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Original article

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Comparative analysis of different modifications of elastic nail osteosynthesis in the treatment of children with extra-articular proximal humeral fractures

D.I. Shabanov^{1,2✉}, A.A. Korobeynikov^{1,2}

¹ Ilizarov National Medical Research Centre for Traumatology and Orthopedics, Kurgan, Russian Federation

² Kurgan Regional Children's Clinical Hospital named after the Red Cross, Kurgan, Russian Federation

Corresponding author: Dmitry I. Shabanov, mitya.schabanov@yandex.ru

Abstract

Introduction The relevance of studying the treatment of proximal humeral fractures in children stems from the high incidence of fractures in this anatomical region and the absence of a standardized treatment approach. This highlights the need for further research to develop treatment protocols that account for the unique characteristics of the pediatric body and the specific features of these fracture types.

Objective of the study was to analyze and compare the outcomes of treating children with extra-articular proximal humeral fractures using double-nail versus single-nail modifications of intramedullary osteosynthesis with elastic nails.

Materials and Methods Patients were divided into two groups. The study group ($n = 39$) patients underwent surgical treatment with a single elastic rod while patients in the control group ($n = 32$) received treatment using a double-nail modification of osteosynthesis. Treatment efficacy was analyzed in both inpatient and outpatient settings with clinical, radiological, and sociological assessment methods.

Results Postoperative parameters (duration of pain syndrome, hospitalization period, return to school, and fracture consolidation time) were comparable in both groups, indicating similar efficacy of the treatment methods in these studied parameters. Statistically significant differences were observed only in operative time, directly linked to the specific surgical techniques employed in each group. The proposed method in the main study group allowed for faster surgery and did not significantly affect other key parameters of anatomical and functional recovery. Patients in both groups were satisfied with the treatment outcomes.

Discussion Unlike the conventional two-nail configuration, the single-rod approach significantly reduces operative time, thereby lowering the risks associated with anesthesia, and slightly reduces the duration of pain syndrome. The study had limitations, including a short follow-up period (no more than 12 months post-injury and 1 month post-implant removal) and a lack of differentiation between fracture configurations (metaphyseal vs. epiphyseal fractures).

Conclusion The single elastic nail osteosynthesis method provides functional recovery of the injured segment and restoration of the child's overall activity comparable to the double-nail technique. Fracture consolidation occurs with correct fragment alignment within standard timeframes.

Keywords: proximal humeral fracture, children, osteosynthesis, intramedullary osteosynthesis

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INTRODUCTION

The relevance of the problem of treating children with fractures of the proximal humerus is associated not only with the high incidence of the injuries to this location, which accounts for 14 % of injuries to the upper limbs and 1.45–2 % of all skeletal injuries [1, 2], but also with long-term impairment of the upper limb function after treatment, especially in late childhood age group [3].

The growth in the number of musculoskeletal injuries, including multiple and combined injuries, as well as the growing demands of patients for quality of life, necessitate the introduction of modern minimally invasive surgical methods in the treatment of children with proximal humerus fractures. Minimally invasive technologies allow for early rehabilitation and maximum restoration of the upper limb functional abilities [4].

Treatment of children with fractures of the proximal humerus is associated with a number of difficulties related to the anatomical and biomechanical characteristics of this segment. The main factors complicating its treatment are: small size of the proximal fragment, which complicates its stabilization and fixation; high mobility of bone fragments due to muscle action and biomechanical load on the shoulder joint; location of the fracture in the area of the epiphyseal plates, which increases the risk of disturbances in bone development [5]. These features require the use of specialized techniques to minimize complications and restore the functional activity of the limb.

Minimally invasive technologies that reduce the risk of complications are preferable among the surgical methods of humeral fractures repair. One of these methods is FIN (Flexible Intramedullary Nailing), which provides stable fixation of fragments due to flexible intramedullary rods, reduces the rehabilitation term, and ensures early activation of patients and return to daily activities [6–8].

Purpose of the study was to compare the outcomes of treating children with extra-articular proximal humeral fractures using two-nail versus single-nail modification of intramedullary elastic osteosynthesis.

MATERIALS AND METHODS

An analysis of surgical treatment of children ($n = 71$) with proximal humerus fractures who underwent surgical treatment at the Red Cross Regional Children's Clinical Hospital (Kurgan) from 2016 to 2023 was conducted. The control group included patients ($n = 32$) operated on using the double-nail technology; their medical records were analyzed retrospectively. The study group included patients of a prospective study ($n = 39$) operated on using the single-nail intramedullary osteosynthesis technology.

Exclusion criteria for both groups were patients with severe traumatic brain injury (SBI), angioneurological complications of the fracture, pathological fractures of the humerus, refusal of the patient/legal representative of the patient to participate in the study.

This study was conducted in accordance with the World Medical Association Declaration of Helsinki "Ethical principles for medical research involving human subjects" as amended in 2000.

Patients' data were analyzed for the following parameters: age, gender, injury location, injury mechanism, fracture type according to the AO PCCF (Pediatric Comprehensive Classification of Long-Bone Fractures) [9], presence of concomitant injuries, condition of peripheral nerves and vessels, postoperative complications, hospitalization time, and implant removal time. Duration of pain was assessed based on the need for analgesics. The location of bone fragments, fixation devices, and fracture healing stages were analyzed using standard radiographic views.

Patients were examined at least once a month at the outpatient stage. To assess functional recovery and patient satisfaction with the treatment, the QuickDASH questionnaire [10] was used. This questionnaire has been validated for children aged 8 to 18 years and is a brief variant of the original questionnaire "Disorders of the Arm, Shoulder, and Hand" (DASH).

The average age of patients at the time of injury was (11.28 ± 2.78) years (range, 7 to 15) in the main study group and (11.15 ± 2.45) years (range, 6 to 16) in the control group. The duration of injury at the time of surgery was from 16 hours to 7 days in the main study group and from 14 hours to 11 days in the control group. There was no significant difference in age and gender between the groups.

The most common mechanism of injury was a fall from height in a domestic setting, recorded in 22 (69 %) cases in the control group and in 26 (67 %) cases in the study group. Other mechanisms included falling from a bicycle or scooter (four patients in both groups), injuries during sport activities including martial arts (three cases in both groups), and high-energy injuries (three patients in the control group and six patients in the study group).

In three children of the control group and five children of the main group, the humerus fracture was accompanied by a closed SBI of the concussion type. In one case, a 7-year old patient of the control group, who was injured in a traffic accident, was diagnosed with a combination of a humerus fracture, SBI, and femur fracture.

In all cases of both groups, fractures were closed. The distribution of fractures according to the AO PCCF is presented in Table 1.

Table 1

Distribution of patients by AO PCCF fracture types

| Fracture | Control group ($n = 32$) | | Study group ($n = 39$) | |
|----------|----------------------------|------|--------------------------|------|
| | No | % | No | % |
| 11E/1.1 | 9 | 28.1 | 9 | 23.1 |
| 11E/2.1 | 12 | 37.5 | 12 | 30.8 |
| 11M/3.1 | 11 | 34.4 | 18 | 46.2 |

Statistical analysis of the study data was performed using Statistica 12.0 software (StatSoft Inc.). The results are presented as the arithmetic mean (M) and standard error of the mean ($\pm m$) for quantitative indicators. To compare mean values between the groups, Student's t-test was used, which is effective when for samples corresponding to the normal distribution. To check the compliance of the distribution of qualitative features with the expected one under the null hypothesis, the Pearson criterion (χ^2) was used. Differences were considered statistically significant at $p \leq 0.05$.

Surgical technique

In a single-nail configuration of intramedullary osteosynthesis, the operation is performed under general anesthesia. The patient was placed on the operating table in a supine position with the possibility of giving the "greeting pose", abduction of the shoulder joint to a right angle with flexion of the elbow joint at 90° .

The entry hole in the distal part of the lateral column is formed using a bone awl 10–20 mm proximal to the lateral epicondyle through a preliminary skin incision. A titanium nail with a pre-curved end is inserted into the medullary canal using a T-handle. Reduction is achieved by gentle

traction and usually requires abduction and internal rotation to eliminate displacement. It is important to remember that the center of rotation of the humerus in fractures of the proximal part, the capsuloperiosteal flap, is located posteromedially. The quality of reduction is checked using radiography in the anteroposterior, lateral projections and Neer's projection [11].

If the reduction is satisfactory, the rod is driven into the proximal epiphysis. In cases of poor reduction due to soft tissue interposition in the fracture zone, it is recommended to increase the deformity in both planes, advance the rod until it reaches the fracture zone and rotate it in the fracture zone with simultaneous traction to release the clamped tissues. Next, the proximal fragment is fixed with a pre-curved rod and rotated to eliminate residual displacement. Upon achieving satisfactory reduction, the rod is impacted into the subchondral bone through the growth plate to ensure maximum fixation stability and prevent rod migration. The stability of the fracture fixation is checked radiographically by rotating the humerus.

RESULTS

The groups were comparable in all preoperative characteristics. In both groups, the rod was pre-bent by 10° to optimize reduction. The nail diameter was selected based on preoperative radiography, considering the ratio of the nail diameter to the diameter of the medullary canal in its narrowest part. For the double-nail configuration, this ratio was 0.3, for the single-rod configuration 0.4 (to improve the stability of fixation). The nail diameter ranged from 2.0 to 3.5 mm. In the control group, a 2.0-mm titanium nail was used in eight cases, a 2.5-mm one in 17 cases, and a 3.0-mm one in seven cases. In main study group patients, 2.0-mm nails were used in four cases, 2.5-mm ones in nine cases, 3.0-mm ones in 21 cases, and 3.5-mm ones in five cases (Table 2).

Table 2

Distribution of patients by nail diameters

| Nail diameter, mm | Control group (<i>n</i> = 32) | | Study group (<i>n</i> = 39) | |
|-------------------|--------------------------------|------|------------------------------|------|
| | No | % | No | % |
| 2.0 | 8 | 25.0 | 4 | 10.3 |
| 2.5 | 17 | 53.1 | 9 | 23.1 |
| 3.0 | 7 | 21.9 | 21 | 53.8 |
| 3.5 | 0 | 0 | 5 | 12.8 |

In the early postoperative period, all patients used a sling bandage until pain relieved, this period did not exceed seven days. During the immobilization period, passive exercise therapy was performed. After the end of immobilization, they switched to active exercise therapy. The average duration of hospitalization was (5.8 ± 2.6) days in the control group and (5.3 ± 2.1) days in the main study group ($p > 0.05$). It was due to pain and the patient's desire to be in hospital.

The time of the surgical intervention was significantly different between the groups (Table 3). The reduction in the surgical time was not only due to the smaller number of implants and, consequently, half of the time required for their placement, but also to the technical simplification of the insertion and removal procedures as there was no crossing of nails.

Pain persisted (assessed by the need for analgesic drugs and on the VAS scale) for (3.7 ± 2.0) days in the main study group and for (3.8 ± 2.1) days in the control group. Children in both groups resumed their studies in educational or preschool institutions within six to 15 days.

Table 3

Duration of the intervention

| Manipulation | Time, min | | P-value |
|-------------------|----------------------|----------------------|---------|
| | Study group | Control group | |
| Implant insertion | 31.0 ± 9.4 (18–65) | 41.0 ± 11.4 (24–70) | < 0.05 |
| Implant removal | 18.0 ± 7.8 (14–35) | 25.0 ± 9.2 (19–38) | < 0.05 |
| Total time | 51.0 ± 17.2 (32–100) | 64.0 ± 20.6 (43–108) | < 0.05 |

At the outpatient stage, children were examined every 4-5 weeks. At each appointment, a clinical test for consolidation was performed, including palpation of the fracture area to exclude pathological mobility and pain during axial loading, as well as an assessment of the restoration of limb function. The functional assessment included the volume of active and passive movements in the joints of the upper limb, muscle tone and trophism. Particular attention was paid to assessing abduction and rotation in the shoulder joint. Besides, consolidation was studied radiographically, including disappearance of the interfragmentary gap, formation of a bone callus of uniform density crossing the fracture line, complete restoration of the cortical bone layer.

Clinical signs of fracture healing were noted in all patients in both groups within one to two months. The decision to remove the implants was made based on a comprehensive clinical and radiological assessment. In the main group, the period before removal of the metal rod was (5.8 ± 1.2) months, in the control group — (5.9 ± 1.4) months.

The results of surgical treatment were evaluated with Flynn system [12]. The criteria for assessing the results included several key parameters that allow one to evaluate both the clinical and functional results of treatment. According to the scale, excellent results were obtained in 37 (95 %) cases in the main group and in 31 (97 %) cases in the control group, sfair results were obtained in two (5 %) and one (3 %) patients, respectively. In all cases in both groups, a fair result was associated with a residual angular deformity of less than 10° . There were no poor outcomes.

Due to the validation of the QuickDASH questionnaire for children aged eight years and older, one child was excluded from the main study group and three children under eight years of age from the control group during the survey. Seven days after the operation, the patients in the main group scored (20.16 ± 1.98) points, while those in the control group scored (20.74 ± 2.21) points; after the rod removal, the main group scored (0.81 ± 0.28) points, while the control group scored (0.74 ± 0.32) points. The scores obtained after the rod removal indicate minimal functional limitations, which corresponds to excellent treatment results according to QuickDASH.

In the control group, four cases of local skin irritation in the area of rod insertion complicated by bursitis were recorded, and five such cases were identified in the main study group. This condition did not require early removal of the implant, stopped after the planned extraction of the fixator within the specified time frame and did not affect the treatment outcome.

Case report

A 12-year-old patient was admitted to the emergency room of the Red Cross Regional Children's Clinical Hospital on March 17, 2022, with a 11E/2.1 humerus fracture falling down the stairs at school on the day of admission to the hospital. Surgical treatment was performed using the single-rod modification of intramedullary osteosynthesis technology (Fig. 1).

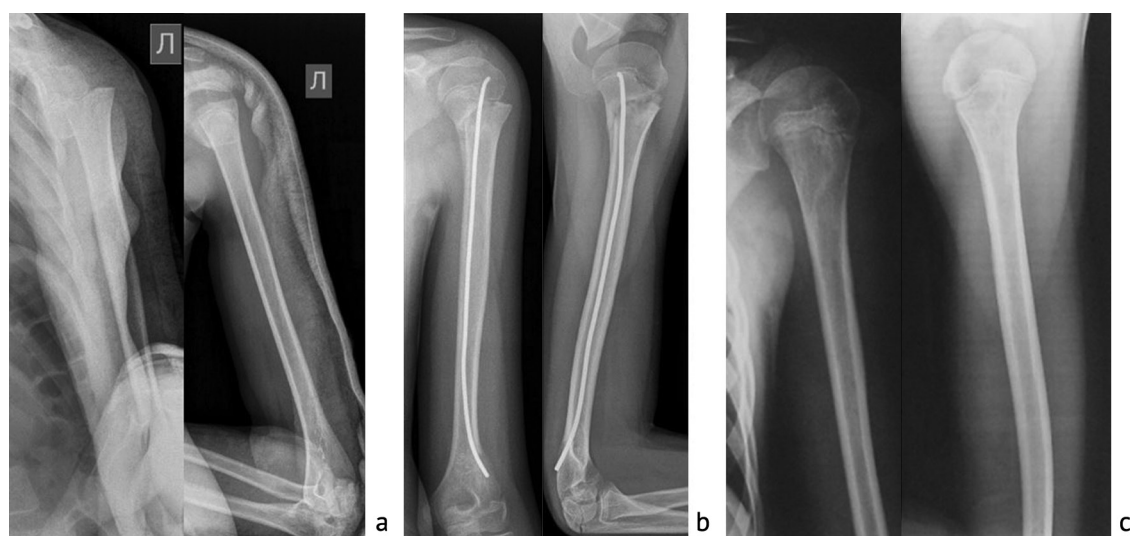


Fig. 1 Patient's radiographs: (a) at admission; (b) one months after surgery; c 12 months after surgery

DISCUSSION

Currently, most pediatric patients with proximal humerus fractures are treated conservatively. The high remodeling potential of this limb segment allows for significant residual displacement [13]. Conservative treatment, despite its popularity and effectiveness, in most cases, especially in complex fractures or in fractures in older children, has a number of limitations and risks: secondary displacement, prolonged immobilization, difficulty in complying with the restrictive regimen [14, 15]. The number of supporters of the surgical method of treatment increase due to high level of demand for quality of life, the need for rapid social reintegration, and the desire to avoid immobilization [16, 17].

Proximal humerus fractures are often unstable, and therefore, the choice of fixation method is critically important and largely determined by the surgeon's skill. Various methods are used to fix proximal humerus fractures in children requiring surgical treatment, including screws, plates, external fixators, percutaneous pin fixation, or elastic intramedullary osteosynthesis [18–20]. Percutaneous Kirschner wire fixation and intramedullary osteosynthesis are the most widely used, and demonstrate similar efficacy and satisfactory clinical outcomes. Kirschner wires are inserted percutaneously and require postoperative limb immobilization. Protruding ends of the wires can cause muscle and soft tissue irritation and are also at risk of migration [21]. In displaced fractures, intramedullary rod osteosynthesis is the method of choice due to excellent functional outcomes, low complication rate and the possibility of early mobilization [22], but it also has its drawbacks. Intramedullary methods, as a rule, are characterized by a long duration of surgical intervention, are associated with increased intra-operative blood loss and the need for subsequent removal of fixation elements [23, 24].

In order to minimize the duration of surgical intervention, a single-nail modification of intramedullary osteosynthesis was proposed. The first mention of this technique belongs to Chee et al. [25], who confirmed its effectiveness in 11 clinical cases. Samara et al. assessed the effectiveness of one retrograde elastic nail in 19 patients and noted stable fixation and the absence of serious complications [26]. The technique is recommended, including for children over 11 years of age with low remodeling potential. Our data that were obtained in a bigger sample are consistent with those findings.

In all cases of our study, reduction was performed with a closed method, which is at odds with the literature, that describes cases of soft tissue interposition and non-reducible fractures [27]. Interposition of the periosteum, deltoid muscle, or long head of the biceps tendon may be an obstacle to closed reduction [28].

In our opinion, the use of a second rod is not mandatory, although it ensures a more uniform distribution of biomechanical loads due to the divergent effect on the stretching and compression zones. One rod creates a directed compression force along the concavity of the arch and acts as an internal splint, fixing the fragments until fracture consolidation, while the residual remodeling potential of the proximal humerus can correct acceptable radiographic deformities [29]. The refusal to use a second nail to prevent rotation of the proximal segment is justified by the remodeling potential and adaptive capabilities of the shoulder joint, the multiplanar mobility of which eliminates the risks of biomechanical disorders [30].

CONCLUSION

The results of the study indicate the clinical effectiveness of the surgical treatment method using retrograde intramedullary osteosynthesis of a single-nail configuration in children with proximal humeral fractures. All patients achieved radiographic union with restoration of full painless range of motion after implant removal.

The single-rod intramedullary osteosynthesis technique provides functional restoration of the damaged segment and the child's overall activity comparable to the double nail technique; fracture consolidates within the usual time term. The use of one nail reduces the surgery time, reduces costs, and simplifies the installation and removal of the implant compared to the double-nail technique. There is no need for long-term immobilization. Children and their parents were satisfied with the treatment results.

Conflict of interest None.

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Ethical standards This study was conducted in accordance with the World Medical Association Declaration of Helsinki "Ethical principles for medical research involving human subjects" as amended in 2000.

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Information about the authors:

Dmitry I. Shabanov — orthopaedic surgeon, post-graduate fellow,
mitya.schabanov@yandex.ru, <https://orcid.org/0009-0006-9364-1959>;

Anatoly A. Korobeynikov — Candidate of Medical Sciences, Head of the Laboratory,
koroban@list.ru, <https://orcid.org/0009-0005-0326-8285>.

Original article

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Results of surgical alloplasty for bone defects of various locations due to distal humerus fractures

A.P. Davydov✉, A.G.Chibrikov, V.Yu. Ulyanov, I.A. Norkin

Saratov State Medical University n.a. V. I. Razumovsky, Saratov, Russian Federation

Corresponding author: Alexey P. Davydov, alexeydawidow@gmail.com

Abstracts

Introduction Currently, up to 30 % of cases after surgical treatment in distal humerus fractures result in permanent disability. It is important to improve the surgical techniques to ensure the restoration of the anatomical integrity of this department.

The **aim** of the work was to perform a comparative analysis of the results of surgical plasty with donor block and cubic cadaver allografts for bone defects of various locations in the distal humerus fractures based on an assessment of bone density and vascularization of the grafted area.

Materials and methods The study involved 56 patients with distal humerus fractures, divided into three groups based on the defect location and two subgroups depending on the method of surgical plastic surgery. A comparative analysis of treatment outcomes was conducted based on the values of the vascularization index of the defect zone obtained by ultrasound study, as well as the Hounsfield index values obtained by computed tomography of the damaged segment. The allograft area was assessed in three zones of interest, the central, marginal and native bone structures.

Results The use of a block allograft provided increase in the values of the Hounsfield index 3 months after surgery in the central graft zone with a defect in the medial column to a value of 190HU ($p = 0.01$), with a lateral defect to 185HU ($p = 0.01$), with a central defect to 170HU ($p = 0.03$); increased the values of the Hounsfield index in the marginal zone 3 months after surgery, the graft area with a medial defect was 210HU ($p = 0.01$), a lateral defect was 200 HU ($p = 0.01$), and a central defect was 185 HU ($p = 0.02$). It provided the increase in the values of the vascularization index of the graft zone with a defect in the medial column by 1.2 times ($p = 0.01$), in the lateral column by 1.15 times ($p = 0.01$), in the central zone by 1.18 times ($p = 0.02$).

Discussion The results of the study indicate that the use of a block allograft increases the density of bone tissue in the marginal and central zones of defect grafting area 3 months after surgery, more expressed if it is localized in the medial and lateral columns, and increases the intensity of blood flow in the defect grafting area 2 months after surgery.

Conclusion Comparison of the results of plastic surgery for post-traumatic bone defects in comminuted fractures of the distal humerus showed the advantage of using native block allograft in defects of the lateral and medial columns due to the optimization of osteointegration processes in the defect zone in the medium-term postoperative period.

Keywords: humerus, comminuted fracture, surgical treatment, allograft, bone density, vascularization

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INTRODUCTION

Comminuted fractures of the distal humerus (DH) are a severe traumatic pathology. Their incidence is 5.7 cases per 100 thousand adults, accounting for up to 15% of all injuries to the humerus [1]. In young working age, such injuries are a consequence of a high-energy mechanism of trauma, in older people they happen due to a low-energy mechanism as a result of falls from one's own height onto the elbow joint. Given the bimodality of the distribution of this type of injury in the population, the relevance of this problem is beyond doubt due to the increase in life expectancy, as well as the growth in the absolute number of users of personal mobility devices, such as electric scooters, unicycles, and others.

Comminuted fractures in patients over 65 years of age and associated osteopenia, as well as small-fragment fractures in young patients may be accompanied by a post-traumatic bone defect. In this case, one of the types of treatment is total elbow arthroplasty. However, due to the high risk of postoperative complications and a significant proportion (70%) of poor treatment outcomes, this surgical treatment is indicated for older patients with a reduced activity index [2]. Open reduction and internal fixation with plates without restoration of the defect area can lead to the impossibility of strong intraoperative fixation of fragments or a reduction in the contact area of fragments in the fracture zone, forcing the surgeon to resort to additional external immobilization in the postoperative period, which contributes to the development of elbow joint contractures [3].

Currently, not only autogenous but also allogeneous grafts, which exist in various forms, can be used as a defect-filling material [4]. Despite its high osteoinductive properties, autogenous grafts have disadvantages such as an expanded surgical field, increased likelihood of postoperative infectious complications, and increased surgical time [5]. The absence of such shortcomings in allografts, high conductive properties, variability of the graft shapes used, and unlimited material allow for filling defects of various geometric proportions [6]. However, if there are no restrictions on the shape of the graft used and the method of retaining it in the defective maternal bed due to the presence of cortical walls when filling a defective cavity, then in the presence of a defect in the axial cortical structures, this problem still exists, especially in cases where prolonged external immobilization is undesirable [7]. Therefore, at present, the development of methods of surgical treatment and plastic surgery of the defect zone aimed at DH reconstruction, which can provide reliable fixation and improve the results of surgical treatment, is relevant [8].

Purpose To conduct a comparative analysis of the results of surgical plastic surgery of bone defects using donor block and cubic cadaver allografts based on an assessment of bone tissue density and vascularization of the grafted zone following fractures of the distal humerus with defects of various locations.

MATERIALS AND METHODS

The study involved 56 patients diagnosed with closed comminuted fractures of the distal humerus of AO type 13C2 and 13C3 with a primary bone defect due to traumatic impact. The injured persons were comparable in age and time since the injury. Indications for surgery were determined according to clinical guidelines for the treatment of patients with distal humerus fractures (Clinical Guidelines "Distal Humerus Fractures", 2024, approved by the NPS of the Ministry of Health of the Russian Federation).

Based on the location of the post-traumatic defect, established by radiography in two standard views and computed tomography of the elbow joint, patients were divided into three groups (Table 1, Figures 1–3):

- Group 1: patients with concomitant post-traumatic defect in the medial column area;
- Group 2: patients with concomitant post-traumatic defect in the lateral column area;
- Group 3: patients with concomitant post-traumatic metaphyseal defect in the central zone.

In regard to defect size, each group was divided into 2 subgroups:

- Type A defect size up to 1.5 cm^2 ;
- Type B defect size in the range of $1.5\text{--}3 \text{ cm}^2$.

Table 1

Distribution of patients based on defect location and size

| Parameters | | Group 1 ($n = 19$) | | Group 2 ($n = 19$) | | Group 3 ($n = 18$) | |
|-------------------------|--------|----------------------|------------|----------------------|------------|----------------------|------------|
| | | 1A | 1B | 2A | 2B | 3A | 3B |
| Number of patients | | 10 | 9 | 9 | 10 | 9 | 9 |
| Females | number | 6 | 6 | 5 | 6 | 5 | 6 |
| | % | 60 | 66 | 55 | 60 | 55 | 66 |
| Age, years | | 42 (21–60) | 37 (25–59) | 39 (19–58) | 46 (22–57) | 44 (28–55) | 39 (25–56) |
| AO fracture type | | 13C3 | 13C2 | 13C2 | 13C3 | 13C2 | 13C3 |
| BMI, kg/m^2 | | 28 (24–32) | 30 (26–34) | 34 (30–39) | 30 (25–32) | 31 (26–35) | 35 (28–38) |
| Time since injury, days | | 4 | 2 | 3 | 5 | 3 | 4 |



Fig. 1 X-rays of a 43-year-old patient with a fracture of the distal humerus and associated bone defect of the lateral column (frontal and lateral views)



Fig. 2 X-rays of a 49-year-old patient with a fracture of the distal humerus and associated bone defect of the central metaphyseal zone (frontal and lateral views)



Fig. 3 X-rays of a 38-year-old patient with a fracture of the distal humerus and associated bone defect of the medial column (frontal and lateral views)

Based on bone defect size and technical feasibility of its fixation, patients underwent two types of surgical reconstruction of the defect area.

Patients with a defect size of up to 1.5 cm³ underwent plastic surgery with a lyophilized, ultrasound-treated allogeneic cadaveric grafts of cubic shape impacted into the bone bed.

Patients with a defect size of 1.5–3 cm³ underwent plastic surgery with the technique that comprised (Fig. 4) [9]:

- formation of a tenon-shaped groove in the area of the maternal bed and a tenon-shaped protrusion on the surface of the graft;
- formation of bone canals connecting the allograft block with the bone marrow cavity;
- insertion of blocking screws through the plate and the bone block of the allogeneic graft in intersecting planes.

To control the consolidation processes, an X-ray study was performed using the universal OPERA SWING system manufactured by General Medical Merate SpA (Italy). Direct and lateral X-ray views of the distal humerus were taken. To objectify the bone tissue mineralization processes and quantitatively assess the rigidity of bone structures, multispiral computed tomography (MSCT) was performed on a Phillips device and the Hounsfield index was calculated (densitometric index scale, HU). An assessment was made of the attenuation of X-ray radiation passing through the examined bone tissue in relation to distilled water. In the case of bone defect filling and the use of an allogeneic graft, a change in this indicator over time during dynamic observation indicates the activity of the reparation and mineralization processes of the bone graft. The Misch classification was used as an evaluation scale, according to which it is possible to compare the absolute indicators in HU units.

To conduct MSCT scanning of the distal humerus, three areas of interest were defined, corresponding to the area of alloplastic material and the adjacent bone:

- zone R1 sized 0.5–1 cm² corresponded to the marginal part of the graft that bordered the recipient bone;
- zone R2 sized 0.5–1 cm² corresponded to the central portion of the allograft;
- zone R3 sized 0.5–1 cm² was portion of the metaphyseal bone that bordered with the graft.

The Hounsfield index was calculated based on the size of the alloplastic material used [10–14].

To establish the activity of metabolic processes in the bone callus formation zone in patients of different groups, the method of ultrasound (US) Dopplerography with the calculation of the vascularization index (VI) was used, which involves counting newly formed vessels in the fracture zone. They appear on the 7–10th day after the injury. The number of vessels increases proportionally to the growth of soft bone callus; by the time of mature callus formation, the activity of this process decreases. The intensity of metabolic processes was calculated by counting the area of visualized vessels in the bone callus zone. The study area was 2 × 2 cm, including the periosteal and intermediary zones proximal and distal to the fracture line (Fig. 5). The calculation was carried out using the formula:

$$VI = S \text{ vessels} / S \text{ bone callus} [15–18].$$

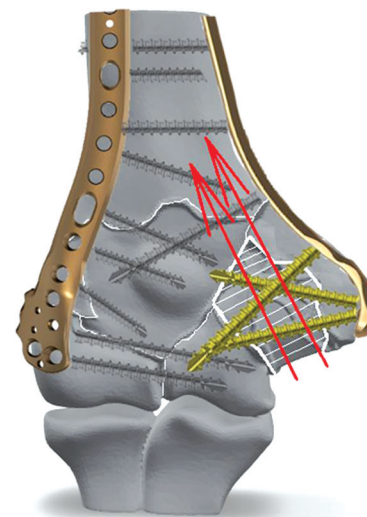


Fig. 4 Alloplasty with block allograft of post-traumatic bone defect in comminuted fractures of the distal humerus

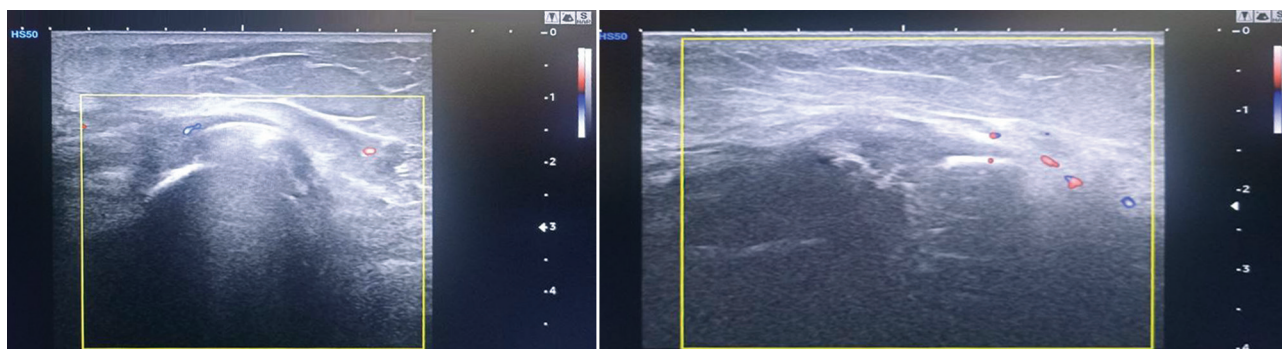


Fig. 5 Ultrasound Dopplerography of the distal humerus fracture zone in a 42-year-old patient: 14 days and 2 months after surgical treatment

The follow-up period of patients in the study groups was 6 months. X-ray study was performed 1.5 months after surgery with dynamic control at 3–3.5 months after surgery to visualize the process of bone callus formation; the final X-ray study at 6 months after the surgery recorded the final signs of fracture consolidation or complications, if any. Computed tomography was performed after 1.5, 3.5, and 6 months to calculate the Hounsfield index, which allowed for an objective comparison of the stiffness of bone tissue and the graft integration, osteoclastic, and initial osteoblastic regeneration stages 6 months after surgery. Doppler ultrasound with VI counting was performed 14 days, 1.5, and 3.5 months after the surgery. The timing is due to the staging of the process of vessel formation in the bone callus that begin to form in the fracture zone 7–10 days after injury, reach the highest density per unit of bone tissue by 1.5–2 months after injury and decrease to the initial value after 3.5 months.

Statistical processing of the obtained data was performed using the IBMSPSS 20 Statistics software package. Due to the discrepancy between most of the obtained data and the normal distribution law, the nonparametric Mann-Whitney U-test, the Wilcoxon test, and the probability index (p) were used to compare the values.

The study was approved by the Ethics Committee of the Saratov Razumovsky State Medical University and was carried out in accordance with the Helsinki Convention. All patients were informed in advance about the conditions of the study and gave written consent to participate.

RESULTS

Evaluating the dynamic changes in the VI indices in the defect zone, an increase in the values was revealed in all subgroups at two months after the operation. The value increased more significantly in subgroups 1B, 2B, 3B — by (7.9 ± 1.27) times ($p = 0.01$), in subgroups 1A, 2A, 3A it increased by (6.9 ± 1.13) times ($p = 0.02$). A decrease in the VI values was noted at 3.5 months after the operation compared to the data obtained 14 days after the operation. Moreover, the average values of VI in subgroups 1A, 2A, 3A were lower by (1.65 ± 1.13) times ($p = 0.001$), and in subgroups 1B, 2B, 3B — by 1.03 times ($p = 0.002$) (Table 2).

The comparison of the indicators showed that the method of bone defect plastic surgery with a block allograft had a positive effect on the value of bone tissue stiffness in the border zone R1 and the central zone R2 at 3 months after the surgery for all defect locations ($p < 0.05$).

The dynamic analysis of the indicators of the central zone of the filled defect noted that the values obtained three months after surgery were lower than the values after 1.5 months for all defect locations ($p < 0.05$).

Table 2

Dynamics of changes in the VI values

| Groups | Average values of VI after surgery, % | | | | | |
|--------|---------------------------------------|------------------|-------|-----------------|-------|----------|
| | 14 days | 2 months | p | 4 months | p_1 | p_2 |
| 1A | 3.46 ± 0.14 | 24.02 ± 0.55 | 0.001 | 3.60 ± 0.09 | 0.017 | > 0.05 |
| 2A | 3.32 ± 0.10 | 25.80 ± 0.68 | 0.001 | 3.61 ± 0.12 | 0.003 | 0.047 |
| 3A | 3.65 ± 0.15 | 23.17 ± 0.83 | 0.002 | 3.80 ± 0.10 | 0.002 | 0.048 |
| 1B | 3.57 ± 0.25 | 28.44 ± 0.46 | 0.012 | 5.42 ± 0.18 | 0.003 | 0.040 |
| 2B | 3.48 ± 0.18 | 29.51 ± 0.29 | 0.019 | 6.18 ± 0.25 | 0.005 | 0.045 |
| 3B | 3.54 ± 0.12 | 27.12 ± 0.72 | 0.022 | 5.90 ± 0.16 | 0.007 | 0.039 |

Notes: p — significance of difference compared with 2-week data; p_1 — significance of difference compared with data after 2 months; p_2 — significance of difference compared with 2-weeks data

The comparison of graft stiffness in the central zone established that in comminuted fractures with a defect in the central metaphyseal zone, the values (170 HU, $p = 0.032$) were 1.12 times lower than in medial defects (190 HU, $p = 0.001$), and 1.1 times lower than in lateral defects (185 HU, $p = 0.002$) (Table 3).

Table 3

Values of the Hounsfield index according to CT data during dynamic monitoring

| | Hounsfield index (HU) values | | | | | | | | | | | | | | | | | |
|-------|------------------------------|-------|-------|---------|-------|-------|---------|-------|-------|----------|-------|----------|----------|----------|----------|----------|-------|----------|
| | 1A | | | 2A | | | 3A | | | 1B | | | 2B | | | 3B | | |
| | 1,5 mon | 3 mon | 6 mon | 1,5 mon | 3 mon | 6 mon | 1,5 mon | 3 mon | 6 mon | 170 | 210 | 250 | 170 | 200 | 260 | 160 | 185 | 270 |
| R1 | 100 | 130 | 200 | 105 | 140 | 205 | 110 | 140 | 200 | 0.031 | 0.003 | 0.046 | 0.03 | 0.009 | 0.02 | 0.001 | 0.026 | > 0.05 |
| p_1 | 0.027 | 0.005 | 0.039 | 0.031 | 0.012 | 0.008 | 0.033 | 0.04 | 0.037 | > 0.05 | 0.015 | > 0.05 | > 0.05 | 0.006 | > 0.05 | > 0.05 | 0.002 | > 0.05 |
| p_3 | | 0.009 | | | 0.01 | | | 0.011 | | | 0.012 | | | 0.013 | | | 0.015 | |
| p_4 | | | 0.02 | | | 0.001 | | | 0.021 | | | 0.03 | | | 0.02 | | | 0.01 |
| R2 | 140 | 120 | 190 | 130 | 120 | 200 | 130 | 110 | 190 | 210 | 190 | 250 | 205 | 185 | 240 | 190 | 170 | 250 |
| p_2 | 0.011 | 0.01 | 0.029 | 0.025 | 0.002 | 0.031 | 0.026 | 0.001 | 0.031 | 0.025 | 0.001 | 0.04 | 0.008 | 0.007 | 0.003 | 0.03 | 0.032 | > 0.05 |
| p_3 | | 0.038 | | | 0.012 | | | 0.003 | | 0.021 | 0.003 | 0.026 | 0.023 | 0.009 | 0.025 | 0.02 | 0.01 | 0.028 |
| p_4 | | | 0.021 | | | 0.001 | | | 0.001 | | 0.014 | | | 0.015 | | | 0.012 | |
| R3 | 220 | 280 | 330 | 210 | 270 | 310 | 230 | 260 | 300 | | | 0.041 | | | 0.01 | | | 0.022 |
| p_3 | | 0.015 | | | 0.012 | | | 0.019 | | 240 | 280 | 320 | 240 | 285 | 305 | 220 | 255 | 300 |
| p_4 | | | 0.01 | | | 0.002 | | | 0.021 | > 0.05 | 0.05 | > 0.05 | > 0.05 | > 0.05 | > 0.05 | > 0.05 | 0.033 | > 0.05 |

Note: p — significance of difference in intergroup comparison; p_1 — significance of probability of R1 value relative to R3; p_2 — significance of difference of R2 relative to R3; p_3 — the correlation coefficient within a group by comparing indicators after 3 and 1.5 months; p_4 — probability value within a group by comparing indicators after 6 months and after 1.5 months

During the observation, 14 cases of treatment complications (25 %) were noted, the majority of which (six cases, 9 %) occurred among patients with a defect in the central metaphyseal zone (Table 4).

Table 4

Complications of surgical reconstruction in distal humerus fractures

| Type of complication | | Number of complications | | | | | |
|-----------------------|-----|-------------------------|-------|-------|------|-------|------|
| | | 1A | 2A | 3A | 1B | 2B | 3B |
| Osteoresorption | n | 0 | 1 | 1 | 0 | 1 | 0 |
| | % | | 1.8 | 1.8 | | 1.8 | |
| | p | | 0.002 | 0.002 | | 0.002 | |
| Delayed consolidation | n | 2 | 2 | 3 | 1 | 1 | 2 |
| | % | 3.6 | 3.6 | 5.3 | 1.8 | 1.8 | 3.6 |
| | p | 0.02 | 0.007 | 0.01 | 0.02 | 0.03 | 0.07 |

DISCUSSION

Allogenic grafting for filling post-traumatic bone tissue defects of the distal humerus is used for anatomical reconstruction of the segment and enables recovery of the physiological biomechanics of elbow joint movements, for which early training of movements is critical. At the same time, insufficient fixation of the graft in the defect zone or compromised stability of bone fragments in the fracture zone may force the surgeon to resort to prolong immobilization. In turn, rigid fixation of fragments and graft due to reduced micromobility of the latter, promotes fracture consolidation and active reparative processes occurring at the "bone — graft" boundary [2, 3, 19–21]. However, analysis of the activity of these processes is almost impossible in *in vitro* material due to inability of recreating many cells with which the graft interacts during osteoreparation. At the same time, the activity of the cellular reactions themselves, successively replacing each other, is influenced not only by the osteoinductive but also by the osteoconductive properties of the graft, such as the architecture and size of the pores. Therefore, the native structure plays an important role in the process of adaptation of the bone graft in the bone bed [22, 23]. Having the roentgenological method in the arsenal, and namely the MSCT of the damaged segment, the area of the defect being filled can be directly studied.

This method allows for quantitative assessment. Since the integration of the bone graft goes through the stage of lysis and subsequent neoosteogenesis in the peripheral zone of the latter in the direction from the periphery to the center, the zone of the graft is divided into three areas of the same radius — R1, R2, R3 [13, 24, 25]. According to the CT data, several patterns can be established in the zones of the examined graft. In R1 zone, a gradual increase in the absolute HU values was noted in all groups, which indicates an increase in the rigidity of the allograft. This phenomenon can be explained by the process of mineralization of the bone graft which begins 1–1.5 months after surgical placement of the allograft into the defect. In this case, the deposition of mineral salts in the substrate of the bone substance accompanies the process of neoangiogenesis in the bone tissue segment that has already passed the lysis stage. Within one zone, the processes of lysis and mineralization of newly formed bone tissue may undergo in parallel in different directions. This phenomenon of simultaneous heterogeneity of the graft may explain the spread of quantitative values of the Hounsfield index [13, 19, 22]. However, the values of the border zone R1 of the graft was, in our opinion, the most important due to the quantitative characteristic of the strength of the contact between the graft and the bone bed. The border zone of contact of the fibrous-bone block type, corresponding to 201–300 HU in patients of subgroups 1A, 2A, 3A, was achieved 6 months after implantation, while in patients of subgroups 1B, 2B, 3B already 3 months after surgery (Table 3). At the same time, the value of 300 HU, corresponding to the bony block, was not achieved in any subgroup [26–28].

In patients of subgroups 1A, 2A, 3A with cadaveric allografts in the form of cubes as a defect filling material, lower initial HU values were noted in the border zone in all study zones R1–R3, which is similar to the data on bone tissue stiffness without defect filling [22, 30]. Given the type and shape of the material used, the surgeon had to additionally fix the graft by pressing it in the defective bed using an extension. In this case, the trabecular architecture of the allograft was destroyed at the border of the "mother bone — bone block" layer, which was manifested by a decrease in the quantitative indicators of bone tissue stiffness and changed the properties and characteristics of the material used. On the one hand, additional pressing of the material promotes its mechanical compaction in the maternal bed, on the other hand, as a result of this manipulation, the quality of the tissue of the transplant used decreased due to microdamage and disruption of the bone architecture and geometry, which is reflected in insufficiently strong fixation of the material [28–30].

The decrease in the Hounsfield index in the R2 zone 3 months after the surgery compared to the values obtained at 1.5 months can be explained by physiological rarefaction of bone substance. During osteoreparation, the formation of new bone tissue occurs through the lysis stage, as a result of which the tissue rigidity expressed in HU decreased. An increase in this indicator by 6 months

after the surgery indicates the predominance of the processes of accumulation of the mineral substrate in the substituted bone tissue over the processes of its decay, which is expressed in an increase in the rigidity of the bone graft. The comparison of the indicators 6 months after the surgery found differences in intergroup comparisons of the corresponding study zones, while the indicators of “healthy” metaphyseal bone tissue without osteopenia were not achieved [23, 25, 29, 31, 32].

The study of the results of Doppler sonography of the fracture zone revealed that all patients had a general tendency towards relatively low values of the vascularization index during the period of reparation and the beginning of the formation of primary bone callus after 2 weeks, as well as by the end of the reparative phase of osteosubstitution at 4 months after the injury. At the same time, at 2 months after the operation, during the period of high activity of the secondary bone callus formation phase, an increase in this indicator was noted. Considering that the active blood supply to the fracture zone, namely the outer part of the bone callus, promotes the differentiation of osteogenic cells into osteoblasts, it can be assumed that the presence of osteoplastic material does not change the general direction of osteoreparative processes [15, 17, 18].

The increase in the area of small newly formed vessels in the bone callus zone noted 2 months after surgery in patients of subgroups 1B, 2B, 3B can be explained by both the higher osteointegrative properties of the material used and additional intraoperative measures that contribute to an increase in bioactive substances in the fracture zone [9]. A decrease in the area of formed vessels in the bone callus zone four months after surgery was more pronounced in the patients of subgroups 1A, 2A, 3A and indicates a decrease in the activity of blood supply and metabolic processes in the bone callus formation zone [16, 17]. In the case of a positive radiographic picture and the presence of signs of fracture consolidation, a favorable course and prolonged nature of osteoreparative processes can be assumed with the use of an allogeneic block transplant.

CONCLUSION

The comparison of the results of using allogenic grafting of different nature in comminuted distal humerus fractures of the 13C2 and 13C3 types, accompanied by posttraumatic bone defects found that the indices of medium-term osseointegration are more pronounced if native allogeneic block-type material is used for defect localized in the area of the medial and lateral columns. However, the complications and poor treatment outcomes determine the need for further study of the use of these materials and methods of bone defect plastic surgery.

Conflict of interest Not declared.

Funding Not declared.

Ethical standards The study was approved by the Ethics Committee of the Saratov Razumovsky State Medical University and was carried out in accordance with the Helsinki Convention.

Informed consent All patients were informed in advance about the conditions of the study and gave written consent to participate.

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Information about the authors:

Aleksey P. Davydov — Assistant, alexeydavidov@gmail.com, <https://orcid.org/0000-0003-4181-3844>;

Andrej G. Chibrikov — Candidate of Medical Sciences, Head of Department, <https://orcid.org/0009-0006-8273-4113>;

Vladimir Yu. Ulyanov — Doctor of Medical Sciences, Associate Professor, Vice-Rector, v.u.ulyanov@gmail.com, <https://orcid.org/0000-0002-9466-8348>;

Igor A. Norkin — Doctor of Medical Sciences, Professor, Head of Department, norkinsgm@gmail.com, <https://orcid.org/0000-0002-6770-3398>.



Validation of video-assisted computer vision goniometry to measure shoulder abduction motor function

S.A. Demkin^{1✉}, A.A. Malyakina¹, S.A. Akhramovich², O.A. Kaplunov¹,
I.E. Obramenko¹, I.E. Simonova³

¹ Volgograd State Medical University, Volgograd, Russian Federation

² LLC «Meta-Technologies», Moscow, Russian Federation

³ Volgograd State Technical University, Volgograd, Russian Federation

Corresponding author: Sergey A. Demkin, smdem@mail.ru

Abstract

Introduction Goniometry is used to measure shoulder abduction range of motion aiding in diagnosis, rehabilitation planning and monitoring progress in rehabilitation evaluating a patient's shoulder function. Computer vision technology holds promising potential for the assessment of movement by unifying and objectifying goniometric studies of different somatometric parameters.

The **objective** was to validate a video-assisted computer vision goniometry of the motor function of shoulder abduction using the potential of neural networks.

Material and methods The study involved 33 volunteers, males and females aged 18 to 56 years, with the weight of 53 to 108 kg and the height of 155 to 195 cm. Measurements of related samples were compared to validate the author's method of goniometric examination of shoulder abduction. Classical goniometry was used for patients of group 1. Changes in the shoulder position were radiologically explored in group 2 and video-assisted goniometry computer vision was employed for examinations in group 3. The study was performed using hardware and software "Arthro-Pro" system. Statistical processing was produced using the Statgraphics software package.

Results The average difference in the abduction was insignificant in groups 1 and 2 measuring $(0.62 \pm 0.63)^\circ$ from a minimum of 5.2° to a maximum of 1° with confidence interval of $p = 0.95$. The difference in the abduction angle ranged from -11.8° to 22.7° in groups 1 and 3 with the average difference of 6° and confidence interval of $p = 0.95$.

Discussion The minor difference in the abduction angles obtained with computer vision technologies and classical goniometry indicated the comparability of the two methods facilitating the possibility of introducing artificial intelligence for assessing musculoskeletal function in clinical practice.

Conclusion The video-assisted computer vision goniometry is practical for measurements of shoulder abduction in clinical practice.

Keywords: shoulder joint, motion capture, computer vision, radiography, goniometry

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INTRODUCTION

Goniometry is used to measure shoulder abduction range of motion aiding in diagnosis, rehabilitation planning and monitoring progress in rehabilitation evaluating a patient's shoulder function [1]. The method was first described by Hippocrates, Celsus Cornelius, Galen and other ancient scientists. Modern goniometry recommendations were reported by V.A. Gamburtsev [1] to diagnose musculoskeletal diseases, were included in the algorithms of trauma and orthopedic services, medical rehabilitation departments, military medical boards, medical and social expert boards and other units.

With a long history of goniometry, there is no unification in studies of somatometric features. There are no adequate techniques for measuring movements in the joint including the shoulder. The lack of standardization of goniometric studies of shoulder movements can be explained by the fact that are produced in a specific manner by researchers with a difficulty of identically positioning a hand-held goniometer even in one patient [2].

The shoulder as the most human mobile joint, is characterized by the maximum degrees of freedom, complexity and multi-component movements making the assessment problematic with the use of manual goniometry and modern motion capture technologies [3]. For decades, various technological solutions have been sought to objectify the method and improve the accuracy. The contactless motion capture technology using marker video recording of human movements is a breakthrough in the objectification of goniometric studies. The disadvantages of the technology include high cost of equipment, the complexity and labor intensity of implementing the method that hinder the mass introduction of the technique into clinical practice. Such factors as lighting, sensor positioning can shift and overlap each other on the human body during movements affect the accuracy of the measurements [4–8].

Computer vision based on the potential of a neural network, which is related to optical markerless and contactless motion capture technology is promising for unification and objectification of goniometric studies of somatometric features. Achievements in training neural networks allow for most accurate recognition of human movements and formation of a projection kinematic model of the human body to produce measurements [9–16]. However, the technique of performing diagnostic movements, lighting and other factors that can interfere with the indicators have a significant impact on the method. Similarly, interpreting the findings and the role in diagnosing diseases accompanied by musculoskeletal dysfunction remains unresolved [17–21].

The existing rules for conducting goniometric measurements on the shoulder joint have some "pitfalls" that affect the movement indicators, including those obtained with computer vision. This would include the "range of motion" parameter itself, which assumes that the measurement begins from the "zero position" and ends with the maximum abduction. The initial (zero) position can be affected by the body position, during the diagnostic exercise, in particular. Scoliosis can change the trajectory of the upper limb movements. Video filming is performed in a plane, and shoulder abduction does not always occur only in the frontal plane, which can distort the measurements [22–26].

Thus, the accuracy of measurements produced with computer vision technologies is determined by the peculiarities of the study of changes in the position of the recognized segments of the shoulder during motion and by the performance of a diagnostic exercise. Considering the current problems, we have developed the "Arthro-Pro" hardware and software system based on computer vision technology (certificate of state registration of the computer program No. 2023667718 dated 08/17/2023). The hardware and software complex allows for video capture and evaluation of human

movements using a specially created algorithm for taking measurements on a projection kinematic model obtained with artificial intelligence and by performing specially developed diagnostic exercises. It is essential to validate the technology with existing goniometric research methods.

The **objective** was to validate a video-assisted computer vision goniometry of the motor function of shoulder abduction using the potential of neural networks.

MATERIAL AND METHODS

The study was conducted at the departments of medical rehabilitation and sports medicine, normal physiology of the Volgograd State Medical University. Volunteers of both genders who met the inclusion criteria ($n = 33$), underwent a medical examination with trauma and orthopedic surgeon, rehabilitation specialist and signed informed consent to participate in a clinical trial approved by Volgograd State Medical University (protocol dated 10.21.2022 No. 2022/149).

Results of related samples obtained during a series of examinations were compared to validate the author's method of goniometric study of shoulder abduction:

- Group 1 included examination with goniometry “Classical goniometry” (CG);
- Group 2 included radiological examination of changes in the position of the bone structures of the shoulder “X-ray” (R);
- Group 3 included examination using the video-assisted goniometry technique “Computer Vision” (CV).

Inclusion criteria for clinical trial:

- clinically healthy men and women with normosthenic body type;
- age from 18 to 60 years;
- normal shoulder functioning according to clinical examination.

Non-inclusion criteria:

- identified shoulder dysfunctions;
- injury to the internal and periarticular structures of the shoulder joint, identified with X-ray, MRI, ultrasound;
- psychomotor, psychoorganic and neurological disorders;
- connective tissue dysplasia syndrome;
- systemic connective tissue diseases.

The study involved men and women aged 18 to 56 years, with a body weight of 53 to 108 kg and a height of 155 to 195 cm.

CG of the shoulder was performed using a hand goniometer. The subject was placed in the basic stance, the movement performed in the frontal plane. The goniometer was applied to the joint from behind at the point where the hinge coincides with the humeral head. One of the branches was placed vertically along the axis of the spine, the other along the axis of the shoulder. The initial position was considered as zero (Fig. 1a) [6]. The result of the examination was the maximum amplitude of the shoulder abduction after three repetitions. Deviation from the anatomical position was described by a positive number of degrees ranging from 0 to 180°. Measurements of the range of motion were performed on the right (Fig. 1b).



Fig. 1 Measuring the amplitude of shoulder abduction using a hand-held goniometer: (a) zero position; (b) maximum abduction

Considering the significant variability of the goniometric values using a hand-held goniometer [6], the shoulder abduction was recorded using radiography (series 2). The analysis of the radiographic image suggested use of the following anatomical landmarks (lines, arrows) assessed in the initial position (Fig. 2a) and at maximum abduction (Fig. 2b).

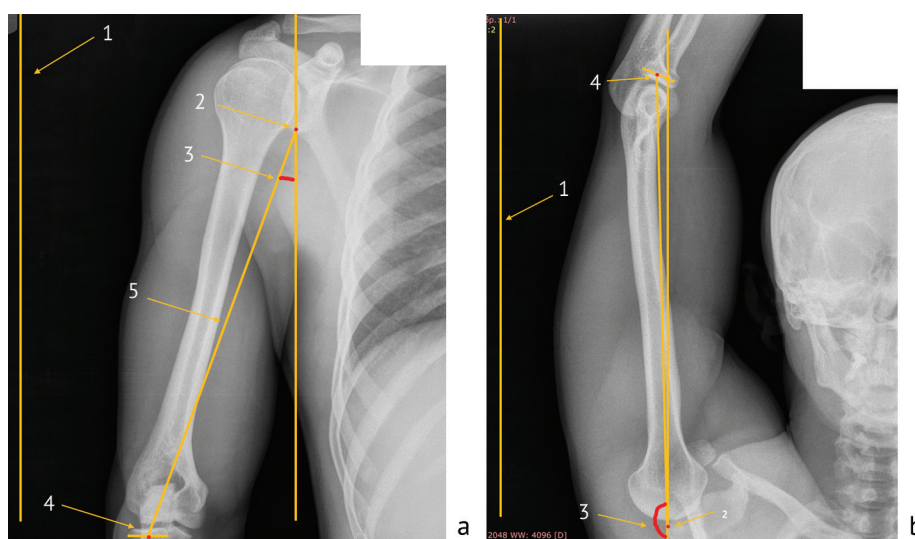


Fig. 2 Radiographs showing the shoulder abduction at: (a) zero position; (b) maximum abduction (1: vertical (template); 2: lower pole of the glenoid, through which the vertical (template) to be drawn; 3: abduction angle; 4: center of the radial head; 5: the line drawn through the lower pole of the glenoid and the center of the radial head)

Measurement of the shoulder movements primarily involves determining the axis of rotation passing through the center of the humeral head and the lateral epicondyle. However, the specified landmarks cannot be accurately compared in the zero position and at maximum abduction of the upper limb due to the bi-planar radiographic image. Anatomical points have been found to be clearly traced both in the zero position and at maximum abduction. These points are located as close as possible to the generally accepted ones (Fig. 2): the lower pole of the glenoid and the center of the radial head, through which a line is drawn. To ensure unification of measurements, the vertical (1) drawn through the lower pole of the glenoid is taken as the second reference point to measure the abduction angle (3) inbetween (Fig. 2).

The amplitude of active shoulder abduction in the 3rd series was assessed using the author's goniometry method of the CV using the hardware and software complex "ArthroPro" including an HD video camera, a tripod and a computer with a preset program. The subject was positioned frontally in relation to the video camera with his shoulder blades pressed against the vertical support. The video camera was placed at a distance of 1.5 m from the subject at a height of 1.5 m from the floor. The position of the arms lowered downwards with the first finger pointing forward was taken as the zero position. Then the subject moved his arms upwards in an arc to the maximum position.

Human movements were recognized using a pre-trained MediaPipe neural network, which processed video images, formed projection points at the shoulder, elbow, wrist, hip, knee and ankle joints, connecting them with lines. The authors introduced a vertical through a point in the shoulder joint to unify measurements. As a result, an abduction angle (arrow) was formed and measurements were recorded by the program (Fig. 3).

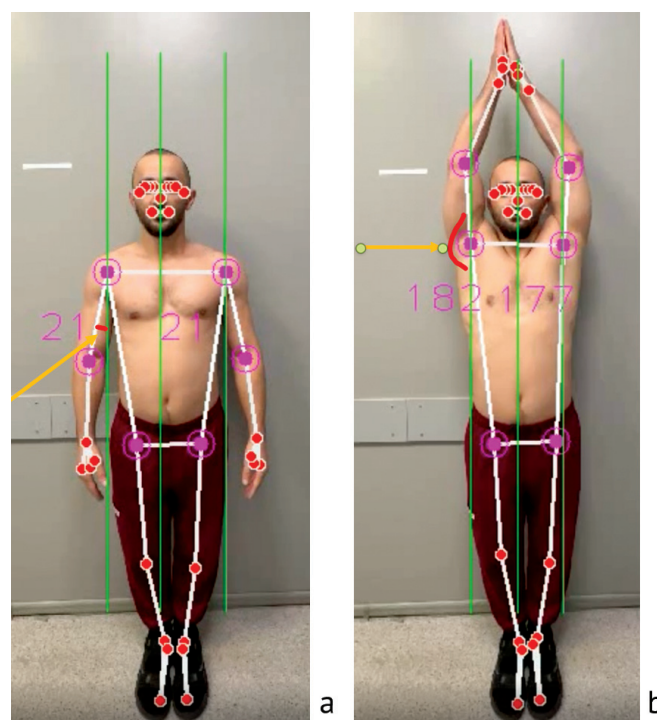


Fig. 3 Shoulder abduction amplitude measured with video-assisted goniometry: (a) zero position; (b) maximum abduction

Confirmation of the compliance of the video-assisted computer vision-based technique with the intended use was obtained using statistical processing of the initial data by analyzing the rank sign criterion, Student's t-criterion, and plotting the Bland-Altman plot in the program. The statistically significant level was set at $p \leq 0.05$.

RESULTS

The average amplitude of abduction in the series of measurements of the CV using Arthro-Pro was $(178.90 \pm 0.63)^\circ$ (confidence interval of reliability $p = 0.95$), and $(179.5 \pm 0.1)^\circ$ (confidence interval of reliability $p = 0.95$) in the KG series.

The observations were paired (Paired Samples with two measurements for each patient), the difference in measurements was analyzed exploring the differences between the two samples. The average difference between the CV and KG amplitude of abduction in the two measurement groups was insignificant, amounting to $(-0.62 \pm 0.63)^\circ$ (confidence interval $p = 0.95$) from a minimum of -5.2° to a maximum of 1° , with the only observation with a difference in readings of 5.2° (greater than 5°) being "sharply outstanding" (Fig. 4a).

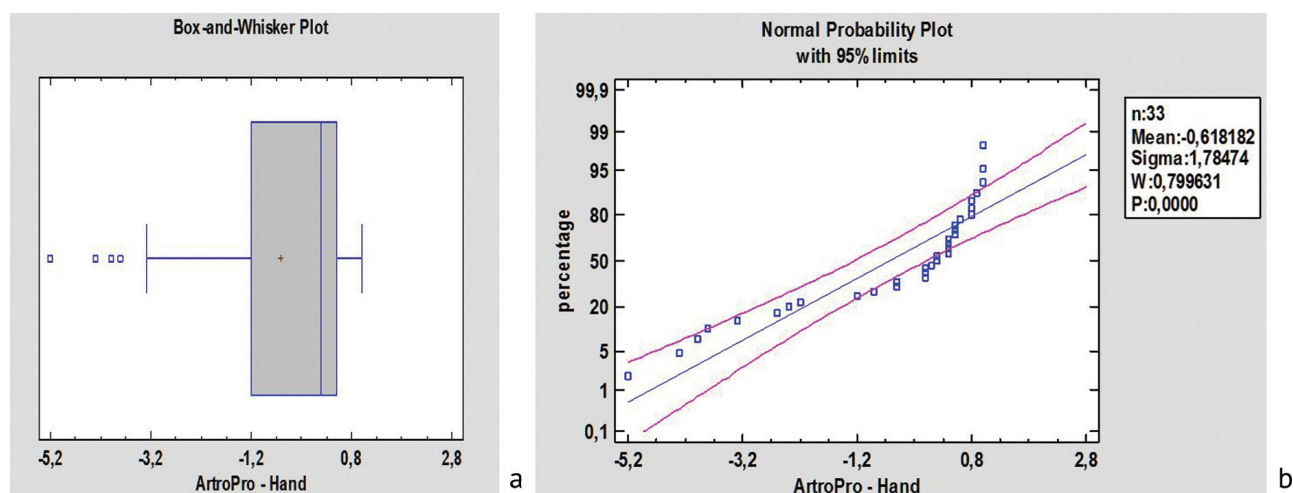


Fig. 4 Graphical analysis of the difference in the amplitude of the shoulder abduction in the clinical-goniometric series and the series using computer vision: (a) "box and whiskers" (Box-and-Whisker Plot); (b) graph on the normal probability paper

The difference in the indicators was not distributed according to the normal law (Fig. 4b) and two criteria were used for comparisons: the rank sign criterion to test the hypothesis that the medians of the two samples were equal, and the Student's t-test (for paired observations) to test the hypothesis that the average difference in the measurements of the abduction angles was zero. Both criteria showed that the hypotheses were true at a significance level of 0.05 (5 %), i.e. the difference in the medians and in the differences in the means of the two samples was insignificant. The average value of the difference was the assumed systematic error.

Thus, the measurements with the CV method contained no systematic error. The Bland–Altman plot is a powerful graphical tool for comparing two measurement methods and assessing the agreement between two sets of data [27]. Also known as difference plots, they are a visual representation of the difference between two measurements on the Y-axis and the average of the two measurements on the X-axis. Figure 5 shows the Bland–Altman chart plotted in Excel.

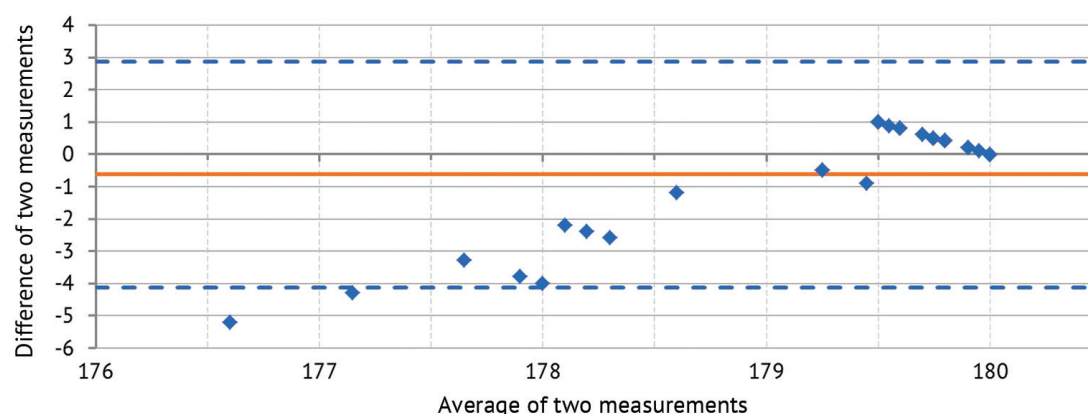


Fig. 5 The Bland–Altman plot

The Y axis shows the difference between the measurements of the CV and KG, and the X axis shows the half-sum of $0.5 \times (CV + KG)$. The horizontal line in the middle $Y = -0.62$ is slightly shifted relative to zero and shows that the average difference in the indicators is insignificant. The dotted lines represent the 95 % limits of agreement (mean difference ± 1.96 standard deviations of the difference), which show how much the measurements obtained by the two methods can differ in the majority

(95 %) of people. In our case, the standard deviation $SD = 1.78$ and the limits of agreement $(-0.62 \pm 1.96)^\circ \times SD$ define the range $(-4.11^\circ; 2.87^\circ)$. The difference within the limits not exceeding 5° has no clinical significance, so the two methods of CV and CG can be used interchangeably.

Measurements the shoulder abduction in the groups were compared using manual (classical) goniometry (CG) and radiology (R). The statistical analysis showed the significant difference. The difference in abduction measured by the two methods ranged from -11.8 to 22.7° , with a mean difference of 6° [confidence interval $p = 0.95$ for it $(6 \pm 2.8)^\circ$]. Therefore, the radiographic method provides on average significantly underestimated values of the abduction angle (on average 6° less). Individual values were both underestimated by 22.7° and overestimated by 11.8° .

A comparison of the shoulder abduction angle measured with computer vision and the X-ray was not performed.

DISCUSSION

Accuracy is an important aspect in measuring shoulder abduction. The shoulder is the most mobile joint and movements are characterized by multicomponentity. A.I. Kapandzhi reported motion occurring primarily at the scapulohumeral joint in the early phase ($0-60^\circ$), although stressing the arm may increase the scapular contribution involving acromioclavicular and sternoclavicular joints. Measurements in the zero position can be affected by the soft tissues of the upper limb, the trunk and scoliosis, which can change the abduction pattern. In classical goniometry, one branch is applied parallel to the spine, which can presumably distort the measurement depending on the axis. The vertical line entered into the Arthro-Pro program through the projection point in the shoulder joint is automatically tied to the template in the background, leveling out scoliotic distortions. This aspect affects the compatibility of the indicators of the compared methods (CG – CV) [28–32].

There are differences in the projection points for the goniometer branches and the verticals of the CV. Projections differ, causing differences in abduction angle. The significant differences in the projections of the points were the reason for the occurrence of cases where the values were outside the confidence interval. The small spread of the mean difference fits into the generally accepted criteria for conducting measurements [1–3, 33–35].

Evaluation of the results of radiographic measurements of the shoulder abduction allowed us to identify a larger interquartile spread of the mean difference in relation to the data obtained with the CV and CG methods. This is largely due to the system of radiographic measurements.

The primary objective is to determine the axis of the shoulder rotation with the line drawn through the center of the humerus head and the lateral epicondyle of the humerus. However, rotation of the humerus during abduction and the biplanar format of radiographic images do not allow for accurate comparison of the rotation axes in the initial position and during maximum abduction of the upper limb. Therefore, there was a need for new landmarks that would be localized precisely and simultaneously in two positions (initial – maximum).

These were the lower pole of the glenoid and the center of the radial head. It is worth noting several other reasons that determine the differences in the parameter measured in series 1, 2 and 3. One of the reasons includes the smaller amplitude of the abduction in the radiological format in comparison with the other two series. Radiography required fixing the arm in the initial and abducted positions for a short period of time, which could cause some lowering of the upper limb in the second position, in particular. The greatest deviations were found with comparison of the shoulder abduction angles (series 1, 2, 3) in subjects with a larger shoulder circumference.

CONCLUSION

The average difference in abduction angles in the CV and KG series does not exceed the generally accepted differences of 5°. Radiological assessment of bone position is associated with the selection of projection points for measurements, which can affect the abduction angle parameters. The findings showed that measuring the amplitude of the shoulder abduction angle using computer vision is a valid method that can be used for goniometric examinations in clinical practice.

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Ethical standards The study was approved by the local ethics committee of the Federal State Budgetary Educational Institution of Higher Education "Volgograd State Medical University" of the Ministry of Health of the Russian Federation (protocol No. 2022/149 dated October 21, 2022).

Informed Consent All patients participating in the study signed a voluntary informed consent to participate in a clinical trial.

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Information about the authors:

Sergey A. Demkin — Candidate of Medical Sciences, Senior Lecturer,
smdem@mail.ru, <https://orcid.org/0000-0002-2914-5807>;

Anastasia A. Malyakina — Assistant Professor, amalyakina0320@bk.ru, <https://orcid.org/0000-0003-3703-6667>;

Sergey A. Akhramovich — General Director, akhramovichsa@gmail.com, <https://orcid.org/0000-0002-5790-2924>;

Oleg A. Kaplunov — Doctor of Medical Sciences, Professor, Professor of the Department,
volortho@mail.ru, <https://orcid.org/0000-0001-6634-4162>;

Irina E. Obramenko — Doctor of Medical Sciences, Associate Professor, Associate Professor of the Department,
custvol@yandex.ru, <https://orcid.org/0000-0001-8677-9024>;

Irina E. Simonova — Candidate of Physical and Mathematical Sciences, Associate Professor,
Associate Professor of the Department, simonova-vstu@mail.ru, <https://orcid.org/0000-0002-6510-4789>.

Original article

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Errors and complications with post-traumatic frontal deformities of the elbow joint corrected with supracondylar osteotomy with the Ilizarov apparatus

Yu.P. Soldatov✉, A.N. Dyachkov

Ilizarov National Medical Research Centre for Traumatology and Orthopedics, Kurgan, Russian Federation

Corresponding author: Yuri P. Soldatov, soldatov-up@mail.ru

Abstract

Introduction Transosseous osteosynthesis has the advantages of controllability, mobility and minimal invasiveness and is commonly used by trauma and orthopaedic surgeons for elbow deformity correction. There is a paucity of publications reporting errors and complications with external fixation devices used to restore the biomechanical axis of the upper limb.

The **objective** was to identify errors and complications in patients with post-traumatic coronal deformities of the elbow joint treated with the Ilizarov apparatus and to determine a rational algorithm for the prevention.

Material and methods The study included 68 patients with elbow deformities in the frontal plane. The patients age ranged from 4 to 56 years. The surgeries were performed between 1990 and 2024. Patients were divided into 2 groups: control and treatment. The control group included 41 patients who underwent correction surgery up to 2018. The limb was realigned either acutely or gradually post op through Ilizarov distraction produced on the concave side of the deformity. In order to prevent errors and complications, since 2018, patients with the condition have been treated according to a protocol developed to contain the sequence of intraoperative and postoperative manipulations taking into account time factors. These patients were included in the treatment group ($n = 27$).

Results Complications were identified in the limb biomechanics (residual deformity, disturbed limb axis); in the joint (contractures); in the bone (comminuted osteotomy, presence of teeth); in the bone regeneration (ischemic regenerate); in the nerves (short-term and long-term neuropathies of the radial and ulnar nerves).

Discussion The number of complications in patients of the treatment group was seven times less compared to literature data, while the total number of complications after supracondylar osteotomy of the humerus and Ilizarov fixation was 1.6 times lower. Review of errors and complications in the treatment of patients with post-traumatic frontal deformities of the elbow joint using supracondylar osteotomy and the Ilizarov fixation facilitated development of a rational algorithm for the correction.

Conclusion The limb axis can be realigned and biomechanics of the elbow joint restored with corrective supracondylar osteotomy of the humerus and manipulations with the Ilizarov apparatus. The algorithm developed for treatment of patients with elbow deformities suggested a strict sequence of actions with time factors, reducing errors and complications in the form of failures in performing osteotomy, residual deformity, poor regeneration, contractures and neuropathies by 6.3 times.

Keywords: elbow joint, deformity, varus, valgus, supracondylar osteotomy, transosseous osteosynthesis, Ilizarov apparatus, errors, complications

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INTRODUCTION

Upper limb injuries can lead to bone deformities, joint contractures, ankylosis, elbow arthritis and can severely limit the mobility and quality of life [1]. A varus elbow is a common complication following distal humerus fractures in children [2, 3] and can lead to degenerative changes on the inner side of the joint including the medial condyle [4]. The deformity interferes with the limb axis with the direction of the force action of the triceps brachii muscle causing elbow instability, compression of the articular surfaces and osteoarthritis [4]. All this is the cause of chronic pain syndrome of the elbow joint and limitations of the function of the upper limb [5]. The growth zone of the humeral condyle does not remain neutral in transcondylar and supracondylar fractures causing formation of the elbow valgus deformity [6].

A prolonged existence of elbow deformity caused by a supracondylar humerus fracture, due to the disruption of the limb axis and displacement of the humeral condyle in the frontal plane can lead to a bayonet-shaped supracondylar deformity. The deformity is described as “supracondylar syndrome” in the literature [7].

Elimination of the acquired elbow deformities and rehabilitation is a huge problem [8]. Failures can be caused by insufficient rigidity of bone fixation after osteotomy and severely traumatic surgery (opening of the joint cavity, damage to the articular structures) [9].

Frontal deformities can be repaired with intra-articular and extra-articular corrective osteotomies to be used with identified location and degree of humerus deformity [10] including supracondylar [11, 12], transverse, wedge-shaped and dome-shaped types [13].

Bone fixation can be performed with skeletal traction or Kirschner wires and cause contractures due to joint immobilization. Supracondylar osteotomy can be fixed with external device using Shantz rods [14] or plating [15, 16].

Transosseous osteosynthesis method has the advantages of controllability, mobility and minimal invasiveness and is commonly used by trauma and orthopaedic surgeons for elbow deformity correction. However, there is a paucity of publications reporting errors and complications with external fixation devices used to restore the biomechanical axis of the upper limb.

The **objective** was to identify errors and complications in patients with post-traumatic coronal deformities of the elbow joint treated with the Ilizarov apparatus and to determine a rational algorithm for the prevention.

MATERIAL AND METHODS

This is a retrospective, cohort, continuous, single-center study. The statistical population is characterized by average values including arithmetic mean and standard deviation ($\bar{X} \pm SD$).

The study was performed in accordance with ethical principles for medical research involving human subjects stated in the Declaration of Helsinki developed by the World Medical Association. Written informed consent was obtained from all patients for publication of the findings without identifying details.

The study included 68 patients with posttraumatic frontal elbow deformities. The patients aged 4 to 56 years were surgically treated at 6 months to 15 years of injury in the years between 1990 and 2024. Elbow fractures had been repaired either conservatively or surgically at a local hospital. Conservative treatment included closed reduction and upper limb fixation with a plaster cast or skeletal traction. Surgical treatment included open reduction, fixation of the humerus with different metal constructs or the Ilizarov frame (Fig. 1).

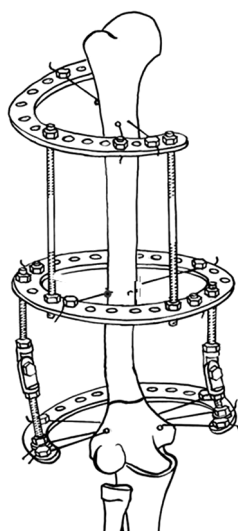


Fig. 1 Anteroposterior view of the Ilizarov frame used to correct elbow deformity in the frontal plane employing supracondylar osteotomy of the humerus (for example, to eliminate elbow varus deformity)

The participants were divided into two groups including controls and treatment cohort. The controls ($n = 41$) underwent surgical treatment up to 2018) with the limb axis being realigned acutely during the operation or gradually in the postoperative period by Ilizarov distraction on the concave side of the deformity. In order to prevent errors and complications, since 2018, patients with the condition have been treated according to a developed algorithm containing a sequence of manipulations to be performed intraoperatively and postoperatively and considering time factors. These patients were included in the treatment group ($n = 27$).

Algorithm for Ilizarov correction of post-traumatic elbow deformities

Operational stage

- Placing wires in the humerus:
 - proximal olive wires to be inserted bilaterally;
 - one or two mid humerus wires to be placed in the oblique sagittal plane;
 - distal wires to be placed above the olecranon fossa (three wires including two olive wires to be inserted bilaterally).
- Assembly of the Ilizarov frame:
 - a half-ring with curved plates attached bilaterally and placed in the proximal humerus;
 - full ring to be attached on the boundary of the middle and distal humerus;
 - a half-ring with curved plates attached bilaterally to be placed in the distal humerus considering the deformity and connected with reference rings using hinges; the plane of the hinges is oriented to the plane of the deformity, the axes of the hinges' rotation are located at the level of the proposed osteotomy.
- Corticotomy to be performed in the supracondylar humerus with pre-drilling of six tunnels at the level of the intended corticotomy.

Postoperative stage

- Distraction to be initiated:
 - after four postoperative days with compression forces to be transferred to the Ilizarov rods into moderate distraction forces; distraction to be performed evenly at the rate of 1 mm four times/day during the next five days.

- Postoperative control of osteotomy:
 - AP and lateral radiographs of the segment after five days of distraction.
- The deformity to be corrected using:
 - distraction with the rods of the frame to be produced on the concave side of the deformity at the rate of 1.5 mm per day six times/day.
- Control of the regenerate quality and the limb axis:
 - AP and lateral radiographs of the segment every 10 days of distraction.
- Final correction of the limb axis:
 - acute translation of the distal bone fragment using the Ilizarov frame (if necessary) for the final correction of the limb axis;
 - comparative radiometry (comparison of the radiograph of the operated arm with the radiograph of the contralateral limb).
- Fixation:
 - control of regeneration once a month;
 - exercising the joint;
 - control of distraction forces on the Ilizarov distraction rods and wire tensioning.

General characteristics of patients with frontal elbow deformities are presented in Table 1. The majority of the patients had elbow varus deformity (89.9 %). Pseudarthrosis of the capitulum of the humerus was diagnosed in seven patients with elbow valgus deformity.

Table 1

General characteristics of patients with frontal elbow deformities ($n = 68$)

| Description | | Control group ($n = 41$) | | Treatment group ($n = 27$) | |
|-------------------------------------|-------------|----------------------------|------|------------------------------|------|
| | | abs. | % | abs. | % |
| Gender | male | 28 | 68.3 | 19 | 70.4 |
| | female | 13 | 31.7 | 8 | 29.6 |
| Age | 4–17 years | 33 | 80.5 | 17 | 63.0 |
| | 18–56 years | 8 | 19.5 | 10 | 37.0 |
| Angulation: | | | | | |
| a) varus elbow deformity: | Total | 34 | 82.9 | 21 | 77.8 |
| | 0° | 7 | 17.1 | 3 | 11.1 |
| | 5–14° | 8 | 19.5 | 9 | 33.3 |
| | 15–24° | 10 | 24.4 | 5 | 18.5 |
| | 25–30° | 9 | 22.0 | 4 | 14.8 |
| b) valgus elbow deformity: | Total | 7 | 17.1 | 6 | 22.3 |
| | 30° | 6 | 14.6 | 5 | 18.5 |
| | 45° | 1 | 2.4 | 1 | 3.7 |
| c) deficient flexion: | 10–19° | 4 | 9.8 | 1 | 3.7 |
| | 20–25° | 3 | 7.3 | 3 | 11.1 |
| d) deficient extension: | 5–14° | 1 | 2.4 | 2 | 7.4 |
| | 15–20° | 2 | 4.9 | 1 | 3.7 |
| | 30° | 4 | 9.8 | 3 | 11.1 |
| e) deficient flexion and extension: | 5–20° | 6 | 14.6 | 3 | 11.1 |
| | 25–55° | 4 | 9.8 | 6 | 22.3 |
| f) absence of deficiency | | 17 | 41.4 | 8 | 29.6 |

Table 1 (continuation)
General characteristics of patients with frontal elbow deformities ($n = 68$)

| Description | | Control group ($n = 41$) | | Treatment group ($n = 27$) | |
|-----------------------------------------------------------|--------|----------------------------|----|------------------------------|------|
| | | abs. | % | abs. | % |
| Radiography: | | | | | |
| a) deformity of the distal humerus: | varus | 34 | 21 | 77,8 | 77,8 |
| | valgus | 7 | 6 | 22,2 | 22,2 |
| b) marginal bone growths of articular surfaces | | 12 | 5 | 18,5 | 18,5 |
| c) deformity and osteophytes of the olecranon fossa | | 13 | 6 | 22,2 | 22,2 |
| d) uneven narrowing of the joint space | | 7 | 5 | 18,5 | 18,5 |
| e) pseudoarthrosis of the capitae eminence of the humerus | | 6 | 1 | 3,7 | 3,7 |

Patients performed elbow exercises for flexion and extension three times a day for 60 minutes, actively (using their own muscle strength) and passively (with weights). The deformity correction lasted for 10–36 days. Fixation of the humerus with the Ilizarov frame on lasted for 21–84 days.

A through drilling of the humerus was performed intraoperatively prior to the corticotomy at the level of the proposed osteotomy in the supracondylar zone using a K-wire (six tunnels) in patients of the treatment group (Fig. 2). The maneuver was used to prevent formation of a teeth-like or comminuted bone fragments that would make bone translation difficult. In this case, the bone "tooth" could be located in the soft tissues after deformity correction and lead to pain.

Fig. 3 shows consecutive postoperative radiographs of a 12-year-old patient of the treatment group with post-traumatic varus deformity corrected according to the algorithm.

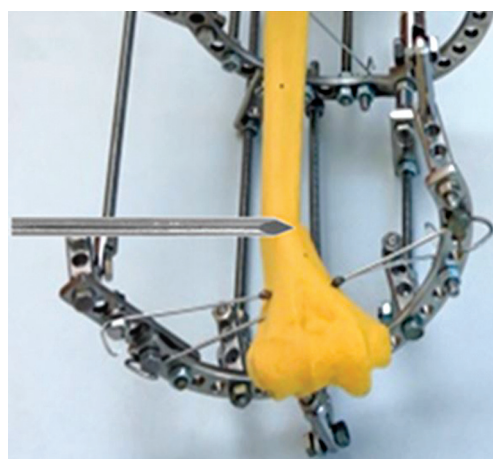


Fig 2 Photo of a humerus model with the Ilizarov apparatus mounted for correction of the frontal elbow deformity with a wire to be used for pre-drilling prior to corticotomy

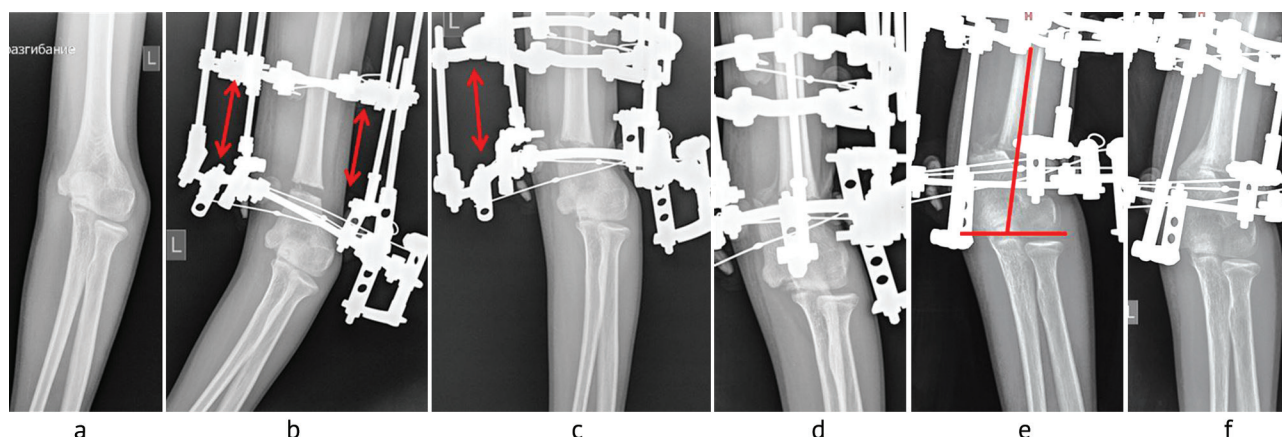


Fig. 3 AP view of the elbow joint of a patient with post-traumatic varus deformity of the elbow joint in the treatment group showing: (a) preoperative view; (b) uniform distraction performed at the rate of 1 mm per day four times/day with the height of the diastasis measuring 5 mm, corresponding to the duration of distraction at five days; (c) ten-day varus correction using distraction performed at the rate of 1.5 mm/day six times/day with two medial rods; (d) twenty-day Ilizarov deformity correction with the distal bone fragment acutely translated by 1.5 cm laterally to restore the limb axis; (e) the last-day deformity correction, the lines of the articular surface of the humeral condyle and the humerus axis are constructed to determine the residual deformity with the correction completed and deformity eliminated; (f) one-month Ilizarov humerus fixation

RESULTS

Four groups of errors were identified in patients of both groups with post-traumatic elbow deformities in the frontal plane that led to a variety of complications during placement of the Ilizarov apparatus in the operating room; performing osteotomy; control of the Ilizarov frame after osteotomy in the operating room; postoperative manipulations with the Ilizarov frame (Table 2).

Table 2

Groups of errors, complications and their prevention during treatment of patients with post-traumatic axial deformities of the elbow joint

| Groups of errors | Description | Possible complications | Prophylaxis |
|------------------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assembly of the Ilizarov frame | Wires placed distal to the olecranon fossa of the humerus | Elbow contracture | Distal humerus wires to be placed proximal to the olecranon fossa |
| | Placement of a ring in the distal humerus | | A half-ring or open ring must be placed in the distal humerus to allow elbow flexion during treatment. |
| | Absence of hinges, tilt of correction supports of the device | Incomplete deformity correction | It is recommended to place hinges with the plane of rotation located in the plane of the deformity, and their axes at the level of the proposed corticotomy. The distance between the rings should be maintained considering the correction maneuvers to be performed. |
| Osteotomy | Osteotomy used in case of altered bone structure | Comminuted osteotomy, presence of „teeth“ | Pre-drilling, corticotomy to be performed prior to osteotomy |
| Intraoperative manipulations with the Ilizarov frame | Diastasis between the osteotomized bone fragments measuring greater than 5 mm | Poor bone regeneration | It is recommended to control the forces on the Ilizarov rods |
| | Acute correction for severe deformities or multiple scars of the humerus | Neuropathy | Gradual correction of the deformity should be performed in the postoperative period. |
| Postoperative manipulations with the Ilizarov frame | Inadequate distraction rate | Poor bone regeneration | A rational algorithm for eliminating deformity correction to be followed |
| | Lack of control over the bone regeneration, the axis of the limb segment | Residual deformity | |
| | | Malaligned bone axis | |

As can be seen from Table 3, these errors led to complications in the biomechanics of the limb (residual deformity, malaligned limb axis), the joint (contractures), the bone (comminuted type of osteotomy, presence of teeth), regeneration (ischemic regenerate bone), nerves (short-term and long-term neuropathies of the radial and ulnar nerves).

Table 3

Distribution of patients in the control and treatment groups according to the complications identified

| Complications | Control group (n = 41) | | Treatment group (n = 27) | | Total (n = 68) | |
|------------------------------------------------------------------------|---------------------------|------|-----------------------------|------|----------------|------|
| | abs. | % | abs. | % | abs. | % |
| Comminuted, teeth-like shape of bone fragments at the osteotomy site | 3 | 7.3 | – | – | 3 | 4.4 |
| Incomplete deformity correction | 6 | 14.6 | 2 | 7.4 | 8 | 11.8 |
| "Bayonet-shaped" supracondylar deformity of the humerus | 4 | 9.8 | – | – | 4 | 5.9 |
| Ischemic regenerate | 6 | 14.6 | – | – | 6 | 8.8 |
| Persistent contractures of the elbow joint, lasting more than 6 months | 6 | 14.6 | – | – | 6 | 8.8 |
| Neuropathy of the radial and ulnar nerves | 4 | 9.8 | 1 | 3.7 | 5 | 7.4 |
| Total | 29 | 70.7 | 3 | 11.1 | 32 | 47.1 |

Comminuted, teeth-like shape of bone fragments was observed at the osteotomy site in control patients who had sclerotic bone or with errors occurred with performing the osteotomy (Fig. 4).

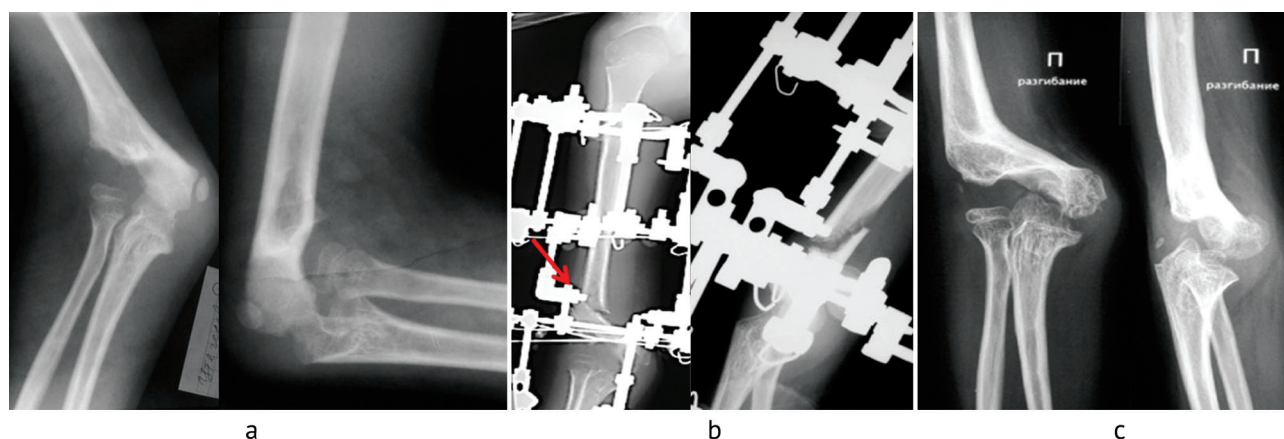


Fig. 4 Photos from radiographs of an 11-year-old control patient with post-traumatic valgus deformity of the right elbow joint, defect of the lateral humerus condyle showing: (a) preoperative view; (b) supracondylar osteotomy of the humerus performed and valgus deformity of the elbow joint gradually corrected; the distal humerus fragment appears to be teeth-like, being located in the soft tissues (shown by the arrow); (c) a favorable outcome being with the bone fragment being demineralized at one year after removal of the Ilizarov apparatus

Incomplete deformity correction was caused by the lack of comparison of the AP and lateral views of the operated limb with the contralateral limb at the last stage of deformity control with the Ilizarov apparatus. There was no linear correction of the humeral axis in the frontal plane (bone translation for coaxiality) in some cases, which led to a “bayonet-shaped” deformity of the distal humerus. Weak bone regeneration was observed in six control patients after intraoperative acute deformity correction.

Six control patients with valgus elbow deformity and pseudoarthrosis of the capitulum of the humerus developed a sharp limitation of movements in the joint after osteosynthesis of the lateral epicondyle of the humerus and capitulum (Fig. 5). Neuropathies developed in control patients after acute valgus correction and were observed at a long term (more

than 6 months). A patient with varus elbow deformity of the treatment group demonstrated short-term (1 month) neuropathy caused by compression of the ulnar nerve by a wire that was removed on the first day after surgery.

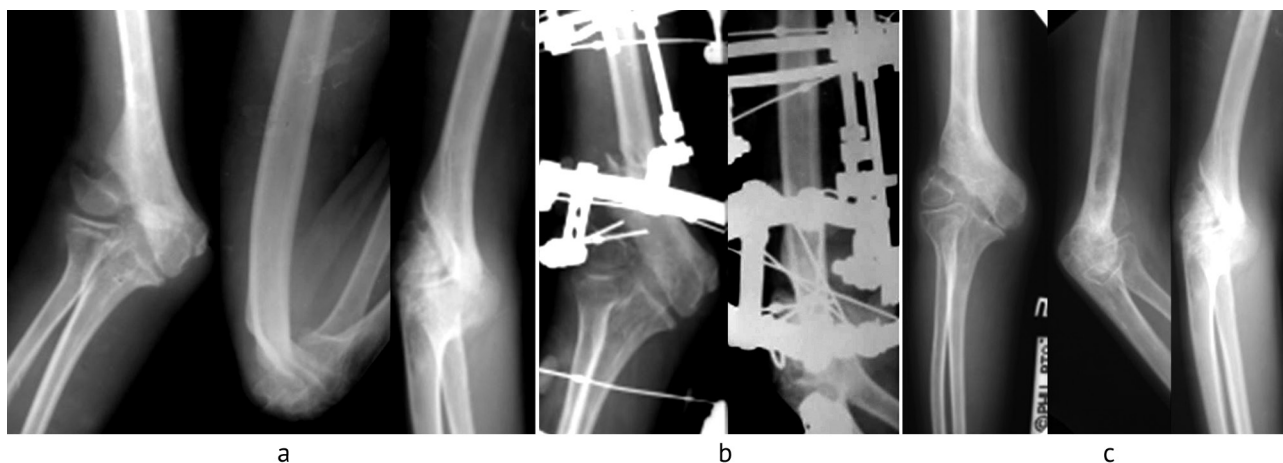


Fig. 5 Photos from radiographs of a 13-year-old control patient with post-traumatic valgus deformity of the right elbow joint, pseudoarthrosis of the capitulum showing (a) preoperative AP and lateral views with the forearm maximally flexed and extended; (b) AP and lateral views showing the supracondylar osteotomy of the humerus performed, the capitulum fixed with the Ilizarov apparatus and cantilever wires with the elbow maximally extended; (c) AP and lateral views showing the joint after removal of the Ilizarov apparatus

DISCUSSION

Trauma and orthopedic surgeons admit that the surgery using supracondylar osteotomy is the optimal method for patients with frontal elbow deformities. According to literature data [16], patients with valgus elbow deformity can benefit from transverse osteotomy for realignment of the limb axis, but a bone defect formed at the site of the osteotomy requires the replacement. An additional operation to repair the defect with biomaterial using autogenous bone filling would complicate and increase the cost of surgical treatment. There is a similar problem with varus deformities of the elbow joint with the surgical wound to be widened aggravating the trauma. Wedge and dome-shaped osteotomies can shorten the limb and prevent the distal humerus from translation to restore the bone alignment. There is associated risk of progressing osteoarthritis of the elbow and a relapse of the joint deformity as the child grows. The incidence of complications with dome-shaped corrective supracondylar osteotomy of the humerus is 14.5 % [17].

The overall risk of various complications after osteotomies is reported to be 14.5 % [17]. The problems can be resolved with transverse corticotomy using transosseous compression-distraction osteosynthesis and deformity correction with the Ilizarov apparatus. The technique was employed for the 68 patients reviewed.

Cases of insufficient deformity correction and the recurrence are described in the literature. Insufficient bone correction requiring additional surgery is more common in patients treated with plate fixation [12]. Varus deformity caused by a laterally protruding humeral condyle may persist after osteotomy in cases with the distal fragment being insufficiently translated for coaxiality [18, 19, 20]. The complication can be avoided with deformity correction algorithm using the Ilizarov frame and acute bone translation.

Non-union of the bone can develop after osteotomies [12]. Delayed consolidation of the supracondylar osteotomy of the humerus was observed in patients with elbow varus deformity repaired with a Y-shaped plate after osteotomy [20]. According to our data, impaired

regeneration occurred after intraoperative acute deformity correction observed in 8.8 % of control patients.

Dissection of the triceps during surgical approaches and osteosynthesis of the humerus condyle in pseudoarthrosis are frequent causes of elbow contractures observed in 4.72 % of patients [21]. Therefore, a sparing approach to the paraticeps is essential [13, 24, 25], and osteosynthesis of the lateral humeral condyle remains a controversial approach in patients with non-union and valgus deformity of the elbow joint after bone osteotomy due to avascular necrosis of the fragment after osteosynthesis [24, 25, 26].

In our opinion, temporary osteosynthesis of the non-union is practical during deformity correction. There is information on intraoperative injuries of the ulnar and radial nerves [24], which are reported in 2.53 % of patients including 78.4 % of cases with temporary injury [17]. Neuropathy of the ulnar nerve can be common with valgus deformity of the elbow joint, when the medial epicondyle of the humerus is displaced relative to the olecranon with the ulnar nerve groove being narrow [26]. Nerve palsies are more common with the posterior surgical approach to the humerus with division of the triceps as compared to the lateral approach with preservation of the triceps [12].

Infectious complications are observed in 9.45 % in patients with elbow deformities post operation [21]. There were no infectious complications of soft tissues and bones in the patients reported in the article.

Data on complications observed in the groups of patients and generalized literature data on the correction of deformities and repair of defects using non-free bone grafting and the Ilizarov frame [27] are presented in Table 4. The number of adverse events in the occurrence of complications in the treatment group was seven times less compared to the literature data. The total number of complications was 1.6 times less after the supracondylar osteotomy of the humerus and Ilizarov fixation as compared to the generalized data.

Table 4

Adverse events and serious adverse events in patients with deformities and defects of long bones treated with the Ilizarov apparatus (literature data [28] and our own data)

| Complications | Literary source data (n = 2242) | | Own data 68 observations | | | |
|----------------------------------------------|------------------------------------|-------|---------------------------|------|-----------------------------|-----|
| | | | Control group (n = 41) | | Treatment group (n = 27) | |
| | abs. | % | abs. | % | abs. | % |
| Adverse events | 588 | 26.23 | 10 | 24.4 | 1 | 3.7 |
| Pin tract infection | 258 | 11.51 | – | – | – | – |
| Contractures | 152 | 6.78 | 6 | 14.6 | – | – |
| Neurological disorders | 111 | 4.95 | 4 | 9.8 | 1 | 3.7 |
| Cutting through soft tissue around the wires | 31 | 1.38 | n/a | | | |
| Broken wires/rods | 18 | 0.80 | – | – | – | – |
| Dermatitis | 11 | 0.50 | – | – | – | – |
| Injury to blood vessels | 7 | 0.31 | – | – | – | – |
| Severe adverse events | 15 | 0.67 | – | – | – | – |
| Osteomyelitis | 14 | 0.62 | – | – | – | – |
| Fatal outcome | 1 | 0.05 | – | – | – | – |

With the extensive experience in Ilizarov treatment of the patients the complications appeared to be predictable and could be successfully treated if identified in a timely manner with no affect on the final outcome [28, 29]. There is a tendency in reduced errors and complications with accumulated individual and collective Ilizarov experience [30] and appropriate and promising application of the method.

CONCLUSION

Analysis of errors and complications in the treatment of patients with post-traumatic frontal elbow deformities using supracondylar osteotomy and the Ilizarov fixation facilitated a rational algorithm developed for the deformity correction. Supracondylar osteotomy of the humerus with osteosynthesis and control of the Ilizarov apparatus are practical for the restoration of the anatomical and biomechanical axes of the limb. The algorithm containing a strict sequence of actions with time factors developed for treatment of patients with elbow deformities provided a 6.3 time reduction in errors and complications performing osteotomy, correcting residual deformity, improving bone regeneration and addressing contractures and neuropathies.

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Ethical Standards The study was carried out in accordance with the Declaration of Helsinki.

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Information about the authors:

Yuri P. Soldatov — Doctor of Medical Sciences, Professor, Leading Researcher, orthopaedic surgeon, soldatov-up@mail.ru, <https://orcid.org/0000-0003-2499-3257>;

Alexander N. Diachkov — Doctor of Medical Sciences, Professor, Chief Researcher, naucaalex@mail.ru.



Histological manifestations of wrist osteoarthritis and their dependence on the duration and severity of the disease

N.A. Shchudlo, T.A. Stupina✉, Sh.K. Kuttygul

Ilizarov National Medical Research Centre for Traumatology and Orthopedics, Kurgan, Russian Federation

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

Abstract

Introduction The possibilities of medical visualization of changes in the articular cartilage and subchondral bone in wrist osteoarthritis are limited. There are few studies devoted to its histological manifestations.

The **purpose** of the work was to determine the relationships between histological features of wrist osteoarthritis and the duration and stage of SLAC/SNAC syndrome.

Material and methods The surgical material of 12 patients who underwent resection of the proximal row of wrist bones or removal of the scaphoid bone and intercarpal arthrodesis was studied. In nine patients, the duration of the disease was shorter than four years and in three it was from 10 to 22 years. Stage I SLAC / SNAC syndrome was detected in two patients, stage II — in six, stage III — in four. Cartilage changes were assessed using the international OARSI scale, the prevalence of subchondral bone necrosis was determined semi-quantitatively (from 0 to 3 points) in 3–10 fields of microscopic views of the from each patient.

Results The OARSI score varied from 1–2 to 5 points if the duration of the disease was shorter than four years and from 3–4 to 4–5 points if it continued from 10 to 22 years. The osteonecrosis score in the compared subgroups was 3 (2÷3)(0–3) and 3 (2÷3)(2–3), $p = 0.11$. In SLAC/SNAC stage I, the OARSI score variability ranges from 1–2 to 4, in stage II — from 2 to 4–5, in stage III — from 3–4 to 5. The osteonecrosis score in the compared subgroups was 2 (1÷2)(1–3), 3 (2÷3)(1–3), and 3 (2÷3)(0–3) ($P^{1-2} = 0.03$; $P^{2-3} = 0.62$; $P^{1-3} = 0.02$).

Discussion The SLAC/SNAC syndrome can be of two types, progressive and stagnant. In the second type, the disease is asymptomatic for a long time. Regardless of the cause of SLAC / SNAC syndrome, all patients with wrist osteoarthritis experience irreversible osteonecrosis of the subchondral bone and bone marrow, which probably reflects the degree of acute or chronic damage to the vessels that feed the bone.

Conclusion With a general tendency for greater degenerative changes in the articular cartilage at a higher stage of SLAC/SNAC syndrome, their histological manifestations vary between individuals at each stage. Osteonecrosis of the subchondral bone is more common in SLAC / SNAC stages II–III than in stage I.

Ключевые слова: SLAC / SNAC syndrome, wrist osteoarthritis, articular cartilage, subchondral bone, histology

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INTRODUCTION

The wrist consists of eight small bones and many articulations between them, which are easily injured, and is a component of the wrist joint, one of the most complex joints in the human body that provides multidirectional movements of the hand relative to the forearm [1].

The most common injuries that lead to post-traumatic osteoarthritis of the wrist are ruptures of the scapholunate ligament or non-union of scaphoid fractures that may cause subsequent development of progressive collapse of the wrist, respectively SLAC and SNAC syndromes (scapholunate advanced collapse and scaphoid nonunion advanced collapse) [2]. As literature reviews show, injuries to the scapholunate ligament are often combined with fractures of the radius or scaphoid bones or other wrist injuries [3]. Injuries to the scapholunate ligament can occur secondarily in crystal arthropathies [4]. Moreover, untreated idiopathic avascular osteonecrosis of the lunate and scaphoid bones (Kienböck's disease and Preiser's disease) can also lead to progressive collapse and osteoarthritis of the wrist [5].

The common factor in the development of SLAC and SNAC syndromes is instability of the scaphoid bone. Therefore, they manifest themselves in a similar and predictable sequence of degenerative changes in the wrist joints [6–10], which are clinically significant: pain during exercise and at rest, restricted range of motion and reduced strength of the wrist grip. The diagnosis and progression of the disease are clarified by radiography, computed tomography and magnetic resonance imaging [6, 11], as well as arthroscopy [12].

Histological characteristics of wrist osteoarthritis are the subject of several studies that established significant correlations between destructive changes in the pseudoarthrotic surface of the scaphoid bone with duration of the injury, hypertrophy of the villi of the synovial layer of the wrist joint capsule with the severity of contracture, osteonecrosis in the scaphoid bone with pain severity [13]. In recent years, pain in osteoarthritis has been linked also with damage to the bone marrow of the subchondral bone [14]. These are grounds for continuing studies of the histological manifestations of wrist osteoarthritis, which is necessary to understand the pathogenesis of the disease and develop treatment tactics.

The **purpose** of the work was to determine the relationships between histological features of wrist osteoarthritis and the duration and stage of SLAC/SNAC syndrome.

MATERIALS AND METHODS

The surgical material from 12 patients (10 men and two women) operated on in 2023–2024 for wrist osteoarthritis was analyzed. The patients underwent resection of the proximal row of wrist bones or quadrilateral arthrodesis.

The age of the patients at the time of surgery ranged from 20 to 65 years (41.50 ± 15.88), the age at the time of injury or the onset of the first symptoms of the disease ranged from 17 to 64 years (35.86 ± 17.04).

Ten patients had a history of trauma (83 %): low-energy in eight (fall from standing height on the hand), high-energy in two (road accident in one and a ball hit in sports in the other), two patients denied trauma. The time since the injury or the onset of pain syndrome in the case of injury denial varied from eight months to 22 years (5.64 ± 7.6).

Four patients (33 %) were diagnosed with SLAC syndrome, and the remaining eight patients were diagnosed with SNAC syndrome. According to the radiological finding, stage I osteoarthrosis (classifications of Vender et al., Watson & Ballet [15]) was detected in two patients, stage II in six patients, and stage III in four patients. Based on radiometric data, DISI (instability of the intercalary segment) deformity was detected in 10 patients (83 %).

The study was conducted in accordance with the ethical standards of the 2013 Helsinki Declaration and approved by the Ethics Committee of the institution (protocol dated 07.10.2022 No. 2 (72)).

The surgical material (removed lunate and/or scaphoid bone or fragments of the latter) was fixed in a 10 % neutral formalin solution. After decalcification in a mixture of formic and hydrochloric acid solutions, the material was subjected to histological processing in a HISTOSAFETM INFILTRATM apparatus for vacuum processing of tissues (ErgoProduction LLC, Russia).

Histological micropreparations (paraffin sections produced with HM450 Thermo Scientific microtome (USA) were stained with hematoxylin and eosin or the Masson three-color method. An AxioScope. A1 microscope with an AxioCam ICc 5 camera and Zenblue software (Carl Zeiss Micro Imaging GmbH, Germany) was used to obtain digital images of the micropreparations. Changes in the articular cartilage were assessed according to the international OARSI scale [16] in a blinded manner.

The extension of subchondral bone necrosis was determined semi-quantitatively (0 to 3 points) in 3–10 fields of view from each patient (78 fields in total) at an instrumental magnification of 400×: 0 points — no signs of necrosis; 1 — signs of osteocyte death involve up to a third of the visual field area; 2 — up to two-thirds of the visual field area; 3 — up to three-thirds (100 %) of the visual field (manifestation of necrotic changes).

For statistical processing of quantitative data, the Excel Attestat application, version 9.3.1 (developer I.P. Gaidyshev, certificate of registration in Rospatent No. 2002611109) was used. Given the small number of compared patient subgroups, hypotheses about differences were tested using the nonparametric Mann – Whitney criterion.

RESULTS

In most patients ($n = 9$), the disease duration did not exceed four years, and in three patients it ranged from 10 to 22 years (Table 1). In the cases of disease duration of less than 4 years ($n = 9$), the articular cartilage assessment according to the OARSI scale varied from 1–2 to 5 points, with a disease duration of 10 to 22 years — from 3–4 to 4–5 points. In SLAC/SNAC stage I, the variability of OARSI assessments was from 1–2 to 4, with SLAC/SNAC stage II — from 2 to 4–5, with SLAC/SNAC stage III — from 3–4 to 5. All patients were found to have extended subchondral bone necrosis, which occupied from 56.67 % to 100 % of the tested area.

The lowest articular cartilage damage (grade 1–2) was observed in one patient (Fig. 1). The articular surface was not disfibered; destructively altered chondrocytes and empty cellular lacunae were detected in the superficial zone. The basophilic line was not detected, the subchondral bone plate was absent in some places, and areas of bone marrow pannus penetration were noted (Fig. 1a). In the subchondral zone, the integrity of the trabecular network was disrupted, osteolysis was pronounced, bone trabeculae with small interstitial osteonecrosis were encountered (Fig. 1b), signs of reparative osteogenesis were noted – osteoblasts on the surface of bone trabeculae (Fig. 1c). Fatty bone marrow, large accumulations of sludged erythrocytes, and erythrocytes outside the vessels predominated in the intertrabecular spaces (Fig. 1c).

OARSI grade 3 cartilage damage was also detected in one patient (Fig. 2). The articular cartilage was present throughout, the superficial zone was defibered, detachment of small cartilage fragments was pronounced, and areas with synovial pannus were encountered (Fig. 2a). The thickness of the calcified cartilage was increased and amounted to $\frac{1}{2}$ – $\frac{2}{3}$ of the non-calcified cartilage.

In the subchondral zone, the integrity of the trabecular network was disrupted, the trabeculae had small interstitial osteonecroses (Fig. 2 b), and signs of reparative osteogenesis were noted (Fig. 2c). Bone marrow fibrosis was present and there were sludged erythrocytes in the vessels.

Table 1

Main characteristics of patients and of surgical material

| No | Age, years | Time since injury, years | Radiographic stage SLAC / SNAC | Cartilage evaluation (OARSI) | Osteonecrosis of subchondral bone (% of tested area) |
|-----|------------|--------------------------|--------------------------------------------------------------------|------------------------------|------------------------------------------------------|
| 1. | 48 | 2,33 | SNAC II | 4 | 100.00 |
| 2. | 23 | 2 | SLAC II Lunate bone necrosis | 4–5 | 75.00 |
| 3. | 41 | 20 | SNAC II | 4 | 93.33 |
| 4. | 61 | 1,5 | SLAC III | 4–5 | 93.33 |
| 5. | 41 | 10 | SNAC III | 3–4 | 86.67 |
| 6. | 51 | 22 | SNAC III | 4–5 | 100.00 |
| 7. | 20 | 2,25 | SNAC I | 1–2 | 56.67 |
| 8. | 31 | 0,75 | SLAC II | 2–3 | 76.67 |
| 9. | 36 | 1,17 | SNAC II | 2 | 89.00 |
| 10. | 21 | 3,6 | SNAC I Aseptic necrosis of the distal pole of the scaphoid bone | 4 | 77.67 |
| 11. | 60 | 1,42 | SLAC II | 2 | 100.00 |
| 12. | 65 | 0,67 | SLAC III | 5 | 70.83 |

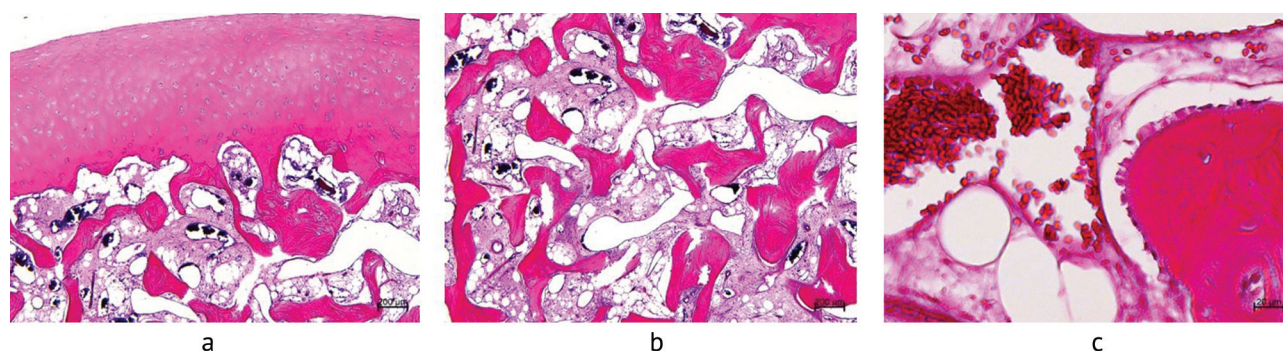


Fig. 1 Photos of micropreparation of patient L, 20 years old (SNAC I, disease duration 2.3 years, OARSI 1–2: (a) general view of the articular cartilage; (b) subchondral zone; (c) sludged erythrocytes, osteoblasts on the surface of bone trabecula. Hematoxylin and eosin staining. Magnification ×40 (a, b), ×400 (c)

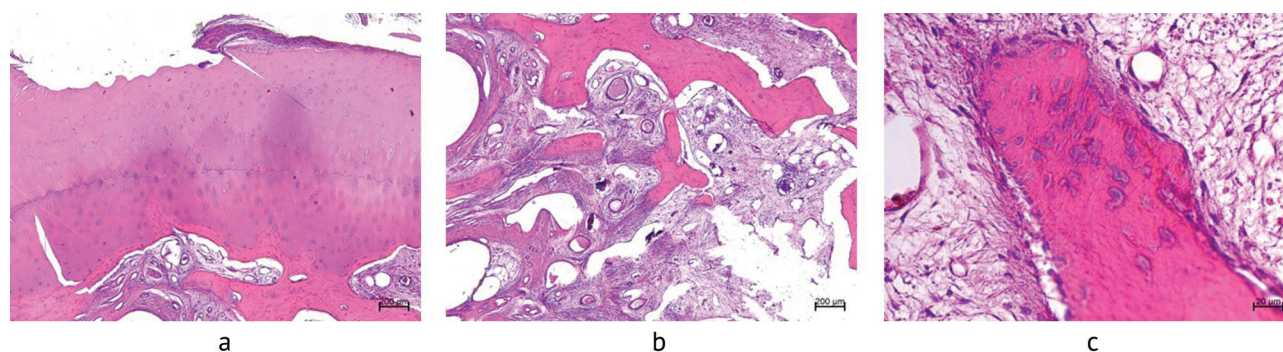


Fig. 2 Microphotos of preparations of patient P, 31 years old (SLAC II, 0.75 years old, OARSI 3): (a) focus of defibering in the superficial zone, synovial pannus; (b) trabeculae with interstitial osteonecrosis, bone marrow fibrosis; (c) newly formed trabeculae surface lined with active osteoblasts. Hematoxylin and eosin staining. Magnification ×40 (a, b), ×400 (c)

OARSI grade 3–4 cartilage lesions were detected in four patients (two with a disease history of less than four years and two from the group with a history of 10 to 22 years). Throughout the entire length, detachment of the superficial and intermediate zones of cartilage is pronounced, so that the articular surface is represented by a deep zone over a large area (Fig. 3a). Areas of replacement of the deep cartilage zone with bone tissue and a new formation of the basophilic section were detected (Fig. 3b). Pronounced necrosis of the subchondral bone was accompanied by smooth resorption, delamination of the ground substance of trabeculae along the adhesion lines. Signs of reparative osteogenesis were not pronounced. Unilocular and bilocular cysts were encountered (Fig. 3c).

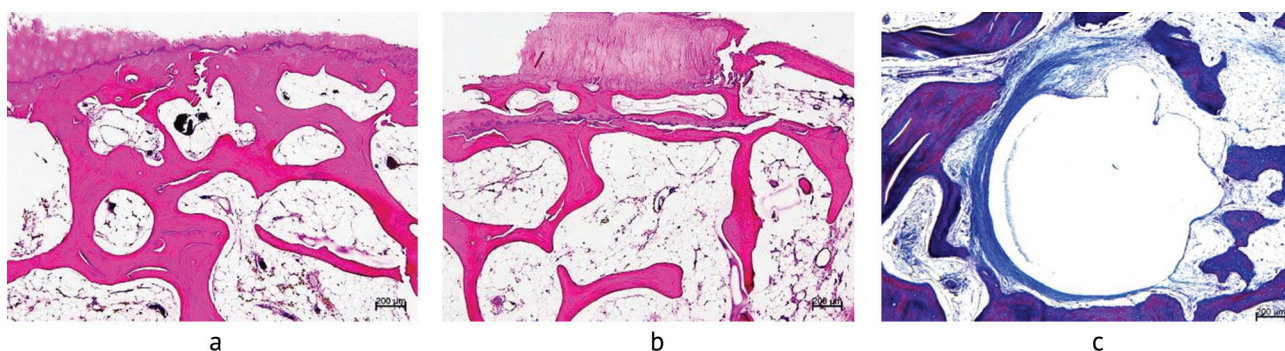


Fig. 3 Microphotos of preparations of patient I, 48 years old (SNAC II, disease duration 2.33 years old, OARSI 3–4): (a) the articular surface is represented by a defibred deep zone of cartilage; (b) progression of the bone formation process towards the articular surface, neoplasm of the basophilic section; (c) subchondral zone, cyst with a thick fibrous capsule. Staining with hematoxylin and eosin (a, b) and the Masson trichrome method (c). Magnification $\times 40$

Cartilage damage grade 4–5 was also detected in four patients (three with a disease history of up to four years, one with a history of 10 to 22 years). The articular cartilage was defibred in some places, covered in other places with synovial pannus; there were giant isogenic groups of chondrocytes in the defibering foci (Fig. 4a). Areas of replacement of the deep and intermediate zones from the side of subchondral zone with bone marrow pannus; there was new formation of the subchondral bone plate covered with connective tissue on top (Fig. 4b). Over a large area there was a thin layer of fibrous tissue. Pronounced osteonecrosis of the subchondral bone, rarefaction of bone trabeculae and signs of osteoclastic resorption, cysts were seen. Signs of reparative osteogenesis are weakly expressed.

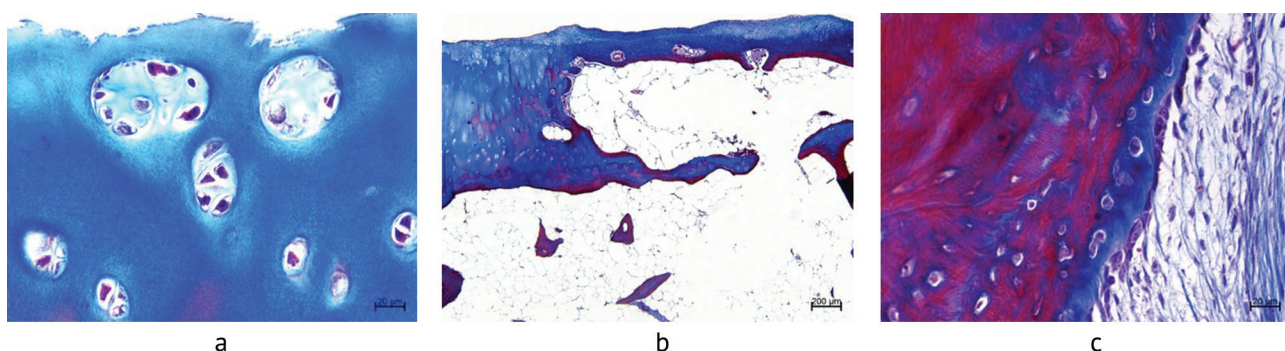


Fig. 4 Microphotos of preparations of patient D, 61 years old, (SLAC III, duration of disease 1.5 years, OARSI 4–5: (a) multi-membered isogenic groups of cells, (b) replacement of articular cartilage with bone marrow pannus, neoplasm of the basophilic section, (c) active osteoblasts on the surface of the subchondral bone plate, bone marrow fibrosis. Staining with the Masson trichrome method. Magnification $\times 400$ (a, c), $\times 40$ (b)

Articular cartilage damage grade 5 was detected in one patient with a disease history of less than a year (Fig. 5), who denied injury. The articular surface was represented by exposed bone tissue since the articular cartilage was absent (Fig. 5a). Severe osteonecrosis, osteolysis, stratification

of the ground substance of bone trabeculae was present (Fig. 5b). There was necrotic detritus in the intertrabecular spaces. Foci of reparative osteogenesis, newly formed trabeculae and extended areas of fibrous replacement of bone marrow are noted (Fig. 5c).

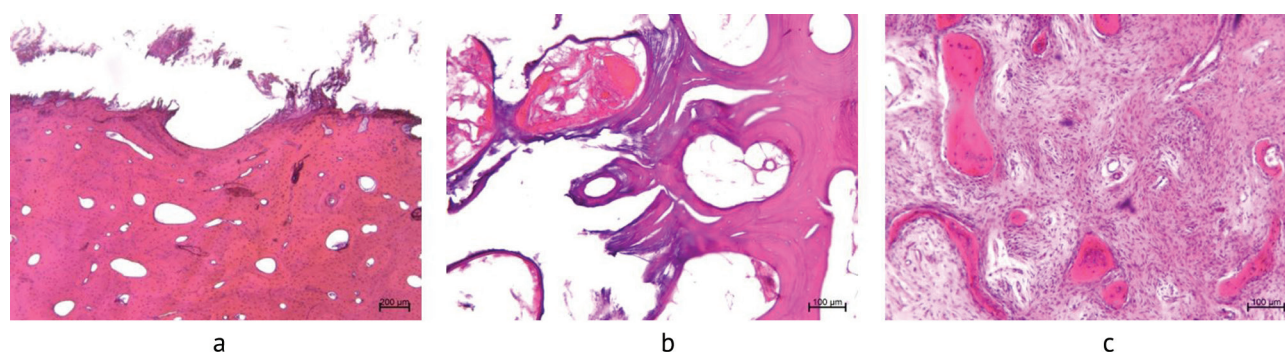


Fig. 5 Microphotographs of patient K., 65 years old (SLAC III, 0.67 years of disease duration, OARSI 5): (a) articular surface is represented by subchondral bone; (b) osteolysis, stratification of the main substance of bone trabeculae; (c) foci of reparative osteogenesis. Hematoxylin and eosin staining. Magnification $\times 40$ (a), $\times 100$ (b, c)

The osteonecrosis score varied from 0 to 3 points in patients with disease history of up to four years and from 2 to 3 points in patients with disease history of 10 to 22 years, the differences being statistically insignificant (Table 2). The median osteonecrosis score was lower in SLAC/SNAC stage I compared to stages II and III at a significance level of 0.05 (Table 3).

Table 2

Osteonecrosis evaluation (points) in regard to disease duration

| Duration of SLAC / SNAC syndrome | Evaluation in points Me (Q1÷Q3) (min–max) | <i>p</i> |
|-------------------------------------|-------------------------------------------|----------|
| Less than 4 years (<i>n</i> = 9) | 3 (2÷3) (0–3) | 0.11 |
| From 10 to 22 years (<i>n</i> = 3) | 3 (2÷3) (2–3) | |

Table 3

Osteonecrosis evaluation (points) in regard to osteoarthritis stage

| Osteoarthritis stage | Evaluation in points Me (Q1÷Q3) (min–max) | <i>p</i> |
|---------------------------------|-------------------------------------------|--------------------|
| SLAC / SNAC I (<i>n</i> = 2) | 2 (1÷2) (1–3) | $P^{1-2} = 0.03^*$ |
| SLAC / SNAC II (<i>n</i> = 6) | 3 (2÷3) (1–3) | $P^{2-3} = 0.62$ |
| SLAC / SNAC III (<i>n</i> = 4) | 3 (2÷3) (0–3) | $P^{1-3} = 0.02^*$ |

Note: * – $p < 0.05$ Mann – Whitney test

DISCUSSION

This is the first study that assessed the articular cartilage damage according to the international OARSI scale and used semi-quantative evaluation of subchondral bone necrosis in wrist osteoarthritis caused by the developed SLAC / SNAC syndromes.

The hyaline cartilage of the wrist bones is several times thinner than the cartilage of large joints, but it is not weight-bearing [17]. Therefore, the development of wrist osteoarthritis is preceded in most cases by acute trauma, including in the group of patients studied by us. Chronic trauma to the wrist during manual labor is not considered a proven factor in wrist osteoarthritis [18], but repetitive microtraumas of the wrist in elite athletes are considered a significant etiological factor [19]. Other authors described widening of the scapholunate space of nontraumatic etiology, which with age causes progressive instability and osteoarthritis of the wrist [20]. However, some patients may not remember the episode of the injury.

As the study showed, regardless of the anamnesis, degeneration of the cartilage of the articular surfaces of the wrist bones developed in most cases within a period of less than four years, and in some cases, less than a year. However, subchondral bone necrosis was detected in all patients and was irreversible, since in no case was it classified as class 1, in which ischemic events do not disrupt the continuity of bone trabeculae, despite the death of osteocytes [21]. Disruption of continuity, lysis and rarefaction of bone trabeculae were expressed in all the cases studied, which reflects the nature and consequences of wrist collapse. The intertrabecular spaces contained predominantly fatty bone marrow; in most patients, areas of its fibrous replacement and cystic degeneration were detected.

The obtained findings suggest the limited possibilities of organ-preserving and chondroplastic surgeries in osteoarthritis of the wrist. According to the international literature reports, radiofrequency chondroplasty performed during wrist arthroscopy creates a high risk for the survival of chondrocytes [22]. A method of bone marrow stimulation thorough arthroscopic drilling has long been recommended for the relief of chronic post-traumatic pain in the wrist, but the technique has not been widely used in clinical practice [23]. One patient after conservative treatment failure for osteoarthritis of the wrist underwent juvenile cartilage allograft plasty [24]; osteochondral auto- and allografts were used to treat cartilaginous defects of the wrist in small groups of two and three patients [25, 26], and costal cartilage grafts as a spacer were used in the treatment of patients with Kienböck's disease [27, 28]. Information on the effectiveness of these methods is currently insufficient.

The gold standard of surgical treatment of SLAC/SNAC syndrome today remains “salvage” operations (resection of the proximal row of wrist bones and quadrilateral arthrodesis), which allow to relieve pain and maintain acceptable functions of the hand [29, 30]. However, the problem of optimal treatment in young patients with initial manifestations of wrist osteoarthritis remains unsolved.

For the development of treatment technologies, further study of clinical and pathological variants of the course of wrist osteoarthritis depending on the mechanism of injury, types of activity, gender and age of patients seems promising. The data obtained indicate that SLAC / SNAC syndrome can have two types of its course, progressive and stagnant. The second type of the disease remains asymptomatic for a long time. Regardless of the cause of SLAC / SNAC syndrome (rupture of the scapholunate ligament, fracture of the scaphoid bone or idiopathic necrosis of the scaphoid or lunate bones), wrist osteoarthritis is accompanied by irreversible osteonecrosis of the subchondral bone and bone marrow in all cases. This fact probably reflects the severity of acute or chronic damage to the vessels feeding the bone.

CONCLUSION

With a general tendency for greater degenerative changes in the articular cartilage at a higher stage of SLAC/SNAC syndrome, their histological manifestations vary between individuals at each stage. Osteonecrosis of the subchondral bone is more common in SLAC / SNAC stages II-III than in stage I.

Conflict of interests None.

Ethical approval The study was approved by the institutional ethics board, protocol (72) dated 07.10.2022).

Informed consent All patients gave informed consent on participation in the study.

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Information about the authors:

Nathalia A. Shchudlo — Doctor of Medical Sciences, Leading Researcher,
nshchudlo@mail.ru, <https://orcid.org/0000-0001-9914-8563>;

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

Shyngys K. Kuttygul — post-graduate fellow, artana.kaz@gmail.com, <https://orcid.org/0009-0009-1072-468X>.



The role of microbiological methods in diagnosis of periprosthetic joint infection in patients with aseptic loosening of total hip arthroplasty

S.A. Linnik¹✉, E.A. Orishak¹, A.M. Ermakov², I.O. Kucheev³, L.Yu. Nilova¹, E.M. Fadeev¹, G. Karagezov¹, D.Yu. Korshunov⁴, Ya.B. Tsololo¹, V.V. Usikov¹, A.V. Polikarpov³

¹ North-Western State Medical University n.a. I.I. Mechnikov, Saint Petersburg, Russian Federation

² Ilizarov National Medical Research Centre for Traumatology and Orthopedics, Kurgan, Russian Federation

³ Hospital for war veterans, Saint Petersburg, Russian Federation

⁴ Federal Center for Traumatology, Orthopedics and Endoprosthetics, Smolensk, Russian Federation

Corresponding author: Stanislav A. Linnik, stanislavlinnik@mail.ru

Abstract

Introduction Instability of the total hip arthroplasty is a common complication and an indication for revision arthroplasty. The implant instability is diagnosed as aseptic with no microbiological culture growth to be obtained through preoperative synovial aspiration. Etiological interpretation of intraoperative findings in cases of so-called "aseptic instability" is critical for determining subsequent treatment strategies.

The **objective** was to determine the role of microbiological methods in diagnosing periprosthetic joint infection (PJI) of the hip.

Material and methods A bacteriological analysis was produced for 173 patients with aseptic instability of total hip replacement. The patients aged 27 to 82 years. Based on laboratory, clinical and microbiological (MB) findings, the patients were divided into two groups. The first group consisted of 118 (68.2 %) patients who underwent one-stage revision and had a favorable postoperative prognosis. The second group consisted of 55 (31.8 %) patients with elevated hematological parameters, local signs of inflammation, positive MB findings and had unfavorable prognosis. These patients underwent two-stage revision arthroplasty. Biopsy samples were tested using polymerase chain reaction (PCR) in cases of minimal microbial load.

Results Positive MB results were registered in 5.1 % of patients in the first group and in 25.5 % of patients in the second group. Intraoperative biopsies revealed positive results in 20.3 % of the first group and 30.9 % of the second group. PCR identified PJI in 7.5 % of MB biopsies and in 19.6 % of aspirates.

Discussion The findings indicated low diagnostic value of microbiological cultures with PCR improving diagnostic accuracy by 7.5 %. Detection of low-virulence microorganisms including coagulase-negative staphylococci required specific evaluation criteria.

Conclusion Microbiological culturing demonstrated moderate sensitivity, in low-virulence infections, in particular, while PCR in low-virulence infections was essential in establishing the microbial etiology of PJI.

Keywords: joint replacement, periprosthetic joint infection, coagulase-negative staphylococci, hip joint, joint instability, microbiological studies, polymerase chain reaction

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INTRODUCTION

Total hip arthroplasty (THA) in the treatment of patients is an effective and safe orthopedic procedure in foreign and Russian surgical practice [1, 2]. With an increase in joint replacement surgeries, the number of complications increases, the most severe of which is Periprosthetic joint infection (PJI) is one of the most challenging and devastating modes of failure following arthroplasty procedures. PJI is estimated to occur in approximately 5–10 % of the replacements [2–7]. Aseptic loosening is a common late complication (20.0–50.3 % of cases) and the most common reason for revision THA [8, 9]. Instability of one or both endoprosthetic components is the predominant cause of aseptic revision THA in 38.1 % of cases according to the registry of the EP of the Vreden Russian Research Institute of Traumatology and Orthopedics. Aseptic loosening of THA reaches 50.3 % of primary revisions and ranks second in frequency after infectious complications and amounts to 20.8 % of re-revisions [8, 10–12].

Preoperative differential diagnosis of PJI and aseptic instability is challenging, especially in the presence of low-virulence pathogens and biofilm-associated infections [13–15]. Cases of suspected aseptic instability of THA can be caused by an undetected infection, which can be verified by in-depth microbiological testing (MBT). An individual reaction of the body to the implant is one of the reasons for aseptic loosening of the implant.

PJI manifests as instability in the operated joint and pain without changes in biochemical parameters, blood cellular reactions or signs of inflammation. The so-called “aseptic instability” of THA may be caused by a subclinical infection caused by low-virulent pathogens, representatives of the patient’s or staff’s microbiota [16–19]. Due to a vague clinical picture and the absence of early laboratory hematological parameters, MBI is prescribed only at the stage of manifestation of signs of exacerbated infectious process, when the microbial component is obvious. Intraoperative infection is one of the reasons for PJI which manifests during the period from several weeks to several months after surgery.

Examination of periprosthetic tissue samples and synovial fluid is the “gold standard” of MBI. The sensitivity is the key limitation of the bacteriological method which usually requires a content of at least 10^3 CFU of microbial cells in the material. Growth of microorganisms can be absent with use of standard bacteriological methods which may be associated with the insignificant quantity and with antibacterial therapy administered before sampling [20–23].

Gram-positive bacteria *S. aureus* and *S. epidermidis* are common etiological agents of PJI with an incidence rate of 60 %. Much less frequently (up to), Gram-negative bacteria and their associations are described as less common causative agents of PJI with reported incidence of 17 % [24–26]. Virulence factors of staphylococci, which include surface proteins that promote tissue colonization, a polysaccharide capsule, protein A, carotenoids, exotoxins, etc., are most characteristic of *S. aureus*.

The presence of a clinical equivalent allows the authors to suggest that a significant portion of the infection is caused by weakly virulent pathogens with a characteristic subclinical course of the infectious process. In such cases, it seems logical to discuss the etiological role of coagulase-negative staphylococci, among which *S. epidermidis*, *S. simulans*, *S. hominis*, *S. capitis*, *S. caprae* and *S. lugdunensis* were of isolated [27–30].

Instability of the implant after THA is a common complication and serves as an indication for revision THA. Growth of weakly virulent microflora have been recently reported with deep MBI of removed implants, and the implant instability cannot be considered aseptic. Diagnostic

algorithms for identifying this pathology continue to be developed and improved because of the lack of a diagnostic test that would allow 100 % detection of PJI.

The **objective** was to determine the role of microbiological methods in diagnosing PJI of the hip.

MATERIAL AND METHODS

The results of different diagnostic methods for PJI were evaluated in 173 patients with aseptic instability of endoprosthetic components, including 61 (35.3 %) male and 112 (64.7 %) female patients aged 27 to 82 years (53.7 ± 7.4). The patients were treated at the Trauma and Orthopedic Clinic of the I.I. Mechnikov North-Western State Medical University between 2020 and 2023. Primary THA was performed for osteoarthritis, femoral neck fractures, and aseptic necrosis of the femoral head. Instability of the endoprosthetic components developed at 1 to 12 years (5.8 on average) after primary endoprosthetic procedures.

Postoperative wounds healing was examined after primary arthroplasty, during postoperative period, the nature and frequency of pain at the operation site prior to instability signs. Signs of inflammation (edema, hyperemia, hyperthermia), the joint function were locally evaluated at the operation site. Preoperative history of 55 patients with endoprosthetic instability showed increased body temperature (up to 38°), greater leukocyte, ESR, CRP count. Diagnostic significance of screening results, including preoperative MBI in the period of re-endoprosthetics, was assessed based on laboratory and clinical findings.

Patients were divided into two groups for prognosis, the choice of treatment strategy and diagnostic findings depending on laboratory, clinical data and MBI evaluated with the EBJIS 2021 criteria. The first group consisted of 118 (68.2 %) patients showing no increase in hematological parameters (leukocytosis, CRP, ESR, neutrophilia, etc.) after primary arthroplasty, no inflammation at the operating site having negative MBI results, i.e. patients with a prognostically favorable postoperative course. These patients underwent one-stage re-arthroplasty. The second group, prognostically unfavorable, consisted of 55 (31.8 %) patients with elevated hematological parameters and local signs of inflammation, an unfavorable postoperative course after primary THA and positive MBI results. Patients in this group underwent two-stage re-arthroplasty upon admission to the clinic.

All patients underwent a comprehensive clinical, hematological and microbiological examination before revision arthroplasty according to the algorithms of international professional societies (Musculoskeletal Infection Society MSIS 2018, European Bone and Joint Infection Society EBJIS 2021).

Clinical and laboratory findings including ESR, CRP counts, leukocytosis, erythrocyte and polymorphonuclear neutrophils synovial count were used to predict PJI. Ultrasound-guided MBI punctures were produced by three-fold puncture from the joint cavity before revision arthroplasty that was performed in all 173 patients with unstable THA: 118 patients of the first group with a favorable prognosis underwent one-stage re-arthroplasty, and 55 patients of the second group underwent two-stage re-arthroplasty.

Removal of unstable components, collection of biopsies for MBI, thorough washing of the surgical wound using pulse lavage, ultrasonic treatment of the surgical wound and installation of a revision implant were performed for patients of the first group. Revision arthroplasty system was selected individually depending on local changes in the operated joint (presence of bone defects, osteoporosis, condition of soft tissues). Patients with an unfavorable prognosis underwent two-stage re-arthroplasty. Debridement was produced first. Biopsy samples (at least five) were taken for MBI after removal

of unstable endoprosthetic components, bone cement and other foreign bodies (screws, wire, etc.), an articulating spacer was normally placed after thorough washing of the surgical wound and the ultrasound treatment. Special molds were used to prepare a two-component spacer with the size selected individually depending on the diameter of the acetabulum and the bone canal of the femur. An antimicrobial composition of prolonged action was used to manufacture the spacer (patent No. 2019109897). The final re-arthroplasty was performed after 3–4 months using revision systems.

Patients of the first group received antibiotic (cefazolin) for prophylaxis for 3–5 postoperative days. Patients of the second group received a course of parenteral antibacterial therapy (approved by a clinical pharmacologist, depending on the microflora identified during MBI) for 7–10 days, followed by oral antibiotic therapy for 6–8 weeks.

MBI of biomaterial obtained intraoperatively is a diagnostically significant method in PJI, especially when identifying microorganism strains of the same phenotype from two or more intraoperative samples [29–32]. Intraoperative extraction of several samples for MBI was performed in all patients. Unstable endoprosthetic components (cup, liner, stem, head) removed, underlying altered tissues, material from the femoral canal and acetabulum, synovial fluid, periprosthetic membrane (if present), smears from the wound and bone pieces were examined.

The samples were cultured on an extended set of nutrient media to isolate aerobic, facultative anaerobic and obligate anaerobic microorganisms and micromycetes. A generally accepted semi-quantitative method with sieving was used, which does not allow for accurate weighing of the material and reliable calculation of the concentration of the pathogen. The growth was assessed according to the categories “from enrichment medium”, “sparse”, “moderate”, “abundant”, “confluent”, which implied the following criteria: when isolating on a dense nutrient medium, growth of 10 colonies of microorganisms of a certain type was assessed as scanty; rated as moderate with 10 to 100 colonies and abundant with greater than 100 colonies.

With continuous growth of microorganisms being not countable, the growth was designated as “confluent”. A reserve enrichment seeding was performed on thioglycollate and sugar broths, followed by seeding on solid media. After washing, the prosthetic fragments (cup, liner, stem, head) were aseptically placed either in wide-necked bottles with liquid nutrient medium or (depending on size) in specially prepared sterile containers with liquid media that ensure complete immersion of the components. The standard method of incubating enrichment cultures involved seeding on solid media after 16–18 hours. In cases of incubating prosthetic components, cultivation in a liquid nutrient medium was prolonged to 72 hours.

Standardized biochemical systems, the MALDI TOF mass spectrometry method were used for identification of various groups of microorganisms.

A cultural study of the material obtained before and during revision arthroplasty does not fully resolve the problem of interpreting the results and assessing the etiological significance of findings with an extremely low microbial load, and does not always allow a diagnosis of PJI. Additional microbiological methods are essential for similar results obtained by different methods interpreting the findings as significant. Therefore, samples obtained during revision arthroplasty were examined with in the polymerase chain reaction (PCR). The theoretical sensitivity of PCR is 1 microbial cell in the test material; the sensitivity of PCR measures 10^2 – 10^3 microbial cells.

Prior to inoculation into nutrient media, the study material was aliquoted by selecting pieces of tissue and taking swabs from native material and prosthetic components, followed by freezing at a temperature of $-80\text{ }^{\circ}\text{C}$ for PCR testing.

Native material was examined for microbial genes, including resistance genes using a programmable amplifier with a real-time fluorescent signal detection system CFX96 Touch (Bio-Rad). The results were analyzed using the software of the device used for PCR with real-time detection. The graphs of fluorescent signal accumulation were analyzed in the corresponding channels, indicating accumulation of the amplification product of gene fragments of the corresponding microorganisms and/or resistance enzymes. The clinical interpretation of positive PCR results was assessed as a significant component of the inflammatory process.

Genes of methicillin-resistant staphylococci were detected in native material using a set of reagents for identification and quantification of DNA of methicillin-sensitive and methicillin-resistant *S. aureus*, methicillin-resistant coagulase-negative *Staphylococcus spp.* in biological material with the PCR method with hybridization-fluorescence detection AmpliSens® MRSA-screen-titer-FL. The presence of *S. aureus* DNA and the *mecA* gene DNA were analyzed. The samples with established *Staphylococcus spp.* DNA were additionally examined for the presence of *vanA* and *vanB* genes using the AmpliSens® MDR VRE-FL reagent kit.

The kit is intended for the qualitative determination of *Enterococcus spp.* DNA and *vanA* and/or *vanB* genes detected to identify vancomycin-resistant enterococci (VRE) strains. However, *vanA* and *vanB* genes can be detected in *Staphylococcus spp.* in some rare cases aggravating the course of the disease and limits resources for therapy [16, 22, 28].

The study was approved by the Ethics Committee of the Mechnikov North-Western State Medical University and was conducted in accordance with the ethical standards set out in the Declaration of Helsinki. Informed consent for publication of the findings was obtained from all patients.

STATISTICA 10 software was used for statistical processing of the results. Quantitative parameters were determined using nonparametric methods χ^2 , Fisher and Mann – Whitney tests. Differences between groups were considered statistically significant at $p < 0.05$.

RESULTS

Patients were representative in terms of gender in both groups. The average age of patients was 57 years (IQR 49–70) in the first group and 61 years (IQR 48–67) in the second group ($p > 0.05$). The median levels of leukocytosis, ESR, and CRP did not differ significantly between the groups prior to re-arthroplasty and measured: $7.8 \times 10^9/L$ and $8.1 \times 10^9/L$; 15.8 mm/h (IQR 13–28) and 19 mm/h (IQR 13–32); 5.0 mg/mL (IQR 1.52–6.7) and 3.5 mg/mL (IQR 1.9–6.1) ($p > 0.05$) in the first and second groups, respectively.

Of 173 patients, positive results of MBI punctures prior to re-arthroplastic surgery were detected in 20 (11.6 %) patients including six (5.1 %) patients in the first group and 14 (25.5 %) cases in the second group. Positive results were mainly represented by coagulo-negative staphylococci ($n = 14$; 70.0 %), gram-negative ($n = 3$; 15.0 %) and microbial associations ($n = 5$; 25.0 %).

Intraoperative MBI of tissue biopsies is essential for the diagnosis of PJI. Positive results were detected in 41 (23.7 %) patients, which is twice as often ($p < 0.05$) as from those taken preoperatively (OR = 2.0; 95 % CI 13.4–22.3). Positive results were obtained in 24 (20.3 %) patients of the first group and in 17 (30.9 %) cases of the second group, which is ($p < 0.05$) twice as high as from preoperative punctures (Table 1).

Table 1

Inoculation with MBI prior to, during and after arthroplasty

| Groups of patients | Number of positive MBI results (culturing) | | | | | |
|--------------------|--------------------------------------------|------|-----------------------|------|---------|------|
| | Preoperative punctures | | Intraoperative biopsy | | Post-op | |
| | abs. | % | abs. | % | abs. | % |
| Group I | 6 | 5.1 | 24 | 20.3 | 7 | 5.9 |
| Group II | 14 | 25.5 | 17 | 30.9 | 6 | 10.9 |

The patients with positive MBI puncture results had positive intraoperative MBI biopsy results. The microbial landscape in 31 (75.6 %) patients with positive punctures coincided with the microbiota obtained during joint puncture in patients with unstable implant.

According to the EBJIS 2021 criteria, PJI was diagnosed in 20.3 % of cases in the first group, and was 1.5 times more common in the second group of patients (30.9 %) ($p < 0.05$).

DNA of significant microorganisms was detected with PCR indicating the presence of PJI in 54 (31.2 %) patients, including 24 (43.6 %) patients in the second group and 30 (25.4 %) patients in the first group. On average, the PCR test could improve the diagnosis of PJI with MBI biopsy by 5.1 % in the first group and by 12.7 % in the second group.

The PCR method allowed us to identify 7.5 % more cases of PJI than with MBI biopsy in both groups, and by 19.6 % greater ($p < 0.05$) than with MBI punctates. The PCR method significantly improved ($p < 0.05$) detection of PJI by 20.3 % after MBI punctures and by 5.1 % after MBI biopsies in the first group, and, PJI was determined ($p < 0.05$) more often in the second group, by 18.1 % and 12.7 %, respectively (Tables 2, 3).

Short-term results (up to 6 months) were reviewed in the patients of both groups (Table 4).

Table 2

Results of culturing and molecular biological research methods

| Groups of patients | Number of patients with positive results | | | | | |
|-----------------------|------------------------------------------|------|-----------------------|------|------|------|
| | Preoperative punctures | | Intraoperative biopsy | | PCR | |
| | abs. | % | abs. | % | abs. | % |
| Group I ($n = 118$) | 6 | 5.1 | 24 | 20.3 | 30 | 25.4 |
| Group II ($n = 55$) | 14 | 25.5 | 17 | 30.9 | 24 | 43.6 |
| Total ($n = 173$) | 20 | 11.6 | 41 | 23.7 | 54 | 31.2 |

Table 3

Quantification of *S. aureus* DNA and *mecA*, *vanA*, *vanB* gene in the diagnosis of PJI

| Groups of patients | Description | Quantification | | | | | |
|--------------------|------------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|------|------|
| | | DNA MSSA | DNA MRCoNS | DNA MRSA | DNA MRS spp. | vanA | vanB |
| Group I | cases of detection of staphylococcal DNA | 6 | 21 | 2 | 1 | – | – |
| | copies/ml sample | $1.1-2.7 \times 10^4$ | $2.4-9.0 \times 10^5$ | $5.8-8.8 \times 10^3$ | 1.2×10^3 | | |
| Group II | cases of detection of staphylococcal DNA | – | 18 | 3 | 3 | – | – |
| | copies/ml sample | – | $1.0-9.4 \times 10^4$ | $1.4-3.1 \times 10^4$ | $1.2-7.7 \times 10^3$ | | |
| Total | 6 | 6 | 39 | 5 | 4 | | |

Table 4

Healing of surgical wounds after re-arthroplasty

| Groups of patients | Number of patients | | | | | |
|-----------------------|------------------------------|------|--------------------------------|------|--------------------|------|
| | Healing by primary intention | | Healing by secondary intention | | Infected, fistulas | |
| | abs | % | abs | % | abs | % |
| Group I ($n = 118$) | 94 | 79.7 | 8 | 6.8 | 16 | 13.5 |
| Group II ($n = 55$) | 36 | 65.4 | 9 | 16.4 | 10 | 18.2 |

Postoperative wounds healed by primary intention in 94 (79.7 %) patients of the first group, which was more common ($p < 0.05$) than that in the second group amounting to 36 (65.4 %) patients. Surgical wound got infected and sinuses developed in 26 (15.0 %) patients including 13.5 % in the first group and was less common ($p < 0.05$) than that in the second group (18.2 %).

Infection was observed in three patients in each group (12.5 % and 16.7 %, respectively). Low-virulent staphylococci were cultured postoperatively with positive PCR results and negative MBI punctures and biopsies. In two cases in each group, in addition to the gram-positive microorganisms identified during the MBI, new gram-negative non-fermenting bacteria *Pseudomonas aeruginosa* were detected.

A significant limitation of MBI (cultural research) includes the limited sensitivity from the standpoint of the need for a sufficient microbial load per unit volume of the material to be able to interpret the results. If a negative result is obtained in culturing, the lower limit of the method's sensitivity is determined by the seeding dose. With seeding on dense nutrient media microbial growth can be detected only under a microbial load of at least 100–1000 microbial cells per ml of the material being examined. New, more sensitive, molecular biological methods are to be introduced. A complex microbiological diagnosis will help to expand diagnostic capabilities and determine the significance of microorganisms with the low virulence and small quantity. The newly approved clinical guidelines “Infection associated with orthopaedic implants” highlights the importance of culture testing indicating the advantage of molecular biological methods over traditional culture testing in examination of patients with infection caused by low-virulence pathogens.

Long-term outcomes (one year after re-arthroplasty) were reviewed in 103 patients of the first and 47 patients of the second groups. Positive results were obtained in 96 (95.0 %) patients of the first group, which was ($p < 0.05$) 10.8 % higher than that in the second group amounting to 38 (80.5 %). Local infectious complications in the form of PJI were detected in 17 (11.3 %) patients, which is nine less than in the period of 6 months after surgery. It can be associated with stable remission after debridement in the cases. Pathogens identified after arthroplasty in 10 (62.5 %) PJI patients of both groups coincided with pathogens obtained during MBI of preoperative punctures and intraoperative MBI of biopsies. Microorganisms were additionally identified with PCR in six patients (37.5 %).

The findings indicated a low significance of preoperative MBI of punctures. Biopsies taken during re-arthroplastic surgery in patients with aseptic instability of implant allow to detect microbiota twice as often. The use of PCR testing facilitated identification of microflora in 7.5 % of cases in patients with negative MBI results preoperatively and during re-arthroplasty surgery indicating the role of PCR testing in patients with a poor prognosis for PJI with a small number of bacteria (10^2 CFU) or their absence.

Clinical instance

A 54-year-old female patient was treated for instability of the right THA at the trauma and orthopedic clinic. In the anamnesis, before the development of instability of the endoprosthesis components, The patient repeatedly developed signs of inflammation at the site of the operated joint that were arrested by antibiotic therapy. Microorganisms were not detected during MBI of the hip aspirate. Revision arthroplasty was performed for the right hip joint. Microbiological examination of biopsies (periprosthetic tissues, synovial fluid, endoprosthetic components) revealed no growth of microorganisms. PCR of biopsies showed methicillin-resistant coagulase-negative *Staphylococcus spp.* The patient developed an increased body temperature of 37.7°, fever, signs of systemic inflammatory response and postoperative wound inflammation at two weeks. The postoperative wound puncture demonstrated pus and *S. epidermidis* cultured with PJI developed.

Therefore, complex microbiological and PCR (if there are less than 10^3 CFU in 1 cm³) studies allowed us to diagnose PJI and choose the optimal treatment strategy for patients with unstable endoprosthetic components.

DISCUSSION

MBI is a significant diagnostical test [16, 32, 33]. However, the key limitation of MBI is the sensitivity, which normally requires a content of at least 10^2 – 10^3 CFU in 1 cm³ of the test material. In most cases, standard bacteriological methods show no growth of microorganisms, which may be due to the small number or antibacterial therapy before sampling. PCR study was performed for the 55 patients of the second group with a poor prognosis for PJI, and for the 118 patients of the first group. The material was characterized by weak bacterial contamination mainly from the enriched medium. There was a scanty growth or the absence from conditionally abiotic objects (prosthetic components) and significant contamination (from moderate to confluent growth) in some biomaterial samples (joint fluid, smears, tissue fragments).

The quantitative equivalent in terms of the copies/mL of sample appears to be an important component in the development and definition of criteria for the etiologic significance of low-virulence microorganisms including coagulase-negative staphylococci, in the development of PJI. The minimum number of copies (at the level of sensitivity of the bacteriological method) is observed exploring endoprosthetic components with the number of copies corresponding to the etiologically significant number of microorganisms studying muscles, tissues and synovial fluid with the PCR method. The fact may indicate “lost” findings with bacteriological testing as the only method and identification of additional positive findings during a parallel study of the material, including material from endoprosthetic components, using the PCR method. We were able to detect 15 additional cases of staphylococci, which is 14.8 % of additional findings from the staphylococcal isolates previously found during bacteriological examination (101 strains).

According to modern algorithms, opportunistic pathogens isolated from one sample of biomaterial in the absence of other signs of infection do not indicate PJI, while the highly virulent microorganisms isolated even from one sample is diagnostically significant. Opportunistic pathogens isolated from only one sample and absence of pathogen growth in intraoperative biomaterial do not rule out PJI [20]. Inagaki et al. reported 80 % of cases of confirmed PJI with the pathogen being identified in the two samples of biological material, 8.3 % of cases in one sample and the pathogen was not identified in 11.7 % of cases. Recurrent PJI are reported in 21 % of cases [34].

With the century-long history of the bacteriological method, the technology remains relevant and reliable for the majority of clinical scenarios. The bacteriological (cultural) method allows for verification of the pathogen assessing the quantity, sensitivity to antimicrobial drugs using several standardized methods. Although the bacteriological method remains the “gold standard” for validating other modern methods of microbiological diagnosis, it has some limitations including relatively low sensitivity, the exacting nature of individual groups of bacteria that would result in unrepresentative results, lack of confidence in the complete interpretation in case of a positive result or a false negative test [20, 31]. The bacteriological examination of the biomaterial and washings from the endoprosthetic components demonstrated no bacterial growth in 76.3 % of cases in the series. In such cases, joint instability is considered aseptic. With weakly expressed inflammation indicators, low virulence of the prevailing pathogens of PJI, postoperative complications are assessed as aseptic loosening of the construct and does not lead to adequate treatment strategy with mandatory antibiotic therapy. The empirical antibiotic therapy can result in low efficiency of bacteriological examination. The PCR method allowed for identification of microorganisms in 54 (31.2 %) of 173 patients, which was ($p < 0.05$) 7.5 % higher than that from intraoperative biopsies and 19.6 % higher than from preoperative punctures. More significant results were obtained in patients of the comparison groups. The PCR improved diagnosis with puncture from 5.1 % to 25.4 % in the first group, from 11.6 % to 43.6 % in the second group. The MBI biopsy improved diagnosis from 20.3 % to 25.4 % in the first group and from 30.9 % to 43.6 % in the second group.

The material examination detected microorganism DNA with a negative culture result that could be interpreted as etiologically significant with the clinical equivalent being the decisive factor in the case requiring revision operations.

The advantage of the combined methods includes the ability to assess the significance of preoperative findings and provide earlier interpretation rather than repeated bacteriological examination determining the surgical strategy for patients with unstable endoprosthetic components. The PCR method introduced into the examination of intraoperative material would facilitate faster etiological decoding, timely application of targeted antibiotic therapy and selection of surgical strategy.

CONCLUSION

Microbiological test in the diagnosis of PJI demonstrated moderate or high sensitivity (43.5–100.0 %) and high specificity (81.2–100.0 %). The use of microbiological (cultural) testing in preoperative material (punctures) allowed for identification of PJI in 5.1–11.6 % and in 23.7–31.2 % of intraoperative biopsies.

The native material examined with the PCR method can facilitate detection of PJI even in the presence of a low-virulence infection with the microbial cell content being less than 10^3 CFU per 1 cm³ or absent with MBI of the “pre-revision” puncture or intraoperative “revision” biomaterial. Microbiological (culturing) testing demonstrates moderate sensitivity, in low-virulence infections, in particular, with the molecular biological testing (PCR) playing a leading role in establishing the microbial etiology of PJI.

Comprehensive microbiological diagnosis would help expand diagnostic capabilities and determine the significance of microorganisms, even with low virulence and small quantities.

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Informed consent All patients gave informed consent for publication of the study results.

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Information about the authors:

Stanislav A. Linnik — Doctor of Medical Sciences, Professor of the Department, stanislavlinnik@mail.ru, <https://orcid.org/0000-0002-4840-6662>;

Elena A. Orishak — Candidate of Medical Sciences, Associate Professor, elena.orishak@szgmu.ru, <https://orcid.org/0000-0002-4562-4402>;

Artem M. Ermakov — Doctor of Medical Sciences, Head of the Clinic, ema_cab@mail.ru, <https://orcid.org/0000-0002-5420-4637>;

Ivan O. Kucheev — Candidate of Medical Sciences, Head of the Department, 9513533@mail.ru, <https://orcid.org/0000-0001-8557-8431>;

Lyudmila Yu. Nilova — Candidate of Medical Sciences, Associate Professor, lyudmila.nilova@szgmu.ru, <https://orcid.org/0009-0005-8898-9152>;

Evgenii M. Fadeev — Candidate of Medical Sciences, Associate Professor, evgenii.fadeev@szgmu.ru, <https://orcid.org/0000-0002-8428-0876>;

Giorgi Karagezov — orthopaedic surgeon, karagezov_87@mail.ru, <https://orcid.org/0000-0002-5234-1697>;

Dmitrii Yu. Korshunov — Head of the Department, dmi02041976@yandex.ru; <https://orcid.org/0009-0005-9819-0598>;

Yaroslav B. Tsololo — Assistant Department, yaroslav.tsololo@gmail.com, <https://orcid.org/0000-0001-7744-0002>;

Vadim V. Usikov — Candidate of Medical Sciences, Associate Professor, vadim.usikov@szgmu.ru, <https://orcid.org/0000-0002-7642-4665>;

Andrey V. Polikarpov — Head of the Department, multifisher@mail.ru.

Original article

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Clinical and functional outcomes of acute distal tibia fractures treated with Ilizarov external fixation: a retrospective study

M. Dhawan¹, B. Nandan¹, M. Sch. Iqbal^{2✉}, S.K. Singh³, M. Prasad⁴

¹ Sir Ganga Ram Hospital, New Delhi, India

² INHS Asvini, Mumbai, India

³ Apex Hospital, Varanasi, India

⁴ Base Hospital Delhi Cantt, New Delhi, India

Corresponding author: Mohammed Schezan Iqbal, dr.schezaniqbal@gmail.com

Abstract

Introduction Distal tibia pilon fractures are complex injuries involving the tibial articular surface. Managing these fractures requires balancing stable fixation with soft tissue preservation. The Ilizarov technique offers a minimally invasive alternative to traditional open reduction and internal fixation (ORIF), allowing for gradual correction and early weight bearing.

This study **aimed** to evaluate functional and radiological outcomes in patients with distal tibia fractures managed by limited open reduction and Ilizarov fixation.

Materials and Methods The study was conducted in a tertiary care hospital's Department of Orthopaedics over two years. The inclusion criteria were patients aged >18 years with distal tibia fractures. Exclusion criteria included refracture, previous surgeries, and associated vascular injury. The study included 20 patients (18 males, 2 females) with a mean age of 39.2 ± 10.5 years. Most injuries (80 %) were due to road traffic accidents. Fracture patterns were classified according to the AO-OTA classification. The surgical procedure involved placing the patient supine under spinal anesthesia. Traction was applied, and fluoroscopy was used to assess reduction. A three-ring tibial Ilizarov frame was assembled and applied, with additional fixation for the calcaneum. The median time to full weight bearing was 26 days.

Results At frame removal, all cases had ankle stiffness, but two months post-removal, 85 % of cases had full ankle range of motion. The median time to frame removal was 17.5 weeks, and the median time to consolidation was 22 weeks. Patellar tendon bearing cast was applied for 3 weeks followed by a PTB brace with foot extension for the next 4 weeks.

Discussion The Ilizarov technique should be considered as a viable option, especially for complex fracture patterns or cases with compromised soft tissue envelopes not amenable to ORIF.

Conclusion The Ilizarov technique represents a valuable approach for managing distal tibia pilon fractures, demonstrating improved clinical outcomes and minimal complications.

Keywords: Ilizarov method, ankle fractures, pilon fractures, distal tibia fractures, clinical outcomes, functional outcomes

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INTRODUCTION

Distal tibia pilon fractures are notoriously complex injuries, involving the articular surface of the tibia. Managing these fractures requires a delicate balance between achieving stable fixation and preserving soft tissue integrity. The Ilizarov technique allows for gradual correction, axial alignment, and controlled distraction osteogenesis. Unlike traditional open reduction and internal fixation (ORIF), which can be challenging in the presence of compromised soft tissues, the Ilizarov method offers a minimally invasive alternative [1]. Advantages of minimized soft tissue disruption, customizable alignment control, ligamentotaxis with biological stimulation and early weight-bearing, all combined to make it an attractive option in the management of these injuries [2].

Our aim was to observe functional and radiological outcomes in patients with distal tibia fractures managed by limited open reduction and Ilizarov fixation with follow-up at the time of frame removal and three months after frame removal. Our primary objectives were to assess the functional outcomes using the Olerud and Molander ankle score (OMAS) [3]), and ASAMI Functional criteria [4]; and radiological outcomes using Teeny – Wiss radiological scoring system [5], time to consolidation with ASAMI Bone criteria [4]. Pain was assessed by visual analog score (VAS). Secondary objectives included assessment of complications including pin-tract infection, pin loosening, vascular/nerve injury, axial deviation, knee and ankle joint stiffness, skin necrosis, foot drop and post-operative stiffness.

MATERIALS AND METHODS

The present study was conducted in a tertiary care hospital at the Department of Orthopaedics over a two-year period from January 2022 to December 2023. All patients were operated on by a single senior surgeon at the Sir Ganga Ram Hospital. Ethical clearance was obtained from the Institutional Ethics Committee prior to the start of the study and written informed consent was obtained from the study participants. The inclusion criteria for our study were age >18 years, a history of distal tibia fracture (open or closed). Exclusion criteria were refracture of the distal tibia, previous surgeries in the affected ankle and any associated vascular injury. The study population was selected among the patients who were admitted with distal tibia fractures, intra-articular or extra-articular and provided a written informed consent to the operative procedure.

We had a total of 20 patients in our study. There were 18 (90 %) males and 2 (10 %) females. Their ages ranged between 24–57 years with a mean of 39.2 ± 10.5 years and median of 39 (30.5–45) years. Most injuries were secondary to road traffic accidents ($n = 16$; 80 %), followed by a fall from a height ($n = 4$; 20 %). Most of the injuries presented closed at the outset ($n = 12$; 60 %), followed by grade I open ($n = 6$; 30 %) and grade II open ($n = 2$; 10 %) as per the Gustilo – Anderson classification for open fractures. We did not encounter any grade III open injuries. Occupations of the study subjects included students ($n = 8$, 40 %), farmers ($n = 8$, 40 %) and business owners ($n = 4$, 20 %). None of the subject cohort had any pre-existing risk factor for delayed union or nonunion in the form of diabetes mellitus, smoking, malnutrition, or usage of anti-inflammatory medications at time of enrollment in the study. Distribution of the fracture pattern as per AO-OTA classification is detailed in Figure 1.

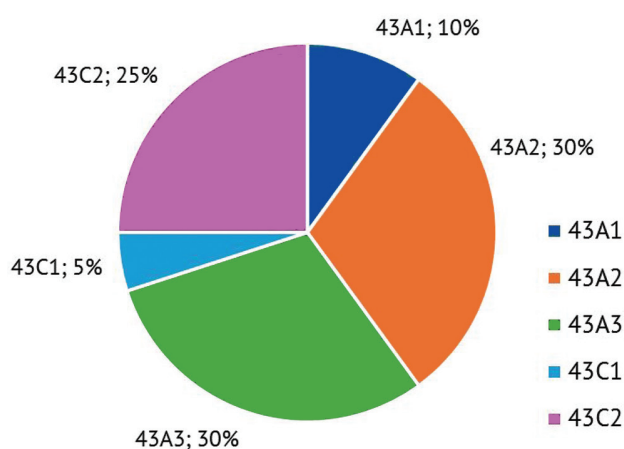


Fig. 1 Distribution of fracture patterns as per AO-OTA classification

Pre-operative management:

All patients presenting with an ankle injury were evaluated and resuscitated as per ATLS protocol, above knee splinting was performed, appropriate wound dressing was done for open injuries and radiographic imaging was carried out. Following imaging, fractures around the ankle joint were classified as per the OTA classification as 43-A, 43-B, and 43-C, based on the fracture configuration (Fig. 2). All subjects having an ankle fracture without significant comminution were subjected to an NCCT with 3D Reconstruction of the ankle for better understanding of the fracture pattern and planning of fixation. Ilizarov fixation was performed in all cases irrespective of blister formation or severe swelling, as wires and half-pins help in decompressing the compartment.



Fig. 2 Fracture images:
(a) AP and lateral X-rays
featuring a 43-C ankle
fracture dislocation as
per OTA classification;
(b) 3D CT scan
of the fracture

Surgical Management

The patient was placed supine on a radiolucent table and procedure was performed under spinal anesthesia. The limb was prepared from the iliac crest till the foot and placed over bolsters. Traction was achieved by an assistant holding the heel and forefoot. Fluoroscopy was used for assessment of reduction achieved after traction and ligamentotaxis. With traction on, fibula was first fixed with an intramedullary 1.8-mm Ilizarov wire inserted from the tip of the lateral malleolus under an image intensifier to achieve length. Fixation of the fibula indirectly reduced tibial fragments in most cases. Distal tibial fracture reduction was carried out either closed using axial traction and push-pull technique using 3-mm K-wire as joystick or limited open reduction either anteriorly or posteriorly, depending on reduction of the articular block. Wherever needed, 4-mm partially threaded cannulated screws were used for articular block reconstruction (Fig. 3). The metaphyseal zone of the injury was not opened to preserve biology. A three-ring tibial Ilizarov frame was assembled on the table using two full rings for diaphyseal fixation and one full ring for epiphyseal fixation. One 5/8th ring was applied in the calcaneum in lieu of a foot frame, for an ankle spanning construct to achieve ankle diastasis and stability. The upper two diaphyseal rings were fixed using two to three 1.8-mm smooth wires and sometimes reinforced with one 5-mm Schanz pin. The third epiphyseal full ring was fixed with three 1.8-mm olive wires passed distal to the fracture site parallel to the ankle joint line with an intervening angle of at least 30 degrees and with one wire to fix the ankle syndesmosis. The wires were duly tensioned after insertion (Fig. 4, 5). All cases which were open fractures, underwent a thorough wound debridement with saline, povidone iodine and hydrogen peroxide, followed by either primary closure or repeat debridement and delayed primary closure. None of our patients underwent any reconstructive procedure in the form of skin grafting or flaps.

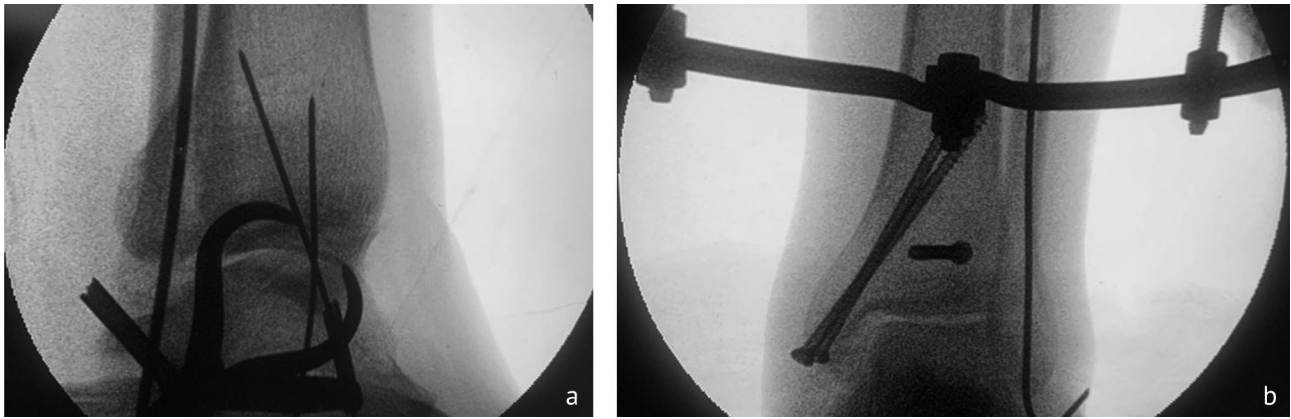


Fig. 3 Intraoperative images: (a) lateral projection of the C-shaped arch of the fracture reduced by closed means and provisional fixation using K-wires; (b) C-arm AP images of the fracture fixation using percutaneous means



Fig. 4 Clinical picture of the Ilizarov frame applied: (a) medial view; (b) anterior view

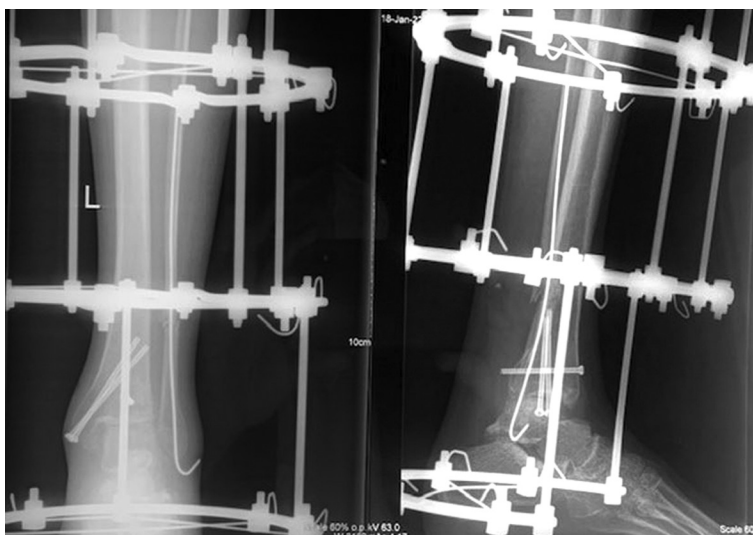


Fig. 5 Post-operative AP and lateral X-rays of the fracture fixation with the Ilizarov frame in situ

Post-operative management

Postoperatively, all patients were encouraged to perform active and passive toe and knee range of motion exercises. All wounds and pin-tracts were dressed using aseptic precautions. All patients started on Tab Aspirin 150 mg once a day for DVT prophylaxis. All patients were mobilized from post-operative day one, with those having OTA 43-A/B fractures allowed to bear weight as tolerated,

and those with OTA 43-C fractures kept non-weight bearing for at least 8 weeks. Functional and radiological evaluation was done at 4 weeks, 8 weeks, at the time of frame removal and three months after frame removal. The end point for frame removal was determined by presence of bridging callus in at least three cortices in AP and lateral radiographs and by clinical impression of pain-free weight bearing following dynamization of the frame. Frame removal usually after 3–4 months was done in the operation theatre under sedation and a PTB (patellar tendon bearing) cast was applied for 3 weeks followed by a PTB brace with foot extension for the next 4 weeks.

Outcomes

The outcomes of the surgery were divided into functional and radiological outcomes. Functional outcome measures included assessment of active ankle range of motion, pain perception using Visual Analogue Scale (VAS) scores, ASAMI criteria for functional result and Olerud and Molander functional scoring system for ankle fractures. Radiological outcome measures were evaluated using Teeny – Wiss scoring criteria for radiological quality of reduction, time to bony consolidation and ASAMI criteria for bone result.

Statistical Analysis

Presentation of the categorical variables was done in the form of number and percentage. Quantitative data was presented as mean \pm SD and as median with 25th and 75th percentiles (interquartile range). Data entry was done on a Microsoft Excel spreadsheet, and the final analysis was done using SPSS version 25 (SPSS Inc, Chicago, Illinois, USA).

RESULTS

All patients were mobilized from the first post-operative day using a walker support. The median time to full weight-bearing was 26 (21.75–30) days (range, 21–36 days). At the time of frame removal, all cases had stiffness in the operated ankle. At three months post-frame removal, 17 (85.00 %) cases had full ankle ROM while 3 (15.00 %) cases had a terminal restriction of dorsiflexion. The median value of frame removal of our study subjects 17.5 (16–20) weeks (range: 14–22). Functional outcomes were evaluated in the form of VAS scores (Table 1), ASAMI Functional Outcome Scoring system (Table 2) and Olerud and Molander Ankle Scoring system (Fig. 6).

Table 1

VAS Scores at time of last follow up
(three months post frame removal)

| Variable | Median (25 th –75 th percentile) | Range |
|-----------|--------------------------------------------------------|-------|
| VAS score | 2.5 (2–3) | 2–5 |

Table 2

ASAMI Functional Outcome Scoring system (three months post frame removal)

| ASAMI functional outcome | Number of patients | Percentage |
|--------------------------|--------------------|------------|
| Fair | 4 | 20.00 % |
| Good | 10 | 50.00 % |
| Excellent | 6 | 30.00 % |
| Total | 20 | 100.00 % |

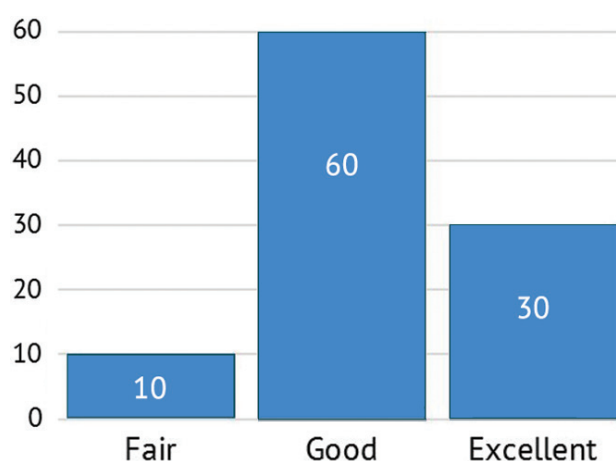


Fig. 6 Olerud and Molander Ankle Scoring system (three months post frame removal)

The median time to consolidation (weeks) of study subjects was 22 (20–24.5) weeks (range, 16–28 weeks). Radiological outcomes were evaluated with ASAMI Bone Outcome Scoring system (Table 3) and Teeny – Wiss Scoring System (Fig. 7).

Table 3

ASAMI Bone Outcome Scoring system
(three months post frame removal)

| ASAMI bone outcome | Number of patients | Percentage |
|--------------------|--------------------|------------|
| Fair | 2 | 10.00 % |
| Good | 10 | 50.00 % |
| Excellent | 8 | 40.00 % |
| Total | 20 | 100.00 % |

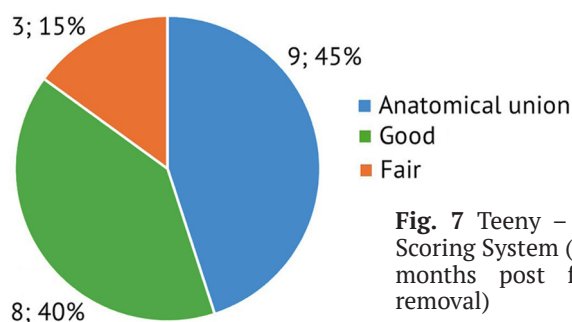


Fig. 7 Teeny – Wiss Scoring System (three months post frame removal)

Additional procedures at the time of primary application of the Ilizarov fixator were done as follows: three cases required primary bone grafting at the tibial pilon fracture site for maintaining subchondral support for impaction fracture patterns. We encountered post-operative complications in 12 cases. Two cases developed features of Complex Regional Pain Syndrome Type-1 at frame removal, which were subsequently managed with medications. Eight cases developed pin-tract infection, despite adequate knowledge and application of pin-tract care; seven of whom were managed with local pin-site debridement and short course of oral antibiotics and one required frame re-application due to pin-tract infection and pin loosening in most of the pins. One patient developed a delayed union which was managed using compression and distraction at the fracture site (accordion maneuver) and local infiltration of autologous bone marrow concentrate injection and went on to complete union. None of our cases developed DVT, nonunion, malunion, limb length discrepancy or rotational malalignment and none of our cases required primary ankle arthrodesis or amputations.

DISCUSSION

Distal tibia fractures are a complex entity to treat [6]. Patients with these fractures are likely to develop complications post-intervention in this area with a relatively poor soft tissue envelope. A rise in rate of complications has been reported following internal fixation in this region compared with other anatomical sites. The application of Ilizarov fixator as a definite treatment for distal tibia fractures has profoundly changed their prognosis. Application of circular frame can be performed in all cases, irrespective of blister formation or severe swelling, as wires and half pins help in decompressing the compartment. By preventing soft tissue stripping needed for open reduction, the procedure minimizes soft tissue injury, decreases rate of infection, and allows early recovery. Our findings are consistent with existing literature in reporting an acceptable functional and radiological outcome following Ilizarov fixation for management of this entity.

Our study included 20 patients with a mean age of 39.2 ± 10.5 years, predominantly male (90 %). This demographic profile is consistent with other studies, such as Osman et al. [7] which reported a mean age of 47 years with 87 % male patients. However, our cohort was slightly younger than the study by V.P. Giannoudis et al. [8], which had a median age of 44 years (IQR 34–55). The predominance of high-energy trauma, particularly road traffic accidents (80 % in our study), aligns with global trends reported in the literature. This is similar to the findings of Osman et al., where 15 out of 30 fractures were due to road traffic accidents [7].

Our study utilized the AO/OTA classification, with a distribution of 43A, 43B, and 43C fractures. This is comparable to other studies, though some, like Osman et al. [7], used the Rüedi and Algoter classification. Giannoudis et al. [8] reported 63 % intra-articular fractures in their series, which is similar to our findings of 65 % intra-articular fractures.

Bony union in our series was achieved in all except one patient in their initial frame and the patient with delayed union went on to achieve bony union following the accordion maneuver and local infiltration of bone marrow concentrate. The median time to consolidation in our study was 22 weeks, with frame removal at a median of 17.5 weeks. This is comparable to the range reported by other studies using the Ilizarov method for distal tibia fractures. For instance, Guo et al. [9] reported an average union

time of 23.4 weeks in their series while Osman et al. [7] reported frame removal at a mean of 22 weeks. However, our time to union was shorter than that reported by Giannoudis et al. [8], who found a median time to union of 166.5 days (approximately 24 weeks). This difference could be due to variations in the definition of union, differences in patient populations, differences in weight-bearing protocols, rehabilitation, and follow-up. Previous meta-analyses also suggest union rates in our series compare favorably with patients treated for distal tibial fracture by internal fixation, with union occurring in 91–98 %. Such results are difficult to interpret due to the varied patient profiles and treatment methods undertaken, making pooled analysis difficult and its results potentially inaccurate [8].

The median time to full weight-bearing in our study was 26 days, which is notably earlier than some other studies. For instance, Giannoudis et al. [8] reported that weight-bearing was often restricted for the first 6–8 weeks in complex intra-articular fractures and Ramos et al. [10] reported weight-bearing at an average of 6 weeks postoperatively. This early mobilization is a significant advantage of the Ilizarov method, potentially contributing to faster rehabilitation [2].

Our study used the Olerud & Molander Ankle Scoring system for functional assessment, with 70 % of patients achieving excellent or good outcomes; these are comparable to other studies using external fixation methods. This is comparable to Osman et al. [7], who reported 73 % excellent or good results using the AOFAS score and slightly better than Giannoudis et al. [8], who reported 62 % good or excellent ankle scores at more than 6 months post frame removal [3]. However, they slightly outperform some internal fixation studies, such as the one by Korkmaz et al. [11], which reported 63 % excellent or good results. The ASAMI functional outcome scores, with 90 % excellent or good results, are particularly impressive and align with the upper range of outcomes reported in the literature for complex distal tibia fractures. The difference obtained in our study could be attributed to variations in scoring systems, patient populations, variations in surgical technique, such as the use of additional internal fixation or the specific configuration of the Ilizarov frame.

The Teeny – Wiss Scoring System results in our study, with 80 % of cases achieving good or excellent reduction, are comparable to or better than many studies using other fixation methods for complex distal tibia fractures. Osman et al. [7] reported excellent and good restoration of articular structure in 24 out of 30 cases.

Our overall complication rate (60 %) is higher than some reports in the literature, primarily due to pin tract infections (40 %). This is higher than the 33 % pin site infection rate reported by Giannoudis et al. [8]. However, our study had no cases of deep infection, osteomyelitis, or non-union, which is better than some reported series. For instance, Osman et al. [7] reported two cases of delayed union, which we did not encounter in our series. Our study may have included a higher proportion of complex fractures, leading to a higher complication rate but potentially better functional outcomes due to more meticulous management. Our study may also have used a broader definition of pin tract infections, leading to a higher reported rate.

Although we were able to assess the functional and radiological outcomes of distal tibia fractures based on available scientific literature, our study did have some limitations, notably:

1. Small sample size: The study included only 20 patients, which limits the statistical power and generalizability of the results.
2. Lack of a control group: The study did not include a control group or compare the Ilizarov method to other treatment options, making it difficult to determine the relative efficacy of this approach.
3. Heterogeneity of fracture types: The study included both intra-articular and extra-articular fractures, which may respond differently to treatment and complicate the interpretation of results.
4. Potential for recall bias: Some outcome measures were collected retrospectively, which could introduce recall bias in patient-reported outcomes.

Future research with larger sample sizes, control groups, and more comprehensive outcome measures would be beneficial to further evaluate the efficacy of the Ilizarov method for distal tibia fractures.

CONCLUSION

The Ilizarov technique represents a valuable approach for managing distal tibia pilon fractures. Our study findings align with existing evidence, demonstrating improved clinical outcomes and minimal complications. The higher complication rate but better functional outcomes in our study highlight the importance of meticulous technique and patient selection in achieving optimal results with this challenging injury. Surgeons should consider this technique as a viable option, especially when dealing with the cases of a complex fracture pattern or those with compromised soft-tissue envelope which are not amenable to ORIF.

Conflicts of Interest None to declare.

Sources of Funding None to declare.

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Information about the authors:

Manish Dhawan — Professor (Dr), MBBS, DNB (Orthopaedics), MNAMS, MCh (Orthopaedics), Head of Orthopaedics, drmanishdhawan@gmail.com;

Brajesh Nandan — Dr, MBBS, MS (Orthopaedics), Senior consultant, brajesh.nandan@yahoo.com;

Mohammed Schezan Iqbal — Surgeon Commander (Dr), MBBS, MS (Orthopaedics), Associate Professor, dr.schezaniqbal@gmail.com;

Sanjeev Kumar Singh — Dr, MBBS, DNB (Orthopaedics), Consultant, sanjeev10079@gmail.com;

Manish Prasad — Col (Dr), VSM, MBBS, DNB (Orthopaedics), Professor, monu60@gmail.com.

Contribution of the authors:

Manish Dhawan — Development of the concept and design of study.

Brajesh Nandan — Research coordination, interpretation and analysis of data obtained.

Mohammed Schezan Iqbal — Collecting and processing material, conducting research, preparing text.

Sanjeev Kumar Singh — Collection of material and data pertaining to research.

Manish Prasa — Analysis, interpretation and editing.

Original article

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The incidence and risk factors related to post-operative dysphagia after anterior cervical spine surgery: a prospective study

J. Singh, N. Singh, P. Gupta , B. Kapil

GGs Medical College and Hospital, Faridkot, Punjab, India

Corresponding author: Pranav Gupta, pranavchd88@gmail.com

Abstract

Introduction Post-surgical dysphagia is one complication particularly common in early postoperative period after Anterior cervical spine surgery (ACSS). However, the pathophysiology of dysphagia after surgery has not been well understood.

This study **aimed** to analyse the frequency and risk factors for developing dysphagia following ACSS and find an effective program to prevent and treat.

Materials and methods A prospective observational study was conducted on 50 patients undergoing ACSS from April 2021 to Oct 2022 at the Department of Orthopedics, Guru Gobind Singh Medical College and Hospital, Punjab (India). Patients were in the age group of 27 to 60 years. The indications for cervical surgeries were traumatic, degenerative, infective and neoplastic involving C2 to C7 vertebra with signs of neural compression unresponsive to conservative treatment. Data on patient age, gender, duration of surgery, intraoperative blood loss, segment operated and the number of segments operated were collected. Follow up time was 24 weeks.

Results Incidence of dysphagia was 20 % (10/50) within first week which reduced to zero at completion of six months of follow-up. Dysphagia was present in 2 % (1/50) patients in age group 21–40 years and 18 % (9/50) patients in age group of 41–60 years. 14.6 % (6/41) males and 44 % (4/9) of females had dysphagia. Prevalence of dysphagia in patients with one affected segment was 9.5 % (4/42), two segments was 80 % (4/5) and three segments was 50 % (1/2). Mean duration of surgery in patients with post-operative dysphagia was 115 mins. Mean blood loss in patients with post-operative dysphagia was 171.40 mL Mean Et (endotracheal) tube cuff pressure in patients with post-operative dysphagia was 24.70 cm H₂O. Within the first week of surgery, there were 10 cases out of which one was mild, six were moderate and three were severe.

Conclusion Despite the fact that some inconsistency is there in the literature regarding risk factors it can be safely concluded from our study that incidence of post-operative dysphagia can be reduced by decreasing blood loss during surgery, reducing surgery time and optimizing Endotracheal tube cuff pressure during surgery.

Keywords: Anterior cervical spine surgery, Blood loss, Cuff pressure, Dysphagia

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INTRODUCTION

Various cervical spine pathologies including trauma and degenerative spinal diseases require Anterior cervical spine surgery (ACSS) [1]. The anterior approach is secure, fruitful, and rate of morbidity and mortality are low. However, a number of complications associated with the anterior approach have been described [2]. Dysphagia is one such complication particularly common in early postoperative period [3]. It is mild to moderate in majority of patients and is transient in nature and resolves gradually within three months of surgery [4, 5]. Its incidence varies in the literature from 1 % to 79 % [6]. Dysphagia can prolong the period of hospital stay and also influence the quality of life of patients in terms of food which patient can eat and difficulty in talking to another person [7]. However, its pathophysiology has not been well understood. There are various factors which lead to dysphagia after ACSS which include operative time, use of instrumentation, design and thickness of plate, extent and duration of intraoperative retraction, endotracheal tube cuff pressure, use of steroids, number of levels operated, revision versus primary surgery leading to wide variation in incidence rates of dysphagia [8]. Other risk factors, such as gender, tobacco consumption, smoking and intraoperative blood loss have also been associated with postoperative dysphagia [9].

This study aimed to analyze the frequency and risk factors for developing swallowing difficulty following anterior cervical spine procedures and find an effective program to prevent and treat. This article was previously posted to the Research Square preprint server on June 13, 2023.

MATERIALS AND METHODS

A prospective observational study was conducted on 50 patients undergoing ACSS from April 2021 to Oct 2022 at the Department of Orthopedics, Guru Gobind Singh Medical College and Hospital, a tertiary care center in Punjab (India). Patients were in the age group of 27 to 60 years and were admitted on first come basis. All patients were assessed clinically based on MRC power grading. Radiologic diagnoses were established in each patient through routine preoperative cervical radiographs and cervical magnetic resonance imaging and computed tomography scans and these were correlated with clinical findings to single out the level of surgery. The indications for cervical surgeries were traumatic, degenerative, infective and neoplastic involving C2 to C7 vertebra with signs of neural compression unresponsive to conservative treatment.

Exclusion criteria were: (i) Patients having preoperative dysphagia; (ii) those with history of previous ACSS; (iii) associated cervical deformity, severe osteoporosis, ankylosing spondylitis and rheumatoid arthritis; (iv) those with history of smoking and tobacco usage.

There were 41 male and 9 female patients in our study with an average age of 49 years. Approval for this study was obtained from the institutional review board. Written informed consent was taken from every patient included in our study. All surgeries were performed at a single institution. All patients were operated under GA which included use of an inflated endotracheal cuff, pressure of which was noted in every surgery. Every individual in this study underwent anterior cervical decompression using Smith-Robinson approach followed by removal of cartilaginous end plates and use of structural autograft bone to achieve fusion followed by anterior plate and screw fixation (Fig. 1, 2). The type of plate was standardized for this study and did not vary from patient to patient except for the length of the plate. Wound was closed over drain which was removed on second postoperative day or when the drain output was less than 30 mL. Postoperatively cervical spine was immobilized in a rigid cervical collar. We recorded the length of each surgical procedure from incision to closure time. Intra operative steroid used was confirmed from anesthetist. On post-operative day one, patient was started on liquid diet and progressed to semi solid and solid food according to patient comfort on consecutive days.

Patients were split into two group, one had patients with postoperative dysphagia and the other did not. Data on patient gender, age, duration of surgery, surgery blood loss, segment operated and the number of segments operated were collected (Table 1). Follow up time was 24 weeks.

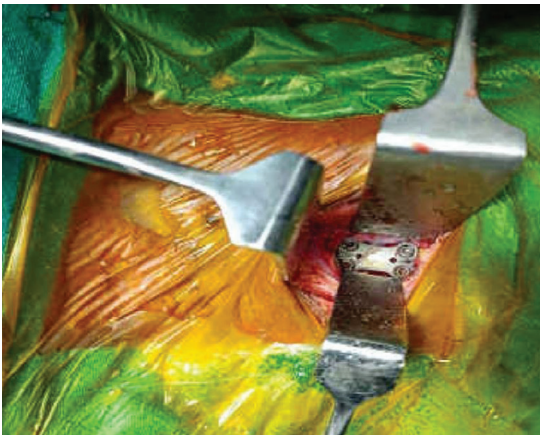


Fig. 1 Illustrating cervical plate positioned at desired level fixed with screws of appropriate length



Fig. 2 X-rays of the cervical spine: (a) in the direct (anteroposterior); (b) lateral projections respectively after ACDF

Post-operative assessment of dysphagia was done within the first week post surgery followed by 12 weeks and 24 weeks by asking the patient at each visit "Do you have any pain, sticky throat feeling or choking when swallowing solid or liquid food?". If the patient responded that they were symptomatic, then further information was obtained to determine the level of severity. The Bazaz grading system is commonly employed to evaluate the severity of dysphagia and so was used in our study [8]. The system defines four grades: none, mild, moderate, and severe dysphagia based on the subjective symptoms. Patients with no episodes of swallowing difficulty were graded as having "none". Patients who experienced rare episodes of dysphagia and did not feel that their dysphagia was a significant problem were graded as "mild". "Moderate" dysphagia was defined as occasional swallowing difficulty with specific foods (ie, bread or meats). "Severe" dysphagia was defined as frequent difficult swallowing with a majority of foods which included liquids (Table 2).

Table 1

Table showing incidence of post-operative dysphagia with respect to various different parameters

| Parameters | | Postop Dysphagia Present | Postop Dysphagia Absent | P value |
|--------------------------------------------------|-------------------|--------------------------|-------------------------|----------|
| Age Group (Years) | 21–40 | 1 | 14 | 0.12 |
| | 41–60 | 9 | 26 | |
| Gender | Male | 6 | 35 | 0.04 |
| | Female | 4 | 5 | |
| No of levels | 1 | 4 | 38 | 0.0001 |
| | 2 | 4 | 1 | |
| | 3 | 2 | 1 | |
| Operated Levels | At or above C4–C5 | 3 | 13 | 0.11 |
| | Below C4–C5 | 1 | 25 | |
| Mean Duration of Surgery (mins) | | 91.25 | 115 | 0.006 |
| Mean Blood Loss (ml) | | 130.8 | 171.4 | 0.0006 |
| Mean ET tube cuff pressure (cm H ₂ O) | | 22.7 | 24.7 | 0.000023 |

Table 2

Table showing grades of post-operative dysphagia with number of dysphagia cases at each follow up

| Grades of Dysphagia | No of Cases | | |
|---------------------|-------------------|----------|----------|
| | Within first week | 12 weeks | 24 weeks |
| None | 40 | 46 | 50 |
| Mild | 1 | 1 | 0 |
| Moderate | 6 | 3 | 0 |
| Severe | 3 | 0 | 0 |

RESULTS

The study included 50 patients. Within first week of surgery, the incidence of dysphagia was 20 % (10/50) which reduced to zero at completion of six months of follow-up. The average age in our study was 49 years. According to age group, dysphagia was present in 2 % (1/50) patients in age group 21–40 years and 18 % (9/50) patients in age group of 41–60 years, but difference was not found to be statistically significant (P value = 0.12). Ratio of male to female was 4:1 (40 males, 10 females). 14.6 % (6/41) males and 44 % (4/9) of females had dysphagia and the difference between the two groups was found to be statistically significant (P value = 0.04).

According to the number of levels that were operated, prevalence of dysphagia in patients involving one level was 9.5 % (4/42), two levels was 80 % (4/5) and three levels was 50 % (1/2) and the difference between the three groups was found to be statistically significant. (P value = 0.0001). To assess if surgical level played a role, we evaluated the prevalence of dysphagia after single-level procedures at C4–5 and above (upper cervical segment) and prevalence of dysphagia after single-level procedures below C4–C5 (lower cervical segment). Patients in which upper cervical segment was operated accounted for 18.8 % (3/16) of dysphagia cases while patients in which lower cervical segment was operated constituted only 3.8 % (1/26) of cases. Thus, cases were more in patients in which upper cervical segment was involved, however, the difference between the two groups was not found to be statistically significant (P value = 0.11)/

Similarly, we performed additional statistical analysis to determine association of duration of surgery, blood loss, endotracheal cuff pressure on incidence of dysphagia in immediate postoperative period. Mean duration of surgery in patients with post-operative dysphagia was 115 mins and mean duration of surgery in patients without post-operative dysphagia was 91.25 mins and this difference was significantly higher (P value = 0.006). Mean blood loss in patients with post-operative dysphagia was 171.40 mL which was significantly higher than mean blood loss in patients without post-operative dysphagia was 130.8 mL (P value = 0.0006).

Mean Et (endotracheal) tube cuff pressure in patients with post-operative dysphagia was 24.70 cm H₂O which was also significantly higher than mean Et tube cuff pressure in patients without post-operative dysphagia which was 22.70 cm H₂O (P value = 0.000023).

Severity of dysphagia was also assessed based on the time that has passed after surgery. Within the first week of surgery, there were 10 cases of dysphagia out of which one was mild, six were moderate and three were severe. After 12 weeks, there were one mild, three moderate and zero severe cases of dysphagia. 24 weeks after surgery, prevalence of dysphagia cases was zero. Thus, there was a declining trend in the number of cases of dysphagia as well as severity of cases as the duration of follow up increased (Table 2).

DISCUSSION

Anterior approach to the cervical spine has served well in treating many spinal pathologies from diverse etiologies like degenerative, traumatic, oncologic, inflammatory, and congenital [9]. Although morbidity and mortality rate associated with ACSS is less, dysphagia is very likely to occur [9]. It has been postulated that oesophageal oedema and traction injury of the nerves involved in the swallowing mechanism are to blame [10].

Several studies have reported the risk factors associated with dysphagia after ACSS, but the results showed wide-range of variations and hardly could draw any firm conclusions [10]. Most common factors associated are advanced age (aged > 60 years), female gender, increase number of operated levels and increased operative time [11]. Lee et al. carried out a study with two years follow up, and found that apart from the above mentioned factors, revision surgeries were also risk factors for dysphagia after ACSS [12].

Older patients (aged > 60 years) are at increased risk for postoperative dysphagia [7]. Although authors of several studies found no correlation between age and dysphagia, study by Kalb et al. found that

the mean age of dysphagic and nondysphagic patients was significantly different (55 and 50 years, respectively, $P = 0.05$) [9]. This could be explained by anatomic and physiological changes seen in elderly patients like weakening of swallowing muscles, decrease in salivary secretions and decrease in elasticity of oesophagus [14]. In our study also, 34.6 % (9/26) of patients in age group 41–60 years had post-operative dysphagia while only 7.1 % (1/14) of patients in age group 21 to 40 years had postoperative dysphagia, however the difference was not statistically significant (P value = 0.12).

Gender is another factor found to predispose the patient to dysphagia post cervical spine surgery. In a few studies the prevalence of dysphagia has been greater in women than men as the former have small anatomical structures, weak muscle strength and higher pain sensitivity [4, 9, 15]. In a study by Lee et al. the frequency of dysphagia was more in females (18.3 %) than males (9.9 %) two years after the surgery [12]. Bazaz et al. in his study reported that though the frequency of dysphagia was not significantly different between men and women in the 1–2 months postoperatively, but in the sixth month of follow-up, the incidence was 24.7 % in women, while 11.7 % in men and this difference was significant ($P = 0.023$) [16]. In our study, incidence of dysphagia among females (44.4 % i.e. 4/9) was more compared to males (14.6 % i.e. 6/41) at the first follow-up and the difference was also statistically significant (P value = 0.04) thus showing that female gender is a risk factor.

The cervical levels involved have also been evaluated to determine whether they have a part in the occurrence of postoperative dysphagia. In upper cervical spine, retropharyngeal space is more than inferior cervical spine due to which soft tissue swelling is more severe, which makes the postoperative dysphagia aggravate [12]. Another reason for increased dysphagia rates in upper cervical spine is that the superior laryngeal nerve sometimes becomes visible when surgical site is at the level of C3/4 or C2/3, due to which chances of causing superior laryngeal nerve damage increases [17]. Chin et al. also found that highest level of plate position at C3 had proportionately increased prevalence of dysphagia than surgery at C4 and below [18]. Many other studies have shown that surgery at a higher level (C3–C4) where there is a smaller soft-tissue envelope would result in increased dysphagia rates [12]. However, study conducted by Lee et al. did not support these findings [12]. We also studied the difference in frequency of dysphagia cases post single-level procedures at upper and lower cervical segment. Patients in which upper cervical segment was operated, prevalence of dysphagia was 18.8 % (3/16) while patients in which lower cervical segment was operated, prevalence was 3.8 % (1/26), however the difference was not statistically significant (P value = 0.11).

In comparative studies conducted after ACSS, post-operative dysphagia was commonly seen with multiple level surgeries as it increases retraction time, prolongs surgery time and leads to more soft tissue swelling [5]. Similarly in a study by Kalb et al. on an average, dysphagic patients had 2.2 levels operated as opposed to 1.84 in non dysphagic patients [9]. Riley et al. found that incidence of postoperative dysphagia in the patients with two or three surgical segments were higher than one segment [1]. In study by Lee et al., prevalence ratio suggested that patients with surgery at three or more levels are almost twice as likely to experience long-term dysphagia than patients with surgery at less than three levels [12]. Lee et al. and R. Bazaz et al. found that patients who underwent ACSS at multiple level had a significant risk of swallowing difficulty in contrast to those who underwent surgery at single-level at four and eight weeks follow-up [12, 16]. Frempong-Boadu et al. too showed that ACSS done at multiple level showed an increased frequency of postoperative swallowing difficulty as compared to those who underwent single level surgery [19]. In the present study, swallowing abnormality was present in 9.5 % (4/42) of patients operated at single level, 80 % (4/5) of patients operated through two levels and 50 % (1/2) of patients operated through 3 levels and the difference between the three groups was found to be statistically significant (P value = 0.0001).

Time span of procedure was another factor which was examined in this study. Increased duration of surgery leads to traction on trachea and esophagus for extended duration which makes soft tissue swelling escalate. Therefore, the incidence of post-operative dysphagia rises [20]. In a study by A. Yoshizawa et al. duration of surgery more than 200 min was associated with post-operative

dysphagia [21]. In a similar study by Xue et al. more operation time (P value = 0.012) was associated with increased prevalence of post-operative dysphagia [21]. In our study, mean duration of surgery in patients with post-operative dysphagia was 115 mins which was significantly higher than mean duration of surgery in patients without post-operative dysphagia was 91.25 mins (P value = 0.006).

Blood loss during surgery is another risk factor whose association with dysphagia was looked for. In a study conducted by Yoshizawa et al. blood loss more than 100 ml was associated with post-operative dysphagia [21]. In a similar study by Riley et al. blood loss superior to 300 ml was associated with an enhanced risk of dysphagia following ACSS [1]. In our study, mean blood loss in patients with post-operative dysphagia was 171.40 ml which was significantly higher compared to patients without post-operative dysphagia in which postoperative blood loss was 130.84 ml (P value = 0.0006).

Observing the endotracheal tube cuff pressure is recommended during ACSS [22]. Keeping the pressure between 15 and 25 cm H₂O is considered important for preventing post-surgical dysphagia [23]. Pressures below 15 cm H₂O can lead to gas leakage and aspiration, while pressures more than 25–30 cm H₂O may cause decrease in tracheal wall capillary blood flow leading to mucosal ischemia, tracheomalacia, tracheal stenosis, tracheal rupture, and tracheoesophageal fistula due to a [23]. In the study by Ural et, risk of developing post-surgical dysphagia significantly decreased with an endotracheal cuff pressure of 20 cm H₂O compared to 25 cm H₂O [3]. Grasso et al. reported a significant reduction in the rate of early dysphagia when the cuff pressure was reduced [24]. In our study, mean Et tube Cuff pressure in patients with post-operative dysphagia was 24.70 cm H₂O which was significantly more than mean Et tube cuff pressure in patients without post-operative dysphagia which was 22.70 cm H₂O (P value 0.000023). Thus, mean Et tube cuff pressure is an essential risk factor to be taken care of during ACCS.

Swallowing difficulties after ACSS are usually transient in nature. Rihn et al, found that the prevalence of dysphagia had declined to 8 % at 12 weeks [5]. Similarly, Bazaz et al. reported that the frequency decreased to 50.2 % at one month post-operatively, and decreased further to 32.2 %, 17.8 % and 12.5 % by two, six and twelve months postoperatively, respectively [16]. A prospective study by Lee et al. found a similar decreasing incidence of 54.2 %, 33.6 %, 18.6 %, and 13.6 % at one, two, six and 12 months postoperatively, respectively [12]. Our own study observed an initial incidence of dysphagia of 20 % within the first week after surgery, which subsequently decreased to 8 % at the 12 week mark and zero at 24 weeks which is comparable to the above-mentioned studies. Thus prevalence of dysphagia following ACSS was high initially, but gradually decreased in both incidence and severity over time, indicating it as a common early complication.

However, there are several limitations in this study. Firstly, the study had a limited sample size due to which accuracy and efficacy of our results on dysphagia assessment were not high enough. A randomized control studies with a larger sample size and a long-term follow-up is necessary to further determine the outcomes. Secondly, the dysphagia was reported just basing on the subjective feeling of patients, which may not be completely reliable as it is not a universally accepted method for determining and measuring dysphagia. Moreover in our study we had majority of patients with single level operated. This selection bias could be eliminated by more randomized controlled studies in future.

CONCLUSION

Discomfort in swallowing after ACSS is a relatively usual phenomenon within the first week of surgery. It is, nevertheless temporary with maximum number of cases settling within 3 months. Despite the fact that some inconsistency is there in the literature regarding risk factors it can be safely concluded from our study that incidence of post-operative dysphagia can be reduced by decreasing blood loss, reducing surgery time and optimizing Endotracheal tube cuff pressure during surgery.

Conflict of interest Not declared.

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Information about the authors:

Jagdeep Singh — Associate Professor (Orthopaedics), jagatwal83@gmail.com, <https://orcid.org/0000-0002-1508-2745>;

Navpreet Singh — Junior Resident (Orthopaedics), Navpreetsingh66@gmail.com;

Pranav Gupta — Assistant Professor (Orthopaedics), pranavchd88@gmail.com; <https://orcid.org/0000-0003-4936-1950>;

Bansal Kapil — Professor (Orthopaedics), kapilortho@gmail.com.



Results of intra-articular and combined interventions in patients with ischemic deformity of the femoral head

M.P. Teplenkiy, V.S. Bunov, A.V. Akimova✉, E.M. Parfenov

Ilizarov National Medical Research Centre for Traumatology and Orthopedics, Kurgan, Russian Federation

Corresponding author: Alina V. Akimova, fu-fu.psinka.16@mail.ru

Abstract

Introduction Extra-articular operations for correction of ischemic deformities of the femoral head are not effective enough. Currently, intra-articular correction methods are used, among which one of the most effective methods is considered to be reduction osteotomy of the femoral head.

Purpose The aim of the work is to evaluate the results of intra-articular and combined interventions in patients with ischemic deformity of the femoral head.

Materials and methods The study included patients with ischemic deformity of the head and proximal femur ($n = 15$), divided into two groups. In the first group ($n = 7$), the patients underwent reduction osteotomy of the head using only the Ganz technique. Patients of the second group ($n = 8$) additionally underwent surgery on one or both joint components: corrective intertrochanteric osteotomy of the femur, pelvic osteotomy, or combined intervention. The joint was fixed with the Ilizarov apparatus.

Results The average D'Aubigne-Postel score in the first group was (14.7 ± 0.3) points, in the second group — (15.0 ± 0.2) points. When analyzing the radiometric data after treatment, a reliable improvement in the parameters characterizing the sphericity and the degree of head centralization was recorded in patients of both groups. Radiographic results of patients in the first group: good result — 3 joints (43 %), fair — 3 joints (43 %), poor — 1 joint (14 %); the second group: good result — 3 joints (38 %), fair — 4 joints (50 %), poor result — 1 joint (12 %).

Discussion Simultaneously with the reduction osteotomy of the head, it is allowed to perform additional surgical interventions aimed at eliminating instability of the hip joint. Conducting a reducing osteotomy of the head in the conditions of a functioning growth plate is considered debatable.

Conclusion Intra-articular interventions that change the shape and improve the congruence of articular surfaces may be an alternative to early arthroplasty in adolescents and young adults in certain clinical situations.

Keywords: ischemic deformity of the femoral head, acetabular dysplasia, femoral head, reduction osteotomy

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INTRODUCTION

Deformity of the femoral head is one of the unfavorable outcomes of ischemic lesions in the proximal femur of various origins [1, 2]. The most common causes of this condition in the treatment of congenital hip dysplasia are Legg-Calvé-Perthes disease and aseptic necrosis of the femoral head [1, 2, 3]. The main morphological signs of the pathology are asphericity and an increase in the size of the femoral head [3]. These changes contribute to the decentration of the head, the formation of femoroacetabular impingement, which is accompanied by dysfunction of the joint and pain [4]. Such a disorder of the joint biomechanics results in an increase in intra-articular pressure and is considered one of the leading causes of early development and rapid progression of coxarthrosis [5]. Extra-articular corrective operations on the proximal femur can improve the centering of the head and partially compensate for intracapsular deformities. However, their effectiveness for correction of the deformity of the femoral head is insufficient [1, 6]. Surgical dislocation with osteochondroplasty can be used for correction of deformed head mainly in the sagittal plane [7]. However, asphericity in the frontal plane cannot be eliminated by resection due to the risk of damage to the feeding retinacular vessels of the femoral head. The optimal option in this case is reduction osteotomy of the femoral head [8, 9].

Purpose of the work is to evaluate the results of intra-articular and combined interventions in patients with ischemic deformity of the femoral head.

MATERIALS AND METHODS

The work is based on a retrospective study of clinical and radiometric characteristics and analysis of the results of surgical treatment of patients with ischemic deformities of the femoral head, operated on in the period from 2014 to 2022. The mean follow-up period was (4.6 ± 0.3) years (from 2 to 10 years).

Inclusion criteria: ischemic deformities of the femoral head developed due to degenerative lesions of the hip joint of various origins, causing disruption of joint relationships and the formation of femoroacetabular impingement; reduction osteotomy of the femoral head in the medical records and the follow-up period of more than two years.

Exclusion criteria: other intra-articular interventions; exclusively extra-articular interventions; follow-up term of less than two years.

Patients with unilateral joint damage at the time of surgery ($n = 15$) were divided into two groups based on the volume of surgical interventions performed: Group 1 — 7 patients (14.0 ± 0.2) years old; Group 2 — 8 patients (16.1 ± 0.4) years old. Patients in the first group underwent only reduction osteotomy of the femoral head, while patients in the second group additionally underwent an extra-articular intervention on one or both articular components. The distribution of patients by gender and etiologic factor is presented in Table 1.

Femoral head reduction osteotomy (HRO) was performed using the Ganz technique in all cases [9, 12]. First, osteotomy of the greater trochanter was performed; next a co-tissue flap was formed to preserve the blood supply to the head. After producing surgical dislocation of the hip, two osteotomies of the head were performed in the sagittal direction. The intermediate fragment was removed, and the remaining bone fragments of the head were aligned and fixed with screws. Next, the head was reduced into the acetabulum. The joint was fixed with the Ilizarov apparatus for 30 days. This operation only was performed in seven cases (group 1).

Table 1

Patient's etiology of the disease and gender

| Gender, etiology | Group 1 (n = 7) | | Group 1 (n = 8) | |
|---------------------------------------------------------------------------|-----------------|------|-----------------|------|
| | No | % | No | % |
| Boys | 5 | 33.3 | 5 | 33.3 |
| Girls | 2 | 13.3 | 3 | 20.1 |
| Perthes disease | 3 | 20.1 | 3 | 20.1 |
| Septic coxitis | 1 | 6.6 | 1 | 6.6 |
| Aseptic necrosis due to hip dysplasia management | | | 2 | 13,3 |
| Aseptic necrosis following treatment of slipped capital femoral epiphysis | 1 | 6.6 | | |
| Posttraumatic aseptic necrosis | | | 1 | 6.6 |
| Idiopathic aseptic necrosis | 2 | 13. | 1 | 6.6 |

Three cases of the second group additionally underwent corrective intertrochanteric osteotomy of the femur. The indication for its implementation was an increased neck-to-shaft angle (two joints) and retroversion of the epiphysis (one joint). Intertrochanteric osteotomy was performed simultaneously with the intervention on the femoral head. The period of fixation with the apparatus in these cases was increased to 45 days. In three cases, pelvic osteotomy was additionally performed in the patients of the second group. The indication for its implementation was acetabular dysplasia (WBS angle $\geq 15^\circ$). Surgery on the pelvic bone was performed two weeks after the surgery on the femoral head. The period of fixation with the apparatus on was 50–55 days. Two cases of the second group underwent additional surgeries on both joint components.

This study presents only radiographic results. The radiographic study was performed using certified equipment (FS #2006/527). Radiographic data are presented without patients' information. Hip joint radiographs were taken in the anteroposterior view before treatment and at the last follow-up. The following radiographic parameters were determined and analyzed: hip extrusion index (EI), hip sphericity index (HSI) [2], ATD (articular-trochanteric distance), lateral displacement index (SL), lateral displacement angle (LDA-angle formed by a vertical line drawn through the teardrop figure and a line tangent to the inferomedial edge of the neck, normally $20-25^\circ$) [10], and the inclination angle of the supporting surface of the cavity (WBS).

The radiographic parameters were assessed according to Kruczynski [10] and the method of the Ilizarov National Medical Research Center of Traumatology and Orthopaedics [11] (Table 2). Kruczynski's evaluation considered the discontinuity of the Shenton line, the angle of lateral displacement, and the shape and centering of the head. The functional outcomes were assessed according to D'Aubigne – Postel.

Table 2

Evaluation of radiographic results according to the Ilizarov Center technique

| Parameters | 3 points | 2 points | 1 point |
|-------------------------------|------------------------------------------------|----------------------------|-------------------------------------------------------|
| Condition of the femoral head | Structure and shape did not change or improved | Shape of the head impaired | Both shape and structure of the femoral head impaired |
| ATD, mm | > 10 | $0-10$ | < 0 |
| EI | $1.0-0.85$ | $0.84-0.65$ | < 0.65 |
| HSI | $1.0-1.4$ | $> 1,4$ | < 1.0 |
| LDA $^\circ$ | < 20 | $20-25$ | > 25 |
| SL, cm | < 0.5 | $0.5-1.0$ | > 1.0 |
| Arthrosis severity | Did not change | Worsened by 1 stage | Worsened by more than 1 stage |

The study was conducted at the Ilizarov National Medical Research Center of Traumatology and Orthopaedics in accordance with the ethical standards of the Helsinki Declaration of the World Medical Association. All patients gave informed consent for conducting the study without their identification.

Statistical analysis of the study results was performed using Microsoft Excel 2007 software. Unweighted variation rows were compiled from the quantitative data. Averages, their error and reliability were determined. The obtained data were processed using nonparametric statistics methods using Wilcoxon and Mann-Whitney U-criteria.

RESULTS

In the first group of patients, the duration of the rehabilitation period was (8.6 ± 0.4) months, and in the second one (10.2 ± 0.3) months.

Evaluation of functional results after treatment revealed gait improvement in both groups (Table 3). In the first group, two patients showed complete restoration of the lower limb weight-bearing and normalization of walking. Hip joint function assessment showed that mobility indices improved in both groups, with the average index being higher in the second group than in the first. Limitation of joint mobility in the horizontal plane remained in all the cases. In the first group, the range of motion in the sagittal plane of more than 80° was recorded in four observations. One patient in the second group showed complete restoration of mobility in the sagittal and frontal planes. Extension contracture persisted in a patient of the first group. The absence of pain or insignificant pain was noted in all cases in the patients of the second group and in six cases of the first group.

Functional results of the first group according to the D'Aubigne – Postel criteria were good (15–18 points) in 3 cases (42.86 %), fair (12–14 points) in 3 cases (42.86 %), and poor (11 points) in 1 case (14.28 %); in the second group: a good result (15–18 points) was recorded in 4 cases (50 %), a fair one (12–14 points) in 4 cases (50 %).

Table 3

Dynamics of functional parameters before and after treatment

| Functional parameter | Before treatment | | After treatment | |
|-------------------------------------|---------------------|---------------------|----------------------|---------------------|
| | Group 1 ($n = 7$) | Group 2 ($n = 8$) | Group 1 ($nn = 7$) | Group 2 ($n = 8$) |
| Mean D'Aubigne-Postel score, points | 10.6 ± 0.2 | 10.3 ± 0.2 | 14.7 ± 0.3 | 15 ± 0.2 |
| Pain, points | 3.2 ± 0.1 | 3.4 ± 0.1 | 5 ± 0.3 | 5.5 ± 0.1 |
| Mean joint mobility, points | 3.4 ± 0.3 | 3.4 ± 0.1 | 4.8 ± 0.3 | 5 ± 0.2 |
| Motion activity, points | 3.8 ± 0.2 | 3.6 ± 0.2 | 5 ± 0.2 | 5.2 ± 0.2 |

The analysis of radiometric data after treatment showed a reliable improvement in the indices characterizing the sphericity and the degree of head centralization in both groups (Table 4). The average sphericity index was higher in the first group; the differences between the groups were statistically insignificant. The shape of the head became oval in most cases. The degree of extrusion decreased in almost all cases: the average EI value in the first group was 0.1 (0–0.15), in the second group it was 0.09 (0–0.12).

The proximal displacement index improved significantly in both groups and in 10 patients corresponded to the norm (0 mm). The lateral displacement index improved significantly only in the second group. In the first group, no statistically significant changes in this parameter were recorded after treatment.

The analysis of the condition of the proximal femur in both groups established a reliable improvement in the relationship between the femoral head and the apex of the greater trochanter was noted.

However, the normal value of the articulothrochanteric distance was found only in two patients of the second group. The average ATD value in the first group was 10.2 mm (5–13) and 10.8 mm (7–16) in the second group.

Table 4

Dynamics of roentgenometric parameters

| Parameter | Group 1 (n = 7) | | Group 2 (n = 8) | |
|-----------|---------------------|--------------|-----------------|--------------|
| | Time point of study | | | |
| | Before surgery | Follow-up | Before surgery | Follow-up |
| HSI | 0.57 ± 0.06 | 0.79 ± 0.02* | 0.55 ± 0.03 | 0.74 ± 0.02* |
| EI | 0.31 ± 0.02 | 0.1 ± 0.03* | 0.37 ± 0.03 | 0.09 ± 0.02* |
| SLI (mm) | 8 ± 1.3 | 3 ± 1.2* | 16.2 ± 1.6 | 4.4 ± 1.2* |
| LDA(°) | 24.3 ± 1.9 | 21.5 ± 1 | 28.7 ± 3.8 | 22 ± 0.9* |
| WBS (°) | 7.8 ± 1.2 | 7.6 ± 1.1 | 19.8 ± 1.5 | 9.3 ± 1.2* |
| ATD (mm) | 3 ± 1.1 | 10.2 ± 1.3* | 3.6 ± 1.8 | 10.8 ± 0.9* |

Note: * — significant difference with the initial value $P < 0.01$

The evaluation of radiological results of the first and second groups was carried out according to the Kruczynski classification and according to the criteria of the Ilizarov National Medical Research Center of Traumatology and Orthopedics (Table 5)

Table 5

Evaluation of radiographic results in the studied groups

| Criteria | Group 1 (n = 7) | | Group 2 (n = 8) | |
|-----------------|-----------------|------|-----------------|------|
| | No | % | No | % |
| Kruczynski | | | | |
| Good | 4 | 57.1 | 4 | 50.0 |
| Fair | 3 | 42.9 | 4 | 50.0 |
| Ilizarov Center | | | | |
| Good | 3 | 42.9 | 3 | 37.5 |
| Fair | 3 | 42.9 | 4 | 50 |
| Poor | 1 | 14.2 | 1 | 12.5 |

Complications

A 23-year-old patient from the first group sustained a femoral neck fracture during osteotomy of the femoral head. The bone fragments were fixed with screws. This complication did not affect the duration of hardware treatment or the outcome.

A 14-year-old patient from the second group had radiographic signs of aseptic necrosis.

Four years after surgery, the first group patient showed signs of arthrosis progression such as subchondral sclerosis and narrowing of the joint space. Severe pain was an indication for hip arthroplasty.

Case reports

The 11-year old patient of the first group with ischemic deformity of the head of the right femur resulting from Perthes disease in stage IIb (Fig. 1). Reduction osteotomy of the head of the right femur according to the Ganz method and fixation of the right hip joint with the Ilizarov apparatus for one month were performed.

Initial functional parameters were: pain — 4 points, mobility index — 2 points, motor activity index — 3 points. Radiological examination revealed a deformed flattened head, sphericity index was 0.5, extrusion index was 0.3, articulothrochanteric distance was 5 mm, cranial displacement index was 7mm.

Nine years later, the patient had no pain at all (6 points), his gait improved (5 points), the joint mobility index increased to 5 points, the sphericity of the head improved (sphericity index is 0.8), the distance from the apex of the greater trochanter to the center of the head increased (9 mm), the extrusion index (0.1) and cranial displacement (3 mm) decreased. The centering of the head in the acetabulum did not change significantly: the angle of inclination of the supporting surface of the acetabulum (7° before and after surgery) and the angle of lateral displacement (from 22° to 20°).

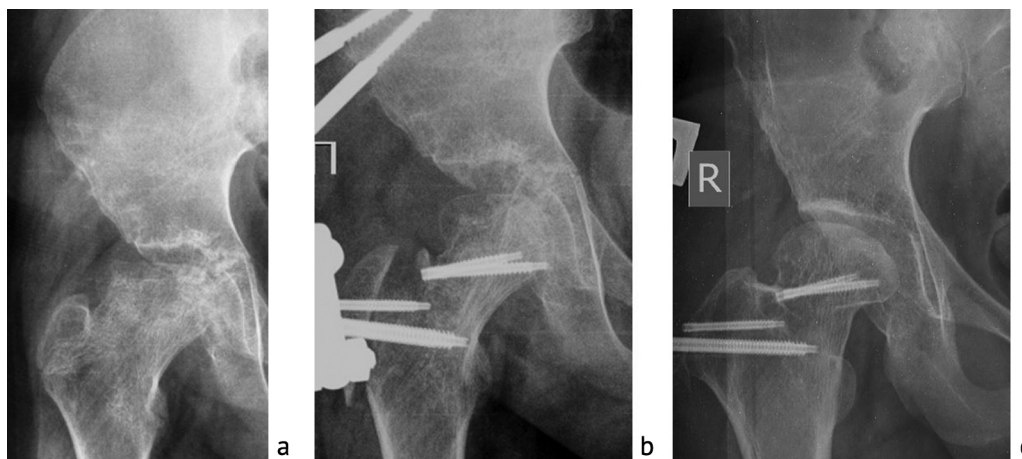


Fig. 1 Patient's radiographs: (a) before treatment; (b) reduction osteotomy of the femoral head; (c) 9-year follow-up

A 13-year old patient of the second group with ischemic deformity of the head of the right femur due to aseptic necrosis of the head in stage IV (Fig. 2). Reduction osteotomy of the head of the right femur according to Ganz was performed; after 14 days an additional osteotomy of the pelvis on the right was performed and the hip joint was fixed with the Ilizarov apparatus for 50 days.

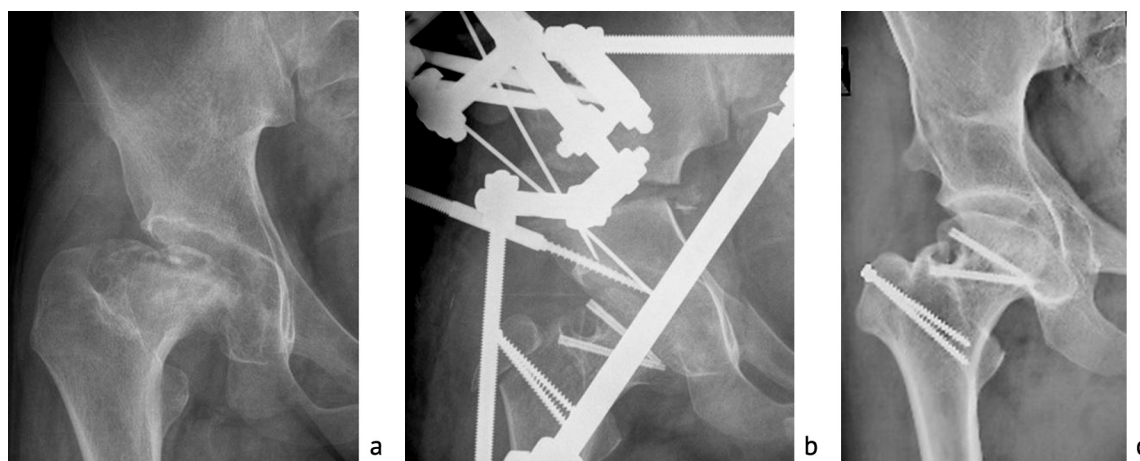


Fig. 2 Patient's radiographs: (a) before treatment; (b) reduction osteotomy of the femoral head, osteotomy; (c) 10-year pelvic old outcome

Initial functional parameters were: pain syndrome — 3 points, mobility index — 2 points, motor activity index — 3 points. Radiological examination revealed a deformed flattened head, high position of the apex of the greater trochanter, discontinuity of the Shenton line. Sphericity index was 0.4, extrusion index was 0.3, artculo-trochanteric distance was 3 mm, cranial displacement index was 15 mm.

At 10-year follow-up, the patient still had minor pain (5 points), her gait improved (6 points), joint mobility increased to 4 points, sphericity index increased to 0.7, artculo-trochanteric distance increased (11 mm), extrusion index (0.08) and lateral (cranial) displacement index (4 mm) decreased.

After pelvic osteotomy, the angle of inclination of the supporting surface of the acetabulum (from 19° to 8°) and the angle of lateral displacement (from 28° to 21°) changed significantly.

DISCUSSION

Ischemic deformity of the femoral head that changes its sphericity and size, causes disorders in joint relationships, is recognized as an important reason of early development and rapid progression of arthrosis in young people [1, 5, 14]. The possibilities of extra-articular reconstructive interventions are significantly limited [1, 6, 15, 16]. Therefore, intra-articular corrective interventions aimed at changing the shape of the head are of great importance. These include osteochondroplasty, cheilectomy, reduction osteotomy of the femoral head [16, 17]. This paper presents the medium-term results of HRO.

The limitations of this study are a small sample of patients and a short follow-up period. Also, the radiometric parameters analyzed were measured only on anteroposterior pelvic radiographs. It was associated with the fact that the main component of the head deformity that was targeted for correction by surgery was in the frontal plane.

The comparison of functional results with the data of other authors revealed that the proportion of good results among our patients was lower (47 %) [1, 9, 18, 19, 20, 21]. The rate of poor outcomes (6 %) did not differ significantly [1, 9, 18]. Siebenrock et al. analyzed the treatment results of 11 patients and noted the absence of reliable differences in the initial and postoperative functional state [1]. In our groups, the preoperative average D'Aubigne – Postel score was significantly lower and statistically differed from the functional result achieved. This may be due to the fact that the main cause of the deformity, according to the literature, was Perthes disease [3, 9, 12, 19, 21]. The incidence of this pathology among the etiological factors in our patients was only 40 %. The rest of the cases were consequences of aseptic necrosis of a different etiology, which are characterized by more pronounced functional and anatomical disorders.

According to the literature, changes in the shape and size of the head do not always ensure subsequent stability of the joint [1, 3, 9, 18]. According to D. Paley, it is possible to use an external fixator in this situation [16, 18]. Most specialists recommend using extra-articular surgeries on the articular components to correct joint instability [1, 3, 14, 17]. A number of authors accept their implementation in the late period during the formation of hip subluxation [9, 18]. According to others, a more common point of view, interventions on the articular components should be performed simultaneously with osteotomy of the head [1, 3, 20, 21]. In the analyzed group, the Ilizarov apparatus was used in all cases. The purpose of its use was not to compensate for remaining instability, but to ensure decompression of the hip joint and create conditions for limb weight-bearing in the postoperative period. The decision on the need to perform additional surgeries on the articular components was made during the preoperative planning. Separate (with an interval of 2 weeks) performance of pelvic osteotomy was due to the specifics of the technology of this intervention. It should be noted that among the patients of the first group, who did not undergo additional extra-articular operations, there were no signs of joint instability. We did not find statistically significant differences in the functional and anatomical results when performing only HRO (Group 1) and using combined interventions (Group 2).

One of the debatable issues remains the possibility of performing the reduction osteotomy of the head in the conditions of a functioning growth zone of the head [1]. According to D. Paley, this condition is a relative contraindication for the use of this operation [16, 18]. According to the opposite point of view, the growth zone does not have a significant effect on the outcome of treatment [3, 20].

The small sample size in our study does not allow for an objective conclusion. However, it should be noted that all four patients with a functioning growth zone of the head achieved a good anatomical and functional result.

Despite the aggressiveness of the intervention, many authors note a low risk of aseptic necrosis [1, 3, 9, 12, 19]. In the analyzed group of patients, this complication was noted in one case. It may have been caused by technical errors in performing the intra-articular intervention.

Heterotopic ossification is considered one of the possible adverse effects of the reduction osteotomy of the head [1, 3]. In the analyzed group, this complication was not observed. One intra-operative fracture of the femoral neck was diagnosed in a 23-year-old patient. According to the literature, this complication may result in early arthroplasty [18]. In the conditions of transosseous osteosynthesis, the violation of the integrity of the femoral neck did not have any effect on the course of the postoperative period and the outcome of treatment.

In one case four years after the operation, joint arthroplasty was performed due to severe functional impairment (pain syndrome). Similar data on conversion to arthroplasty are provided by D. Paley [16, 18].

It should be noted that most reports on the use of HRO have small size of patients' sample and short follow-up periods [1, 3, 20, 21]. Therefore, the impact of this intervention on the course of the degenerative process in the joint requires further study.

The preliminary results we obtained are necessary for planning further research with a larger number of subjects and a longer follow-up period.

CONCLUSION

The preliminary results obtained in this study and literature data suggest that intra-articular interventions that reshape and improve the congruence of articular surfaces may be an alternative to early hip replacement in adolescents and young adults in certain clinical situations.

Conflict of interests None.

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Ethical standards The study was conducted in accordance with the ethical standards of the Helsinki Declaration of the World Medical Association.

Informed consent Patients' parents gave informed consent for the study.

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Information about the authors:

Mikhael P. Teplenkiy — Doctor of Medical Sciences, Head of Department, orthopaedic surgeon, teplenkiymp@mail.ru, <https://orcid.org/0000-0002-1973-5192>;

Vyacheslav S. Bunov — Candidate of Medical Sciences, researcher, bvsbunov@yandex.ru;

Alina V. Akimova — post-graduate fellow, orthopaedic surgeon, fu-fu.psinka.16@mail.ru;

Eduard M. Parfenov — orthopaedic surgeon, ed.ortoped@mail.ru.

Original article

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Antistaphylococcal activity of 3D-printed titanium implants with magnesium-containing multicomponent coating

E.M. Gordina¹✉, S.A. Bozhkova¹, D.V. Labutin¹, M.V. Bogma², A.A. Eruzin²¹ Vreden National Medical Research Center of Traumatology and Orthopedics, Saint Petersburg, Russian Federation² JSC "Radiotekhnokomplekt", Saint Petersburg, Russian Federation**Corresponding author:** Ekaterina M. Gordina, emgordina@win.rniito.ru

Abstract

Introduction Titanium has been successfully employed as artificial implants in orthopedic surgery for decades. Surgical intervention, specifically the implantation of medical devices, carries a risk of implant-associated infection (IAI), the causative agents of which are staphylococci in more than half of the cases.

The **objective** was to evaluate the antibacterial, antibiofilm activity and cytocompatibility of a multicomponent coating with magnesium and silver oxides on the surface of 3D titanium samples.

Material and methods The MgO-AgO-MgO complex The MgO-AgO-MgO complex was applied to 3D samples of medical titanium. Elemental analysis was performed using a TM 4000 Plus scanning electron microscope. The samples were incubated with bacteria for 24 hours to identify antibacterial activity against *S. aureus*. *S. aureus* biofilms were formed by immersing the test samples in a nutrient medium with bacteria. After a 24-hour incubation, the samples were washed, placed in an ultrasonic washer, and then sonication fluid was seeded using the sector seeding method. The cytocompatibility of the coating was assessed on a culture of eukaryotic cells of the Vero line.

Results Elemental analysis and mapping confirmed the uniform distribution of oxides on the surface of 3D titanium samples. The coating was characterized by antibacterial activity against *S. aureus* for three days. The MgO-AgO-MgO complex effectively prevented *S. aureus* adhesion and microbial film formation, while the control samples showed biofilm formation by staphylococci. However, cytocompatibility analysis of the 3D samples showed no viable cells after 72 h of incubation in a medium with an extract from coated titanium samples.

Discussion Despite a decrease in antibacterial properties on day 4, the MgO-AgO-MgO complex prevented microbial adhesion to the surface of the samples which ensured protection of the implant from the formation of microbial biofilm. The cytotoxicity of the complex was caused by significant activation of lipid peroxidation reactions, which resulted in suppression of the viability of eukaryotic cells.

Conclusion The MgO-AgO-MgO coating prevents primary interaction between the pathogen and the abiotic surface, which is one of the main factors in preventing the development of IAI and the relapses after revision surgeries with implant replacement. However, the high level of cytotoxicity requires further modification of the coating application technique and its composition.

Keywords: implant-associated infection, antibacterial coating, magnesium, oxides, silver, *S. aureus*

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INTRODUCTION

Infections that occur after implant placement can cause serious problems associated with long-term administration of antibacterial drugs, implant rejection and the risk of challenging complications [1, 2]. The incidence of periprosthetic joint infection (PJI) after primary total hip and knee arthroplasty ranges from 0.2 % to 2 % [1]. Increased life expectancy leads to an increased arthroplastic surgeries worldwide that are estimated to involve cases of PJI in the coming decades [3]. Kurtz et al. estimated that by the year 2030, there will be a 613 % increase in TKA, and 174 % for THA as compared to 2015 [4]. Implant-associated infections (IAI), especially those caused by antibacterial-resistant bacteria, affect the economic healthcare costs [5].

Broad-spectrum systemic antibacterial drugs are normally prescribed to prevent the development of postoperative infectious complications [6, 7]. A sufficiently high concentration of an antibiotic is difficult to be achieved in the bone infection site. Systemic administration of antibiotics can cause side effects and the risk of bacterial resistance to antibiotics.

New technologies including 3D printing have opened up potential opportunities in the design of medical implants to allow implant manufacturing according to the anatomy of a specific patient [8–11]. Titanium and titanium alloys are the most commonly used biocompatible materials for the production of 3D medical implants [12, 13]. For orthopaedic implants, titanium and titanium alloys are considered superior to cobalt-chromium and stainless steel due to their lower elastic modulus and better biocompatibility [14]. Metal surfaces generally do not have sufficient antibacterial properties, and a lot of research are aimed at developing methods for modifying surface properties to provide an antibacterial effect for implantable devices [15–17]. Many strategies have been proposed for imparting antibacterial properties to implants including surface modification. Physicochemical modification methods cause changes in the chemical composition of the surface and nanostructure that would affect the implant interacting with the bacterial cell, disrupting molecular recognition by bacteria, and/or physically preventing pathogen adhesion and biofilm formation [18]. Such biofilm existence allows bacteria to evade various antibacterial drugs and immune factors, spread to new loci and infect previously uninfected tissues of the body, thereby ensuring the chronic course of the disease and the impossibility of total eradication of the pathogen [18–21].

The application of antibacterial coatings as a promising method of modifying the implant surface should provide high antibacterial properties, prevent the attachment of bacteria to the surface and the biofilm formation. The objective was to evaluate the antibacterial, antibiofilm activity and cytocompatibility of a multicomponent coating with magnesium and silver oxides on the surface of 3D titanium samples.

MATERIAL AND METHODS

The MgO-AgO-MgO complex was applied to 3D samples of medical titanium in accordance with the original method (Priority 202590080 dated 23.12.2024). The resulting samples are shown in Fig. 1.

To explore the surface, 3D samples were fixed on a holder and placed in the chamber of a scanning electron microscope (SEM) TM 4000 Plus (Hitachi), which had an XFlash 610 Mini energy dispersive spectrometer. The spectrometer resolution was 143 eV with the measurement accuracy of 0.01–1 %. The coating composition was determined with elemental analysis performed at an accelerating voltage of 15 keV, a working distance of 10 mm, a probe current of 1.4 nA, a probing depth of 0.5–1 µm, and a characteristic X-ray radiation sampling angle of 25°. Detection was carried out over the entire surface of the sample at several points by assessing the emitted X-ray radiation. Stereophotographs of the samples were obtained on an MSP-1 LOMO microscope.

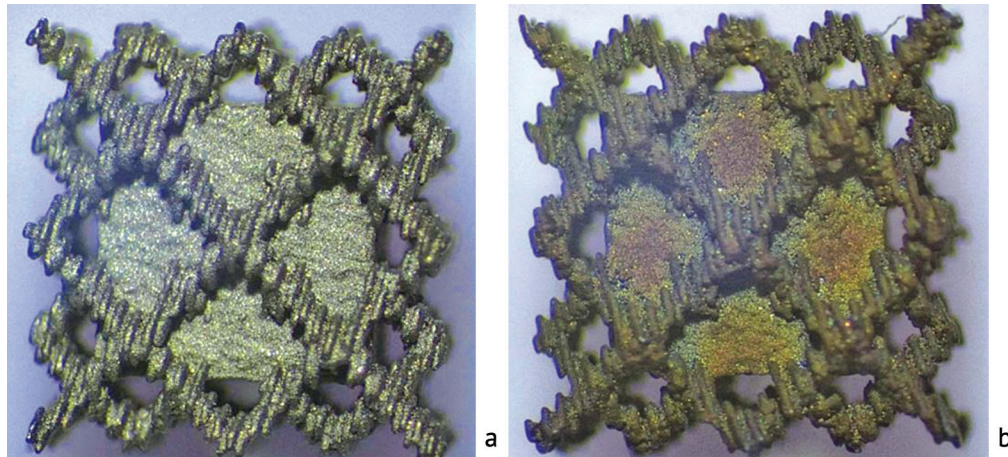


Fig. 1 3D titanium samples: (a) a sample having no coating to be tested; (b) a sample coated with the MgO-AgO-MgO complex:

ThreeD samples were immersed in 1 ml of Mueller-Hinton broth (MHB) containing 1×10^6 CFU/ml bacteria and incubated for 24 h at 37 °C to detect the presence and duration of antibacterial activity of the MgO-AgO-MgO complex against *S. aureus* ATCC 29213. Non-coated samples were added to MHB as a control. The MgO-AgO-MgO complex was considered active with a statistically significant difference between the optical density (OD) values of incubation media with test samples and the control (incubation media with non-coated samples). If signs of bacterial growth were recorded in the test tubes after 24 hours of incubation, broth cultures were seeded, and the grown colonies were identified after 24 hours. MHB without signs of growth was drained and replaced with 1 ml of MHB with 1×10^6 CFU/ml *S. aureus* ATCC 29213, the procedure was repeated daily with signs of growth seen in the test tubes.

Biofilms of the reference strain *S. aureus* ATCC 29213 were formed by immersing the test 3D titanium samples in 3 ml LB broth containing 1×10^5 CFU/ml bacteria, incubated at 37 °C for 24 h, after which the planktonic culture was removed, the samples were washed twice with saline and dried. The samples were transferred to 1 ml of physiological solution in Eppendorf tubes and placed in an ultrasonic washer for 5 min at 37°C. The contents of the tubes were then mixed using a vortex and 100 µl of sonication liquid was seeded onto the surface of Columbia agar. The dishes were incubated for 24 h at 37 °C and then counted.

The MALDI-TOF MS method was used to confirm the species identity of the grown colonies. Vero cells were grown in Dulbecco MEM/F12 medium with high glucose content and 10 % fetal bovine serum, 100 U/ml penicillin and 100 mg/ml streptomycin (Capricorn, Germany), dividing every 3–4 days in a ratio of 1:3. The titanium samples were placed in 3 ml of cell culture medium and incubated for 24 hours in a shaker at 150 rpm at +37 °C to obtain the extract. To assess viability, 2000 Vero cells were seeded into the wells of a 96-well plate. After 24 hours of cell attachment, 200 µl of the previously obtained extract in the culture medium were added to the wells. Vero cells in wells with standard medium without extract were used as a control. A solution of 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) was added to the wells after 72 h at a final concentration of 1 mg/ml and incubated for another 3 h. With MTT removed, 100 µl of dimethyl sulfoxide were added to the wells and incubated in a shaker at 200 rpm for 5 min. Then, the difference in OD at wavelengths of 570 nm and 620 nm was measured using an INNO-S spectrophotometer, subtracting the signal from empty wells. Vero viability was determined as the proportion of OD 570–620 nm in the samples relative to the control. The experiment was repeated three times.

Statistical analysis The results were analyzed using the Prism 9.0 program (GraphPad, USA) and the unpaired t-test method. Values of $p < 0.05$ were considered statistically significant.

RESULTS

The results of elemental analysis and mapping confirmed the presence and uniform distribution of silver oxide (AgO) and magnesium oxide (MgO) on the surface of 3D titanium samples. There was 39.3 % silver (Ag) content, 10.6 % magnesium (Mg), 15.5 % oxygen (O). No impurities of other elements were recorded (Fig. 2, 3).

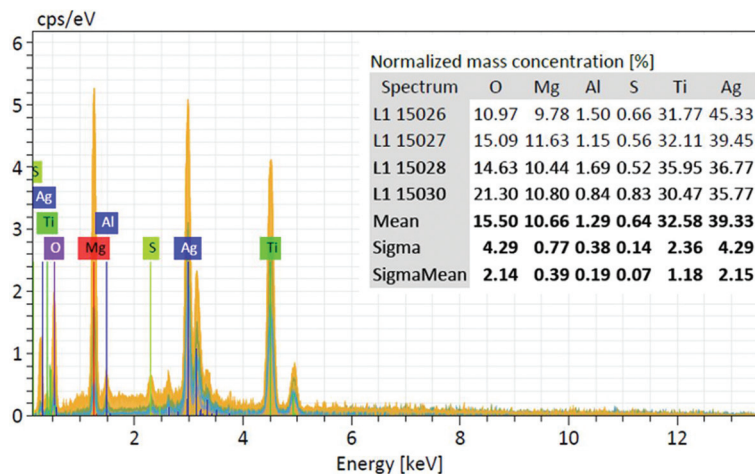


Fig. 2 Results of elemental analysis of titanium 3D sample with MgO-AgO-MgO complex

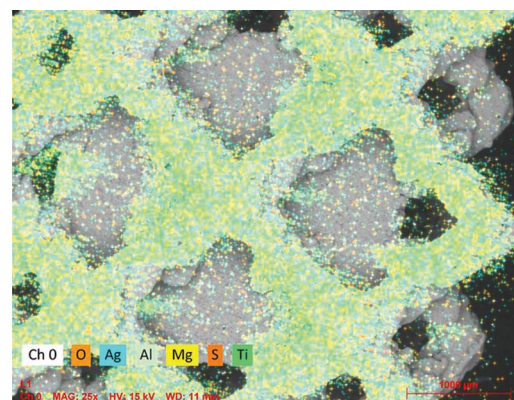


Fig. 3 Distribution of silver (Ag), magnesium (Mg) and oxygen (O) on the surface of titanium (Ti) 3D sample

The 3D titanium samples with MgO-AgO-MgO were characterized by antibacterial activity against the reference strain *S. aureus* ATCC 29213 (MSSA) for three days (Fig. 4). There were no signs of bacterial growth in the test tubes with samples coated with MgO-AgO-MgO, unlike the native samples, with the sediment and a turbid nutrient medium seen in the test tubes. The presence of *S. aureus* in the test tubes was confirmed using the MALDI-TOF-MS method.



Fig. 4 Test tubes with incubation media of 3D samples and bacteria after 24 hours of incubation

The tested samples with the original coating were characterized by the presence of anti-biofilm activity. The MgO-AgO-MgO complex effectively prevented the adhesion of *S. aureus* and the formation of a microbial film on the surface of 3D titanium samples, while the control samples showed staphylococci forming a biofilm with a sufficient number of bacterial cells to initiate the infectious process (Table 1). The adhesion of staphylococci to the surface was significantly lower compared to the control samples on the fourth day of incubation, despite the presence of signs of bacterial growth in test tubes with experimental samples.

Table 1

The number of microbial cells on the surface of samples

| Day | Number of microbial cells, CFU/ml | | <i>p</i> |
|-----------------|-----------------------------------|----------------------------|----------|
| | Samples with MgO-AgO-MgO complex | Control non-coated samples | |
| 1 st | 5 ± 2 | $1 \times 10^8 \pm 0$ | < 0.05 |
| 2 nd | 5 ± 2 | $1 \times 10^8 \pm 0$ | < 0.05 |
| 3 ^d | 10 ± 3 | $1 \times 10^8 \pm 0$ | < 0.05 |
| 4 th | $1 \times 10^2 \pm 30$ | $1 \times 10^8 \pm 0$ | < 0.05 |

Analysis of the cytocompatibility of the 3D samples obtained in ex vivo experiments using the culture of eukaryotic cells of the Vero line showed the absence of viable cells after 72 hours of incubation in a medium with an extract from coated titanium samples. The medium with an extract from non-coated samples had no evident effect on the viability of Vero cells (Fig. 5).

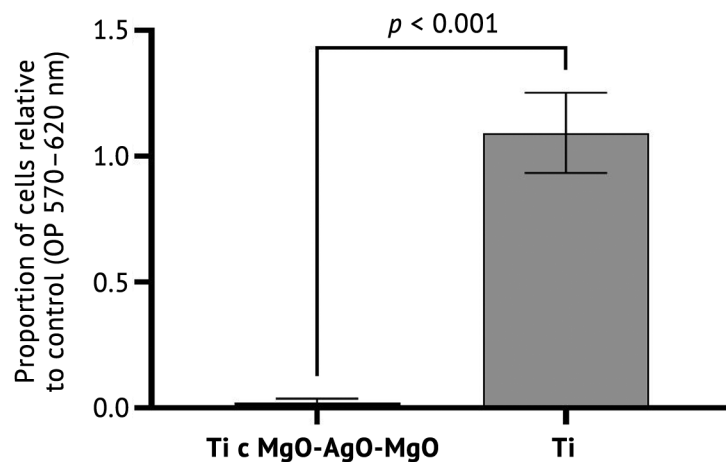


Fig. 5 Viability of Vero cells after 72 h of incubation with titanium sample extracts

DISCUSSION

Biomaterials play a key role in the success of orthopedic and dental surgeries. Pure titanium and titanium alloys are the most common materials used for permanent implants in contact with bone. Titanium has been successfully used as artificial implants in orthopedic surgery for decades due to the excellent mechanical and chemical properties, good corrosion resistance and biocompatibility. However, any surgical intervention associated with implantation carries a risk of IAI. Infections are caused by staphylococci in more than 55 % of orthopedic cases [22]. A retrospective study of the dynamics in the spectrum of orthopedic infection pathogens showed *S. aureus* developing in 31.3 %, *S. epidermidis* in 18.7 %, coagulase-negative staphylococci (except *S. epidermidis*) in 5.8 % over 12 years [22]. Staphylococci are capable of forming biofilms on the surface of implants and surrounding tissues, internalizing osteoblasts and osteocytes, and it is essential to prevent formation of a mature biofilm on the implant and a persistent microbial focus [23].

Bacterial resistance to metal nanoparticles is an extremely rare phenomenon, so data on the possibility of their use for surface modification by applying an active coating with metal particles and imparting anti-adhesive and antibacterial properties to implants are of considerable interest. The coatings we obtained contain magnesium and silver oxides. Magnesium ions play a key role in the formation

of hydroxyapatite crystals [24]. Magnesium stimulates osteoblast proliferation and promotes bone formation; a decrease in magnesium levels affects the expression of proinflammatory cytokines and cause bone resorption [25].

The antibacterial activity of magnesium is known [26, 27]. Coelho et al. reported the antibacterial properties of magnesium oxide introduced into a bone tissue substitute based on hydroxyapatite [28]. Zhao et al. demonstrated the antibacterial performance of a complex of magnesium and titanium dioxide against staphylococci [29]. Xiang et al. reported antibacterial properties of a complex with magnesium on the surface of titanium [30]. The studies do not contain data on the duration of the antibacterial activity of the coatings with magnesium developed by the authors. The multicomponent coating of 3D titanium samples with a complex of magnesium and silver oxides MgO-AgO-MgO we obtained showed pronounced antibacterial performance against *S. aureus* ATCC 29213 for three days. It is known that pathogen adhesion includes two stages [31]: an initial reversible interaction occurs between bacteria and implant surfaces in the first stage, while specific and non-specific interactions occur between bacterial cell wall proteins and implant surface binding molecules in the second irreversible stage. Despite a decrease in antibacterial properties on the fourth day of incubation, the MgO-AgO-MgO complex significantly prevents microbial adhesion to the surface of titanium 3D images to ensure protection of the implant from microbial biofilm.

It is important that any modification of the implant surface must be safe for the tissues of the body surrounding the implant in addition to pronounced antibacterial properties. Titanium dental implants coated with magnesium oxide are characterized by antibacterial properties *in vitro* and cytocompatibility. Zhao et al. modified the titanium surface with magnesium-doped titanium dioxide. The authors showed that such a complex promoted osteoblast adhesion, proliferation and differentiation, osteogenesis via the ERK/c-Fos signaling pathway and early osseointegration of titanium implants [29]. Xiang et al. developed a magnesium coating that potentiated the viability, proliferation, and osteogenic differentiation of bone marrow mesenchymal stem cells [30].

The antibacterial effect of metal oxides, including magnesium, can be realized through oxidative stress, damage to the bacterial cell wall, and disruption of proteins and DNA [32]. The cytotoxicity of the titanium 3D samples with MgO-AgO-MgO that we identified could be caused by significant activation of lipid peroxidation reactions, which resulted in suppressed viability of eukaryotic cells of the Vero line.

CONCLUSION

The original coating we obtained demonstrated a high clinical potential as a multifunctional antibacterial coating for the surfaces of orthopedic implants printed on a 3D printer, preventing the possibility of primary interaction of the pathogen with the abiotic surface, which was one of the main factors in preventing IAI and the relapses after revision surgeries with implant replacement. However, the high level of cytotoxicity requires further modification of the coating application technique or its composition to reduce the level of cytotoxicity maintaining the antibacterial activity of the complex.

Conflicting Interests The authors declared no potential conflicts of interest with respect to the authorship and/or publication of this article.

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Information about the authors:

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

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

Dmitry V. Labutin — Junior Researcher, mailbox@dlabutin.com, <https://orcid.org/0000-0002-4405-7688>;

Marina V. Bogma — Candidate of Pharmaceutical Sciences, specialist in low-temperature plasma,
mvbogma@gmail.com, <https://orcid.org/0009-0002-8446-5114>;

Alexander A. Eruzin — Candidate of Technical Sciences, engineer, vacuum metallization section,
specialist in low-temperature plasma, chemical-man@yandex.ru, <https://orcid.org/0000-0003-2327-2466>.

Original article

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Experimental topographic and anatomical substantiation of hybrid osteosynthesis of the fibula in patients with ankle fractures

V.O. Tsapenko✉, Yu.B. Kashansky, R.V. Vashetko, I.P. Kondratiev, A.V. Polikarpov

St. Petersburg Research Institute of Emergency Medicine named after I.I. Dzhanelidze, Saint Petersburg, Russian Federation

Corresponding author: Vladimir O. Tsapenko, vovantsapa@mail.ru

Abstract

Introduction Ankle fractures are one of the common injuries treated by orthopaedic surgeons. The lack of a standard medical care can be associated with poor outcomes, high disability rates with conservative treatments. Reported outcomes following operative fixation vary widely in the literature and infectious complications can complicate the rehabilitation process.

The **objective** was to show a clinical possibility, safety and feasibility of a new method of fibula fixation in ankle fractures using necropsy material and to reduce negative consequences after surgical treatment.

Material and methods Major vessels and nerves were isolated in the lower third of tibia in 11 biomannequins, AO 44C1 and 44C2 fractures obtained mechanically and fibula fixed using the technique offered. Forces were applied to the injury site through mechanical stress tests.

Results The fixation method did not lead to a conflict between fixing screws and major vessels and nerves. No visible changes in the fibula position were noted in the biomannequins with the foot brought to extreme positions of plantar and dorsal flexion, with stress tests causing valgus and varus deformities.

Discussion As opposed to conventional surgical treatments of ankle fractures, no large incisions are required with the technique to place implants. There is no need to use plates, and the fracture can be fixed using the paired bone of the injured segment instead. Fixation screws can be inserted transcutaneously through soft tissue punctures. The new method is associated with less trauma, less quantity of metal needed and reduced probability of infectious complications. It can be used for AO 44C1 and 44C2 fractures in medical institutions with different availability of equipment.

Conclusions Ankle fractures can be repaired with the technique offered causing no damage to the major vessels and nerves at the surgical site. Stress tests showed stable fibula fixation achieved in all cases avoiding mobility at the fracture site. The new technique can facilitate normal reparative osteogenesis in clinical practice.

Keywords: osteosynthesis, ankle fracture, trauma

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INTRODUCTION

Ankle fractures are often considered a routine pathology [1–4] and are still commonly underestimated and overlooked. Inadequate strategies for treating ankle fractures can lead to poor outcomes [5–12]. The best treatment for ankle fractures remains a topic of debate and depends on the specific fracture and patient factors. Conservative (non-surgical) treatment of ankle fractures, particularly those that are unstable or displaced, can lead to poor outcomes and ankle fracture surgery comes with a risk of fracture-related infection [13–16].

In recent years, a progress has been made in the treatment of patients with diaphyseal fractures of the limbs, and significantly less so when the fracture is localized in the metaepiphysis or is intra-articular. Besides simple fracture entities resulting from low energy trauma, there are comminuted ankle fractures associated with significant soft tissue damage and bone displacement [17]. Ankle fractures, including pilon and malleolus fractures, are prioritized based on their severity and stability [18, 19].

Early application of conventional methods of osteosynthesis with metal constructs can lead to poor outcomes. Open reduction and internal fixation (ORIF) for ankle fractures, while often effective, can present several disadvantages and potential complications [20]. Early intervention and rehabilitation after an ankle fracture can significantly improve outcomes and functional recovery [21]. Minimally invasive osteosynthesis has been reported to be superior to open reduction and internal fixation in the treatment of different long bone fractures. All of the above served as a reason for developing a method of fracture fixation, which, in contrast to traditional approaches, is less traumatic and metal-intensive, and allows for reliable bone fixation that would result in complete fusion.

The **objective** was to show a clinical possibility, safety and feasibility of a new method of fibula fixation in ankle fractures using necropsy material and to reduce negative consequences after surgical treatment.

MATERIAL AND METHODS

The study was performed using 11 lower limbs of biomanikins to be used for the method of osteosynthesis proposed. The intact tibia of the traumatized bone was used for the fibular fixation instead of extra-osseous or intraosseous implant (Patent “Method to repair tibial and forearm fractures”) [22, 23].

Two pairs of Kirschner wires were placed transcutaneously in the distal tibia and fibula lateral-to-medial. The wires were placed in cutting planes with an arbitrary divergence from 6° to 30° in-between them and passed through the cortices of the fibula and tibia of the simulated injured segment of the limb at a distance of (4.2 ± 0.3) cm from the tip of the lateral malleolus to the distal wires (the first distally located wire) and (9.1 ± 0.3) cm from the tip of the lateral malleolus to the proximal wires (the fourth proximal wire). In this way, fixation of the fibula to the tibia was simulated that could replace the plate or another implant (Fig. 1).

Then the skin-fascial flap was removed, tissue preparation was performed to isolate the anterior tibial vascular bundle and the peroneal nerve. Position of the wires in relation to the vascular-nerve formations was visually determined, and distances from them to the apex of the lateral malleolus were measured in the frontal and parasagittal planes (Fig. 2). The fibula was osteotomized between

the pairs of wires at a distance of (6.2 ± 0.2) cm from the apex of the lateral malleolus using the Gigli saw (Fig. 3). The pins were removed and fibula fracture was temporarily fixed with a bone holder (Fig. 4). The next stage included osteosynthesis using the proposed method with screws placed in the channels formed by the wires in such a way that they also passed through the fibula and tibia cortices (Fig. 5).

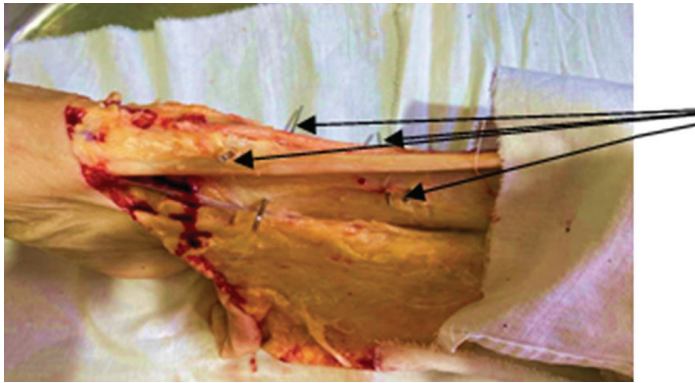


Fig. 1 Kirschner wires placed in the tibia and fibula

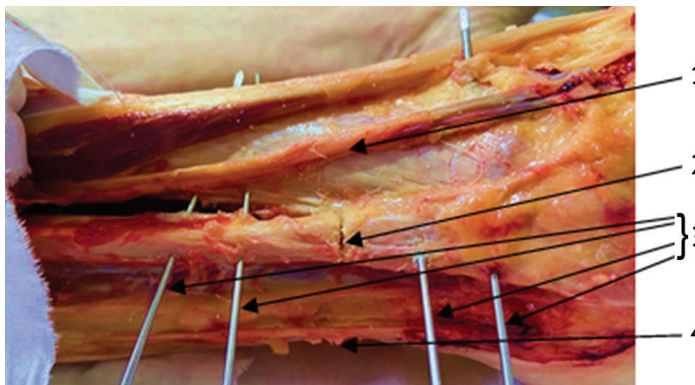


Fig. 2 Wires positioned relative to the vascular-nerve bundles: (1) anterior tibial artery; (2) Kirschner wires; (3) peroneal nerve

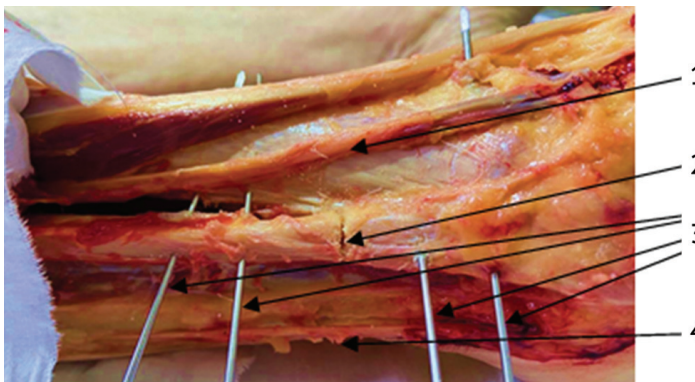


Fig. 3 Condition after fibular osteotomy: (1) anterior tibial artery; (2) line of the fibula fracture formed; (3) Kirschner wires; (4) peroneal nerve

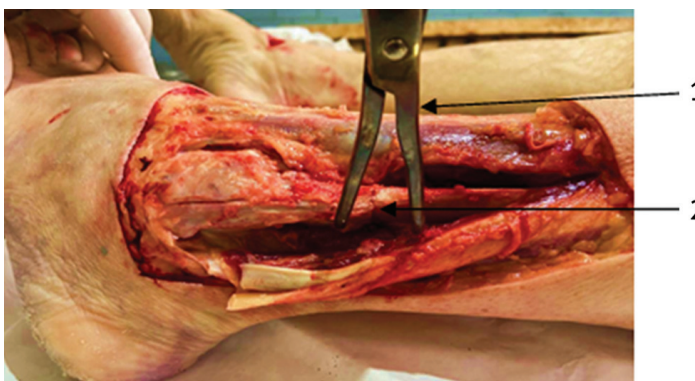


Fig. 4 Temporary bone fixation: (1) bone holder; (2) line of the fibula fracture

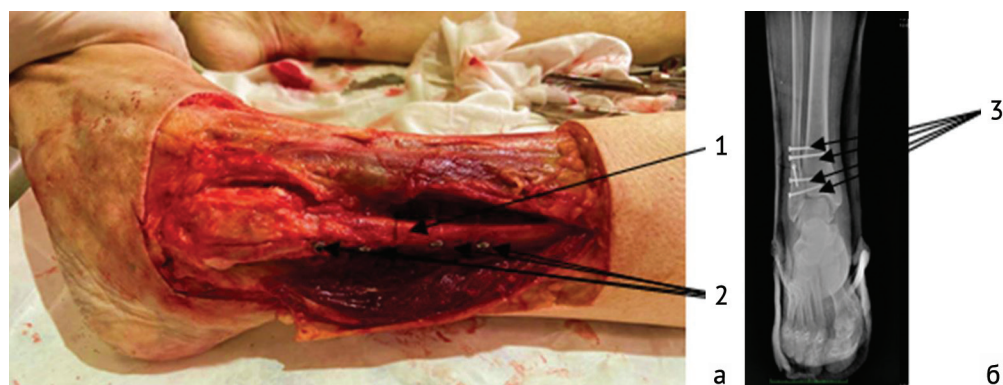


Fig. 5 Osteosynthesis of the fracture using the method proposed (a) and an X-ray of the injured segment after osteosynthesis using the scheme proposed (b): (1) line of the fibular fracture; (2) screw heads after the insertion; (3) cortical screws

Visual assessment of fracture fixation was performed using stress tests aimed at maximum medialization and lateralization of the foot, and using the extreme positions of plantar and dorsal flexion.

RESULTS

The measurements are presented in Table 1.

Table 1

| Measurements | | | | | | | | | | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------|------|------|------|------|------|------|------|------|------|----------------|
| Measurements | Nº preparation | | | | | | | | | | | Average values |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | |
| Distance from the wires at the fracture level at the tibiofibular syndesmosis, drawn perpendicular to the long axis of the tibiofibular joint, cm | | | | | | | | | | | | |
| to the anterior tibial artery | 1.2 | 1.1 | 1.3 | 1.0 | 1.3 | 1.2 | 1.0 | 1.1 | 1.3 | 1.2 | 1.0 | 1.1 ± 0.2 |
| to the peroneal nerve | 1.9 | 2.1 | 2.0 | 1.8 | 2.3 | 2.1 | 1.7 | 1.8 | 1.9 | 2.2 | 1.8 | 1.9 ± 0.4 |
| Length of the fibula from the head to the top of the lateral malleolus, cm | 41.5 | 40.2 | 42.4 | 41.0 | 41.2 | 42.0 | 41.3 | 41.9 | 40.3 | 42.1 | 41.7 | 41.4 ± 0.5 |
| Distance from the top of the lateral malleolus, cm | | | | | | | | | | | | |
| to the fracture site formed, cm | 6.3 | 6.2 | 6.4 | 6.0 | 6.3 | 6.5 | 6.1 | 6.3 | 6.2 | 6.0 | 6.4 | 6.2 ± 0.2 |
| to the distal wires (1st DW) | 4.5 | 4.1 | 4.4 | 4.2 | 4.0 | 4.2 | 4.3 | 4.4 | 4.0 | 4.5 | 4.1 | 4.2 ± 0.3 |
| to the proximal wires (4th PW) | 9.4 | 9.0 | 9.1 | 8.9 | 8.7 | 9.0 | 9.2 | 9.1 | 9.3 | 9.1 | 9.3 | 9.1 ± 0.3 |
| Distance from the wires at the level of a line drawn perpendicular to the long tibial axis, cm | | | | | | | | | | | | |
| to the anterior tibial artery at the level of the exit of the bundle of wires | 1 st distal wire | 4.8 | 5.0 | 4.9 | 4.7 | 5.1 | 5.0 | 4.9 | 4.7 | 4.8 | 5.1 | 4.9 ± 0.2 |
| | 4 th proximal wire | 4.7 | 4.8 | 4.6 | 4.6 | 4.9 | 5.1 | 4.8 | 4.8 | 4.6 | 5.0 | 4.7 ± 0.4 |
| to the peroneal nerve at the level of the entry of the bundle of wires | 1 st distal wire | 2.6 | 2.4 | 2.5 | 2.4 | 2.3 | 2.5 | 2.6 | 2.2 | 2.4 | 2.5 | 2.3 ± 0.3 |
| | 4 th proximal wire | 2.2 | 2.5 | 2.1 | 2.5 | 2.2 | 2.6 | 2.3 | 2.4 | 2.5 | 2.3 | 2.3 ± 0.3 |

The objective data obtained confirmed the results of visual control. It can be suggested that the method proposed does not cause a conflict of wires, which are located at a significant distance from major vascular-nerve formations.

DISCUSSION

Literature review showed that the method of treating ankle fractures depends on the type of injury. If the ankle joint remains stable after the injury, the conservative treatment methods provide excellent results. However, J.D. Michelson reported non-displaced syndesmosis injuries requiring fixation after stress testing [24]. Immobilization of fracture dislocations in the ankle joint using various conservative means can lead to a loss of reduction and complications with soft tissues. The risks can be reduced by surgical treatment with use of external fixation devices [25, 26]. Unstable ankle joint are repaired with surgical methods. Fixation plates are reliable for comminuted fracture [27]. Intramedullary osteosynthesis can be used for fixation of unstable distal fibula fractures [28]. This is supported by an experimental study that has proven the advantage of the fixation method compared to conventional plating [29].

Injuries of the tibiofibular syndesmosis can be repaired with dynamic fixation using metal buttons combined with a thread as reported by Lazko [30]. Gafurov considers this method a good alternative to traditional static fixation using a positional screw [31]. With the advantages of dynamic fixation, the technique can be expensive and static methods remain an important trauma and orthopedic tool [30, 31]. Murphy does not see a significant difference between the methods, although the latter may cause postoperative complications and a greater rate of re-operations [32].

The hybrid method of fibula osteosynthesis is characterized by the entry and exit points of the screws being located in the area of the anterior tibial artery and peroneal nerve. The study was aimed at demonstrating the safety of the method offered and some advantages compared to the traditional method of osteosynthesis of the lower fibula third.

Therefore, the method of osteosynthesis can be used to repair ankle fractures AO 44C1, 44C2 in clinical practice. The new method is associated with less trauma, less quantity of metal needed and can be offered for medical care provided for patients in institutions with varying levels of equipment, reducing financial costs for the treatment of the cohort of patients.

CONCLUSION

Предложенный Ankle fractures can be repaired with the technique offered causing no damage to the major vessels and nerves at the surgical site. Stress tests showed stable fibula fixation achieved in all cases avoiding mobility at the fracture site. The method of hybrid osteosynthesis of the fibula provides stable bone fixation at the fracture site in patients with ankle fractures and is safe and technically feasible in clinical scenarios. The findings allow us to recommend the method for use in clinical practice.

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Information about the authors:

Vladimir O. Tsapenko — Junior Researcher, vovantsapa@mail.ru;

Yuri B. Kashansky — Doctor of Medical Sciences, Leading Researcher;

Igor P. Kondratyev — Candidate of Medical Sciences, senior researcher;

Anatoly V. Polikarpov — Candidate of Medical Sciences, orthopaedic surgeon, dr.polikarpov@gmail.com;

Rostislav V. Vashetko — Doctor of Medical Sciences, Leading Researcher.



Variant of bone restoration in humeral nonunion with a free fibular autograft in the conditions of transosseous osteosynthesis

Sh.M. Davirov¹, P.U. Urinbaev², Dz.Sh. Mansurov², F.A. Gafurov², D.Yu. Borzunov^{3,4}✉

¹ Samarkand branch of the Republican specialized scientific and practical medical center of traumatology and orthopedics, Samarkand, Uzbekistan

² Samarkand State Medical University, Samarkand, Uzbekistan

³ Ural State Medical University, Yekaterinburg, Russian Federation

⁴ Central city clinical hospital No. 23, Yekaterinburg, Russian Federation

Corresponding author: Dmitry Yu. Borzunov, borzunov@bk.ru

Abstract

Introduction Failures in surgical rehabilitation of patients with humeral fractures result in the formation of a multicomponent complex of pathological symptoms, including nonunion or bone defect, changes in the shape and length of humeral fragments, development of persistent angiotrophic disorders of the upper limb and contractures of the shoulder and elbow joints. Despite the effectiveness of using metal implants, there are risks in surgical osteosynthesis in complex anatomical and functional lesions.

The **purpose** of the work was to demonstrate a new technology of bone plasty with free fragments of the fibula as a bone-plastic material for restoring the integrity of the humerus in bone nonunion and defects in the conditions of transosseous osteosynthesis and transosseous fixation of the grafts with wires.

Materials and methods A free autograft of the fibula shaped as a cylindrical fragment, which was resected proximally to the ankle joint level at 8.0-9.0-cm distance, was used as a bone plastic material. The fibula graft was fragmented intraoperatively. Fragments were implanted along the periphery of the humerus fragments overlapping of the pseudarthrosis site. Free autografts of the fibula were transosseously fixed with wires. A wire/half-pine Ilizarov apparatus with three external supports was placed to fix the segment.

Discussion The "gold standard" material for bone plasty is autogenous bone. If defects and pseudoarthroses of the humerus are located in the distal metaepiphysis, the application of the fibular cylinder-shaped fragment with intraosseous reinforcement of the humeral bone is technically difficult. Open co-aptation of the humeral fragments with adequate contact between them and application of the optimal autogenous bone-plastic material which overlaps the pseudarthrosis zone to increase the volume of bone mass ensure the restoration of bone regeneration in the pseudarthrosis zone. External fixation is optimal for fixation of bone fragments and grafts.

Conclusion The originality of the developed technology lies in the use of several free bone autografts from the fibula implanted along the periphery of the humeral fragments junction. The area of active osteogenesis is thus created due to the combined effect of open co-aptation of the ends of the humeral fragments with resection of the endplates and bone autogenous grafts that overlap the problematic area. Additional transosseous fixation of bone autografts with wires ensures the stability of free grafts. Controlled fixation of humeral fragments with compression and adequate contact of the fragments is achieved with the Ilizarov apparatus.

Keywords: nonunion, pseudarthrosis, humerus, fibular autografts, transosseous osteosynthesis, Ilizarov, bone plasty material

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INTRODUCTION

The Federal State Statistics Service of the Russian Federation reports that upper limb injuries accounted for 34.6 % to 34.9 % of all skeletal injuries and their consequences in the period from 2020 to 2023. Unfortunately, not all patients with skeletal injuries of the upper limb had satisfactory treatment outcomes. Thus, humeral nonunion and bone defects are detected in 2 up to 30 % of cases following humeral fractures [1]. As a rule, due to failures of surgical rehabilitation, patients develop a multicomponent pathological symptomatic complex, including nonunion or bone defect, changes in the shape and length of humeral fragments, persistent angiotrophic disorders in the upper limb, and contractures of the shoulder and elbow joints [2]. Pathological processes reflect themselves in the architecture of the bone tissue of the humeral fragments, such as their eburnation and atrophy, while the fragments have a mosaic combination of sclerosis and osteoporosis areas throughout [2].

According to the current literature, orthopaedic trauma surgeons prefer dynamic DCP/LCP plates and intramedullary locked osteosynthesis as fixation means. At the same time, while recognizing the effectiveness of internal metal structures, the authors acknowledge the risks of surgical intervention failures and, in some cases, failures of osteosynthesis in complex anatomical and functional injuries of the humerus [1, 3–6].

Purpose The aim of the work was to demonstrate a new technology of bone plasty with free fragments of the fibula as a bone-plastic material for restoring the integrity of the humerus in bone nonunion and defects in the conditions of transosseous osteosynthesis and transosseous fixation of the grafts with wires.

MATERIALS AND METHODS

A retrospective evaluation of humeral bone reconstruction with free fibular autografts in the conditions of transosseous osteosynthesis and transosseous fixation of grafts with wires was performed. The novelty of the technology has been confirmed by an application for a patent for the invention "Autotransplantation of the fibula for defects of the diaphysis of long bones" registered with the Federal Institute of Industrial Property (reg. No. 2024137957 dated 17.12.2024).

Technical performance

A free autograft of the fibula shaped as a cylindrical fragment up to 7 cm long which was resected proximally at 8–9 cm from the ankle joint level was used as a bone-plastic material. The resected autograft of the fibula was divided into two cylindrical fragments and fragmented lengthwise into several pieces. Then, the pseudarthrosis site was approached, the endplates of the humerus fragments were resected, and the humerus fragments ends were adapted for contact. To increase the volume of bone mass in the pseudarthrosis and bone defect site for expected increase in the strength properties of the future callus, the prepared previously bone autografts were implanted along the periphery of the pseudarthrosis site, overlapping the humerus fragments junction. To exclude possible autograft migration, they were additionally fixed with transosseous wires inserted into the soft tissues of the humerus along the periphery. After hemostasis control, the wound was sutured tightly layer by layer. To fix the segment, the Ilizarov apparatus was used, consisting of three external supports in the wire/half-pin variant of bone fragment fixation. Considering the transosseous fixation of bone grafts and the end-to-end contact between the fragments of the humerus, we refrained from traditional supporting compression at the junction of the fragments in the postoperative period, and actually switched to a neutral version of transosseous osteosynthesis. After the fragments showed union in radiographs and in clinical consolidation test, the Ilizarov apparatus was dismantled.

Case report

A 38-year-old patient was admitted to the clinic on 23.04.2024. The injury was 19 years old and the patient had undergone multiple failed surgeries. Unfortunately, the patient did not have complete medical reports on the previous stages of treatment.

Nonunion of the patient's left humerus was classified as a pseudarthrosis with a normotrophic type of bone formation according to the Weber & Cech classification [7] and verified as a defect-pseudarthrosis of the left humerus with anatomical shortening of 6 cm according to the classification of Shevtsov et al. [2].

The previous surgeries resulted in numerous pointed and linear scars along and combined contractures of the left shoulder and elbow joints with a sharp limitation of the function of the upper limb. Movements at the level of the left elbow joint were possible mainly due to pathological mobility in the area of the neoarthrosis (Fig. 1).



Fig. 1 Photo and radiographs of the left humerus in two projections at admission to the hospital

At the Samarkand branch of the RSNPMC TO, the patient underwent open co-aptation of the fragments of the left humerus. The ends of the fragments were economically resected, the bone marrow canals were opened, and end contact was achieved between them. Fragments of the fibula were implanted into the pseudarthrosis site of the humerus along the periphery and were additionally fixed with wires. Fixation of the segment was carried out with the Ilizarov apparatus of three supports in a wire/half-pin arrangement (Fig. 2). During the dynamic examination, the patient regularly underwent clinical examinations and X-ray studies, while positive dynamics of graft reorganization and the formation of bone callus in the pseudarthrosis zone of the humerus fragments were observed (Fig. 3).

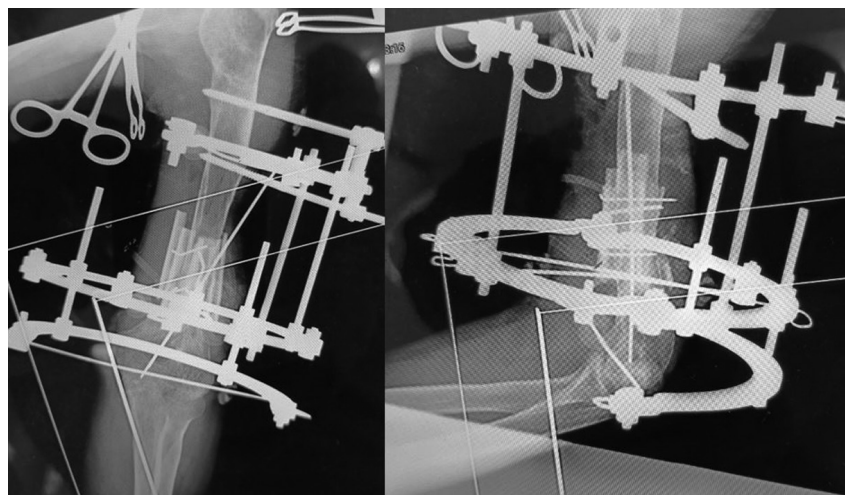


Fig. 2 Intraoperative radiographs of the left humerus in two projections taken on 26.04.2024

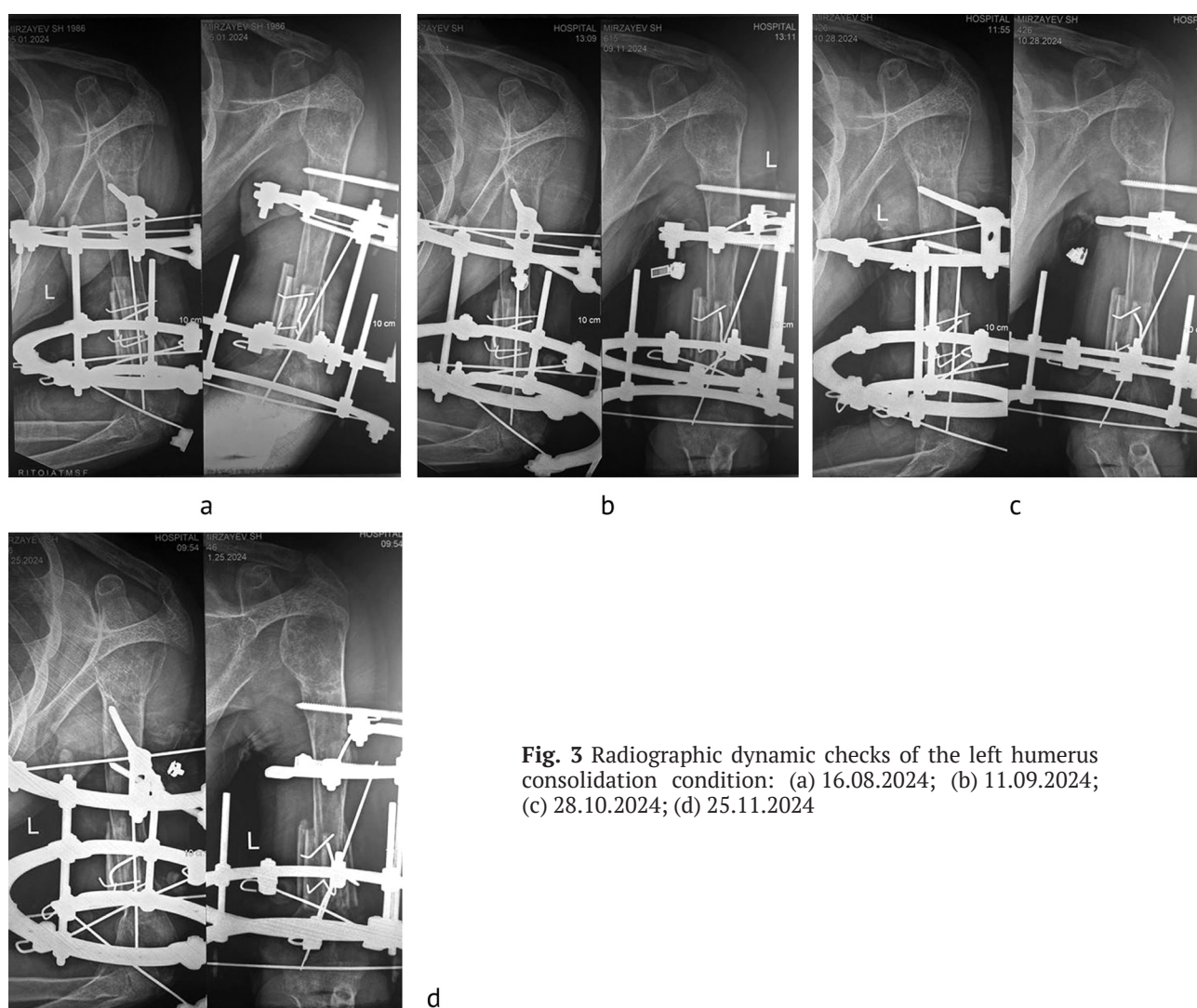


Fig. 3 Radiographic dynamic checks of the left humerus consolidation condition: (a) 16.08.2024; (b) 11.09.2024; (c) 28.10.2024; (d) 25.11.2024

The radiographic control and clinical consolidation test showed bone union and augmented bone mass at the pseudarthrosis level. Free autografts of the fibula were undergoing remodeling, lysis and signs of osteonecrosis of bone tissue were absent. The Ilizarov apparatus was dismantled (Fig. 4). Three months after dismantling the apparatus, the treatment result was preserved, remodeling of newly formed bone tissue was complete (Fig. 5).



Fig. 4 Photos and radiographs of the left humerus in two projections upon the dismantling of the Ilizarov fixator and removal of transosseous wires on 14.01.2025



Fig. 5 Radiographs of the left humerus in two projections at a 3-months follow-up after Ilizarov apparatus removal on 14.04.2025

DISCUSSION

We believe that external fixation can be considered as an alternative variant of osteosynthesis in complex clinical situations. Obviously, this idea is not new. According to our data, the possibility and effectiveness of transosseous osteosynthesis in the treatment of patients with pseudarthrosis and defects of the humerus were first described in the dissertation research of V.I. Shevtsov [8]. Despite the long history of successful use of transosseous osteosynthesis in the treatment of patients with defects and pseudarthrosis of the humerus, there is no reason to claim that this fixation option is widespread and popular. Most publications devoted to this problem were written by researchers of the Ilizarov Center [2, 9–11].

However, recent publications by the authors from Uzbekistan report on the successful use of transosseous osteosynthesis to correct deformities and manage pseudarthrosis of the humerus [12–15]. The choice of osteosynthesis and fixation of humeral fragments is not the only problem in the surgical rehabilitation of patients with defects and nonunion of the humerus. To restore the integrity of the humerus, open coaptation of the ends of the fragments is required for a tight contact between them, opening the bone marrow canals and application of bone-plastic materials, mainly allo- and autografts in the case of bone defects [1, 16].

It is known that the “gold standard” of bone-plastic material is autogenous bone, while the use of fibula as the most accessible autograft has been recognized effective and popular [4, 17–20]. Certainly, researchers would prefer to use a vascularized fibula with restored arteriovenous bypass [21–27]. However, this technology is complex, two-stage, requires the use of microsurgical techniques, creates problems in the donor site, the replant itself has risks of thrombosis of arteriovenous shunts, and in a number of clinical situations the operation is technically impossible [28–31].

According to our data, the fibula was first used for humeral reconstruction with intramedullary fixation of the graft by Wright et al. [4]. In the literature, one can find publications on the successful use of a free non-vascularized fibula in patients with pseudarthrosis of the humerus, and the authors of those reports preferred plates with angular stability for fixation of fragments [16, 17, 20].

An experience of successful management of atrophic defects of the humerus was published: a free autograft of the fibula was implanted into the bone marrow canal of the humerus, fixation of fragments and maintenance of compression were carried out with the Ilizarov apparatus [32]; the novelty of the developed technology was confirmed by a Russian patent [33].

However, in a number of clinical situations, intraosseous implantation as an option for a post-traumatic defect in the distal humerus and intramedullary canal reaming in the intercondylar zone of the humerus are impossible due to the anatomical features of the humerus and the risks of iatrogenic fractures during canal formation. Therefore, when defects and pseudoarthroses of the humerus are located in the distal metaepiphysis, the use of the fibula in the cylinder-fragment design with intraosseous reinforcement of the humerus is technically impossible with the previously proposed technology [32, 33].

Based on the literature data on the search and development of new innovative bone-plastic materials, it should be noted that to date, autografts, which have no risks of negative immune responses and are capable of complete organotypic restructuring, are still optimal in terms of osteoinductive and osteoconductive properties [32, 34]. The key disadvantage of bone autografts is the limited volumes of this bone-plastic material [35]. At the same time, in a number of complex clinical situations with bone defects of the upper limbs, significant volumes of implantation material are not required. Rational use of available donor material can provide the necessary volumes of lost bone tissue.

Based on this concept, we considered the possibilities of managing humeral bone defects with free autografts from the fibula as quite sufficient and rational. The patient's case presented as a clinical example had a pseudarthrosis of the humerus localized in the distal metaphysis, had combined persistent contractures of the adjacent joints, and pronounced pathological mobility of bone fragments. Given the features of the pathological anatomical and functional changes in the patient's upper limb, the use of dynamic DCP/LCP plates or intramedullary locking fixators was questionable, since these instruments have limitations in strength and time of action.

According to the literature, the main cause of nonunion and failures after reconstructive interventions is the lack of rigid and stable fixation of the humerus fragments [5, 6, 36, 37]. Adequate contact between the ends of the fragments is necessary to achieve union [38]. Open coaptation of the humerus with adequate contact between the fragments and the use of optimal autogenous bone-plastic material ensures bone regeneration in the pseudarthrosis site. In our opinion, with this type of bone grafting, external fixation devices have undeniable advantages in fixing humerus fragments and bone grafts. An enhanced volume of bone mass in the pseudarthrosis zone resulting

from bone remodeling in the adaptation zone of the fragment ends and organotypic restructuring of free autografts allows us to recommend this technology for restoring the integrity of the humerus not only in normotrophic pseudarthrosis but also in atrophic nonunion.

CONCLUSION

The originality of technology lies in the use of several free bone autografts formed from the resected fibula fragment and implanted along the periphery of the humeral fragments junction. Currently, despite the active search and development of innovative bone grafting materials, the most effective and generally accepted method is the use of autografts, with the fibula used as the “gold standard” for bone grafting. The area of active osteogenesis is created due to the combined effect of open coaptation of the ends of the humeral fragments with resection of the endplates and bone autogenous grafts that overlap the problematic area. Additional transosseous fixation of bone autografts with wires ensures the stability of free grafts. Controlled fixation of humeral fragments with compression and adequate contact of the fragments is achieved with the Ilizarov apparatus.

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Information about the authors:

Sharof M. Davirov — PhD, orthopaedic surgeon, Head of the Department,
sharofd1976@mail.ru, <https://orcid.org/0009-0003-0954-4573>;

Paizilla U. Urinbaev — Doctor of Medical Sciences, Professor of the Department;

Dzhalolidin Sh. Mansurov — Candidate of Medical Sciences, Head of the Department;

Farrukh A. Gafurov — PhD, Assistant of the Department;

Dmitry Yu. Borzunov — Doctor of Medical Sciences, Professor, Professor of the Department,
borzunov@bk.ru, <https://orcid.org/0000-0003-3720-5467>.



Overcorrected lower limb axis as an outcome of unicompartmental knee arthroplasty

N.N. Kornilov, D.V. Chugaev, P.P. Ivanov, M.Sh. Magomedov✉, T.A. Kulyaba, A.S. Phil

Vreden National Medical Research Centre for Traumatology and Orthopedics,
St. Petersburg, Russian Federation

Corresponding author: Magomed Sh. Magomedov, dr.magomedovmsh@gmail.com

Abstract

Introduction Unicompartmental knee arthroplasty (UKA) is an effective surgical procedure used in patients with gonarthrosis with a part of the knee being severely affected. Insufficient or excessive correction of the lower limb axis can cause a poor outcome of partial arthroplasty.

The **objective** was to evaluate ways that would help prevent insufficient or excessive correction of the lower limb axis with UKA and demonstrate techniques preventing and solving the surgical problem using a clinical example.

Material and methods A patient presented with valgus deformity at the knee level, knee pain and inability to walk without support was seen at the Vreden National Medical Research Centre for Traumatology and Orthopedics. The patient underwent UKA three years ago. The radiographs showed sparing resections of the femur and tibia, the working surface of the polyethylene liner/tibial implant component being 5 mm proximally to the articular surface of the lateral condyle of the tibia.

Results and discussion The limb axis was corrected by 6° during revision arthroplasty. The patient had no limping at one year and the result of the operation was rated as excellent measuring 45 OKS scores. The authors reviewed prerequisites of the complication in question and ways to prevent it. Iatrogenic causes primarily associated with surgical technique are reviewed.

Conclusion Inadequate mechanical alignment is characterized by a heterogeneous identity in UKA and can be caused by ineffective preoperative planning and specific anatomy of the patient, intraoperative technical failures.

Keywords: knee joint, unicompartmental knee arthroplasty, UKA, partial arthroplasty, overcorrected limb axis, complications of total joint replacement.

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INTRODUCTION

Unicompartmental knee arthroplasty (UKA) is generally recognized with many benefits including a minimally invasive procedure, organ-preserving approach, the possibility of rapid recovery and easy rehabilitation with the effect of a “forgotten knee joint” [1]. It appears to be logical towards expanding indications for the surgical intervention in patients with gonarthrosis and the general increase in partial arthroplasties worldwide [2]. Current indications for UKA formulated by Goodfellow [3] and reported by other authors include simple clinical and radiological criteria for patient selection, which are identical for any implant model. However, a personalized approach to knee arthroplasty suggests a greater number of factors to be considered preoperatively including the axis of the patient's limb, geometry of the bones that form the knee joint, the extent and nature of wear of the articular surfaces of the condyles, the elasticity of soft tissue stabilizers, the degree of meniscus damage and the extent of the extrusion, the presence, size and localization of osteophytes [4]. Differences in the parameters can influence the success or failure of UKA.

Postoperative limb alignment is one of the most important factors that would influence the long-term outcome of UKA. The overloaded lateral portion of the joint after partial medial arthroplasty and overcorrected axis would lead to persistent pain, associated ligament imbalance and other mechanical factors causing rapid lateral wear of the cartilage and progression of gonarthrosis and the need for revision [5, 6]. Numerous studies have shown that the optimal surgical outcome can be achieved with the limb realigned to pre-arthrosis condition in medial involvement and often expressed in the preservation of residual varus deformity [7, 8]. In contrast to this, insufficient correction of deformity is a generally recognized risk factor for a poor outcome at a mid-term in patients with medial gonarthrosis treated with periarticular osteotomies and total replacement. The scenario is different with partial arthroplasty: the more the limb realigned to the “average population” values, the faster the arthrosis progresses in the contralateral portion of the joint [9, 10]. The deformity correction with partial arthroplasty should be the sum of the replacement of the remnants of the cartilaginous cover of the affected subchondral bone, meniscus and marginal osteophytes removed being minimally necessary for endoprosthesis positioning. Exceeding the limit and the release of intact soft tissue stabilizers, would result in overcorrection of the limb axis after UKA. This study is devoted to the analysis of the causes of such errors.

The **objective** was to evaluate ways that would help prevent insufficient or excessive correction of the lower limb axis with UKA and demonstrate techniques preventing and solving the surgical problem using a clinical example.

MATERIAL AND METHODS

A 52-year-old patient G. presented with valgus deformity of the right lower limb, knee pain increasing with ambulation and inability to walk without support was seen at the Vreden National Medical Research Centre for Traumatology and Orthopedics. Her history showed that she suffered moderate pain in the right knee joint in the last three years and aggravated during intense physical activity and walking. Complex conservative treatment she had as an outpatient provided no lasting effect. The patient was examined in one of the regional specialized medical institutions and was diagnosed with the right-sided medial gonarthrosis that was repaired with UKA of the medial portion of the right knee joint using an implant with a fixed polyethylene liner. The patient developed severe pain in the operated knee post op with a change in the characteristics compared to preoperative condition. She had a visible change in the limb axis, significant difficulties in walking and bending the knee joint. First her complaints were interpreted as a normal course of the early postoperative period, and the patient underwent comprehensive rehabilitation. There was no improvement

in the intensity of the above symptoms throughout the postoperative period, she had poor quality of life and could walk only with additional support, which necessitated revision surgery. Upon admission to the hospital, the patient could ambulate with additional support on crutches and had significant, gentle, right-sided lameness. The valgus deformity of the right lower limb at the knee joint level measured 8° . Tibia adduction test with the knee slightly flexed to relax the posterior capsule showed rigid deformity that could not be corrected to bring the limb to the neutral axis. There was diffuse pain in the right knee being more severe in the lateral portion, and extension contracture with a range of motion $0^\circ/0^\circ/85^\circ$. The function was rated with modified Oxford Knee Score (OKS) measuring 11 indicating a significantly impaired function. Radiographs showed UKA with the medial portion of the right knee replaced (Fig. 1). Economical resections of the femur and tibia were seen and telerentgenography demonstrated valgus alignment of the limb 8° (MAD = 29 mm), posterior tilt of the tibial component within the reference values (Fig. 2). The working surface of the polyethylene liner module/tibial component of the implant was 5 mm proximal to the articular surface of the lateral condyle of the tibia. There were no radiographic signs of instability of the endoprosthetic components or wear of the liner.

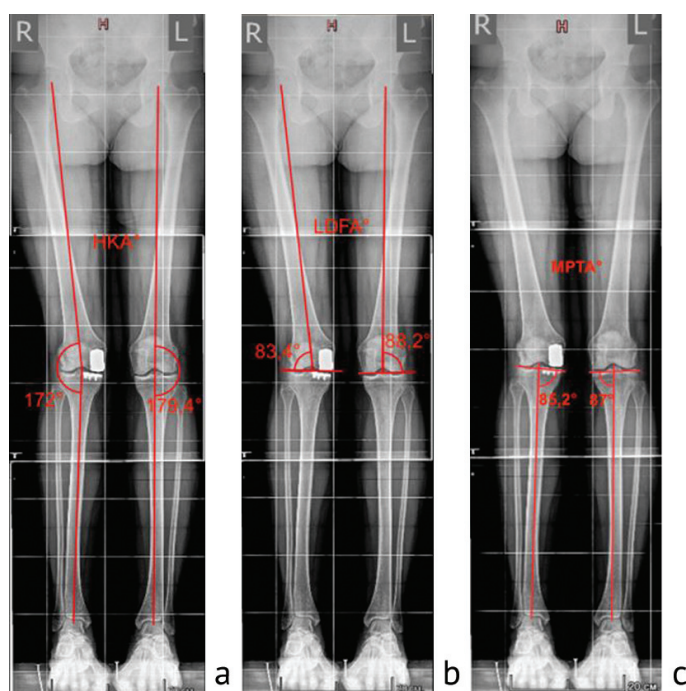


Fig. 1 Reference angles and lines measured after UKA using full length standing AP showing (a) valgus alignment of the right lower limb; (b, c) decreased LDFA and MPTA due to inadequately positioned components in the frontal plane

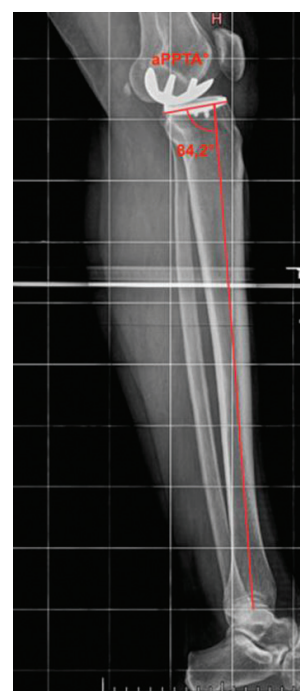


Fig. 2 The index of the inclination angle of the articular surface of the tibial component in the sagittal plane after UKA

Clinical and radiological findings of the patient revealed that the pain was caused by overcorrected limb axis during the previous UKA, "overtightened" medial ligaments and hyperpressed lateral part of the knee joint, imbalance of the extension and flexion gaps leading to a limited range of motion in the right knee joint. Revision procedure of the right knee joint was performed using a standard primary instrumentation system (Fig. 3). The limb axis was corrected by 6° during revision arthroplasty. The posterior tilt of the tibial component was within the reference values (Fig. 4). Bone cuts were made at the bottom of the defects formed after the removal of the UKA components, and a standard primary knee replacement was applied to preserve the posterior cruciate ligament with an all-polyethylene (all poly) tibial component, 1 mm thick, cemented fixation.

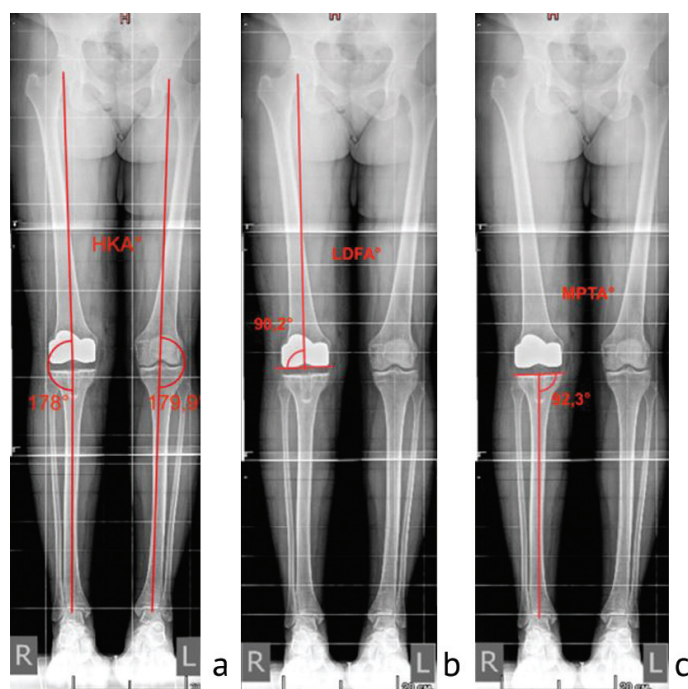


Fig. 3 Reference angles and lines measured after TKA showing (a) the limb axis corrected by 6°; (b, c) reference values of LDFA and MPTA restored



Fig. 4 The index of the inclination angle of the articular surface of the tibial component after TKA

Full range of passive movements was intraoperatively achieved in the right knee joint. The postoperative period was uneventful, the postoperative wound healed by primary intention. The patient regained the ability to move independently without additional support at 4 weeks of standard rehabilitation as an outpatient, and restored the range of motion in the knee joint to an acute angle of flexion with ROM of 0°/0°/110°. The patient had no limping at a year of the revision surgery and the outcome was rated as excellent with 45 scores measured with the modified OKS scale.

DISCUSSION

Marketing of implants complicates the task for the orthopaedic surgeon who starts partial arthroplasty practice. Implants with a mobile liner are nearly identical with different manufacturers using the Oxford concept, while endoprostheses with a fixed liner have heterogeneous design. Developed in 1982, the Oxford UKA is one of the most commonly used implants worldwide [11, 12, 13]. The original and repeatable technology, numerous scientific studies on various aspects on the use of the implant [14, 15, 16], a significant number of training technical videos on professional video resources, training opportunities with theoretical courses, biomannequins and in the operation theater facilitate a sufficient understanding for the surgeon of how to implant this type of artificial joint properly. In contrast, fixed platform endoprostheses are not a unified model differing only in name. This is a very heterogeneous group of implants, significantly different in surgical technique, in implantation philosophy, tribology and biomechanics. The circumstance creates space for a large number of surgical nuances, which being neglected make the surgical intervention extremely labor-intensive, with a low degree of repeatability [17]. Despite the apparent simplicity, the learning curve for a surgeon using even the most modern instrumental systems for partial arthroplasty with a fixed liner can reach hundreds of procedures, in contrast to a mobile one, where a couple of a dozen can be sufficient [18].

Adherence to individual surgical traditions formed during professional training and daily practice would involve a routine surgical technique to include the length of access, trauma of manipulations with soft tissues that affect the knee balance, for example, a deep portion of the tibial collateral ligament with the attachment to the plateau to be maintained during UKA, and the complete removal of the osteophytes from the condyles of the femur and tibia. If a surgeon commonly uses TKA in his daily surgical practice, then the hyperrelease of medial stabilizers, popularized in the arthroplasty manuals of the last century, being aggravated by excessive removal along with osteophytes and intact bone, will automatically lead to a clinically significant increase in the flexion and/or extension gaps. The manipulations would result in the use of a polyethylene liner of excessive thickness compared to the resections performed in order to create optimal tension of the capsular-ligamentous apparatus during UKA, which will serve as a mechanical substrate for hypercorrection of the mechanical axis of the limb [19]. Then soft tissue dissection should not reach the middle of the tibial condyle at the resection level during UKA. It is important to remember that the ideal candidate for UKA of the medial knee is a patient with a morphological stage of gonarthrosis with the wear of the articulating “bone on bone” surfaces and varus deformity of the limb up to 15° formed [20, 21, 22].

What about a significant group of patients who suffer terminal degenerative lesions of the medial knee and maintain a neutral axis of the limb due to the specific geometry of the diaphyses and/or metaphyses of the femur and/or tibia? The answer seems obvious: the presence of a “bone on bone” scenario in the tibiofemoral joint that we plan to replace is important for us. And this is the group of patients that are at risk of hypercorrection of the limb axis [23]. This is because the medial proximal tibial angle of 90° or more requires asymmetric resection of the tibial plateau, which can be accomplished intraoperatively with insufficient precision. A deep cartilaginous defect of the loaded portion of the medial femoral condyle in combination with meniscus extrusion will lead to translation of the mechanical axis of the limb into a valgus alignment due to excessive mobility of the medial joint, attempts to create optimal tension of the soft tissues intraoperatively and constitutional valgus deformity of the limb will become an insurmountable obstacle to successful partial arthroplasty. The ways to overcome the circumstance do not seem obvious: whether to perform a cut of the tibial plateau taking into account the so-called “Cartier angle” [24] with 3° varus relative to the mechanical axis of the tibia, or to perform UKA in the cohort of patients using robotic systems or computer navigation [25, 26] or TKA? The options can be largely debatable. In this clinical scenario, cutting the tibial plateau at 3° varus would aggravate the situation with the flat surface between the femoral component and the liner of a fixed-liner implant. The cut will cause the femoral component to “roll” along the uneven plateau in the medial direction and lead to a greater “tightness” of the medial portion. There is a large number of modern studies reporting the results of robotic surgery or joint replacements using navigation systems, and even these factors allow for errors in the positioning of endoprosthetic components in 10–11 % of cases [27]. With the use of standard instrumentation systems, this deviation from the ideal position can be even more pronounced. The surgeon factor cannot be underestimated speaking about the results after UKA [28]. Hamilton et al. [29] conducted a meta-analysis to assess outcomes of UKA depending on the surgeon's experience. The best results and a decreased frequency of revisions are observed with surgeons who perform more than 24 UKAs per year. More than 20 % of a surgeon's knee replacement surgeries should be UKA to achieve optimal results. Initial experience of orthopaedic surgeons performing partial arthroplasty was associated with the criteria of Kozinn, Scott [18], according to which patients with a body weight of less than

82 kg were considered ideal candidates for UKA. The procedure was technically more difficult in obese patients placing the extramedullary guide and cutting blocks due to technical limitations related to the definition of bone landmarks. The high load in the bone-implant interface in obese patients was also considered as one of the reasons for a decrease in implant survival. Over time, the concept changed and a large number of studies indicated that obesity should not be considered a contraindication [30, 31, 32].

There is no negative effect of high BMI on this parameter reported in the publications analyzing predictors of the risk of hypercorrection of the mechanical axis of the limb in UKA [17, 33]. Hip-knee ankle angle (HKA) is essential for predicting the accuracy of component positioning and correction of the limb axis in the frontal plane in UKA [34, 35, 36, 37]. A slight hypocorrection of the mechanical axis is recommended despite the continuous debate on the target HKA angle after partial knee arthroplasty. Patients who had varus deformity before surgery and who retain a residual deformity of 3° after UKA demonstrate the best functional results [38, 39, 40, 41]. Nakano et al. [42] reported an arithmetic hip-knee-ankle angle (aHKA) as a new method of morphological assessment. The following formula is used to measure aHKA: $180^\circ - \text{LDFA}^\circ$ (lateral distal femoral angle) + MPTA° (medial proximal tibial angle). The authors showed that aHKA correlated more accurately with postoperative LDFA $^\circ$ angles. The cuts were produced using a portable accelerometer-based navigation system to achieve target values. Kokubu et al. [43] conducted a retrospective study and reported an improvement in functional results early postop in patients with a change in the postoperative aHKA angle within $\pm 3^\circ$.

Shih et al. [44] and Asada et al. [34] reported accurate positioning of the femoral and tibial components in UKA by measuring FCCA (femoral coronal component angle) and TCCA (tibial coronal component angle). FCCA is the angle between the axis drawn through the middle of the femoral component and the mechanical axis of the femur. TCCA is the angle between the line parallel to the tibial component and the line perpendicular to the mechanical axis of the tibia. Khaw et al. [45] explored implant survival depending on the accurate positioning of the femoral and tibial components and concluded that patients with FCCA from 0° to 2° and TCCA from 2° to 4° had the best functional results at 10 years. Patients with optimal measurements (FCCA 0° to 2° and TCCA 2° to 4°) had a significant advantage with 15-year implant survival. The lack of assessment of the accurate component positioning in the sagittal plane is a significant limitation of these studies. The thickness of the insert and the depth of the resected medial tibia during UKA are the intraoperative signals about the degree of postoperative correction of the mechanical axis of the limb. Kuroda et al. [46] reported a correlation between the magnitude of a changed HKA angle before and after surgery, the thickness of the liner, and the depth of resection of the medial tibia. The choice of liner size is based on the surgeon's assessment of the "tension" of the medial collateral ligament during surgery. However, this assessment may be subjective. The surgeon may choose a thicker liner to avoid apparent intraoperative instability, for example, in patients with hyperelastic soft tissue stabilizers, which may lead to overcorrection of the mechanical axis of the limb and valgus deformity after surgery [47]. Extrusion of the medial meniscus can cause valgus hypercorrection of the limb axis after UKA in patients with preoperative varus deformity. Resection of the extruded meniscus leads to a loss of "tension" of the medial collateral ligament increasing the mobility of the medial portion of the knee joint with a need of a thicker liner.

Ishibashi et al. [48] conducted a retrospective study and reported the impact of medial meniscus extrusion on preoperative magnetic resonance imaging on the mechanical axis of the limb after UKA. The degree of extrusion was measured according to the method described by Costa et al. [49] with the use of the PACS system. The authors reported a direct correlation between the postoperative changes in the HKA angle and the preoperative degree of meniscus extrusion. The average distance of meniscus extrusion was (8 ± 2) mm. Liu et al. [47] reported similar results. The geometry of the anterior tibia may entail errors in determining the resection depth during UKA. The shape of the tibial plateau is complex and asymmetrical. Hashemi et al. [50] reported a large variability in the depth of concavity of the medial plateau and the slope of the tibia in the frontal and sagittal planes in patients with gonarthrosis. The tilt of the tibia to the medial side in the frontal plane varies from -1° to $+6^\circ$, and the depth of concavity of the medial section can vary from 1.2 to 5.2 mm. A cut above the bottom of the defect of the tibial plateau can be one of the common mistakes in determining the level of resection. This may result in inadequate orientation of the tibial component and a change in the TCCA angle beyond the normal values.

There have been more publications reporting staged UKA of the adjacent portion of the knee joint, instead of conversion to TKR. Fuchs et al. [51, 52] reported maintained joint proprioception being comparable to that of healthy people of the same age as a significant benefit of bicompartamental endoprosthesis (BCE) over total replacement to be achieved due to preserved cruciate ligaments. The issue of better kinematics after BCE compared to TKA remains controversial. Some authors support this hypothesis [53], while others believe that there are no significant differences in kinematics of patients who underwent BCE and TKR, in contrast to UKA [54]. Pandit et al. [55] reported outcomes of 27 knee joints with significant improvement in functional results and the absence of revisions after staged BCE, the transition to arthroplasty of the adjacent section was not applicable in the clinical case with a contracture of more than 10° and a deformity in the frontal plane of more than 5° being a contraindication for staged BCE [56, 57].

CONCLUSION

Inadequate mechanical alignment during UKA can be caused by deficient preoperative planning, individual elasticity variations in soft tissue stabilizers and technical intraoperative errors. Adequate patient selection, careful preoperative planning based on the radiographs and long-standing films, the morphological type of the limb deformity, magnetic resonance imaging of the joint, taking into account the nature of bone wear, the preservation and position of the meniscus at the contact site between the femur and tibia and the parameters of the marginal osteophytes, hypermobility of the affected portion of the knee joint, accurate surgical technique are essential for prevention of the complication.

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Informed consent The patient gave informed consent for publication of the study results.

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Information about the authors:

Nikolay N. Kornilov — Doctor of Medical Sciences, Professor, orthopaedic surgeon, drkornilov@hotmail.com, <https://orcid.org/0000-0002-6398-2377>;

Dmitriy V. Chugaev — Candidate of Medical Sciences, orthopaedic surgeon, dr.chugaev@gmail.com, <https://orcid.org/0000-0001-5127-5088>;

Pavel P. Ivanov — orthopaedic surgeon, ppivanov@rniito.ru;

Magomed Sh. Magomedov — clinical resident, dr.magomedovmsh@gmail.com;

Taras A. Kulyaba — Doctor of Medical Sciences, orthopaedic surgeon, taraskuliaba@mail.ru;

Alexey S. Phil — Candidate of Medical Sciences, orthopaedic surgeon, asfil@rniito.ru.



Efficiency of using antibacterial coatings on titanium implants in the treatment of gunshot fractures

D.V. Davydov^{1,2}, L.K. Brizhan¹, A.A. Kerimov¹, I.V. Khominets^{1✉}, K.K. Bekshokov², A.A. Gritsyuk^{1,3}, E.A. Kukushko¹, V.D. Besedin¹

¹ Burdenko Main Military Clinical Hospital, Moscow, Russian Federation

² Patrice Lumumba Peoples' Friendship University of Russia, Moscow, Russian Federation

³ Sechenov First Moscow State Medical University, Moscow, Russian Federation

Corresponding author: Igor V. Khominets, khominets24_91@mail.ru

Abstract

Introduction High risk of infectious complications in gunshot wounds remains a pressing issue in military medicine. Analysis of the structure of sanitary losses shows that limb injuries account for 55 % to 81.4 %, with about 35 % of them accompanied by bone fractures. Performing operations for the final stabilization of these fractures under the conditions of primary microbial contamination is associated with a high risk of infectious complications. However, the use of antibacterial coatings on internal implants significantly reduces the risk of such complications.

The **purpose** of the work, based on the analysis of Russian and foreign literary sources, is to determine the effectiveness of using antibacterial coatings on titanium implants for gunshot fractures.

Materials and methods The search for scientific publications was carried out in the search engines eLibrary, PubMed and Connected Papers using the keywords: antibacterial coatings, gunshot fractures, implant-associated infection, internal osteosynthesis, infectious complications, antibacterial coating, gunshot fractures, infectious complications, peri-implant infection. The sources were selected based on the hypothesis of the possibility of using antibacterial coatings in clinical practice. The search depth was from 2009 to 2025.

Results and discussion The existing systems for delivering antibacterial drugs to the surgical intervention area demonstrate high clinical efficacy in the prevention of peri-implant infection. To date, the most studied agents for creating coatings are metal ions, polymers, as well as composites containing antibacterial / antiseptic drugs. The most effective are multifunctional and intelligent coatings that have a combined effect on microbial biofilms due to their pronounced anti-adhesive and biocidal properties. There is a shortage of research on the use of multifunctional coatings in traumatological and orthopedic practice. There are no publications in the world literature devoted to the use of antibacterial coatings in the treatment of gunshot fractures and their consequences.

Conclusion The use of polymer and multifunctional antibacterial coatings, hydrogels, as well as oxides of silver, iodine and zinc demonstrate high efficiency in the prevention of infectious complications after internal osteosynthesis, and, in our opinion, can be considered for use in clinical practice in the treatment of gunshot fractures of limb bones.

Keywords: antibacterial coating, internal osteosynthesis, gunshot fractures, infectious complications, peri-implant infection

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INTRODUCTION

To date, two most significant problems can be identified in the treatment of combat surgical pathology that have not lost their relevance over a long period of time: the combination of gunshot wounds with extensive tissue defects and a high rate of infectious and inflammatory complications caused by multiresistant microflora [1, 2]. The development of infectious complications related to bone fractures caused by firearms and ammunition is primarily associated with the severity of the resulting tissue damage, primary microbial contamination of the wound canal, as well as the development of secondary necrobiotic changes in the tissues surrounding the wound canal caused by the damaging effect of firearms.

Wounds caused by firearms and explosives have a number of characteristic features that have a direct impact on the rate of complications and treatment tactics. Among them are a complex configuration of the wound canal, uneven extent of dead and necrotic tissue around the wound canal, primary microbial contamination, and frequent combination of these wounds with bone fractures and injuries to the vascular-nerve structures [3]. The peculiarities of wound ballistics under the influence of wounding projectiles lead to extensive complex (soft tissue and bone) defects, which, according to their pathomorphological properties, are characterized by significant damage to the bone marrow cavity and their own nutrient arteries, thereby causing hypoxia of the surrounding tissues that slows down the reparative processes and is often the trigger for the development of gunshot osteomyelitis [4]. Thus, the analysis of the treatment outcomes of 148 wounded with gunshot fractures of the limb bones conducted by Khominets et al. revealed the development of infectious complications among patients in the main and control groups in 5.8 % and 9.7 %, respectively [5]. Lee et al. established the development of infectious and inflammatory complications after osteosynthesis in 14 % of cases in a multicenter retrospective study analyzing complications of gunshot fractures of the tibia [6].

Additional complications in the treatment of gunshot fractures are caused by the presence of microflora in the wound canal that is diverse in composition and resistant to antibiotics. It largely determines the ineffectiveness of classical treatment methods [7].

Based on the above, final reconstructive and restorative operations (osteosynthesis, joint arthroplasty, etc.) in gunshot fractures are possible only with stabilization of the patient's general condition and compliance with strict recommendations for switching to internal fixation [8]. However, even if these requirements are met, there remains a high risk of infectious complications during osteosynthesis.

In this regard, the development and optimization of existing systems for the delivery of antibacterial, antiseptic and reparative agents to damaged tissues for the prevention and treatment of infectious and inflammatory complications is one of the promising advanced technologies in the provision of comprehensive specialized medical care to patients with gunshot wounds accompanied by skeletal bone fractures [9, 10].

The **purpose** of the work, based on the analysis of Russian and foreign literary sources, is to determine the effectiveness of using antibacterial coatings on titanium implants for gunshot fractures.

MATERIALS AND METHODS

The search for Russian-language sources was conducted on the eLibrary platform (electronic library) using the following keywords and phrases in Russian and English: antibacterial coatings, gunshot fractures, implant-associated infection, internal osteosynthesis, infectious complications. The search depth was from 2009 to 2025 inclusive. The search for foreign sources was carried out in the PubMed search system, as well as using the ConnectedPapers analytical tool based on artificial intelligence using the Seminal works functions to display a list of key thematic works and Derivative works functions

to display new, relevant works, systematic reviews and meta-analyses that are in the area of interest of the authors. The search on the ConnectedPapers resource started with the article: Akshaya S, Rowlo PK, Dukle A, Nathanael AJ. Antibacterial coatings for titanium implants: recent trends and future perspectives. *Antibiotics (Basel)*. 2022;11(12):1719. doi: 10.3390/antibiotics11121719.

Inclusion criteria:

- full-text scientific studies that report on the results of the analysis of the efficiency of various antibacterial coatings used in traumatology and orthopaedics, including open and gunshot fractures;
- full-text systematic literature reviews and meta-analyses that depict the topic of antibacterial coatings in surgery published 5 to 10 years ago.

Exclusion criteria: abstracts of scientific conferences, authors' theses of their candidate and doctor-of medical sciences dissertations, and articles that do not fully correspond to inclusion criteria.

Eighty studies were selected for analysis (70 foreign and 15 domestic).

RESULTS

Current state of the problems of implant associated infection

The development of purulent and inflammatory processes in the area of surgical intervention is a serious complication of osteosynthesis. Their treatment is significantly complicated by the presence of a metal implant colonized by microbial biofilms in the inflammation focus. The rate of these complications in the postoperative period after the operation of internal osteosynthesis ranges from 2 to 22.4 % in civil fractures [11]. Implant-associated infection is the most challenging issue in the treatment of gunshot fractures as infectious complications develop more frequently than in open fractures sustained in the peacetime [12].

According to the results of various studies, the rate of periprosthetic infection can grow up to 15 % even in planned surgical interventions of large joint replacement [13]. Traditionally, the prevention and treatment of implant-associated infection implies radical surgical treatment, local and systemic antibiotic therapy, and implantation of cement "spacers" that release antibacterial drug molecules [14]. However, the widespread use of broad-spectrum antibiotics can have pronounced toxic effects on the body and lead to an increase in the number of antibiotic-resistant bacteria, which requires a search for alternative methods of prevention and treatment of peri-implant infection [15].

The presence of orthopaedic implants in the inflammation focus inevitably leads to the adhesion of colony-forming bacteria which form a microbial biofilm on their surface, that is capable of resisting the effects of the body's defense system and antibiotics [16]. A biofilm can be defined as a microbial community of bacteria attached to the substrate and embedded in the matrix that they produced during their life activity [17]. Bacteria in the biofilm state demonstrate increased resistance to antimicrobial agents and lower susceptibility to the effects of the body's immune defense systems [18]. There is information in the international literature that the formation of biofilms on the surface of implants can develop within 12-18 hours after surgery [19]. In this regard, the main goal of treatment for implant-associated infection is precisely the prevention of biofilm formation.

Characteristics of the main agents of implant-associated infection in gunshot injuries

Injuries caused by firearms and explosives are the most complex type of wounds due to massive tissue damage in various locations, exposing sterile areas of the body to contamination by a huge number of bacteria. In combat injuries, the basis for the development of infectious complications is contamination by bacteria from one's own microflora or by those that have entered the wound from

the environment along with exogenous agents (bullets, tissue fragments, dust, dirt, water). Moreover, secondary contamination from nosocomial sources is also possible at the stages of providing medical care [20]. In addition, the species composition of etiologic agents in contaminated gunshot wounds is influenced by the type of wounding projectile, the damaged area of the body, the time interval between the injury and surgical treatment, climatic factors, and the ecological/geographical and sanitary/hygienic conditions of the area.

Among the microbiological agents associated with the formation of microbial biofilm on implants and the subsequent development of implant-associated infection, the most studied are *S. aureus*, *S. epidermidis*, *P. aeruginosa*, and also methicillin-resistant *S. aureus* (MRSA) [21].

Kryukov et al. devoted their work to the analysis of antibiotic resistance of the microflora in the wound discharge and compared the results of the study of wound discharge in 2022 and in 2020. They discovered a sharp change in the spectrum of pathogens of wound infection: an increase in the proportion of *Acinetobacter spp.*, *Bacillus spp.*, *Enterococcus spp.*, *P. aeruginosa*, *Klebsiella pneumoniae*; a decrease in the proportion of a number of gram-negative bacteria, including *Proteus spp.* и *Escherichia coli*; an expressed 5-fold reduction of *Streptococcus spp.* and *S. aureus* [7].

Bacterial adhesion to the surface of a titanium implant is the first stage in the development of implant-associated infection. The most common microbial agents causing the development of this infectious complication are staphylococci *S. aureus* and *S. epidermidis*; they are encountered in 18.4 to 37.4 % of cases [22]. The ability of *S. aureus* to form a 3-D structure that is composed from bacteria and extra-cellular polymers (polysaccharides and/or proteins), called a biofilm, is a central link in the development of infection associated with the presence of implants in the body.

The development of multidrug resistance in microorganisms is one of the most significant problems worldwide and is considered a threat to the national security [23]. Multidrug-resistant strains of *S. aureus* determine the difficulties in preventing and treating infectious complications of bone fractures, which is especially important for providing care in resource-limited settings. In a cohort study, Vijayakumar et al. reported that 75 % of isolates obtained from 100 patients were resistant to gentamicin, 81 % to ciprofloxacin, and 59 % to cefotaxime [24].

Another significant microbial agent that causes the development of infectious complications in the injured is *P. Aeruginosa*, a gram-negative opportunistic pathogen that plays an important role in the development of infectious complications in gunshot fractures due to its ability to reproduce in various environments, form biofilms, and be resistant to antibiotics [25]. Gunshot wounds, especially those sustained outdoors and/or in combat conditions, are often contaminated with soil, water, and other objects that act as reservoirs for *P. aeruginosa* in the environment. In medical facilities *P. aeruginosa* is also able to colonize the body of the injured patients, especially during their prolonged stay in hospital [26].

The above-mentioned bacteria exist on the surface of titanium implants in the form of microbial colonies and are protected by a capsule, which causes the resistance of microorganisms to the action of antibacterial agents. It should be noted that not all cases of microbial contamination of implants during surgical intervention are accompanied by the development of clinically expressed peri-implant infection and frequently develop in the form of microbial carriage, which is confirmed by the data of Knabl et al. [27].

These features of the infectious process in the presence of orthopedic implants in the body necessitate the development of a strategy to prevent colonization on the implant surface, and one of them may be a coating containing antibiotics or intraoperative application of a therapeutic gel to the implant.

Antibacterial coatings of titanium implants

Titanium and its alloys are currently recognized as the "gold standard" due to their resistance to corrosion and good biocompatibility with bone tissue. Over the past fifty years, they have been widely used in traumatology and orthopedics as a material for the manufacture of implants, endoprosthesis components and fixators for osteosynthesis of bone fractures (intramedullary pins, bone plates and screws) [28]. According to Wang et al., titanium or its alloys by themselves are not able to prevent possible implant-associated infection while systemic antibiotic therapy, despite its proven effectiveness, has a number of shortcomings (toxic effects on organs and tissues, difficulty in delivering the drug to the surgical site, development of antibiotic resistance in bacteria) [29]. A promising direction for the prevention of implant-associated infection in the surgical area is coating of titanium implants with antimicrobial agents. To achieve these properties, the surface of the implants is coated with antibacterial substances using various surface modification methods.

The existing coatings against bacterial infections can be divided into two categories: passive (to prevent bacterial attachment) and active (to kill bacteria and inhibit their growth). Passive coatings are designed to prevent infection by resisting pathogen adhesion instead of directly killing them. This strategy is commonly used to modify the surface structure of the implant. Standard materials for passive coatings include polyethylene glycol, hyaluronic acid, and others. Active coating uses metal ions, antibiotics, and antimicrobial peptides to functionalize the implant surface and kill bacteria through contact elimination or release of antibacterial agents into the surrounding tissue. In addition, other biomaterials that promote osseointegration, angiogenesis, and immunomodulation can be applied with antibacterial materials [30].

According to Bruellhoff et al., the "ideal" antibacterial coating applied to the surface of implants used in traumatology and orthopedics should be biocompatible and not cause a local irritating effect; it should also exhibit pronounced bactericidal properties in the early postoperative period while maintaining surface bactericidal activity against a wide range of microorganisms throughout the entire period of implantation. Moreover, the coating should prevent bacterial adhesion to the implant surface and suppress the formation of microbial biofilms [31].

Currently, the application of an antibacterial coating mostly creates an additional layer on the surface of the implant without damaging the natural properties of the basic material. This can be done using various methods, such as electrochemical deposition, ionized jet deposition, sol-gel method, microarc oxidation, and others [32, 33]. To prevent infectious complications or formation of biofilms and improve integration into tissues, coatings can contain various antimicrobial agents: antibiotics, inorganic elements, polymers, hybrid organic and organic components, bacterial peptides [34] (Fig. 1).

Coatings containing antibacterial and/or anticeptic preparations

According to the literature, the most commonly used agents for the prevention of infectious complications after internal osteosynthesis surgery are coatings based on antibacterial drugs. For the coating of an implant that releases an antibiotic, the concentration of the drug and the rate of its release are of decisive importance. Clinical trials have proven the effectiveness of coatings

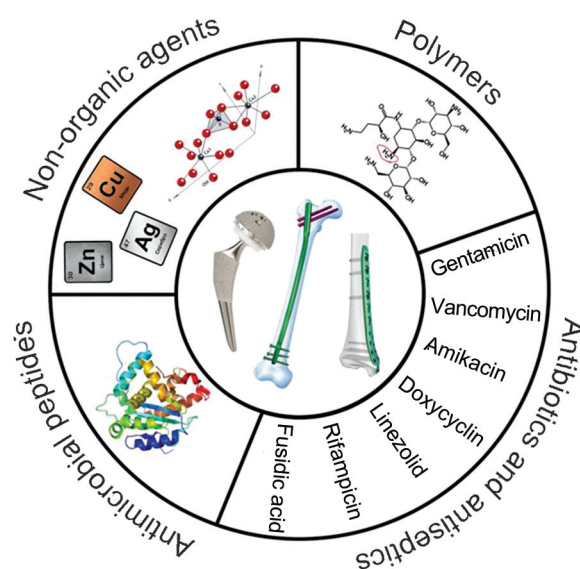


Fig. 1 Types of antibacterial coatings on implants (authors' diagram)

containing antibiotics (gentamicin, vancomycin, amikacin, doxycycline, linezolid, rifampicin and fusidic acid) against a wide range of pathogens of surgical infection [21].

Gentamicin is a popular antibiotic with a broad bactericidal spectrum, low toxicity, and high biocompatibility; it is widely used in clinical practice for many infections. The degree of gentamicin's bactericidal effect depends on the concentration of the drug in the antibacterial coating. According to some reports, gentamicin-based coatings improve osseointegration and prevent the development of osteomyelitis, and are also effective against infections caused by *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Escherichia coli*. Numerous studies have been conducted proving the effectiveness of amoxicillin, vancomycin, and tetracycline as implant surface coatings to prevent infection [35].

According to the results of the study by Harris et al., implants having an anti-adhesive coating with the addition of amikacin showed a combined effect on the main pathogens of implant-associated infection and exhibit high biocidal activity *in vitro*, and can be used in the manufacture of coatings for orthopedic implants [36]. However, the use of antibiotics on the surface of the implant raises concerns about antibiotic resistance due to the prevalence of antibiotic-resistant bacterial strains.

Doxycycline is a broad-spectrum antibiotic with documented high bactericidal activity against the main pathogens of implant-associated infection (including MRSA). It is less nephrotoxic and penetrates into body cells more effectively than gentamicin [37]. Linezolid is a synthetic antibiotic with a low potential for the development of intrinsic resistance and no cross-resistance to other systemically administered antibiotics. It has 100 % oral bioavailability, good pharmacokinetics and good penetration into connective tissues. Moxifloxacin used in sol-gel coatings provides anti-infective activity both *in vivo* and *in vitro* in Ti-implants [38]. The use of the antibiotic fosfomycin, according to a study by Gulcu et al., is not effective in killing bacteria and preventing biofilm formation [39]. An important disadvantage of coatings based on antimicrobial drugs is a continuous decrease in the concentration of the antimicrobial drug over time.

In our country, researchers of the Ilizarov National Medical Research Center of Traumatology and Orthopedics discovered in an experimental study that applying a calcium phosphate coating containing antibiotics to the titanium surface can effectively suppress the growth of gram-negative microflora and may be successfully used to prevent the development of implant-associated infection. However, the effectiveness of these coatings directly depends on the antibiotic used and its concentration [40].

Bone cement based on polymethyl methacrylate with the addition of heat-stable antibacterial drugs of local bactericidal action has been actively used in orthopedic clinics for a long time both for the treatment and prevention of peri-implant infection [41]. Moreover, bone cement impregnated with antibiotics has proven its effectiveness in the treatment of open fractures, including gunshot fractures, which has been confirmed by a number of studies [42, 43]. However, the study of long-term results of using this method revealed obvious disadvantages: short-term release of antibacterial drugs, formation of biofilms on the cement coating, unpredictable concentration of the drug in the surrounding tissues, and some others. At the same time, despite all the existing shortcomings, this method remains to this day the “gold standard” for treating patients with bone and joint infection, the effectiveness of which ranges from 60 to 87.5 %, and the rates of infection recurrence range from 6.3 to 40 % [44].

Another popular approach to preventing the development of implant-associated infection is the application of antiseptics to the surface of implants. The use of antiseptics has an immediate effect compared to the delayed effect of antibiotics, since they directly affect the bacterial cell membrane, unlike the inhibition of bacterial DNA-dependent RNA synthesis or inhibition of bacterial RNA polymerase and protein synthesis, which are embedded in the mechanism of action of antibiotics [45].

Antibacterial coatings based on metal and metal oxide nanoparticles

Metal nanoparticles and their oxides are capable of exerting selective bactericidal action on prokaryotic cells by recognizing them through metalloproteins and the metal particle transport system. These nanoparticles are capable of providing long-term antibacterial and bacteriostatic action by generating reactive oxygen species that damage the structure of bacterial cells, disrupting metabolic reactions and inhibiting DNA synthesis, which ultimately causes cell death [46]. Moreover, metal oxides interact with bacterial cells based on the action of electrostatic forces that destroy the bacterial cell wall, enzymes and DNA through the so-called "oxygen explosion". Metal nanoparticles and their oxides usually kill bacterial cells in several ways, including interaction with the lipid bilayer of bacterial cell walls, adhesion to cytosolic proteins of bacterial cells (including DNA and enzymes). Examples of metals used in antibacterial coatings include silver, gold, iron, gallium, zinc oxide, magnesium oxide and titanium oxide, which have effective bactericidal effects against various gram-positive and gram-negative bacteria [47]. However, according to Zhang et al., caution should be taken when using coatings based on metals and their oxides, since high concentrations of metal ions and their oxides can cause local and systemic damaging effects on cells and tissues of the body [48].

Silver

Today, silver is one of the most widely used metals for the production of titanium implant coatings. Silver ions have a broad spectrum of antibacterial activity and have a long-lasting antibacterial effect, which is less dependent on the drug resistance of bacteria and is able to prevent bacterial adhesion to the surface of implants. Moreover, coatings with silver ions are characterized by good biocompatibility, very low geno- and cytotoxicity, and potential for use in various types of biomaterials [49].

Silver nanoparticles also have significant biocidal activity against multidrug-resistant bacteria and fungi and, compared to local and systemic use of antibiotics, are an attractive alternative for reducing the risk of drug resistance in bacteria [50].

An analytical review by Q. Yang and L. Chen showed that the antimicrobial properties of silver-containing coatings directly depend on the amount of released ions [51]. Theoretically, a higher concentration of silver ions in the local depot system leads to a better antimicrobial effect. However, toxic effects increase with increasing concentration of silver ions, and their excess in the human body can cause damage to the liver, kidneys, lungs, heart and intestines. The cytotoxicity of silver ions in various mammalian cells depends on their size, dose and shape, as well as on the duration of interaction with the cells. Silver nanoparticles are capable of not only accumulating in the liver and spleen, but also are able to cross the blood-brain barrier, causing brain damage. *In vitro* cell culture tests have shown that silver nanoparticles are toxic to several human cell lines, including human bronchial epithelial cells, human umbilical vein endothelial cells, red blood cells, human peripheral blood mononuclear cells, human immortal keratinocytes, liver cells, and others. However, a number of studies have shown that low concentrations of silver ions can have an antibacterial effect without serious side effects on the body. On the other hand, silver ions exhibit antibacterial properties only at concentrations above 0.2 %. Slow release of silver ions and their therapeutic concentration are key factors in clinical practice. However, it should be taken into account that too slow release of silver ions from the coating surface is not able to exert the desired antibacterial effect [52].

In a study by Thukkaram et al., titanium substrates, legated with silver nanoparticles obtained by plasma electrolytic oxidation of titanium followed by ion implantation, exerted a pronounced bactericidal effect against methicillin-resistant *Staphylococcus aureus* and antibiotic-resistant *E. coli*. The antibacterial activity of the coating and the release of ions depended on the concentration

of silver ions. The study observed an initial rapid release of silver ions at concentrations suitable for preventing infections after implantation, followed by a slow, sustained release of ions over seven days [53].

Thus, silver ions included in antibacterial coatings have a pronounced antibacterial effect against gram-positive and gram-negative bacteria, affecting them by various mechanisms. In addition, various forms of silver can be used as an antibacterial substance in orthopedic implants, gels, ointments and surgical instruments, providing its wide use in medical practice.

Copper, zinc and selenium

In addition to silver, other metals with pronounced antibacterial activity include copper, zinc, and selenium. These alloying metals are in demand due to their antibacterial nature, low cost, and ability to stimulate osteogenesis. The mentioned metals are microelements necessary for the body to ensure the normal functioning of systems and organs, so their use in antibacterial coatings helps to increase the biocompatibility of surgical implants introduced into tissues. Moreover, according to Zhu et al., zinc-containing coatings promote osteoblast differentiation and improve the corrosion resistance of titanium implants [54].

A study by Wang et al. showed that titanium substrates containing polylactic acid-based coatings with different concentrations of copper chloride (CuCl_2) effectively inhibited the growth of *Staphylococcus aureus* and exerted an osteogenic effect *in vitro* and *in vivo*. *In vitro* studies demonstrated a dose-dependent burst release of Cu^{2+} ion and its antibacterial effect against *Staphylococcus aureus* [55].

Selenium nanoparticles are a beneficial platform for the development of the next generation of antimicrobial coatings, as they have the ability to kill microbes through multiple mechanisms, are stable *in vitro* and *in vivo*, and can be easily immobilized on various surfaces. Moreover, selenium deposited on microporous titanium dioxide coatings with calcium and phosphorus on titanium substrates can improve the antibacterial, anti-oncogenic, and osteogenic properties of the implant [56].

Zhou et al. found that a coating containing 8 wt. % selenium is optimal and provides 97 % eradication of *E. coli* and *S. aureus*, maximum osteogenic activity, and exhibits anti-oncogenic properties. Higher doses of selenium inhibit cell proliferation, while low doses do not have a significant antibacterial effect [57].

Similarly, zinc in the form of zinc complexes and zinc oxide nanoparticles exerts its antibacterial activity. Zinc complexes exhibit antifungal activity, while zinc oxides exhibit their antimicrobial activity through two different mechanisms, namely the release of reactive oxygen species (photocatalytic process) or zinc oxide nanoparticles, which lead to the formation of intracellular oxygen radicals, causing cell damage [58].

Iodine

Iodine-containing antibacterial coatings and antiseptics have a broad spectrum of bactericidal action, and also exhibit high biocidal activity against various viruses and fungi. Therefore, it makes them a very effective means for preventing the development of postoperative complications [59]. In addition, being a microelement necessary for the synthesis of thyroid hormones, iodine practically does not cause allergic reactions.

Inoue et al. established experimentally that an iodine coating applied to the surface of titanium implants exhibits an active biocidal effect against MRSA, *P. aeruginosa*, methicillin-resistant *S. epidermidis* and *C. albicans*. Moreover, the antibacterial efficiency of the titanium surface coated with iodine was higher than that of titanium implants with an oxide film applied by anodization [60].

Yamaguchi et al. developed a new solution and method for thermal treatment of the implant surface by ion-exchange reaction using a layered calcium titanate structure, in which a large amount of positively charged iodine ions are introduced into the titanium implant and onto its surface. The thus formed iodine-containing calcium titanate slowly releases 5.6×10^{-6} iodine ions over 90 days [61].

The results of the mentioned studies indicate that titanium implants with iodine coating may have great potential in the development of innovative antibacterial implants that may prevent the early onset of peri-implant infection, including during osteosynthesis of gunshot fractures.

Other metals

Coatings containing calcium, strontium, gallium, and bismuth can also be used to enhance the biologically active properties of titanium implants. Katunar et al. reported that strontium-containing ceramics enhance bactericidal action and promote bone tissue growth and regeneration [62]. In addition, Zhao et al. found that a microporous coating of titanium dioxide legated with zinc or strontium promotes osteoblast adhesion and inhibits the growth of *Staphylococcus aureus* [63].

Thus, one of the most important limitations of all metals used as antibacterial coatings is the lack of available *in vivo* data with long-term results generalizing the use of these implants in clinical practice.

The presented results of the *in vitro* and *in vivo* studies included in this review strongly suggest that trauma- and orthopaedic surgeons use traditional and new antimicrobial implant surface modifications in the treatment of patients with peri-implant infection. The lack of experience with their use in clinical settings raises concerns regarding the long-term results of these implants and the growth of multidrug-resistant microorganisms as a result of their clinical use.

Antibacterial inorganic coatings with osteointegrative properties

Antibacterial coatings that have the property of increasing implant osseointegration include coatings based on hydroxyapatite ($\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$), magnesium, and others. Hydroxyapatite, being a natural inorganic component of bone tissue, has proven itself in clinical practice due to its high biocompatibility and bactericidal activity. The crystalline structure of hydroxyapatite allows for the small-scale replacement of Ca^{2+} with various foreign ions, promoting osteoblast adhesion and expanding the possibilities of modifying the surface of implants to increase bactericidal activity and osteoconductive properties [64].

Batebi et al. developed the structure of antibacterial hydroxyapatite by replacing various Ca^{2+} in it with Ag^+ , Cu^{2+} and Zn^{2+} ions. Among these ions, silver nanoparticles were most effective in disrupting the integrity of the bacterial cell by binding to proteins and enzymes inside the bacteria. This seriously damaged the cell and disrupted its basic functions (regulation of enzymatic signaling activity, permeability, cellular oxidation, respiratory processes), which ultimately led to the death of the bacteria [65]. Turkoz et al. synthesized a hydroxyapatite composite with the addition of silver and fluorine ions by precipitation and found that the presence of fluorine in the composite not only improved the antibacterial effect of hydroxyapatite against *E. coli*, but also increased its density and osteointegrative properties. The authors showed that the resulting compound had good antibacterial activity against *E. coli* and *S. aureus* cells and improved the osteointegrative properties of implants [66].

Magnesium and its compounds are biodegradable materials used in traumatology and orthopedics, have high mechanical strength and rigidity, along with other biodegradable materials, which allows them to firmly hold bone fragments when used as a material for the manufacture of orthopedic implants. Moreover, being a macroelement that is required for normal vital activity, magnesium passes from implant coatings into the surrounding bone tissue, accelerating reparative bone

regeneration and osteointegrative properties of implants. Besides, magnesium actively prevents colonization of *S. aureus* on the surface of implants which allows it to be used as a material for the manufacture of antibacterial coatings. At the same time, magnesium also exhibits pronounced antifungal properties [67]. According to the review by Pogorielov et al., the inclusion of magnesium in surgical implants accelerates the formation of hard bone callus due to osteoblast adhesion and bone remodeling [68].

Coatings based on antimicrobial peptides

Coatings based on antimicrobial peptides (AMPs) are currently widely used as an alternative to conventional methods of treating the surface of titanium implants, since they have a broad spectrum of action and require low concentrations for an effective antimicrobial effect. They are also able to reduce the growth of antibiotic-resistant bacterial strains. The amino acids that make up these peptides can be cationic or amphipathic, interacting with the plasma membrane of bacteria, leading to their death [69]. Currently, there are many studies devoted to studying the effectiveness of using AMPs. Caselli et al. claim that AMPs on the surface of implants enhance the antimicrobial effects of photocatalytic titanium oxide nanoparticles without having a toxic effect on the body [70]. Keikhosravani et al. demonstrate the successful use of CATH-2 AMP in the development of titanium implant coatings, which suggests promising results in the development of antibacterial coatings for the prevention of biofilm formation and the treatment of peri-implant infection [71].

Coatings based on polymers

Both natural and synthetic polymers are used to create antibacterial coatings for the surface of titanium implants, as they can be easily modified with bioactive components. Polymers based on chitosan, nitrogen-containing polyethylenamines and quaternary ammonium compounds have their own biocidal properties, while other polymers are included in antibiotics to obtain antibacterial activity. Although the application of antibiotics to polymers does provide the desired antibacterial effect, it does not provide long-term release of the drug. Compared to synthetic polymers, most natural polymers lack mechanical strength and rapid degradation, which can lead to uneven release of drug particles from the implant. Therefore, these polymers are often included in inorganic systems such as metal oxides, hydroxyapatite, etc., to enhance the antibacterial effect. Therefore, to provide biocidal action, it is possible to modify the polymer chain by adding a quaternary amine unit, which will give the polymer bactericidal properties, instead of converting the polymer into a carrier of antibiotics [72].

There are many examples of using such modifications of polymer coatings. Kaleli-Can et al. found that titanium implants coated with diethyl phosphite, applied by plasma polymerization, demonstrate excellent cytocompatibility and suppress biofilm formation. *In vitro* studies have shown the antibacterial activity of this coating against *S. aureus* and *C. albicans* cells, which proves the promising potential of their use in the treatment of patients with peri-implant infection [73]. The antibacterial coating based on polyhexamethylene biguanide developed by Peng et al. allowed for almost 100 % suppression of *S. aureus* and *E. coli* growth on the implant surface. *In vivo* studies on the infected rat model also confirmed the bactericidal nature of the developed coating [74].

One of the promising polymers with antibacterial properties which are currently actively used for the development of implant coatings is chitosan. It is a natural cationic polysaccharide with good biocompatibility and lack of cytotoxicity. Its positively charged amino groups can generate electrostatic interactions with negatively charged membranes of bacterial cells, thereby changing the permeability of cell membranes and causing lysis and death of bacteria. Therefore, chitosan is expected to become an effective means for preventing biofilm formation on the surface of orthopedic implants. Peng et al. evaluated the effect of hydroxypropyltrimethylammonium chloride chitosan

at three different component concentrations (6 %, 18 % and 44 %) on preventing biofilm formation on the surface of titanium implants using *in vitro* tests and found that three types of the developed compound, especially the last two, could significantly inhibit biofilm formation on the surface of implants and also exert an effective therapeutic effect on previously formed mature biofilms [75].

Multifunctional and intelligent coatings

Along with imparting bactericidal properties to the implant surface, the strategy of developing antibacterial coatings can be implemented by increasing the biocompatibility of implants, enhancing their osteogenic effects, and providing them with immunomodulatory and antitumor properties. Coatings with such additional functions can directly stimulate reparative bone regeneration. At the same time, stimulation of osteogenesis and osseointegration can also reduce bacterial adhesion and proliferation. However, bone regeneration is suppressed under the conditions of bacterial infection, presence of bone sequesters and vascularization deficiency what will lead to infection persistence. In this regard, future research in this area should determine how to effectively restrain infection and enhance the bone regeneration process using multifunctional coatings [76].

To date, there are many works in the world literature devoted to the study of smart coatings. Zhang et al. developed a peptide sequence sensitive to *S. aureus* using vancomycin and a peptide conjugate, and then conjugated an antibiotic with this specially created peptide. The conjugate was then bound to the surface of a titanium implant, where the peptide can be recognized and cleaved by an enzyme secreted by *S. aureus*, which allows the release of the antibiotic only in the presence of *S. aureus*, thereby achieving delivery of the antibacterial agent precisely when the infectious process occurs [77].

Zhang et al. described a pH-sensitive self-adapting coating with antibacterial, anti-inflammatory, and osseointegration properties. This smart coating consisted of an antibacterial copolymer containing quaternary ammonium salts deposited on a titanium surface by self-assembly of layers. The change in surface charge of the coatings was confirmed by measuring the zeta potential, the coatings demonstrated a negative charge in a neutral environment and a positive charge in an acidic environment. An acidic environment triggers the antibacterial effect of the positive control. This effect is reversed when the pH is high, creating a self-adapting coating. *In vitro* tests showed that this coating was highly effective against *E. coli* and *S. aureus* [78].

Polymeric gels

In recent years, the use of so-called polymer gels as local depot systems for the prevention of postoperative infectious complications has attracted increasing attention from researchers. A clinical review by Pressato et al. showed that modification of the surface of titanium implants and delivery of antimicrobial substances using local depot systems, in addition to systemic antibiotic therapy, are promising and highly effective in reducing the risk of peri-implant infection. However, this area requires further study, since there is no literature data on the long-term effectiveness and safety of this technique [79].

A clinical study of polymer hydrogels based on unsaturated derivatives of polyvinyl alcohol, conducted in 2023 at the Priorov National Medical Research Center of Traumatology and Orthopedics, demonstrated the release of more than 70 % of the antibacterial drug loaded into the gel from the matrix composition versus 10 % from polymethyl methacrylate over the entire study period (28 days). Moreover, the maximum release of the drug (up to 90 %) was observed during the first week [80].

Thus, polymer hydrogels containing antibacterial drugs have a wider range of potential clinical applications compared to bone cement due to their bioresorbable nature and controlled release of the antimicrobial agent, providing a ten- to hundred-fold increase in local drug concentrations

around the implant. In addition, hydrogel resorption eliminates the risk of developing antibiotic resistance in bacteria, which is typical for polymethyl methacrylate.

Application of additive technologies in the production of antibacterial coatings

In recent years, additive (3D) technologies have come to the forefront in the production of medical devices. The main advantage of 3D printing is the ability to manufacture customized implants with complex geometric shapes for specific patients, as well as parts with high fatigue strength and corrosion resistance. In traumatology and orthopedics, additive technologies have been successfully used for a long time in joint replacement and other reconstructive surgeries. However, due to the relative novelty of 3D printing technology, there is a lack of basic scientific knowledge about this process (phase formation, new alloying elements, etc.) in the production of titanium medical implants along with the difficulties in carrying out post-processing procedures (sterilization, polishing, filling the mesh structures in implants) [81].

Golovko et al. analyzed the effectiveness of the antibacterial coating they produced based on chitosan and polyvinylpyrrolidone. They showed that the antibacterial coating developed using 3D printing had high biocompatibility, atraumatic properties, elasticity, and adhesion to the wound surface. In addition, the team of the authors found that the use of additive technologies for the production of a bioengineered structure ensures the maintenance of aseptic conditions, the necessary humidity, pH, and temperature in creating implants [82].

Inzana et al. studied the effectiveness of additive manufacturing in the treatment of implant-associated infection and demonstrated that local delivery of rifampicin and vancomycin to the surgical site from a 3D-printed calcium phosphate scaffold is more effective than antibacterial spacers made of polymethyl methacrylate, which is not capable of transporting rifampicin. However, this method does not lead to the eradication of microbial biofilm, which creates the need to modify the surface of these implants in order to impart bactericidal properties to them [83].

DISCUSSION

Based on the analysis of current literature, it can be concluded that the diversity of existing coatings with antibacterial properties indicates that the search for an “ideal” method for preventing peri-implant infection is still incomplete. The development of these technologies remains a relevant topic for scientific research.

Local depot systems for the delivery of antibacterial and antiseptic drugs to the surgical intervention area used in clinical practice prevent the development of implant-associated infection with varying degrees of effectiveness (Table 1). However, there is still no consensus on the properties that an “ideal” antibacterial coating should have. Most researchers are inclined to believe that the combination of highly effective bactericidal action and resistance to bacterial attachment, good biocompatibility, stimulation of osseointegration and osteogenesis is a promising direction for the development of new antibacterial implant coatings [10, 30, 31, 84].

Based on the analysis, we concluded that the main requirements for antibacterial coatings are:

- 1) biological compatibility of coatings and the absence of local irritating effects on tissues;
- 2) high biocidal activity, maintained over a long period of time and under conditions of fluctuating thermochemical parameters of the internal environment of the body;
- 3) effective biocidal action against a wide range of microorganisms (bacteria, viruses, fungi);
- 4) combination of anti-adhesive and biocidal properties in coatings, which have a complex effect on pathogens of implant-associated infection;
- 5) prevention of the development of bacterial resistance to antibiotics by using coatings.

Table 1

Efficiency of antibacterial coatings in clinical practice

| Composition | Technique of coating | Antimicrobial efficiency <i>in vitro/in vivo</i> | Reference |
|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Coatings that contain antibacterial preparations | | | |
| Cis-2-decenoic acid (C2DA) and amikacin | Coating of titanium with phosphatidylcholine and antibiotic additive | Decreased biofilm formation | [36] |
| Titanium implants coated with a biodegradable polymer-lipid encapsulation matrix with the addition of doxycycline | Polymer-lipid encapsulation | Suppression of MRSA and MSSA growth on implants | [37] |
| Kirschner wires coated with polylactic acid with added fosfomycin | Chemical precipitation from solution | Addition of fosfomycin to polylactic acid does not have effect on prevention of implant-associated infection | [39] |
| Antibiotic-impregnated titanium alloy discs with calcium phosphate coating | Micro arc oxidation | High biocidal efficacy against pathogens causing peri-implant infection | [40] |
| Antibiotic-loaded polymethyl methacrylate mantle on iliac bone graft | Application of the mantle to the surface of the implants | Effective prevention of infection in the treatment of open fractures | [43] |
| Coatings containing antiseptic preparations | | | |
| Titanium discs immersed in solutions of 6 different antiseptics | Immersion of discs in antiseptic solutions | High antibacterial activity against <i>P. gingivalis</i> and <i>S. mutans</i> | [45] |
| Coatings based on nanoparticles of metals and their oxides | | | |
| Ion legated Ag TiO ₂ | Plasma electrolytic oxidation | Considerable reduction ($p < 0.05$) in number of <i>E. coli</i> , <i>S. aureus</i> on implant surface | [53] |
| Microporous coating of implants with ions of Cu and TiO ₂ | Micro arc oxidation | Effective inhibition of <i>Staphylococcus aureus</i> growth, increased biocompatibility and osteogenic effect <i>in vitro</i> and <i>in vivo</i> | [55] |
| Titanium implants coated with TiO ₂ and nanoparticles of Se | Surface nucleation | High biocidal activity, antibacterial, anti-oncogenic and osteogenic properties on the surface of the titanium implant | [56] |
| Se, applied to microporous coatings made of TiO ₂ with Ca and P on titanium implants | Micro arc oxidation | 97 % eradication of <i>E. coli</i> and <i>S. aureus</i> in <i>in vitro</i> on implants surface, osteogenic and antioncologic properties | [57] |
| Hydroxyapatite based coating with application of ZnO on implant surface | Chemical precipitation from solution | Sharp reduction in the number of <i>E. coli</i> and <i>S. aureus</i> after 4 hours of exposition | [58] |
| Coatings based on nanoparticles of metals and their oxides | | | |
| Implants coated with calcium titanate with added iodine | A method of heat treatment of the implant surface that controllably incorporates 0.7 % to 10.5 % iodine into titanium | Antibacterial activity against MRSA, <i>E. coli</i> and <i>S. aureus</i> 99 % | [61] |
| Bioactive Si-based coating with Sr-doped bioactive glass particles | Sol-gel | Enhanced antibacterial effect and imparting osteogenic properties to implants | [62] |
| Coating of implant surface with TiO ₂ , doped with ions of Zn and Sr | Micro arc oxidation | Reduction in the number of colonies of <i>S. aureus</i> on implant surface | [63] |
| Antibacterial inorganic coatings with osteointegrative properties | | | |
| Composite coating containing Ag, F and hydroxyapatite | Sol-gel | Reduction in the number of <i>E. coli</i> by 96 % for 6 hours after implantation | [65] |
| Coating based on hydroxyapatite containing ions of Ag and F | Precipitation method | High antibacterial activity against <i>E. coli</i> and <i>S. aureus</i> and improved osteointegration properties | [66] |

Table 1 (continued)

Efficiency of antibacterial coatings in clinical practice

| Composition | Technique of coating | Antimicrobial efficiency <i>in vitro/in vivo</i> | Reference |
|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Coatings based on antimicrobial peptides | | | |
| Coating of TiO ₂ with synthesized AMP LL-37 | Photocatalytic method | Enhanced antimicrobial effects of TiO ₂ without toxic impact on the body | [70] |
| Titanium implants with applied AMP CATH-2 | Polymer layer-by-layer assembly and electrospray method | High antibacterial activity against <i>E. coli</i> and <i>S. aureus</i> , biocompatibility with body cells | [71] |
| Coatings based on polymers | | | |
| Titanium coated with plasma-polymerized diethyl phosphite | Plasma polymerization | High biocidal activity <i>in vitro</i> against <i>S. aureus</i> and <i>C. albicans</i> | [73] |
| Ester block polymers with the addition of diethyl (hydroxymethyl) phosphonate | Reversible addition-fragmentation transfer (RAFT) polymerization | Almost antibacterial activity against <i>S. aureus</i> and <i>E. coli</i> | [74] |
| Chitosan-based coating with hydroxypropyltrimethylammonium chloride with varying degrees of quaternary ammonium substitution | Polymerization of chitosan and glycidyltrimethylammonium molecules | Significant inhibition of formation and destruction of already formed biofilms | [75] |
| Multifunctional and smart coatings | | | |
| pH-sensitive antibacterial polymer containing cationic quaternary ammonium salts and carboxyl groups | Layer-by-layer self-assembly method | The coating has good antibacterial and anti-inflammatory properties during implantation and shows good osseointegration efficiency | [78] |
| Polymer gels | | | |
| Polymer gel based on hyaluronic acid impregnated with various antibiotics | Polymerization of molecules | Release of more than 70 % of the antibacterial drug impregnated into the gel from the matrix composition versus 10 % from polymethyl methacrylate within 28 days | [80] |
| Coatings produced using additive technologies | | | |
| Coating of 4 % hydrogel of medium molecular weight chitosan with the addition of 1 % povidone-iodine and dermal fibroblasts | Extrusion 3D Bioprinting Method | High biocompatibility, atraumatic nature and adhesion of the coating to the wound surface, effective antibacterial and regenerative effects | [82] |
| 3D Printed Calcium Phosphate Scaffold with Rifampicin and Vancomycin Addition | Extrusion 3D Bioprinting Method | Significant efficacy in preventing implant-associated infection in study <i>in vivo</i> | [83] |

Our systematic review of the literature allows us to conclude that improving current technologies of antimicrobial coatings for titanium implants should primarily consider the development of polymer coatings, hydrogels, multifunctional intelligent coatings, as well as additive technologies that allow the coating to be applied by 3D printing [10, 30, 31, 84, 85].

As for possible use of the above-mentioned technologies in the treatment of gunshot fractures, we are inclined to believe that even despite the high risks of infectious complications during osteosynthesis of such fractures, their development can be prevented by using polymer, multifunctional coatings, hydrogels, as well as oxides of metals such as silver, iodine and zinc during surgery.

CONCLUSION

To date, there is a wide variety of coatings with antibacterial properties that are successfully used in clinical practice for treatment and prevention of implant-associated infection. However, in the international literature there are still no research works devoted to studying the effectiveness of the above coatings in the treatment of gunshot fractures.

The search for and development of effective methods for the prevention of infectious complications in the treatment of gunshot fractures remains a topical issue for scientific research.

Conflict of interest Authors declare that they do not have conflicts of interests.

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Information about the authors:

Denis V. Davydov — Doctor of Medical Sciences, Professor, dvdavydov@yandex.ru, <https://orcid.org/0000-0001-5449-9394>;
 Leonid K. Brizhan — Doctor of Medical Sciences, Professor, Brizhan.leonid@mail.ru, <https://orcid.org/0000-0002-0391-8912>;
 Artur A. Kerimov — Candidate of Medical Sciences, kerartur@yandex.ru, <https://orcid.org/0000-0001-5783-6958>;
 Igor V. Khominets — Candidate of Medical Sciences, khominets24_91@mail.ru, <https://orcid.org/0000-0003-0964-653X>;
 Kazbek K. Bekshokov — Resident of the Department, kazbek.bekshokov.99@mail.ru, <https://orcid.org/0000-0002-2667-341X>;
 Andrey A. Gritsyuk — Doctor of Medical Sciences, Professor, drgaamma@gmail.com, <https://orcid.org/0000-0003-4202-4468>;
 Evgeniy A. Kukushko — doctrauma87@gmail.com, <https://orcid.org/0000-0002-2941-9601>;
 Vladimir D. Besedin — BesedinVD@yandex.ru, <https://orcid.org/0000-0001-9087-1421>.



Specifics of rotational planning and intraoperative alignment of the femoral component in the knee implant with navigation devices (systematic review)

R.A. Zubavlenko✉, D.A. Markov, V.V. Ostrovskij

Razumovsky Saratov State Medical University, Saratov, Russian Federation

Corresponding author: Roman A. Zubavlenko, sarniiton@yandex.ru

Abstract

Introduction The optimal rotational alignment of the femoral component in a knee implant with navigation devices is important for total knee arthroplasty. Measured resection and gap technique are available intraoperative methods to determine the rotation of femur with navigation devices, but each of these methods has its advantages and disadvantages. These aspects have contributed to the development and clinical validation of navigation tools for large joint arthroplasty.

The **objective** of this study was to evaluate the efficacy of determining the rotational alignment of the femoral component in a knee implant with mechanical and robotic navigation devices as a basis for processing intraoperative decision making by surgeons.

Material and methods The planning, execution and reporting of this systematic review were conducted in accordance with the established Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. Initially we identified 366 studies that corresponded to the main focus of this research, and 158 studies were selected for analysis after the duplicates had been excluded. Ultimately, only 11 studies fully met the selection criteria. The evaluation included the article data, the type of mechanical or robotic navigation device, the number of cases, the complication rate, and the specifics of the preoperative, intraoperative, and postoperative methods used for determining the rotation of the femoral component in a knee implant in the cohorts reviewed. A total of 1,198 total knee arthroplasties reported in those studies were analyzed.

Results and discussion It should be noted that in most of the scientific papers on the postoperative complications of surgeries that involved various navigation devices, the information about them was incomplete or the patients with complications were excluded from the study. In general, the incidence of complications averaged 2 %.

Conclusions When the navigation devices are used, the preoperative planning of the femoral component alignment frequently remains unperformed, and techniques and reference points used in surgeries are the same as in the traditional technique. The postoperative monitoring of rotational alignment of the knee implant is performed exclusively when complications are detected.

Keywords: total knee arthroplasty, mechanical and robotic navigation devices, femoral component malrotation, patellofemoral pain, knee endoprosthesis rotation, preoperative planning, intraoperative techniques, postoperative rotation assessment

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INTRODUCTION

Total knee arthroplasty is one of the most effective methods of treating progressive osteoarthritis of the knee joint (terminal stages) that ensures restoration of the lower limb weight-bearing. Over the past two decades, this technique has undergone significant improvements including surgical tactics, development of accompanying instruments and materials used to manufacture endoprosthesis components. Despite this, 20 % of patients show poor results after surgery [1, 2].

According to the findings of analysts, precise rotational positioning of the endoprosthesis components and alignment of the limb axis are key issues that determine patient's satisfaction and necessary functional results after total knee arthroplasty [3–5]. However, it should be noted that the task of achieving the correct positioning of the endoprosthesis components is quite difficult for surgeons, since visual and tactile assessment of anatomical structures is often difficult, especially in the presence of severe deformations and post-traumatic changes.

It is known that malrotation of the femoral component of the knee implant significantly affects the kinematics of the joint and results in tracking disorders, subluxation and dislocation of the patella, instability during flexion, development of arthrofibrosis and accelerated wear of the knee implant components [6, 7]. Therefore, these issues lead to active development of navigation tools for large joint arthroplasty and its clinical testing.

Many authors opine that the use of mechanical and robotic navigation in total knee arthroplasty allows for more precise bone resection and optimal implant placement, and also provides balanced extension and flexion gaps (femoral component rotation) that best match the anatomy of the human skeleton and help maintain the natural balance of ligaments [3, 8, 9]. This reduces the likelihood of excessive stress and wear of the endoprosthesis components, as well as the development of pain in the anterior knee joint, which is largely associated with improper rotation of the implant. The use of mechanical and robotic navigation tools initiates preoperative planning with an examination of the affected joint and the entire lower limb of the patient using computed tomography (CT), which is performed along with standard radiography. The use of this methodology in combination with full length X-rays in the direct, lateral and axial projections allows to determine the size and quality of the bone, the anatomical and mechanical axis of the lower limb, and rotation of the femur and to identify any possible deformities. Intraoperatively, surgeons use mechanical devices (tensioners) to install the femoral component in primary and revision knee arthroplasty, based on the gap balancing technique.

In the case of robotic computer navigation systems, rotational positioning of the femoral component of the knee implant is based on the measured resection, including the one oriented by the level of antetorsion of the proximal femur (neck) [10, 11]. The presented methodological approaches have significant theoretical potential to improve clinical outcomes. However, there is an ongoing debate regarding the effectiveness of mechanical and robotic navigation systems compared to visual-manual techniques. Researchers have not reported statistically significant differences in postoperative outcomes, despite favorable radiographic studies [7]. Therefore, we attempted to identify relevant studies and conduct a meta-analysis of the capabilities of navigation devices in the context of correct rotational positioning of the endoprosthesis in total knee arthroplasty.

The **purpose** of this study was to evaluate the efficacy of determining the rotational alignment of the femoral component of a knee implant with mechanical and robotic navigation devices as a basis for processing intraoperative decision making by surgeons.

The main hypothesis of this study is to substantiate the evidence base of anatomically and clinically superior results of mechanical and robotic navigation devices compared to visual-manual techniques used in surgical orthopedics.

MATERIALS AND METHODS

A systematic review of the available literature was performed using several combinations of synonymous or related terms: femoral component rotation, robotic arthroplasty systems, mechanical navigation devices in total arthroplasty, knee endoprosthesis component positioning, total knee arthroplasty, patellofemoral pain after arthroplasty. The search was conducted in the PubMed, Google Scholar, Web of Science, CyberLeninka and eLibrary databases from March 10 to March 31, 2025, with no time limit. Peer-reviewed journals were considered: the results presented in randomized controlled trials, prospective trials and retrospective studies. The search was limited to Russian-language and English-language sources.

One of the authors studied the titles and abstracts of the sources presented in the listed abstract databases with subsequent full-text selection of materials in the areas of the search. References in the literature sources were subsequently also studied in detail as potentially informative in the field of interest. In the event of detecting contradictory data in the available literature, consensus was reached with the involvement of senior authors.

Studies were considered to be relevant to the goals and objectives of the study if they had the following mandatory formal characteristics:

- The source included a detailed description of mechanical and/or robotic navigation devices used in primary or revision total knee arthroplasty;
- The source reflected the possibilities of either pre-, intra-, or postoperative assessment of the rotation of the femoral component of the endoprosthesis using navigation devices;
- The sources provided evaluation of complications after the use of navigation devices.

In addition to language restrictions, this review excluded review studies without an exploratory component, technical notes that did not contain descriptions of patients, results of experimental studies performed on animals, or in vitro tests.

Planning, execution, and reporting of this systematic review were carried out in accordance with the established PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines recommended for the correct conduct of systematic reviews and meta-analyses of data.

Figure 1 shows a flow chart of the literature source selection process. Initially, 366 publications relevant to the main vector of this study were identified. After removing duplicate publications, 158 sources were accepted for consideration. From that set of literature sources, 85 full-text works were extracted according to the title and abstract. After a detailed review of the texts, 74 articles were excluded from the analytical review based on non-compliance with the stated inclusion and exclusion criteria. This systematic review includes 11 studies that met the selection criteria.

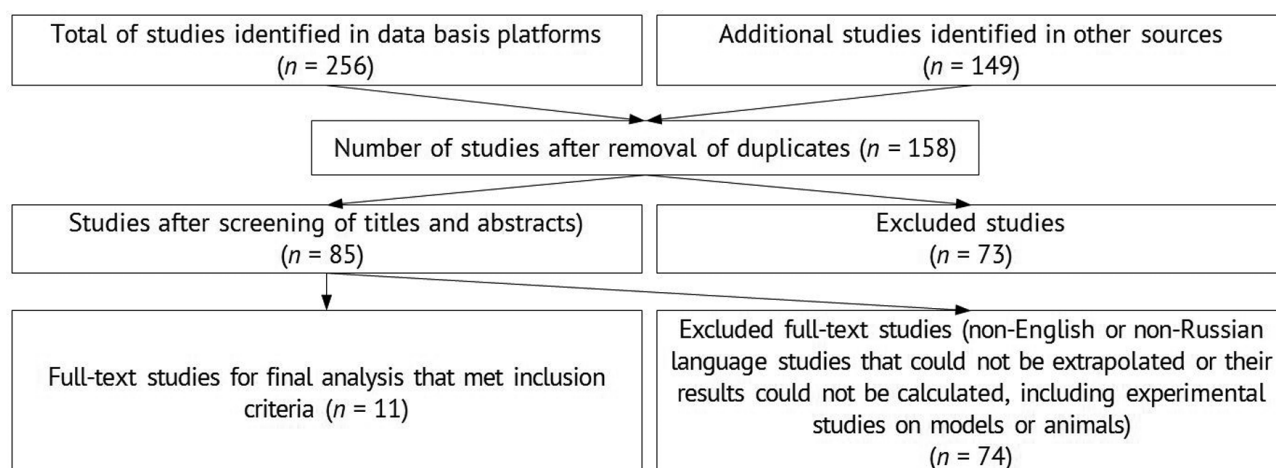


Fig. 1 Method of literature sources selection according to PRISMA

RESULTS AND DISCUSSION

The results of 1,198 total knee arthroplasty operations presented in the literature sources were analyzed. It should be emphasized that in most scientific papers, information on postoperative complications was insufficient, or patients with complications were excluded from the studies. The average incidence of complications was 2 %.

According to the literature, revision knee arthroplasty is frequently performed due to pain in the anterior region. It should be noted that it is the rotational alignment of the femoral component of the endoprosthesis that has a direct impact on the patellofemoral joint and, as a consequence, on the final clinical results [12, 13]. The rotation of the femoral component must be carefully adjusted with the same precision as the alignment of the component in the frontal and sagittal planes. It also seems natural to strive for correct patellar centration in arthroplasty. The introduction of new mechanical and robotic navigation devices makes this a fundamental principle, since the centration process determines the rotation imparted to the femoral component [14, 15].

In order to ensure gap balance and determine the amount of rotation of the femoral component of the endoprosthesis in robotic surgery, two main methods are used: measured resection and gap technique. Preoperative planning using mechanical devices such as FUZION is not performed since the assessment of rotational positioning of the femoral component is based on the gap technique [16]. Bensa et al. conducted a randomized control study comparing the measured resection and gap technique methods in total knee arthroplasty using a force sensor immediately before implant placement. The results showed that the use of the gap technique resulted in a greater dispersion of rotation of the femoral component due to an increase in the thickness of the posterior resection of the femur (which expands the space for flexion) [17].

As a rule, preoperative planning for knee arthroplasty using robotic navigation devices is based on computed tomography (CT) data, which in some cases requires the use of specialized software that is not always available. In contrast to these methods, in mechanical navigation devices and visual-manual techniques, preoperative assessment of the topography of joint components is based on the analysis of radiographs in direct, lateral and sometimes axial projections, which is not always sufficiently informative.

Despite the fact that traditional knee arthroplasty has proven its effectiveness and availability, as well as constant innovations in the field of implants and surgical instruments, a significant number of patients

remain dissatisfied with the results of this type of surgery. The reasons for this phenomenon can be both well known and uncertain and difficult to identify. Striving to achieve the ultimate goal of a reliable, painless and durable joint, the orthopedic surgeon increasingly relies on robotic navigation systems that allow him to measure the parameters of the knee joint, select a endoprosthesis and implement a surgical plan using standardized approaches [18–20]. Active development of robotic arthroplasty is due to good results based on strict standards for positioning the implant components, correct restoration of the axis of the lower limb and long-term postoperative stability of the joint [21–24]. This approach is designed to eliminate potential inaccuracies in implant positioning and alignment, thereby reduce the number of patients dissatisfied with the result and improve their quality of life.

It has been established that navigation systems assist in reduction of errors in component positioning, especially in the sagittal plane. However, the question remains open as to whether new technologies, which have been discussed in numerous studies above, will be able to predict and reproduce intraoperative rotation of implant components, improve postoperative functional recovery, and increase the clinical effectiveness of the surgical approaches used [21, 22, 25].

Assessing the overall results of the effectiveness of mechanical and robotic navigation systems in large joint arthroplasty, it is possible to determine the special significance of aligning the axes of the lower limbs with their use, which ensures the accuracy of implant positioning. Today, there is no doubt that maintaining the mechanical axis in a safe range limited to $\pm 3^\circ$ can contribute to a significant increase in implant survival. This parameter is a determining factor affecting the survival of the implant. In case of the mechanical axis deviation from the permissible values, the risk of implant dislocation and instability increases significantly and can lead to a disorder in functional recovery and an increase in the rate of revisions [26].

External rotation of 3° from the posterior femoral condyles is considered acceptable and is generally accepted in the measured resection method. However, the relationship between precise implant positioning and clinical outcomes remains controversial [26]. Many systematic reviews show that visual-tactile techniques and navigation systems do not show a significant difference in achieving the planned clinical outcomes, which is consistent with our own results [27]. Thus, the question arises whether 180° mechanical alignment and 3° external rotation of the femoral component are universal “normal” parameters and whether this should be the routine goal of total arthroplasty for all patients. Based on a study of 250 healthy patients, a varus angle of 1° in women and 2° in men was found to be normal [28]. Furthermore, these studies demonstrate significant variability in natural knee anatomy among the 4,884 patients who underwent CT scanning, with only 5 % of the overall population demonstrating natural neutral alignment [29]. In the majority of patients undergoing total knee arthroplasty, the knee may be forced into an unnatural position, potentially leading to negative clinical outcomes despite achieving neutral alignment. Given the variability in coronal knee alignment in patients without osteoarthritic disease and the wide variability in all alignment parameters, the need for a more precise and individualized approach to knee arthroplasty is evident [30].

As follows from the presented literature data, the setup and registration of a robotic or mechanical navigation systems in total arthroplasty are unique, require detailed development and lead to an increase in the overall time of the operation [31]. This study showed that when using mechanical or robotic navigation, a longer period of time is spent on completing the integration of the endoprosthesis than in the visual-tactile technique group, which may be due to the complexity of performing individual stages, the inexperience of the operator and a longer training period for this methodology. Significant time during the operation is devoted to performing such tasks as adjustment, fixation of the femur and tibia, as well as their alignment [32].

It should be noted that an increase in the duration of surgical intervention may lead to an increased likelihood of infectious complications, which, in turn, can cause irreversible changes in both the soft tissues and bone structures of the joint [33].

The data on the studies, types of mechanical or robotic navigation devices used, number of observations, number of complications (%), and features of the pre-, intra- and postoperative methods for determining the rotation of the femoral component of the knee joint endoprosthesis of the patients' samples are reflected in Table 1.

Table 1

Number of patients, navigation device, methods of pre-, intra- and postoperative determination of the rotational position of the femoral component of the knee endoprosthesis

| Authors (s), ref. number | Mechanical or robotic navigation device used | Number of cases, <i>n</i> | Complications, % | Preoperative planning of component rotation | Intraoperative method of implant rotation determination | Postoperative control of implant rotation |
|------------------------------|----------------------------------------------------------------------------------|------------------------------|---------------------|------------------------------------------------------|------------------------------------------------------------------|-------------------------------------------------|
| Petukhov et al. [34] | Medtronic, Stryker и Brain LAB | 120 | 2.5 % | Not performed | Measured resection | Not performed |
| Blyth et al. [35] | Electromagnetic navigation systems | 101 | Not available | CT | Measured resection | CT |
| Matassi et al. [36] | i-ASSIST accelerometer-based navigation system | 18 | Not available | CT or MRI | Combined technique | CT |
| Nam et al. [37] | MAKO (Stryker, Mahwah, NJ) | 154 | Not available | CT | Measured resection | Not performed |
| Lychagin et al. [38] | T-Solution One® (THINK Surgical Inc.) | 29 | Not available | CT | Measured resection | Not performed |
| Airapetov et al. [39] | Robotic assistant | 20 | Not available | CT | Measured resection | Not performed |
| Lychagin et al. [40] | T-Solution One® (THINK Surgical, Inc.) | 47 | Not available | KT | Measured resection | Not performed |
| Chandrashekar et al. [41] | CUVIS Joint™ | 500 | Not available | CT, preoperative J planner™ | Measured resection | CT |
| Blum et al. [42] | OMNIBotics and ultracongruent system OMNI Apex (Corin USA, Raynham, MA) | 32 | 1.9 % | CT | Measured resection | CT |
| Vanlommel et al. [43] | ROSA Total Knee System | 90 | Not available | CT | Measured resection | CT |
| Maciąg et al. [44] | Dynamic tensioner FUZION | 87 | Not available | Not performed | Gap technique | CT |

Given the key aspects, the results should be interpreted with caution and cannot be extrapolated to all systems. Due to the progress in mechanical and robotic navigation systems, there is a need for new studies to evaluate the latest advances in this area, including long-term follow-up, to draw more accurate conclusions regarding the results and benefits.

Thus, total knee arthroplasty performed using mechanical and robotic navigation devices demonstrated more effective restoration of the mechanical axis of the lower limb compared to the group of patients operated using visual-tactile technology. However, the rotational position of the implant components in the pre- and postoperative periods was not always assessed, and the operation time using the standard technique was shorter by 30-40 minutes.

CONCLUSION

Preoperative planning of the femoral component rotation is often not performed when mechanical and robotic navigation devices are used, and the same techniques are utilized during the surgical intervention as in the traditional technique of total knee arthroplasty.

Postoperative monitoring of the rotational positioning of the knee endoprosthesis is carried out only if complications are detected. The studies of this review mainly assess mechanical alignment and clinical results evaluated with the WOMAC score.

Total arthroplasty performed according to the traditional technique involves a longer observation period and shows comparable results in terms of range of motion. Further research is needed to fully analyze the long-term benefits and economic feasibility of using mechanical and robotic navigation systems.

Conflict of interest None.

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Information about authors:

Roman A. Zubavlenko — Junior Researcher, sarniiton@yandex.ru, <https://orcid.org/0000-0001-8225-1150>;

Dmitriy A. Markov — Candidate of Medical Sciences, Head of the Department, m-makar@yandex.ru, <https://orcid.org/0000-0002-1323-5592>;

Vladimir V. Ostrovskij — Doctor of Medical Sciences, Director, sarniito@yandex.ru, <https://orcid.org/0000-0002-8602-2715>.

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