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Results of Knee Joint Replacement with an Endoprosthesis of Our Own Design

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Abstract Malignant tumors predominantly affect the distal femur and proximal tibia, accounting for approximately 60% of primary skeletal tumors. This study evaluates the outcomes of knee joint reconstruction using a domestically designed endoprosthesis, addressing the limitations posed by high costs of foreign-made implants. The research encompasses 21 patients aged 16–38 with malignant bone tumors, treated at the Republican Specialized Scientific and Practical Medical Center of Oncology and Radiology. Preoperative diagnostics included CT, MRI, and biopsy to assess tumor extent and histological features. Post-resection, a custom-designed fixed-hinge titanium endoprosthesis was implanted, yielding excellent functional outcomes in most cases. Complications included aseptic loosening in two patients and one instance of local tumor recurrence. The study highlights the feasibility and efficacy of local endoprosthesis designs, reducing dependence on costly imports and advancing organ-preserving oncology practices.

Keywords Malignant bone tumors, Endoprosthesis, Osteosarcoma, Organ-preserving surgery, Bone tumor reconstruction, Onco-orthopedic innovations

1. Introduction

The bones that form the knee joint are most frequently affected by malignant tumors - the distal metaphysis of the femur and the proximal metaphysis of the tibia. This area accounts for about 60% of primary tumors [5,6,13,17]. Until the end of the 70s of the last century, the method of treating tumors of this localization was considered to be surgical and mainly mutilating (amputation and disarticulation) operations were performed. The prognosis for patients with these tumors was unfavorable. The survival rate of patients with osteosarcomas and Ewing's sarcomas did not exceed 10%. With the introduction of chemotherapy, a combined approach to the treatment of malignant bone tumors appeared. The development of effective chemotherapy regimens, progress in bioengineering and surgical techniques made it possible to perform organ-preserving operations and endoprosthetics [7,8,10,14]. The risk of limb amputation has decreased more than 3 times: from 23% in 1980 to 7.4% at present [11,12]. Life expectancy and duration of the relapse-free period after The outcomes of organ-preserving operations, provided adequate resection is performed, are similar to those after amputation. Today, the standard for organ-preserving surgery for limb tumors is endoprosthetics. [2,16]. The first person in the world to develop and implement an all-metal total hip joint endoprosthesis and a linked knee joint endoprosthesis was Konstantin Mitrofanovich Sivash in 1956. Subsequently, together with S. T. Zatsepin, he developed oncological versions of these endoprostheses. [1]. This endoprosthesis was the starting point for a new direction in reconstructive surgery for tumor lesions of the bones that form the knee joint, saving the functioning limb of thousands of patients. served as a prototype for many designs that are still used today (3]. In the 1980s, the pioneer of Russian onco-orthopedics N.N. Trapeznikov advised performing organ-preserving surgeries only for strict indications, taking into account the biological characteristics of the tumor: the degree of anaplasia, growth rates, and tendency to metastasize [2]. One of the founders of foreign onco-orthopedics can be considered Henry Jaffe, who published his work “Tumors and Tumorous Conditions of Bone and Joints” in 1958. In the 1970s, the Benoit-Gerrard Company (Caen. France) developed prostheses with a fixed joint and adapted them to segmental reconstruction of resected bone. In the first half of the 1980s, rotational knee and hip prostheses appeared. In the last 30 years, modular endoprostheses have been widely used to reconstruct resected bone segments. Today, these are standard of organ-preserving treatment for patients with bone tumors [18].

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The advantage of endoprosthetics after resection of the articular end with a tumor, in contrast to other reconstruction methods, is the one-stage compensation of massive bone defects by the implant while maintaining the support capacity and movements in the joint, which ensures optimal restoration of function and a higher level of quality of life for the patient, expanding the possibility of self-care and continuation of complex treatment [4]. Despite the significant successes achieved in the development of surgical intervention techniques using various designs of endoprostheses for oncological orthopedics, the search for an "ideal endoprosthesis" that meets all the requirements of modern oncoorthopedics continues, as evidenced by many publications [2,7,8,15]. In Uzbekistan, 320-350 patients with primary bone tumors are diagnosed per year. The incidence rate is 1.0 per 100 thousand people, which corresponds to global indicators [9]. Only 15-20 endoprosthetics of the knee joint and its constituent bones are performed annually. Considering that more than half of primary skeletal tumors occur in the bones that form the knee joint, the actual number of patients who need these surgeries is several times greater. In knee joint endoprosthetics, we use foreign-made devices, the cost of which, depending on the manufacturer, ranges from 30 to 60 million sum. Due to the high cost, not all patients have the opportunity to purchase an endoprosthesis. Therefore, organ-preserving operations with reconstruction and restoration of the knee joint are performed on a limited number of patients. The development and implementation of a new domestic endoprosthesis for replacing defects of the distal end of the femur, knee joint, proximal end of the tibia is certainly a solution to an important medical and social problem.

The aim of the study. To analyze the results of reconstructive surgical interventions on the knee joint using a new endoprosthesis of our own design.

Table 1. Distribution of patients by gender and age

Gender	Under 18	19-30	Over 30	Total
Men	4	5	2	11
Women	1	8	1	10
Total	5	13	3	21

The femur was affected in 17 cases, the tibia in 4. From the anamnestic data it became known that more than half of the patients before hospitalization in our department received treatment with an incorrect diagnosis. Most often, degenerative-dystrophic and inflammatory diseases of the knee joint were erroneously diagnosed at the place of residence, while physiotherapy was prescribed. The main causes of diagnostic errors were neglect of radiographic examination in case of persistent pain syndrome in the knee joint or incorrect interpretation of radiographs. Examination of patients according to the protocol included generally accepted research methods: collection of anamnesis and clinical examination, laboratory and clinical studies, radiography of the affected segment. Most patients underwent specific research methods: CT, MRI. Comparative analysis of the data obtained by CT and MRI allowed us to clarify the nosological affiliation, prevalence and relationship with the anatomical structures of the tumor process. If there was a suspicion of vascular involvement in the tumor process, angiography of the affected segment was included in the preoperative examination plan, which made it possible to identify the relationship between the tumor and the main vessels.

2. Materials and Methods of the Study

The study included 21 patients with tumors of the distal femur and proximal tibia undergoing treatment in the surgical department of tumors of the musculoskeletal system of the Republican Specialized Scientific and Practical Medical Center of Oncology and Radiology "RSSPMCOR". Of these, 11 were men and 10 were women aged 16 to 38 years (Table 1).

Biopsy of the pathological lesion and pathomorphological examination were the final stage of the examination. In the preoperative period, the diagnosis was verified clinically, radiologically and morphologically in all patients.

According to the examination, in 17 patients the tumor was localized in the distal femur and in 4 in the proximal tibia. According to the X-ray examination data: in 6 cases there was a lesion of the epiphyseal region spreading to the metaphysis, and in the remaining 15 cases - a lesion of the metadiaphyseal region of the bone; in 10 cases osteolytic, in 5 - osteoblastic and in 6 - mixed forms of the tumor were detected; on 15 radiographs, various types of periosteal reactions were determined. For the purpose of morphological verification, an open biopsy of the tumor was performed in all patients. Osteosarcoma was verified in 12 patients, giant cell tumor in 3, chondrosarcoma in 1, fibroma and xosarcoma in 1, adamantinoma in 1, Ewing's sarcoma in 1 and a malignant variant of GCT in 2 (Table 2). In 9 patients with malignant tumors, grade III malignancy was determined, in 5 - II.

Patients with osteosarcoma, Ewing's sarcoma and mesenchymal chondrosarcoma underwent 3-5 courses of neoadjuvant chemotherapy in the preoperative period. All patients underwent organ-preserving surgery - knee arthroplasty. Primary prosthetics was performed in 19 cases. Revision surgeries were performed in 2 patients for a previously installed metal-cement spacer. The purpose of the procedure was to reconstruct the flexion-extension apparatus of the knee joint. Based on the analysis of the long-term results of using various foreign-made implants (K.M. Sivash modified by S.T. Zatsepin, Beznoska, "Chunli"), an individual endoprosthesis of a new design was developed to replace the knee joint (Figure 1). In 2018, a patent for utility model No. FAP 01290 was obtained. The diagram-drawing of the endoprosthesis design is presented in Figure 2.

Table 2. Distribution by localization and histological structure

Localization	Osteosarcoma	Mesenchyme, chondrosarcoma	Fibromyxosarcoma	Giant cell tumor	Malignant Giant Cell Tumor	Adamantinoma	Ewing's sarcoma
Femur	9	1	-	3	2	1	1
Tibia	3	-	1	-	-	-	-
Total	12	1	1	3	2	1	1

Figure 1. General view of the knee joint endoprosthesis of a new design

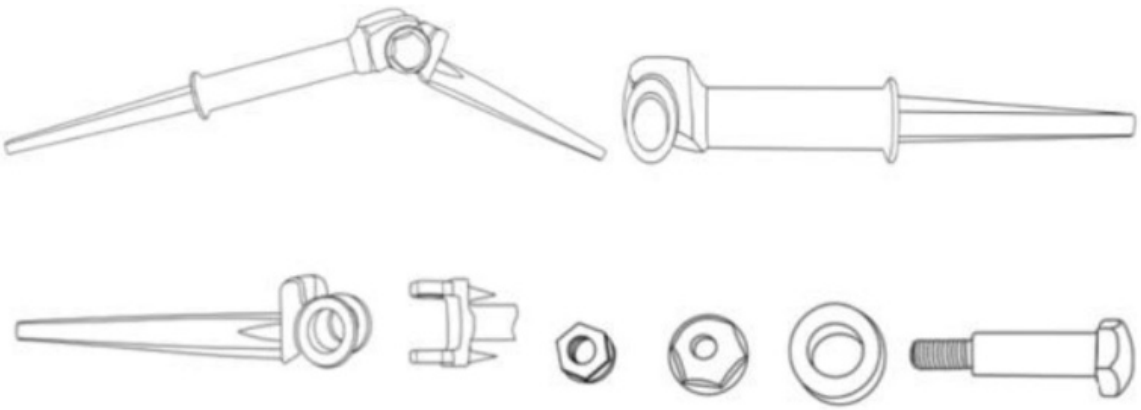

Figure 2. Schematic drawing of the knee joint endoprosthesis of a new design

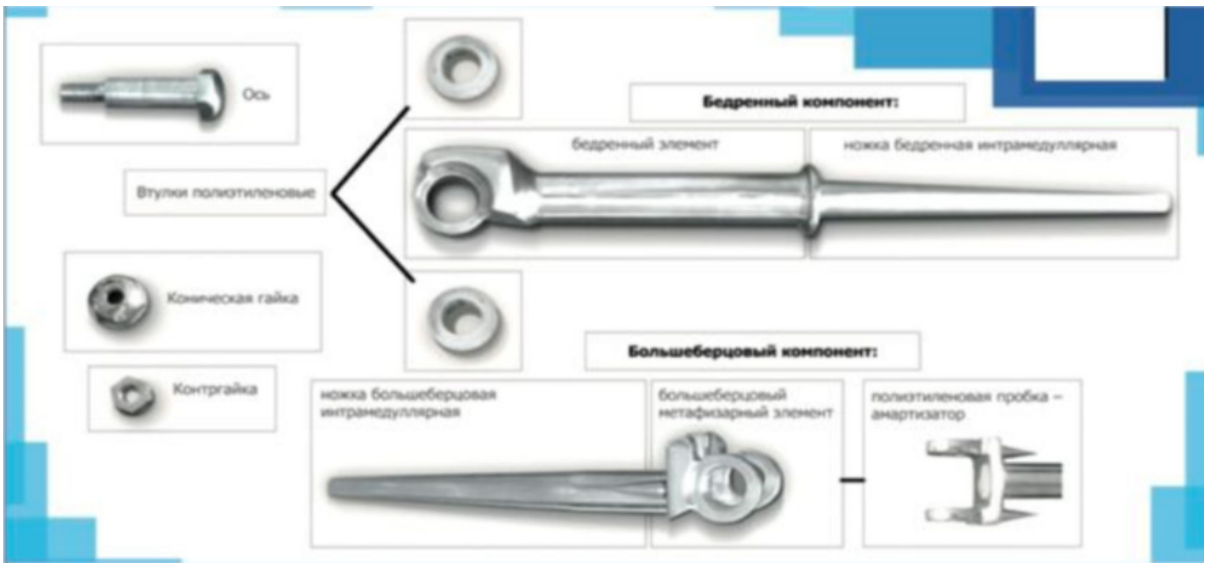

Figure 3. Components of a new design knee joint endoprosthesis

The endoprosthesis is designed to replace extensive defects of the distal femur or proximal articular section of the tibia and knee joint that occur after resection for malignant tumors. It is a custom-made fixed-hinge endoprosthesis. It has implantable femoral and tibial components that are connected to each other by a hinge joint using an axis, bushings, a lock nut and a conical nut (Figure 3). The advantage over rotational endoprostheses is the stability of the hinge joint, which is necessary to achieve the support function in case of extensive defects that occur after resection of the bone affected by the tumor with the surrounding muscles. All metal parts of the endoprosthesis are made of homogeneous materials based on titanium alloys, grades specified by GOST 19807-91, in accordance with ISO 5832/111, ISO/TK 5832/11, BT 1-0. VT 1-2. VT 1-3, VT 1-4. OT 1. OT 2. OT 3. OT 4, approved for implantation. Titanium alloys are biologically inert, their elastic modulus is close to bone, which is especially important for megaprostheses with a large surface area subject to intense cyclic loading. Individual elements are made of ultra-high molecular weight polyethylene according to ISO 5834-2.

The endoprosthesis is manufactured individually based on pre-determined calculated dimensions based on the results of X-ray. CT examination with 3D modeling.

Technique for performing surgery for tumors of the distal femur. If a soft tissue component of the tumor extending outward is detected, an antero-external approach is performed. The skin incision begins along the anterior edge of the tractus iliotibialis in the middle third of the thigh, continues in the projection of the intermuscular space of the m. vastus lateralis and m. rectus femoris, along the outer edge of the patella, and ends in the area of attachment of the patellar ligament to the tibia. Tumor isolation begins through the intermuscular space between m. vastus lateralis and m. rectus femoris. If a soft tissue component of the tumor extending inward is detected, an internal-lateral approach is performed. At the first stage of the operation, the main vessels are visualized and isolated. To facilitate this stage, it is recommended to transect the sartorius muscle in the area of the inferior opening of the Hunter canal. After isolation of the vascular bundle, the intervention continues in the space between the medial vastus and rectus femoris muscles. Then, a transverse osteotomy (resection) of the femur is performed above the upper pole of the tumor by at least 5 cm. The lateral and cruciate ligaments of the knee joint are crossed, which allows for maximum mobility of the resected segment, which significantly facilitates the isolation of the tumor and ligation of numerous vessels. The next stage is the preparation of the sawed femur and the proximal end of the tibia for implantation of the endoprosthesis. Using a saw, the proximal articular surface of the tibia is crossed by about 1 cm. A set of cylindrical cutters (reamers) are used to expand the canals of the femur and tibia to the required diameter of the endoprosthesis legs. First, the tibial implant-component of the endoprosthesis is fixed with cement in the tibial canal, then the femoral one, and the limb axis is aligned. After the cement crystallizes, the hinge joint is assembled, the function and stability of the endoprosthesis fixation are checked.

Technique of performing surgery for tumors of the proximal tibia. The medial parapatellar approach is used. The incision starts from the lower third of the thigh and ends in the middle third of the leg or at the border of the lower and middle thirds. After dissecting the skin and subcutaneous fat, the articular capsule is cut off in a circle 1-2 cm from the point of attachment to the tibia. The cruciate ligaments are crossed near the point of attachment to the femur. The inner articular surface of the proximal tibiofibular syndesmosis is cut off with a straight chisel. If the proximal tibiofibular syndesmosis is involved in the pathological process, the head of the fibula is resected. Then the fibers of the anterior tibial muscle are cut off so that part of them remains on the affected bone. The proper ligament is cut off. The tendons of m. gracilis, m. semitendinosus et m. semimembranosus are taken on holders and cut. exposing the popliteal fossa. The internal head of the gastrocnemius muscle and the soleus muscle are partially mobilized to expose the vessels and nerves. The tibia is resected 4-6 cm distally from the lower border of the tumor. The articular end of the femur is filed down. Using a set of cylindrical cutters (reamers), the canals of the femur and tibia are expanded to the required diameter of the endoprosthesis legs. The femoral implant component of the endoprosthesis is fixed first in the femoral canal using bone cement, then the tibial one, and the limb axis is aligned. After the cement crystallizes, the hinge joint is assembled, the function and stability of the endoprosthesis fixation are checked. Intra- and postoperative management. Immediately before the operation (30-40 minutes before the skin incision), broad-spectrum antibiotics were prescribed to prevent infectious complications, the administration of which continues for 5-7 days of the postoperative period. Throughout the operation, careful hemostasis and irrigation of the wound (washing) with a large amount of antiseptic solution are performed. In order to prevent hematoma formation, a tube for active drainage of the wound is brought out of the cavity through the counter -opening, which, depending on the state of the wound, is removed on the 2nd-4th day after the operation. In the early postoperative period (the first day), the patient should be under observation in the intensive care unit, where transfusion and infusion therapy is continued. In order to prevent thromboembolic complications and congestive pneumonia, on the second day, patients were activated in bed (therapeutic exercises). Getting up and dosed walking with crutches began on the 2nd-4th day, taking into account the general condition and functional state of the preserved muscles of the lower extremities. For maximum restoration of function, early passive and active development of the knee joint is necessary.

3. Results

The duration of operations is 90-180 minutes. There were no intraoperative complications. Average blood loss was 500 ml. The endoprosthesis installation was performed without technical difficulties; all patients achieved adequate replacement of post-resection defects, which demonstrates

the correctness of preoperative planning and the accuracy of the calculated sizes. Primary wound healing was achieved in all cases. The observation periods ranged from 13 months to 5 years. In the late period, aseptic instability of the endoprosthesis stem developed in two patients (9.5%). In the first case, 8 months after revision surgery for a previously installed metal-cement spacer in a patient diagnosed with osteosarcoma of the distal metadiaphyseal part of the right femur G3 T2N0M0, condition after combined treatment (4 courses of neoadjuvant chemotherapy + resection of the distal femur with installation of a spacer + 5 courses of adjuvant chemotherapy). When analyzing this case, we came to the conclusion that the predisposing factors for instability were the large length of the post-resection defect (24 cm) and, as a consequence, the short medullary canal of the femoral stump, into which the endoprosthesis stem was installed. In the second patient, after 52 months. Loosening was detected clinically and confirmed under fluoroscopic control. In both cases, surgery was performed - extraction of the proximal endoprosthesis stem from the canal, removal of bone cement residues, reinstallation of the stem with cement fixation. In the postoperative period, standard management with wound healing by primary intention. Observation periods are 11 and 23 months, knee joint function is restored by 80%. Tumor recurrence was detected in 1 patient (4.7%) with osteosarcoma in the soft tissues of the thigh 18 months after surgery. Excision of the recurrent tumor was performed, which did not affect the functional outcome. The functional results of treatment were assessed using the generally accepted international MSTS (Musculo Skeletal Tumor Society Score) system. After resection of the distal femur, all patients showed excellent and good functional results. knee joint function recovery according to the MSTS scale was 80-90%;. After resection of the proximal tibia, all patients showed good results, knee joint function recovery according to the MSTS scale was 75-80%.

4. Conclusions

More than half of primary malignant tumors of the skeleton occur in the bones that form the knee joint. Therefore, the improvement of existing and the development of new methods for reconstructing this joint in tumors of the proximal tibia and distal femur are one of the main innovative areas in modern oncology. Implants of foreign manufacturers are not widely available due to their high cost. The development, introduction into production and use of endoprostheses of our own designs will solve both medical and economic problems in the treatment of patients. Thus, the widespread introduction into practice of a new endoprosthesis of our own design will improve the results of organ-preserving operations with the replacement of defects in the bones that form the knee joint.

5. Clinical Example

Patient Sh., born in 1994. Diagnosis: Osteosarcoma of the distal metadiaphysis of the right femur G 2, T2N0M0, stage HB. The diagnosis was made in April 2015. After 5 courses of neoadjuvant chemotherapy according to the AR regimen, a good clinical effect was achieved (partial tumor regression). On 08.01.2016, an operation was performed - resection of the distal part of the right femur with replacement of the defect with a knee joint endoprosthesis of our own design. There were no intraoperative and postoperative complications. On the 2nd day, the patient began to move with crutches. Postoperative histological conclusion - osteosarcoma. Grade III therapeutic pathomorphosis. Taking into account the histological conclusion, the patient underwent 4 courses of adjuvant chemotherapy according to the same regimen. After 1 month, the knee joint function was restored by 40%, after 9 months by 90%.

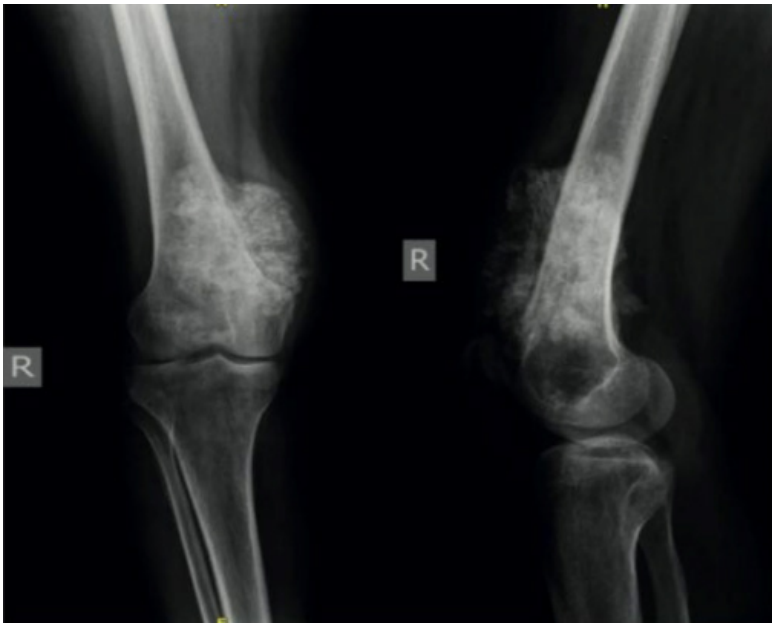

Figure 4. Radiographs. Osteosarcoma of the distal metaphyseal part of the right femur

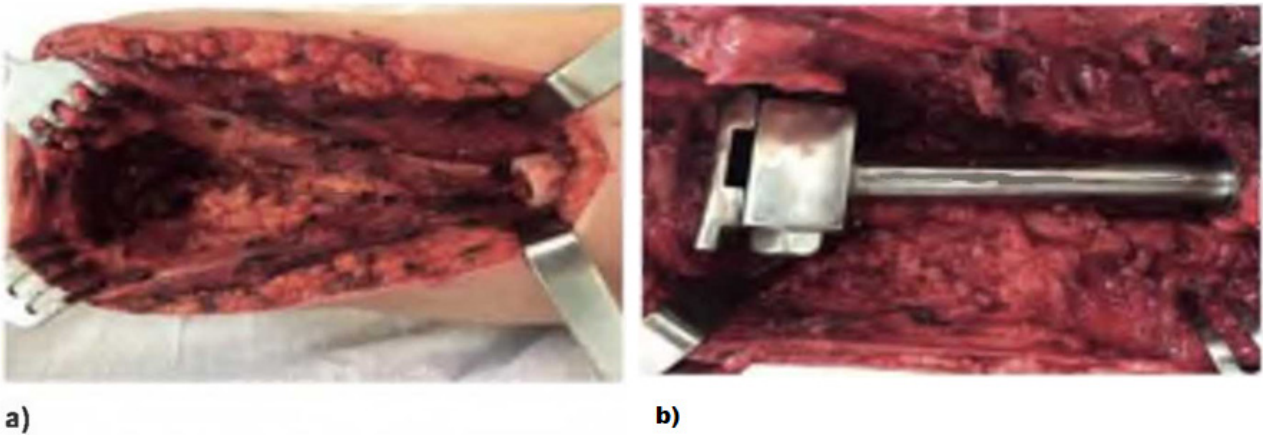

Figure 5. Photo: a) the resulting defect after resection; 6) an endoprosthesis is installed

Figure 6. Photo. Removed macropreparation

Figure 7. Radiographs. Condition after resection of the distal femur and proximal articular surface of the tibia with knee arthroplasty: a) early postoperative period; b) 5 years later

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