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Modular endoprosthetic replacement for proximal tibia tumor patients

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of the article

Key words: malignant bone tumors, modular endoprosthesis, proximal tibia.

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The major method of malignant bone tumors treatment is surgery. The most important task of an orthopedic surgeon is to preserve an adjacent joint. Currently, there are a large number of various reconstructive surgeries, including structural bone allograft, allocomposite and modular endoprosthetics replacement.

The aim: to analyze the results of surgical treatment for proximal tibia malignant tumors using modular endoprosthesis.

Materials and methods. The results of proximal tibia (PT) modular endoprosthetic replacement in 48 patients with PT tumor lesions were evaluated. The patients were divided into two groups: I (n = 36) – tumor resection and primary modular endoprosthesis, II (n = 12) – revision modular endoprosthetic replacement due to complications. Complications were divided into oncological, mechanical and non-mechanical. The functional outcomes were measured using the MSTS and TESS scores.

Results. During the treatment, 10 (21.2 %) patients underwent myofascioplastic amputation at the middle third of the thigh: due to periprosthetic infection – 8 people and tumor recurrence – 2.

It was found that the patients got back to regular way of life on average in 2.0–2.5 months. Functional results on the MSTS score were 73 ± 12 %, on the TESS score – 74 ± 16 %, which corresponds to good functional results. Among the patients, who underwent limb salvage surgery, no tumor recurrence was detected during a follow-up period from 6 months up to 11 years.

Conclusions. The choice of surgical treatment depends on the size of tumor, its location, pathohistomorphological picture, age, presence of pathological fractures, vascular and nerve tumor invasion. The use of modern designs of PT modular tumor endoprostheses and perfect surgeries makes it possible to minimize complications.

Ключові слова: злоякісні пухлини кісток, модульне ендопротезування, проксимальний відділ великогомілкової кістки.

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Модульне ендопротезування проксимального відділу великогомілкової кістки в пацієнтів із пухлинним ураженням

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Основний метод лікування злоякісних пухлин кісток – хірургічне втручання. Найважливіше завдання ортопеда полягає у збереженні суглоба. Нині є велика кількість різноманітних реконструктивних операцій, включаючи структурну кісткову алопластику, алокомпозитне та модульне ендопротезування.

Мета роботи – проаналізувати результати хірургічного лікування злоякісних пухлин проксимального відділу великогомілкової кістки (ПВВК) із використанням модульного ендопротезування.

Матеріали та методи. Здійснили оцінювання результатів модульного ендопротезування ПВВК 48 пацієнтів із пухлинними ураженнями. Хворих поділили на дві групи: I (n = 36) – первинне модульне ендопротезування після видалення пухлини, II (n = 12) – ревізійне модульне ендопротезування з приводу ускладнень. Розрізняли онкологічні, механічні та немеханічні ускладнення. Функціональний результат оцінювали за допомогою шкал MSTS і TESS.

Результати. Під час лікування 10 (21,2 %) пацієнтам здійснили міофасціопластичну ампутацію на рівні середньої третини стегна: 8 хворим через перипротезну інфекцію, 2 особам у зв'язку із рецидивом пухлини.

Встановили, що в середньому за 2,0–2,5 місяця пацієнти поверталися до нормального життя. Функціональні результати за шкалою MSTS становили 73 ± 12 %, за шкалою TESS – 74 ± 16 %, і це відповідає хорошим функціональним результатам. У пацієнтів, яким виконали органозберігальну операцію, протягом періоду спостереження від 6 місяців до 11 років рецидиви пухлини не діагностували.

Висновки. Вибір хірургічного лікування залежить від розміру пухлини, локалізації, патогістоморфологічної картини, віку, наявності патологічних переломів, інвазії судин, нервів. Використання сучасних конструкцій модульних ендопротезів ПВВК і досконалих оперативних утручань дає можливість мінімізувати кількість ускладнень.

Модульное эндопротезирование большеберцовой кости у пациентов с опухолевыми поражениями

О. Е. Вырва, И. А. Скорик, В. Д. Товажнянская

Основной метод лечения злокачественных опухолей костей – хирургическое вмешательство. Важнейшей задачей ортопеда является сохранение сустава. В настоящее время существует большое количество различных реконструктивных операций, включая структурную костную аллопластику, аллокомпозитное и модульное эндопротезирование.

Цель работы – проанализировать результаты хирургического лечения злокачественных опухолей проксимального отдела большеберцовой кости (ПОБК) с использованием модульного эндопротезирования.

Материалы и методы. Проведена оценка результатов модульного эндопротезирования ПОБК 48 пациентов с опухолевыми поражениями. Пациентов поделили на две группы: I (n = 36) – первичное модульное эндопротезирование после удаления опухоли, II (n = 12) – ревизионное модульное эндопротезирование по поводу осложнений. Осложнения разделяли на онкологические, механические и немеханические. Функциональный результат оценивали с помощью шкал MSTS и TESS.

Результаты. Во время лечения 10 (21,2 %) пациентам проведена миофасциопластичная ампутация на уровне средней трети бедра: 8 обследованным в связи с перипротезной инфекцией, 2 больным в связи с рецидивом опухоли.

Установлено, что в среднем через 2,0–2,5 месяца пациенты возвращались к нормальной жизни. Функциональные результаты по шкале MSTS составили 73 ± 12 %, по шкале TESS – 74 ± 16 %, что соответствует хорошим функциональным результатам. Среди пациентов, перенесших органосберегающую операцию, в течение периода наблюдения от 6 месяцев до 11 лет рецидивы опухоли не обнаружены.

Выводы. Выбор хирургического лечения зависит от размера опухоли, ее локализации, патогистоморфологической картины, возраста, наличия патологических переломов, инвазии в сосуды и нервы. Использование современных конструкций модульных эндопротезов ПОБК и совершенных оперативных вмешательств позволяет минимизировать количество осложнений.

Ключевые слова: злокачественные опухоли костей, модульное эндопротезирование, проксимальный отдел большеберцовой кости.

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Nowadays, major method of malignant bone tumors treatment is surgery, and the most important task of a surgeon, in addition to removing the tumor, is to preserve the adjacent joint. Volume of surgery at this pathology depends on size of pathological focus and cortical layer integrity of the affected bone. This involves usage of various techniques – from partial resection to massive periarticular reconstructive surgery. Partial resection is an affordable method of surgery, but it is very difficult to completely remove a tumor using this method, even with modern tools. Therefore, there is a risk of tumor local recurrence. Thus, it is recommended to perform extensive resection or resection "en block", especially in case of local tumor recurrence, pathological fracture with aggressive course of malignant tumor. This method allows a tumor removal within healthy tissue, so that the tumor itself is not damaged and its cell dissemination does not occur, so the risk of recurrence is close to zero. However, after resection of the tumor, there is a large enough defect that requires immediate replacement. Currently, there are a large number of various reconstructive limb-salvage surgeries, including structural bone allograft, allocomposite and modular endoprosthetic replacement etc.

The proximal tibia (PT) is one of the most common sites for primary malignant bone tumors [1,3]. In this segment of skeleton, we observed up to 15 % of all osteosarcomas, 11 % of Ewing's sarcomas and 6 % of chondrosarcomas [5,6,11,15,27]. By the end of 1970s, above-knee amputation was the standard treatment procedure for PT malignant tumors [7,10,14–16]. Today, thanks to advances in radiological diagnostics, immunohistochemical studies, radical changes in general principles of treatment for primary malignant bone neoplasms, complex chemotherapy and improvement of surgeries it has changed. For example, technical modernization of endoprosthesis structures, organ-preserving surgery has become a standard method of treatment [1,2,5,6,8,9,11,15,16,27,28]. PT modular tumor endoprosthetic replacement is difficult to perform due to changeability of anatomical structure – there is a risk of injury of tibial nerve and popliteal vessels. Moreover, together with a complex surgical performance, there are problems with closing the defect with soft tissues [2–7,9,11–13,15]. For these reasons, the reconstruction of PT after tumor removal is associated with a large number of complications compared to other parts of the skeleton – from 40 to 70 % according to different authors [3,4,7,8,10,13,14,16,21,22,24–28]. These include infections, structural disorders, aseptic instability, local recurrence, and a number of soft tissue lesions [3,8,11,17–26]. To further standardize complications, E. R. Henderson et al. [8] proposed a classification that was adopted in 2014 by the International Society of Limb Salvage (ISOLS). According to it, complications related to soft tissue incontinence are classified as type 1, aseptic instability – type 2, endoprosthesis fracture and periprosthetic fractures – type 3, infection complication – type 4 and local recurrences – type 5.

Aim

To analyze the results of surgical treatment for proximal tibia malignant tumors using modular endoprosthesis.

Materials and methods

We evaluated results of surgeries (PT modular endoprosthesis) performed at Bone Tumor Department, Sytenko Institute of Spine and Joint Pathology, in 48 patients that had tumor lesions of PT. Patients' age ranged from 12 to 74 years old, among them, there were 20 men (41.7 %) and 28 women (58.3 %). Division by nosological groups is given in *Table 1*.

Patients were divided into two groups: I (36 people) – primary modular endoprosthesis after tumor removal, II (12 patients) – revision modular surgery for consequences of tumor endoprosthesis (patients with complications who underwent primary surgery in other hospitals).

During the surgery, we used modular endoprosthesis of different systems: Global Modular Reconstruction System (GMRS, Stryker, USA), Modular Universal Tumor and Revision System (MUTARS, Germany), System of Individual Modular Endoprostheses of Bones and Joints (SIMEX, Ukraine).

Complications that occurred after modular endoprosthesis were divided into oncological, mechanical and non-mechanical (Hendeson classification [8]). According to this classification, there were 5 types of complications:

I – associated with soft tissue failure (rupture of knee ligament, wound dehiscence and other defects of soft tissues);

II – aseptic instability;

III – structural disorders and periprosthetic fractures;

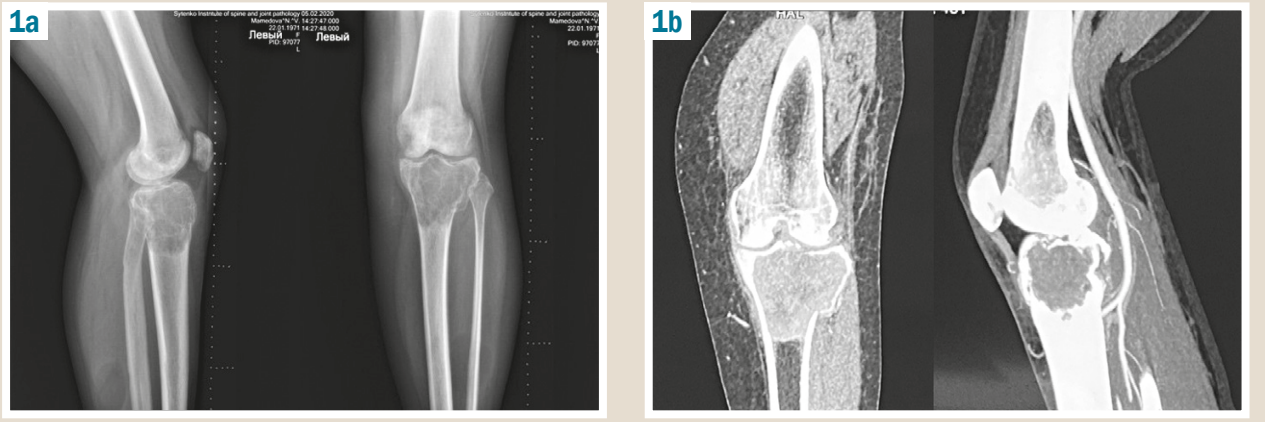


Fig. 1. X-ray images (a) and CT (b) of the PT, patient M., 49 years old.

Table 1. Division of patients by nosological groups

Nosology	Group of patients	
	I (primary modular endoprosthesis)	II (revision surgery)
Chondroblastoma (n = 7)	5	2
Desmoplastic fibroma (n = 1)	1	–
Histiocytoma (undifferentiated pleomorphic sarcoma) (n = 6)	4	2
Giant cell tumor (n = 18)	16	2
Lymphoma (n = 1)	1	–
Osteosarcoma (n = 12)	7	5
Synovial sarcoma (n = 1)	–	1
Metastases (n = 2)	2	–
Overall (n = 48)	36	12

Table 2. Division of complications by type

Type of complication	Group of patients		Total
	I	II	
I	1 (2.78 %)	2 (16.6 %)	3 (6.25 %)
II	1 (2.78 %)	0	1 (2.08 %)
III	0	0	0
IV	9 (25 %)	3 (25 %)	12 (25 %)
V	2 (5.55 %)	0	2 (4.17 %)
Overall	13 (36.1 %)	5 (41.6 %)	18 (37.5 %)

IV – infection;

V – local tumor recurrence (*Table 2*).

During the treatment, 10 (21.2 %) patients underwent a myofascioplastic amputation at the middle third of the thigh: due to periprosthetic infection – 8 people and tumor recurrence – 2.

Results were evaluated by modern bioethical requirements of the Sytenko Institute of Spine and Joint Pathology National Academy of Medical Sciences of Ukraine (protocol No. 174 29.01.2018, No. 201 02.03.2020).

The functional outcome was evaluated using the MSTS and TESS scores. The MSTS score [8] allows evaluating functional condition of a patient by a doctor after comprehensive treatment of the bone tumor. The TESS score [7] was developed to assess functional state of patient at home and it is more subjective in terms of patients' feelings. The results of both scores were evaluated as a percentage by the following gradations: excellent result – from 75 % to 100 %, good – from 70 % to 74 %, average – from 60 % to 69 %, satisfactory – from 50 % to 59 %, unsatisfactory – less 50 %.

The data were statistically processed using the Microsoft Excel licensed software package. We used the methods of variational and alternative analyzes. For the data we used Mann–Whitney U test and Student criterion.

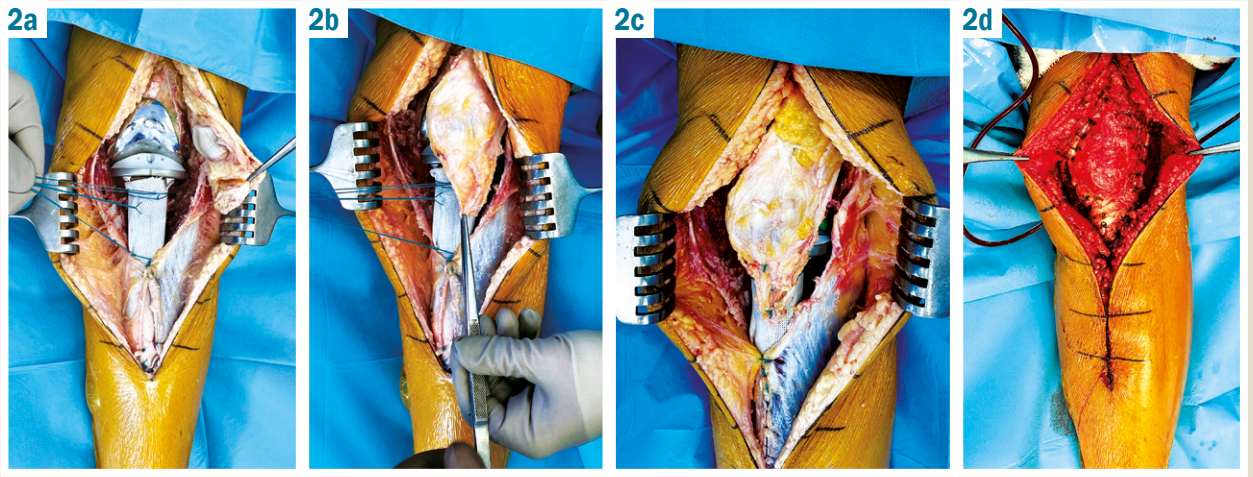
Results

As an analysis result, it was found that the patients got back to regular way of life on average in 2.0–2.5 months. Functional results on the MSTS score were 73 ± 12 %, on the TESS score – 74 ± 16 %, which corresponded to good functional results. Among the patients, who underwent limb-salvage surgery, no tumor recurrence was detected during a follow-up period from 6 months up to 11 years.

In our clinic, we use this kind of surgical treatment for PT tumors (III stage) because this method yields successful results. It helps to achieve full function of the knee joint in the shortest possible time.

A case report: a 49-year-old female patient M. applied to the Sytenko Institute of Spine and Joint Pathology National Academy of Medical Sciences of Ukraine with severe pain under left knee. She had a history of slight pain for about 2 years. In the home area, she received treatment for left-sided gonarthrosis (anti-inflammatory therapy, chondroprotectors etc.) with no stable positive effect.

On November 14, 2019, she was injured following a fall, when a pathological fracture of PT was detected. After a comprehensive examination at the clinic, the patient was diagnosed with chondroblastoma of the left PT, stage III according to the Enneking classification. The pathological fracture of the left PT is presented in *Fig. 1*. A surgery was performed: removal of PT tumor "en block" (segmental resection), replacement of the post-resection PT defect with modular endoprosthesis (*Fig. 2*). During the surgery, we performed a reattachment of the musculofascial complex to an attachment tube (*Fig. 3, a*). The next surgery step was a reattachment of the left knee extensor apparatus (*Fig. 3, b*) and fixation of the patella ligament to the attachment tube (*Fig. 3, c*). The next step was a suture fixation the knee joint capsule (*Fig. 3, d*).



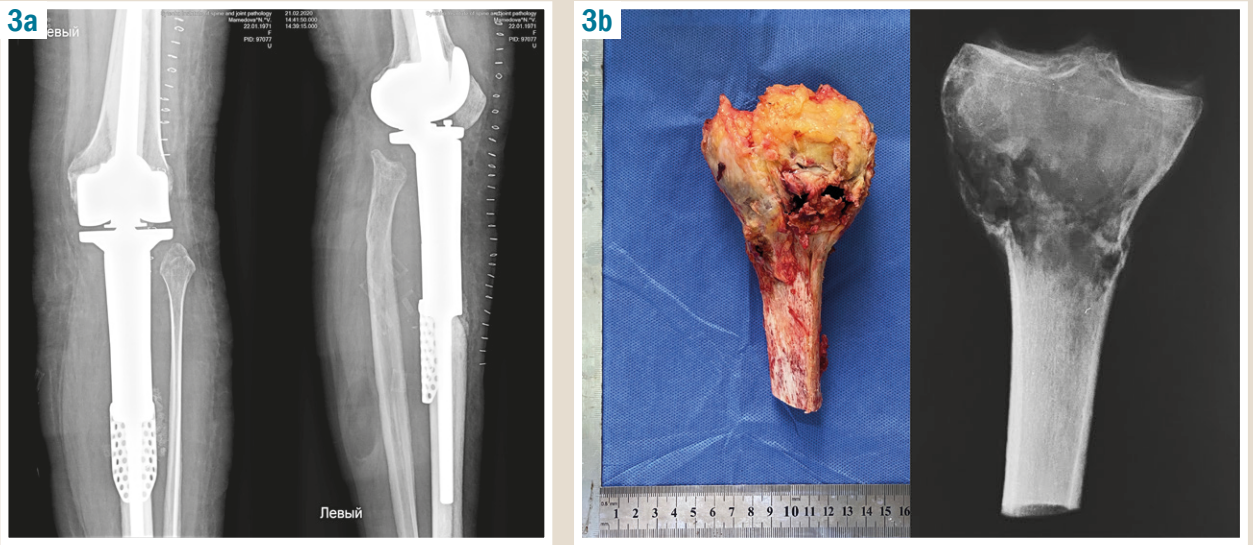


Fig. 2. Intraoperative pictures: reattachment of the knee joint extensor apparatus and soft tissues. Patient M., 49 years old: **a)** reattachment of the musculofascial complex to the PT modular endoprosthesis; **b)** reattachment of the left knee extensor apparatus; **c)** suture fixation of the knee joint capsule to the attachment tube; **d)** wound after the restoration of soft tissue defect of the PT.

Fig. 3. X-ray images of the PT, patient M., 49 years old, after the surgery (**a**) and PT tumor specimen (**b**).

Fig. 4. Figures of the knee function, the 9th day after PT modular endoprosthetic replacement, patient M, 49 years old.

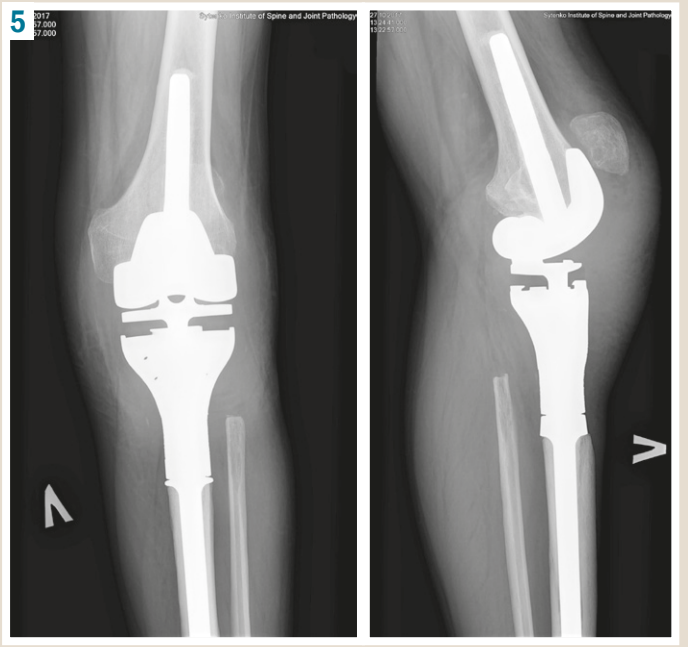


Fig. 5. X-ray images with knee ligament detachment after primary endoprosthetic replacement using the GMRS system (Stryker, USA).

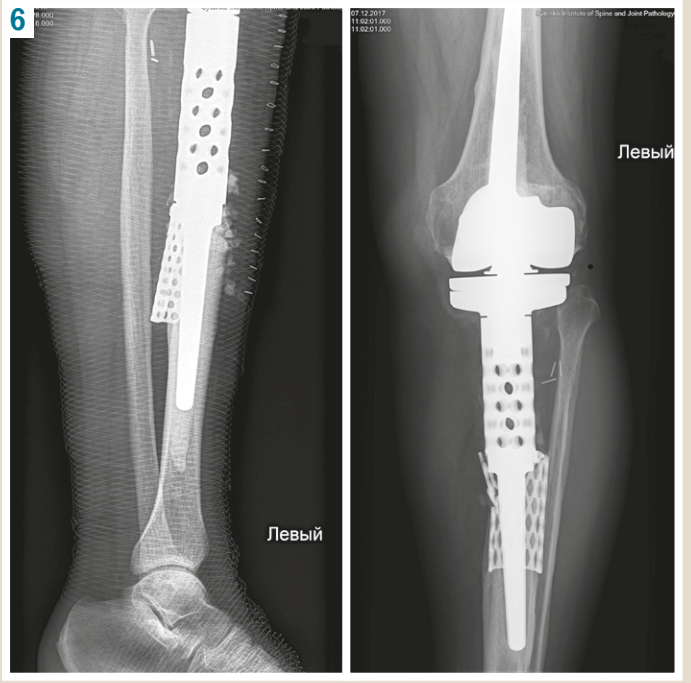


Fig. 6. X-ray images: aseptic instability of the tibial stem endoprosthesis.

9 days after the surgery, the patient was able to walk without support (*Fig. 4*). The full range motion was achieved in 4 weeks after the surgery. Two months after the surgery, the patient returned to daily life activities.

A revision surgery was performed in 18 (38.5 %) cases during a period from 3 weeks to 13 years after PT modular endoprosthesis implantation due to complications. Moreover, in 12 cases (25 %), we had to perform an originally implanted endoprosthesis removal with a metal-cement spacer replacement of the bone and joint defect: in group I – 9 (25 %), in group II – 3 (25 %). Two (4.17 %) myofascioplastic amputations were performed for tumor recurrence.

Complications associated with soft tissue failure. Type I complications were registered in 3 (6.25 %) patients: in group I – 1 (2.78 % of all group complications), 6 months after the PT modular endoprosthetic replacement, in group II – 2 (16.6 %), in 2 weeks and 1 year, respectively. In all the observations, the endoprosthesis was preserved. Among the complications, we observed 3 cases of knee ligament detachment (*Fig. 5*). In our opinion, this happened due to an orthopedic regime violation by a patient.

The surgery involved fixing knee ligament to proximal module of the tibial endoprosthesis. Knee ligament fixation was performed using the attachment tube (manufactured by Implantcast, Germany) or a nylon tape (manufactured by Ethicone, J&J) with a duplication of the knee ligament from the knee joint capsule.

One patient in group II showed formation of a stable extensor contracture of the knee joint. We consider a soft tissue fibrotization as a cause of it. After all, each surgery is a significant injury to a segment or limb, and given a presence of infection in this area in a past history, the formation of massive scars in such a case is inevitable.

Aseptic instability of the endoprosthesis (type II complications) according to our data was detected in only 1 patient (2.78 %) 6 years after the primary PT modular endoprosthetic replacement. The patient was initially fitted with cementless ceramic-coated endoprosthesis stem. An interesting fact was a usage in the tibial component design of extramedullary plate with a ceramic coating, which was firmly fused with tibia and soft tissues around it. As a result of the limb functional activity after the surgery, the metal plate could not withstand load, which led to extramedullary fracture and aseptic instability of the tibia endoprosthesis (*Fig. 6*). In this case, a revision surgery was performed, the endoprosthetic tibial component was replaced without removing the attachment tube. The knee extensor apparatus and knee joint capsule were fixed to it during surgery. Performed manipulations made possible a full weight bearing and active knee range of motion at the shortest time (on the 3rd day) after the surgery.

Mechanical complications, such as periprosthetic fractures, fractures of the endoprosthesis components (type III) were not observed in our study.

Type IV complications – periprosthetic infection was detected in 12 patients out of 48, ie 25 % of all complications. The terms of its development ranged from 12 days to 4 years. In group I, 9 (25 %) cases were registered, in group II – 3 (25 %). In all the patients, during the first stage of revision surgery, we removed the implant and performed radical surgical treatment of wound with an excision of pathologically altered tissues, active “pulse lavage” wound debridement and implantation of a metal-cement spacer VancoGenx (manufactured by Tecres, Italy), loaded with two antibiotics – Vankomicin and Gentamicin. In 6–8 months after the revision surgery, during the second stage, we performed revision PT modular endoprosthetic replacement. All cases during postoperative period were accompanied by prolonged extensor contracture of the knee joint.

Eight patients underwent the myofascioplastic amputation at the middle third of the thigh due to severe generalized

infection with complex defects of soft tissues which could not be treated with the limb salvage procedures.

Type V complications. Local tumor recurrence was detected in 2 (5.55 % of all complications) patients of group I: 6 months after surgery in patients with low-grade chondrosarcoma of the proximal tibia; 3 years after the surgery in patient with osteosarcoma of the proximal tibia. Both patients underwent the myofascioplastic amputation at the middle third of the thigh.

Discussion

Currently, in our opinion, only type of surgery during malignant PT tumor is "en block" tumor resection. However, after such surgical procedure, an onco-orthopedist must solve a problem of a large volume defect replacement. Today, structural allografts, modular and allocomposite endoprostheses are used for this purpose. Each of these methods has certain advantages and disadvantages. Complications include non-oncological ones such as infections, allograft resorption, soft tissue failure, and so on. In our experience, in case of massive defects formed after tumor removal, the most effective method of surgery is modular endoprosthetic replacement, which allows to perform ablastic tumor removal and in the shortest possible time to activate patients for their limb function restoration [2,4,9,11,20].

An experimental study (laboratory rats) was conducted on the basis of Sytenko Institute of Spine and Joint Pathology. We proved expediency of using polyethylene terephthalate for fixation of soft tissues, as only this material use allows preserving anatomical structures as much as possible. In addition, in case of extensor apparatus fixation of the knee joint, only in polyethylene terephthalate use, tendon-like tissue is formed in the area of knee ligament attachment [3,11,13,17–20].

Modular tumor endoprosthesis is a system without ability to self-regulate with limited using. No matter how perfect the implanted structure is, it will always be a foreign body for human organism, which it will try to separate (forming a dense connective tissue capsule) or reject, in case of an immunoconflict reaction. Therefore, it is very difficult to single out one main reason that could lead to the development of a certain complication. It is only possible to name the factors of conflict between the implant and patient's body that caused the development of complications.

Failure of the knee joint extensor apparatus, according to the literature, is observed in about 5.8–12.0 % of cases of all complications in the PT area [3,7,8,15,16,22–24]. Based on the results of our study, they were detected in 6.25 % of all surgical procedures and were caused by a sharp flexion of the knee joint with a simultaneous load on the limb.

Modular endoprosthesis tibial stem aseptic instability was observed in 1 case, which amounted to 2.08 % of complications among all surgical interventions. Mavrogenis A. F. et al. [13] reported aseptic instability in approximately 6 % of cases with PT modular endoprostheses. Under conditions of this complication, there is a pain syndrome in the lower limb, the only method of treatment is revision surgery with the replacement of endoprosthesis. This volume of surgery is standard in the case of aseptic instability.

Mechanical complications were not detected in our study in any of systems of tumor endoprostheses. Although according to published data, they occur quite often – from 2 % to 12 % [3,7,8,15,16,23]. The loads that happen at friction node of the knee endoprosthesis are usually 20–40 times higher than that at a healthy knee joint, depending on a hinge design. Any breakage in this part of the endoprosthesis requires revision surgery.

Periprosthetic infection is the most common complication, which, according to various authors, happens from 11 % to 36 % [3,7,8,15,16,23,27,28]. Among our patients, infectious complications were detected in 12 people (25.5 %). In the standards of the PT reconstruction during deficiency of soft tissues, it is recommended to initially use the gastrocnemius muscle flap to cover the endoprosthesis, as a protection against possible skin injury and to reduce a risk of trophic disorders in this area. However, we did not find any association with infection progression depending on the use of the muscle flap. It should be noted that infectious complications in both groups were almost the same share – about 25 %.

Acute and chronic infectious processes cause different approaches to treatment. Acute infectious complications included suppurations that developed during the first 3 weeks after primary surgery, chronic ones included deeper and destructive inflammatory processes that were diagnosed after this period.

In the case of an acute infectious complication, such treatment methods as open debridement, wound lavage, long-term washing of the joint cavity with antiseptics, massive antibacterial therapy, VAC therapy, etc. can be used. Some authors even recommend one-stage revision endoprosthetic replacement, although positive results, according to various sources, are observed only in 27–30 % of patients [3,7,15,16,23]. In case of purulent complications treatment that developed in the late period, these methods did not lead to positive results, so optimal combination of antimicrobial therapy, radical surgical treatment of infection lesions with mandatory removal of implants and bone cement, implantation of temporary metal-cement spacers combined with adequate drainage and detoxification therapy is needed [3,7,8,15,16,22–24].

In our study, the surgeries were performed, which provided a comprehensive approach to treatment of infection, taking into account modern technologies. However, the number of cases that were accompanied by a long-term infectious process and ended in amputation, was quite large – 8 patients.

Local tumor recurrence was detected in 2 patients (5.55 % of all complications and 4.25 % of all cases), which was due to the primary type of tumor, late treatment of patient in a specialized hospital and difficult clinical situation. All the patients underwent amputation of the affected limb with subsequent prosthetics. In such cases, there was a very high risk of tumor recurrence after revision surgery, so it was considered inappropriate. According to modern treatment standards and designs of new exoprostheses, amputation at the thigh level is the method of choice.

Conclusions

1. Treatment of primary malignant PT tumors is a complex problem, the study of which must not stop today. The choice of surgical treatment depends on the tumor volume,

tumor site, pathohistomorphological picture, patient's age, presence of pathological fractures, vascular and nerve tumor invasion. The use of modern designs of PT modular tumor endoprostheses and perfect surgeries makes it possible to minimize mechanical complications.

2. Clinical analysis of treatment results among 48 patients with malignant PT tumors shows that resection "en block" allowed to avoid oncological complications during the follow-up period from 6 months up to 14 years. The use of modular endoprostheses, reinsertion of soft tissues on body of endoprosthesis and knee extensor apparatus reattachment after tumor removal, as well as early activation of a patient contributed to a good functional result on the MSTS score 73 ± 12 % and on the TESS score – 74 ± 16 %.

3. The most complex and common complication was early and late periprosthetic infection.

4. Adequate fixation of the knee joint extensor apparatus gave patients the opportunity to obtain a good functional result on the MSTS score 72 ± 12 % and on the TESS score – 74 ± 16 % of cases.

5. Despite the number of complications and complexity of surgery in patients with malignant PT tumors, the method of replacing post-resection defects with modular endoprostheses is justified, as it allows to obtain 61.8 % of positive results, as evidenced by the clinical study.

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