years (70.7 %). The majority of patients (89.0 %) had multilevel spinal canal stenosis (Table 1).

Cervical laminoplasty was performed at levels C3–C6 and C3–C7 in 68.3 % of patients (Table 2).

Table 1

Distribution of patients by age, gender and number of levels of stenosis in the cervical spine

Age	Gender		Number of stenosis levels				
	Males	Females	2	3	4	5	Total
36–40	1	–	–	1	–	–	1
41–45	2	1	–	3	–	–	3
46–50	8	1	1	8	–	–	9
51–55	9	2	2	5	4	–	11
56–60	19	3	8	8	7	–	23
61–65	16	–	2	5	8	1	16
66–70	12	3	2	7	6	–	15
71–75	4	–	1	2	1	–	4
Total	71	11	16	39	26	1	82

Table 2

Distribution of patients by the level of cervical spine laminoplasty

Extension of fixation	Number of patients		Total	
	Males	Females	abs.	%
C2–C4	1	–	1	1.2
C2–C5	1	–	1	1.2
C2–C6	1	–	1	1.2
C2–C7	1	–	1	1.2
C3–C5	5	–	5	6.1
C3–C6	26	5	31	37.8
C3–C7	22	3	25	30.5
C4–C6	7	1	8	9.8
C6–C7I	4	2	6	7.3
C5–C7	2	–	2	2.4
C5–Th1	1	–	1	1.2
Total	71	11	82	100

Methods

1. Polypositional and functional radiography was performed in all 82 patients.

2. Multislice spiral computed tomography (MSCT) was performed in all 82 patients using an Aquilion One X-ray computed tomography system (1385 Shmoishigami, Otawara-shi, Tochigi 324-8550, Japan, 320 detector lines; maximum number of slices was 640).

MSCT was used to assess bone quality (density, structure, dimensions of the vertebral body, arches). Vertebral density measurements were carried out on axial and sagittal sections (total density, density

of cancellous bone, compact layer). The density of the cortex of the vertebral arch in different layers was studied. If necessary, 3D reconstructions were made (Fig. 1).

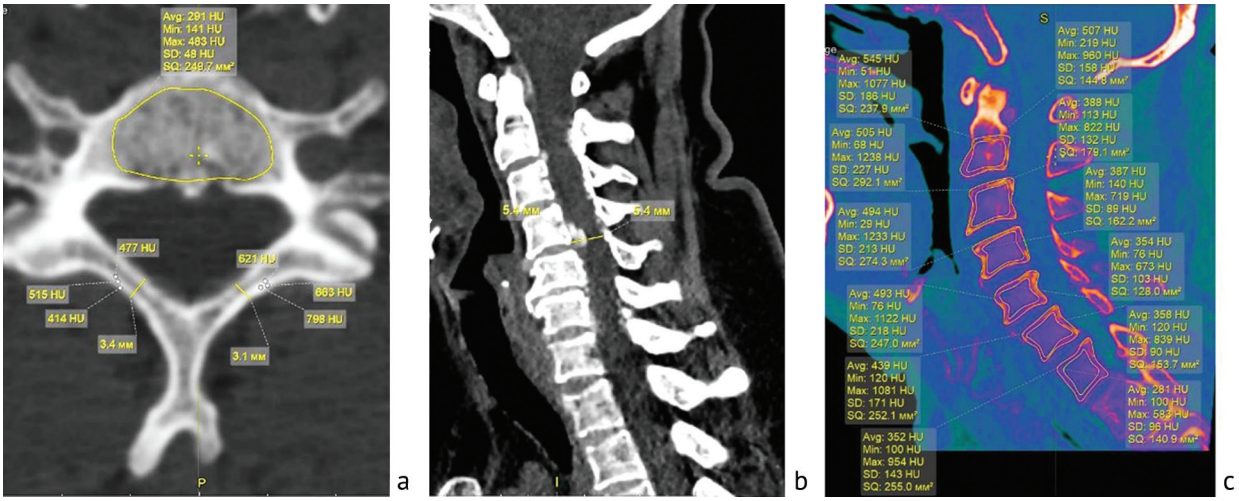

Fig. 1 MSCT of the cervical spine in patients with degenerative disease of the spine and spinal canal stenosis; axial plane, measurement of trabecular (spongy) bone density of the vertebral body, density of the compact layer and thickness of the vertebral arch C5 (*a*), sagittal plane (*b*), sagittal plane, measurement of the total density of vertebrae C3–C7 and trabecular bone density (*c*)

Inclusion criteria:

1) Stenosis of the cervical spine according to MSCT and MRI, complete radiological archive;

2) No history of surgery on the cervical spine;

3) Available patient's consent to the publication of data obtained during the study, without personal identification.

The study was carried out in accordance with the ethical standards of the Declaration of Helsinki of the World Medical Association with amendments by the Ministry of Health of the Russian Federation. All patients signed informed consent for publication of data without personal identification.

Statistical processing of density parameters was carried out using the Attestat program for Microsoft Excel. To confirm the conclusions about the differences between the results obtained in the two groups, given the small samples, the Mann – Whitney U test was used. The sample parameters given below in the tables had the following designations: M — mean, σ — standard standard deviation, n — number of patients, p — achieved level of significance. The critical level of significance when testing statistical hypotheses in this study was taken equal to 0.05.

RESULTS

A study of the total density of vertebrae from C3 to C7 in the sagittal plane showed its increase from level C3 to C4, and from level C5 and caudally there was a decrease in the indicators in descending order, reaching a minimum at C7 level (Table 3).

Table 3

Total vertebral density in patients with cervical spinal stenosis depending on the level, HU

Parameter	Density, HU					
	C2	C3	C4	C5	C6	C7
Mean value, *M*	394.4	445.3	452.2	439.8	411.9	337.1[1]
Standard deviation, σ	51.7	57.4	65.7	74.8	66.4	38.9

[1] — $p < 0.044$

The results of studying the total and local density of cancellous bone of the cervical vertebral bodies are presented in Figure 2.

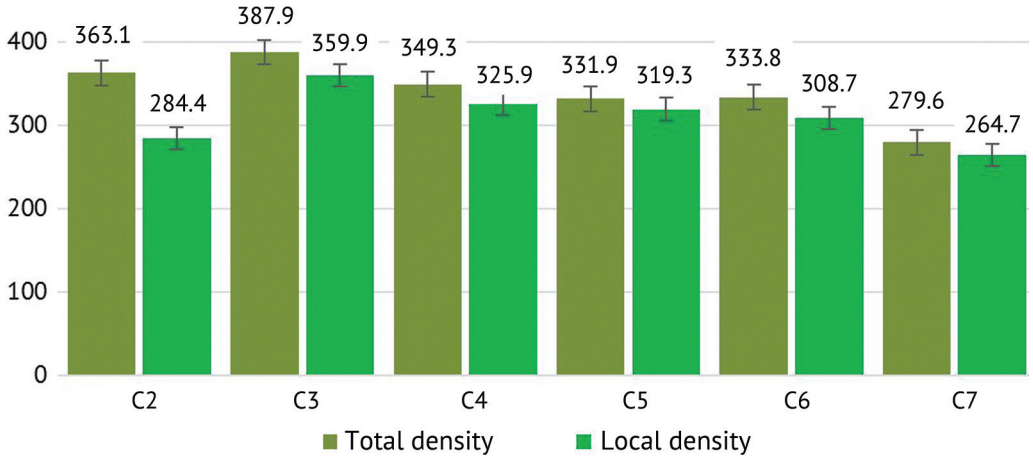

Fig. 2 Diagram of the total and local cancellous bone density of cervical vertebral bodies

Measurement of the density of the vertebral body compact layer in the sagittal plane along the anterior and posterior surfaces showed that the density of the compact layer of bone tissue was higher in the posterior parts of the vertebral bodies compared to the anterior ones, but without significant differences. This is due to the fact that the boundaries of the compact layer and trabecular bone on axial sections are clearly visualized, while in the sagittal plane the boundaries are determined conditionally. The study of the density of the compact layer of the cervical vertebrae along the anterior and posterior surfaces showed that the differences in axial density are significant, except for C7. As for C7 vertebra, it had minimal density with resorption zones and minimal differences along the anterior and posterior surfaces, and therefore the density indicators did not differ (Table 4).

Table 4

Density of the compact layer of vertebrae along the anterior and posterior surfaces in the axial plane, HU

Zone of interest	Density of the compact layer of vertebrae in the axial plane, HU				
	C3	C4	C5	C6	C7
Anterior vertebral surface	449.1 ± 60.8	547.2 ± 21.8	628.5 ± 53.9	436.1 ± 63.1	312.0 ± 45.6
Posterior vertebral surface	516.6 ± 51.6	821.3 ± 48.9[1]	972.4 ± 61.6[2]	599.7 ± 75.7[3]	309.25 ± 42.8

[1] — $p \leqslant 0{,}041$; [2] — $p \leqslant 0{,}034$; 3 — $^{p} \leqslant 0{,}05$

The local total and pointed density of the three layers of the cortex was also studied, since the density of the osteon (central) layer was much higher than the density of the outer and inner plates, which must be considered in preoperative measuring of the density of the vertebral arch to which the plates are fixed during laminoplasty (Fig. 3).

Statistical data on the density of various layers of the vertebral arch cortex are presented in Figure 4.

The density of the osteon layer is 33.3 % greater than the density of the inner plates and 10.4 % greater than the density of the outer plates. This should be taken into account when measuring cortical density of the arch. Measuring in the area of the inner plates, the layer of which is thinner than the osteon layer, very low density values can be obtained. It is necessary to measure the density of all layers not only pointwise, but also by determining the local total density of all layers of the cortex, which was measured in the area of interest in the form of a circle covering the entire thickness of the cortex (ROI = 1.5–2.2 cm2). The local density of all layers of the vertebral arch cortex ranged from 700 to 1150 HU, averaging (785.15 ± 38.4) HU, and in the area adjacent to the facet joints, the density was slightly higher in 75.6 % of patients.

Measuring the thickness of the vertebral arches in the axial plane at an equal distance from the central axis of the vertebra revealed that in 83 % of patients this indicator differed on the right and left sides. On the right the thickness was lower in 45 % of patients (Fig. 5).

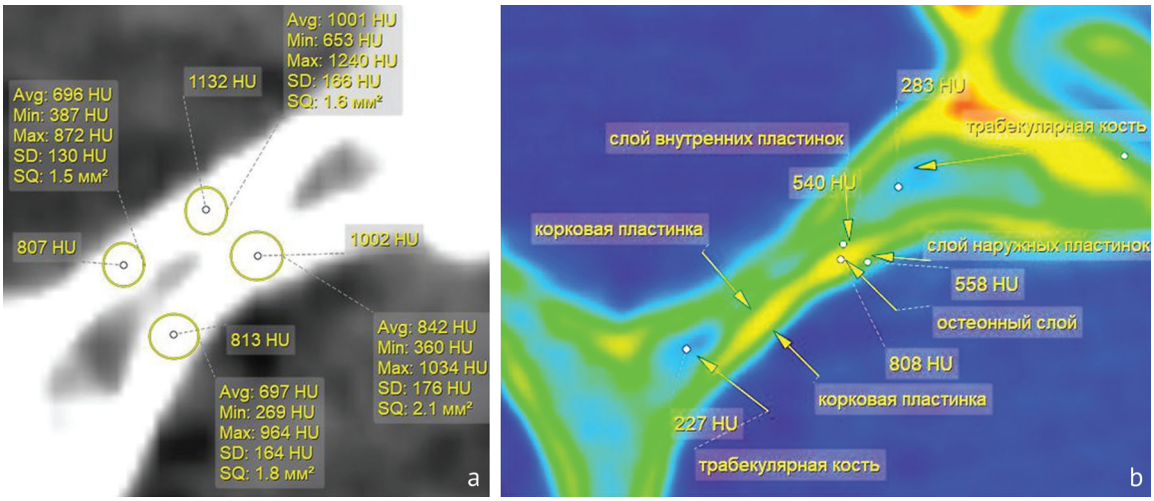

Fig. 3 MSCT of the cervical spine. Axial section of C5; scheme for measuring the total local density of the vertebral arch cortex (*a*); enlarged fragment of the vertebral arch cortex. Determination of the density of the cortex layers. Filter (palette) perfusion (*b*)

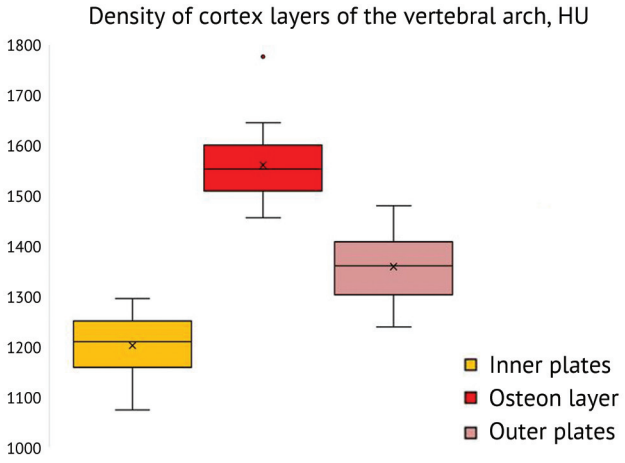

Fig. 4 Diagram of the pointed density of the cortex layers of the vertebral arch. Note In the diagram, the color represents the mean, the horizontal line represents the median, the box represents the interquartile range, and the vertical lines represent error bars

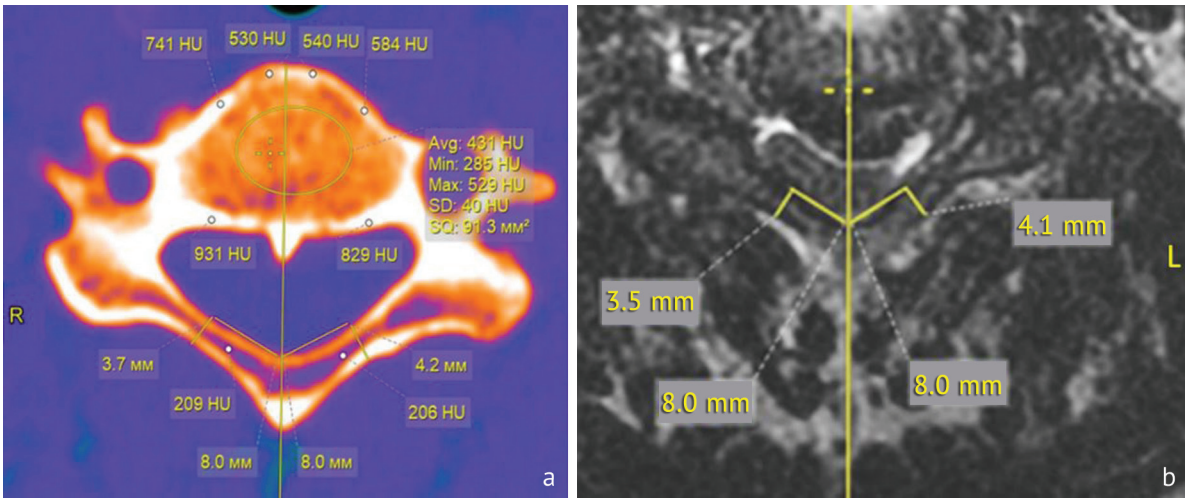

Fig. 5 MSCT of the cervical spine of patient Yu., 65 years old. Axial plane, measurement of the thickness of the C5 vertebral arches at two levels (*a*), MRI of the cervical spine of the same patient, axial plane, Ax T2FRFSE. Measuring the thickness of the arches of the C4 vertebra (*b*)

Table 5 presents data on the thickness of the vertebral arches at levels C3 and C5 on the right and left; measurements were made in all cases at a distance of 8 mm from the central axis of the vertebra.

Table 5

Thickness of vertebral arches at levels C3 and C5 in patients with their different thicknesses

Arch thickness, mm	Zone of interest	
	C3	C5
Right	3.8 ± 0.5	4.1 ± 0.6
Left	4.0 ± 0.3	4.3 ± 0.8

Measuring the thickness of the vertebral arch closer to the facet joint showed that it was by 1.2–1.5 mm greater.

DISCUSSION

MSCT is able to determine not only the nature and extent of changes in the spine but also to study the quantitative density characteristics of the vertebrae in CSS. It enabled to objectively evaluate the state of trabecular and compact bone tissue assessed in Hounsfield units (HU). This conclusion is confirmed by the research of Mikhailova et Lukyanenko [23]. The work of Schröder et al. used micro-CT and MSCT in all examined patients and found that the density of cancellous bone was significantly higher in the cervical vertebrae (average 177.6 HU) than in the thoracic (average 94.4 HU) or lumbar vertebrae (average 62.8 HU, $p < 0.001$). In our study, the density of cervical vertebrae was significantly higher than those data. This is due to the fact that patients with one or two vertebral fractures were examined at the age of (84.3 ± 8.4) years in the mentioned above work, while in our sample the mean age did not exceed (58.9 ± 7.9) years, and there were no patients with vertebral fractures. Moreover, we studied trabecular bone density over the entire vertebral area in the axial plane, whereas the authors mentioned examined a small area in the center of the vertebra. It did not always reflect the overall density [24]. Histomorphometric study (a "gold standard" for studying bone quality) of Grote et al. found that trabecular bone density in the cervical spine was markedly higher than in the thoracic or lumbar spine [20]. Bone loss in the cervical spine was shown to be less with age than in other parts of the spine. There was no significant age-related loss of trabecular density in the C3 and C4 vertebrae, which is consistent with the data of Schröder et al. [24, 25]. In the studies that used MSCT, cancellous bone density in HU was determined for vertebrae C2–C6 on each sagittal, coronal and axial CT images [21]. According to the authors, the mean values of density in Hounsfield units (HU) that can be attributed to osteopenia and osteoporosis were (284.0 ± 63.3) and (231.5 ± 52.8), respectively. The density indicators of the two upper cervical vertebrae (C2 and C3) had a higher density than other segments [21]. According to our data, the trabecular density of the vertebrae was much higher, averaging (387.89 ± 49.14) — (333.81 ± 46.09) for C3–C6. We also studied the density of various layers of the vertebral arch cortex, which is an important object in the surgical scenario. The highest density corresponded to the osteonic layer, which coincides with the data of Dyachkova et al. [26]. The local density of all layers of the vertebral arch cortex ranged from 700 to 1150 HU, averaging (785.15 ± 38.4) HU.

According to Zaidi et al., MSCT assessment of the density of various structural formations of the vertebrae in patients with degenerative changes in the spine should be given the greatest importance [15]. First of all, assessing bone density becomes increasingly important as patient's age grow. Determination of bone quality is critical to treatment success, especially for the prevention of osteoporotic fractures, but is also part of optimal surgical preparation for spine surgery and screw position monitoring [24, 27]. The data obtained indicate a tendency for the total density of the cervical vertebrae to increase from C3 to C5 and to decrease caudally, with minimal density in C7 without signs of osteoporosis. A similar trend is characteristic of trabecular bone. According to Liang et al., it is necessary to determine not only the general and local density of the vertebrae, but also to study it at three levels in the sagittal plane (upper third, central part, lower third) to clarify the effect of disc degeneration on vertebral density [28]. Significant differences in compact bone density along the posterior surface of vertebrae C3–C5 were revealed on axial sections. There is a moderate

asymmetry in the thickness of the vertebral arch on axial sections. The density of the osteon layer of the vertebral arch cortex differs significantly from the density of the outer and inner plates. The total density of the compact layer of the vertebral arch cortex exceeds 785.15 ± 38.4 HU, which is sufficient density for the vertebral arch with regard to all its layers for safe insertion of fixation screws.

CONCLUSION

The data obtained substantiate the need to include the study of the density of the vertebral bodies, of the vertebral arch and its thickness in the MSCT data processing algorithm to develop a plan for surgical intervention in patients with cervical spine stenosis in order to obtain objective data on the quality of the bone.

Conflict of interest *The authors declare that this work, its topic, subject and content do not involve competing interests. The opinions expressed in this article are those of the authors of the manuscript.*

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Original article
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An alternative method for measuring patient's sagittal balance parameters in sitting and standing positions

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Abstract

Introduction The understanding of the biomechanics of movements in the spinopelvic segment plays an important role in the successful treatment of patients with hip-spine syndrome. Analysis of the biomechanical processes occurring in the biokinematic chain of the spine-pelvis-hip during the transition from standing position to sitting position allows us to conclude that the acetabular axis of rotation of the pelvis in space is not the only one. Classical methods for measuring PI, PT, overhang S1 are applicable for patients in a standing position and use the hip joint as a starting point, since it is the point of rotation of the pelvis in space in a standing position. Previously, using mathematical modeling, we described spatial changes in the pelvis during a given change in the body position and showed the presence of a second point of pelvis rotation in space, which appears in a sitting position. We assumed that in a sitting position, it is necessary to use other methods for calculating indicators of spinopelvic relationships for their determination.

Purpose of the study was to evaluate the parameters of patients' sagittal balance using the proposed alternative method in standing and sitting positions.

Materials and methods Medical documentation and the results of X-ray examination of 20 patients with unilateral idiopathic coxarthrosis who underwent total hip replacement surgery were analyzed. The radiographic parameters were calculated: PI, PT, overhang S1 in standing and sitting positions, anterior inclination of the acetabular component; parameters PI ischial, PT ischial, deviation of the ischial tuberosities in standing and sitting positions were proposed and calculated.

Results The study shows that there is no statistical difference in the values of the angles PI standard for a standing position and PI ischial for a sitting position. It corresponds to objective data and is generally accepted. Examples of changes in radiographic parameters of the sacral slope and the deviation of the ischial tuberosities were shown reflecting the rotation of the pelvis in space through the second, ischial axis, that confirm the biaxial concept of pelvic rotation.

Discussion The calculations demonstrated the possibility of using alternative indicators of spinopelvic relationships (PT, distance of overhang of the sacrum (overhang S1), deviation of the ischial tuberosities). They enabled assessment of the spatial transformation of the pelvis and the ability to predict the spatial position of the acetabulum, which is an important factor for successful treatment of patients with combined pathology of the hip joint and spine.

Conclusion Our findings complement the biaxial concept of pelvic rotation. An alternative method for measuring sagittal balance parameters in a sitting position has been proposed. Further research is required to assess the practical significance of this method.

Keywords: spine, hip joint, lower extremity, spinopelvic relationship, orientation, parameters

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INTRODUCTION

Dislocation of the head of the hip joint implant or instability of the hip implant occurs in approximately 3 % of patients after surgery. This complication is the most common early complication of total hip replacement and the most common reason for revision interventions in total hip replacement. The identified risk factors are repeated interventions, low level of surgeon's skills, female gender, age over 70 years, history of previous fractures or arthritis, obesity, the nature of the joint damage and the complexity of the replacement performed, the size of the acetabular component relative to the implant head, and the method of suturing the surgical wound [1].

The spinopelvic relationships recently described in numerous publications show a great interest of orthopaedic surgeons in understanding the kinematics of the pelvis to prevent complications after hip replacement, since the instability of the implant is frequently associated with various deviations in the spinopelvic balance [2–16]. The study of Legaye et al. describes the main parameters of the spinopelvic balance and methods for their measurement [17]. Classical measurements of spinopelvic parameters such as SS, PT, PI and overhang S1 are performed on a lateral radiograph of the pelvis relative to the upper endplate of the sacrum and the femoral heads.

Thus, Legaye et al. formed the idea of pelvic rotation only relative to the heads of the femurs with static centers of rotation, which is a paradigm for orthopaedists. Subsequent investigations considered spinopelvic relationships solely based on the standing position, and for planning operations on the spine, the surgeons proceeded only from spinal curves in the standing body position, without considering their inevitable changes in the sitting position. It obviously does not correspond to real postures in everyday life.

In a previously published article, we used mathematical modeling to describe spatial changes in the pelvis by changing body positions from a standing position to a sitting position, with the formation of a second point of rotation of the pelvis in space, being the ischial tuberosities [18]. Based on that, we made the assumption that in a sitting position, calculations of spinopelvic balance parameters should be made with a different method.

The purpose of the work was to evaluate the parameters of the patient's sagittal balance in standing and sitting positions using the proposed alternative method.

MATERIAL AND METHODS

The study included 20 patients: 8 men (mean age 57 years) and 12 women (mean age 62 years) with ASA II physical status (classification of the American Association of Anesthesiologists) who underwent total hip replacement surgery for unilateral idiopathic coxarthrosis and a healthy contralateral joint, who had a fully restored hip joint function 4–6 months after surgery (Harris hip score 70–75 points), without clinical manifestations of hip-spine syndrome. Non-inclusion criteria were bilateral coxarthrosis, limited range of motion in the contralateral joint, significant difference in the length of the lower extremities (more than 2 cm), dislocations and subluxations in the hip joint, installation of the acetabular component outside the Lewinnek "safe zone", malposition of the femoral component, dislocation, traumatic dislocation of the femoral component which occurred under significant force (trauma, fall from height, etc.), history of periprosthetic infection, obesity of the third grade or more, concomitant pathology of the lumbar spine with clinical manifestations.

The patients took radiographs of the pelvis in standing and sitting positions, in frontal and lateral projections.

Parameters studied:

1. PI ischial (Fig. 1): the angle between a line drawn perpendicular to the middle of the upper endplate of the S1 vertebra and a line connecting the middle of the upper endplate of the S1 vertebra with the lowest point of tuberosity of the ischium (or the middle of the ischium) bone;

2. PT ischial (Fig. 2): the angle between the line connecting the middle of the upper endplate of the S1 ver-tebra with the lowest point of the tuberosity of the ischium, and a vertical line drawn through the lowest point of the tuberosity of the ischium;
3. Deviation of S1 relative to the ischial tuberosities (Fig. 3): the distance between the middle of the upper endplate of the S1 vertebra and a vertical line drawn through the lowest point of the ischial tuberosity. The classic parameter “overhang of S1” reflects the overhang of the S1 vertebra, and ultimately of the pelvis over the support. In the standing position, the support is on the heads of the femurs, in the sitting position on the ischial tuberosities;
4. classical PI (Fig. 4): the angle between a line drawn perpendicular to the middle of the S1 endplate and a line connecting the middle of the S1 endplate to the center of the femoral head;
5. PT is the angle between the vertical and the line connecting the middle of the upper endplate of S1 to the center of the femoral heads.

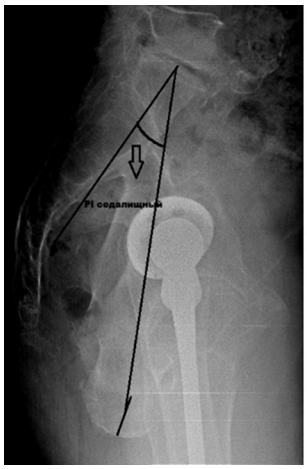

Fig. 1 PI ischial

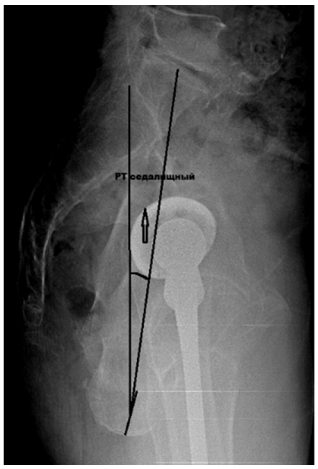

Fig. 2 PT ischial

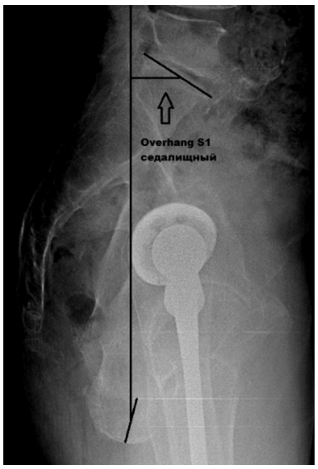

Fig. 3 Deviation of ischial tuberosities

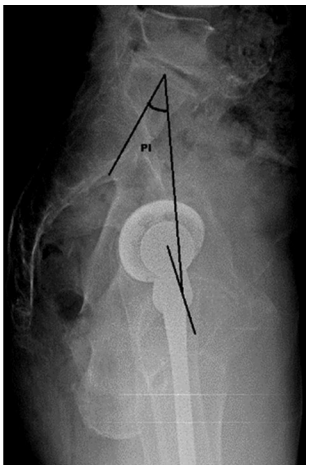

Fig. 4 PI angle

Empirical data distributions were tested for agreement with the law of normal distribution using the Shapiro – Wilk test. Due to non-normality of the data, non-parametric tests were used to compare the parameters. We compared the data obtained with alternative measurements of the parameters PI, PT and overhang S1 and the lateral slope of the acetabulum with the results obtained with the standard measurement using the paired Wilcoxon test. Descriptive characteristics are presented as median [first quartile; third quartile] (MED [Q1; Q3]), mean ± standard deviation (MEAN ± SD), minimum and maximum values (MIN–MAX). To assess the differences between the compared indicators, the pseudomedian of paired differences (PMED) with a 95% confidence interval (95 % CI) and the standardized mean difference (SMD) with a 95% CI were calculated. The difference was considered statistically significant if $p < 0.05$. All statistical calculations were carried out in the IDE RStudio (version 2023.09.0 Build 463 — © 2009–2023 Posit Software, PBC) in the R language (version 4.1.3 (2022-03-10)).

RESULTS

Comparing the results of the standard and ischial PI angles, no significant differences were noted depending on changes in body positions, which corresponds to the concept of incidence (Table 1, Fig. 5 and Fig. 6).

Table 1

Table of values of pelvic incidence (PI, PT) standard and ischil, sacral overhang (overhang S1) and lateral inclination of the acetabular component in standing and sitting positions

Parameter, n = 20		MED [Q1; Q3], Mean ± sd; MIN-MAX		Comparison of standing vs sitting	
		Standing	Sitting	Evaluation of difference PMED [95 % CI] SMD [95 % CI]	Wilcoxon test, p
PI standard		52.5 [49.75; 56.25], 54.4 ± 10.41; 40–78	52.5 [50; 56.25], 54.5 ± 10.4; 39–78	0 [0; 0.5], 0.01 [–0.61; 0.63]	0.813
PI ischial		35 [31; 40.25], 36.75 ± 8.25; 25–55	34 [31.5; 39.25], 36.15 ± 8.37; 22–53	0.5 [0.5; 2], 0.07 [–0.55; 0.69]	0.173
Comparison standard vs ischial	PMED [95 % CI] SMD [95 % CI]	17.5 [17; 17.5], 1.88 [1.13; 2.63]	18 [17.5; 18.5], 1.94 [1.18; 2.7]	–	
	Wilcoxon test, p	< 0.001*	< 0.001*		
PI standard		11.5 [6; 18.25], 12.6 ± 8.18; 1–27	40.5 [35; 44.5], 38.6 ± 10.51; 12–56	26 [25.5; 27.5], 2.76 [1.88; 3.64]	< 0.001*
PI ischial		–5.5 [–12; 3.25], –3.95 ± 8.4; –16–9	20.5 [15.75; 23.5], 19.55 ± 8.03; 1–32	23.5 [22,5; 24], 2.86 [1.97; 3.75]	< 0.001*
Comparison standard vs ischial	PMED [95 % CI] SMD [95 % CI]	17 [16.5; 17], 2.13 [1.58; 2.67]	20 [19.5; 20], 2.16 [1.61; 2.71]	–	
	Wilcoxon test, p	< 0.001*	< 0.001*		
Overhang S1, mm		24.5 [9.75; 36.75], 26.25 ± 17.33; 3–57	75.5 [70.25; 81.25], 73.85 ± 14.68; 32–100	46.5 [36.5; 57.5], 2.96 [2.05; 3.87]	< 0.001*
Lateral inclination of the acetabulum, °		39.5 [30; 48.5], 39.5 ± 11.36; 18–59	61 [51.75; 68], 60.2 ± 12.15; 38–83	20.5 [16; 25], 1.76 [1.02; 2.5]	< 0.001*

Note: * significantly different values, $p < 0.05$

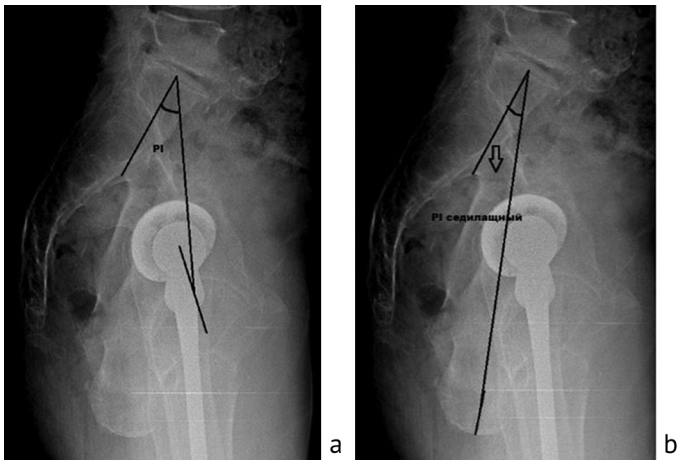

Fig. 5 Lateral radiograph of the pelvis in standing position: *a* finding the PI angle in standing position; *b* finding the PI ischial angle in standing position

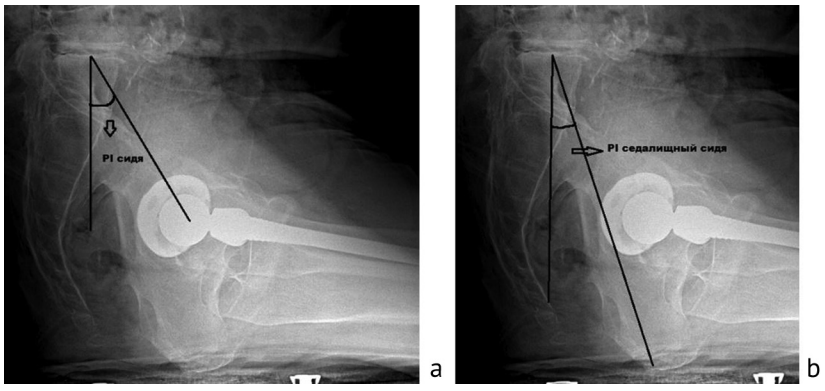

Fig. 6 Lateral radiograph of the pelvis in sitting position: *a* finding the PI angle in sitting position; *b* finding the PI ischial angle in sitting position

When comparing the values of pelvic inclination angles with their standard measurement (PT standard), these changes are consistent with the generally accepted concept. By changing body positions, the angle of inclination of the pelvis in standing position averages 11.5°, and in sitting position reaches 20.5° with an angle difference of 9° ($p < 0.001$), which, in fact, does not contradict the concept of rotation of the pelvis around an axis, drawn through the centers of rotation of the femoral heads. However, if we consider the differences in the angles of inclination of the pelvis (PT ischial) relative to the ischial tuberosities, as a support and the corresponding axis of rotation, then in the standing position the pelvic tilt will be –5.5°, and in the sitting position, respectively, +20.5° with the difference in angles is up to 25°, the values of the standing and sitting angles differ by 2.5 times (Table 1, Fig. 7). This is explained by the true deviation of the pelvis when resting on the ischial tuberosities, since in the final phase of taking the sitting position there is no support on the heads of the femurs bones, and, accordingly, the pelvis cannot rotate relative to them according to the laws of physics. Thereby, the heads of the femurs and acetabulum are displaced posteriorly with simultaneous separation, which is demonstrated in a mathematical model [18].

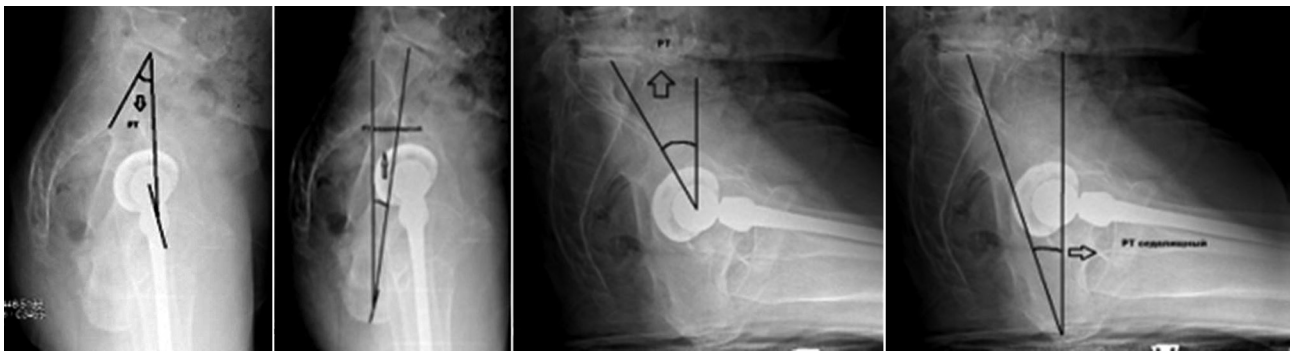

Fig. 7 Lateral radiograph of the pelvis with calculation of standard PT and PT ischial in standing and sitting positions

The last statement is confirmed by the obtained results of measuring overhang S1 (overhang of the sacrum) (Table 1, Fig. 8). Please note that, according to the incidence matrix, the distance (graph) between the vertices (the middle of S and the center of rotation G) relative to the pelvis is constant, and changes that occur when changing the position of the body relative to the vertical drawn from point S are possible only when the pelvis rotates. Thus, in standing position, the average values of overhang are 26.25 ± 17.33 mm with a median of 24.5 mm; the range of values in the group from 9.75 to 36.75 mm reflects the rigidity or excessive mobility of the spinopelvic relations, while by sitting, due to retroversion, the overhang of the sacrum over the center of rotation (acetabulum) decreases, the sacrum shifts backwards increasing the distance from the center of rotation by an average of 75.5 mm ($p < 0.001$).

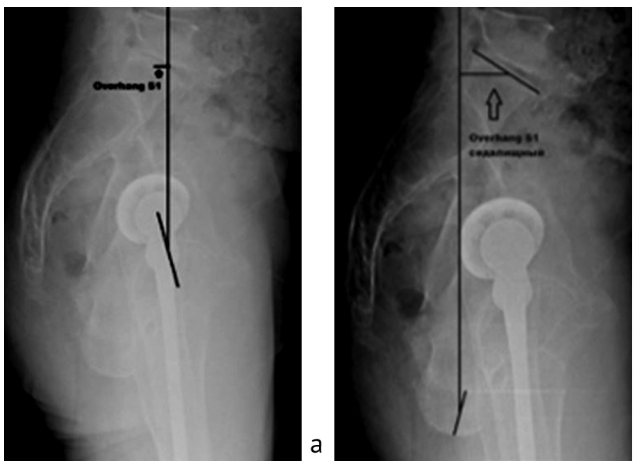

Fig. 8 Lateral radiograph of the pelvis in standing position: *a* finding the value "overhang of S1" in standing position; *b* finding the values of "deviation of the ischial tuberosities" in standing position

Our judgments of sacral deviation are based on determining the distance between two landmarks that are a vertical line drawn from the middle of the endplate and the center of rotation, which is static, as generally accepted. However, if we add a third landmark, taking it as zero, we can evaluate the spatial transformation of the previous landmarks relative to the last one. For this purpose, we introduced a third landmark, proposing the concept of "deviation of the ischial tuberosities" by analogy with the overhang of the sacrum (overhang S1). When measuring the "deviation of the ischial tuberosities," the distances O and V in the standing position were 49.5 mm and 23.5 mm, respectively. But in sitting position, the distances O_1 (15 mm) and V_1 (61) change in inverse proportion, with distance O decreasing and distance V increasing (Table 2, Fig. 9). Changes in the values of $V–V_1$ distance correlate with changes in the values of overhang S1, which reflects the backward inclination of the pelvis (retroversion of the pelvis) and corresponds to the generally accepted deviation; however, a decrease in the $O–O_1$ distance reflects the linear displacement of the acetabulum backward relative to the ischial tuberosities during support on them with a displacement of on average up to 50 mm, while the linear displacement S_1 is 84 mm. This difference is explained by the difference in radii, if the point of rotation of the pelvis upon completion of acquiring the sitting position is the ischial tuberosities.

Table 2

Values of "Deviation of the ischial tuberosities relative to the middle of the endplate S_1 (V) and the centers of rotation of the femoral heads (O) in standing and sitting positions"

Deviation of the ischial tuberosities, *n* = 20		MED [Q1; Q3], MEAN ± SD; MIN-MAX		Comparison standing vs sitting	
		Standing	Sitting	Evaluation of difference PMED [95 % CI] SMD [95 % CI]	Wilcoxon test, *p*
Relative to the rotation centers of femoral heads (O)		49.5 [44.75; 54.25], 48.4 ± 8.88; 27–61	15 [7.75; 21], 14.55 ± 8.13; 1–29	35.5 [28.5;40.5] 3.98 [2.89;5.07]	< 0.001*
Relative the middle of the endplate S_1 (V)		23.5 [15; 36], 25.25 ± 18.64; –23–55	–61 [–70.75; –49.25], –56.7 ± 25.87; –92–24	86.5 [72;99] 3.63 [2.61; 4.66]	< 0.001*
Comparison O vs V	PMED [95 % CI] SMD [95 % CI]	23.5 [15.5;29.5] 1.59 [0.87; 2.3]	74.89 [68.5; 80.5] 3.72 [2.68; 4.76]	–	
	Wilcoxon test, *p*	< 0.001*	< 0.001*		

Note: * significantly different values, $p < 0.05$

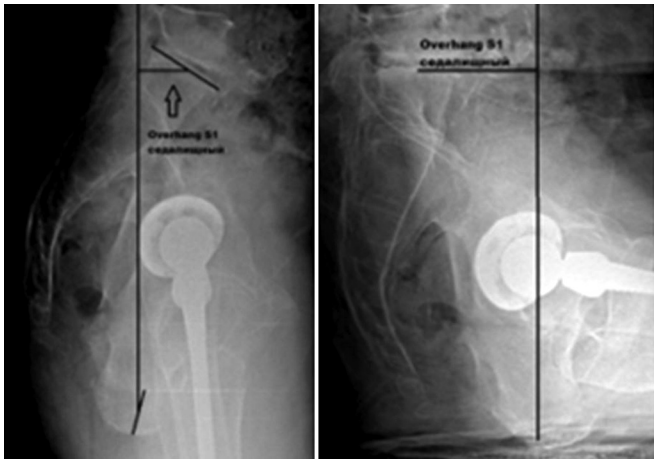

Fig. 9 Lateral radiographs of the pelvis with calculation of the deviation of the ischial tuberosities in standing and sitting positions

Having shown radiographic signs of pelvic kinematics relative to two axes of rotation, in confirmation of the correctness of the mathematical model of pelvic rotation described by us earlier, we assumed that if a second body is installed into the incidence matrix (pelvis), then the spatial transformation of the second body will correspond to the kinematics of the pelvis.

We have come to understand the following situation: if a second body (acetabular component) is installed in a stable rigid incidence matrix (pelvis) with its rigid fixation, then the spatial transformation of the acetabular component will correspond to the kinematics of the pelvis, making turns similar to the rotation of the pelvis. In this case, the spatial transformation of the acetabular component can be assessed by determining the anterior inclination angle of the acetabulum (lateral angle of acetabulum inclination) on lateral radiographs in standing and sitting positions.

A comparative analysis of the lateral inclination of the acetabular component in standing and sitting positions showed significant differences in the angle of lateral inclination (Table 1).

DISCUSSION

The support of the structures of the ilium on the head of the femur forms the points of rotation of the pelvis, centers of rotation, with the formation of the axis of rotation of the latter, characteristic of standing position. For judging pelvic rotation Legaye et al. introduced the parameters of "the sacral slope (SS)" and "the pelvic tilt (PT)". The peculiarity of these parameters is that they are measured in relation to the horizontal SS and vertical PT lines, which are relative zeros [17]. Thereby, the lines that form the above parameters are interconnected. Their relationship is described by the theory of graphs and incidence as a fundamental feature of rigid systems, in particular the pelvis, which has constant rigidly interconnected landmarks with stable connections (distance, angles and direction), which in discrete mathematics is called the incidence matrix [19]. The incidence of the vertices corresponds to the middle of the endplate and the centers of the heads of the femurs, and the edges of the graph are the line connecting them, as well as the vertical and horizontal lines that create the adjacency of the graph vertices to form the parameters SS, PT, PI. Thus, the pelvic incidence (PI) allows us to establish other incident vertices (anatomical landmarks) and connection graphs (horizontal and vertical lines drawn from selected anatomical landmarks) in a connected rigid system, which we used in our work.

From the works of Kapandzhi, we know that there are two main trabecular systems that transfer loads from the spine via the sacroiliac joint to the acetabulum and ischium, bearing the body weight in sitting position [20]. We find confirmation of the existing loads on the femoral heads in the work of Philippot et al., in which the authors describe the positioning of the acetabulum above the femoral head, while the extended hip in standing position allows the load of the upper body to be shunted to the pelvis [21]. The ischial tuberosities in sitting position take on the weight of the body and become fulcrum points, similar to the support of the structures of the iliac bones on the heads of the femurs in standing position. Thus, a second axis of rotation of the pelvis is formed, characteristic of sitting position. In our previous study, we used mathematical modeling to describe spatial changes in the pelvis in changing body positions [18]. For practical purposes, we decided to evaluate changes in the position of the pelvis in lateral radiographs with the possibility of proving the rotation of the pelvis around two axes depending on its position, standing or sitting. To do this, we used new methods for determining spinopelvic parameters.

The method we used is similar to that described by Legaye et al., using the principles of the incidence matrix [17, 18]. But in our study, the radiographs of the pelvis in the lateral view taken in standing posture were supplemented by an additional lateral X-ray of the pelvis taken in sitting position, with the calculation of new parameters: PI ischial, PT ischial, deviation of the ischial tuberosities. Since we assumed that there is rotation of the pelvis if the support goes to the ischial tuberosities in sitting position, we designated the ischial tuberosities with the corresponding point, connected them to the middle of the endplate of the S1 segment of the sacrum and drew a vertical line, obtaining the angles PI ischial and PT ischial pelvic, inherent in the sitting position, similar to PI standard and PT standard pelvic, characteristic for standing position with the pelvis resting on the heads of the femurs. Further, using the parameter to "overhang of S1", in contrast to it, the concept and the parameter "deviation of the ischial tuberosities" was introduced, correlating the ischial tuberosities already designated

by a point with the point indicating the centers of rotation of the heads of the femurs, using vertical lines drawn through the previously designated landmarks by dots. It is assumed that these angles and linear values relative to the vertical zero would characterize the rotation of the pelvis relative to the ischial tuberosities while taking a sitting position, by transition from one axis of rotation of the pelvis to another. We also assumed that the rotation of the pelvis relative to the ischial axis is based on the physical principle of rotation of the wheel with the formation at each point of contact with a hard surface of an instantaneous center of rotation with a linear displacement of the overlying axis of rotation. According to our hypothesis, the acetabular axis (intercapitular axis, a conventionally drawn line through the centers of rotation of the acetabulum) of pelvic rotation is not static, but shifts in space by a linear amount in the direction of pelvic rotation.

Currently, there are studies that question the integrity of the Lewinnek safe zone concept by installing the acetabular component [23]. Many researchers studying the causes of implant instability and searching for the optimal orientation of the endoprosthesis cup focused their attention on the spinopelvic relationship. Thus, McKnight et al. pointed to the importance of the association between the impingement syndrome, implant dislocations and the motion of the spinopelvic complex [7]. The influence of spinopelvic motion on the implantation of the acetabular component was described by Sharma et al. [24]. Phan et al. classified patients according to the flexibility of the spinopelvic segment and whether the spinal deformity was balanced in an attempt to determine the position of the acetabular component and the sequence of treatment in a patient with both spinal pathology and hip pathology [11]. Riviere et al. presented spinopelvic relationships based on patient PI and spinal and pelvic mobility and described “hip users” and “spine users” with their inherent PI, PT, and functional movement patterns [25]. In their other work, they also proposed a method for determining the optimal installation of the cup to create a functional safe zone depending on the type of spinopelvic relationship [26]. Vigdorchik et al. conducted a large study showing the importance of using a personalized approach to arthroplasty in spinal pathology, using the hip-spine classification in preoperative planning [27]. Batra et al. presented their treatment regimen for patients with hip-spine syndrome, based on the degree of mobility of the spine and the characteristics of its relationship with the pelvis [28].

Lazennec et al. described spinopelvic relationships in standing and sitting positions, which were interpreted quite simply, explaining that the spine-pelvis-hip motion is synchronized to ensure hip flexion without conflict between the greater trochanter and the innominate bone or the lesser trochanter with the ischium [22]. However, the evaluation of the pelvic movements was based only on one SS parameter, the slope of the sacrum with a value from 35° to 20°. The statement that sacral slope is the most accurate indicator of dynamic changes is not refuted by us [28, 30].

In our study, which is based on the principle of pelvic incidence, we demonstrated the possibility of using other indicators of spinopelvic relationships (PT, overhang distance S1, deviation of the ischial tuberosities), which allow us to assess the spatial transformation of the pelvis, which was the main goal of this study.

The data we obtained show that there is no statistical difference in the values of the angles PI standard in standing position and PI ischial in sitting position and correspond to objective data that are generally accepted. The term “Overhang S1” proposed by Legaye, overhang of the sacrum S1, reflecting the linear displacement of the sacrum during rotation of the pelvis, corresponds to the concept of uniaxial rotation of the pelvis exclusively around the axis drawn through the heads of the femoral bones, since they are supports, what we indicated above, referring to the works Kapandji and Stefl et al. [20, 30].

However, it is difficult to explain the large backward turn of the pelvis only by rotation relative to one axis. After all, when a person makes successive transitions from lying to standing position and from standing position to sitting position, the movements of the pelvis consist of an increasing

version (tilt) of the pelvis back from 20° to 40°. At the same time, it was noted that the sagittal orientation of the acetabular component or the anterior tilt of the acetabulum (acetabular tilt) changes (increases) consistently with this movement of the pelvis [29]. Accordingly, the second mechanism that provides such variability in the posterior pelvic tilt is complemented by rotation of the pelvis when resting on the ischial tuberosities, which is proven by changes in the values of the overhang of the sacrum, pelvic tilt and deviation of the ischial tuberosities (O, V).

Based on this, it becomes clear that there is a linear posterior displacement during retroversion of not only the S1 endplate, but also of the acetabulum, since these anatomical formations are components of the whole (pelvis). The posterior inclination of the pelvis which we described in a previous article using a mathematical model with the separation of the acetabulum and the head of the femur and formation of a gap of up to 8 mm fully corresponds to the biaxial concept of pelvic rotation. Thus, the significance of the sagittal orientation of the acetabular component becomes clear. Analysis of the angles of the sagittal orientation of the acetabular component, which in our work we called the lateral inclination of the acetabular component, showed changes in the angle up to 30° in accordance with the increase in the version of the pelvis. Tight fixation of the acetabular component with the formation of the vertex of the graph, according to the incidence of the pelvis, results in accurate repetition of the movements of the pelvis and would predict the angle of inclination of the acetabular component in sitting and standing positions. Accordingly, in sitting position, an increase in the angle of lateral inclination of the acetabular component with a linear displacement of the component backwards and separation of the head of the implant and the acetabular component with a decrease in the jump distance will create a high risk for implant dislocation, what possibly lies in the pathogenesis of type VI instability according to the Classification System for the Unstable Total Hip Arthroplasty modified by Wera et al. [31].

CONCLUSION

The findings obtained with the radiographic study and the calculation of radiographic parameters complement the notion of biaxial concept of pelvic rotation, and the obtained data on the changes in the angle of inclination of the acetabular component by changing body position do not contradict the data obtained previously, what confirms the correctness of our results. Further research is required to assess the practical significance of the proposed method for determining the parameters of the spinopelvic balance.

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Features of motor stereotype kinematics and kinetics in children with achondroplasia: a comparative cross-sectional study

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Abstract

Introduction The study of the kinematic and kinetic parameters of gait in children with achondroplasia would allow a more detailed understanding of the features of their locomotion and determine the strategy of planned treatment.

Purpose To evaluate features of locomotor kinematics and kinetics in children with achondroplasia and compare with peers without orthopedic pathology.

Materials and methods The locomotor profile was assessed by video gait analysis. Kinematic data were recorded by Qualisys7+ optical cameras (8 cameras) with passive marker video capture technology synchronized with six dynamic platforms KISTLER (Switzerland). The analysis of kinematics and kinetics was carried out in the QTM (Qualisys) and Visual3D (C-Motion) programs with automated calculation of the values of indicators of the total peak power in the joints. Three groups were formed for gait analysis: 1) children 6–7 years old, achondroplasia (6 subjectsle, $n = 12$ limbs); 2) their peers, children without orthopedic pathology, 6–7 years old (8 subjects, $n = 16$ limbs); 3) children without orthopedic pathology 3–4 years old similar in height (8 subjects, $n = 16$ limbs).

Results In children with achondroplasia, statistically significant disorder in locomotor kinetics and kinematics were found. The former are associated with a longitudinal deficiency of limb segments and decreased walking speed. The latter are not associated with a longitudinal deficit, but manifested in all planes, namely: an increase in the maximum forward inclination of the pelvis, a flexion position in the hip and knee joints, and dorsal flexion of the ankle joint; increased maximum angle of hip abduction and varus deformity of the knee joint; increased rotational range of motion of the pelvis.

Discussion Since the characteristic features of the main gait profile begin to appear in children by the age of 4–5 years, and is associated with the formation of the activity of central and spinal generators that induce the self-organization of motor stereotypes, we believe that the deviations detected in the locomotor kinematics are secondary pathogenetic manifestations of the kinetics due to the longitudinal deficit in limb segments.

Conclusion Features of locomotor kinetics in children with achondroplasia are due to the longitudinal deficit of the limb length and are associated with low walking speed. Significant deviations of the locomotor kinematics were not associated with the longitudinal deficit of the segments, but were detected in all planes and are related to the entire biomechanical chain.

Keywords: achondroplasia, healthy children, gait analysis, locomotor kinetics and kinematics, limb lengthening

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INTRODUCTION

Achondroplasia is a skeletal dysplasia, a genetic disease with an incidence of 3.7–4.6 per 100 thousand newborns [1, 2]. Disproportional body constitution in achodroplasia is characterized, among other things, by a violation of the coefficient of proportionality between the height and body weight: a significant selective lag behind healthy peers in long bone growth of the lower extremities and to a less extent in the growth of the contractile part of the muscles, but complete preservation of their contractile properties [3, 4, 5].

It should be considered that in children under 5 years of age, the age when the maximum muscle strength parameters are recorded, the anatomical and functionally optimal lengths of the limbs do not coincide. Longitudinal muscle growth in young children may runs independently of bone growth, while in adolescents it is largely influenced by bone traction [6].

Other gait features include excessive abduction of the femurs combined with a flexion position in the hip joints, hypermobility of the knee joints in the frontal plane with the formation of varus deformity of the knee joint due to the tibia [7] and its recurvatum [8, 9].

The above features in combination with a wide pelvis, varus and torsion deformities of the lower legs, thoracolumbar kyphosis, lumbar lordosis, and reduced muscle strength together lead to delayed motor development and impaired walking function [2, 9, 10, 11, 12]. The consequence of biomechanical disorders is an inevitable increase in energy consumption by walking: increased oxygen consumption and intensified metabolism during motor tests [13]. In the literature, kinetic analysis of gait in children with achondroplasia, including joints, have been reported without comparison with the control group [10, 14].

The number of works that studied the kinematic and kinetic features of gait in children with achondroplasia is limited and insufficient [8, 15]. Uncertainty adds to the observation of a weak correlation between radiological and kinematic parameters describing angular deformities. The standard for gait assessment is three-dimensional computer-assisted gait analysis (3DGA). A combination of kinetic and kinematic parameters of the general gait pattern is recommended as an expert level for objective documentation of detected changes [16, 17].

The study of kinematic and kinetic parameters of gait in children with achondroplasia would allow to understand details of locomotion in such a disproportional condition, especially in comparison with peers (by age) and children without skeletal dysplasia but with the closest definitive dimensions of the lower limb segments, and to monitor changes in the parameters during growth of the children that undergo pathogenetic pharmacological treatment [10, 18, 13].

The purpose of the work was to assess the characteristics of locomotor kinematics and kinetics in children with achondroplasia in comparison with their peers without orthopedic pathology.

MATERIALS AND METHODS

The locomotor profile was assessed using computer gait analysis (CGA) in 6 children (12 limbs) with achondroplasia in an inpatient setting. Inclusion criteria were a confirmed diagnosis of achondroplasia, age 6–7 years, and no previous pathogenetic pharmacological or orthopaedic surgical treatment. The comparison groups included 16 children without orthopaedic pathology. Healthy children were selected for examination according to the criterion of a similar age (6–7 years) and or to the criterion of close “standing height” in a group of children 3–4 years old as far as examination of younger children to study gait parameters is technically difficult. The examined children underwent a computer analysis of walking parameters at the Ilizarov Center Gait Analysis Laboratory. They walked independently, barefoot, on a 7-meter platform at their usual speed.

There were three groups in the study:

Group I, children in the age of 6 to 7 years with achondroplasia (6 subjects, 12 limbs);

Group II, children in the age of 6 to 7 years without achondroplasia (8 subjects, 16 limbs);

Group III, children in the age of 3 to 4 years without achondroplasia who had the closest height with the affected children in standing position (8 subjects, 16 limbs).

Kinematic data were recorded using Qualisys 7+ optical cameras (8 Qualisys cameras) with passive marker video capture technology; synchronized with six KISTLER dynamometer platforms (Switzerland). For setting the markers, the IOR model was used. Analysis of kinematics and kinetics was carried out in the QTM (*Qualisys*) and Visual3D (*C-Motion*) programs with automated calculation of values [19]. Indicators of the total (generation + relaxation) peak power of the joints were calculated [20]; the total general peak power being the sum of the absolute values of generation and relaxation; values of useful peak power being the difference between the absolute values of generation and relaxation on the kinetics graphs [21]. Overall mechanical efficiency was defined as the ratio of positive (useful) peak power to total power [22].

The AtteStat 12.0.5 program was used for statistical data processing [23]. Due to the number of subjects in the groups, nonparametric statistics were used to process the results, accepting a significance level of $p \leqslant 0.05$. Quantitative characteristics of the sample populations are presented in the table as medians with a percentile distribution level of 25÷75% and a number of cases (*n*) equal to the number of limbs. The statistical significance of differences was determined using the unpaired Wilcoxon test.

A permission to conduct the study was obtained from the Ethics Committee of the National Ilizarov Medical Research Center for Traumatology and Orthoapedics (protocol dated October 21, 2021 No. 2(70)). The studies were conducted in accordance with the ethical standards of the Declaration of Helsinki of the World Medical Association "Ethical Principles for Medical Research Involving Human Subjects" as amended in 2000, and the "Rules of Clinical Practice in the Russian Federation" approved by the Order of the Ministry of Health of the Russian Federation dated June 19, 2003 No. 266. The parents of children who participated in the study were present during the tests and gave informed consent for its conduct and publication of research results without personal identification.

RESULTS

Table 1 presents anthropometric data of children of all three groups. The height of patients with achondroplasia was significantly different not only from their peers (by 8.8 σ), but also from children aged 3–4 years (by 2.3 σ). The weight of children and the length of the lower limbs differed significantly only with the group of peer children; there were no significant differences with the group of 3-to-4-year old children.

Table 2 shows the spatiotemporal parameters of gait.

The presented data show that the length of the gait cycle and walking speed in the group of children with achondroplasia were significantly reduced only in comparison with the second group (peers 6–7 years old), which is obviously associated with a significantly shorter length of the lower limbs.

The parameters of movement kinematics are presented in Table 3.

Table 1

Anthropometric data of the examined children

Parameter	Group I (*n* = 6)	Group II (*n* = 8)	Group III (*n* = 8)
Height, cm	97.5 (90÷98,0) *P^2 = 9.19E-6* *P^3 = 0.00169*	120 (117 ÷ 122)	102 (102 ÷ 103)
Weight, kg	17.5 (16.1÷19.0) *P^2 = 0.0347*	23,0 (19,6 ÷ 25,8)	15.4 (14.9÷17.4)
Lower limb length, cm	42.0 (38.0÷44.0) *P^2 = 1.41E-05*	54.5 (52.0÷56.0)	44.0 (42.4÷45.0)

Note: P^2 — level of significance by comparing the parameter of the achondroplasia group with group II; P^3 — level of significance by comparing the parameter of the achondroplasia group with group III

Table 2

Spatiotemporal indices of gait

Parameter	Group I (*n* = 6)	Group II (*n* = 8)	Group III (*n* = 8)
Walking speed, m/sec	0.67 (0.65÷0.68) *P^2 = 0.012*	1.04 (0.97÷1.05)	0.78 (0.72÷0.82)
Length of gait step, m	0.57 (0.53÷0.73) *P^2 = 0.037*	0.97 (0.85÷1.02)	0.74 (0.69÷0.79)
Duration of stance phase, %	62.4 (61.5 ÷ 63.5)	61.9 (61.4 ÷ 62.3)	62.6 (61.7 ÷ 63.8)
Duration of swing phase, %	37.4 (36.3 ÷ 38.3)	38.0 (37.7 ÷ 38.5)	37.4 (36.3 ÷ 38.3)
Duration of double support phase, %	25.3 (22.5 ÷ 28.5)	22.9 (22.5 ÷ 24.6)	25.3 (22.5 ÷ 27.9)
Gait cycles per minute	70.6 (61.7÷72.4)	64.5 (63.3÷65.4)	65.1 (62.1÷66.8)

Note: *P^2* — level of significance by comparing the parameter of the achondroplasia group with group II

Table 3

Kinematic parameters

Parameter	Group I (*n* = 12)	Group II (*n* = 16)	Group III (*n* = 16)
Gait profile score (GPS)	12,3 (11.0÷13.9) *P^2 = 0.00367, P^3 = 0.011*	8,2 (8.0 ÷ 8.4)	9.7 (9.0 ÷ 10.3)
Foot position at initial contact, °	6.6 (3.4÷10.2) *P^2 = 0.00098, P^3 = 0.00011*	−0.3 (−2.6÷1.9)	−2.6 (−3.4÷0.5)
Angle of maximum dorsiflexion of the foot in stance phase, °	16.7 (15.2÷18.2) *P^2 = 0.00015, P^3 = 9.27E-06*	11.6 (10.2÷14.3)	10.6 (8.5÷12.1)
Foot position in swing phase,°	12.5 (7.8 ÷ 14.5) *P^2 = 0.00759, P^3 = 0.00090*	5.7 (2.8 ÷ 6.9)	4.7 (1.8 ÷ 6.6)
Range of plantar flexion, °	20.1 (16.2÷24.1) *P^2 = 0.0009, P^3 = 0.02434*	28.8 (24.6÷32.6) *P^{2-3} = 0.0167*	24.8 (21.8÷25.6)
Supination in stance phase, °	6.1 (1.3÷7.7) *P^2 = 0.0229*	0.7 (−1.8÷2.5)	1.45 (0.45÷4.3)
Angle of foot orientation relative to the movement vector (max value of internal rotation), °	5.8 (1.6÷9.2)	8.2 (4.7 ÷ 13.1)	9.9 (8.0 ÷ 12.6)
Angle of knee flexion at the initial contact of the stance phase;°	6.7 (0,5÷17.2)	3.4 (1.4 ÷ 7.6)	3.7 (0.7 ÷ 5.8)
Angle of peak knee extension in the stance phase,°	10,7 (8,5÷26,7)	5,7 (1,7 ÷ 8,4)	5,3 (2,3 ÷ 9,4)
Angle of maximum flexion in the swing phase , °	72.6 (70.3÷77.7) *P^2 = 0.00187, P^3 = 4.8E-05*	64.6 (61.6÷67.9)	62.8 (60.6÷64.2)
% of gait cycle of maximum knee flexion in swing phase	73.5 (72.0÷76.3)	73.5 (72.7÷74.3)	75.0 (73.0÷75.3)
Varus (+) / valgus (−) of knee joint (max values), °	5.8 (0.0÷11.5) *P^2 = 0.0388, P^3 = 0.00872*	−0.15 (−2.9÷1.2)	−2.0 (−5.0÷2.0)
Angle of hip flexion at the initial contact of stance phase,°	39.9 (33.5÷41.9) *P^2 = 0.0114, P^3 = 0.00173*	29.6 (24.7÷35.0)	27.5 (24.8÷29.6)
Maximum angle of hip extension in stance phase, °	−0.7 (−6.1÷6.6) *P^2 = 0.00236, P^3 = 0.000321*	−11.7 (−15.2÷−7.7)	−13.6 (−16.6÷−7.3)
Angle of maximum hip abduction, °	10.3 (8.9÷ 14.9) *P^2 = 0.00813, P^3 = 0.000763*	4.7 (2.6÷7.8)	6.2 (3.5÷7.3)
Hip joint range of motion, °	40.3 (39.1÷ 47.4)	45.3 (43.4÷48.9)	43.1 (41.3÷44.2)
Femur rotation (max internal rotation), °	8.2 (3.3 ÷ 18.4)	14.6 (7.6 ÷ 16.6)	13.1 (0.1 ÷ 13.9)
Angle of maximum anterior tilt of the pelvis, °	17.1 (14.8÷18.9) *P^2 = 0.000829, P^3 = 5.92E-05*	8.4 (5.3÷12.4)	8.9 (6.4÷10.8)
Range of pelvic rotation by walking, °	27.2 (18.1÷33.3) *P^2 = 0.000529, P^3 = 4.4E-05*	14.2 (12.8÷18.2)	13.1 (12.7÷14.5)

Note: *P^2* — level of significance by comparing the parameter of the achondroplasia group with group II; *P^3* — level of significance by comparing the parameter of the achondroplasia group with group III

In the groups of healthy children, there were significant differences related to age only in the parameter “range of plantar flexion,” which has a correlation with walking speed ($r = 0.412$, $n = 32$, $p < 0.05$). With regard to kinematic parameters in children with achondroplasia (Table 3,

Fig. 1), one can note a significant increase in the integral indicator of the gait profile score (GPS), which is proposed as a quantitative parameter for identifying typical features of the gait nature.

We should focus on the foot in the dorsiflexion position. There is significant supination of the foot in the stance phase, but there are no significant rotational positions of the foot relative to the vector of movements. Varus deformity of the knee joint was detected, associated with deviation of the biomechanical axis of the lower limb, typical of achondroplasia. In healthy children, physiological valgus of the knee joint was found: for 3 to 4-year old children, maximum deviations of the knee joint for valgus of up to 5.0° were recorded, for 5 to 6-year old children it was up to 2.9°.

The flexion position of the femur at the beginning of the stance phase of the gait cycle and a decrease in the angle of femur extension were recorded, which was concordant with the increase in knee joint flexion in the swing phase. There is a significant increase in the anterior tilt of the pelvis and an increase in its rotational movements.

The total gait assessment in the group of patients with achondroplasia also shows a greater deviation from the norm.

In the examined group of patients, knee joint recurvatum which was combined with extension of the femur was detected in only one patient (Fig. 2). In the normal position of the pelvis and a fully preserved range of motion in the ankle joint, the kinetic parameters reflected a pronounced decrease in the strength parameters of the flexors and extensors of the femur and lower leg.

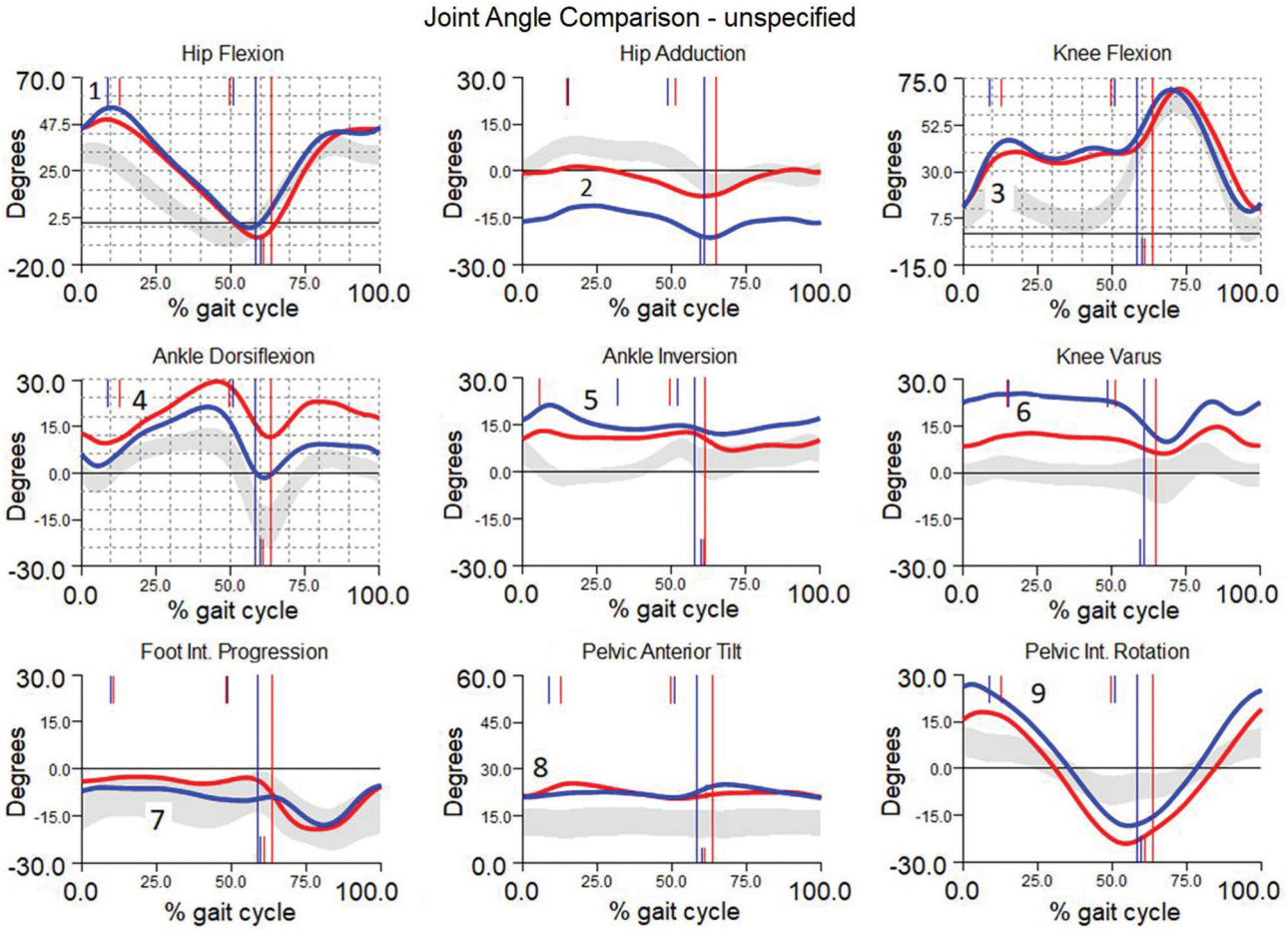

Fig. 1 Example of kinematic graphs showing flexion (1) and abduction of the hip (2), flexion of the knee joint (3), dominant position of the foot in dorsiflexion (4), supination of the foot in the stance phase (5), knee joint varus deformity (6), normal rotational position of the segments relative to the movement vector (7), increased anterior tilt of the pelvis (8) and its rotational movements (9)

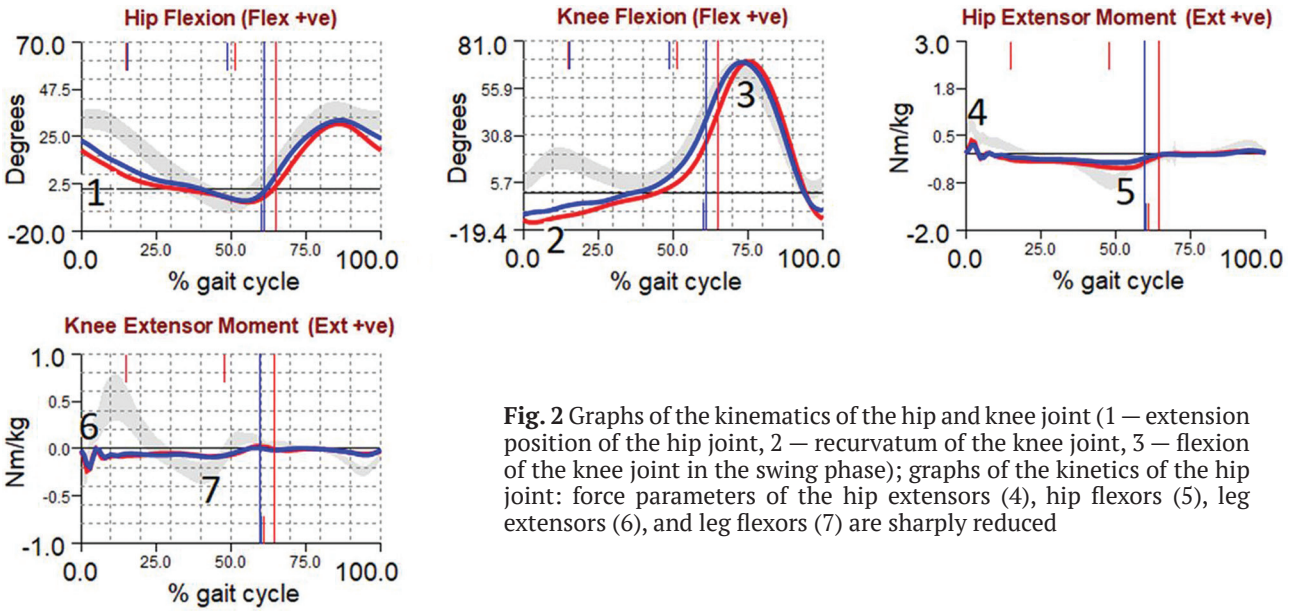

Fig. 2 Graphs of the kinematics of the hip and knee joint (1 — extension position of the hip joint, 2 — recurvatum of the knee joint, 3 — flexion of the knee joint in the swing phase); graphs of the kinetics of the hip joint: force parameters of the hip extensors (4), hip flexors (5), leg extensors (6), and leg flexors (7) are sharply reduced

Tables 4 and 5 present the kinetic parameters of walking in the groups examined.

In the groups of healthy children, a significant age-related increase in the strength parameters of the muscles involved in the motor stereotype was recorded with an increase in walking speed (femur flexors and extensors, femur adductors) and in a heel lift push.

The functional capabilities of the femur extensors and flexors and the lower leg extensors in children with achondroplasia had a significant difference only relative to the peer group (where the mechanical lever is larger). Similar lengths of the segments of the lower extremities (children aged 3–4 years and without orthopedic problems) were not accompanied by significant differences in the strength parameters of these muscle groups. But the indices of the muscle groups responsible for knee flexion and plantar flexion were also significantly reduced in relatively healthy children aged 3–4 years reflecting the influence of the reduced walking speed in such patients. Reduced strength parameters of the adductor muscle group of the femur are a criterion for a decompensated varus deformity of the biomechanical axis of the lower limb.

Table 4

Kinetic parameters of lower limb joints (relative moment of force normalized by weight; N·m/kg)

Parameter	Group I (n = 12)	Group II (n = 16)	Group III (n = 16)
Hip extension	0.36 (0.33÷0.53) $P^2 = 0.00574$	0.62 (0.55÷0.89) $P^{2-3} = 0.00290$	0.49 (0.38÷0.57)
Hip flexion	−0.25 (−0.34÷ −0.21) $P^2 = 0.00218$	−0.48(−0.56÷−0.31) $P^{2-3} = 0.01668$	−0.32 (−0.38÷−0.28)
Hip adduction	0.32 (0.23÷0.37) $P^2 = 1.94E\text{-}05$, $P^3 = 7.2E\text{-}05$	0.62 (0.57÷0.66) $P^{2-3} = 0.02615$	0.53 (0.45÷0.57)
Knee extension	0.24 (0.09÷0.31) $P^2 = 0.03465$	0.34 (0.25÷0.48)	0.31 (0.21÷0.36)
Knee flexion	−0.11 (−0.13÷−0.04) $P^2 = 0.01789$, $P^3 = 0.005327$	−0.18 (−0.26÷−0.12)	−0.18 (−0.24÷−0.11)
Knee extension at heel lift push	0.06 (0.03÷0.11) $P^2 = 0.041$	0.13 (0.09÷0.14) $P^{2-3} = 0.000111$	0.05 (0.03÷0.07)
Dorsal flexion	−0.09 (−0.10÷−0.08)	−0.14 (−0.15÷−0.09)	−0.11 (−0.13÷−0.09)
Plantar flexion (take-off force)	0.58 (0.53÷0.79) $P^2 = 7.2E\text{-}05$, $P^3 = 0.003993$	1.1 (1.05÷1.21) $P^{2-3} = 2.6E\text{-}06$	0.86 (0.83÷0.91)

Note: P^2 — level of significance by comparing the parameter of the achondroplasia group with group II; P^{2-3} — level of significance by comparing the parameter of group II with group III.

Table 5

Indicators of total (generation + relaxation) peak joint power, normalized by weight (W/kg)

Parameter	Group I	Group II	Group III
Hip joint	1.12 (0.86÷1.62)	1.27 (1.05÷1.46)	1.1 (0.94÷1.22)
Knee joint	1.24 (0.83÷1.81)	1.65 (1.46÷2.15)	1.48 (1.30÷1.69)
Ankle joint (push-off)	2.05 (1.41÷2.17) $P^2 = 0.001253$	3.0 (2.62÷4.0) $P^{2-3} = 0.000205$	2.03 (1.85÷2.27)
Total peak power of all limb joints	4.58 (3.31÷6.25) $P^2 = 0.03075$	6.13 (5.38÷7.06)	4.8 (4.05÷5.09)
Useful peak power of all limb joints	0.63 (0.24÷1.01) $P^2 = 0.000763$	1.66 (1.39÷2.73) $P^{2-3} = 0.000974$	0.88 (0.62÷1.27)
Efficiency of joint function, %	58.7 (53.9 ÷61.5) $P^2 = 0.001476$	63.7 (61.8 ÷67.2)	61.0 (58.0 ÷63.4)

Note: P^2 — level of significance by comparing the parameter of the achondroplasia group with group II; P^{2-3} — level of significance by comparing the parameter of group II with group III.

In patients with achondroplasia, the indicators of normalized weight (W/kg) peak power of the push-off, total and useful peak power of joint work were significantly reduced relative to healthy children of the second group, but did not significantly differ from the parameters of healthy 3–4-year old children, where the length that forms the push was almost of the same lever (segment length).

DISCUSSION

Disorders of enchondral osteogenesis in achondroplasia, mainly in the growth plates, lead to pronounced changes in the skeleton, characterized, first of all, by disproportionate short stature [2, 3, 12, 18]. These growth anomalies are reflected, in particular, in altered gait function, accompanied by lower efficiency and increased energy consumption [13, 15, 24].

Relative to weight, the moments of muscle power of the flexors and extensors of the foot are reduced by 15–30 % in patients with achondroplasia, of flexors and extensors of the lower leg by 40–60 % compared with healthy peers [25]. In this pathology due to a shortened lower limb segment, age-related differentiation of the flexor and extensor muscles is delayed: up to 12 years, the maximum strength of the flexor muscles is 30–50 % greater than the maximum strength of the extensor muscles, i.e. the calculated index of antagonistic muscles corresponds to the values of children aged 4–5 years whose segment lengths are approximately equal to those with achondroplasia [26].

Compared with adults, children exhibit lower joint kinetics, speed, and power even after adjusting for age-related dimensional differences due to lower levels of maximum voluntary muscle activation, which is associated with their relative inability to engage or use their “fast twitch” motor fibers, type II [27]. The age-related increase in muscle force parameters in the groups of healthy children is consistent with the data on the kinetics of locomotor stereotypes in healthy children in various speed ranges of movement, where a significant positive correlation was found between walking speed and the total general ($r = 0.907$; $n = 104$) and useful peak power ($r = 0.475$; $n = 104$) of the joint muscles [22].

The temporal parameters of the gait structure determine the walking speed, and the relative duration of the stance phase and the double-support phase decreases with increasing walking speed [28]. Despite the no-lower walking speed in patients with achondroplasia, the temporal parameters of the gait structure (the relative duration of the support, non-support and double-support periods of the gait cycle) do not differ significantly in the groups of patients. The results obtained are consistent with the literature: the predominance of axial deviations with extremely insufficient limb

length determines gait features characterized by shortened stride length, low walking speed [8, 10] and increased rhythm in the absence of differences in the relative walking speed taking into account the length of the limbs [14].

The optimal strategy for improving the condition of children with achondroplasia also requires studying the gait pattern, features of kinematic and kinetic parameters, both from the point of view of treatment planning and for carrying out objective multifactorial monitoring of the effectiveness of therapy [9, 10, 12].

A limited number of studies on the gait of individuals with achondroplasia using instrumental analysis can be found in the literature [8, 10, 24, 29, 30]. Some of the works were carried out to study locomotor function in adults or only after surgical treatment [10, 13, 30, 31]. A number of walking features specific to achondroplasia have been identified by various authors. Kinematic features in the sagittal plane in walking are characterized by a dominant flexion position in the hip, knee and ankle joints (dorsal flexion) [8, 14], which may be a compensatory position due to the anterior tilt of the pelvis. Excessive anterior pelvic tilt may be caused by weakness of hip extensors and abdominal muscles [32]. Structural changes in the lumbar spine (lordosis combined with stenosis) [33, 34, 35] may also contribute to rotation of the pelvis that leads to compensatory adjustments of the underlying segments. Our study also revealed a significant limitation of extension in the hip joint in children with achondroplasia, a decrease in plantar flexion in combination with a significantly greater dorsiflexion in the stance phase of the gait cycle. The newly identified feature is a more pronounced flexion of the knee joint in the swing phase in comparison with the control groups, which can be explained by the flexion position in the hip joint and leads to an increase in passive flexion in the knee joint in the swing phase of the gait cycle.

According to the literature, recurvatum of the knee joint is recorded in patients with achondroplasia [14], which is predisposed by the specific anatomy of the proximal tibia (smaller than normal inclination of the articular surface) [11]. In our study, computer gait analysis in five patients did not reveal recurvatum in the knee joint during the support phase. It is likely that sufficient motor control compensates for this anatomical disorder. In one patient (16% of cases), recurvatum in the knee joint was found, and the kinetics reflected a pronounced decrease in the power parameters of the flexors and extensors of the hip and lower leg (Fig. 2).

A decrease in the magnitude of kinetic parameters (both moments of force and generated power) in the sagittal plane was revealed in patients with achondroplasia in comparison with healthy peers, which is obviously due to the shorter length of the mechanical lever segments. We found that there were no differences when compared with children of similar segment lengths (but younger age). Making comparisons with children aged 3–4 years, it is necessary to consider that at this age the general parameters of the locomotor pattern have not yet been fully formed [36, 37, 38]. The characteristic appearance of the main gait profile begins to appear in children at approximately 4–5 years of age, which may be associated with the formation of the activity of spinal central generators that induce self-organization of motor stereotypes (spinal central pattern generators — CPG). The works of other authors indicate the correspondence of kinetic changes in the sagittal plane to flexion in the joints in patients with achondroplasia [8, 14], but a comparison of the parameters with healthy children with similar segment lengths was not carried out.

It is known that muscle force parameters and peak joint power in patients with achondroplasia are determined by the length of the lever (the length of the limb segment) while their physiological maturity is preserved [39, 40]. A decrease in joint power indicators is also associated with a lower walking speed, because a reliable positive correlation between the power parameters of locomotion and walking speed was found [22].

We believe that the absent differences in the parameters of generated power and moment of force in comparison with younger children with similar lengths of segments of the lower extremities justifies the strategy of lengthening the longitudinal size of long bones (pharmacologically and/or surgically) precisely from the point of view of reducing the gait energy consumption in achondroplasia and, accordingly, an increase in motor capabilities.

The identified changes in kinematics in the horizontal plane are not as pronounced as in the sagittal plane. Noteworthy is the significant increase in the range of pelvic rotation. We regard this feature as compensatory, aimed at increasing stride length. This is also noted by other researchers [8, 31]. The works of Kierman et al [8] and Broström et al [14] describe increased external hip rotation of the femur, which was not found in our patients. In the frontal plane, increased hip abduction was observed in children with achondroplasia. Anatomically, the pelvic organs in children with chondroplasia are vharacterized by a wider and more horizontal acetabulum [9]. Hip flexion position may also contribute to increase in hip abduction and knee varus. Increased hip abduction coupled with hip flexion position also influences frontal plane kinematics with a decrease in hip adduction force vector during walking.

Kierman et al [8] opine that the internal torsion of the lower leg compensates for the external rotation of the femur, and the orientation of the foot, as a result, does not deviate significantly from the patient's movement vector. In our study, no significant deviations of the foot were found either. It is obvious that rotational movements and mutually compensating torsion deformities of the femur and lower leg (if they are found) in achondroplasia do not significantly affect the gait and are not primary pathological elements.

Changes in the frontal plane are caused by varus deformity of the lower limb axis and instability of the knee joint. This determines the amplitude of movements in adduction of the tibia, the emergence of a compensatory valgus vector of the moment of force, which can be measured using 3D computer analysis [41], and based on its value, a conclusion can be drawn about compensated or decompensated instability of the knee joint. As children develop and grow, their legs change their shape, starting with an O-shape, passing through an X-shape period, forming physiological valgus of the knee joint, which we observe in groups of healthy children. In this case, the biomechanical axis of the lower limb passes through the middle of the hip and knee joints, close to the outer edge of the talus block, as a result of weight-bearing on the joints is even [42]. Our study fully confirms the importance of varus deviation of the biomechanical axis for the kinematics and kinetics of movements. The deviation is usually bilateral and symmetrical, located mainly at the level of the tibia, and has a complex three-dimensional deformation, which is associated with a relative excessive length of the fibula [43].

Another characteristic feature of achondroplasia is frontal weakness of the knee joint due to the changes in the proximal attachment points of the collateral ligaments.

Moreover, foot supination was found, which was significantly different from the parameters of peers or healthy children with similar limb lengths. We believe that excessive inversion is of a compensatory adaptive nature. We interpret the spatiotemporal characteristics of gait in children with achondroplasia either as a consequence of insufficient length of segments (decreased stride length, increased gait cycles per minute) or as gait instability (increased relative duration of the double-support phase).

It is obvious that the strategy for correcting gait disorders is to increase the length of the segments of the lower extremities to restore the proportions along with elimination of angular deformities. This would result in both an improvement in stride length and a reduction in energy consumption in walking.

Computer (3D-instrumented) gait analysis is a valuable and necessary method of evidence-based medicine in monitoring the effectiveness of surgical and/or pathogenetic pharmacological treatment (vosoritide).

CONCLUSION

Disorders in the kinematic parameters of walking in children with achondroplasia affect the entire biomechanical chain. They are found in three planes: an increase in the maximum anterior tilt of the pelvis, flexion in the hip and knee joints, along with dorsiflexion of the ankle joint in the sagittal plane; an increased maximum hip abduction angle and varus deformity of the knee joint in the frontal plane; an increased rotational range of motion of the pelvis in the horizontal plane.

Deviations of kinetic parameters are determined by a smaller lever (segment length) and a lower walking speed. A similar length of segments of the lower extremities (with children aged 3–4 years without orthopaedic problems) is not accompanied by significant differences in the power parameters of the femur and lower leg extensors. The kinetics of the group of flexor muscles of the lower leg and foot is determined by the speed parameters of walking.

Changes in the horizontal plane are compensatory in nature; if orientation of the axis of the foot relative to the vector of movement is normal they are not pathological.

Conflict of interest *Not declared.*

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Ethical statement *The study was carried out in accordance with the ethical standards of the Declaration of Helsinki (revised in October 2013), approved by the institutional ethics board (protocol No. 2(70) dated October 21, 2021).*

Informed consent *Voluntary informed consent was obtained from all patients for publication of the study results without disclosing their identity.*

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Russian versions of FADI and FAAM for preoperative and postoperative assessment of the foot function

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Abstract

Introduction Self-administered questionnaire recommended by international orthopaedic community is a practical instrument for use in pathological conditions related to the foot and ankle.

The objective was to validate the Russian-language versions of the FADI and FAAM questionnaires to be filled out by orthopaedic patients with forefoot disorders before and after surgical treatment.

Material and methods The study included 100 adult patients with forefoot disorders to be surgically treated. The average age of the patients was 52 ± 12.1 years with 97 % being females and 26 % being athletes. The patients completed the FADI and FAAM questionnaires preoperatively and at 2 months after surgery and they were requested to fill out the SF-36 questionnaire and the LEFS scale preoperatively.

Results The Cronbach's α value was 0.91 for activities of daily living and 0.94 for sports measured with both questionnaires. The reproducibility of the questionnaires was demonstrated by high ICC values (⩾ 0.992) and no changes (ES < 0.01) in stable patients. Satisfactory construct validity was confirmed by significant correlations in activities of daily living and sports activities; criterion validity was confirmed by the dorsiflexion angle in the MCP1 and the daily ($p < 0.001$) and sports activities ($p < 0.05$). Convergent validity of the FADI and FAAM was identified with correlations measured with SF-36 and LEFS. Patients with moderate/severe impairment in range of motion had worse functional status scored with the FADI and FAAM as compared with those who had no/mild impairment. A significant improvement was seen postoperatively in non-athletes ($p < 0.001$). Sports activity significantly improved postoperatively in athletes ($p < 0.05$).

Discussion A limitation of the study includes the sample consisting mostly of patients with one type of orthopaedic pathology (valgus foot). Another limitation is that the majority of patients were females, and the patients were treated in the same health care facility. We can conclude that in the future it would be advisable to test the Russian versions of the FADI and FAAM questionnaires in patients with other foot pathologies and to conduct multicenter studies using these questionnaires.

Conclusion The FADI and FAAM scores measured in the Russian population showed greater sensitivity to changes in the foot/ankle joint in individuals who had indications for surgical treatment for a foot condition.

Keywords: foot pathology, functional disorders, surgical treatment, questionnaires, FADI, FAAM, validation

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INTRODUCTION

Patient's opinion of musculoskeletal pathology affecting his/her daily activity and quality of life is essential for evaluation of surgical outcomes of orthopaedic patients [1, 2]. Reporting patient-reported outcome measure is included in the international recommendations for the management of patients with musculoskeletal disorders [3]. Functional disorders of the foot and ankle and associated limitations can be assessed by the patient using specially designed questionnaires [4]. There are questionnaires that are recommended by the international orthopaedic community for assessing foot and/or ankle joint in different conditions including those during surgical interventions, for use in clinical studies and clinical practice [5–7]. These instruments include the Foot and Ankle Disability Index (FADI) and the Foot and Ankle Ability Measure (FAAM) [8, 9]. Both questionnaires are characterized by good psychometric parameters and are widely used abroad for research and practical purposes to evaluate patient condition and assess the effectiveness of treatment. An important advantage of these tools is that they consider aspects necessary for sports performance and can be applied to athletes. There were Russian versions of the FAAM and FADI questionnaires [10]. In accordance with international recommendations [11, 12] the development of a new language version of the questionnaire to be used in a new language environment is associated with a validation procedure to assess the psychometric properties of the instrument and test it in a population of patients with a specific pathology. The Russian versions of the FAAM and FADI questionnaires to be tested in patients with foot pathology to be surgically treated will create an evidence-based practice for evaluation of the effectiveness of surgical orthopaedic intervention.

The **objective** was to validate the Russian-language versions of the FADI and FAAM questionnaires and test them in orthopaedic patients before and after surgical treatment of forefoot pathology.

MATERIAL AND METHODS

The study was performed at the trauma department No. 2 of the High Medical Technologies Clinic named after N.I. Pirogov St. Petersburg State University (the study protocol was approved by the Biomedical Ethics Committee, protocol No. 07/22 dated 07/07/2022). The study included patients aged ⩾ 18 years with foot and/or ankle pathology who had indications for surgical treatment. Patients with cognitive impairment, which could prevent adequate completion of the questionnaires, were not included in the study. The patients signed informed consent prior to the research. The patients completed the FADI and FAAM questionnaires, the SF-36 general quality of life questionnaire and the Lower Extremity Functional Scale (LEFS) preoperatively. Some patients completed the FADI and FAAM twice before surgery, one day apart, to assess the reproducibility of the questionnaires. The patients completed the FADI and FAAM questionnaires at two months of surgery. The FADI questionnaire is developed to assess physical function for individuals with foot and ankle related impairments [11]. It consists of two subscales: the main part contains 26 items, divided into two scales: 22-item Activities of Daily Living subscale and 4-item pain subscale. The 8-item Sports subscale assesses more difficult tasks that are essential to sport (FADI-Sport). Each item is scored on a 5-point Likert scale (4 to 0) from 'no difficulty at all' to 'unable to do'. The maximum score on the daily activity scale is 104. The maximum score on the sports activity subscale is 32. The Sports Activity Scale also includes separate questions about the current level of functional status during sports (a score of 100 indicates the condition before the onset of problems with the foot and ankle, '0' means inability to perform normal daily activities) and the level of functional status at present (includes 4 options: normal, almost normal, reduced, significantly reduced level). The FAAM questionnaire was developed based on the FADI questionnaire. It is a region-specific tool for comprehensive assessment of the functioning of the foot and ankle joint in patients with a variety of disorders [12–15]. The questionnaire includes two scales evaluating daily activity (21 items, similar to the FADI items) and sports activity (8 items, similar to the FADI items). Five questions included in the FADI Activities of Daily Living scale are missing: a question about foot/ankle function during sleep and four questions about pain. The patient evaluates the current level of functional status performing normal daily activities on a scale from 0 to 100 scores.

The RAND 36-item Health Survey is comprised of 36 items that assess eight health concepts: physical functioning (PF), role limitations caused by physical health problems (RLPHP), role limitations caused by emotional problems (RLEP), social functioning (SF), emotional well-being (EWB), energy/fatigue (E/F), pain (P), general health perceptions (GHP). Each item is scored on a 0 to 100 scale so that the lowest and highest possible scores are set 0 and 100, respectively [16]. The LEFS contains 20 items to rate the degree of difficulty in performing different physical activities due to problems in the lower extremities; a 5-point scale is used, from 0 (extreme difficulty/unable to perform activity) to 4 (no difficulty). The total score ranges from 0 to 80, with higher scores indicating better function [17].

The reliability, validity and sensitivity of the Russian versions of the FADI and FAAM were analyzed for assessment of the psychometric properties. The reliability of the questionnaires was determined by calculating Cronbach's α coefficient for assessment of the internal consistency and the reproducibility identified with the test-retest method. Correlations were determined between the scores of the daily and sports activity scales of the FADI and FAAM questionnaires for assessment of the construct validity. For criterion validity, correlations of the FADI and FAAM scores were assessed with the dorsiflexion angle (DA) in the 1st metatarsophalangeal joint (MTP1). Discriminant validity analysis was performed using the "known groups" method based on comparison of the FADI and FAAM scores in groups of patients with no impairment in the range of motion, mild impairment, and with impaired range of motion of moderate or severe severity measured with the DF angle in MTP1. Convergent validity was assessed by correlations of the FADI and FAAM scores and the SF-36 and LEFS scores.

Effect size of changes on questionnaire scales were determined preoperatively and at two months of surgery to examine sensitivity to changes. As part of testing the Russian versions of FADI and FAAM, changes in the postoperative scores were compared with preoperative values in athletes and non-athletes. The applicability of the Russian versions of FADI and FAAM for the focal patient population was determined based on the understandability and ease of filling out the questionnaires, and the quality of completion. The study included 100 orthopaedic patients with a forefoot condition. Table 1 presents general characteristics of the sample. The majority of patients were females (97 %). The mean age was 52 years (20÷73). Hallux valgus was the main diagnosis in 98 %. Pathology of the foot was diagnosed in 47 % on the right and in 53 % on the left.

The mean (standard deviation) preoperative DF angle in MCP1 was 38.9° ± 19.9° (range 0÷70°. Impaired range of motion in the MCP1 was

Table 1

Characteristics of patients

Description		Value
Gender, %	Male	3
	Female	97
Age	Mean, standard deviation	52 ± 12.1
	Median (interquartile range)	55 (42.8; 61.3)
	Range	20–73
Marital status, %	Married	71
	Single	8
	Divorced	6
	Widow	15
Education, %	Higher	56
	Secondary special	26
	Secondary	12
	Incomplete secondary	6
Employment, %	Employed	70
	Student	1
	Unemployed	29
Going in for sports, %	Yes	74
	No	26
Disability, %	There is	98
	There is, among them:	2
	Grade 2	1
	Grade 3	1
Comorbidity, %	None	15
	There is	85
Principal diagnosis, %	Hallux valgus	98
	Hallux rigidus	2
The side involved, %	Right	47
	Left	53

classified as mild in 17 %, moderate in 13 % and severe in 27 %. No impairment was detected in 43 % of patients. The mean preoperative LEFS foot function scored 60.8 ± 16.7. Professional athletes made up a quarter (26 %) of the sample and represented the following sports: running (*n* = 5), cycling (*n* = 5), skiing (*n* = 4), dancing (*n* = 4), swimming (*n* = 4), table tennis (*n* = 2), track and field athletics (*n* = 2), equestrian (*n* = 1), football (*n* = 1).

Statistical analysis Quantitative data were presented as mean and standard deviation, M ± SD. Qualitative data were described by absolute and relative frequencies of occurrence, *n* (%). The nature of the data distribution was determined using the Shapiro – Wilk test. A comparison test for two samples — the Student t-test or its non-parametric analogue — the Mann - Whitney test was used to compare two unrelated groups. The Student's t test or the paired nonparametric Wilcoxon signed rank test was used to compare two related groups. The intraclass correlation coefficient (ICC) was used to assess the relationship between variables at two points of questionnaire completion with the test-retest method. Spearman's r correlations were used to assess associations between continuous variables. The strength of a correlation was measured with r:and considered weak at $0.1 < r < 0.39$; as moderate at $0.4 \leqslant r < 0.69$ and strong at $r \geqslant 0.7$ [18]. Cronbach's α coefficient was calculated for assessment of the internal consistency of the questionnaire. Effect sizes (ES) were determined to examine changes in scores over time. The effect size was considered small with ES = 0.2–0.5, as medium with ES = 0.5–0.8 and large with ES > 0.8 [19]. All tests were two-sided, differences between groups were considered statistically significant at $p < 0.05$. Statistical analysis was performed using SPSS 23.0 software.

RESULTS

Psychometric properties of Russian versions of FADI and FAAM

Reliability

The Cronbach's α coefficient was identical and amounted to 0.91 for the FADI and FAAM daily activity and to 0.94 for sports. The reproducibility assessment showed no change in activities of daily living (FADI: (79.2 ± 16.6) vs. (79.3 ± 16.7); ES = 0.008; FAAM: (83.9 ± 14.4) vs. (84 .1 ± 14.0); ES = 0.008), as well as sports activity (68.8 ± 24.5) versus (68.8 ± 24.0); ES < 0.001 with both questionnaires repeated by patients in stable condition. The intraclass correlation coefficient ICC indicator was 0.999 (95 % CI: 0.997–0.999; $p < 0.001$) for the FADI daily activities, 0.992 (95 % CI: 0.980–0.997; $p < 0.001$) for the FAAM daily activities, 0.999 (95 % CI: 0.998–1.000; $p < 0.001$) for sports when the FADI and FAAM questionnaires were first completed and then refilled. In general, both questionnaires were characterized by good internal consistency and reproducibility indicating acceptable reliability of the Russian versions.

Validity

The correlation coefficient Spearman's r of the activity of daily living and sports was 0.470 (95 % CI: 0.301–0.610, $p < 0.001$) as measured with FADI and 0.482 (95 % CI: 0.315–0.620, $p < 0.001$) as determined with FAAM. The data indicate satisfactory construct validity of both questionnaires. Statistically significant positive correlations were established for the FADI and FAAM scores of activities of daily living, for sports with the value of the DF angle in the MCP1. The correlation coefficient Spearman's r was 0.388 (95 % CI: 0.208–0.543, $p < 0.001$) for the FADI daily activity score and the TC angle in MCP1, 0.403 (95 % CI: 0.224– 0.555, $p < 0.001$) for the FAAM daily activity score and the DF angle in MCP1 and 0.227 (95 % CI: 0.032–0.406, $p = 0.023$) for sports and the DF angle in MCP1. Table 2 presents Spearman's r correlation coefficients for the FADI and FAAM daily activity scores, the SF-36 sports activity scores and the LEFS total score.

Table 2

Correlations between FADI and FAAM scales, SF-36 and LEFS scales

Scale	Total LEFS score	PF	RLPHP	P	GHP	E/F	SF	RLEP	EWB
FADI Activities of Daily Living	0.531**	0.532**	0.430**	0.471**	0.393**	0.460**	0.414**	0.274*	0.316**
FAAM Activities of Daily Living	0.581**	0.557**	0.463**	0.492**	0.432**	0.334**	0.406**	0.234*	0.226*
Sports	0.441**	0.437**	0.369**	0.399**	0.193	0.227*	0.291**	0.214*	0.174

Note: * correlation coefficients are statistically significant at $p < 0.05$; **correlation coefficients are statistically significant at $p \leqslant 0.001$. Health concepts measured with SF-36: PF, physical functioning; RLPHP, role limitations caused by physical health problems; *P*, pain; GHP, general health perceptions; E/F, energy/fatigue; SF, social functioning; RLEP, role limitations caused by emotional problems; EWB, emotional well-being.

Statistically significant correlations of moderate or weak strength were obtained for the scores of both questionnaires and the total LEFS score and for the SF-36 score. In general, the findings indicated acceptable criterion and convergent validity of the Russian versions of the FADI and FAAM questionnaires. Using the "known groups" method, statistically significant differences in the activities of daily living and sports measured with FADI and FAAM were demonstrated in the group of patients with no impairment and mild impairments in the range of motion in the MCP1 compared to the group of patients with moderate and severe impairment in the range of motion in the MCP1 (Fig. 1).

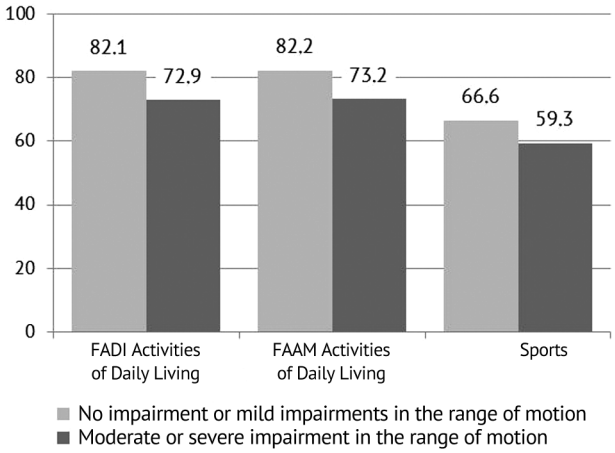

Fig. 1 The mean scores of the activities of daily living and sports measured with the FADI and FAAM questionnaires in patients with varying degrees of impairment in range of motion based on the DF angle in the MCP joint

Patients with moderately and severely impaired range of motion had lower ADL scores (worse foot condition) than those with no or mild impairment in the range of motion (FADI: (72.9 ± 14.5) vs. (82. 1 ± 10.2), $p < 0.001$; FAAM: (73.2 ± 14.9) vs. (82.2 ± 10.9), $p = 0.001$). There were no statistical differences between the groups on the sports activity scale. The findings indicated good discriminant validity of the ADL of the Russian versions of FADI and FAAM.

Sensitivity

Changes in ADL and sports of the FADI and FAAM questionnaires were analyzed at 2 months of surgery and compared with preoperative values (Table 3). There was a significant improvement in the scores of both questionnaires postoperatively ($p < 0.001$). Changes in the FADI and FAAM ADL scores corresponded to a moderate ES effect size (0.403 and 0.443) and to a larger effect size (0.781) for the sports.

Table 3

Mean scores of ADL and sports measured with the FADI and FAAM questionnaires completed preoperatively and postoperatively

Scales	Pre-op		At 2 months		*p*	ES
	mean	Standard deviation	mean	Standard deviation		
FADI Activities of Daily Living	78.44	12.86	83.63	3.63	< 0.001	0.403
FAAM Activities of Daily Living	78.60	13.32	84.50	4.63	< 0.001	0.443
Sports	63.69	22.83	81.53	7.30	< 0.001	0.781

Therefore, the Russian versions of FADI and FAAM were highly sensitive to postoperative changes in the foot.

Testing of Russian versions of FADI and FAAM in orthopaedic patients before and after surgical treatment of forefoot pathology

Testing of the FADI and FAAM questionnaires suggested analysis of changes in the ADL and sports scores, in the postoperative level of the foot functionality associated with ADL and with sports in patients and comparison with preoperative scores. The analysis was performed for the whole sample and separately in athletes and non-athletes (Fig. 2). As seen from the figure, significant improvements were seen on the scales of both questionnaires at 2 months and with additional parameters in the whole sample and in non-athletes. Athletes demonstrated improvement in most parameters and statistically significant changes were established for sports and functional foot scores associated with ADL and sports (Fig. 2).

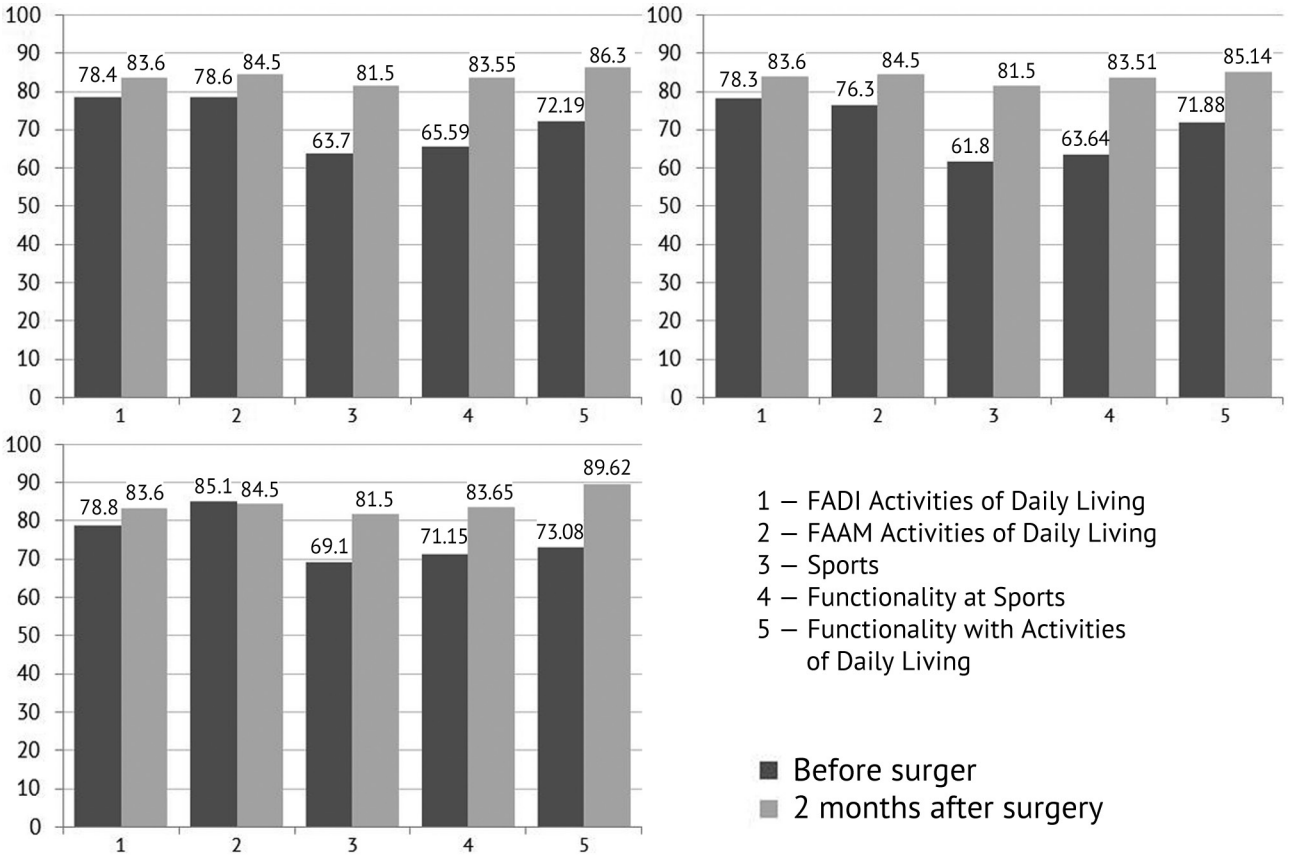

Fig. 2 Mean FADI and FAAM scores for activities of daily living, for sports, average foot function during activities of daily living, during preoperative ADL and at 2 months postoperatively in the total sample (*a*), non-athletes (*b*) and in athletes (c)

The suitability of data on the completion of questionnaires was explored for the use in the focal patient population. All questionnaires were completed by the patients with no items missed (0 % missing data). A small number of patients showed minimum (0) and maximum scores (100) on the scales, i.e. the "floor and ceiling effect" was not evident. Preoperative data demonstrated the proportion of answers with maximum values in 3 % on the sports scale, 1 % and 0 % on the FAAM and FADI ADL, respectively. None of the patients showed minimum score in ADL and sports. The findings indicated the high quality of the data and confirmed that respondents could understand the questions that cause no discomfort to them when answering and posed no difficulties when choosing an answer. On average, it took 8 minutes to complete the FADI questionnaire, and 12 minutes to fill out the FAAM.

DISCUSSION

Patient-administered questionnaires are widely used for a comprehensive assessment of foot and ankle dysfunction and associated limitations in orthopaedic patients [7]. They have been shown to be informative and useful in determining the effectiveness of surgical treatment and rehabilitation [2, 3]. The FADI and FAAM questionnaires are most common tools recommended by the international orthopaedic community for assessing the foot and/or ankle, including intraoperative evaluation [12]. The questionnaires are widely used for scientific and practical purposes abroad [8, 20]. Previously, we developed the Russian versions [6]. However, a new language version of the questionnaire can be used if its psychometric properties have been tested and the instrument has been tested in a focal patient population [21–23]. This study was aimed to analyze the psychometric properties of the Russian versions of the FADI and FAAM questionnaires and test them in a domestic sample of patients who needed surgical treatment for forefoot condition. Validation was produced in accordance with modern international recommendations [13, 14]. Different aspects of the reliability and validity of the FADI and FAAM questionnaires were explored. Both questionnaires were shown to have good internal consistency and reproducibility.

High Cronbach's α coefficient was obtained for the FADI and FAAM questionnaires with identical score for ADL that amounted to 0.91 and 0.92 for sports. The findings were similar to those determined with validations of the questionnaires performed in other countries [24–26, 27]. High intraclass correlation coefficients ICC were obtained with 0.999 for the FADI ADL, 0.992 for the FAAM ADL and 0.999 for the sports with questionnaires being completed twice by patients in a stable condition characterizing the reproducibility. Our data on the reproducibility of FADI and FAAM were not inferior to the results reported in other studies [26, 28, 29].

An extensive analysis of the validity: criterion, convergent and discriminant was performed for the validity of the Russian versions of the FADI and FAAM questionnaires. Based on the Spearman's *r* correlation coefficient between the ADL and sports scores, satisfactory construct validity of both questionnaires was shown. A correlation analysis was used for the FADI and FAAM questionnaires with the TC angle in the MCP1 to assess the criterion validity. As part of the assessment of convergent validity, a correlation analysis was performed for the FADI and FAAM scores, the SF-36 and the total LEFS scores. The significant correlations indicated acceptable criterion and convergent validity of the Russian versions of the FADI and FAAM questionnaires. There were statistically significant differences in the ADL and sports scores measured with FADI and FAAM in patients with no or mild impairments in the range of motion in the MTP1 compared to the patients with moderate or severe impairments in the range of motion in the MTP1. These findings indicated good discriminant validity of the questionnaires. In general, the findings reflected the reported results on the validity of the FADI and FAAM questionnaires [25, 26, 28, 30, 31]. The types of validity assessed in our series were not reported in other series. This suggested that our results on the reliability of the Russian versions of the FADI and FAAM questionnaires had a good evidence. The sensitivity of the Russian versions of the FADI and FAAM questionnaires was determined by estimating the effect size ES of changes in scores after foot surgery. There were significant positive postoperative changes in ADL and sports scores measured with FADI and FAAM suggesting a moderate ES effect size (0.403 and 0.443), and a larger effect size (0.781) for the sports. The ES values were similar to those reported in other studies [32]. In our series, the period for filling out the questionnaire after surgery was shorter and amounted to two months, instead of six months as mentioned in other studies. The Russian versions of the FADI and FAAM questionnaires were sensitive to changes in the foot after surgical treatment and can be recommended for self-administered surveys. However, some validation studies failed to assess the sensitivity of the FADI and FAAM questionnaires.

Modern recommendations for assessing the psychometric properties of a newly developed language version of the questionnaire [14] suggest testing of the sensitivity to changes as a necessary component of the validation procedure. Testing of the instrument in a focal patient population is of particular interest. We tested the Russian versions of the FADI and FAAM questionnaires in patients with foot pathology who were indicated for surgical treatment. Parameters of the questionnaires were analyzed preoperatively and at two months. The analysis was performed for the whole sample, in athletes and in non-athletes. Non-athletes showed significant postoperative improvements in FADI and FAAM scores, in the functionality of the foot with ADL and sports. Athletes demonstrated significant improvements in sports, in the functionality of the foot during normal ADL and during sports. In addition to that, good completion rates with no extreme values in the scores ("floor and ceiling effect") were demonstrated indicating their suitability and informativeness for monitoring the foot condition in orthopedic patients during treatment. The advantages of our study include, first, the comprehensively analysis of the psychometric properties of the Russian versions of the FADI and FAAM questionnaires using different methods. Secondly, the questionnaires were tested in the domestic population of patients undergoing surgical treatment of foot pathology. And finally, the questionnaires were tested in a group of non-athletes and a group of athletes. The presence of a sports activity scale in the FADI and FAAM questionnaires distinguishes them favorably from other instruments focused on assessing the condition of the foot and ankle and associated limitations [15, 32–34]. The specific testing among athletes seems extremely valuable. The study has a number of limitations. The main limitation is that the sample consisted mainly of patients with one type of orthopaedic pathology, hallux valgus. Another limitation of the study is that the majority of patients were females. Another limitation is that all patients were treated in the same health care facility. We can conclude that in the future it would be advisable to test the Russian versions of the FADI and FAAM questionnaires in patients with other foot pathologies and to conduct multicenter studies using these questionnaires.

CONCLUSION

The Russian versions of the FADI and FAAM questionnaires are reliable and valid tools for assessing the condition of the foot/ankle joint in orthopAedic patients. the FADI and FAAM questionnaires were found to be sensitive to changes in the foot/ankle joint in the Russian patients who had indications for surgical treatment of the foot. Significant improvements were recorded in the postoperative scores of both questionnaires in patients with forefoot condition. The information content of the FADI and FAAM questionnaires in athletes and their sensitivity to postoperative changes in the foot/ankle joint in patients of this cohort were demonstrated. The results of testing the FADI and FAAM questionnaires indicate that the instruments are convenient and understandable for patients, are informative for monitoring the condition of the foot/ankle joint, and can be recommended for use in domestic clinical studies and clinical practice.

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Experience in early minimally invasive fixation of pubic symphysis disruption with a system of transpedicular screws in patients with combined pelvic trauma (pilot study)

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Abstract

Introduction Challenges of treating the injuries of pubic symphysis in patients with combined pelvic injury require developing new techniques for stable minimally invasive osteosynthesis in the acute period of trauma.

Purpose of the work was to assess the application of low invasive fixation of the pubic symphysis with a system of transpedicular screws in the patients with combined unstable pelvic injuries in the acute period of the traumatic disease.

Materials and methods The results of treatment of 12 patients with polytrauma with unstable pelvic injury with rupture of the pubic symphysis who were treated at Dzhanelidze Research Institute of Emergency Medicine, St. Petersburg, in the period from 2017 to 2023, were analyzed. All the patients underwent final minimally invasive fixation of the pubic symphysis with a system of transpedicular screws in the early period of the traumatic disease.

Results The overall assessment of the results in 12 patients found no complications or technical errors during the installation of transpedicular screws. Control CT scans of the pelvis showed that osteosynthesis was stable in all patients, and the position of metal was correct in all. One patient from the study group died in the clinic from massive pulmonary embolism. The long-term results in 11 patients in the period from 6 months to 3 years after trauma were evaluated as excellent and good anatomical and functional results in 10 patients, one case had fair outcome.

Discussion The use of bone plates to fix ruptures of the symphysis pubis leads to disruption of its physiological mobility, and the patient's activity in the postoperative period can cause an implant fracture. Original dynamic plates and wire cerclage help avoid this complication; however, all these techniques involve significant surgical trauma and blood loss, as well as the risk of postoperative wound suppuration. Minimally invasive methods of fixation using cannulated screws, systems such as Endobutton, Tight Rope can reduce intraoperative trauma and the risk of complications (blood loss, suppuration); however, the procedure for their installation is quite complex and lengthy, and for greater stability, external fixation of the pelvic ring is often required. The proposed minimally invasive fixation of the pubic symphysis with a system of transpedicular screws avoids a lot of shortcomings and is sufficiently stable.

Conclusion The method of minimally invasive fixation of the pubic symphysis with a system of transpedicular screws meets current requirements in the treatment of patients with polytrauma and unstable pelvic injury, and it may be successfully used in the acute period of trauma.

Keywords: rupture symphysis pubis, combined injury, minimally invasive osteosynthesis, pedicle screws, osteosynthesis of the pubic articulation

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INTRODUCTION

Disruption of the pubic symphysis, as a component of unstable pelvic ring injury, occurs in 13–15 % of patients with combined trauma. In the structure of injuries to the anterior pelvic ring, isolated symphyseal disruption occurs in 8.9 % of cases, in combination with fractures of the pubic and ischial bones in 7.1 % of cases. Disruption of the pubic symphysis usually results from a high-energy mechanism of injury [1, 2, 3].

The use of the external fixator (EF) for temporary stabilization of the pelvis in the early stages after trauma has become the "gold standard" in trauma surgery, while the final fixation of the pelvic ring, including the pubic symphysis, is frequently performed after stabilizing the patient's condition [4, 5]. Conservative treatment of traumatic pubic symphysis disruption is often ineffective and leads to a significant number of poor results (20–25 %), which are associated with unresolved symphysis reduction, inadequate fixation, concomitant sacroiliac joint disruptions, various sacral fractures, and post-traumatic deformation of the pelvic ring [1, 2].

The accepted optimal method for restoring the anatomy of the pelvic ring is osteosynthesis with internal constructs. Systems for internal fixation of the pubic symphysis range from screws with cerclages to plates of various designs [6, 7, 8]. Traditional methods of bone osteosynthesis of the pelvic bones are commonly invasive, so they cannot always be applied in severe conditions of the injured. For this reason, the development of various minimally invasive methods for fixation of the pubic symphysis continues.

Current treatment approach for unstable pelvic injuries in combined trauma is based on the concept of Orthopedic Damage Control and is part of the algorithm for treating severe trauma — ATLS (Advanced Trauma Life Support). This involves measures to eliminate life-threatening consequences of trauma, temporary stabilization of the pelvic ring with an EFA, prevention of infectious complications. Then, stabilization of the general condition is conducted, and prevention and treatment of complications are carried out. Subsequently, during the period of relative or complete compensation of the body's vital functions, the final osteosynthesis of pelvic bone fractures is performed.

At present, the problem of choosing the optimal method of internal fixation for ruptures of the symphysis pubis remains acute, since many issues on this topic have been insufficiently studied and are controversial. Obviously, there is a need to continue research on the development and improvement of optimal methods of internal fixation for unstable pelvic injuries with rupture of the pubic symphysis in the acute period of injury, based on the principles of minimally invasive osteosynthesis.

Purpose of the work was to assess the application of low invasive fixation of the pubic symphysis with a system of transpedicular screws in the patients with combined unstable pelvic injuries in the acute period of the traumatic disease.

MATERIALS AND METHODS

Treatment results of 12 patients with combined pelvic trauma were analyzed, who sustained unstable injury to the pelvic ring accompanied by a rupture of the pubic symphysis, and who were hospitalized at the Dzhanelidze Research Institute of Emergency Medicine (first level trauma center, St. Petersburg) from 2017 to 2023.

During the examination upon admission of the patients, specialists from the anti-shock team established the mechanism and circumstances of the injury, carried out instrumental diagnostics, and assessed the severity of the condition and injury.

The structure of unstable injuries of the pelvic ring according to the classification of Muller AO-OTA/ASIF [15] was as follows: A2 — 1 case (8.4 %), B1 — 3 cases (25.0 %), B2 — 2 cases (16.5 %), B3 — 1 case (8.4 %), C1 — 5 cases (41.6 %) (Table 1).

All patients underwent minimally invasive fixation of the pubic symphysis with a transpedicular system in the acute period of the traumatic disease.

There were 7 (58.4 %) males and 5 (41.6 %) females. Circumstances of injuries were fall from a height in 5 cases (41.6 %), road traffic accidents such as vehicle injury in 3 cases (25.0 %), one motorcycle injury (8.4 %), compression injury under load in 3 (25.0 %). The average age of the patients was (37.6 ± 10.9) years.

Criteria for inclusion in the study group were working age (from 18 to 65 years), mild traumatic brain injury (AIS scale ⩽ 4 points), morphology of damage to the pelvic ring that allowed to use minimally invasive internal fixation of the pubic symphysis with a system of transpedicular screws: isolated (rupture of the symphysis with a divergence of more than 2.5 cm or with an overlap) or in combination with cannulated screws (a combination of rupture of the symphysis with fractures of the horizontal ramus of the pubic bone in the Nakatani II–III region).

In the patients with combined trauma in the acute period of the traumatic disease, to make tactical decisions, we used the authors' tactics of differentiated specialized high-tech surgical care for pelvic injuries, developed by our team, which allows us to take into account the criteria for the risk of developing a lethal outcome and to differentiate in detail patients according to the prognosis for poor outcome. Thus, the optimal sequence of therapeutic and diagnostic measures was built. The severity of the injury was determined in scores on the ISS and MFS-P (MT) scales, the age of the patients was considered (as a criterion for comorbidity), the severity of traumatic brain injury was assessed using the Glasgow Coma Scale [16], and the mechanism of pelvic injury was assessed by Young – Burgess classification [17]. Using the developed logit model, the probability of an unfavorable or favorable outcome was predicted in a binary system [18]. Thus, the average severity of injury was (23.2 ± 12.4) points according to ISS and (7.9 ± 4.6) points according to MFS-P (MT) (Table 1).

Table 1

Data on the injured individuals included in the study that had pubic symphysis disruption

#	Age	Sex	Injury cause	Mechanism of pelvic injury	AO/ OTA	ISS	MFS-P	Associated injuries
1	57	m	Road accident (passenger)	Complete rupture of sacroiliac ligament (APC III)	C1.2.	41	17.8	Brain concussion. Multiple bilateral rib fractures. Lung contusion. Extraperitoneal bladder rupture
2	47	f	Traffic accident (driver)	Fracture of the pubis with involvement of the anterior column of the acetabulum (low fracture), of the ischium, fracture of the sacrum (Denis 1) (type LCI)	B2.1.	34	8.1	Moderate brain contusion. Multiple rib fractures. Lung contusion. Heart bruise. Hemopneumothorax. Grade 3 splenic rupture. Closed fracture of the left humerus
3	55	m	Compression	Partial rupture of the sacroiliac ligament (APC II)	B1.1.	13	3.1	Brain concussion
4	34	m	Catarauma	Fracture of the pubic and both ischial bones, Fracture of the sacrum (Denis 2) (type VS)	C1.3.	27	9.8	Brain concussion. Lung contusion. Compression fracture of the body of Th12, L2 vertebrae, stage 2. Open fracture of the calcaneus. Extensive damage to the soft tissues of the pelvis according to the Morel – Lavallee type
5	28	m	Catarauma	Sacrum fracture (Denis 2) (type VS)	C1.3.	17	8.9	Brain concussion. Lung contusion
6	32	f	Catarauma	Sacrum fracture (Denis 2) (type VS)	C1.3.	14	7.3	Brain concussion

Continuation of Table 1

Data on the injured individuals included in the study that had pubic symphysis disruption

#	Age	Sex	Injury cause	Mechanism of pelvic injury	AO/ OTA	ISS	MFS-P	Associated injuries
7	19	f	Mototrauma (driver)	Pubic bone fracture, partial rupture of the sacroiliac ligament (APC II)	B1.1.	10	3.3	Brain concussion
8	32	f	Compression	Partial rupture of sacroiliac ligament (APC II)	B3.1.	10	3.2	Brain concussion. Vaginal rupture, stage 2
9	44	m	Road accident (passenger)	Partial rupture of sacroiliac ligament. Butterfly fracture of both pubic and ischial bones (APC II)	B1.1.	9	6.2	Brain concussion. Perineal rupture. Lacerated and bruised wound of the scrotum
10	46	f	Catarauma	Partial rupture of the symphysis pubis. Butterfly fracture of both pubic and ischial bones (LCI)	A2.3.	13	3.5	Moderate brain contusion. Orbital wall fracture
11	32	m	Compression	Fracture of both pubic and ischial bones. Sacrum fracture (Denis 2) (LCI)	B2.1.	9	6.2	Brain concussion. Posterior urethral rupture
12	30	m	Catarauma	Fracture of both pubic and ischial bones. Sacrum fracture (Denis 1) (VS type)	C1.3.	36	16.3	Moderate brain contusion. Multiple rib fractures. Lung contusion. Hemopneumothorax. Closed fracture of the proximal femur. Posterior urethral rupture

The severity of traumatic brain injury according to the Glasgow Coma Scale was (14.1 ± 1.3) points. Upon admission, seven (58.4 %) patients had life-threatening consequences of injuries that required emergency surgical interventions: ongoing intra-abdominal bleeding in one patient, tension pneumothorax in one, and ongoing external bleeding in two patients. In thatgroup, five (41.6 %) patients were found to have ongoing intrapelvic bleeding, therefore, to achieve final surgical hemostasis, angiography with embolization was used in two cases and extraperitoneal pelvic tamponade was used in one case, and anti-shock sacroiliac screws were used in all patients in the mentioned group. The life-threatening consequences of the injury were eliminated in the anti-shock operating room soon after admission to the trauma center.

Multiple injury to the pelvis was diagnosed in six patients (50 %): rupture of the posterior urethra was present in two (16.5 %), extraperitoneal rupture of the bladder, rupture of the vagina, extensive damage to the soft tissues of the pelvis according to the Morel – Lavallee, perineal rupture (one case of each).

All the admitted underwent spiral computed tomography (SCT) in the anti-shock department of the trauma center of five areas of the body (head, chest, spine, abdomen and pelvis) according to the "Polytrauma" program on a Toshiba Aquilion PRIME 128 CT system (Japan). While assessing pelvic scans, the morphology of damage to the pelvic ring was clarified. If damage to internal organs and blood vessels was suspected, SCT was supplemented with contrast support.

The final minimally invasive internal osteosynthesis of the damaged structures of the unstable pelvic ring was carried out in five patients during the acute period of the traumatic disease immediately upon admission, and in two patients after preliminary extrafocal stabilization of the pelvis during the period of relative stabilization of their condition (48–72 hours after the injury).

To fix the pubic symphysis, a system was used consisting of two locking transpedicular screws inserted into the vertical branches of the pubic bones from top to bottom and connected by a metal rod. The assessment of the position of bone structures and metal structures was carried out

using polypositional fluoroscopy on a General Electric OEC 9900 Elit C-arm (USA). After indirect reduction on an orthopedic table with the elimination of all types of displacement in the unstable pelvic ring, the anterior semi-ring was initially fixed with internal metal structures or EF, and then osteosynthesis of the damaged posterior pelvic structures was performed.

Minimally invasive fixation of the pubic symphysis with a system of transpedicular screws was performed according to the developed method with minimal tissue trauma: metal implants were installed through small incisions, only the heads of the transpedicular screws were in contact with the periosteum, the rest of the element were located epiperiosteally. Thus, the contact of the implants with the periosteum was reduced, which allowed minimal disturbance of blood supply to the bone [19].

Short-term results of treatment were assessed using the VAS scale, which allows one to objectively assess the subjective satisfaction (based on a range from 0 to 10, where 0 indicates maximum dissatisfaction, and 10 complete satisfaction), the duration of bed rest was considered.

All patients after internal pelvic osteosynthesis underwent a control study to assess the position of the metal structures and restoration of the anatomy of the pelvic ring. To assess long-term results, 11 patients were observed at the following time-points: after 6 weeks, 3 months, 6 months, and 12 months after surgery and annually thereafter for up to three years. Functional treatment results were evaluated using the Majeed scale, including such criteria as pain, the ability to sit and walk, the ability to have sexual intercourse and perform labor activities (work) [20].

Functional abilities and quality of life in 11 patients were determined using the nonspecific SF-36 questionnaire, reflecting general well-being and satisfaction, those aspects of the patient's life that affect the state of the health [21]. The SF-36 questionnaire consists of 36 questions grouped into eight scales. They form two parameters: psychological and physical components of health.

The database of patients was created in Microsoft Office Excel 2010. Descriptive statistics methods were used to analyze the data. Given that the study did not compare groups, normally distributed continuous data were expressed as mean ± standard deviation. Statistical analysis of the data was carried out using the BioStat 2009 program (Analyst Soft Inc., USA).

RESULTS

The majority of patients with a favorable outcome, determined using the developed prognostic logit model, underwent internal fixation of the injured pelvis in the first hours after injury. A patient with a vaginal rupture underwent suturing; two patients with a rupture of the posterior urethra underwent cystotomy, urethral tunnelization according to Albarran – Vishnevsky and drainage of paravesical tissue according to Buyalsky – McWhorter.

In all the cases, the rupture of the pubic symphysis was synthesized with a system of transpedicular screws according to the proposed method. To treat injuries to the posterior structures of the pelvis, sacroiliac cannulated screws were additionally used. In three cases, rupture of the symphysis was accompanied by unilateral or bilateral fractures of the rami of the pubic bone, for osteosynthesis of which cannulated screws were installed using the antegrade technique. The surgical procedure was completed with fixation of the symphysis pubis using the proposed transpedicular system. In three patients with type C1.3 pelvic ring injury, for reliable fixation of damaged posterior structures, in addition to fixation with sacroiliac cannulated screws, a unilateral lumbopelvic system based on transpedicular screws was installed using a minimally invasive technique.

Two patients with an unfavorable prognosis underwent temporary fixation of the pelvis with an EF system for elimination of diastasis in the symphysis pubis and fixation of the posterior structures with sacroiliac cannulated screws (combined osteosynthesis) in the anti-shock operating room. One patient underwent laparotomy and splenectomy to stop ongoing intra-abdominal bleeding,

and one patient underwent extraperitoneal pelvic tamponade. Two days later, one patient (after removal of tampons from the pelvic cavity) underwent final suturing of an extraperitoneal rupture of the bladder with the application of a cystostomy and drainage of paravesical tissue. During the period of relative stabilization of the condition (from 1 to 3 days), those patients underwent stabilization of the damaged pelvic structures: dismantling of the EF, internal antegrade osteosynthesis of the fracture of the horizontal ramus of the pubic bone with a cannulated screw, and fixation of the pubic symphysis with a minimally invasive transpedicular system.

Fixation of the pubic symphysis with a minimally invasive method using a transpedicular system was accompanied by small intraoperative blood loss, and the risks of infectious complications decreased. Surgical access with this technique retains impermeability of the prevesical space that contributed to the preservation of biological tamponade and reduced the risk of intrapelvic bleeding. One patient developed massive pulmonary embolism 5 days after the operation, which was the cause of death. Visceral complications associated with combined trauma were also observed: pneumonia in three cases, including the development of sepsis in one of them. Local complications such as bedsores over the heads of transpedicular screws or suppuration of postoperative wounds were not observed when using this method of fixation of the pubic symphysis in the studied group. The average period of bed rest ranged from 3 to 12 days after injury and depended on the nature of the damage and the severity of the condition.

None of the patients had iatrogenic complications, technical errors in internal osteosynthesis, or malposition of transpedicular screws in the area of the pubic symphysis according to checking SCT of the pelvis. The average length of hospital stay was (31.3 ± 13.9) days. The average level of pain on the VAS scale was (3.4 ± 1.2) points. In one patient, after discharge, a screw migrated through the anterior cortical plate of the pubic bone (he constantly violated the treatment regimen). This required removing the system 1.5 months after installing it.

The long-term results of treatment were studied in 11 patients; a quantitative assessment of the functional state of the pelvis according to Majeed was (87.8 ± 12.2) points (min — 61, max — 100). Ten patients had an excellent or good result, and one had a fair treatment result. The fair result was due to secondary displacement of fragments in the posterior semi-ring and partial dysfunction of the pelvic organs (Table 2).

According to the final nonspecific questionnaire SF-36 to assess the quality of life, five patients showed good results on selected scales (the higher the value of the indicator from 0 to 100, the better the score on the selected scale), primarily reflecting the physical component of health (Table 3).

Table 2

Majeed functional scores (1989)

Majeed scale parameters	Mean score, $M \pm m$	
Mean score	87.8 ± 12.2	
Pain (30 points)	26.8 ± 4.0	
Work (20 points)	17.1 ± 3.6	
Sitting ability (10 points)	8,5 ± 1,6	
Sexual intercourse (4 points)	3.5 ± 0.5	
Standing ability (12 points)	11.2 ± 1.8	
Gait (12 points)	9.5 ± 2.7	
Walking (12 points)	11.1 ± 1.4	
Clinical evaluation of the results:	number	%
Excellent	7	63.6
Good	3	27.3
Fair	1	9.1
Poor	0	

Table 3

SF-36 questionnaire results, $n = 11$

Quality of life parameters	Mean score, $M \pm m$
Physical health	
Physical functioning, points	67.7 ± 31.3
Physical role, points	65.9 ± 28.0
Pain, points	69.1 ± 24.5
General health, points	69.4 ± 16.8
Emotional components of health	
Vitality, points	69.5 ± 18.2
Social function, points	44.5 ± 10.2
Emotional role, points	82.0 ± 27.1
Mental health, points	73.7 ± 17.6
Physical health component, points	44.5 ± 9.2
Emotional health component, points	48.5 ± 7.9

The results obtained indicate the effectiveness of the chosen treatment tactics, the correct choice of implants and their combinations for final stable internal fixation.

Case report

Patient G., 54 years old, was admitted to the trauma center one hour after injury (compression of the pelvis with a heavy load). A combined injury with rotationally unstable injury to the pelvic ring was diagnosed: ruptures of the pubic and right sacroiliac joints (Tile BI); acute blood loss; shock stage I. In the anti-shock department, the general condition was of moderate severity, blood pressure was 125/85 mm Hg, rhythmic pulse, heart rate 75 beats/min. Consciousness on the Glasgow Coma Scale was 15 points. The severity of injury on the ISS scale was 13 points. Upon examination, clinical signs of unstable pelvic injury were identified and temporary fixation with a pelvic belt (T-POD, USA) was immediately performed. SCT of the pelvis revealed a rupture of the symphysis pubis with a diastasis of 2.5 cm, and a partial rupture of the right sacroiliac joint (Fig. 1).

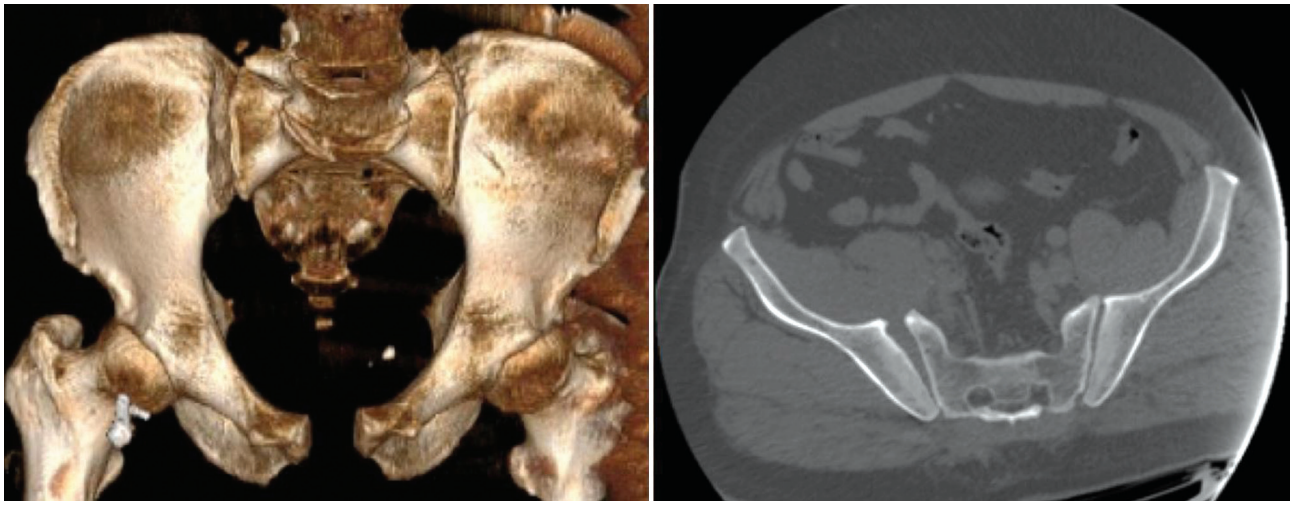

Fig. 1 SCT of patient G. at admission

The diastasis in the pubic symphysis was eliminated and fixed with a transpedicular system according to the described minimally invasive technique soon after admission. The right sacroiliac joint was fixed with a sacroiliac cannulated screw (Fig. 2).

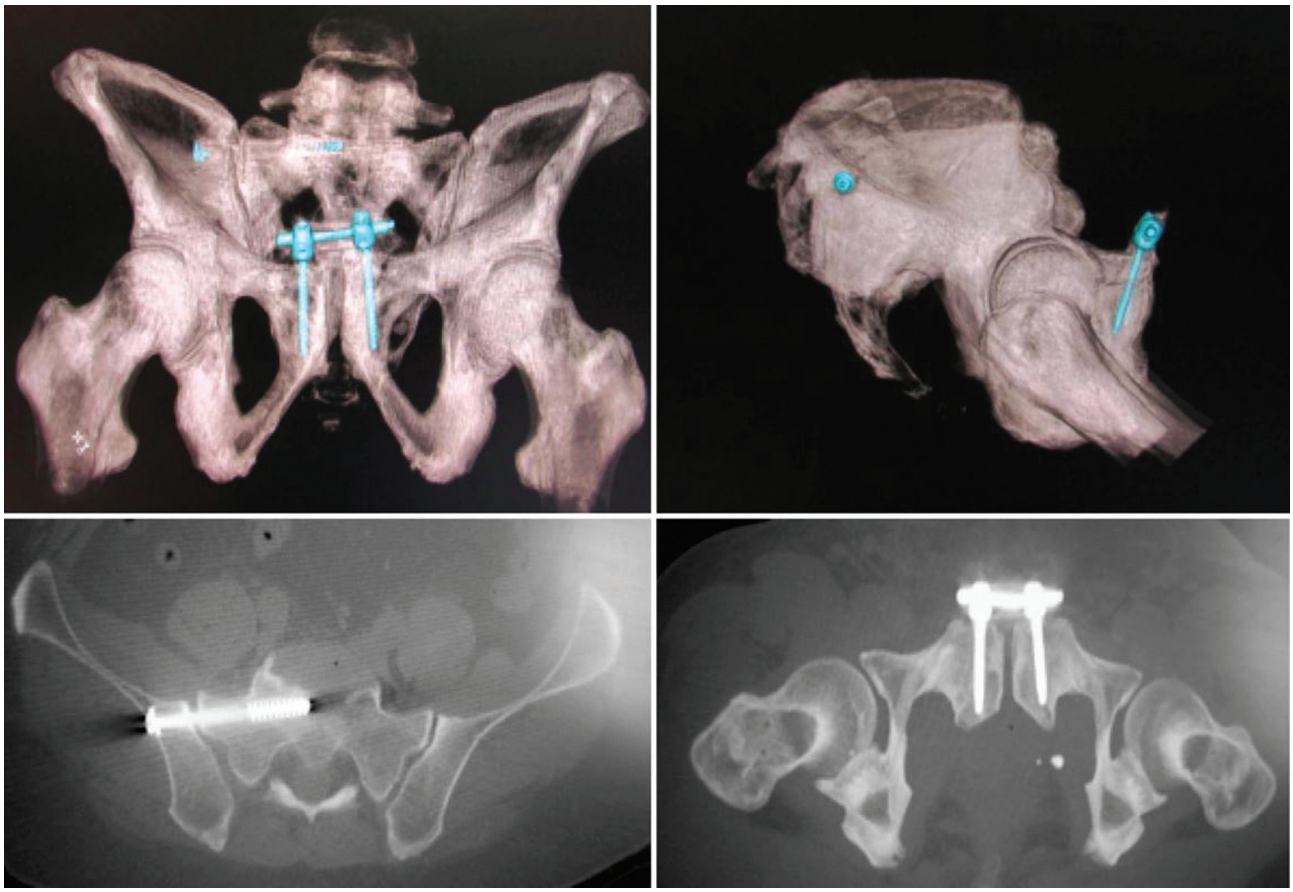

Fig. 2 SCT of patient G. after the operation

The patient was activated in bed from the third day after surgery. Walking with crutches with a dosed weight-bearing on the right lower limb was recommended. The patient was discharged for outpatient treatment after 20 days. The metal structures of the pelvis were completely removed 6 months after discharge. After 18 months the patient was re-examined, good treatment results were revealed: Majeed score — 98 points; SF-36 score: physical functioning — 95, physical role functioning — 100, pain — 100, general health — 85, general physical health component (PH) — 57.4 points.

The patients gave their voluntary informed consent for the publication of their clinical findings.

DISCUSSION

Recovery of vital body functions and treatment of complications may take a fairly long time after polytrauma (up to 3–4 weeks or more). Surgical interventions in the pelvic area performed during such a long period are traumatic, accompanied by large blood loss and a high risk of iatrogenic damage [6, 22].

Various surgical treatment methods have been proposed to fix the pubic symphysis. An external fixation device used in the acute period of injury is also applicable as a method of final stabilization of the damaged pubic symphysis. The operation is low-traumatic, takes relatively little time, and allows the patient to be mobilized early. The advantage of such fixation of the pubic symphysis is the patient's early activation and relatively good tolerance of the fixator. The use of EF is indicated up to four weeks after injury and in the presence of inflammatory changes in the area of the pubic symphysis and unorganized hematoma. However, the disadvantages of EF are also known: the need for constant care of pin tracts in the area, an increased risk of tissue suppuration around the pin wounds, loosening and migration of transosseous elements, the inability of the EF to retain the reduction of the posterior structures of the pelvis which can lead to early secondary displacement of fragments [2, 4].

The most common technique, presented as the "gold standard," is open plating of the pubic symphysis. Some authors classify it as a low-traumatic intervention and consider it possible to fix the pubic symphysis with a plate simultaneously with laparotomy or pelvic tamponade in emergency care [14, 23]. For this purpose, DCP, LC-DCP or special reconstruction plates are frequently used. The plates are installed superiorly and/or anteriorly relative to the pubic symphysis. This method of fixation achieves absolute (static) stability of the pubic symphysis, which can provoke a fatigue fracture of the plate in the postoperative period (> 23–30 % of clinical observations), since physiological mobility in the joint is disrupted when the patient becomes active, and loosening and subsequent failure of the implant lead to repeated diastasis in the pubic symphysis, persistent pain syndrome and severe impairment of static and dynamic functions [24, 25].

Ananyin et al. described the use of an original dynamic pelvic plate installed on the pubic symphysis, which, in their opinion, provides physiological micromobility in the joint and dynamic but stable fixation of the pelvic ring [26].

All these methods involve dissection of the rectus abdominis muscles in surgical approaches, which increases the risk of damage to the bladder and large vessels [14, 22]. The use of one plate along the upper edge of the symphysis for rotationally unstable pelvic injuries is sufficient to stabilize the pelvic ring. For vertically unstable pelvic injuries, two plates are used along the upper and anterior surface of the symphysis with the simultaneous installation of two iliosacral screws on the side of a complete rupture of the sacroiliac joint [27]. Simonian et al. show equally high efficiency in stabilizing the pelvis both with installing a plate on top of the symphysis on two and four 4.5 or 3.5 thick screws, and with installing two plates on six screws. Also, biomechanical bench studies of this author show that the most durable design for stabilizing a rupture of the pubic symphysis is biplanar fixation of the pubic symphysis with anterior and superior plates or a specially designed biplanar "box plate" [28].

Chen et al. evaluated the symphysis fixation technique that included the use of the Endobutton technique. After a mean follow-up of 23 months (range, 18 to 26 months), 15 patients achieved excellent Majeed scores with no migration of implants [10].

Recently, an innovative method of spare surgery for ruptures of the pubic symphysis has been proposed using new types of Tight Rope fixators for dynamic percutaneous stabilization with successful results. The fixator itself consists of two metal buttons (round and oblong) connected by a continuous self-tightening loop made of fibrous thread, which allows manual tightening, without tying a knot, and intraoperative adjustment of the degree of cortical fixation. This dynamic implant in the surgical treatment of ruptures of the pubic symphysis provides semi-rigid and durable fixation, allowing minor physiological movements, which reduces the load on the fixator itself, being a successful alternative method for the treatment of traumatic diastasis of the symphysis pubis type II, leading to results similar to percutaneous fixation with cannulated screws. Additional external fixation of the pelvic ring provides greater stability in the early postoperative phase. The best indication for the use of Tight Rope fixators is APC-II type pelvic injuries (type B1 or B2 in accordance with the accepted Tile classification). The authors state that the advantages of the four-point fixation system are a minimally invasive installation technique, less intraoperative blood loss, minimal risk of complications and rapid recovery [9]. Secure dynamic bone fixation reduces the load on the pubic symphysis during ligament healing and micromotion, which decreases the risk of implant failure. There is no need to remove the implant. Disadvantages are the complex procedure and a relatively longer operating time. Contraindications to the use of the method are open pelvic injuries, combined fractures of the acetabulum, fractures of the anterior semi-ring of the pelvis in combination with ruptures of the symphysis pubis and medical contraindications. Subsequent clinical experience and biomechanical studies regarding this method of dynamic implant fixation may facilitate its use in more complex clinical cases, such as APC-III pelvic injuries, in which simultaneous stabilization of damaged posterior pelvic ring structures is required.

There is evidence of percutaneous fixation of the pubic symphysis with cannulated screws. We may discuss several options for inserting cannulated screws, when the screws are located parallel to each other (horizontally or obliquely) and when they cross each other. Yu et al. compared this surgical technique with plate fixation of the symphysis pubis in a study of clinical and biomechanical outcomes. The authors noted a significantly shorter operative time (26 versus 69 minutes) and less intraoperative blood loss (10 versus 172 ml) in the screw fixation group. At a mean 29-month follow-up (range, 18 to 54 months), measuring the pubic symphysis diastasis in each group, a similar distance in the screw and plate fixation groups (4.8 vs. 4.5 mm) was found [27]. Similarly, Chen et al. conducted a retrospective comparative study of the results of treatment of patients who underwent fixation of the pubic symphysis with cannulated screws or plates. A significantly less blood loss in the screw fixation group (18 vs. 157 mL) was found. However, according to the results of 21 months (range, 18 to 26 months) there was little difference in the incidence of complications such as revision surgery (2 vs. 6), infection (2 vs. 8), or symphyseal malunion (8 vs. 14) [29]. A biomechanical study by Cano-Luis et al. concluded that there is sufficiently good rigidity in fixing a rupture of the symphysis pubis with two cannulated screws [30]. The authors of those studies concluded that percutaneous fixation may achieve similar results to plate fixation reducing operative time and blood loss. Thus, minimally invasive fixation of the symphysis pubis with cannulated screws reduces the risk of intraoperative complications, but does not significantly improve treatment results compared to fixation with plates.

There are known methods for fixing the symphysis pubis using metal flexible implants with thermometallic memory made of NiTi (titanium nickelide). The authors indicate that their use enabled them to achieve good fixation and micromobility in the area of the symphysis pubis [31]. There is also a known method for fixing ruptures of the pubic symphysis with sets of U-shaped staples [11]. However, that method involves a traumatic approach and there is the risk of bladder damage. The proposed metal structures are not manufactured at an industrial scale.

Osteosynthesis of the symphysis pubis with various types of wire cerclage is rarely used in modern conditions due to traumatic approaches and unstable fixation; it is rather of historical significance. However, according to a biomechanical study carried out by Varga et al., wire cerclage fixed to two cancellous screws, the optimal diameter of which is 6.5 mm with continuous threading, inserted into the rami of the pubic bones parasymphysially, may achieve fixation that, while being functionally stable, prevents synostosis of the pubic symphysis [32].

As for surgical approaches for the symphysis pubis fixation, it is worth mentioning the classic Pfannenstiel approach, which is used most, and the ilioinguinal approach as modified by Stopp, which is considered less traumatic [14, 34]. As one of the low-traumatic and fairly well-known approaches to the symphysis pubis, a vertical median approach has been proposed, which allows for good exposure of the symphysis pubis with the articulating bones, which provides sufficient conditions for applying a plate or installing transpedicular screws [34]. Thus, the aponeurosis of the rectus abdominis muscles is not crossed, and there is less risk of vascular damage. The vertical midline approach should be considered as an alternative to classical approaches for the use of minimally invasive transpedicular screw fixation techniques.

All of the above methods of fixation of the symphysis pubis require classical open surgical approaches to the pubic symphysis with their inherent disadvantages [6, 22, 35]. Lately, a variant of fixation of the symphysis pubis with endoscopic support was described [36].

At the moment, the scientific research conducted by us includes a small number of clinical observations, which does not allow for a full statistical analysis of the effectiveness of the proven method of minimally invasive fixation of ruptures of the symphysis pubis, and the reliability of the final results has not been fully reflected. To obtain more complete clinical data, further study is required with a larger sample size and a longer observation period, a comparative

analysis with the use of other methods of fixation of the symphysis pubis. Biomechanical studies of this technique are also necessary.

However, the success of using the method under consideration in our clinical practice for various injuries of the pelvic ring, including for vertically unstable injuries, multiple pelvic trauma (open injury with perineal rupture, extensive soft tissue injuries of the Morel – Lavallee type, ruptures of the pelvic organs), allows us to recommend its study within the framework of surgery for injuries of the pelvic ring and fractures of the acetabulum as an interdisciplinary pathology at the intersection of various specialties. Future research should focus on the long-term outcomes and effectiveness of new innovative techniques for fixation of pubic symphysis ruptures.

CONCLUSION

The minimally invasive fixation of the pubic symphysis with a transpedicular system proposed by us corresponds to the principles of current minimally invasive pelvic osteosynthesis. Due to its low-traumatic nature, it may be used in the acute period of a traumatic disease, ensuring early rehabilitation.

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The effect of the IL-6 monoclonal blocker on the course of aseptic femoral head necrosis in the experiment (pilot study)

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Abstract

Background There is currently no pathogenetically based treatment for aseptic necrosis of the femoral head. One of the most promising areas of possible targeted therapy is the use of genetically engineered drugs, including monoclonal blockers of proinflammatory cytokines, aimed at inhibiting inflammation and indirectly reducing the activity of osteodestruction. The aim of the work is to evaluate the effectiveness of the use of the IL-6 monoclonal blocker in the course of aseptic necrosis of the femoral head in an experiment.

Purpose Evaluate the preliminary results of the use of the IL-6 monoclonal blocker in the course of aseptic necrosis of the femoral head in an experiment.

Materials and methods Surgical induction of aseptic necrosis of the femoral head was performed in 18 male Wistar rats. The animals were divided into two groups of 9 individuals each. The first group did not receive any treatment, the second received therapy with a monoclonal IL-6 receptor blocker, starting from the second week of the experiment, one injection once every two weeks. All animals were removed from the experiment at 4, 6 and 8 weeks after the induction of aseptic necrosis, 3 rats from each group at a time. Total RNA was isolated from the femoral head on the aseptic necrosis side and the conditionally healthy side as a control. The expression of genes of regulatory proteins of osteogenesis was studied by PCR. To study the features of osteodestructive processes, histological examination of femoral head preparations in all animals was conducted.

Results Histological preparations of femoral heads of the second group animals were characterized by less pronounced osteodestructive, chondrodestructive processes compared to the animals that did not receive therapy. The mRNA profile of the rats of the second group displayed an increase in the expression of genes encoding proteins involved in osteoreparation at all stages of the experiment. At the same time, the activity of genes encoding proteins of proinflammatory cytokines, regulatory molecules of osteoclastogenesis was reduced relative to the first group.

Discussion The data obtained indicate an important role of inflammation in the regulation of osteodestruction. Inhibition of the biological action of IL-6 contributed to inhibition of the expression of osteoclastogenesis genes, increased activity of bone metabolism genes, and caused a decrease in the intensity of osteodestruction and activation of osteoreparation.

Conclusion Preliminary results of the use of a monoclonal blocker of the proinflammatory cytokine IL-6 indicate the inhibition of osteodestructive and strengthening of osteoreparative processes due to the correction of the expression of bone metabolism genes during the progression of aseptic necrosis of the femoral head in rats in an experimental model.

Keywords: aseptic necrosis, genetically engineered drugs, osteodestruction, IL-6 monoclonal blocker, osteoblastogenesis, osteoclastogenesis, osteoinduction, anti-inflammatory therapy

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INTRODUCTION

Aseptic necrosis of the femoral head is a pathological process that develops in stages and in which osteoresorption in the early stages is replaced by activation of osteoreparation in later stages [1, 2, 3]. The result of bone destruction may be the development of deforming coxarthrosis, gross incongruence in the hip joint with the need for its replacement. The pathogenesis of avascular necrosis of the femoral head is not fully understood; however, recently there has been a tendency towards increasing interest in studying disorders of the regulation of bone homeostasis at the molecular and cellular levels [4, 5]. The most commonly used option for conservative therapy in aseptic necrosis of the femoral head is physical therapy aimed at improving blood supply to the proximal femur for enhancing ossification along with compliance with the orthopaedic regimen [6]. This treatment cannot be considered as a targeted treatment and in some cases does not have significant effect. To develop new pathogenetically based strategies for the treatment of osteogenesis disorders, a detailed understanding of the pathophysiological mechanisms of changes in bone tissue metabolism and possible ways of effecting on them is necessary.

The balance of bone tissue remodeling is maintained due to the functioning of a large number of intracellular and intercellular signaling pathways, phosphorylation processes, and the synthesis of regulatory molecules [7, 8]. The main signaling pathway aimed at differentiation and activation of mature osteoclasts is the receptor activator of nuclear factor kappa β, its ligand and osteoprotegerin (RANK-RANKL-OPG) system [9, 10]. The interaction of the membrane receptor activator of nuclear factor kappa β (RANK) with its ligand (RANKL) leads to translocation of nuclear factor kappa β (NFkβ) into the cell nucleus and activation of intracellular pathways, resulting in the induction of differentiation of progenitor cells into a mature osteoclast and subsequent activation. Some research works indicate one of the leading roles of increased osteoclastogenesis in the development of bone destructive processes in avascular necrosis [11, 12].

A number of signaling molecules, including pro-inflammatory cytokines, may be important in regulating RANKL synthesis. The biological effect of pro-inflammatory cytokines, such as IL-6, IL-1β, TNFα, has been proven, aimed at increasing the expression of RANKL, activating osteoclastogenesis and, as a consequence, increasing osteolysis [13, 14, 15]. Moreover, the role of pro-inflammatory cytokines in apoptosis and autophagy of osteoblasts through the mitogen-activated protein kinase (MAPK)/nuclear factor-κB (NF-κB) signaling pathway has been discovered [16]. Regulation of osteoclast activity and, consequently, impact on bone homeostasis is possible through correction of the activity of pro-osteoclastogenic mediators. Thus, a number of research studies reveal an increased concentration of pro-inflammatory cytokines in the synovial fluid in the early stages of avascular femoral head necrosis and consider these regulatory molecules as a possible therapeutic target for the treatment of this disease [17, 18].

A large number of signaling pathways are involved in the regulation of osteoblastogenesis activity: canonical and non-canonical wnt (wingless) / b catenin, JAK (Janus Kinase) / STAT (Signal Transducer and Activator of Transcription), MAPK (mitogen-activated protein kinase) [19, 20, 21]. Along with antiresorption therapy, it is possible to use anabolic therapy, the purpose of which is to enhance osteoinduction in aseptic necrosis of the femoral head. An earlier study of the expression of genes encoding proteins of pro-inflammatory cytokines, molecules involved in osteoclastogenesis, osteoblastogenesis, and bone matrix proteins in rats after surgical induction of aseptic necrosis of the femoral head showed an earlier suppression of the osteogenic component of bone homeostasis than an increase in the osteoresorptive component [22].

Considering the key importance of tissue hypoxia due to hypoperfusion in the development of avascular necrosis of the femoral head, a number of studies link the pathogenesis of osteodestructive processes with overexpression of hypoxia-induced factor 1α (HIF-1α). Thus, a model experiment on piglets resulted in detection of an increased concentration of the HIF-1α protein in the femoral

head during the manifestation of avascular necrosis [23]. It is known that the HIF-1α protein plays an important role in the processes of remodeling and maintenance of bone homeostasis [24, 25, 26]. At the same time, a number of research studies have found an inductive effect of both gene overexpression and the HIF-1α protein itself on the concentration of RANKL and, as a consequence, activation of osteoclast differentiation from progenitor cells [27, 28]. Accordingly, antiresorption therapy aimed at reducing the intensity of osteoclastogenesis would be possible by correcting the activity of HIF-1α as one of the trigger factors in avascular necrosis.

Thus, the regulatory mechanisms that determine the high activity of osteoclasts are being studied in order to develop a targeted therapy aimed at normalizing intercellular interactions. Effective correction of various links in the pathogenesis of osteodestruction would significantly improve the quality of life of patients with aseptic necrosis.

Purpose of the work was to evaluate the preliminary results of the application of the IL-6 monoclonal blocker in the course of aseptic necrosis of the femoral head in an experiment.

MATERIALS AND METHODS

A model experiment was carried out on 18 male Wistar rats, weighing (250 ± 25) g, at the age of three months. To induce aseptic necrosis of the femoral head, all animals underwent surgical manipulations that comprised a dense ligature with absorbable Vicryl suture material around the femoral neck to create a zone of hypoperfusion, as well as introducing 1.5 ml of a 2 % rheopolyglucin solution into the joint cavity to increase intra-articular pressure. The model of induction of aseptic femoral head necrosis is protected by a patent of the Russian Federation [29].

The animals are then divided into two equal groups. Animals of the first group did not receive treatment (comparison group). Animals of the second group received an injection of sarilumab (kevzara), a monoclonal blocker of the IL-6 receptor, starting from the second week of the experiment, one injection once every two weeks, at a dose of 15 mg per kg of body weight (study group). They were kept in cages of three animals with free access to food and water. All animals were removed from the experiment by decapitation at 4, 6 and 8 weeks after the induction of aseptic necrosis, three rats from each group. The experiment was carried out in accordance with the "Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes" adopted by the Council of Europe (Strasbourg, France, 1986), and Council Directive 86/609/EEC of 24.11.1986 "On the harmonization of laws, regulations and administrative orders of the participating countries regarding the protection of animals used for experimental and scientific purposes" on the basis of the Kemerovo State Medical University and the Research Institute of the Communist Party of the Soviet Union (Kemerovo).

After removing the animals from the experiment, extirpation of the femurs was performed, both from the side of aseptic necrosis manifestation and from a conditionally healthy side as a comparison. The proximal epiphysis was separated from the femur and divided into two equal parts. A part of the femoral head was used for histological examination. The specimen was prepared with a standard acid-free method using EDTA salts and stained with hematoxylin and eosin. To evaluate the morphometric parameters, ImageJ software was used to identify the colored bone beams as a pixel value, which enabled to quantify the morphometric parameters.

A part of the femoral head, both affected by aseptic necrosis and a healthy one, was used to isolate total RNA using the RNeasy MicroKit kit (QIAGEN, Germany) according to the manufacturer's protocol. The quality and quantity of isolated RNA was determined on a Qubit 4 spectrophotometer (Invitrogen, USA) by assessing the RIQ index (RNA Integrity and Quality) using the Qubit RNA IQ Assay Kit (Invitrogen, USA).

Gene expression levels were determined by quantitative reverse transcription polymerase reaction using the High-Capacity cDNA Reverse Transcription Kit (4368814, Thermo Fisher Scientific,

Waltham, MA, USA). Primers were synthesized on an ABI 3900 high-throughput DNA synthesiser (Thermo Fisher Scientific, Waltham, MA, USA) by Evrogen (Moscow, Russia). Results of qPCR were normalized using three reference genes *actb*, *tbp*, *b2m* in accordance with existing recommendations. The expression of the studied genes was calculated using the 2-ΔΔCt method. Gene expression was studied for *il4*, *il6*, *il1b*, *tnfa*, *tgfb*, *sp7*, *runx2*, *opn/spp1*, *bmp2*, *bglap*, *rankl*, *alpl*, *hif1a*.

Statistical processing of the obtained results was carried out in Statistica for WINDOWS software packages from StatSoftInc (USA), version 10.0 according to the rules of variation statistics. The study used Wistar rats kept under the same optimal conditions, so the Shapiro – Wilk W-test showed a normal distribution. Quantitative data were presented as mean and standard error (M ± m). Comparison of the values of metric indicator levels in unrelated samples was carried out using the Student's t test. The probability of a type 1 error was taken as 5 %, and a second type error as 20 %; accordingly, the level of statistical significance was detected at $p < 0.05$, which corresponds to standard requirements. A pure line of Wistar laboratory rats was used in the experiment, which determined the genetic homogeneity of the studied groups. Thus, the study of even a small sample enabled statistical processing of the results obtained.

RESULTS

Histological study

The motor activity of the rats that received injections of a monoclonal IL-6 blocker recovered faster than in the comparison group. Thus, all rats of the study group were able to stand on their hind legs 4 weeks after induction of aseptic necrosis, while in the comparison group only a part of the animals could bear weight on the pelvic limbs at 6 weeks after the start of the experiment (Fig. 1).

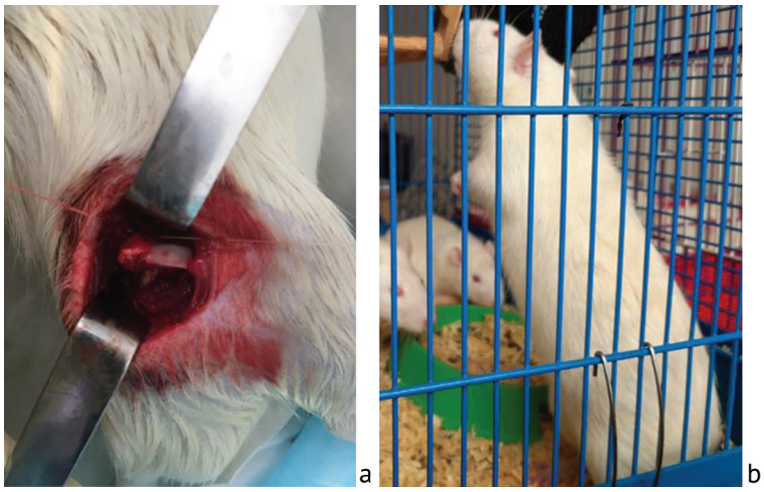

Fig. 1 Photos of the experiment: *a* surgical induction of aseptic necrosis of the femoral head; *b* axial load on the hind legs in rats of the study group

The histological picture of preparations of the femoral heads in both groups confirmed the development of chondrodestructive and osteodestructive processes. The study revealed empty bone lacunae; part of the bone tissue was replaced by dense fibrous tissue. In the areas of osteoresorption, active osteoclasts were identified as giant multinucleated cells. The number of osteoblasts, which were defined as mononuclear cells, increased primarily in the areas of osteosclerosis. However, the course of avascular necrosis differed. Progressive osteoresorption from the fourth to the sixth week was noted in animals of the first group, while signs of osteoreparation were visualized only in the eighth week of the experiment. In the group of animals receiving the monoclonal IL-6 blocker drug, isolated osteolytic processes were recorded only in the fourth week; active osteoblasts, areas of revascularization and bone restoration were visualized in the sixth and eighth weeks along with osteodestruction.

Four weeks after surgical induction of aseptic necrosis, a change in the normal architecture of the bone trabeculae of the cancellous substance to a wave-like arrangement was visualized in the rats that did not receive treatment, and the density of trabeculae was reduced. The intermediate layer of yaline cartilage was characterized by sparseness; most of the chondrocytes were located in the outer layer. Chondrocytes lost their elliptical shape, and signs of destruction of their nucleus were

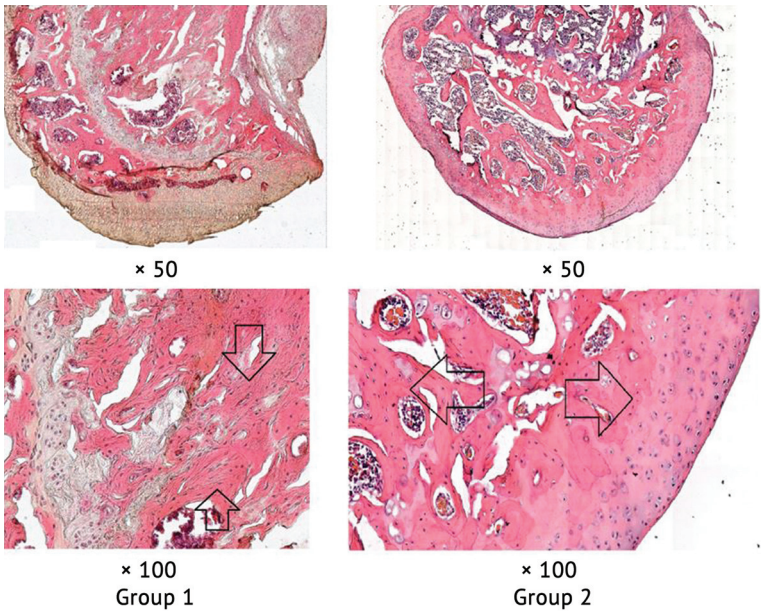

Fig. 2 Histological picture at 4 weeks after the manifestation of aseptic necrosis (hematoxylin and eosin staining). Group 1: arrows show the wavy position of bone trabeculae; group 2: arrows show a uniform arrangement of chondrocytes, normal architecture of the spongy substance

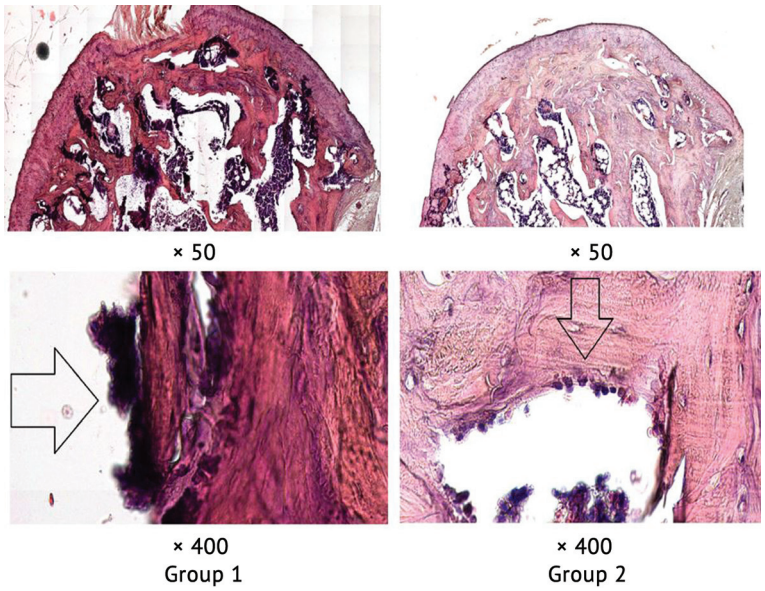

Fig. 3 Histological picture at 6 weeks after the manifestation of aseptic necrosis (hematoxylin and eosin staining). Group 1: arrows show active osteoclasts; group 2; arrows show active osteoblasts

revealed. In animals of the second group, preparations of the femoral heads largely preserved normal architecture, and the loss of bone trabeculae was lower than in rats of the first group. The arrangement of chondrocytes in hyaline cartilage was more uniform (Fig. 2).

In preparations of the femoral heads bones of the first group animals, six weeks after the start of the experiment, signs of progressive osteoresorption were observed, and a further loss of bone trabeculae density was diagnosed in comparison with preparations taken after four weeks of the aseptic necrosis modeling. The number of active osteoclasts and bone resorption lacunae increased from the fourth to the sixth week of the experiment. Part of the hyaline cartilage was replaced by fibrous tissue. In the animals of the second group, active osteoblasts were determined in the areas of bone sclerosis along with signs of osteodestruction in the form of loss of a part of the bone trabeculae and their wavy arrangement in the preparations of the femoral heads. At the same time, the loss of bone trabeculae density in the animals treated with a monoclonal IL-6 blocker was lower than in rats of the first group (Fig. 3).

After 8 weeks, the first signs of osteogenicity were noted in the femoral heads of rats that did not receive treatment. Thinning of the articular cartilage, loss of some chondrocytes, and bone trabeculae were visualized. At the same time, along with replacement of the spongy substance with dense fibrous tissue, active osteoblasts were determined. In the rats of the second group, hyaline cartilage was characterized by greater preservation of the density of chondrocytes in both the outer and intermediate layers. Bone trabeculae had a high density, zones of mineralization with a large accumulation of active osteoblasts, and areas of bone revascularization were identified. The number of osteocytes increased compared to the preparations taken 6 weeks after the induction of aseptic necrosis (Fig. 4).

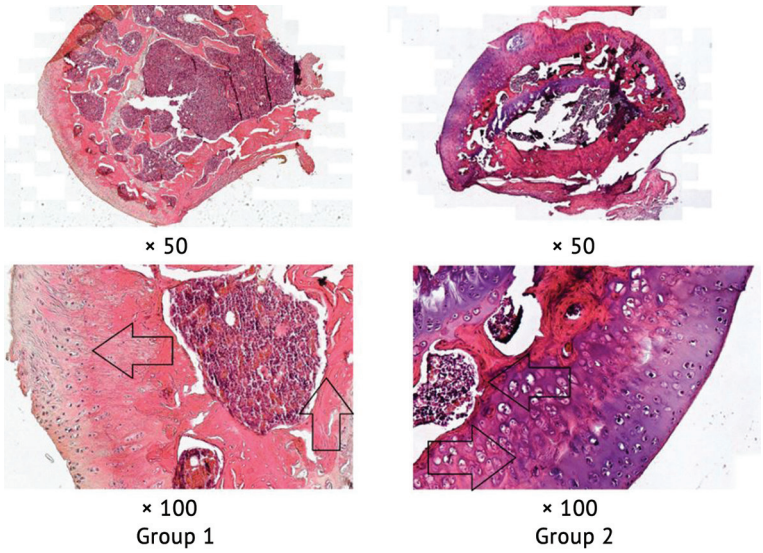

Fig. 4 Histological picture at 8 weeks after the manifestation of aseptic necrosis (hematoxylin and eosin staining). Group 1: arrows show uneven distribution of chondrocytes in hyaline cartilage, active osteoblasts; group 2: arrows show a uniform, dense distribution of chondrocytes in hyaline cartilage and an area of bone mineralization

The use of ImageJ software allowed us to quantify changes in bone trabecular density. Thus, in the rats that did not receive treatment, the course of avascular necrosis was accompanied by a rogressive loss of bone density from the fourth to the sixth week. At the same time, in the eighth week of the experiment, a slight increase in the density of the bone trabeculae was noted. A tendency towards a decrease in the density of bone trabeculae from the fourth to the sixth week and recovery in the eighth week of the experiment was also recorded in the study group. However, the volume of bone trabeculae in the animals that received anti-inflammatory therapy with a monoclonal IL-6 blocker was significantly greater than in the rats without treatment at the sixth and eighth weeks after the induction of avascular necrosis (Table 1).

Table 1

Histological findings of trabecular volume (%)

Week of experiment	Comparison group	Study group	*p*-level
4	31.45 ± 1.03	33.67 ± 1.43	> 0.05
6	23.03 ± 1.23	30.78 ± 1.32	0.02*
8	24.43 ± 1.29	31.66 ± 1.36	0.03*

Note: * — significant difference

Changes in mRNA profile

Features of the functioning of signaling pathways for bone tissue remodeling and their regulation at the molecular and cell level determined the activity of osteoresorptive and osteoreparative processes. One month after the surgical induction of avascular necrosis, the greatest differences were obtained in the dynamics of changes in genes encoding proteins associated with osteoinduction. Thus, in animals of the second group along with a decrease in the expression of the gene for the pro-inflammatory cytokine interleukin 6 (*il6*), the expression of the osteocalcin gene (*bglap*), the encoded protein of which is secreted by osteoblasts and is involved in the regulation of bone remodeling, and the alkaline phosphatase gene (*alpl*), which determines the intensity of bone mineralization, increased significantly , the transforming growth factor b (*tgfb*) gene, the encoded protein of which enhances revascularization and is involved in osteoreparation processes. Moreover, in rats treated with a monoclonal IL-6 blocker, the expression of the hypoxia-induced factor 1α (*hif1α*) gene was significantly reduced. In the animals of the first group, the expression of the secreted phosphoprotein 1 (*spp1*) gene increased significantly. The protein encoded by this gene promotes the adhesion of osteoclasts to the bone matrix and has high specificity for hydroxyapatite and osteoclast membrane proteins (Table 2).

Six weeks after the induction of aseptic necrosis of the femoral head, overexpression of the proinflammatory cytokine genes *il6*, *tnfα*, as well as the nuclear factor κβ (*rankl*) receptor activator ligand gene was observed in the rats that did not receive treatment (comparison group). This gene encodes one of the main proteins of the RANK–RANKL–OPG signaling pathway, aimed at the differentiation and activation of osteoclasts. At the same time, in the animals treated with a monoclonal IL6 blocker, the expression of the *il6*, *tnfα* gene was significantly suppressed. The intensity of *rankl* gene expression did not differ from the conditionally healthy limb. Also, in rats of the main group, increased expression of genes aimed at enhancing osteoblastogenesis was recorded, such as the bone morphogenetic protein gene (*bmp2*), the transcription factor gene (*sp7*), involved in osteoblast differentiation, and the expression of *tgfb* genes remained increased. However, it is worth noting the increased expression of the *spp1* gene, which may indicate osteoclast activity (Table 3).

Two months after the development of avascular necrosis of the femoral head, overexpression of the *il6*, *tnfα* genes was retained in the rats of the first group. The intensity of *rankl* gene expression decreased slightly compared to the previous period, but was higher than in a conditionally healthy limb. The synthesis of *spp1* mRNA gene increased. However, changes in the mRNA profile in the femoral heads of the untreated animals also indicate increased osteogenesis. The expression of *alpl* genes increased. In the rats of the second group, an increase in the expression of genes encoding proteins was retained, the biological action of which is aimed at enhancing osteoreparation. The synthesis of the mRNA genes *runx2* and *sp7* remained increased. However, against this background, the intensity of *rankl* gene expression was increased compared to a conditionally healthy limb (Table 4).

Table 2

mRNA profile after 4 weeks

Gene	Comparison group	Study group	*p*-level
bmp2	1.097 ± 0.219	0.831 ± 0.137	> 0.05
alpl	0.484 ± 0.095	2.445 ± 0.738	0.02*
hif1a	1.031 ± 0.563	0.342 ± 0.059	0.04*
rankl	1.216 ± 0.609	1.157 ± 0.583	> 0.05
runx2	0.934 ± 0.319	0.891 ± 0.204	> 0.05
sp7	1.051 ± 0.421	1.774 ± 0.538	> 0.05
bglap	0.684 ± 0.137	3.637 ± 0.926	0.01*
spp1	7.691 ± 1.823	0.624 ± 0.137	< 0.001*
tgfb	0.964 ± 0.371	3.092 ± 0.957	0.01*
tnfa	1.142 ± 0.296	0.806 ± 0.172	> 0.05
il6	1.125 ± 0.325	0.79 ± 0.148	0.04*

Note: * — significant difference.

Table 3

mRNA profile after 6 weeks

Gene	Comparison group	Study group	*p*-level
bmp2	1.613 ± 0.419	2.462 ± 0.816	0.03*
alpl	2.394 ± 0.751	2.936 ± 0.973	> 0.05
hif1a	0.768 ± 0.143	1.287 ± 0.419	> 0.05
rankl	11.076 ± 3.054	1.019 ± 0.326	0.001*
runx2	3.831 ± 0.904	0.501 ± 0.118	0.01*
sp7	1.998 ± 0.673	3.095 ± 1.008	0.04*
bglap	0.702 ± 0.179	1.043 ± 0.307	> 0.05
spp1	0.447 ± 0.103	2.297 ± 0.713	0.01*
tgfb	0.943 ± 0.319	2.331 ± 0.784	0.02*
tnfa	14.471 ± 4.107	1.918 ± 0.607	< 0.001*
il6	3.844 ± 0.916	0.054 ± 0.014	< 0.001*

Note: * — significant difference.

Table 4

mRNA profile after 8 weeks

Gene	Comparison group	Study group	*p*-level
bmp2	1.613 ± 0.419	2.462 ± 0.816	0.03*
alpl	2.394 ± 0.751	2.936 ± 0.973	> 0.05
hif1a	0.768 ± 0.143	1.287 ± 0.419	> 0.05
rankl	11.076 ± 3.054	1.019 ± 0.326	0.001*
runx2	3.831 ± 0.904	0.501 ± 0.118	0.01*
sp7	1.998 ± 0.673	3.095 ± 1.008	0.04*
bglap	0.702 ± 0.179	1.043 ± 0.307	> 0.05
spp1	0.447 ± 0.103	2.297 ± 0.713	0.01*
tgfb	0.943 ± 0.319	2.331 ± 0.784	0.02*
tnfa	14.471 ± 4.107	1.918 ± 0.607	< 0.001*
il6	3.844 ± 0.916	0.054 ± 0.014	< 0.001*

Note: * — significant difference.

DISCUSSION

Changes in the mRNA profile during the progression of aseptic femoral head necrosis are characterized by extreme heterogeneity. At the same time, some patterns of synthesis of genes encoding regulatory proteins of osteogenesis can determine the course of osteodestructive and osteoreparative processes.

The development of avascular necrosis in the animals that did not receive therapy, according to histological examination, was accompanied by a progenitor course of osteoresorptive and chondrodestructive processes up to 8 weeks after the hypoperfusion zone of the femoral head had been applied. Only eight weeks after the start of the experiment, the first signs of osteoreparation were detected in histological preparations.

At the same time, changes in the mRNA profile of the proximal femoral epiphysis show a tendency toward overexpression of proinflammatory cytokine genes and osteoclastogenesis genes from the fourth to the eighth week. Thus, increased expression of the *il6, tnfα, rankl* genes was observed both in the sixth and eighth weeks of aseptic necrosis. These genes encode proteins of pro-inflammatory cytokines and key molecules of the osteoclastogenesis signaling pathway. Song et al. in their study of the proteome in patients with aseptic necrosis of the femoral head noted an increase in the concentration of pro-inflammatory cytokines and attribute great importance to the increase in nonspecific inflammation in the processes of dysregulation of bone homeostasis [30]. The biological effect of proinflammatory cytokines is aimed at inducing the RANK–RANKL–OPG signaling pathway, enhancing the differentiation and activation of mature osteoclasts. There are a number of research studies confirming the overexpression of these inflammatory mediators in the early stages of the development of aseptic femoral head necrosis [31, 32]. Thus, it is logical to consider the relationship between an increase in the level of mRNA in the head of the femur of both the proinflammatory cytokine genes *il6, tnfα*, and the *rankl* gene, and the histological picture of the progressive destruction o bone and cartilage tissue. The data obtained indicate the important role of inflammation in the regulation of osteodestruction.

Moreover, at the fourth and eighth weeks after surgical induction of avascular necrosis, overexpression of the *spp1* gene was observed. Studies of the concentration of secreted phosphoprotein 1 (*spp1*) in osteoblasts due to the development of avascular necrosis of the femoral head showed a significant increase in the concentration of this protein compared with a conditionally healthy limb [33]. It is known that the encoded protein of the *spp1* gene promotes the attachment of osteoclasts to the bone matrix [34]. Besides, an increase in *spp1* gene expression may promote the activation of osteoclastogenesis through the PI3K/AKT signaling pathway [35]. Thus, an increase in the expression of the gene in the histological picture of progressive osteodestruction from the fourth to the eighth week of the experiment can also be considered as one of the factors contributing to the intensification of resorption processes.

However, in the eighth week of the experiment, a large number of active osteoblasts were determined by examining histological preparations of the animals from the first group. At the same time, the expression of genes encoding proteins involved in bone mineralization and osteoblastogenesis (*bmp2, alpl, bglap*) increased. Thus, the processes of regeneration and destruction of bone tissue are largely due to the changes in the mRNA profile of the femoral head.

Changes in the study of histological preparations of the femoral head in the rats treated with a monoclonal blocker of IL-6 were characterized by a less intense course of osteodestruction compared to the animals of the first group. The density of bone trabeculae, the architectonics of the spongy substance, and changes in the hyaline cartilage were less pronounced and more consistent with findings in the conditionally healthy limb. Moreover, already from the sixth week after surgical induction of avascular necrosis, signs of osteoreparation were visualized in the preparations.

The dynamics of changes in the mRNA profile of genes encoding regulatory proteins of osteogenesis had its own characteristics. Expression of the gene for the pro-inflammatory cytokine *il6* was expectedly reduced in the fourth and sixth weeks of the experiment. Maximum inhibition of *il6* gene activity was obtained in the sixth week, while a slight increase in the expression was observed in the eighth week. The activity of the *tnfα* gene varied depending on the time after the manifestation of aseptic necrosis. Thus, the expression of the *tnfα* gene in the fourth week of the experiment was slightly reduced, while in the sixth and eighth weeks it was increased compared to a conditionally healthy limb. It is worth noting that the activity of the pro-inflammatory cytokine genes *il6, tnfα* at all stages of the experiment in the rats of the second group was significantly lower than in the first group. The presented data indicate inhibition of nonspecific inflammation due to the therapy with a monoclonal IL-6 blocker.

A decrease in the intensity of the biological action of the pro-inflammatory cytokine IL-6 can be associated with changes in the expression of genes encoding proteins that regulate osteoclastogenesis and the activity of osteolysis processes. The most striking picture of osteoclastogenesis inhibition was observed at week 6 of the experiment. Thus, in the animals that did not receive specific treatment, overexpression of the *rankl* gene was observed, while in the rats treated with a monoclonal blocker of IL-6, the expression of the gene did not differ from that of a conditionally healthy limb. However, at the same time, in the rats of the second group, an increase in the expression of the *spp1* gene was recorded, which may indicate processes of osteolysis and, possibly, indirect pathways of activation of mature osteoclasts.

The first four weeks after the induction of avascular necrosis in the animals of the second group were accompanied by increased expression of genes associated with osteoinduction and revascularization, such as *sp7, bglap, alpl, tgf*β. The predominance of the expression of the genes encoding proteins of osteoblastogenesis, extracellular bone matrix, and bone mineralization was maintained from the fourth to the eighth week of the experiment, while the nature of the mRNA profile somewhat changed in regard to the time elapsed since the manifestation of aseptic necrosis of the femoral head. There are a number of research studies that reveal the effectiveness of antiresorptive, anti-inflammatory therapy in experimental model of aseptic necrosis of the femoral head in animals [31, 32, 36]. The effectiveness of treatment was assessed using data from microcomputed tomography, histological, and immunohistochemical studies, which showed an increase in bone tissue repair processes and a decrease in osteoresorption compared to a conditionally healthy limb. However, studies of the molecular and cellular mechanisms of osteogenesis regulation during the use of monoclonal blockers of proinflammatory cytokines are very few.

The intensity of expression of the *sp7* transcription factor gene was increased throughout the experiment in the rats of the second group. The protein encoded by this gene is a member of the zinc factor family of transcription factors, which play a fundamental role in the processes of differentiation of osteoblasts from progenitor cells, chondrogenesis, as well as maintaining the balance in the differentiation of mesenchymal cells along the osteogenic and chondrogenic pathway [37]. Increased expression of the *sp7* gene in the fourth, sixth and eighth weeks after the induction of avascular necrosis by administration of a monoclonal IL-6 blocker may indicate increased chondrogenesis and osteogenesis. Moreover, in the rats of the second group, the expression of the alkaline phosphatase gene *alpl* was increased from the fourth to the eighth week of the experiment. These findings confirm an increase in bone tissue metabolism along with suppression of the biological effect of the pro-inflammatory cytokine IL-6.

Thus, the preliminary results of the use of a monoclonal blocker of the proinflammatory cytokine IL-6 show a more favorable course of aseptic necrosis of the femoral head in rats. Greater preservation of the density of bone trabeculae, the structure of hyaline cartilage, and cancellous bone was obtained in the animals that received specific anti-inflammatory therapy. The dynamics of changes in the mRNA profile in the rats of the study group indicate inhibition of the expression of osteoclastogenesis and osteolysis genes (*rankl, spp1*) due to a decrease in the activity of the proinflammatory cytokine genes *il6, tnf*α. At the same time, the expression of genes encoding regulatory proteins of osteoblastogenesis and bone tissue mineralization was increased at all stages of the experiment. However, it is worth noting that the results obtained are relevant in the case of early administration of the specific anti-inflammatory therapy with genetically engineered drugs, before the stage of femoral head fragmentation. Moreober, some regulatory proteins are synthesized at the post-translational level. Further research with a larger sample size will allow us to draw more reliable conclusions about the effectiveness of anti-inflammatory therapy in correcting bone homeostasis. Also, the study of the methods of targeted therapy and of the pathogenesis of avascular necrosis should assess the concentration of regulatory proteins involved in osteogenesis and bone tissue remodeling processes.

CONCLUSION

The preliminary results of the application of a monoclonal blocker of the pro-inflammatory cytokine IL-6 indicate inhibition of osteodestructive and enhancement of osteoreparative processes by correcting the expression of bone metabolism genes in the course of aseptic necrosis of the rat's femoral head in an experimental model.

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Evaluation of long-term results of single intraoperative electrical neurostimulation after autologous plastic surgery of a resection defect of the tibial portion of the sciatic nerve in adult rats

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Abstract

Introduction World literature data indicate the effectiveness of single intraoperative electrical stimulation (IES) of the proximal segment of the damaged nerve to stimulate its regeneration, but there is no data on its effect on the long-term results of autoplasty of resection defects.

The purpose of the work was to evaluate the long-term results of a single IES after autologous plastic surgery of the tibial portion of the sciatic nerve in rats.

Materials and methods Thirty rats after autologous repair of the resection defect of the tibial portion of the sciatic nerve were divided into series 1 (unstimulated control, $n = 16$) and series 2 (single IES for 40 minutes, $n = 14$). At 4 and 6 months after surgery, the static sciatic functional index (SFI) and morphometry of epoxy transverse semithin sections of the tibial nerve at the level of the middle third of the leg were assessed. For comparison with the normal values, the corresponding data from 7 intact rats were used.

Results The number of animals with excellent results of SFI restoration was 12.5 % in series 1 and 50 % in series 2 ($p = 0.05$). The numerical density of regenerated myelinated fibers (MF) exceeded the norm: in series 1 — by 63 % ($p < 0.01$) and 34 % ($p < 0.01$), in series 2 — by 58 % ($p < 0.01$) and 47 % ($p < 0.01$), respectively. In series 2, there were greater values in comparison with series 1: the median diameters of MFs were by 11.7 % and 15.7 %, the median diameters of their axons were by 5.4 % and 11.9 %, the median thickness of the myelin sheath was by 17.0 % and 24.1 %, respectively ($p < 0.05$ 4 months and $p < 0.01$ 6 months after surgery). Four months after surgery in series 1 and 2, the numerical densities of endoneurial vessels exceeded the intact control by 134 % ($p < 0.05$) and 156 % (0.05), their average diameters by 18 % and 16 % ($p < 0.01$) respectively, and lumen diameters increased only in series 2 by 8 % ($p = 0.07$). After 6 months of the experiment in series 1 and 2, the numerical densities of microvessels decreased, but significantly exceeded the control by 66 % ($p < 0.05$) and 83 % ($p < 0.05$), the average diameters — by 14 % and 36 % ($p < 0.05$), lumen diameters — by 26 % ($p < 0.05$) and 50 % ($p < 0.01$), respectively.

Discussion The difference between stimulated and unstimulated animals in all MF size parameters 6 months after surgery was greater than after 4 months, indicating a persistent neuroregenerative effect.

Conclusions A significant increase in the diameters of regenerating nerve fibers in the tibial nerve, as well as the diameters of their axons and the thickness of the myelinated sheaths 4 and 6 months after autoplasty of the tibial portion of the sciatic nerve in the group of animals with a single 40-minute IES of the proximal portion of the sciatic nerve indicates the promoting effect of the applied additive effect on regenerative axono- and myelinogenesis. Increase in the lumens and improvement of blood flow of the endoneurial vessels of the tibial nerve in the series with IES ensured the stability of the neuroregenerative effect. The functional significance of the effects of a single IES is confirmed by a significantly higher percentage of animals with excellent results in restoring the static functional index.

Keywords: rats, sciatic nerve, autoplastic, intraoperative electrical neurostimulation, sciatic functional index, hystomorphometry

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INTRODUCTION

Peripheral nerve injuries occur in 3.3 % of upper extremity [1] and in 1.8 % of lower extremity trauma [2]. They vary significantly in mechanisms of injury, severity of injury, and treatment outcomes. During military conflicts, the incidence of damage to the nerves of the extremities increases significantly; they frequently lead to disability with severe social and personal consequences for the injured [3].

Despite the potential of restoring the functions of damaged peripheral nerves in mammals and humans [4], their regeneration after complete anatomical cutting requiring surgical intervention occurs slowly and usually incompletely: no more than half of the patients achieve good or excellent results in restoring sensitivity and movements [5]. Unsatisfactory results of treatment of nerve injuries in the clinic setting have a fundamental biological basis. These include post-traumatic apoptosis of sensory neurons [6], the latent period of regeneration during which the axons of the proximal segment of the nerve do not grow into the damaged area [7], low rate of regenerative growth, especially in adults [8], scar formation [9, 10] , destruction of denervated target organs [11], including their capillaries [12].

A variety of techniques for electrical stimulation of peripheral nerves may accelerate and improve the recovery of motor and sensory functions [13, 14, 15]. Since a great number of patients do not have the opportunity to receive a course of rehabilitation treatment, the interests of many researchers in recent years have focused on studying the effects of a single intraoperative electrical stimulation (IES).

In a randomized study of 36 patients who underwent reconstructive surgery on the digital nerves, it was found that one hour-long session of low-frequency IES (20 Hz, 1 hour) improved all types of sensitivity by 5–6 months after surgery compared with the unstimulated group, but the difference was not statistically confirmed [16].

Animal experiments have demonstrated the positive effects of a single IES in various models of nerve injury in the femur and tibia. In focal demyelination of the tibial nerve of rats, IES accelerated the clearance of demyelination products and subsequent remyelination [17]. By modeling neuroma in continuum of the sciatic nerve of rats, a single IES of the proximal section of the damaged nerve improved the recovery of limb function after 4 to 8 weeks, but after 3 months differences with the unstimulated group were leveled out [18]. In experiments on transection and suture of the tibial nerve of rats, it was found that even a 10-minute IES accelerates the growth of the suture zone with regenerating axons [19]. Similar results were obtained by other authors when transecting and suturing the sciatic nerve of mice [20], who also proved an increase in the number of neurons entering regeneration in series with electrical stimulation. After transecting and microsurgically suturing the femoral nerve of 10-week-old rats, one-hour IES caused a more rapid recovery of functional parameters in comparison with sham-stimulated animals, reaching the preoperative level at 5 months after injury, which, according to the authors, is associated with an increase in the number of motor neurons that correctly reinnervated target organs [21].

Following autoplasty of the common peroneal nerve in young rats, a single IES of the proximal segment of the nerve provided an increase in the number of sensory and motor neurons entering regeneration, as well as an increase in the number of myelinated nerve fibers regenerating into the distal segment of the damaged nerve 6 weeks after surgery [22].

Following autoplasty of the sciatic nerve, IES improved the motor function of the limb of rats in the period from 2 to 12 weeks compared with unstimulated animals, however, sensory testing and histomorphometry of the distal segment of the nerve and gastrocnemius muscles did not reveal any merits in the series with IES [23].

In the available literature, we did not find data on the effect of single intraoperative electrical stimulation on the long-term results of autoplasty of mixed nerves. This fact determined the purpose of our study.

The purpose of the work was to evaluate the long-term results of a single intraoperative electrical neurostimulation after autologous plastic surgery of a resection defect of the tibial portion of the sciatic nerve.

MATERIALS AND METHODS

The experiment was performed on 30 male laboratory Wistar rats (age 8–15 months, weight 360–460 g). The animals were kept in controlled hygienic conditions and had access to water and food. The experiment was carried out in accordance with the European Convention for the Protection of Vertebrate Animals, Directive 2010/63/EU of the European Parliament and the Council of the European Union for the Protection of Animals Used for Scientific Purposes and SP 2.2.1.3218-14; GOST 33217-2014; GOST 33215-2014. The study design was approved by the institutional ethics committee (protocol No. 2 (57) dated May 17, 2018). For anesthesia and pain relief, the animals were injected intramuscularly with 0.8 mg of xylazine hydrochloride and 0.4 mg of tiletamine/zolazepam per 100 g of body weight, and the hair on the right thigh and lower leg was cut.

In the operating room, after treating the skin with iodine-alcohol tincture and performing a non-projection skin incision, the access was made to the right sciatic nerve at the level of the middle third of the thigh using a sharp-blunt method through the biceps muscle. Under an 8x magnification of an operating room microscope (OPMI-6, Germany), epifascicular longitudinal epineurotomy incisions were made with a sharp vascular microprobe and iridectomy scissors to isolate the tibial portion of the sciatic nerve. After resection of its 6 mm section, interfascicular autologous repair of the resulting defect was performed using microsurgical suture 9–0/10–0 caliber material. In series 1 of non-stimulated control animals (n = 16), at the end of autoneuroplasty, the wound was sutured layer-by-layer with 3-0 caliber absorbable suture material. In series 2 of the study group (n = 14), immediately after autoneuroplasty, electrodes were installed on the proximal portion of the nerve. Using the system of electrical stimulation of peripheral nerves ElSI.08.ice (registration certificate No. RZN 2017/5382; LLC High Medical Technologies), for 40 minutes. intraoperative stimulation of the proximal segment of the nerve was performed with monopolar electrical pulses of a rectangular shape with an amplitude of 0.25 mA, a frequency of 20 Hz and a duration of 100 μs. The wound was sutured at the end of the electrical stimulation session.

To ensure comparability of the experimental groups by age, a pair of rats underwent surgery on each operating day: one without stimulation, the other with stimulation; one pair of eight-month-old rats were both without stimulation.

In the postoperative period, studies of the static sciatic functional index (SFI) were carried out according to the modified method [24], considering the semiotics of denervation-reinnervation syndrome (Table 1). To do this, each rat was placed in a box made of transparent plastic with holes for air access. The box was fixed on a tripod and placed above the table on which the mirror was placed. Using a fluorescent lamp, the box was illuminated and the reflection of the rat's feet in the mirror was photographed, from 3 to 5 shots from each rat were taken. Digital photos were saved in the computer memory, and then the spread of their toes was measured in the Photofiltre program (Fig. 1): total (between the first and fifth toes) and intermediate (between the second and fourth toes). The ratio of the spread of the toes of the involved foot to the corresponding spread of the contralateral foot in fractions of a unit was used as the SFI. Measurements of the toe spread in animals were not carried out if the foot of the involved limb had no support on the pads of the paws, but on the dorsal and/or lateral surface of the foot if contractures and deformities developed. The SFI rating scale is also presented in Table 1.

Table 1

Semiotics of denervation-reinnervation syndrome and assessment of the static sciatic functional index in the long-term period after autoplasty of the tibial portion of the sciatic nerve

Symptoms	Evaluation
Support on the dorsal and/or lateral surface of the foot in developed contractures and deformities of the metatarsus and toes. Support on the pads of the paws without the speading toes or with partial restoration of the spread and hyperextension in the metatarsophalangeal joints and flexion in the interphalangeal joints	poor
Correct foot position with the presence of intermediary spread and adduction of either the first or fifth toe	fair
The toes are separated symmetrically. Intermediary or total span of 0.8 or more, or in some shots both spans of 0.8 or more	good
Indices of intermediary and total spread 0.8 and more	excellent

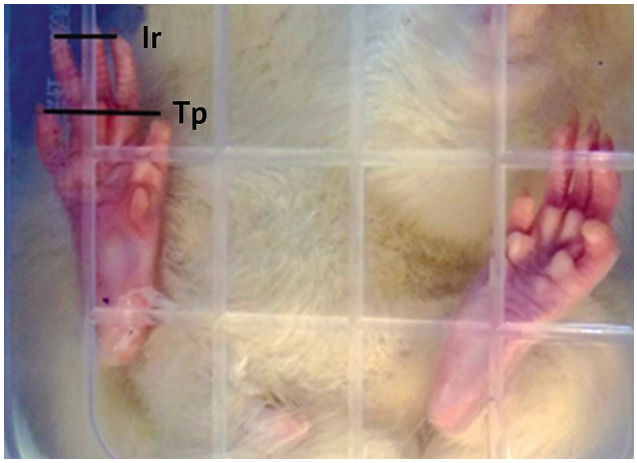

Fig. 1 Photo of the reflection of a rat's feet when it is placed in a plastic box. Normal position of the foot of the contralateral limb with a pronounced Ir — intermediary toe spread and Tp — total toe spread; lack of finger spreading in flexion of the interphalangeal joints of the foot of the involved limb and denervation atrophy of small muscles of the foot

Animals were removed from the experiment. Dissected samples of sciatic and tibial nerves were subjected to aldehyde-osmium fixation and embedded in Araldite to obtain semi-thin sections. Sections were cut with diamond knives on a Nova LKB ultramicrotome (Sweden), stained with toluidine blue and the polychrome method — methylene blue, azure II and basic fuchsin. Microscopy of sections and acquisition of digital images was carried out using an AxioScope. A1 microscope and an AxioCam digital camera (Carl Zeiss MicroImaging GmbH, Germany). 15–30 endoneurial microvessels and 400–500 myelinated nerve fibers were histomorphometrically examined in each animal at 1000× magnification. Their numerical densities in 1 mm^2 of the bundle area were determined, the diameters of the fibers, their axons and the thickness of the myelinated sheaths were measured, and histograms of the distribution of fibers by diameter were constructed with a step of 1 μm. The proportion (%) of destructively altered nerve conductors was calculated. The diameters of microvessels and their lumens were measured, and the modified Kernogan index was determined as the ratio of the lumen diameter to the vessel diameter. For comparison with the norm, we used histomorphometric data from 7 adult intact rats, close in age to the experimental rats at the time of euthanasia, age 16–19 months (in this group there are no interindividual statistically significant differences in the studied quantitative indicators).

Statistical data processing was performed in the Attestat software, version 9.3.1 (developed by I.P. Gaidyshev, certificate of registration with Rospatent No. 2002611109). Samples were checked for normal distribution of values using the Kolmogorov and Shapiro – Wilk tests; pairwise comparison of experimental series with each other and with intact controls was carried out using the Mann – Whitney, Chi-square, and Fisher's exact tests. The values of histomorphometric parameters were presented as medians and quartiles — Me [Q1; Q3]. The significance level of differences is 0.05.

RESULTS

A significant difference was obtained between series 1 and 2 in the rate of excellent results when SFI was assessed in the long term after surgery (Table 2).

Table 2

Distribution of static sciatic functional index scores in the long-term period after autoplasty of the tibial portion of the sciatic nerve

Result	Series 1 — autoplasty (n = 16)		Series 2 — autoplasty + IES (n = 14)		P^{1-2}
	number	%	number	%	
Poor	9	56.25	4	28.57	0.16
Fair	1	6.25	0	0	0.55
Good	4	25.00	3	21.43	1.00
Excellent	2	12.50	7	50.00	0.05

P^{1-2} — Levels of significance of differences by comparing groups of unstimulated and stimulated animals using Fisher's exact test; * — differences significant at $P \leqslant 0.05$

It is important to note that the age of the 7 rats that achieved excellent results in the series 2 varied from 8 to 13 months at the time of the operation.

Microscopic examination of the distal zone of the sutures showed that in series 1 and 2 after 4 and 6 months post- surgery, the endoneurium and epineurium of the graft were abundantly neuroticized by regenerating myelinated and non-myelinated fibers. Some of them were located as part of minifascicles or regeneration clusters (Fig. 2).

Transverse semi-thin sections of the tibial nerve at the level of the middle third of the tibia (Fig. 3) also revealed a large population of regenerated myelinated and unmyelinated fibers and a few regenerative clusters. In the endoneurium of regenerating nerves, fibroblasts, macrophages, perineural and mast cells, as well as nucleated profiles of myelinated and unmyelinated fibers, were more common than in intact nerves (Fig. 3).

At 6 months after surgery, compared with the previous period, the number of large myelinated fibers increased both at the level of the graft and in the tibial nerves at the level of the middle third (Fig. 2, c, d; Fig. 3, c, d), which was visually more noticeable in stimulated animals.

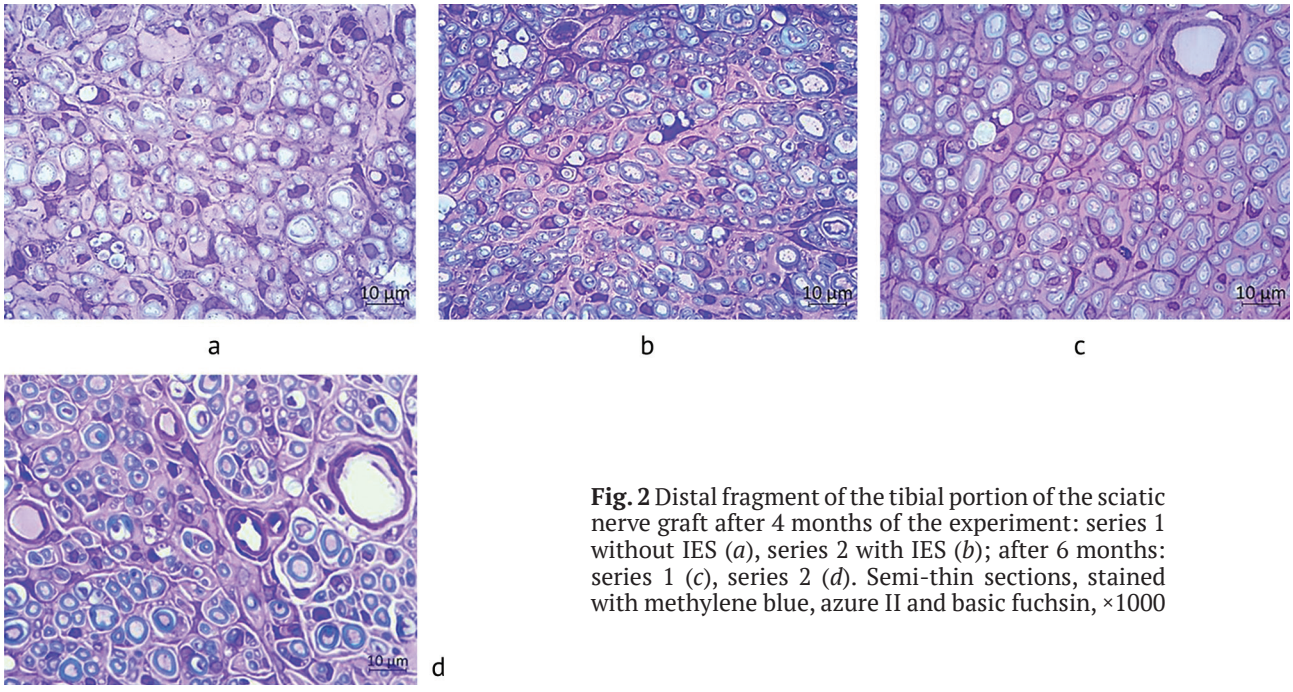

Fig. 2 Distal fragment of the tibial portion of the sciatic nerve graft after 4 months of the experiment: series 1 without IES (*a*), series 2 with IES (*b*); after 6 months: series 1 (*c*), series 2 (*d*). Semi-thin sections, stained with methylene blue, azure II and basic fuchsin, ×1000

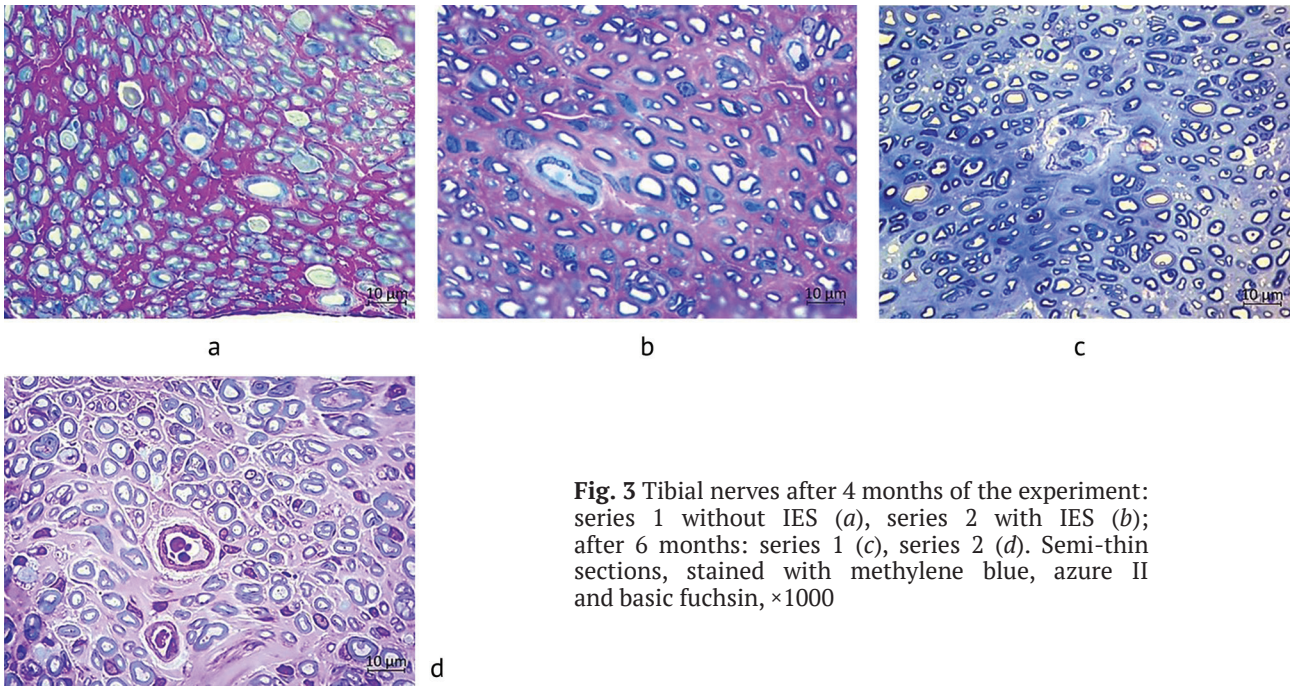

Fig. 3 Tibial nerves after 4 months of the experiment: series 1 without IES (*a*), series 2 with IES (*b*); after 6 months: series 1 (*c*), series 2 (*d*). Semi-thin sections, stained with methylene blue, azure II and basic fuchsin, ×1000

A histomorphometric study of the tibial nerve showed that the numerical density of regenerated fibers after 4 and 6 months post-surgery significantly exceeded the norm: in series 1 by 63 % and 34 %, in series 2 by 58 % and 47 %, respectively (Table 3). Proportion of destructively changed conductors after 4 and 6 months post-surgery in experimental animals was significantly lower than the values of intact nerves (Table 3).

Table 3

Numerical densities and proportions (%) of destructively altered myelinated nerve fibers of the tibial nerve in 1 mm^2 of section area after 4 and 6 months post-surgery, Me [Q1; Q3]

Series/experiment term	Numerical density of myelinated fibers		Proportion of destructively altered myelinated fibers	
	4 months	6 months	4 months	6 months
Series 1 — autoplasty (n = 16)	24444 [19182; 28280] P^{1-2} = 0.319465 P^{1-K} = 0.0000002*	20207 [18140; 22618] P^{1-2} = 0.187249 P^{1-K} = 0.000573*	4,46 % [2,79; 5.73] P^{1-2} = 0.072117 P^{1-K} = 0.001244*	4,05 % [2,38; 5.06] P^{1-2} = 0.99999 P^{1-K} = 0.00046*
Series 2 — autoplasty + IES (n = 14)	23786 [22142; 24882] P^{2-K} = 0.0000001*	22142 [20498; 23411] P^{2-K} = 0.000289*	5,58 % [3,85; 6.05] P^{2-k} = 0.030766*	4,05 % [2,38; 5.06] P^{2-K} = 0.00014*
Intract controls (n = 7)	15040 (12859; 15499)		6,75 % (5,70; 8,13)	

P^{1-2} — significance levels of differences in compared groups of unstimulated and stimulated animals using the Mann – Whitney test: P^{1-K}, P^{2-K} — significance levels of differences between each group of operated animals and intact controls according to the Mann – Whitney test; * — differences are significant at $p < 0.05$

The dimensional characteristics of myelinated regenerating fibers were significantly greater in series 2 compared to series 1 (Table 4) after 4 and 6 months post-surgery: median diameters of fibers by 11.7 % and 15.7 %, median diameters of their axons by 5.4 % and 11.9 %, median thickness of the myelin sheath by 17.0 % and 24.1 %, respectively. However, even at the end of the experiment, all dimensional characteristics of the fibers in both groups of experimental animals were significantly smaller than the intact nerve.

The distribution of myelinated fibers in regard to the diameter of series 1 and series 2 was significantly different from the distribution in the intact nerve (Fig. 4). Even after 6 months post-surgery it remained unimodal, the number of histogram classes was reduced. However, at both 4 and 6 months after surgery, in series 2, the main peak of the histogram was shifted to the right compared to series 1, and the number of histogram classes was one class more; and this difference between the series after 6 months was confirmed statistically (Fig. 4).

Table 4

Dimensional parameters of myelinated fibers of the tibial nerve at 4 and 6 months post-surgery, Me [Q1; Q3]

Parameter	Series 1 — autoplasty (n = 16)		Series 2 — autoplasty+IES (n = 14)		Intact controls (n = 7)
	4 months (n = 7)	6 months (n = 7)	4 months (n = 8)	6 months (n = 8)	
Fiber diameter (μm)	3.24 [2.52; 4.03] P^{1-K} = 0.00119* P^{1-2} = 0.00267*	3.50 [2.79; 4.04] P^{1-K}= 0.00119* P^{1-2} = 0.00982*	3.62 [2.91; 4.37] P^{2-K} = 0.00014*	4.05 [3.14; 5.12] P^{2-K} = 0.00268*	6.73 [5.50; 8.75]
Axon diameter (μm)	2.23 [1.65; 2.87] P^{1-K} = 0,.00119* P^{1-2} = 0.02914*	2,42 [1,84; 2,84] P^{1-K} = 0,00119* P^{1-2} = 0,00450*	2,35 [1,82; 2,94] P^{2-K} = 0,00174*	2,71 [2,02; 3,53] P^{2-K} = 0,0027*	4.34 [3.54; 5.18]
Thickness of myelinated membranes (μm)	0.53 [0.40; 0.63] P^{1-K} = 0.00119* P^{1-2} = 0.02831*	0.54 [0.44; 0.62] P^{1-K} = 0.00119* P^{1-2} = 0.0027*	0.62 [0.50; 0.75] P^{2-K} = 0.00038*	0.67 [0.53; 0.83] P^{2-K} = 0.00255*	1.02 [0.72; 1.30]

P^{1-2} — significance levels of differences in compared groups of unstimulated and stimulated animals using the Mann – Whitney test: P^{1-K}, P^{2-K} — significance levels of differences between each group of operated animals and intact controls according to the Mann – Whitney test; * — differences are significant at $p < 0.05$

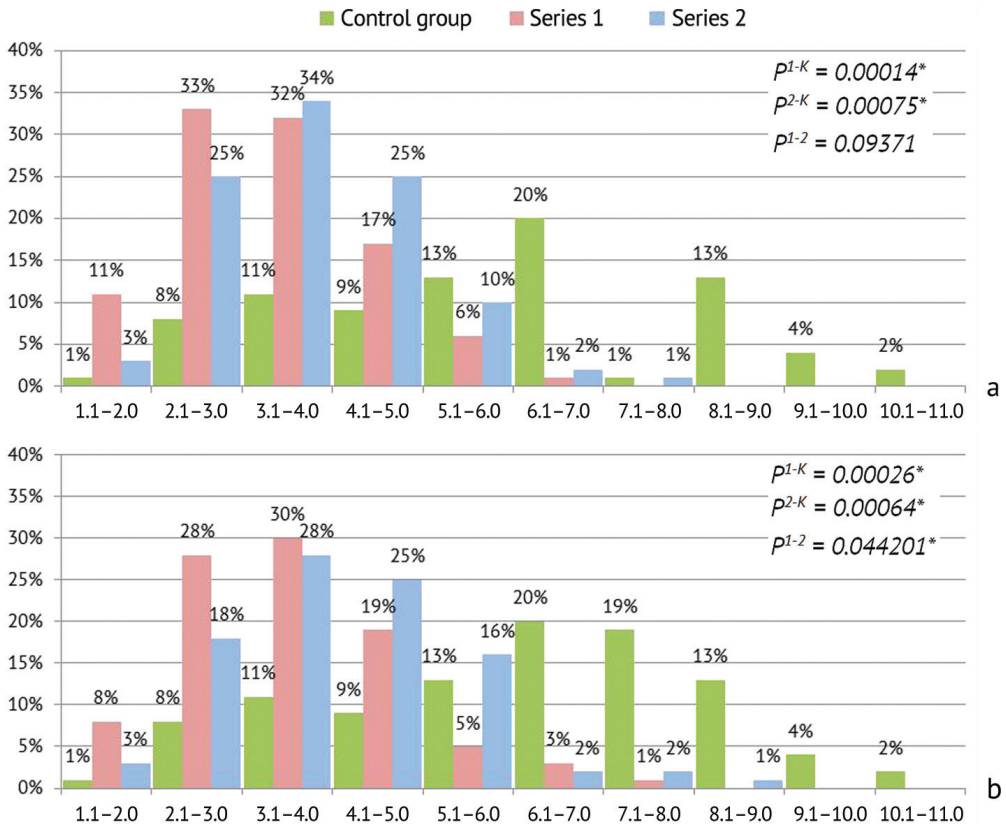

Fig. 4 Histograms of the distribution of myelinated fibers by diameter: *a* — 4 months after operation; *b* — 6 months after operation. The abscissa axis is the diameters of the fibers in microns, the ordinate axis is their percentage in the sample; P^{1-2} — significance levels of differences between unstimulated and stimulated animals of series 1 and 2; P^{1-K}, P^{2-K} — significance levels of differences in each series with intact control using the Chi-square test

A study of endoneural vascularization showed that at 4 months after surgery in series 1 and 2, the numerical densities of endoneurial vessels significantly exceeded the intact control by 134 % and 156 %, their average diameters by 18 % and 16 %, respectively, and the lumen diameter increased only in series 2 by 8 % (Table 5) . A decrease in the Kernogan index parameter in series 1 at this time relative to the control indicates a deterioration in the throughput of blood vessels. After 6 months in series 1 and 2, the numerical densities of microvessels decreased, but significantly exceeded the control by 66 % and 83 %, the average diameters — by 14 % and 36 %, the diameters of the lumens — by 26 % and 50 %, respectively (Table 5). At the same time, there were no significant differences in the Kernogan index parameter between the series at this period of the experiment (Table 5).

Table 5

Dimensional parameters of the endoneurial vessels of the tibial nerve after 4 and 6 months of the experiment, Me [Q1; Q3]

Parameter	Series 1 — autoplasty (n = 16)		Series 2 — autoplasty + IES (n = 14)		Intact controls (n = 7)
	4 мес. (n = 7)	6 мес. (n = 7)	4 мес. (n = 8)	6 мес. (n = 8)	
Numerical density of vessels	200 [109; 219] P^{1-K} = 0.01935* P^{1-2} = 0.25751	142.13 [130.69; 168.27] P^{1-K} = 0.00618* P^{1-2} = 0.715001	219 [109; 274] P^{2-K} = 0.00695*	156.31 [132;183] P^{2-K} = 0.03213*	85.64 [82.21; 127.88]
Vessel diameter (μm)	14.49 [12.56; 16.88] P^{1-K} = 0.00206* P^{1-2} = 0.854221	14.08 [11.91; 17.82] P^{1-K} = 0.00138* P^{1-2} = 0.01454*	14,29 [11.86; 17.53] P^{2-K} = 0.00743*	16,76 [13.45; 19.14] P^{2-K} = 0.00007*	12,32 [9.31; 15.30]
Lumen diameter (μm)	4.81 [1.75; 6.72] P^{1-K} = 0.355172 P^{1-2} = 0.126962	5.97 [3.64; 7.77] P^{1-K} = 0.06917 P^{1-2} = 0.00692*	5,10 [3.62; 7.29] P^{2-K} = 0.49948	7.09 [5.30; 10.01] P^{2-K} = 0.00001*	4,72 [3.28; 5.92]
Kernogan index	0.30 [0.15; 0.43] P^{1-K} = 0.00075* P^{1-2} = 0.002664*	0,42 [0.30; 0.44] P^{1-K} = 0.14051 P^{1-2} = 0.05255*	0,39 [0.28; 0.46] P^{2-K} = 0.29573	0.42 [0.39; 0.52] P^{2-K} = 0.31603	0,41 [0.32; 0.48]

P^{1-2} — significance levels of differences in compared groups of unstimulated and stimulated animals using the Mann – Whitney test: P^{1-K}, P^{2-K} — significance levels of differences between each group of operated animals and intact controls according to the Mann – Whitney test; * — differences are significant at $p < 0.05$

DISCUSSION

Compensation for functional deficits caused by nerve damage occurs through three mechanisms: reinnervation of denervated target organs through regeneration of damaged axons, reinnervation through collateral sprouting of undamaged axons, and remodeling of the central nervous system circuits related to lost functions [25].

To assess the severity of the regenerative component of morphofunctional recovery of nerve damage in animal models, the most informative method is histomorphometry of transverse semi-thin sections distal to the damage zone, which has found wide use in preclinical studies of neuroregeneration.

Thus, Oliveira et al noted correlation between the sciatic functional index and the numerical density of regenerating fibers in sciatic nerve damage of rats in the early stages of regeneration (up to 2 months after surgery), which the authors assessed as an adequate tool for assessing functional deficits [26]. According to Martins et al, of the 17 histomorphometric and electrophysiological parameters studied, only the average diameter of myelinated fibers proximal and distal to the injury zone correlated with the sciatic functional index at six months after surgery [27].

The noted pattern is apparently not accidental. Radial growth of axons, increasing the diameter of regenerated fibers, initiates only after contact of growth cones with target organs [28]. However, restoration of the normal size of regenerating fibers does not occur until 6 months after injury, even in the rat nerve compression model, when axonal regeneration occurs inside endoneural tubes that have preserved their integrity [29]. According to Ikeda et al, 7 months after transection and suturing of the sciatic nerve of rats, the average diameter of the regenerated nerve fibers did not exceed 50 % of the value of the intact nerve [30].

In our study, the median diameter of regenerated myelinated fibers at the level of the middle third of the leg was 52 % of the value of the intact group in unstimulated rats and exceeded 60 % in stimulated rats. This gives reason to believe that reinnervation of target organs in our experiments continued actively in both stimulated and unstimulated animals, but by 6 months after autoneuroplasty was not completed. The most significant result of our study is a significant difference in all dimensional parameters of regenerating nerve fibers in the groups of unstimulated and stimulated animals, proving the effectiveness of a single 40-minute session of IES of the proximal nerve segment. It should also be noted that the difference between stimulated and unstimulated animals in all dimentional parameters of myelinated fibers 6 months after surgery was greater than after 4 months, and indicates a persistent neuroregenerative effect.

The assessment of endoneural vascularization of the tibial nerve performed in our study at 4 and 6 months after autoneuroplasty of the tibial portion of the sciatic nerve also indicates the revascularizing IES effect.

Studies on vascularization of regenerating nerves are few, but they show an increase in the size of intraneural vessels under the influence of neuropeptides, as well as vasodilation and neoangiogenesis associated with increased secretion of vasogenic factors by resident and recruited macrophages [31]. In our study, the numerical density of endoneurial vessels and their diameters significantly exceeded the corresponding parameters of intact nerves in both groups of experimental animals. However, four months after surgery, the lumen diameter increased only in the stimulated rats by 8 %, which, along with changes in the Kernogan index, indicates a better flow rate in endoneurial vessels in this series compared to unstimulated controls. Six months after surgery, hypervascularization of the endoneurium persisted in both series, but in the stimulated rats, the diameters of endoneurial vessels and their lumens significantly exceeded the values of unstimulated rats by 19 %.

The obtained histomorphometric data are consistent with the results of the functional assessment.

According to clinical studies, good nerve function recovery after autoneuroplasty may only be obtained in patients under 25 years of age [32]. Our experiments used rats of age groups that, as reported, are characterized by a decrease in the level of antioxidants and the development of metabolic syndrome [33]. Thus, the results of our study may be translated into clinical practice for not only young but also middle-aged patients.

CONCLUSION

A significant increase in the diameters of regenerating nerve fibers in the tibial nerve, as well as the diameters of their axons and the thickness of the myelinated sheaths 4 and 6 months after autoplasty of the tibial portion of the sciatic nerve in the group of animals with a single 40 minute IES of the proximal portion of the sciatic nerve indicates the promoting effect of the applied additive effect on regenerative axono- and myelinogenesis.

Increase in the lumens and improvement in the blood flow rate of the endoneurial vessels of the tibial nerve in the series with IES ensured the stability of the neuroregenerative effect.

The functional significance of the effects of a single IES is confirmed by a significantly higher percentage of animals with excellent results in restoring the static functional index (50 % vs 12.15 % in unstimulated controls).

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New finger reconstruction technologies using 3D printing

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Abstract

Introduction The use of 3D printing technology in finger reconstruction improves accuracy of the procedure minimizing the donor defect and optimizing the appearance and function of the finger. The use of this technology in the finger reconstruction with an osteocutaneous radial forearm flap with axial blood supply and lengthening of the digital stumps and metacarpals remains poorly explored.

The objective of the study was to demonstrate new methods of preoperative planning for finger reconstruction and improve surgical outcomes.

Material and methods Outcomes of five patients treated with original methods based on 3D technology were retrospectively evaluated during preoperative planning, reconstruction of the thumb using an osteocutaneous radial forearm flap with axial blood supply, relocation of the stump of the third finger and lengthening of the stumps of the first and second metacarpals. The patients could achieve consolidation of interpositional bone allografts following lengthening of the finger stumps, stability of the bone base of the finger, organotypic restructuring of the marginal allograft during plastic surgery with an osteocutaneous radial forearm flap, and a functional position of the reconstructed thumb using the middle finger stump.

Results and discussion An individual device for planning finger reconstruction allows identification of the optimal size and position of the finger in three planes, which is essential for patients with severe hand deformities to avoid corrective procedures. An individual guide was used to osteotomize the radius to harvest a vascularized graft providing a cutout of a given size and shape and a cortical-cancellous allograft being identical in shape and size to replace the donor bone defect. The combined use of Masquelet technology and distraction of the finger stump or a metacarpal improved conditions for consolidation and restructuring of the interpositional allograft preventing fractures and infection.

Conclusion The use of 3D technology in finger reconstruction using an osteocutaneous radial forearm flap with axial blood supply and distraction of the finger stumps and metacarpals can improve surgical outcomes.

Keywords: Ilizarov method, Masquelet technique, 3D printing, finger stump, osteocutaneous radial forearm flap

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INTRODUCTION

3D printing technology has been developed in medicine over the past decade to be used in various medical applications; it offers promising opportunities to improve learning outcomes, surgical training and an individual treatment approach enhancing the efficiency of outcomes [1–3]. In surgery, 3D printing can be used to create geometrically complex and highly detailed personalized constructs and the one-time production, for preoperative planning, design of orthopaedic products and prosthetses in accordance with the specific requirements of the surgeon and patient [3–6], to create auxiliary devices, adapted for a specific patient, for intraoperative use, hardware and custom-made devices, implantable prostheses, rapid prototyping of surgically implanted products and training applications [7–10]. The advantage of the technology is that individual implants and casts can be made in accordance with the anatomy of a particular person [9, 11]. However, there is a paucity of studies reporting the use of the technology in hand surgery. There are few publications in the literature on the use of technology in toe transplantation and replacement of the donor defect with flaps by microvascular anastomoses. The technique helps to reduce operating time providing digital and accurate circuit diagrams to complete the operation. The authors created a model of the big toe and the second toe to understand the extent of tissue to be harvested from the donor site. This model was also applied to repair the donor site defect by using appropriate superficial circumflex iliac artery (SCIA)-based iliac skin-bone flap [9]. Preoperative planning for hallux reconstructions with second toe transfer using 3D printing was reported. Computed tomography angiography (CT angiography) is used to map the vasculature of the donor site, while CT findings are used to create three-dimensional models of the soft tissue and skeleton of injured and intact arms. Based on the reformatted model (a mirror of an intact hand), models of the soft tissues and skeleton of the fingers were created using a 3D printer. The toe model was also used to determine the level of osteotomy on the donor foot. This allowed optimization of the function and appearance of the reconstructed thumb minimizing injury to the donor site [12, 13]. The method can accurately calculate the skin and bone dimensions of the donor site as a reference for surgery and perform the operation according to the model [14]. The technology is also used to simulate the size of a skin-fat flap to replace soft tissue defects of a finger in emergency cases [15] and during hand transplantation [16]. Possibilities with 3D technology in other methods of finger reconstruction have not been explored. Different aspects of pre- and intraoperative use of 3D technology in skin-osseous reconstruction of the fingers and lengthening of the digital stumps and metacarpals are aimed at optimizing preoperative planning and precision of the procedure improving results, reducing the donor defect and the complication rate.

The purpose of the work was to demonstrate new methods of preoperative planning and reconstruction of fingers improving surgical outcomes.

MATERIAL AND METHODS

We retrospectively evaluated results of skin-osseous reconstruction with a radial flap of the first finger in two patients, lengthening of the stumps of the first and second metacarpals in two patients and relocation of the stump of the third finger in one patient using the technologies devised. Reconstruction of the first finger was scheduled using the device developed for both patients.

Technical performance

RF patent 211603 “Device for preoperative planning for reconstruction of the first finger” [17].

A device for preoperative planning for the finger was created using hybrid parametric modeling, topological optimization and additive 3D printing technologies. It was equipped with a socket for the finger stump, fixed on the hand with Velcro tape or adhesive tape with the distal part of the socket being connected with a ball joint with the ability to be fixed in a certain position

with a sleeve connected to the piston with the ability to extend and fix the position achieved with a threaded rod, followed by measuring the finger length being restored and the angles of the fixation to the stump of the first finger (Fig. 1, a, b).

RF patent 2747694 "Method of skin-osseous reconstruction of a finger and a guide for its implementation" [18].

An individual model of the radius was created based on computed tomography and then, using this model, a guide was created for harvesting the graft at the donor bone site (Fig. 2). The guide for skin-bone reconstruction of the finger contained a groove for a saw blade and a central axial hole; it was manufactured individually according to computed tomography data using 3D printing, depending on the intended size and shape of the graft. The length of the guide at the distal end was at least 1 cm longer than the intended graft, and the length at the proximal end was at least 2.5 cm. The device consisted of two equal palmar and dorsal parts. The axial hole precisely corresponded to the lateral surface of the radius at the site of the planned graft. The groove for the saw blade was shaped as a scaphoid; in the middle, at the distal end of the guide, a continuous slot 2 mm wide was made to accommodate the intermuscular septum and the vessels. A "protrusion-groove" connecting component and two holes for the pins were secured proximally (Fig. 2, a, b).

RF patent 2796438 "Method of distraction lengthening of the metacarpal stump" [19].

An osteotomy site and the required dimensions of the distracted distal fragment of the metacarpal and the cross section at the level of osteotomy were determined with computed tomography of the hand at the stage of preoperative planning. Then, a hollow cylindrical spacer model was formed using hybrid parametric modeling (Fig. 3). The length and inner diameter of the spacer were measured depending on the distraction intended. The internal cross-section of the spacer corresponded to the cross-section of the distracted metacarpal at a distance of 0.5 cm from the site of the intended transverse osteotomy. The spacer had a semi-open through longitudinal rectangular groove 2 mm wide. The end edge of the groove ended at a distance of 0.5 cm from the opposite edge of the 1.5 cm long spacer. The ends of the spacer should be inserted to a depth of 0.5 cm on the ends of the proximal and distal bone fragments and considering the diastasis of the bone fragments by 0.5 cm. A matrix was created using 3D printing technology based on the spacer manufactured from PLA polymer material. The matrix was intraoperatively filled with bone cement containing gentamicin. The spacer was removed with the bone cement being hardened. A transverse osteotomy of the metacarpal was performed in the middle third using an oscillatory saw. The bone cement spacer was placed with a solid end on the proximal end of the distal fragment of the metacarpal. A Kirschner wire was placed intramedullary through the distal fragment of the metacarpal and the axial hole of the spacer. The proximal end of the wire was U-shaped with the short branch of the wire being inserted into the groove of the spacer until the bend area stopped at the end edge of the closed part of the groove and the proximal end of the distal fragment. The distal end of the wire was pulled out. The second end of the spacer with a groove was placed on the proximal fragment of the metacarpal. The Ilizarov frame with a reference ring was mounted to the forearm with screw rods attached. The distal end of the intramedullary wire was fixed to the screw rods. The postoperative wound was sutured. Gradual distraction of the distal fragment was performed at 5 days at a rate of 1 mm per day along with the cement spacer. The second stage of the operation was performed with distraction of the distal metacarpal fragment completed. In this case, the resulting osteogenic membrane was dissected along the entire length of the distraction defect and the ends of the metacarpal fragments. The intramedullary wire and spacer were removed, preserving the distraction regenerate.

The distraction defect was repaired with a cortical-spongy allograft with the transverse dimensions not exceeding the outer diameter of the spacer. The resulting distraction regenerates at the distal and proximal fragments of the metacarpal were preserved. Osteosynthesis of bone fragments

and graft was performed with wires. The resulting osteogenic capsule was sutured with interrupted absorbable sutures over the graft and the contact area of the metacarpal fragments. The subcutaneous tissue and skin over the osteogenic capsule were sutured in layers.

RESULTS

Case report

A 45-year-old patient Ch. was admitted to the PIMU hospital for a severe mechanical injury resulting in a stump of the first finger at the level of the metacarpal head, severe adduction contractures of the first metacarpal bone, stump of the third finger and deformity of the fourth finger, flexion contractures of the second finger in the interphalangeal joints, intra-articular comminuted fracture the head of the main phalanx, ulnar deviation of the middle phalanx of the fourth finger on the right side (Fig. 1, c). The patient wanted to restore pinch grip I with preserved finger II. The patient presented with sharply limited functionality of the hand on admission with no grip, 15–20° range of motion in the metacarpophalangeal, interphalangeal joints of the second finger and the carpometacarpal joint of the stump of the first metacarpal bone. The length of the stump of the first finger was 5.5 cm. The patient refused a toe transplant and skin-osseous reconstruction of the first finger with the radial flap. The reconstruction of the first finger included transfer of the stump of the third finger due to the lack of the grip function. Limited function of the second finger and poor opportunities for the improvement, adduction contracture of the first metacarpal necessitated measurements of the adequate length and position of the reconstructed first finger. A computed tomography scan of the injured hand was performed preoperatively with established clinical and radiological diagnosis. Then a tailored made device was developed to measure the size and position of the reconstructed finger depending on the size of the stump of the third finger using hybrid parametric modeling, topological optimization and additive 3D printing technologies. The device was used to measure the length of the reconstructed finger and position in three planes. The size of the sleeve corresponded to the dimensions of the stump of the third finger being transferred. The device was fixed to the stump of the first finger using Velcro adhesive tape passed through the eyelets of the socket. The patient underwent functional testing of the hand was produced by gripping small-, medium- and large-sized objects using a device fixed to the stump of the first finger. The position and length of the reconstructed finger were empirically measured by gradual extension and fixation of the piston using the nut of the threaded rod and by changing the position of the sleeve together with the piston in three planes with fixing the hinge with a stopper ensuring the possibility of performing a pinch grip with a deformed second finger. The patient's professional requirements for the restored grip function were also considered. The length of the first finger and its position in the frontal, sagittal and horizontal planes were measured. The finger length was 6.5 cm measured from the base of the bushing to the distal end of the piston. The angle of radial abduction, palmar abduction, and rotation of the sleeve together with the piston were measured using an angle ruler. The magnitude of palmar abduction was 45°, radial abduction was 35°, and rotation of the sleeve with the piston was 90°. These parameters corresponded to the position and length of the stump of the third finger being transferred to the position of the first finger. According to measurements, the length of the finger being formed together with the metacarpal bone should have been 11.5 cm (the length of the first finger of the healthy hand together with the metacarpal bone was 10 cm). Dimensions and fixation angles of the stump transferred were used intraoperatively to transfer the stump of the third finger and fix it to the stump of the first metacarpal bone. A pinch grip of the reconstructed first finger with the stump of the middle phalanx of the second finger, with the fourth and fifth finger was achieved. There was no need to perform corrective operations to change the position of the first finger after the surgery. The patient could adapt to the new grip of the hand, hold small- and medium-sized objects using the I and II fingers, could hold large objects using the I and preserved IV, V fingers and use the reconstructed finger in everyday life

and manufacturing activities. The distance between the first and second fingers with maximum abduction of the reconstructed finger and extension of the second finger measured 7 cm and 12 cm in the normal side. Abduction of the first finger and the adduction of the first to the second finger was restored (Fig. 1, c, d, e).

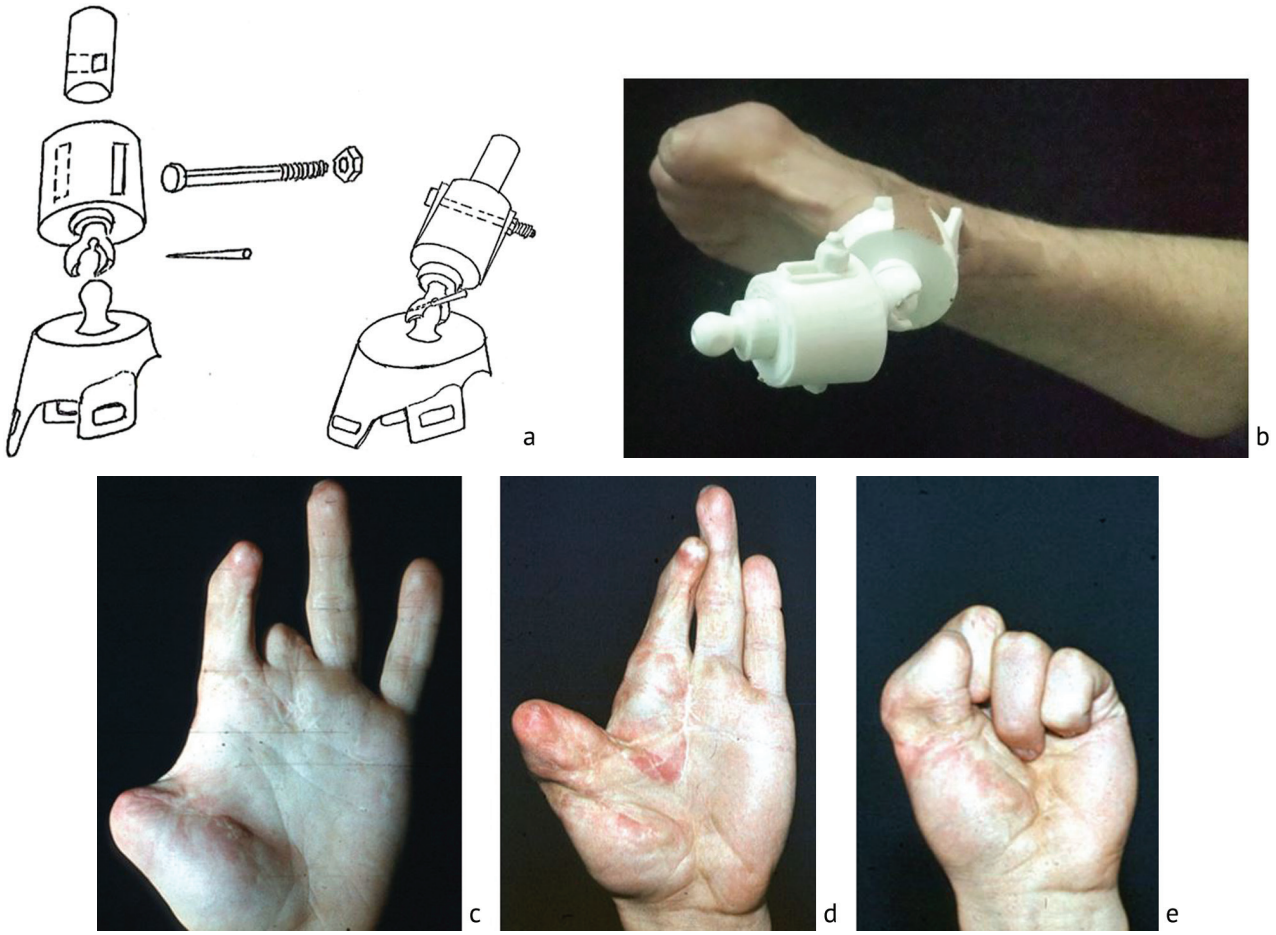


Fig. 1 A device for preoperative planning of reconstruction of the first finger: (*a*) components and the assembly; (*b*) the device fixed to the stump of the first finger; (*c*) preoperative appearance of the hand; (d) abduction function of the first finger; (*d*) double-sided grip function

A 25-year-old patient S. was treated at the PIMU hospital for the stump of the first finger on the left side at the base of the main phalanx, a soft tissue defect of the radial edge of the hand (Fig. 2, g). The patient sustained an industrial injury on 07/06/19 when her left hand got trapped by a processing machine. Soft tissue reconstruction of the first finger was produced for the patient and the soft tissue defect on the hand was repaired with plastic surgery using a non-free inguinal axial skin-fat flap (13/06/19). On 10/02/20, skin-osseous reconstruction of the first finger on the left side was performed by transfer of a skin-bone radial flap using a peripheral vascular pedicle. The required dimensions of the bone frame, the size and shape of the radial bone graft, the length of its vascular pedicle were preoperatively measured for the reconstructed finger and a computed tomography scan of the forearm performed. Then a tailored radial osteotomy guide was manufactured using hybrid parametric modeling, topological optimization and additive 3D printing technologies. The radial artery with a skin-fat flap was intraoperatively mobilized preserving the intermuscular septum with septal and periosteal vessels at the site of grafting. Two parts of the guide were applied to the osteotomy site and connected to each other. Then the guide, as a single block, was temporarily fixed to the site of the radial bone grafting using wires (Fig. 2, c). In this case, the intermuscular septum with septal vessels was placed in a continuous slot of the guide to prevent the injury with the radial artery being located laterally. A marginal scaphoid osteotomy of the radius was

performed using a guide. The blade was pressed against the groove of the guide driving the saw. Integrity of the septal and periosteal vessels extending from the radial artery and adequate blood supply to the graft were preserved with a smooth plane of the sawdust provided. Avascular cortical-spongy allograft was cut out using the same guide (Fig. 2, d) corresponding to the marginal defect of the radius and the blood-supplied graft in length, thickness and shape and exceeding in width by 0.5 cm. Avascular allograft was placed in the defect of the radial bone and fixed with two wires and prophylactic plating of the radial bone performed (Fig. 2, e, f). The marginal avascular radial bone graft was congruent with the defect and adhered tightly to it. Vascularized radial bone graft together with a skin flap was transferred to the stump of the first metacarpal and the first finger reconstructed. The postoperative period was uneventful. The wounds healed by primary intention. The skin flap healed well indicating the preservation and functioning of the septal vessels. Evident signs of consolidation of the radial bone graft were identified at two months indicating the preservation of the periosteal vessels and the blood supply. No pathological fracture of the radius was detected at a long term with complete consolidation and reconstruction of the allograft achieved with complete elimination of the marginal defect (Fig. 2, f). The patient was examined at two years. The length of the reconstructed finger was 55 mm corresponding to the postoperative length of the intact first finger on the other side. The reconstructed finger had a functionally advantageous position. The bilateral grip of the hand was restored. The distance between the ends of the fifth finger and the reconstructed first finger is 19.5 cm with maximum abduction, as on a healthy hand. Pain and thermal sensitivity of the reconstructed finger were determined. The scar of the donor wound on the forearm was normotrophic and insignificant. The opposition function of the first finger was restored: the Kapangzhi test scored 9. Control radiographs of the left hand showed complete consolidation of the first metacarpal bone and the radial bone graft. The function of the first finger and hand grip were restored (Fig. 2, i, j). There were no signs of resorption of the reconstructed bone on the left side. Control radiographs of the forearm showed complete consolidation and replacement of the donor radial bone defect with an allograft at two years which was crucial for prevention of pathological fracture at the donor site.

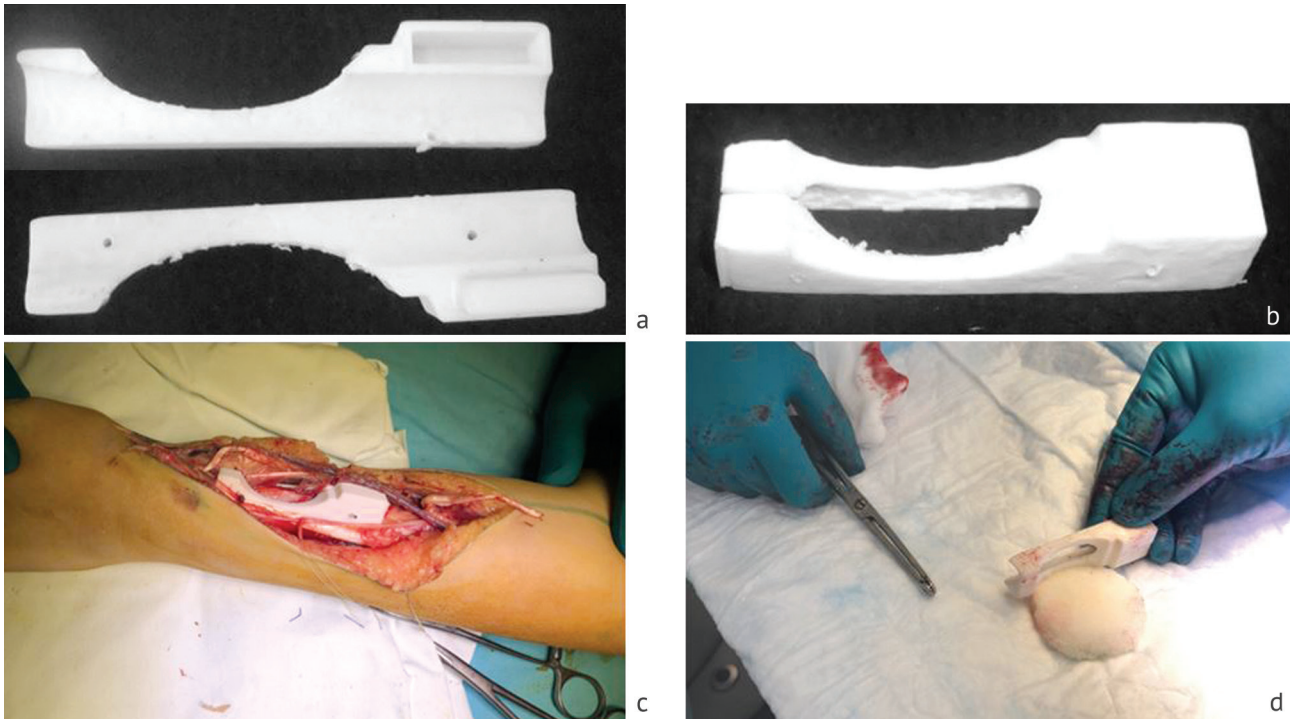
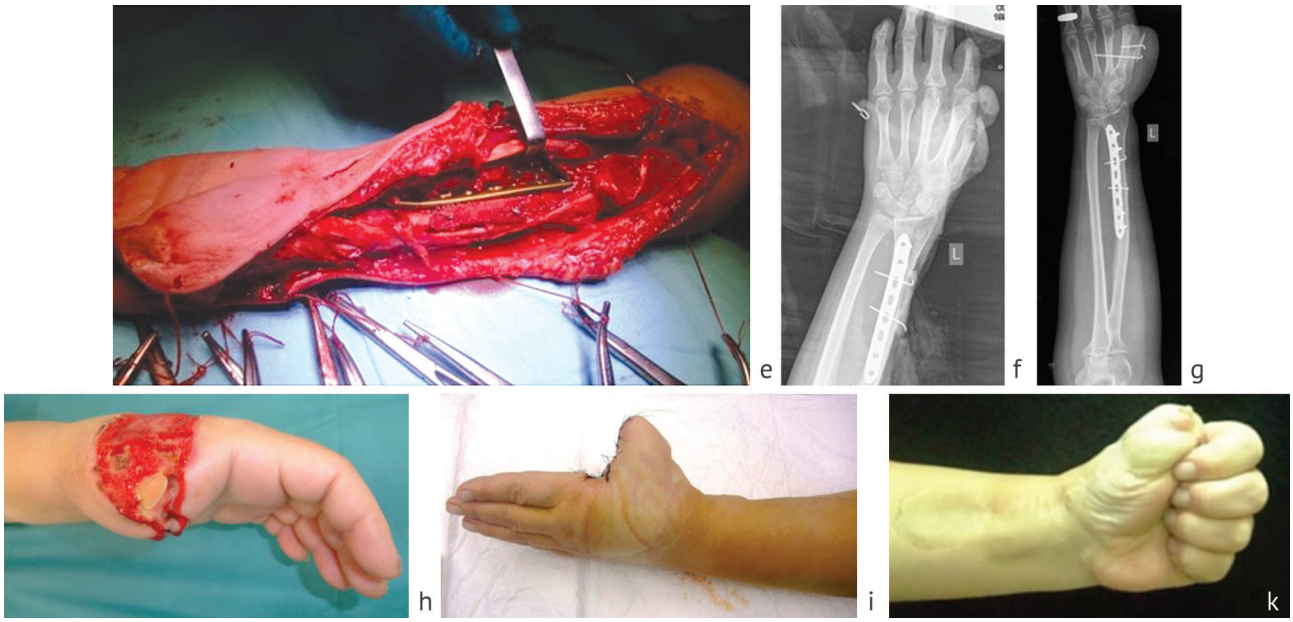


Fig. 2 A method for skin-bone reconstruction of the finger and a guide for its implementation: (*a*) components of the precision guide with the palmar and dorsal parts; (*b*) the guide assembled; (*c*) the guide used for vascularized grafting; (*d*) the guide used for corticocancellous allografting to replace the marginal defect of the radius



Continuation of the Fig. 2 A method for skin-bone reconstruction of the finger and a guide for its implementation: (*e*) alloplasty of the donor defect of the radius and plateing for prophylactic bone fixation; (*f*) postoperative radiograph of the hand and the forearm; (*g*) radiograph of the hand and forearm at one year; (*h*) preoperative appearance of the hand; (*i*) abduction of the first finger; (*j*) grip function of the hand

A 22-year-old patient A. was admitted to the PIMU hospital for the stumps of the 1st, 2nd, 3rd, and 4th fingers at the level of the proximal thirds of the main phalanges, the stump of the 5th finger at the level of the distal third of the main phalanx on the left side (Fig. 3, a). The patient was injured at work on 10/19/21 as a result of her hand getting caught in the rotating mechanism of the machine. Primary surgery was performed for the crushing injury of fingers I–V and the stumps of the fingers were formed. Necrosis of skin flaps at the ends of the finger stumps developed postoperatively. Soft tissue defects measured 2 cm by 6 cm ter debridement. Thin, ulcerating scars fused to the underlying bones were observed preoperatively at the ends of the stumps of the fingers with no grip of the hand (Fig. 3, a). Defects on the end surface of the stumps of fingers II–IV and finger I were previously replaced by plastic surgery with a Filatov stem to form a loop (06/04/22 and 17/05/22) (Fig. 3, b). The first stage of the stump lengthening of the first and second metacarpal bones was performed upon re-admission on September 14, 2022 to restore the function of bilateral hand grip using the technology developed (Fig. 3). The required cross-sectional dimensions of the first and second metacarpal bones were determined preoperatively at the mid level and at a distance of 0.5 cm from the middle. They turned to be equal to 10 mm. Hybrid parametric modeling and topology optimization were used to model a matrix and spacer of a hollow cylindrical shape such that its cross-section corresponded to the cross-section of the distracted metacarpal bone at a distance of 0.5 cm from the transverse osteotomy site. The length of the spacer was 1.5 cm, the thickness of the spacer wall was 1 mm. The spacer had a semi-open through longitudinal rectangular groove 2 mm wide and 1 cm long. A PLA matrix was made Using additive 3D printing technologies (Fig. 3, c). Transverse osteotomies of the first and second metacarpal bones were performed at the mid level. The matrix was filled with bone cement and a spacer formed as a hollow cylinder after hardening. The spacer was placed with a solid end on the proximal end of the distal fragment of the second metacarpal bone (Fig. 3, d). A Kirschner wire was placed intramedullary through the distal fragment of the metacarpal bone and the axial hole of the spacer. The proximal end of the wire was U-shaped with the short branch being inserted into the groove of the spacer until the bend area stopped at the end edge of the closed part of the groove and the proximal end of the distal fragment.

The distal end of the wire was pulled out. Another end of the wire was placed on the proximal fragment of the metacarpal bone. A similar distracting wire was placed on the first metacarpal bone without a spacer. The distal ends of the intramedullary wires were fixed to the screw rods of the Ilizarov reference

ring. Gradual distraction of the metacarpal bones was performed postoperatively at a rate of 1 mm per day (Fig. 3, e). The bone fragments were separated by 35 mm. The second stage of distraction lengthening was performed on 15/11/22 with the external fixation device removed and an incision made along the postoperative scar. A well-defined hypervascular induced capsule developed in the distraction defect, extending 0.5 cm onto the ends of the bone fragments. The capsule had the same uniform wall thickness of 2 mm. The resulting capsule was dissected longitudinally along the distraction defect and the ends of the metacarpal bone fragments. The intramedullary wires and spacer were removed (Fig. 3, f). An endosteal bone regenerate 1.5 cm long developed at the proximal end of the distal fragment. Marginal lamellar bone regenerates 1 cm long and a mature regenerate shaped as a spur having a bone structure could be identified at the end of the proximal fragment. The distraction defect was repaired with a cortical-spongy allograft with the transverse dimensions not exceeding the outer diameter of the spacer (Fig. 3, g). The resulting distraction regenerates at the distal and proximal fragments were preserved. Osteosynthesis of bone fragments and grafts with wires was performed. The resulting osteogenic capsule was sutured with interrupted absorbable stitches over the graft and at the site of the contacts with metacarpal fragments (Fig. 3, h). The graft and the metacarpal contact site were completely covered with an osteogenic capsule. The subcutaneous tissue and skin over the osteogenic capsule were sutured in layers. The distraction regenerate was less pronounced in the first metacarpal bone. Plastic repair of the defect was performed using a cortical-spongy allograft fixed with wires (Fig. 3, i). The hand was immobilized with a plaster cast for five weeks. The wounds healed by primary intention. Primary healing of bone fragments and grafts being more pronounced on the second metacarpal bone was observed after removal of the cast. Two months later, the Filatov stem loop was divided with the distal portions of the first and second fingers formed. The patient was examined at six months postsurgery. The length of the first ray was 8 cm, the second ray was 9 cm. The distance between the ends of the stumps with the first ray abducted was 4 cm (Fig. 3, j). The treatment resulted in the function of bilateral hand grip restored (Fig. 3, k). The elongated stumps had adequate soft tissue coverage without signs of prolapse of the distal sections. Signs of consolidation and restructuring of allografts could be seen radiographically (Fig. 3, l).

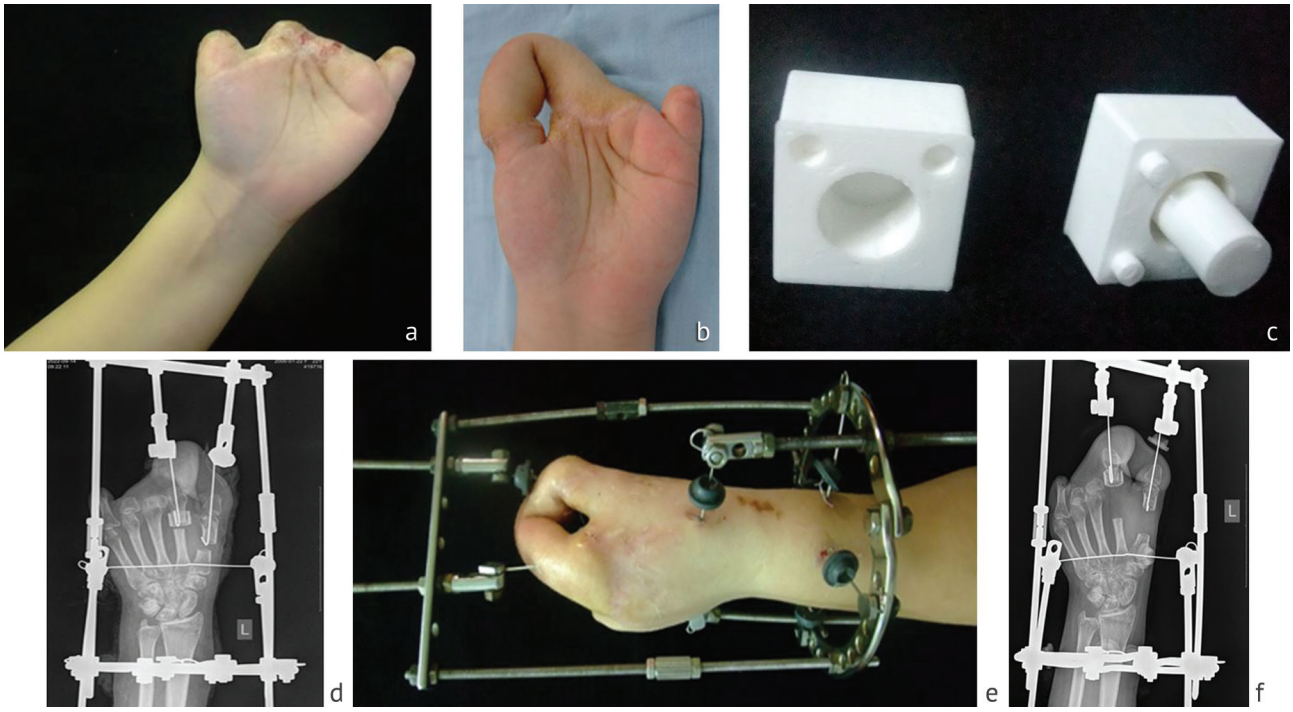
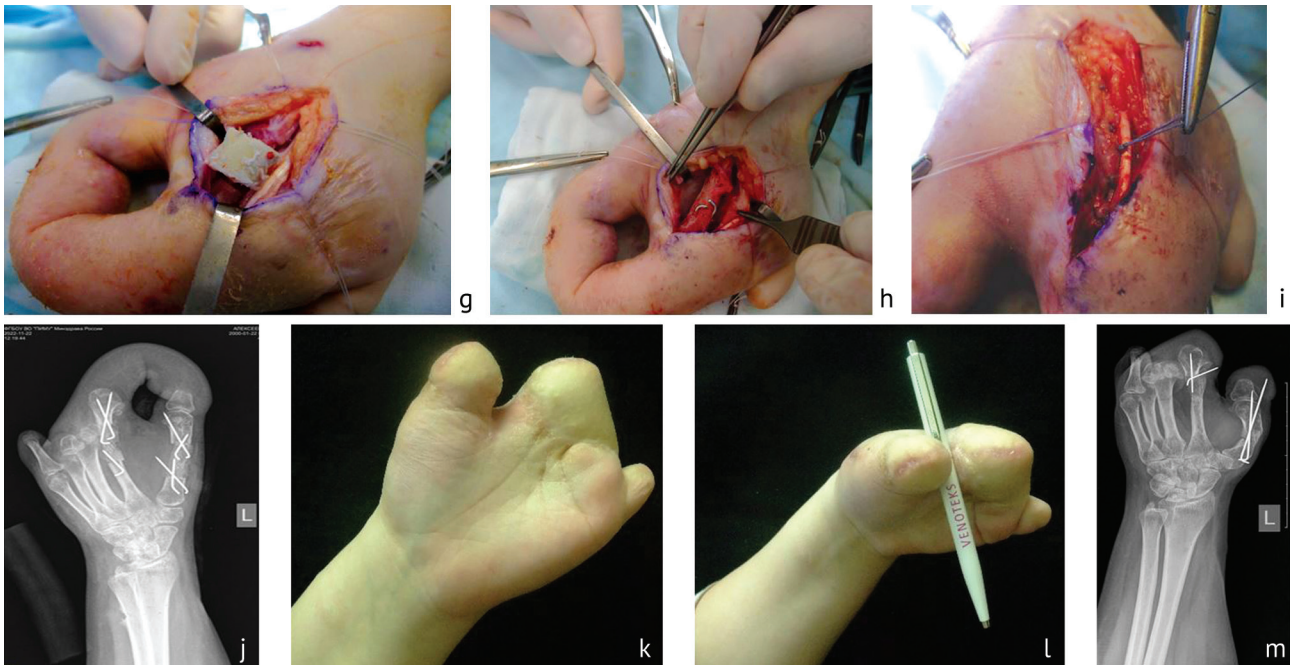


Fig. 3 Lengthening of the metacarpal stump: (*a*) preoperative appearance of the hand; (*b*) appearance of the hand after transplantation of the Filatov stem; (*c*) appearance of the matrix for intraoperative manufacturing of a hollow cylindrical spacer; (*d*) radiograph of the hand before the distraction of the stump of the second metacarpal bone together with a cylindrical spacer; (*e*) appearance of the hand after distraction with the Ilizarov frame; (*f*) radiograph of the hand after distraction of the stump of the second metacarpal bone together with a cylindrical spacer



Continuation of the Fig. 3 Lengthening of the metacarpal stump: (*g*) appearance of a cylindrical bone cement spacer after distraction; (*h*) the distraction defect of the second metacarpal bone replaced with a cortical-cancellous allograft; a well-defined induced membrane seen throughout the defect; (*i*) the inductive capsule sutured over the graft; (*j*) radiograph of the left hand after the second stage of reconstructive surgery; (*k*) abduction of the stump of the first ray; (*l*) hand grip; (*m*) radiograph of the hand at 6 months postsurgery

DISCUSSION

The effectiveness of reconstructive intervention is determined by its adequate planning. Preoperative 3D models for planning finger reconstruction are a rigid integral structure that does not allow changing the size and position of the components simulating phalanges of the finger in different planes. Well-known preoperative models are used in isolated absence of the first finger with no need for the functional position of the joints to be determined relative to the rest involved fingers [13, 14]. This makes the choice of the optimal position of the restored finger relative to the preserved segments of the hand difficult in case of a severe deformity. he known method of planning the length gain allows for the optimal length of the first finger to be identified for the distraction of the stump in each specific case, but it is not possible to determine the functionally advantageous position of the reconstructed finger relative to the rest of the fingers [20]. A tailored digital model with variable biomechanical parameters is created with the method offered, and the patient is involved in the preoperative planning. The model has adjustable biomechanical parameters including the length of the first finger, position of the phalanges in the joints and relative to the longitudinal axis. The device is an individual prefabricated construction with components being able of imitating the main and nail phalanges with the possibility of changing their position in the joints and rotational position, changing the length of the model of the main phalanx depending on the nature of the hand defect and the reconstruction method. The device helps to avoid corrective procedures for the reconstructed finger through changed position.

The problem of minimizing the donor defect during radial flap reconstruction is essential. Prevention of pathological fractures at the site of bone graft harvest is the most important thing in this case with the complications being a limiting factor in the use of the method. Reconstruction of the finger with a skin-bone radial flap suggests precise determination of the depth of the cut to prevent critical values and a fracture. Different approaches are used for this purpose to include rounded corners, locking holes, C-arm guided wires, use of a Mitchell trimmer, a screw depth gauge, a protective metal tape located in a longitudinal section, etc. which fail to provide sufficient precision marginal osteotomy of the radius [21, 22]. In addition to that, the osteotomy plane is not smooth enough with a scaphoid cutout, in particular, due to possible slipping of the saw blade off the rounded surface

of the bone shaft. There is a risk of injury to the axial and septal vessels of the radial bone graft. Occasionally increased depth of the cut can significantly reduce bone strength. Some authors suggest intraoperative use of the marginal defect model created preoperatively as a template to follow during osteotomy [23]. This technique has similar disadvantages. For skin-bone reconstruction of a finger, we use 3D technologies for the basic stage of the operation harvesting a vascularized graft and preparing an allograft for plastic surgery of the marginal defect of the radius. A single-use instrument is created for a specific patient. A patient-specific 3D radius print allows for precise preoperative planning. No special tools could be found for such interventions in the available literature. We can create a tailored-made tool implementing our method for marginal osteotomy using 3D printing. The method helps to prevent undercutting (cutting) of the bone with smooth sawdust surface of the radial bone and the graft being formed to ensure the tight contact along the osteotomy plane. With the critical depth of the cut being exceeded, the device can optimize conditions for bone grafting by forming a graft that precisely matches the size, surface and shape of the marginal defect. The smooth surfaces of the osteotomy and allograft ensure the tight contact and optimal conditions for fusion and reconstruction during bone grafting to allow a qualitatively new result and restored structure of the donor bone. Depending on the clinical scenario, the guide can be created to form a scaphoid, rectangular, or any other graft shape.

In the last decade, the Masquelet method has become common in repair of bone defects of different etiology [24–28]. Some authors question the effectiveness of the technique [29]. There are reports about the advantages of combined distraction and the Masquelet technique to address bone defects. There is a known method of bone defect repair using a bone cement spacer to be placed in the tibial defect. The second stage of the procedure includes osteotomy and transport of the vascularized bone graft into the osteogenic capsule using the Ilizarov external fixation at the site of the osteoinductive membrane at 6–8 weeks [30]. However, the possibilities of this approach have not been explored in finger reconstruction. There is a risk of nonunion, fracture, prolapse and infection with use of interpositional graft with soft tissues scars, in particular [31, 32]. The need for soft tissue interventions in such unfavorable conditions with use of the Masquelet technology is emphasized by many authors [26]. The risk of the complications is minimized with the technique offered. Our method is based on the development and implantation of the original device consisting of a hollow cylindrical distractable spacer made of bone cement. The method ensures restoration of adequate soft tissue coverage of the stumps, formation of an osteogenic capsule, concurrent distraction of the stump, regeneration with the avascular bone interposition graft being surrounded by osteogenic membrane and vascularized tissues along the entire length and at the site of bone contact. Conditions for consolidation and graft reconstruction are improved in such cases preventing complications and reducing the treatment time.

CONCLUSION

The use of 3D printing technology in planning finger reconstruction using different methods, creation of tailored-made surgical instruments for plastic surgery using a skin-bone radial flap improved treatment results. The combined use of the distraction and the Masquelet method provided adequate functional results in finger reconstruction and prevention of complications in repair of an extensive soft tissue defect.

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Clinical case
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Total ankle arthroplasty in an adolescent who suffered hematogenous osteomyelitis of tibia

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Abstract

Introduction Acute hematogenous osteomyelitis can persist as chronic infection in pediatric patients due to delayed diagnosis and treatment. An extended bone defect of the limb caused by osteomyelitic destruction is a rare clinical scenario in pediatric surgery. Metaepiphyseal and articular involvement suggests specific and long-term treatment with a high risk of disability.

The objective was to report a clinical case of a teenager who suffered chronic hematogenous osteomyelitis of the tibial bones and raise awareness of primary diagnosis and treatment.

Material and methods A clinical case of a teenager treated for extensive destruction of the tibial bones caused by chronic hematogenous osteomyelitis is reported. Clinical and functional evaluation of the effectiveness was produced at the stages of treatment.

Results A positive functional result was achieved due to staged surgical treatment including radical debridement of the chronic infection nidus followed by total ankle arthroplasty.

Discussion Acute hematogenous osteomyelitis persisting as chronic infection could be caused either by a wait-and-see strategy when the patient first sought medical help or a long-term follow-up. There is no consensus on the use of reconstruction or replacement of large long bone defects extended to the joints caused by chronic infection. Staged treatment including total joint replacement with custom-made endoprosthesis can be one of the options.

Conclusion Staged surgical treatment including radical debridement followed by delayed total joint replacement with custom-made endoprosthesis provided satisfactory functionality for the limb without signs of infectious and inflammatory activity at a follow-up period of more than a year.

Keywords: joint replacement, ankle joint, osteomyelitis, cement spacer, surgical site infection, pediatric orthopaedics, clinical case

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INTRODUCTION

Acute hematogenous osteomyelitis is a common invasive infection encountered in the pediatric population [1, 2, 3]. Despite the decreased incidence of the disease in recent years and the success of antibacterial therapy, the risk of transition from an acute process to a chronic condition is high and is estimated at 30–40 % [2, 3]. Regardless of the cause, chronic bone infection remains a difficult and challenging problem; relief as a result of treatment can lead to permanent disability of the patient due to severe orthopaedic consequences [4].

The case report demonstrates the importance of timely diagnosis, routing and treatment of an adolescent patient with acute hematogenous osteomyelitis of the tibia and associated orthopaedic complications.

The objective was to report a clinical case of a teenager who was treated for chronic hematogenous osteomyelitis of the tibial bones and raise awareness of primary diagnosis and treatment.

MATERIAL AND METHODS

A 17-year-old patient, a resident of the regional center, was seen by the authors and presented with pain, swelling, a fistula in the right leg and failed weight-bearing on the right lower limb.

The onset of the disease occurred at the age of 15 years (2018) in the form of acute pain, swelling of the lower third of the right tibia, hyperthermia of 38 °C. He was examined by a pediatric surgeon at a regional hospital and received outpatient treatment including antibacterial (amoxicillin + clavulanic acid per os) and anti-inflammatory therapy. He was hospitalized five days later due to persistent symptoms and diagnosed with acute hematogenous osteomyelitis of the right tibia. According to the documentation provided, drilling of the distal metadiaphysis of the right tibia was produced and antibacterial therapy recommended including ceftriaxone, gentamicin, lincomycin, metronidazole. There were no microbiological findings reported. He was followed up by a pediatric surgeon on an outpatient basis after discharge from the hospital. A fistula developed in the lower third of tibia within three months. The patient changed dressings and underwent repeated courses of antibiotics.

The patient was admitted to the pediatric surgical department of a multidisciplinary hospital, Moscow, at four months and was diagnosed with chronic hematogenous osteomyelitis of the lower third of the right tibia. According to the documentation, bone re-drilling was produced, *St. epidermidis* identified with no data on sensitivity, a course of antimicrobial therapy with ceftriaxone, amikacin, ciprofloxacin administered. The patient was discharged from the hospital and an elective surgical treatment offered with no specific description of the procedure. He was followed up by a pediatric surgeon for 18 months, seen by an orthopaedic surgeon and an oncologist who ruled out a tumor process and recommended debridement.

The patient was seen by the authors of the publication after 22 months from symptom onset. On admission he had evidence of normal health with no clinical signs of a systemic inflammatory reaction; normothermia; used crutches with no support on the right tibia. Measurements of an absolute length of the lower limbs showed D < S by 1 cm due to shortening of the tibia. The patient had neither active nor passive movements in the right ankle joint with painful attempts to move the limb. He was unable to bear weight on the limb due to pain. Soft tissues were swollen in the lower third of the right tibia and the ankle joint. He had hyperesthesia on the medial and the anterior portions of the tibia, a fistula-ulcer with scanty serous-hemorrhagic discharge (Fig. 1, a). The patient could maintain movements and sensitivity in the toes. Imaging examination with radiography and CT scan demonstrated diffuse lesion of the distal epimetadiaphysis of the right tibia and widespread fine-focal destruction, larger cavities, sequestration, damage to the articular surface and narrowing of the joint space (Fig. 1, b).

Fig. 1 Photo and radiographs of the patient produced on admission showing (*a*) appearance of the limb; (*b*) lateral view of tibia and the ankle; (*c*) sagittal CT slice

RESULTS

Based on the nature and the duration of the disease the condition was recognized as chronic osteomyelitis of the tibia resulting from acute hematogenous osteomyelitis. Staged treatment was indicated to the patient due to persistent local signs of an active inflammatory process, severely impaired functionality of the ankle joint and impaired capacity to maintain weight on the lower limb. Radical debridement was produced at the first stage.

The surgical treatment performed for the patient included osteonecrectomy of the lower third of the tibia with extensive resection of the distal epimetadiaphysis of the tibia within healthy tissues, placement of a gentamicin-loaded cement spacer, excision of a fistula-ulcer at the right ankle joint, stabilization of the tibia and the foot with Ilizarov frame using wires and half-pins (Fig. 2). The surgical material (necrotic bone tissue) was sent for bacteriological and histological examination.

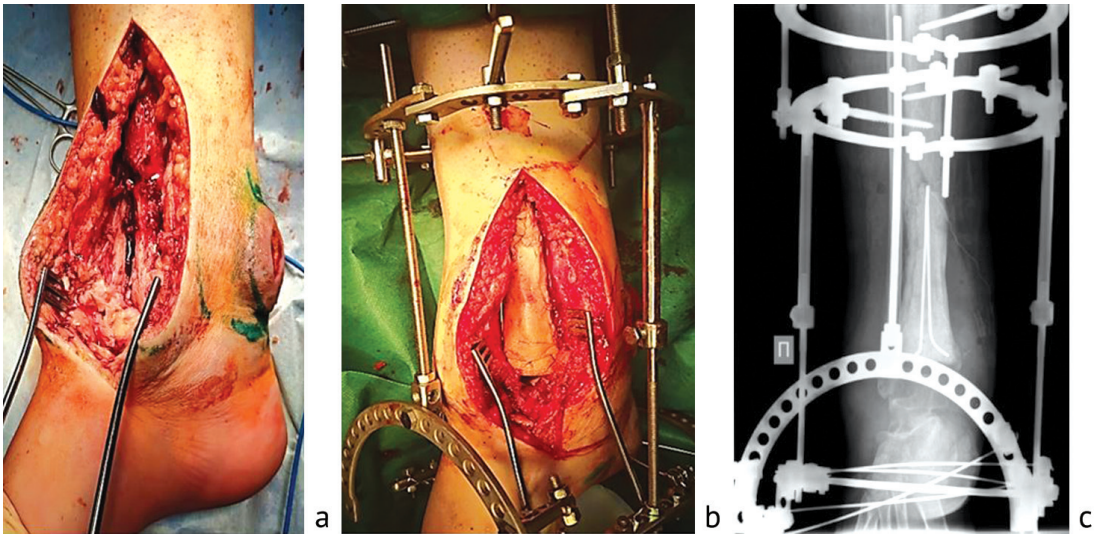

Fig. 2 Photo and radiograph of the patient's distal tibia on the right: (*a*) diffuse necrotic changes in the distal epimetadiaphysis of the tibia; (*b*) cement articulating spacer placed after debridement; (*c*) postoperative radiograph showing tibia and the foot fixed with frame using wires and half-pins

Bacteriological examination detected no microflora growth. Histological examination showed bone and cartilage degeneration, fragments of fibrous and granulation tissue with moderate lymphoplasmacytic infiltration, leukocytes indicating chronic nonspecific osteomyelitis (Fig. 3).

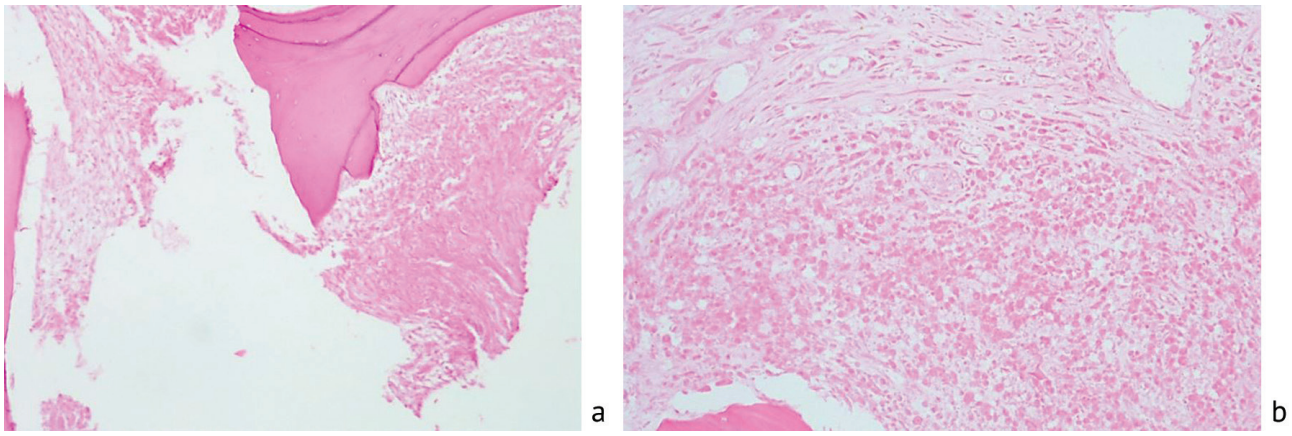

Fig. 3 Histological preparations of surgical material showing (*a*) dystrophic changes in bone tissue, foci of coagulation necrosis without a cellular reaction, stained with hematoxylin and eosin, ×100; (*b*) inflammatory infiltrate in the interosseous cells, stained with hematoxylin and eosin, ×200

Hyperthermic syndrome persisted for seven postoperative days because of antibacterial therapy using cefazolin, rifampicin, metronidazole. With the assistance of a clinical pharmacologist, the therapy was replaced with amoxicillin with clavulanic acid and vancomycin. The hyperthermic syndrome relieved after days. The antibacterial therapy lasted for 4 weeks with regression of tissue edema and exudative process in the fistulectomy area and healing of postoperative wounds. The patient received medication therapy to address local trophic processes (pentoxifylline, aprotinin). The sutures were removed after 20 days. No clinical and laboratory signs of exacerbation of the inflammatory process were noted at 9 months, and the next stage of surgical reconstruction was scheduled.

Two surgical options offered to repair 12 cm defect of the distal epimetadiaphysis of the tibia included bifocal compression-distraction osteosynthesis and ankle fusion and total replacement of the distal tibia and the ankle joint to regain weight-bearing capacity. Strategy options, potential complications, risks and outcomes were discussed with the patient and legal representatives, who refused bifocal osteosynthesis and arthrodesis.

A tailored modular constrained implant of the ankle joint and distal metadiaphysis of the tibia was manufactured to repair the extensive post-resection defect (Fig. 4).

Fig. 4 Design of total ankle replacement

The external fixation device was removed due to long-term clinical and laboratory remission and a trephine biopsy of the tissues of the lower third of the tibia, talus and tibia was performed. No growth of microorganisms was detected with bacteriological examination of biopsy specimens. After 14 days. After dismantling, the cement spacer was removed at 14 days with the external fixation off and the ankle joint was totally replaced. No intraoperative macroscopic signs of infection and inflammation were detected. The spacer bed was lined with a hypervascularized connective tissue membrane (Fig. 5, a).

The tibial shaft and trochlea tali were resected as estimated. The proximal and distal modules were placed and fixed by press-fit, connected to each other after positioning the fitting components (Fig. 5, b, c). The postoperative period was uneventful, the surgical wound healed by primary intention. Microbiological analysis of the surgical material showed no growth of microorganisms. Gradual weight-bearing on the limb was encouraged after two weeks to be followed by full weight-bearing at one month.

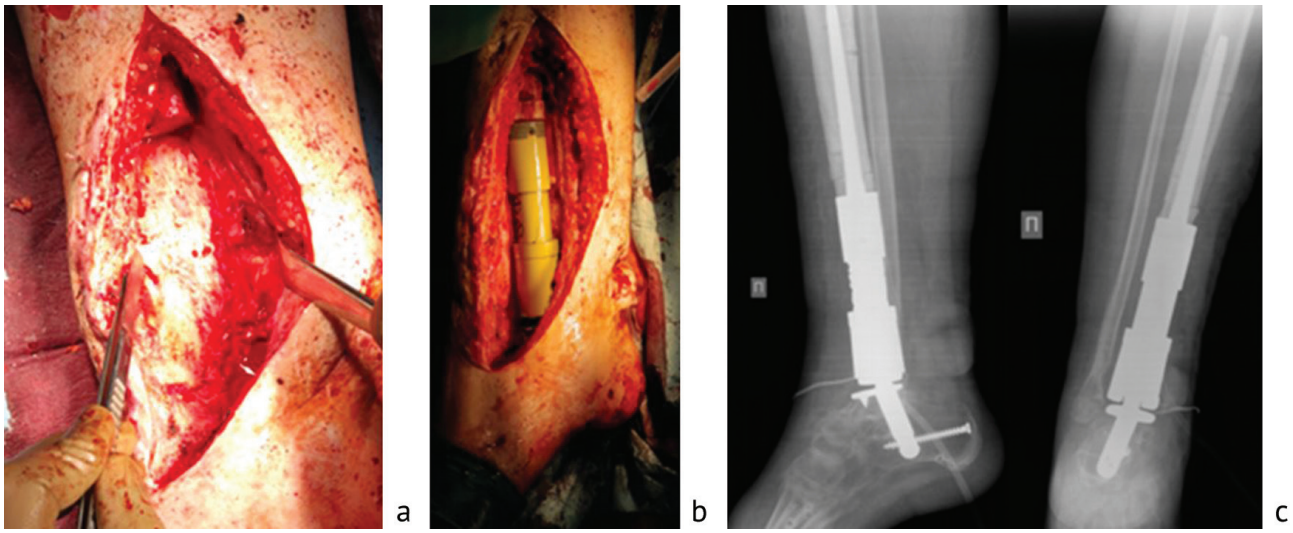

Fig. 5 Intraoperative photographs and radiographs showing: (*a*) the spacer bed being represented by a hypervascularized connective tissue membrane, (*b*) endoprosthesis implanted, (*c*) AP and lateral views of the tibia

The patient could walk without means of support at 14 months and experienced a slight feeling of discomfort walking over a distance of more than 2 km. There were no local signs of inflammation, the axis and length of the limb were restored. The implant was adequately positioned radiologically with no signs of peri-implant bone resorption (Fig. 6).

Fig. 6 Photographs and radiographs of the patient's tibiae and the ankle at 14 months of total ankle replacement (3 years from the onset of the disease)

The quality of life was evaluated preoperatively and at 14 months using the SF-36 questionnaire survey [5] at the time of the first admission to the clinic with physical functioning scoring 25 and 49, respectively, and the mental health scoring 37 and 57. The foot function scored 50 and 77 preoperatively and postoperatively on the AOFAS scale [6], respectively.

DISCUSSION

Diagnosis and treatment of acute hematogenous osteomyelitis in children are presented in modern educational and scientific publications [2, 3], while chronic nonspecific osteomyelitis, recurrent osteomyelitis are not common in pediatric practice. The development and progression of the condition are often accompanied by delayed diagnosis and difficulties in selection of treatment options [4].

Most authors suggest that chronic osteomyelitis should be treated with radical resection of the osteonecrotic bone to be followed by grafting the residual bone cavity with antibiotic-loaded osteoplastic material [7–9] to prevent hematoma, an ideal breeding ground for microorganisms,

and create a local antimicrobial depot in a therapeutic concentration and promote bone restoration. However, with extensive destruction requiring extensive resections, the resulting bone defects cannot be fully repaired using bone graft. Bone reconstruction can be produced using bifocal osteosynthesis with an external fixation device [10] that can be optionally combined with intramedullary nailing [11, 12], Masquelet technique [13] and microsurgical technique can be employed for soft tissue defects [14]. The techniques are practical for impaired diaphysis and/or metaphysis of long bones to restore weight-bearing capacity and the mechanical axis of the limb to help patients return to a normal lifestyle. With the involved epiphysis, dysfunction of the joint becomes an additional problem leading to disability.

Hikichi et al. reported a clinical case of successful arthroplasty used to treat local infection of the articular surface of the pylon [15], while extensive ankle injuries can be repaired with arthrodesis [16]. Total ankle arthroplasty (TAA) has become an alternative to arthrodesis and has been associated with the current technological advancements, new materials and design options with the outcomes being comparable with the two techniques [17–19]. The survival rate of implants is 81–97.7 % at 5 years and 69–86 % at 10 years [20, 21]. Based on their own experience Mikhailov et al. reported an algorithm for the choice of arthrodesis and total ankle replacement [22]. A study of static and dynamic parameters of supportability and the gait showed that the latter was approaching a physiological level at 24 months of ankle replacement, that suggested maintaining ankle mobility [23] and arthrodesis could be offered for complications of ankle replacement [24].

The problem is that the experience presented relates to classical arthroplasty for primary and secondary crusarthrosis without significant bone destruction. Replacement of a bone segment and simultaneous joint replacement is performed for oncological cases.

Sokolovsky et al. reported the experience of using modular ankle implants in 20 patients over 11 years with mechanical and non-mechanical complications noted in 39.4 % of cases, requiring repeated interventions for complete replacement of the implant [25]. Over 10 years, Karpenko et al. reported the use of staged operations in 3 (33.3 %) of 9 cases of modular ankle replacement due to instability and infectious complications [26]. Zhao et al. performed a systematic literature review and reported better functional results with biological reconstruction of the distal tibia and ankle arthrodesis and a comparable rate of complications compared to modular arthroplasty for tumors [27].

No data on the ankle joint replacement resulting in osteomyelitis could be found in the available literature. In our case, bifocal osteosynthesis with the external fixation device and ankle arthrodesis was the preferred option to restore the limb support. However, the patient and his parents chose the alternative option after discussion of the possible complications, and the treatment allowed the patient to maintain mobility in the joint, at least for the follow-up period. Now the patient is under dynamic observation and remains at risk of developing late complications. However, the positive outcome allows us to expand indications for total ankle replacement towards etiological group of post-infectious lesions and reduce age restrictions on the use of the method.

CONCLUSION

The clinical case demonstrated the relevance of the problem of organizing care for children and adolescents with bone infection and destructive lesions. With outpatient and inpatient care provided by multidisciplinary medical institutions (regional and federal centers), there was a difficulty for specialists to identify an adequate treatment option and that resulted in a long idle period of diagnosis and treatment. This led to a complicated clinical status and chronification of primary acute hematogenous osteomyelitis. The result reported demonstrated the possibility of preserving the support and motor function of the ankle joint with total ankle replacement using a tailored modular implantation after the arrest of the infection. Sufficient experience

and long-term results of ankle replacement are needed for unbiased judgments about the optimal strategy. The design (clinical observation) and the limited of follow-up period of 14 months should be considered as limitations on the reliability of the publication.

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Ethical Approval *the authors obtained the informed consent of the patient for examination, treatment, collection, storage and analysis of medical documentation data for scientific and educational purposes, and their publication. the authors confirm that there is no data in the article that is not subject to publication.*

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Clinical case
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Ankle joint replacement for necrosis of the talus, crusarthrosis, equinovarus and adducted foot

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Abstract

Introduction Surgical treatment of patients with avascular osteonecrosis of the talus and post-traumatic hindfoot deformity is associated with high morbidity, difficulty of early disease detection, the discrepancy between patient expectations and orthopaedic requirements for surgical outcomes due to traditional methods. The use of customized ankle joint replacement may be a potential solution to this problem.

The objective was to evaluate the results of treatment of a patient with avascular osteonecrosis of the talus, crusarthrosis and hindfoot deformity using an original replacement method for the ankle joint and the talus.

Material and methods A 30-year-old patient with post-traumatic avascular osteonecrosis of the talus, crusarthrosis, equinovarus and adducted foot underwent replacement of the ankle joint and talus using the method developed by the authors. Radiographic and tomographic methods were used for diagnosis. The VAS scale, AOFAS, FFI, EFAS questionnaires and pedobarography were used to assess clinical and functional results.

Results The results of treatment evaluated at 12 months showed maintained foot deformity correction, stability of a tailored construct with no signs of loosening and osteolysis. The clinical and functional result showed a 81/2 VAS decrease in pain, functional status improved by 4.3 times with functional foot index (FFI) improved by 2.2 times according to the AOFAS scale at 12 months.

Discussion Orthopaedic surgeons are conducting research aimed at preserving ankle motion in the treatment of avascular osteonecrosis of the talus. A serious problem is associated with concomitant deformities of the hindfoot and available implants fail to solve this problem.

Conclusion The surgical method offered for the patient provided good clinical and functional results with the hindfoot deformity corrected within one stage reducing the treatment time.

Keywords: avascular necrosis, aseptic necrosis, osteonecrosis, arthrodesis, arthroplasty, ankle joint, talus, custom-made talus prosthesis, ankle joint replacement

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INTRODUCTION

Avascular osteonecrosis of the talus (AOT) is a severely disabling disease. Osteonecrosis of the talus (OT) of different etiology is difficult to diagnose in the early stages of the disease and patients seek medical attention in advanced stages developing a severe deformity of the hindfoot and ankle joint [1]. Surgical treatment of the condition is generally accepted [2]. Massive loss of the talus bone, post-traumatic changes in the ankle joint result in a complex fixed hindfoot deformity preventing primary and revision ankle replacement to maintain motion in the joints of the hindfoot. In retrospect, the main treatment method was considered to be Astragalectomy was historically recommended for avascular necrosis of the talus of different origins in cases of the most severe lesions of the talus including fragmentation, resorption and inability to preserve the joints surrounding the talus [3]. The functional outcomes of the procedure fail to comply with the current level of patient expectations and orthopaedic requirements for the results of surgical treatment [4].

Surgical treatments of OT of different etiologies and the consequences include tibiotalocalcaneal arthrodesis, panarthrodesis of the foot with massive bone auto- and alloplasty of defects added by reconstructive interventions as indicated [2]. With all the advantages the surgical treatment can be associated with significant disadvantages including high morbidity, irreversible loss of movement in the functionally important joints of the hindfoot, high risk of nonunion, high incidence of residual deformities and long periods of limb immobilization [5–8]. Methods aimed at preserving biomechanics in the joints of the hindfoot are essential for the total AOT [9]. Additive technologies, interaction between surgeons and engineers and the use of safe materials and alloys are practical for developing original designs and new surgical treatments using modern technologies [10].

In addition to AOT, concomitant deformity of the hindfoot and ankle joint is essential for determining indications for ankle replacement. This can be an absolute contraindication to primary ankle replacement using existing designs [11]. Some authors support multi-stage surgical treatment to include deformity correction, osteotomy of adjacent bones, arthrodesis of subtalar, talonavicular, calcaneocuboid joints and bone auto- and allograft of defects at the first stage [12] creating conditions for ankle joint replacement at the second stage of surgical treatment with preserved talus structure. Otherwise, there is a high risk of instability of the endoprosthetic components and infection. A logical question arises: how to overcome the shortcomings and improve the results of treatment of patients with post-traumatic equino-varo-adduction deformity of the foot and ankle joint with osteonecrosis of the talus of different etiologies, with post-traumatic osteoarthritis of the ankle joint maintaining movement in the joints of the hindfoot? In our opinion, a potential solution may include a custom-made implant for the talus with use of additive technologies, a surgical procedure performed with the method we have developed for replacement of the ankle, talonavicular, subtalar joints using an original implant of the talus, reproducing the lost anatomy and spatial orientation of the hindfoot, ankle joint, adapting its configuration with the articulating surface of the fixed liner and the tibial component of the ankle implant [13].

The objective was to evaluate the results of treatment of a patient with avascular osteonecrosis of the talus, crusarthrosis and hindfoot deformity using an original replacement method for the ankle joint and the talus.

MATERIAL AND METHODS

Data for the study included findings of a 30-year-old patient with post-traumatic avascular necrosis of the talus that resulted in post-traumatic osteoarthritis of the ankle joint and adduction

equinovarus deformity of the foot and ankle joint. An original method of ankle joint replacement was employed for surgical treatment using tailored-made implants obtained with 3D reconstruction and modeling of the intact talus and contralateral ankle joint. Clinical effectiveness included hindfoot deformity correction, stable implant and absent signs of osteolysis around the components seen at the follow-up examination. Outcome measures included conventional radiography, multislice computed tomography, static and dynamic pedobarography, questionnaires and scales for assessment of the foot and ankle function: American Orthopedic Foot & Ankle Society (AOFAS) score, European Foot and Ankle Society (EFAS) score, Foot Function Index (FFI) and visual analog scale (VAS) pain. The group of authors obtained consent from the patient to participate in the study and publish the results without personal identification.

RESULTS

In 2022, a female patient Sh. born in 1992, was admitted to the 4th trauma and orthopaedic department (department of foot and ankle surgery) of the City Clinical Hospital named after S.S. Yudin (Moscow). She presented with pain, severe hindfoot deformity on the right side, persistently limited motion in the ankle, subtalar, talonavicular joints, swollen soft tissues of the right ankle joint. The patient reported home accident in 2014, she fell from her own height on her right foot and sustained an open fracture of the talar neck on the right foot with subtalar, talonavicular and ankle dislocation, Hawkins Type IV type IV [14] (Fig. 1, a, b). She was delivered to the trauma department of the hospital as an emergency. Surgical treatment performed for her included open reduction and screw fixation of the right talus (Fig. 1, c, d). The postoperative period was uneventful, the bone healed by primary intention, and the lower limb was immobilized with a plaster cast for three months. With bone consolidation, plaster immobilization was suspended and the patient was treated conservatively. In 2016, the screws were removed at the place of residence with technical difficulties (fracture of screws); the components were partially removed due to the high probability of traumatic injury to the talus. Between 2016 and 2022, the pain progressed, hindfoot deformity and persistently limited range of motion developed with swollen soft tissues in the ankle. The right foot appeared adducted and supinated with the apex of the deformity at the the talonavicular joint. She developed fixed equinus alignment at the level of the ankle joint and varus deformity of the calcaneus at the level of the subtalar joint accompanied by persistent painful contracture.

The patient could take no more than 5,000 steps per day. Conservative treatment failed and a comprehensive physical and radiological examination was performed. Anteroposterior and lateral views of both feet and ankle joints (Fig. 1, e, f) showed collapsed talus, post-traumatic varus deformity of the talus, foreign bodies with screw debris in the body of the right talus, post-traumatic right-sided grade III crusarthrosis.

A multislice computed tomography of the right ankle joint (Fig. 2, a, b) demonstrated the outcome of post-traumatic aseptic necrosis of the talus and deformed right ankle. The articular surfaces appeared to be indistinct, uneven, and subchondral osteosclerosis of the articular surfaces with cyst-like restructuring noted. The joint space was filiformly narrowed. A 3D reconstruction of the ankle with 3D modeling of the right foot showed varus deformity of the talus, supinated and adducted foot, collapsed talus and foreign bodies with screw debris in the body of the talus). Radiographs and MSCT of the ankle indicated signs of post-traumatic avascular necrosis of the talus and its complications in the form of collapsed talus, multiple cysts in the tibia,

talus, etc. Based on clinical findings and data from instrumental examination methods, a diagnosis was made: The patient was diagnosed with post-traumatic avascular necrosis of the talus, collapsed trochlea of the talus of the right foot, grade III deforming osteoarthritis of the ankle joint, fixed adduction equinovarus deformity of the right foot and adducted forefoot. Surgical treatment using our patented method (Patent 2800562 of the Russian Federation “Method of ankle joint replacement for post-traumatic equinovarosis adduction deformation of the foot and ankle joint with necrosis of the talus of different etiologies with post-traumatic osteoarthritis of the ankle joint") was offered for the patient to preserve the biomechanics of motion in the ankle, subtalar, talonavicular joints, correct hindfoot deformity and reduce postoperative rehabilitation [13].

Fig. 1 Anteroposterior and lateral views of the right ankle joint showing (a, b) a fracture of the talar neck with dislocation in the subtalar, talonavicular and ankle joints (2014); (c, d) fracture-dislocation of the talus reduced, internal fixation with screws performed (2014); (e, f) outcome of AOT, collapsed talus, post-traumatic varus deformity of the hindfoot, screw debris in the body of the right talus, post-traumatic right-sided grade III crusarthrosis (2022)

The operation using the method of ankle joint replacement offered consisted of the following steps:

Preoperative planning MSCT of the contralateral normal talus and its mirror reconstruction were performed. A tailored-made talus implant was created considering such parameters as the shape, size, and volume of the intact contralateral talus, mirrored and adapted to the implantation side.

On the block of the tailored-made talus implant, a dovetail-type notch was formed, matching to the polyethylene insert of the ankle joint implant in shape and size. Measurements, relationships and spatial orientation of the talus in the subtalar, talonavicular, and ankle joints were assessed using a virtual model, evaluating the talo-metatarsal angle [15], axis of the talus [16], talocalcaneal angle (Keith angle) [17].

Surgical procedure A tourniquet was applied, Achilles lengthening performed, access made along the anterior surface of the ankle joint between the tendons of the long extensor of the 1st toe and the tibialis anterior muscle, the skin and subcutaneous fat were dissected layer by layer to the bone, protecting the neurovascular bundle, and subperiosteal dissection performed in the lateral and medial directions to expose tibial pylon, talar neck and head, ankle joint, the synovial membrane of the ankle joint was excised, the remains of the fragmented talus were resected and removed with astragalectomy performed (Fig. 2, c, d). A tailored-made implant of the talus adapted to the polyethylene insert and the tibial component of the ankle implant in shape and size was placed in the bed, the tibial component of the ankle joint was installed, an impactor fixed into the tibial component to press the polyethylene insert and the polyethylene insert was implanted (Fig. 2, e, f).

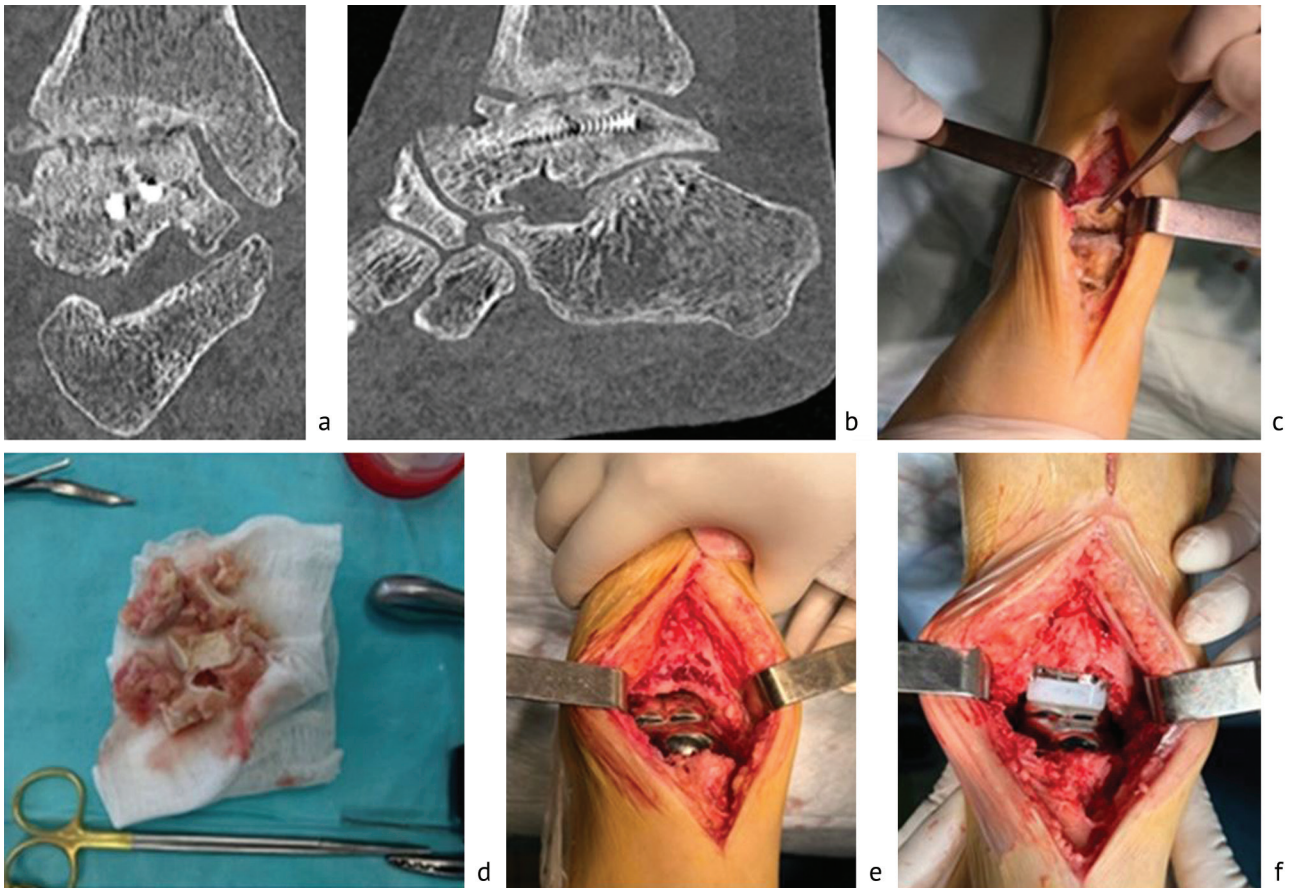

Fig. 2 Coronal and sagittal MSCT scans of the ankle joint showing (a, b) outcome of post-traumatic AOT, collapsed talus, multiple cysts of the tibia and talus. Intraoperative photos demostrating (c) surgical approach to the ankle joint; (d) fragmented, necrotic talus; (e) implanted tailored-made implant of the talus; (f) tailored-made implant of the ankle joint and talus assembled with a tibial component and a polyethylene liner

Hemostasis was performed after removal of the tourniquet, the wound sutured in layers, an aseptic bandage applied and immobilization produced with a deep posterior plaster splint. The drainage was removed the next day.

Postoperative treatment Dressings were changed, subsequent immobilization produced with a removable rigid orthosis and medication administered. The patient was recommended to walk with crutches without weight-bearing on the operated lower limb for 4 weeks. Immobilization and anticoagulant therapy were suspended at 4 weeks as planned. The patient started to bear weight on the operated leg using crutches and gradually abandoned them over a month with a follow-up examination. Massage, physiotherapy, kinesiotherapy and physical therapy were administered. A dynamic control examination using radiography and MSCT of the operated ankle and foot was produced at 12 months (Fig. 3, a–h).

The concomitant adduction equinovarus deformity of the foot was corrected due to exact fit of the talus block and the polyethylene insert fixed into the tibial component of the ankle implant to ensure motion in the ankle, subtalar, and talonavicular joints. The patient was asked to fill in questionnaires preoperatively and at 12 months to assess pain using the visual analog pain scale (VAS) [18], functional parameters using AOFAS [19] and the functional foot index (FFI) [20], EFAS score [21] and the results of static and dynamic pedobarography. The findings demonstrated a significant improvement with decrease in pain, improved functionality (Table 1) and biomechanics of the foot, a decrease in the overload of the hindfoot and more uniform distribution of axial load between the forefoot, middle and hindfoot (Fig. 3 f, g). At the last follow-up visit, the patient was able to produce more than 9000 steps per day.

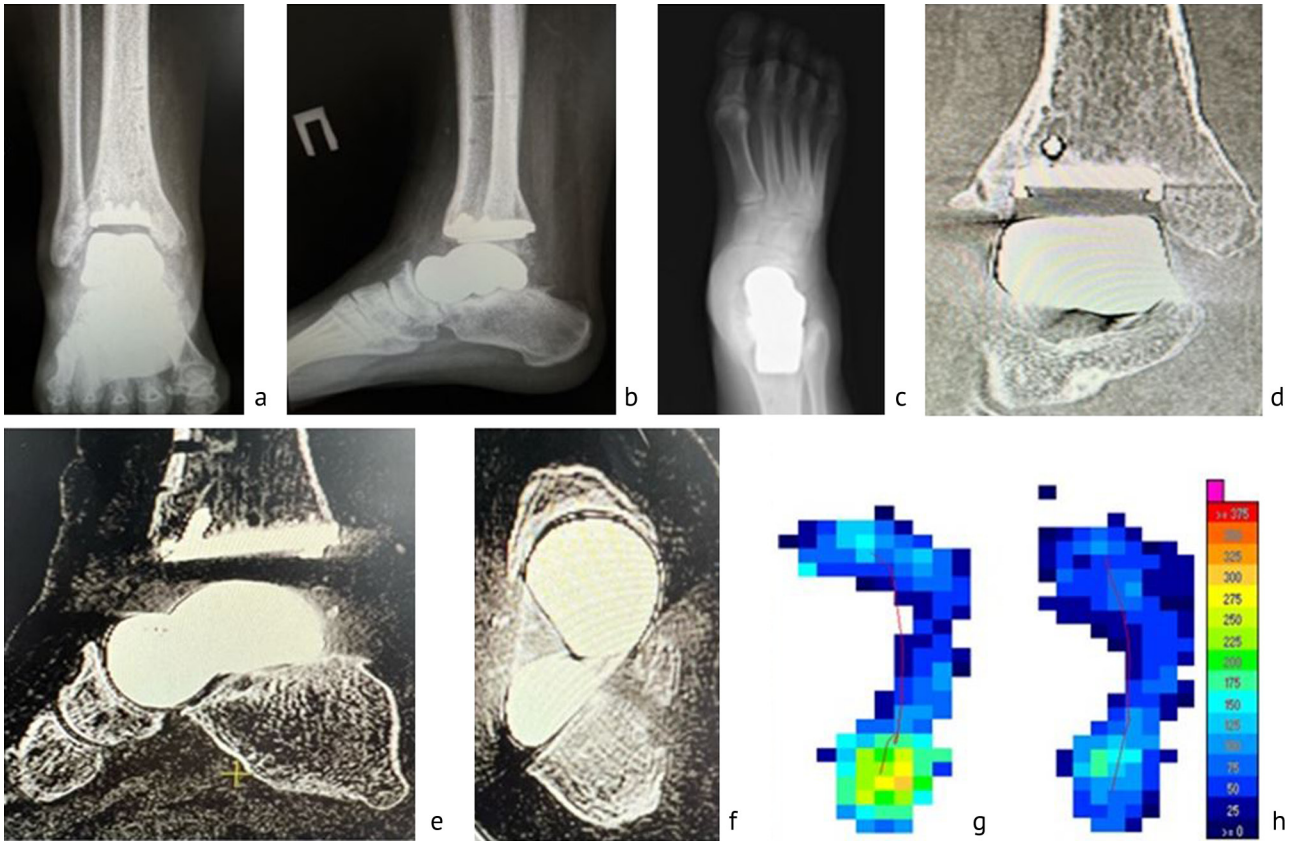

Fig. 3 Anteroposterior and lateral views of the right ankle joint showing (a, b) AP view of the right foot with imitated support (c) at 12 months. Coronal, sagittal, axial MSCT scans of the right ankle and foot (c, d, e). Precise relationship of the custom-made talus implant in the subtalar, talonavicular joints with the congruence and alignment provided between the implant, polyethylene liner and tibial component of the ankle replacement. Results of pedobarography of the right foot: prior to tailored-made implantation of the ankle joint and talus (f), at 12-month follow-up (g). There is a decrease in the overload of the hindfoot with weight-bearing evenly distributed between the anterior, middle and posterior portions of the foot

Table 1

Assessment of the clinical and functional condition of the foot using questionnaires

Scale/ Questionnaire	Pre-op	12-month follow-up
VAS	85	10
AOFAS	36	80
FFI	100	23
EFAS	12.5	31.5

Note: VAS, Visual Analogue Scale; AOFAS, American Orthopedic Foot & Ankle Society; FFI, Foot Function Index; EFAS, European Foot and Ankle Society

DISCUSSION

Severely displaced fractures and fracture-dislocations of the talus (Hawkins type IV) should be reduced and fixed with or without external fixation shortly after injury to arrange for the next stage of surgical treatment including open reduction and internal fixation. Surgical treatment suggests special care for removal of the periosteum with the resection needed only for anatomical reduction. Rigid, stable internal fixation should be provided with cortical lag screws to be placed at or below the midpoint of the talar head and locking plates can be added. The timing of the definitive procedure for displaced fractures is not associated with the risk of osteonecrosis; it is important to preserve the talus length and restore the anatomy [22]. However, the risk of post-traumatic AOT can range from 50 % to 100 % at a long term even with excellent anatomical open reduction and internal fixation of bone fragments [23–25]. The extent of preoperative bone displacement can be the best predictor for post-traumatic avascular necrosis. Avascular necrosis is associated with cysts and scarry degeneration in the body of the talus, collapse and fragmentation resulting in severe post-traumatic deformities of the hindfoot and ankle joint, persistent contractures and severe pain. Post-traumatic AOT, concomitant severe deformities of the hindfoot and ankle joint can prevent primary ankle joint replacement using commercially available implants with low regenerative potential for bone fusion and a high risk of early instability. Development of new surgical methods can be a promising and relevant solution aimed at preserving biomechanics in the joints of the hindfoot in patients with avascular osteonecrosis, total bone involvement and concomitant deformities of the hindfoot and ankle joint. Treatment of acute cases causes great difficulties for trauma surgeons and outcomes of the disease are compromising for orthopaedic surgeons. Long periods of immobilization, nonunion, shortening of the lower limb, severe deformities can lead to disability of patients with the majority being young and active individuals. Our experience and foreign publications on talus arthroplasty demonstrate good long-term results from the use of the complex constructs [26]. The authors report successful results of talus replacement in the treatment of patients with traumatic extrusion of the talus in pediatric populations [27] and in adult patients [28].

A natural proposal arises for a paradigm shift in the approach to treating patients with traumatic loss of the talus, fracture-dislocations accompanied by massive bone loss. In our opinion, a potential and promising solution may include an individual approach to the trauma and orthopaedic patients, patient-specific talus replacement using additive technologies, a combination of the tibial pylon with implantation, the tibial component of the ankle implant and polyethylene liner as indicated. There are discussions regarding materials of the friction pair of a tailored-made implant, the relationship to the capsular-ligamentous apparatus of the ankle joint, one-/two-stage surgical treatment (stage 1:

correction of hindfoot deformity, stage 2: ankle joint replacement), cemented or cementless fixation of a tibial component, fixation of the talus implant in the subtalar joint. Two types of materials can be used to create a tailored-made talus implant: TI64ELI alloy and zirconium ceramics. The use of implants made of steel, aluminum oxide ceramics, titanium alloys are reported [26, 29]. The capsular-ligamentous apparatus of the ankle joint was repaired according to indications in two cases: (1) distal tibiofibular syndesmosis, (2) anterior talofibular ligament). The talus implant was not fixed to the subtalar and talonavicular joints in all our clinical cases. Concomitant deformities of the hindfoot are associated with technical difficulties in creating a custom-madetalus implant. The usual mirrored model of an intact talus does not correspond to the implantation site in shape and size with post-traumatic changes, that would result in failure of performing total talus arthroplastyand ankle joint. If the implantation is produced in the case, then the persistent post-traumatic deformity and pain would raise a question about a long-term survival.

The technical result of the invention we offered and introduced into practice includes correction of the talus deformity, pain relief and preserved range of motion in the ankle, subtalar and talonavicular joints through the use of a custom-made talus implant in combination with a tibial component and a polyethylene insert of the ankle implant fixed in it [13]. The specific feature of the implant was that the shape, size, volume of the intact talus were measured, adapted the bone to the measurement parameters and spatial orientation in the subtalar, talonavicular and ankle joints, the site of implantation, evaluated such parameters as the talo-metatarsal angle, axis of the talus, talocalcaneal angle (Keith's angle). The risks were properly explained and discussed with the patient. With ankle arthrodesis presented to her as an alternative procedure, the patient selected for total ankle arthroplasty using our method. Our team and the patient were satisfied with the outcome at one year. Each case of AOT requires an individual differentiated approach to treatment. Due consideration and care must be taken treating patients with associated hindfoot deformities, with careful preoperative planning and appropriate preparation of implantation considering all factors that may affect implant survival. We performed 9 custom-made implantations between 2019 and 2023 using the method offered.

CONCLUSION

The patient treated with the surgical method devised showed good clinical and functional results with the hindfoot deformity corrected in one stage reducing the treatment time. Custom-made talus implantation facilitated concomitant hindfoot and ankle deformity correction with the use of additive technologies, preserving biomechanics in the hindfoot joints and providing good short- and long-term results.

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Clinical case
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Clinical development of ileofemoral thrombosis caused by malposition of the ileosacral screw

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Abstract

Introduction Treatment of unstable injuries of the pelvic bones is one of the unsolved problems in modern traumatology. The instability of the injuries is determined by the nature of the destruction of the posterior semi-ring of the pelvis. The most used technique for osteosynthesis of sacral fractures for unstable pelvic injuries is ileosacral screw fixation.

The purpose of the work was to demonstrate a clinical case of an iatrogenic complication: ileofemoral thrombosis caused by compression of the internal iliac vein due to malposition of the ileosacral screw.

Materials and methods Medical records of a 34-year-old patient injured in a traffic accident (front seat passenger) were studied, who was referred from a district hospital on the fourth day after the injury diagnosed with a fracture of the transverse process of L2 vertebra on the left, closed fracture of the pubic and ischial bones on the left, fracture of the lateral mass of the sacrum on the right. Alcohol intoxication. Traumatic shock stage 1. Treatment results were monitored throughout the inpatient and outpatient treatment periods. Long-term follow-up was 6 months.

Results Timely suspicion of the complication based on physical examination data with CT angiography that assisted to exclude internal bleeding and urgently carry out repeated surgical intervention to correct the implant malposition, reosteosynthesis of S1 body without loss of reduction, to achieve regression of the clinical picture of ileofemoral thrombosis, and also to mobilize the patient in the shortest possible time. During inpatient treatment, regression of the symptoms of the complication was achieved, the patient was fully activated, and was discharged for outpatient follow-ups.

Discussion Variability in the anatomy of the sacrum and the characteristics of fractures hinder the navigation while inserting iliosacral screws, which in some cases result in malposition. Compression of the common iliac vein without damaging it causes difficulty in blood outflow and the development of a clinical picture of ileofemoral thrombosis in the early postoperative period.

Conclusion This clinical case shows that X-ray images in standard views are not a reliable method for diagnosing sacral injuries and are not sufficient for preoperative planning. The use of standard C-arm did not provide sufficient intraoperative visualization to correctly assess the position of the iliosacral screw, especially in cases with sacral dysmorphia. The 3D volumetric image reconstruction significantly influenced the correct perception of the anatomical structure of the bony structures of the pelvis. Malposition of the screw and its exit to the anterior surface of the sacrum caused disruption of the iliac vein outflow and development of thrombosis in the early postoperative period.

Keywords: ileosacral blockage, malposition, ileofemoral thrombosis

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INTRODUCTION

Management of unstable injuries of the pelvic bones is one of the unsolved problems in modern traumatology. The instability of the injuries is determined by the nature of the destruction of the posterior semi-ring of the pelvis. Of all the possible variants of posterior pelvic fractures, the most common are sacral fractures [1, 2, 3]; they constitute 0.82–2.1 cases per 100 thousand people (about 3 % of all skeletal fractures) [4, 5, 6]. The most common technique for osteosynthesis of sacral fractures for unstable pelvic injuries is ileosacral screw fixation [4, 7, 8]. The technique has been quite well studied and has several variations depending on the characteristics of the fracture [3, 7, 9, 10, 11, 12]. It is demanding in terms of surgical skills, material and technical base of the medical institution.

The purpose of the work was to present a clinical case of an iatrogenic complication: ileofemoral thrombosis caused by compression of the internal iliac vein due to malposition of the ileosacral screw.

MATERIALS AND METHODS

All materials and methods are presented here with the informed consent of the patient's legal representative and in compliance with the ethical principles of the 2013 revision of the Declaration of Helsinki. The material was the medical records of a 34-year-old patient who was injured in a traffic accident (front seat passenger) and was referred to our institution from a district hospital on the fourth day after the injury with the diagnosis: fracture of the transverse process of L2 vertebra on the left; closed fracture of the pubic and ischial bones on the left, fracture of the lateral mass of the sacrum on the right. He was under alcoholic intoxication.

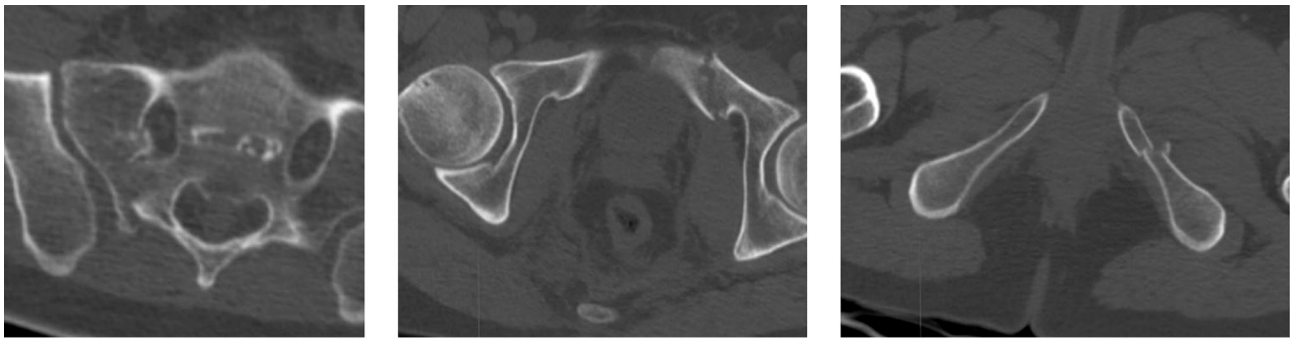
Patient's results were monitored throughout inpatient and outpatient management. The follow-up was 6 months.

RESULTS

The patient was hospitalized at the trauma department of the National Ilizarov Medical Research Center on the fourth day after the injury. Upon admission, according to ultrasound scanning of the vessels of the lower extremities and physical examination, there were no signs of thrombosis of the lower extremity vessels. Admission X-rays of the pelvis in three projections revealed a double fracture of the left pubic bone and left ischium without displacement of bone fragments (Fig. 1). Computed tomography (CT) scans confirmed injuries to the pubic and ischial bones, and additionally detected a fracture of the lateral mass of the sacrum on the contralateral side (Fig. 2).

a b c

Fig. 1 Radiographs of the pelvis upon admission: *a* — plain view; *b* — inlet projection; *c* — outlet projection



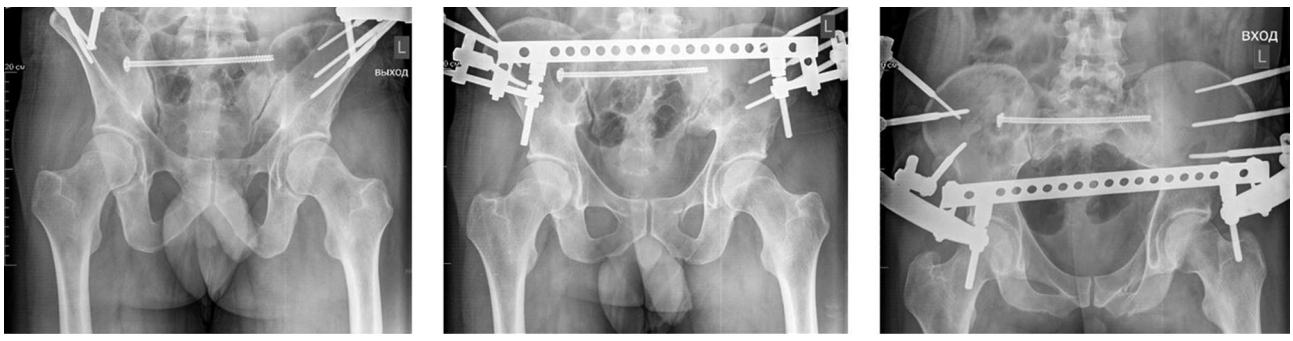
a b c

Fig. 2 CT sections with visualization: *a* — fracture of the right lateral mass of the sacrum; *b* — fracture of the left pubic bone; c — fracture of the left ischium

The surgical intervention plan was as follows. Due to the damage to the lateral mass of the sacrum on the right and a rupture of the anterior parts of the SIL on the left, it was decided to insert two iliosacral screws and fix the anterior semi-ring of the pelvis with the Ilizarov apparatus. The patient was prescribed anticoagulants in a prophylactic dosage (Enoxparin 0.4 subcutaneously once a day). Significant laboratory tests data at the time of admission: PTI — 106 %; hemoglobin — 107 g/l; erythrocytes — 3.52×10^{12}/l; hematocrit — 32.7 %; platelets — 181×10^{9}/l; leukocytes — 6.5×10^{9}/l; ESR — 35 mm/h.

Description of surgical intervention On 10.05.23, under the control of the image intensifier, a wire was passed through the ilium into the body of S1 on the left. A 7/80-mm cannulated screw was inserted along the wire. The screw deviated inwards into the pelvic cavity; it was not possible to change the screw direction. A decision was made to place one screw transsacral on the right. Under the control of the image intensifier, a wire was passed through the ilium into the body of S1 transsacrally. A 7.0-mm cannulated screw with a washer was inserted along the wire. The X-ray checks showed that the position of the screw was satisfactory in all projections. Three half-pins were inserted into the iliac crests. The front frame of the external fixation device was assembled. Due to the difficulties in screw insertion and the staged surgical intervention, the duration of the operation was three hours. Blood loss was approximately 150 ml.

First postsurgical day The patient was verticalized, moved within the ward independently using crutches. He complained of moderate pain in the area of surgical intervention (iliac crests). Control radiographs showed the results of the surgical intervention, the positioning of the elements of the external fixation apparatus and the iliosacral screw in three projections (Fig. 3). A control CT check of the pelvic bones was not available on the first day after surgery due to the operating regime at the institution on that day. Laboratory tests: hemoglobin — 84 g/l; erythrocytes — 2.67×10^{12}/l; hematocrit — 25.4 %; platelets — 442×10^{9}/l; leukocytes — 10×10^{9}/l. The patient was somatically stable, there was no tachycardia, blood pressure did not drop.



a b c

Fig. 3 Checking radiographs after surgery: *a* — outlet projection; *b* — overview projection; *c* — inlet projection

Second postsurgical day Examination of the patient did not detect negative changes in the somatic condition; blood test control: hemoglobin — 80 g/l; erythrocytes — 2.67×10^{12}/l; hematocrit — 24.8 %; platelets — 412×10^{9}/l; leukocytes — 7.1×10^{9}/l. The patient had no complaints at the time of examination. Data for ongoing bleeding were not available. He received anticoagulant therapy at the same dosage (Enoxparin 0.4 subcutaneously once a day).

Fourth post-surgical day Physical examination revealed severe swelling of the left thigh (+6 cm). Ultrasound scanning of the vessels of the lower extremities was performed. Its findings were echo signs of ileofemoral thrombosis on the left, thrombophlebitis of the left GSV of the upper third of the thigh, lymphadenopathy of the inguinal node on the left. In the lumen of the left common femoral vein, echogenic thrombotic masses measuring 25.4×9.6 mm were visualized; thrombotic masses passed into the left GSV measuring 19.4×5.1 mm with preservation of weak parietal blood flow, compression of the veins was incomplete. The left superficial and deep veins of the thigh and the left popliteal vein were not visualized due to severe lymphostasis of the subcutaneous fat. LSV on the right was 2.0 mm, the course was straight, there were no blood clots; on the left, it was 2.1 mm, the course was straight, there were no blood clots. Severe lymphostasis of the SF at all levels of the left thigh and left popliteal fossa. Moderately pronounced lymphostasis of the SF at all levels of the lower leg. The iliac vessels (arteries and veins) were not visualized due to intestinal loops distended with gas. The left femoral artery and deep femoral artery were not visualized due to severe lymphostasis. The walls of the visible arteries of the lower extremities were smooth, the IMT was not thickened — up to 0.6 mm, the ASC was not visualized. The blood flow was of the main type at all levels of the lower extremities, the blood flow speed was not reduced. A previously planned CT scan of the pelvis was performed to assess the position of the iliosacral screw. The CT scan (Fig. 4) showed that the end of the screw protruded to the anterior surface of the sacrum on the left by up to 1.5 cm.

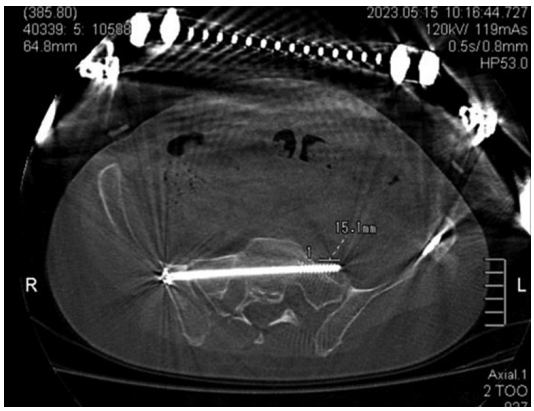


Fig. 4 CT section shows the screw protruding on the anterior surface of the sacrum

To exclude the damage to the iliac vessels with the screw, contrast CT angiography was performed (Fig. 5). It found that contrast enhancement of the arteries was not impaired; expansion, decreased contrast, blurred contours of the left external iliac vein (up to 1.8 cm on the left, up to 1.3 cm on the right), and the common femoral vein. Swelling of the soft tissues of the left thigh. The ileosacral screw on the left protruded into the pelvic cavity up to 2 cm. There were no obvious signs of compression of the vascular structures (pronounced artifacts from the metal structure). Despite the absence of obvious signs of compression, due to artifacts from metal structures, the presence of compression was indirectly suspected by the expansion of the left iliac vein distal to the place where the screw protrudes into the pelvic cavity. There was no evidence of vascular damage or ongoing bleeding; the frequency of anticoagulant therapy was increased to 2 times a day.

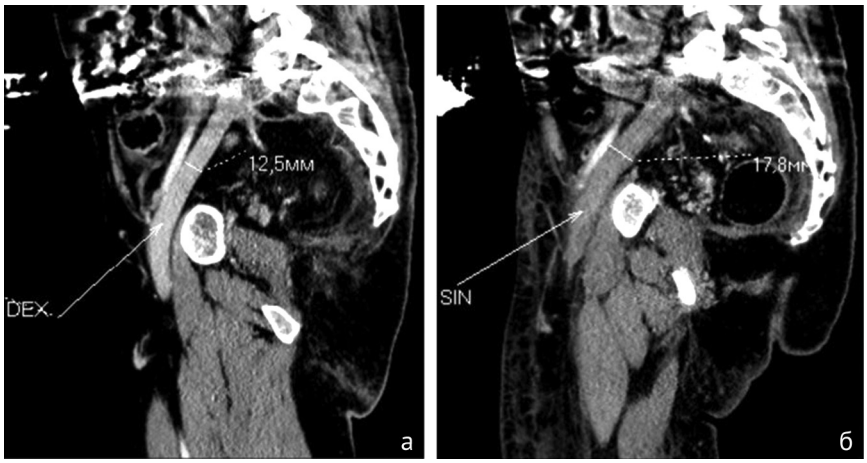


Fig. 5 CT sections with contrast, displaying: *a* — diameter of the iliac vein on the right; *b* — diameter of the iliac vein on the left

Based on the data of instrumental and physical examinations, indications were given for repeated surgical intervention: removal of the iliosacral screw, reosteosynthesis of the lateral mass of the sacrum with insertion of the screw through the corridor in S2. Considering the high risks of intraoperative bleeding from the iliac vessels and initial anemia (hemoglobin — 80 g/l; red blood cells — 2.67 × 10^{12}/l; hematocrit — 24.8 %), a preventive blood transfusion of 2 units of compatible red blood mass was performed. The next day the patient was taken to the operating room. The implant position was controlled in the operating room using a C-arm. In the postoperative period, to assess the positioning of the screw, radiographs in four projections (Fig. 6) and computed tomography (Fig. 7) were performed.

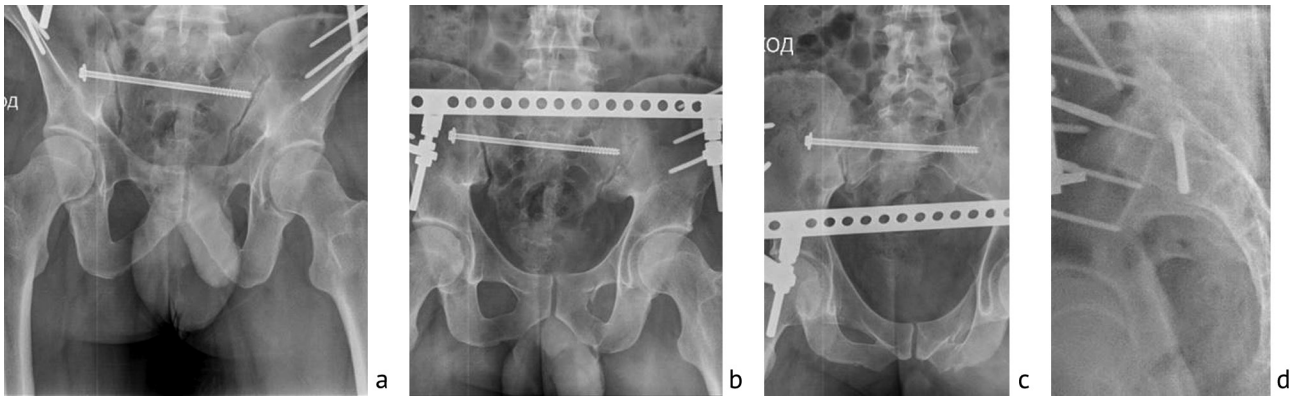


Fig. 6 Radiographs of the pelvis in 4 projections after repeated surgery: *a* — outlet projection; *b* — overview projection; *c* — inlet projection; *d* — sacrum in lateral projection

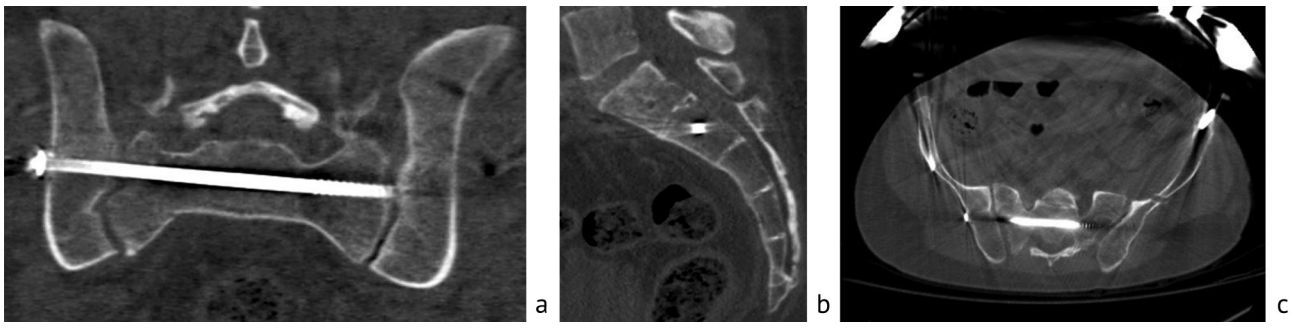


Fig. 7 Sections of multiplanar CT reconstruction of the pelvis, displaying the position of the screw: *a* — frontal plane; *b* — sagittal plane; *c* — horizontal plane

Monitored blood tests after repeated surgery were: hemoglobin — 99 g/l; erythrocytes — 3.34×10^{12}/l; hematocrit — 31 %; platelets — 435×10^{9}/l; leukocytes — 9×10^{9}/l. In the postoperative period, the patient was verticalized the following day but axial load on the left limb was excluded. He continued to receive anticoagulants in the same dosage. Clinical manifestations of phlebothrombosis regressed during the first week. A control ultrasound study of the vessels of the lower extremities was carried out on the seventh day after reintervention. The findings were echo signs of ileofemoral thrombosis on the left, phlebothrombosis of the left superficial vein of the thigh, popliteal vein in weak recanalization, thrombophlebitis of the left GSV of the upper third of the thigh in the stage of weak recanalization, lymphadenopathy of the inguinal node on the left.

An outpatient follow-up examination was carried out one month after surgery. The patient had no complaints, moved independently without additional means of support fully loading the limb. Ultrasound scanning of the vessels of the lower extremities was performed. At the time of the examination, there was no evidence of acute thrombosis of the veins of the lower extremities. Echo signs of incompetence of the left valves of the GSV were revealed. The external fixation device was removed after 1.5 months.

During inpatient treatment, regression of the symptoms of the complication was achieved; the patient was fully activated and discharged for outpatient observation.

The patient was interviewed at three and six months after the surgical intervention: he returned to work after the wounds had healed at the sites where the half-pins and screws were inserted, and had no complaints.

DISCUSSION

Variability in the anatomy of the sacrum and the characteristics of fractures make navigation difficult during insertion of iliosacral screws that may result in their malposition [11, 13, 14, 15]. Cases of neurological disorders associated with insertion of screws in the projection of the sacral foramina and sacral canal were described [6, 15, 16], and a case of damage to the superior gluteal artery from the side of screw insertion [17] as well as cases of malposition accompanied by the screw coming out on the inner surface of the sacrum were reported [17]. In the available literature, we have not found a description of the clinical picture of ileofemoral thrombosis associated with the mentioned above malposition of the ileosacral screw. In most cases of screw malposition, visual radiographic control using standard C-arm views satisfied the surgeons. The above clinical case confirms that radiological images in standard views are not a reliable method for diagnosing sacral injuries and are not sufficient for preoperative planning [9, 18]. The same applies to standard projections of multislice computed tomography (axial, coronal, sagittal). The combination of the imaging methods used in pelvic trauma is necessary to assess the nature of damage to the pelvic bones for planning reconstructive operations aimed at restoring normal anatomy and reliable fixation of injuries [7, 11, 19].

The 3D volumetric image reconstruction helps a lot to correctly perceive the anatomical structure of the bony structures of the pelvis. However, the need to standardize the imaging protocol for pelvic examination remains relevant [8]. The ability for a surgeon to study a 3D volumetric image in detail by changing its position in space can significantly increase the efficiency of its perception. Thus, careful preoperative planning with regard to the anatomy of each patient aimed at the acceptable corridors for the placement of iliosacral screws helps to avoid their incorrect placement. In order to prevent such complications, the use of non-standard X-ray views during surgery was proposed [17]. An alternative way to prevent such complications is the use of navigation systems [16, 20, 21, 22].

It is advisable to conduct a control MSCT study after such operations. Compression of the common iliac vein without damaging it causes difficulty in blood outflow and the development of a clinical picture of ileofemoral thrombosis in the early postoperative period. Timely suspicion based on physical examination data assisted with CT angiography enabled to exclude internal bleeding and urgently carry out repeated surgical intervention to eliminate implant malposition, reosteosynthesis of the S1 body without loss of reduction, to achieve regression of the clinical picture of ileofemoral thrombosis, and also to mobilize the patient in the shortest possible time .

CONCLUSION

The use of standard C-arm views did not provide sufficient intraoperative visualization to correctly assess the position of the iliosacral screw in the case with sacral dysmorphia. Malposition of the screw and its protrusion to the anterior surface of the sacrum, which was not detected intraoperatively, caused a disruption of the outflow of the iliac vein and promoted thrombosis in the early postoperative period. Patients after minimally invasive surgical interventions for sacral fractures require careful medical supervision. It is advisable to perform MSCT study as early as possible after such operations.

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Clinical case
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A 3D German-designed brace used to treat adolescent idiopathic scoliosis

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Abstract

Introduction Adolescent Idiopathic Scoliosis (AIS) is a condition that affects an otherwise healthy child 10 years of age or older and is the high risk of severe deformity and surgery. Different brace applications include the Milwaukee Brace, Boston Scoliosis Brace, TLSO and others, and the success rates of orthoses vary. With little experience in the use of the Chêneau-type corset, the brace provides an effective means for the active correction of scoliotic spinal deformity.

The objective was to demonstrate an outcome with a 3D functional corrective German-designed corset used to treat a patient with AIS in the period from the onset of the curve to the onset of skeletal maturity.

Material and methods The medical history of patient S. including anamnestic, clinical and radiological findings recorded 2018 and 2023 when she used a 3D German-designed (3D GD) corset. The corset design was defined as 3CL/B2 according to the Lehnert – Schroth scoliotic classification as modified by Rigo.

Results The left-sided thoracolumbar curve of a 9-year-old patient with a Risser sign of 0 and a Cobb angle of 25° at baseline decreased to 12° at the age of 16 years (Risser sign — 5) due to bracing.

Discussion The AIS was diagnosed in the patient at the age of 5 years and bracing was initiated at the age of 9. The curve correction using 3D GD brace was based on the principles offered by Chêneau. The patient used the corset for 20 hours per day. The initial brace correction was 90 %. The curve decreased from Cobb angle 25° to 12° over a six-year period of brace treatment with no need for surgery. Three cases with identical outcomes were reported with the use of the Boston and Chêneau braces in AIS.

Conclusion The clinical case showed effective use of the 3D GD corset as a new exponent of corsets developed on the principles offered by Chêneau to prevent surgical treatment by the time of skeletal maturity.

Keywords: corset, adolescent idiopathic scoliosis, nonsurgical treatment

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ВВЕДЕНИЕ

Idiopathic scoliosis is the most common form of morphological scoliosis that can develop in healthy children during any period of development [1]. Scoliosis at a Cobb angle of 10º or more in a patient aged 10 years or less is termed as “early attack of scoliosis” due to poor prognosis as compared to a curve in adolescents [2]. Observation and bracing are most common nonsurgical treatments for patients with juvenile idiopathic scoliosis (JIS). Corsets are used for children with curves at a Cobb angle of 25 to 60° to stop the progression of the deformity and prevent surgical correction [3–7]. The success of bracing for JIS varies from 12.5 % to 95 % due to different examination methods, brace designs, and duration of follow-up [7–11], indicating a lack of consensus and uniform recommendations for the treatment. Milwaukee Brace, Boston Scoliosis Brace, and thoraco-lumbo-sacral orthosis (TLSO) are most common corsets used for children with JIS [5].

The corsets based on the principles offered by J. Chêneau (Chêneau brace) and made manually or using a computer-aided modeling and manufacturing (CAD/CAM) have been recently used in Central Europe for treatment of patients with adolescent idiopathic scoliosis (AIS) [12, 13]. The basic idea of the braces includes the design of highly specific contact and expansion zones on the positive matrix of the patient's body, producing regional derotation of the vertebrae in the curve with cranial and caudal anti-rotational forces. The augmented Lehnert-Schroth classification [14] and its modification according to Rigo [15] are used for tailored brace designs. Chêneau-type brace used to address AIS can prevent the progression of curves to levels requiring surgical treatment [16, 17]. This type of corset is used in the treatment of patients with AIS in Russia [18] and in the Republic of Belarus [19].

The objective was to demonstrate an outcome with a 3D functional corrective German-designed corset used to treat a patient with AIS in the period from the onset of the curve to the onset of skeletal maturity.

MATERIAL AND METHODS

This is a case report of a 9-year-old patient S. with a verified diagnosis of JIS treated with bracing. Review of the medical history, clinical and radiological findings and instrumentation methods of examination of the patient were performed in accordance with the ethical standards of the 1975 Declaration of Helsinki revised in 2013. The study received a favourable opinion from the relevant institutional ethics committee. Written informed consent for the participation in the research project was obtained from the subject's parent/legally acceptable representative.

The available medical documentation used included the history, dynamics in clinical and radiological parameters of the patient’s body and the spine under pressure of therapy using a 3D German-designed (3D GD) corset between 2018 and 2023. The 3D GD corset used in this case was a functional corrective corset, a Russian derivative of the Chêneau corset. The design of the 3D GD corset was classified as 3CL/B2 according to grading of a curve offered by Lehnert – Schroth / Rigo. The corset was used for 20 hours per day.

A standing posterior-anterior radiograph of the spine was produced using a Millenium teleradiography device prior to the use of a corset, with the corset on and subsequently during treatment (once a year). The Cobb angle was measured in degrees to quantify the magnitude of the curve. With the size and direction of the curve identified magnetic resonance imaging (MRI) of the spine was produced for the patient.

The effectiveness of bracing was assessed according to the SRS criteria [20]. An improvement suggested a decrease in the Cobb angle by more than 5°; stabilization suggested the Cobb angle

ranging between +5° to –5°, a poor outcome resulted in an increase in the Cobb angle by more than 5° or a Cobb angle measuring more than 45° at the time of skeletal maturity with an indication for surgical treatment.

The Risser sign was used to measure skeletal maturity with the degree of ossification of the iliac apophysis evaluated by x-ray on a scale 0–5 [21]. The patient started treatment at Risser = 0 which indicated skeletal immaturity, and completed treatment at Risser = 5, which indicated completed skeletal growth. The patient had to replace the corset during the treatment maintaining its design due to the growth of the spine and body.

Scoliosis was diagnosed in a patient S. born in 2006 at the age of 5 years according to her mother and according to available medical documentation. Her mother reported a radiological curve of about 30° an x-ray with unavailable radiographs.

The patient received treatment under our supervision since November 2016 (at the age of 9 years) at the pediatric surgery clinic of Yaroslavl State Medical University at the Rodnik Zdorovya medical center (Yaroslavl). A physical examination revealed asymmetry of the waist triangles and protrusion of the left scapula, and a radiograph of the spine showed a Cobb angle of 6° for a small right-sided thoracic (Th3–Th10) curve and a Cobb angle of 25° for a left-sided thoracolumbar curve (Th10–L4) (Fig. 1). Risser sign = 0. According to, spinal cord pathology was ruled out with MRI of the spine.

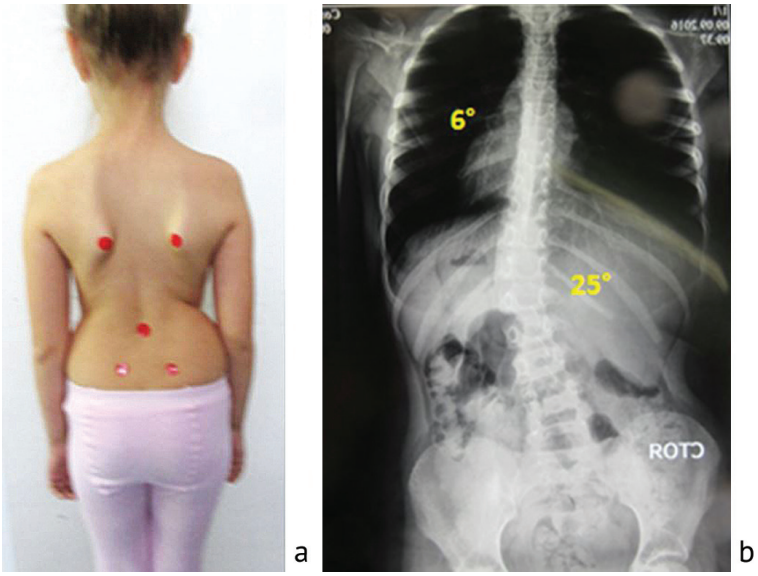

Fig. 1 Appearance (*a*) and AP view (*b*) of patient S. at the age of 9 years (December 2016) showing Risser sign = 0, right thoracic Th3–Th10 (6°) and left thoracolumbar Th10–L4 (25°) curves

RESULTS

The Gensingen brace (corset No. 1) was initially used for the treatment under the supervision of Dr. Weiss. Starting from 2018, the patient was treated with domestically produced alternative (corset No. 2 and No. 3) — the 3D GD functional corrective corset. The technique for a positive 3D NS corset was developed by Mogilyantseva (Fig. 2). A radiograph of the spine with the corset on was produced at a month. The in-brace correction is presented in Figure 3. The patient was requested to use

The patient was examined every 3–4 months during the treatment. The corset effect and the quality were clinically monitored, and belts were replaced and corrective pads placed, if needed. The extent of correction was assessed radiographically (Fig. 4).

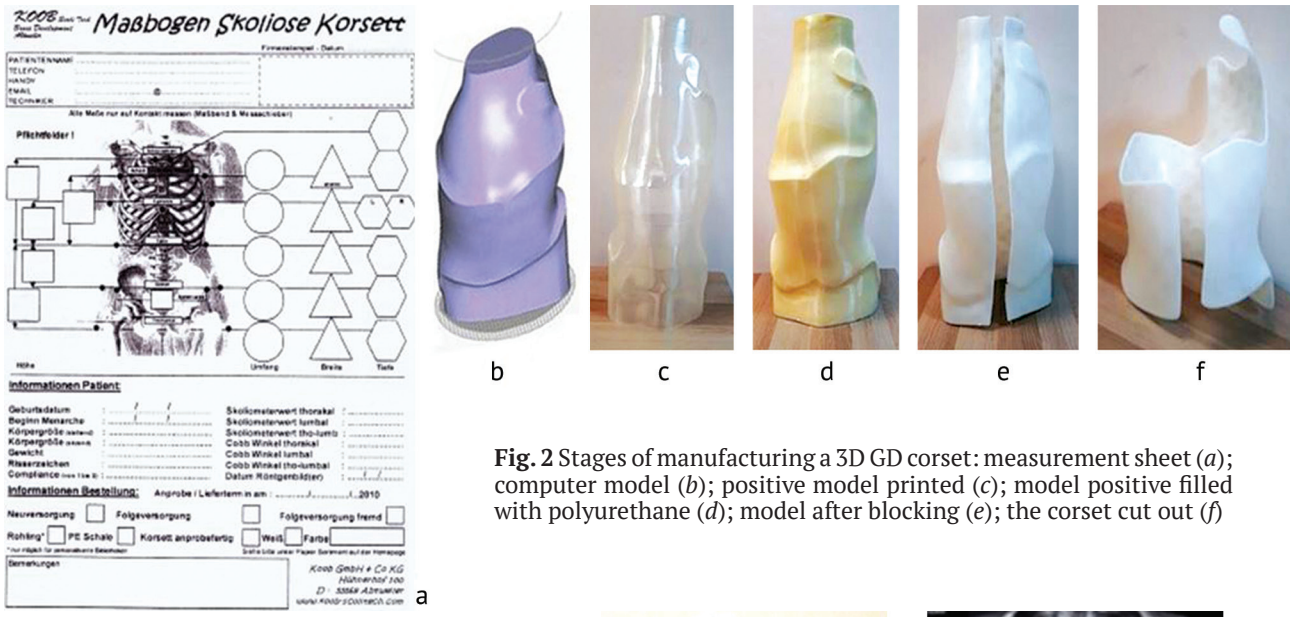

Fig. 2 Stages of manufacturing a 3D GD corset: measurement sheet (*a*); computer model (*b*); positive model printed (*c*); model positive filled with polyurethane (*d*); model after blocking (*e*); the corset cut out (*f*)

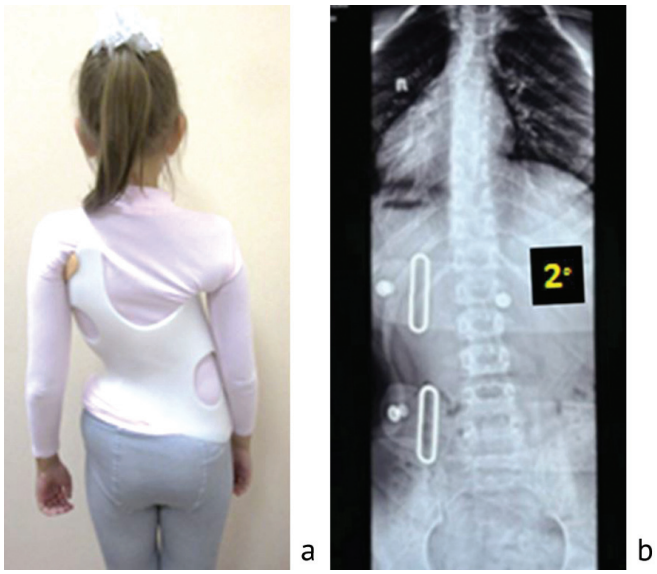

Fig. 3 Appearance (*a*) and radiograph of the spine (*b*) of patient S. wearing corset No. 2 (design 3CL/B2). The in brace correction of the thoracolumbar curve achieved by 90 %

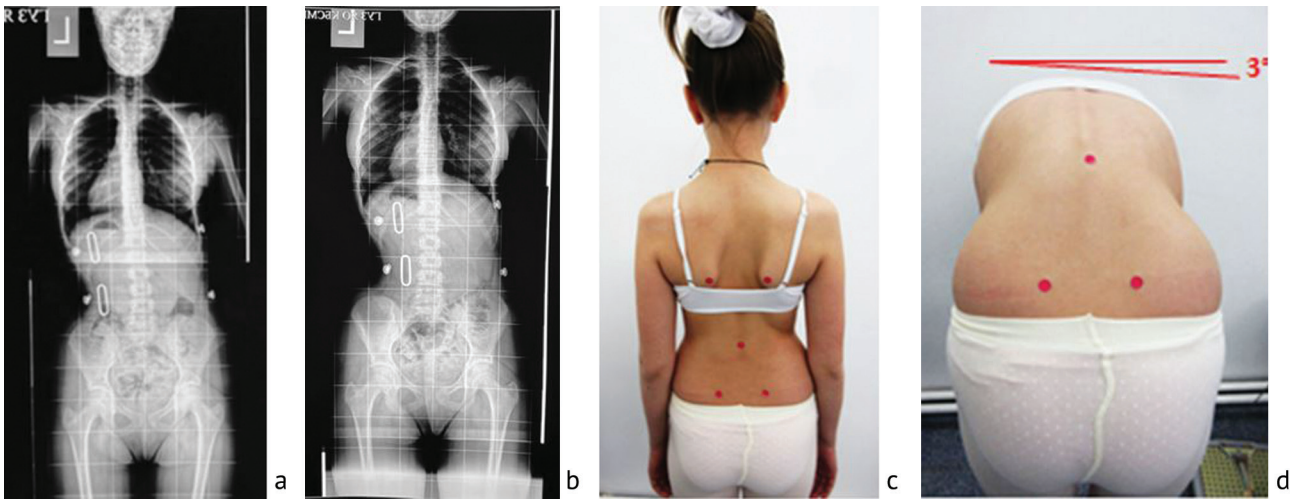

Fig. 4 Radiographs of the spine of patient S. wearing corset No. 2 in September 2018 (a) and March 2019 (b). The correction of both curves maintained. Appearance of patient S. from the back standing position (c) and anatomical landmarks used to measure the parameters of the back surface with the Adam test (d) in March 2019 (at 21/2 year follow-up)

The patient aged 13 years with Risser sign = 2 experienced a sharp “growth spurt” in August 2019 that required a scheduled replacement of the corset (corset No. 3). The curve outside the brace decreased to 3° (Fig. 5) by that time and she completed treatment with the residual Cobb of 12° at the age of 16 in January 2023 (Fig. 6).

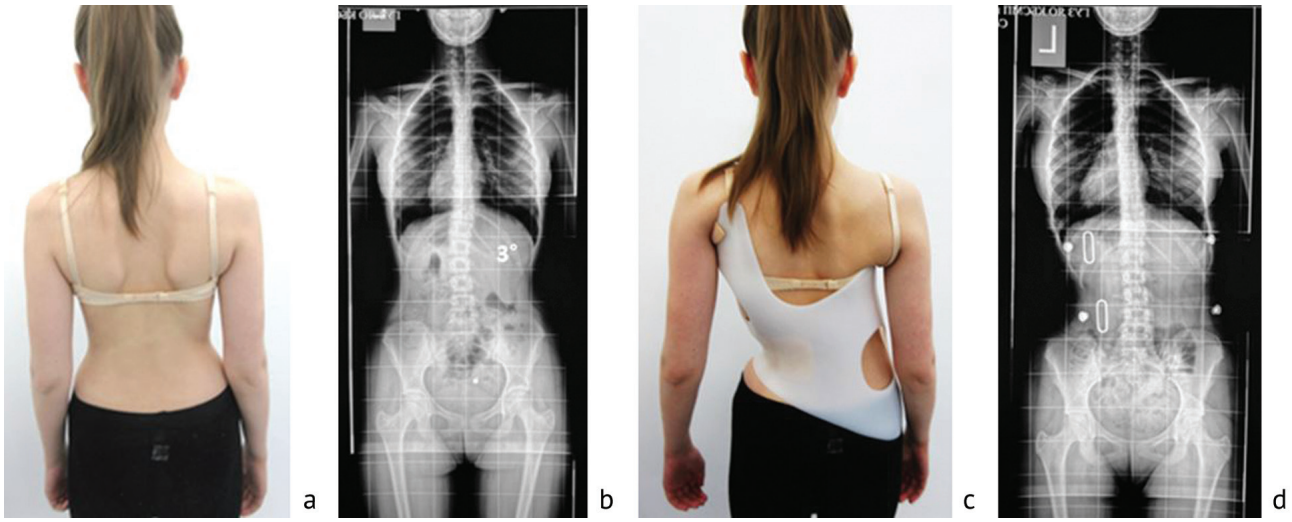

Fig. 5 Appearance (*a*) and radiographs of the spine of patient C. (*b*) without the corset (August 2019, Risser sign = 2). Correction of the thoracolumbar curve maintained (Th10–L4) at 3°. Appearance (*c*) and AP view (*d*) of the spine of patient S. wearing corset No. 3 (December 2020). Correction of both curves maintained

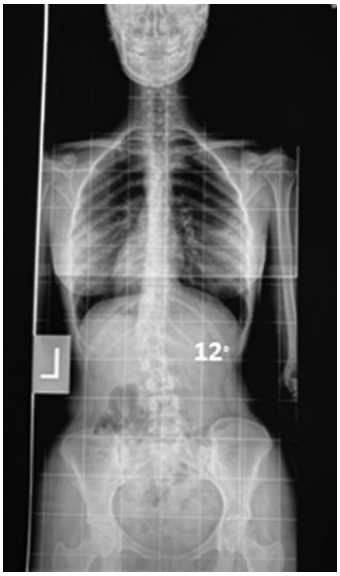

Fig. 6 AP view of the spine of patient S. aged 16 (Risser sign = 5) without a corset. The right-sided thoracic curve Th3–Th10 corrected, the left-sided thoracolumbar curve Th10–L4 measuring less than 12°

DISCUSSION

Patient S. started treatment with the brace at the age of 9 years with the Cobb angle of 25°. These parameters suggested juvenile scoliosis. With the JIS progressing at a rate of 4–7° per year [6], the information from the anamnesis that the onset occurred at the age of 5 years was reliable. We could not established whether that the patient's original curve was 30° because of the lost radiograph.

According to the SRS criteria, the Cobb of 25° in children and adolescents is an indication for bracing [5]. Timely treatment of the patient was essential.

Verification of JIS in a patient with a left-sided curve greater than 20° required MRI of the spine to rule out intraspinal pathology [22]. Hydromyelia was not detected in our patient.

The choice of the brace design was associated with lack of consensus on brace treatment for patients with JIS and the ability to select the most effective brace options. According to authors from Central Europe, the Chêneau brace and the Gensingen brace showed the greatest effectiveness in correcting scoliosis in patients with AIS [17].

The second author of this article received training from Dr. Weiss, who was a student of Chêneau and continued develop the design. Starting from 2018, the patient continued treatment with the 3D GD corset, a domestic analogue of the Gensingen corset. As a sign of gratitude to the developer of the classification of scoliotic arch models and corresponding corset designs, we termed our corset as a 3D German-designed corset." In design and effect on the patient's body and spine complied with the basic principles developed by Chêneau and his follower Weiss [23]. The CAD/CAM technology was used for manufacturing to allow individual use and accurate application of pressure to the appropriate areas of the body as compared to the plaster casts considering the contours of the patient's body. The production of the 3D GD corset was organized by the second author of this article at the Center for German Technologies for the Treatment of Scoliosis (St. Petersburg, Russia).

The 3D GD brace can provide for different designs and constructs to treat patients according to the scoliotic models resulting from radiography. A 3CL/B2 corset design was approved for patient S. according to the augmented classification of scoliosis graded by Lehnert – Schroth [12] and modified by Rigo [13] and the brace did not change during the treatment process.

The best effect was obtained with full-time wearing of the corset (23 hours a day) [13]. A similar mode was recommended for patient S.

The radiograph showed the in brace correction and the potential of the expected therapeutic effect [24]. The in brace correction was 90 % in our patient and was a good prognostic sign for the success of treatment.

There were three case reports describing patients with JIS treated using Boston [6] and Chêneau braces [18, 26]. The authors of these publications reported successful correction of scoliosis in patients by the time of skeletal maturity, eliminating the need for surgical correction. Our clinical case demonstrated the successful outcomes with the 3D GD functional corrective corset used to treat a patient with JIS.

CONCLUSION

The case report showed the high efficiency of the 3D GD corset as a representative of a new generation of braces based on the principles offered by Chêneau, in the treatment of a patient with JIS to allow timely initiation and full duration of treatment, to avoid the need for surgical treatment by the time of skeletal maturity.

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

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The Faculty of Advanced Training in Transosseous Osteosynthesis at the Kurgan Ilizarov Center is 45 years old

In 2024, the Teaching Faculty in Traumatology, Orthopaedics and Related Disciplines at the National Ilizarov Medical Research Center for Traumatology and Orthopaedics turns 45 years. It is a successor of the Faculty for Advanced Training in Transosseous Osteosynthesis for orthopedic surgeons and has been a forge of scientific and professional medical personnel throughout its existence.

The history of the faculty is closely intertwined with the history of the Ilizarov Center. The brilliant idea of Gabriil Abramovich Ilizarov led to a qualitative breakthrough in the treatment of patients with orthopaedic diseases and injuries and gave impetus to scientific research. The Ilizarov method has become one of the greatest achievements in contemporary world medicine.

Professor G.A. Ilizarov, Doctor of Medical Sciences, the founder of the transosseous osteosynthesis method and a novel scientific direction in traumatology and orthopedics, Academician of the Russian Academy of Sciences

The historical period of popularization of the Ilizarov method began in the 70s of the last century. KNIIEKOT (Kurgan Research Institute of Experimental and Clinical Orthopedics and Traumatology, hereinafter referred to as the Institute) was included in the leading scientific institutions of the Soviet Union. Doctors from different regions of the USSR sent letters to the Ministry of Health of the RSFSR and the Ministry of Health of the USSR with requests to organize advanced training courses for orthopaedic surgeons to master the Ilizarov method of transosseous osteosynthesis. The issue of training specialists for the growing young staff of the institute itself also became urgent.

There was a long discussion about the need and possibility of training orthopaedic traumatologists in a new discipline, the Ilizarov transosseous osteosynthesis, directly in the city of Kurgan. There was no higher educational medical institution in the Kurgan region. Therefore, the Ministries of Health of the USSR and the RSFSR made a compromise decision on April 27, 1979 to establish the department of Traumatology and Orthopaedics on the basis of KNIIEKOT but affiliated to the Faculty of Advanced Training for physicians at the Sverdlovsk Medical Institute.

The first head of the department was Doctor of Medical Sciences, Professor Anatoly Dmitrievich Li. On approval of G.A. Ilizarov, he formed a team of teachers of the department that included the head of traumatology unit B.K. Konstantinov, MD; Candidate of Medical Sciences, Associate Professor V.G. Trokhova; V.A. Safonov, MD; V.C. Kamerin, MD; doctor V.M. Kanaev; doctor A.P. Bochanov.

The first head of the Department of Traumatology and Orthopaedics, Prof. A.D. Li and the first staff of the Department for Advanced Training at KNIIEKOT (1979)

First group of the training course surgeons (1979)

All teachers of the department were practicing surgeons and were also actively involved in research activities. The principle of synthesis of theoretical, practical and scientific research justification of the method has been currently implemented by the staff of the department in the educational process, providing course students with theoretical knowledge, practical experience and developments in the scientific field.

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The plans and training programs were designed as 3-month cycles for young specialists and 1.5-month courses for specialists with experience in traumatology and orthopedics.

The first training course of advanced knowledge and skills in transosseous compression-distraction osteosynthesis for domestic specialists, in which 26 doctors took part, was held in September 1979.

The program of training included participation in morning conferences, lectures, clinical rounds, practical classes in three rooms allocated to the department, work in the operating room, instrumentattion room, dressing room, and seminars.

The geography of the participants was large: Yaroslavl, Kaluga, Tambov, Tomsk, Orel Region, Leningrad Region, Perm Region, Krasnoyarsk Territory, Belarusian SSR, Kazakh SSR, Chechen-Ingush ASSR, Dagestan ASSR, Ukrainian SSR, Uzbek SSR, Mongolian People's Republic.

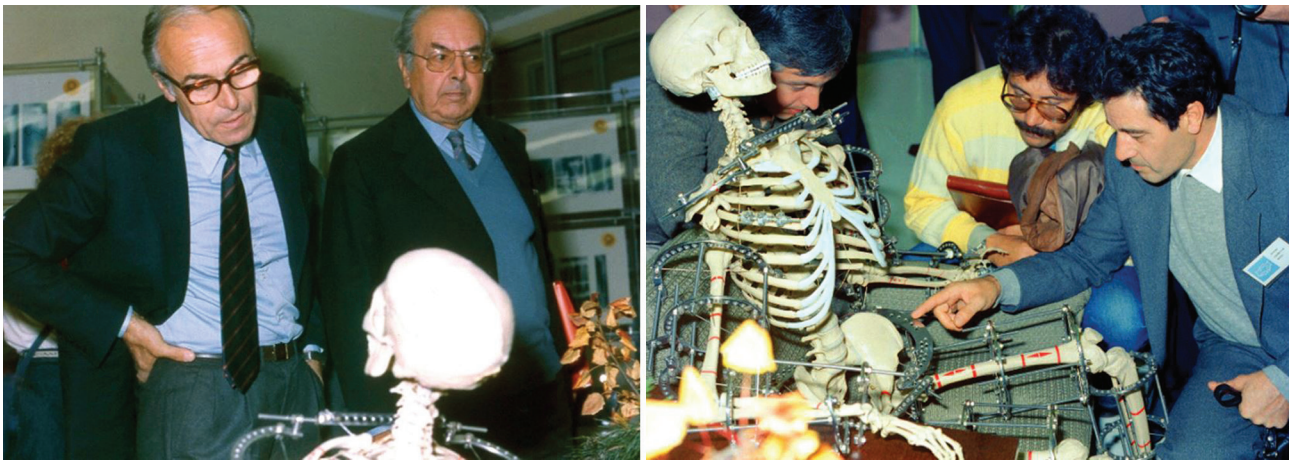
The training process under the guidance of professors G.A. Ilizarov and A.D. Li additionally involved specialists from other fields: A.A. Sveshnikov, V.A. Shchurov, Yu.N. Bakhlykov, L.A. Popova, V.D. Makushin, F.N. Zusmanovich, S.B. Lieberman.

There were so many surgeons that were willing to take the course that for some time two departments of advanced training were formed: the Department of Traumatology and the Department of Orthopaedics. Traumatology questions were supervised by Prof. A.D. Li and orthopedic training by Prof. G.A. Ilizarov.

In 1983, when the developments of G.A. Ilizarov became known in Europe, a group of Italian surgeons arrived at the institute (Prof. A. Bianchi-Maiocchi, the young doctor Maurizio Catagni who is nowadays a world-famous orthopaedic surgeon, doctor Angelo Villa and Prof. N. Benedetti).

G.A. Ilizarov worked with them personally and conducted preoperative discussion of patients and operations. The department teachers and other staff provided demonstrations of patients during and after treatment.

The Italian doctors asked to show the Ilizarov apparatus assemblies on bone models with a detailed explanation of each manipulation. For this purpose, specialists from the pilot plant within 24 hours built a stand for training in the apparatus mounting. Everything they saw shocked the Italians; they had never seen such results in the treatment of patients with injuries and orthopaedic pathologies. Once they returned home, there appeared the publications in Italian newspapers declaring that a second revolution had occurred in Russia, and now it was a revolution in traumatology and orthopaedics, and G.A. Ilizarov was called the Michelangelo of orthopaedics.



Italian specialists at the training course

G.A. Ilizarov always considered traveling abroad to give lectures and conduct demonstrative operations to be an educational process and described technological techniques in his lectures in great detail. Gabriil Abramovich received invitations from different countries, and he willingly shared his experience of using the apparatus and applying the method.

Information about the achievements of G.A. Ilizarov also reached the USA, and the first orthopaedic surgeon to arrive at the institute from this country was the now world famous doctor Dror Paley. He visited the institute twice in 1986, then in 1987 and 1988. Leaving home, he told Prof. V.I. Shevtsov: “I dealt with fractures, joint replacement and other banal operations. Now I will work only with the Ilizarov apparatus and become an American Ilizarov.” His dream came true.

In the late 1980s, Prof. Stuart Green visited the institute and studied the Ilizarov method very thoroughly. In 1990, he was appointed editor of G.A. Ilizarov’s monograph published in English at Springer.

G.A. Ilizarov among foreign specialists

It was the work with foreign specialists that significantly stimulated the educational process, helped to better organize it, adding more practical classes, which always aroused sincere interest.

The number of applications from foreign and domestic colleagues for training in the Ilizarov method grew every year. The appeal of Prof. G.A. Ilizarov to the Ministry of Health of the USSR to increase the number of trainees in one cycle to 50, and then to 100 persons was approved. Therefore, a large number of leading employees of the institute were involved in the implementation of educational programs of the department.

Comfortable conditions were created for the training course participants: they were provided with rooms in the institute's living facilities, equipped classrooms and halls for workshops. Moreover, cultural and entertainment programs were organized. Classes were conducted in specially equipped rooms and operation theaters in various forms: lectures, seminars, case discussions and work-shops. At work-shops, with the help of teaching aids and visual materials, the course participants practiced the procedures of insertion, installing, and dismantling the Ilizarov apparatus components. After studying a specific topic within the framework of a seminar and practical classes, the students applied the acquired knowledge and skills of the original Ilizarov method in operating rooms. Their complete immersion in clinical activities contributed to the practical acquisition of the technique of transosseous osteosynthesis in the treatment of patients.

The two teaching departments functioned until 1984. Students did not really welcome this division; they were more attracted to orthopaedics. Therefore, both departments were again combined into one faculty for advanced training in traumatology and orthopedics.

In 1985–1987, the staff of the faculty was enlarged with new specialists of the highest category: N.M. Klyushin, V.K. Noskov, N.M. Murzikov, V.M. Shigarev, I.A. Kataev, G.E. Karagodin, S.Ya. Zyryanov, A.G. Karasev, D.I. Shakhmatov, V.D. Shatokhin and others. All faculty teachers conducted classes with both domestic and foreign specialists.

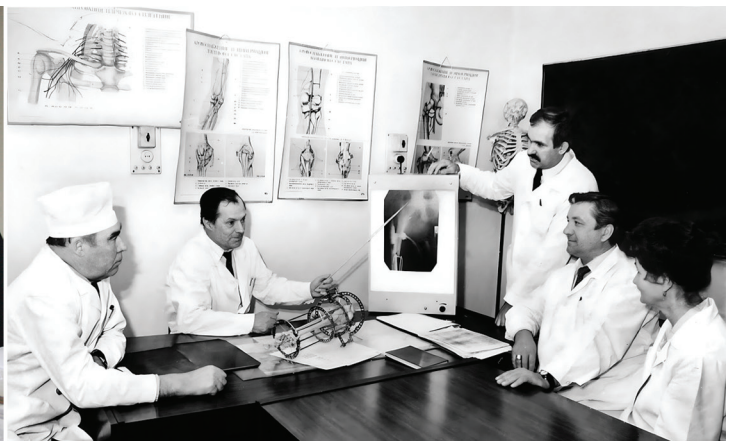
The work of the faculty was not limited to the walls of the institute; the teaching staff interacted with educational, scientific and medical organizations in the USSR and abroad, participating in scientific and practical conferences at various levels, internships, advanced training courses, and conducted large-scale research in the field of rehabilitation of patients with congenital developmental disorders of the musculoskeletal system. All this ensured the acquisition of advanced developments in science and clinical experience and formed new approaches to training surgeons in technologies for treating patients with bone pathology.

In connection with the need to systematize and expand scientific research at the institute, as well as to meet the need for qualified specialists in the field of traumatology and orthopedics, clinical residency and postgraduate studies were opened at the institute (Order of the Ministry of Higher and Secondary Special Education of the USSR dated February 1, 1984 No. 73). Candidate of Medical Sciences V.G. Trokhova was appointed responsible for the organization of postgraduate studies and V.C. Kamerin, associate professor, candidate of medical sciences, was in charge of the residency

The faculty continued to develop and soon acquired the international appraisal. In 1988, the 1st and 2nd international courses on limb lengthening were held on the basis of the Center, that was then called All-Russian Scientific Research Center for Restorative Traumatology and Orthopaedics. In the following years, the courses were conducted for specialists from Poland, the USA, Portugal, Italy, Mexico, India, England and other countries. In 1989, negotiations were held and a cooperation agreement was signed with the Ministry of Health of Poland. As a result of the negotiations, many specialists from Poland were trained at the Center, and the department professors repeatedly traveled to Poland to conduct courses.

In 1991, Prof. Sergey Ivanovich Shved, MD, the disciple and successor of academician G.A. Ilizarov, was appointed head of the Faculty of Traumatology and Orthopaedics. He had much experience in training and research work on the treatment of patients with multiple and combined injuries, improvement of primary specialized care, and primary surgical treatment of open and gunshot fractures for persons of different age groups.

Professor S.I. Shved



Discussion of a clinical case

The faculty, like the entire Center, went through quite difficult times. In 1992, the founder of the method, Academician Gavriil Abramovich Ilizarov passed away. The collapse of the Soviet Union significantly complicated the work of the Center as funding was limited, but did not cool the ardor of researchers, doctors and teachers.

A huge contribution to the preservation of the Center's advances and the development of the Teaching Faculty of Traumatology and Orthopedics in that difficult time was made by then General Director of the Russian Ilizarov Scientific Center (1992–2009), corresponding member of RAMS, professor, doctor of medical sciences Vladimir Ivanovich Shevtsov. Under his guidance, the Center entered a new stage of development, design and implementation of innovative methods of diagnosis and rehabilitation of patients. It was not only possible to maintain, but to expand and improve the educational process. New areas of treatment and, accordingly, educational programs emerged: microsurgery and replantation, joint arthroplasty and arthroscopy. Advanced technologies of internal osteosynthesis and highly effective combinations of transosseous and internal techniques were introduced.

Staff of the faculty

The Center signed agreements with Richards Medical, USA (represented at that time by N. Zelensky and R. Wigginton); Tokyo University, Japan (represented by Professor T. Kurokawa); South Korean company Seoul Meditech (represented by Mr. Dong); Brazilian ASAMI. Under the terms of the agreements, groups of 25–30 specialists came from these countries twice a year, and 55–60 orthopaedic surgeons came from Brazil once every two years. The duration of training was 7–10 days; in addition to short-term courses, there were also programs that continued from 3 to 6 months.

Working moments at the courses

Working moments at the courses

The faculty and international department staff always organized cultural programs for course participants: playing Russian game gorodki, football matches, skiing competitions, visiting a Russian sauna and field trips, which were very popular with foreign guests.

Before the start of an international football match between the teams of KNIIEKOT (Russia) and Smith & Nephew (USA)

Japanese specialists are mastering an old Russian game gorodki

In 2005, the All-Russian Scientific Research Center for RTO was renamed into the Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopaedics, and it was given federal status. Russian legislation underwent changes. The legitimacy of the activities of the Center's teaching faculty was disputable as there was no higher medical educational institution in Kurgan. The solution was the proposal of the Tyumen Medical Institute to open a branch of their Chair of Traumatology on the basis of the Center. For several years, the students of the training courses studied transosseous osteosynthesis technologies in Kurgan but received certificate documents from the Tyumen University. This did not impair the effectiveness of the training and allowed us to retain the excellent teaching staff.

Times have changed, and state requirements for educational programs have changed. In 2015, the teaching faculty of the Ilizarov Center and its educational programs for the first time passed state accreditation

of educational activities. In 2016, the Center's additional professional education programs were approved by the Russian Ministry of Health and posted on its portal of continuing medical and pharmaceutical education.

From 2012 to the present, the head of the Faculty of Traumatology and Orthopedics is Doctor of Medical Sciences, Prof. Yuri Petrovich Soldatov.

Yuri Petrovich conducts clinical and organizational work, combining it with work on training scientific workers, development of the faculty and education in general. He also is the director and compiler of new educational programs for postgraduate and residency programs, advanced training for doctors that have been implemented face-to-face and through the NMFO portal.

Professor Yu.P. Soldatov conducts the training

In 2020, the Ilizarov Center was renamed into the National Ilizarov Medical Research Center for Traumatology and Orthopedics (NIMRC TO). Under the organizational and methodological guidance of the Center, there are 27 healthcare entities of the Russian Federation constituent subjects from the Ural Mountains to the Kuril Islands. This fact significantly increases the role and responsibility of the teaching department as an important link in advanced postgraduate education in the specialty of traumatology and orthopedics.

The expansion of the range of academic disciplines related to medicine required to enlarge the teaching staff. Today there are 16 teachers working at the teaching faculty, including 8 professors (A.V. Burtsev, MD; A.G. Karasev, MD; D.A. Popkov, MD; E.V. Zhdanova, MD; O.K. Chegurov, MD; A.V. Gubin, MD; Doctors of Biological Sciences E.N. Shchurova and M.V. Stogov); 5 assistant professors (K.A. Dyachkov, MD; O.G. Prudnikova, MD; A.A. Grin, MD; candidate of biological sciences T.A. Silantyeva, candidate of medical sciences A. S. Sudnitsyn); and 2 faculty assistants (candidate of veterinary sciences A.A. Yemanov and doctor of medical sciences S.A. Lukin).

On the basis of the Center, there is an accreditation and simulation center, where the teachers of the educational faculty are Prof. A.V. Popkov, MD; A.V. Kaminsky, MD, I.V. Sutyagin MD, and O.Yu. Germann, MD.

The staff of the faculty, relying on accumulated experience, develop modern and innovative educational technologies. All the nuances of presenting the material to course students were worked out, based on practical use and the development of surgical skills. Students are immersed in the atmosphere of a working team. During rounds in the departments, in discussion of clinical cases, at planning the operations and, of course, in the operating room, a great number of surgeons and doctors, not only the faculty teachers, are involved in the teaching process at the Center. The opportunity to study various surgical techniques and approaches to solving complex clinical problems significantly expands the horizons of our course

participants, residents and post-graduate students and shows the versatility of the Ilizarov method and other educational areas.

Currently, teaching is carried out according to postgraduate educational programs in four groups of specialties: clinical medicine, biomedical sciences, biological sciences, fundamental medicine (specialties of traumatology and orthopedics, pathological physiology, human and animal physiology, cell biology); specialized residency program in the specialty "Traumatology and Orthopedics"; and 27 programs of additional professional education. Educational programs in all areas are certified and have state accreditation.

Over 45 years of the teaching department's history, 754 training cycles for orthopaedic surgeons and traumatologists have been conducted, in which 10,343 participants from 75 countries of the world were taught. Between 1984 and 2023, 146 young scientists completed post-graduate studies and 283 doctors completed residency.

Today, the work of the faculty and educational department of the Federal State Budgetary Institution National Ilizarov Medical Research Center for Traumatology and Orthopaedics of the Russian Ministry of Health is greatly demanded. In the conditions of the special military operation, the Center's technologies are in great need throughout the country. Restoring the limb length, supportability and function using the Ilizarov technologies and those developed by the Center have turned into everyday tasks of orthopaedic surgeons and traumatologists.

Additional confirmation of the demand for the Ilizarov method in the world orthopaedic community was demonstrated at the ASAMI (Association for the Study and Application of the Ilizarov Method) congress, which was held on March 29–31, 2024 in India with the participation of hundreds of doctors from different countries. The Ilizarov method remains competitive and widely used all over the world, and new devices are being developed for limb lengthening and deformity correction.

Congratulations to the staff of the Teaching Faculty in Traumatology, Orthopaedics and Related Disciplines of the Ilizarov Center on its 45th anniversary! A difficult but particular path has been passed and continues. New vibrant educational programs are emerging and modern approaches to medical education are in demand.

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