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Method of preparation individual instrument for knee arthroplasty

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Objective. To improve the results of total knee arthroplasty by developing a methodology for the design and manufacture of an individual instrument for the implants accuracy installation. Methods. An analysis of the literature on various concepts of alignment was carried out. In practice, one of them was chosen depending on the clinical case. For preoperative planning, a CT scan of the lower extremities was performed with the capture of the pelvis or hip joint; feet completely or up to the calcaneus (CT 64 or 128 slices were used for better visualization and increased accuracy). With the help of RadiAnt DICOM, the 3D model was converted into an STL file, which was uploaded to the FreeformPlus program, where preoperative planning was done. The program allows not only to assess the presence of varus or valgus deformity of the limb, to determine its degree, but also other deformities of the lower legs. In the program, after assessing the deformity, we perform preoperative planning using one of the concepts: anatomical, mechanical, or kinematic. After choosing the concept and virtual correction of the limb, we prepare an individual instrument and print is with additive technology. In addition, we print joint parts of the femur and tibia, which allows the surgeon to orient himself intraoperatively. Results. Thanks to the completed work and software, it was possible to improve the results of knee arthroplasty by increasing accuracy implants installing. The developed technique of 3D-design and manufacture of an individual tool allowed us to use any of the alignment concepts with high accuracy. Preoperative planning increases the deformity understanding because surgeon himself, not the engineer, does it. Conclusions. Developed technique of three-dimensional modeling of the lower extremity makes it possible to correctly plan, manufacture and put into practice a patient specific tool for knee arthroplasty, taking into account the individual characteristics of the lower extremity.

Мета. Покращити результати ендопротезування колінного суглоба за допомогою розроблення методики проєктування та виготовлення індивідуального інструмента для точності встановлення компонентів ендопротеза. Методи. Проведений аналіз літератури щодо різних концепцій вирівнювання. На практиці обирали одну з них залежно від клінічного випадку. Для проведення передопераційного планування виконували КТ нижніх кінцівок із захопленням таза або кульшового суглоба; стопи повністю або до надп'яткової кістки. Для кращої візуалізації та підвищення точності використано КТ 68 або 128 зрізів. За допомогою RadiAnt DICOM переводили 3D–модель у STL–файл, який завантажували в програму FreeformPlus, де виконували передопераційне планування. Програма дає змогу не лише оцінити наявність варусної або вальгусної деформацію кінцівки, визначити її ступінь, а й інші деформації стегнової кістки чи кісток гомілки. У програмі після оцінювання деформації виконуємо передопераційне планування з використанням однієї з концепцій: анатомічне, механічне чи кінематичне. Після вибору концепції та віртуальної корекції кінцівки готуємо індивідуальний інструмент. Окрім нього, друкуємо частку стегнової кістки та гомілки, що дає змогу хірургу орієнтуватись інтраопераційно. Результати. Завдяки виконаній роботі й освоєнню програмного забезпечення вдалося покращити результати ендопротезування колінного суглоба, збільшити точність встановлення компонентів ендопротеза. Розроблена методика 3D–проєктування та виготовлення індивідуального інструмента дала змогу використовувати будь-яку з концепцій вирівнювання з високою точністю. Передопераційне планування підвищує розуміння хірурга кожного разу, оскільки він, а не інженер, виконує її. Висновки. Використання розробленої методики тривимірного моделювання нижньої кінцівки дало можливість правильно спроєктувати, виготовити та застосувати на практиці інструмент для ендопротезування колінного суглоба з урахуванням індивідуальних особливостей анатомії нижніх кінцівок пацієнта. Ключові слова. Колінний суглоб, гонартроз, ендопротезування, індивідуальний інструмент.

Key words. Knee joint, gonarthrosis, endoprosthesis, individual instrument

Introduction

Total knee arthroplasty is the main method of surgical treatment of patients with end-stage gonarthrosis. Over the years, this operation has changed, its technique and tools for conducting were improved, and indications were expanded.

Today, there are many modifications of knee implants for different cases, but they do not cover all possible variants of the anatomy of the knee joint. In addition, the results of knee arthroplasty largely depend on the correct installation of the structure. Therefore, orthopedists have always been interested in the accuracy of knee replacement surgery. Many methods are used to achieve the correct position of the endoprosthesis: from fluoroscopic stage control during the operation to computer navigation and robotics.

For a long time, the goal of total knee arthroplasty was neutral mechanical (180°) alignment of the limb with joint lines perpendicular to the mechanical axes [1]. The survival rate of the prosthesis using this method is 96.3 % in 15 years, 94.8 % in 20 [2]. Most patients experienced a significant reduction in pain and improved function. However, the question remains why 20 to 30 % of all patients have pain or remain dissatisfied with the function of the limb after total knee arthroplasty [3, 4]. The main, so to speak, disadvantage of mechanical alignment is a violation of the natural function of the knee, since it is suitable only for 2.05 % of men and 1.77 % of women according to phenotypes [2].

Anatomical alignment involves restoration of the neutral mechanical axis of the lower extremity to 180° ± 1.5° and the anatomical inclination of the tibial and femoral bones. This alignment according to knee joint phenotypes is suitable for 18.97 % of men and 17.70 % of women. The problem lies in the difficulty of performing a three-degree section of the femur and tibia with a conventional instrument [5, 6]. Thanks to the 3D planning and the preparation of the individual instrument for the installation of the components of the knee replacement, this became easy to reproduce.

Numerous studies of long-term results of knee arthroplasty showed that the functional results of mechanical alignment leave much to be desired, about 20–25 % of patients remain dissatisfied [7, 8]. Therefore, the elaboration of the kinematic alignment technique today already seems absolutely necessary, as well as the increased interest of surgeons in it [9]. Kinematic alignment involves restoration of the knee joint to its original «pre-arthritic» state, that is, restoration of all three of its axes, which makes it possible to minimize the release of ligaments and the trauma of the operation [10]. The method of kinematic alignment is conditionally divided into two types: 1) without any restrictions regarding the initial deformation of the knee joint; 2) limited by «safe» deviations (90° ± 5° at the hip and lower leg) [11]. In recently published findings, it is indicated that the function of the knee joint in the department after treatment was significantly better in patients who underwent arthroplasty according to the rules of kinematic alignment, than in those who used the technique of mechanical alignment [12, 13]. It is worth noting that kinematic alignment is suitable for all knee joint phenotypes in 100 % of cases.

One of the disadvantages is the issue of how to find a balance between the improvement of joint function and the durability of the endoprosthesis [14].

An individual tool for installing a knee joint endoprosthesis is one of the possibilities for precise positioning of implants. At the same time, we install components according to the results of preoperative planning. The method is based on planning based on a computer tomogram of the lower extremities, the work with which is carried out by the company-manufacturer of the endoprosthesis, and the surgeon receives individual tools for the main sections of the femur and tibia with recommendations for the operation. The individual instrument for knee arthroplasty has turned out to be the most accessible for our clinical practice of all modern precise methods of endoprosthesis installation.

The purpose of the study: to improve the results of endoprosthetic repair of the knee joint by developing a methodology for designing and manufacturing an individual tool for the accuracy of installing the components of the endoprosthesis.

Material and methods

To determine which alignment is suitable in different situations, knee joints were divided into 3 groups according to phenotypes [15–17].

To create a customized instrument, it is necessary to know the dimensions of all components of the endoprosthesis and the distance between the cut and the holes for the guide pins in the cutting blocks for the tibia and femur. This information can be obtained by measuring the trial components of the endoprosthesis and the instrumentation for its installation.

For preoperative planning, a CT scan of the lower extremities was performed with the capture of the pelvis or hip joint; feet completely or up to the calcaneus. CT 68 or 128 slices were used for better visualization and increased accuracy.

Computer tomography of the lower extremities in RadiAnt DICOM format was used for planning. The software allows us to build a three-dimensional model of the lower extremities in STL format from CT scans (Fig. 1), which we loaded into the specialized three-dimensional modeling program FreeformPlus. The peculiarity of 3D modeling is that the axis of the limb is not drawn on a flat model, as in ordinary radiography, but establishing frontal and sagittal planes, at the intersection of which the axis of the lower limb is located. After constructing the planes, we find the axis and determine the direction of the plane of the knee joint. Having assessed the deformations, one can choose one of three concepts of alignment of the axis of the limb – kinematic, mechanical or anatomical. We mostly used kinematic alignment, but when making a custom instrument, we also marked the position of the guides on it for mechanical alignment as well, to be able to change tactics during surgery.

For accurate design, the study involved planning based on the 3D model of the lower extremity in the FreeformPlus software.

Results and their discussion

Having obtained a three-dimensional model (Fig. 2, a), it is possible to separate the femur and bones of the lower leg and foot and work with them separately (Fig. 2, b). However, their position relative to each other should be remembered in the software in order to combine them in the original form if necessary. Next, it is necessary to establish the frontal and sagittal planes of the femur (Fig. 2, c), at the intersection of which will be the axis of the femur, which, as usual, is the basis for planning the axis of the lower limb.

After determining the axis of the hip, we look at the position of the lower leg; we can assess the degree of deformation and perform the necessary correction (Fig. 3). Thus, we complete the alignment of the axis of the limb and proceed to the design of the resection planes of the femur and tibia in the extended position. The degree of limb axis correction depends on which method of alignment is planned to be used in the patient (Fig. 4).

Fig. 1. 3D STL model in InVesalius 3.1

In accordance with the thickness of the femoral implant, we plan the level of resection (Fig. 5). Let us analyze the mechanical alignment – the front surface of the knee joint is set at an angle of 90° relative to the mechanical axis of the femur. It is worth noting that at this stage, owing to the software, we can apply any type of alignment (Fig. 4).

Having determined the plane of resection of the femur, we find the positions for inserting the guide pins of the block for cutting the femur, the distance from the plane of resection and between them depends on the design of the conductor of the planned endoprosthesis model. At this very stage, the position of the pins determines not only the frontal and sagittal inclinations, but also the rotation of the femoral component. Next, we use our own original virtual, experimentally developed template (Fig. 5) to build an individual tool and combine it with the landmarks of the distal and posterior resection of the femoral condyles. With the help of a special software module, the template acquires the shape of the surface of the femur in the places of contact of its supports (Fig. 6, a). Thus, the model of the individual instrument occupies the only correct position due to close contact with the surface of the femur. To control the correct position of the tool during the operation, we use 3D printing to make a conductor for the distal part of the femur, on which we apply the contact zones of the tool with the bone. This provides a possibility to accurately set it during the operation (Fig. 6, c).

Next, we move to the tibia and repeat the algorithm (Fig. 7), first establishing the desired resection plane with a frontal slope (in this case, 90°) and a tibial slope of 5°, the value of which was determined based on the preserved external plateau.

After preparing the templates, we measure the height of the filed part of the tibia and determine the thickness of the tibial liner. We apply the patient's last name, the thickness of the files and liner, and the size of the implants to the templates.

Having received ready-made templates, we prepare them for 3D printing (Fig. 8, a, b). For surgical intervention, we print the articular ends of the bones and individual templates in order to control their correct position of the templates on the femur and tibia bones during the operation (Fig. 8, c, d). Templates underwent presterilization treatment and then they were sterilized by the gas method using ethylene oxide.

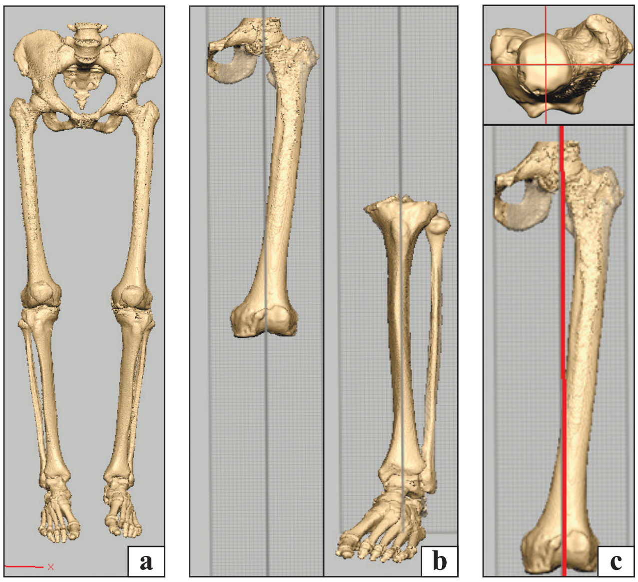

Fig. 2. Stages of 3D modeling: a) 3D model in the software; b) separation of the femur from the tibia; c) the axis of the femur at the intersection of the frontal and sagittal planes

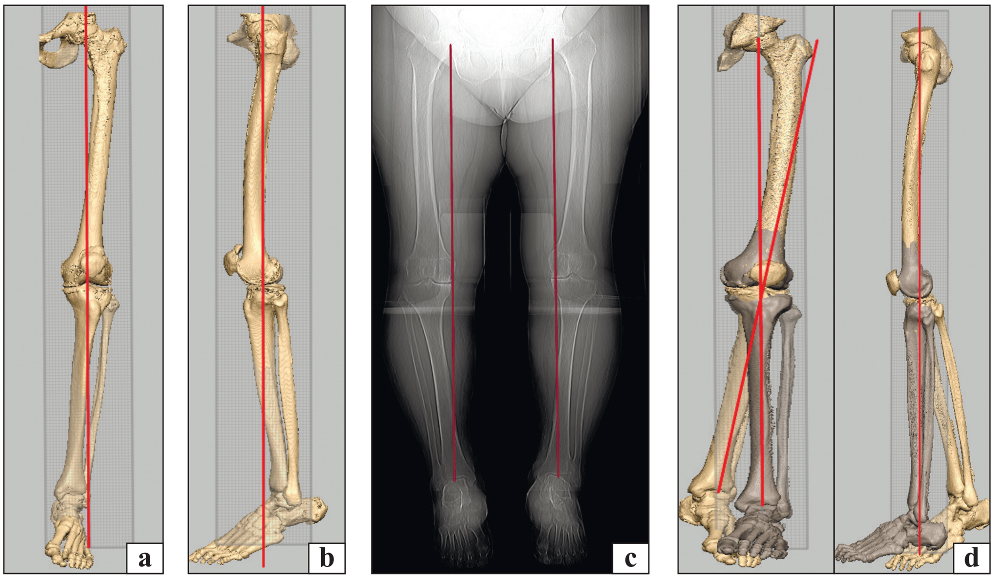

Fig. 3. Construction of a three-dimensional model of the lower limb, assessment of the degree of deformation, alignment of the mechanical axis: anterior (a) and lateral (b) views; radiographs of the lower extremities before surgery (c); correction of the axis of the limb, the axis of the tibia and femur coincide (mechanical alignment 180°)

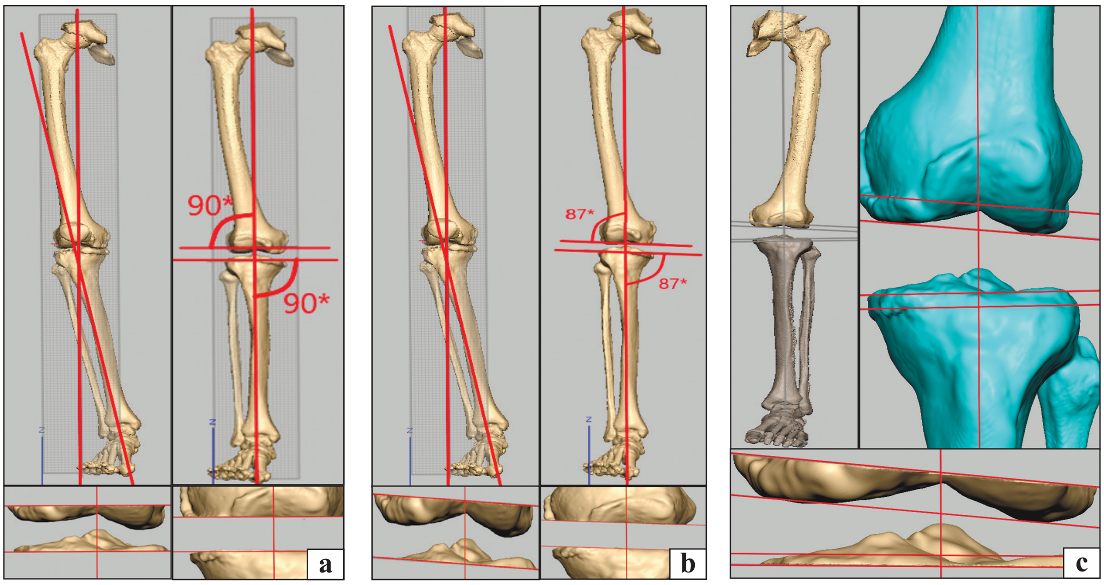

Fig. 4. The main concepts of restoration of the axis of the lower limb: a) mechanical; b) anatomical; c) kinematic

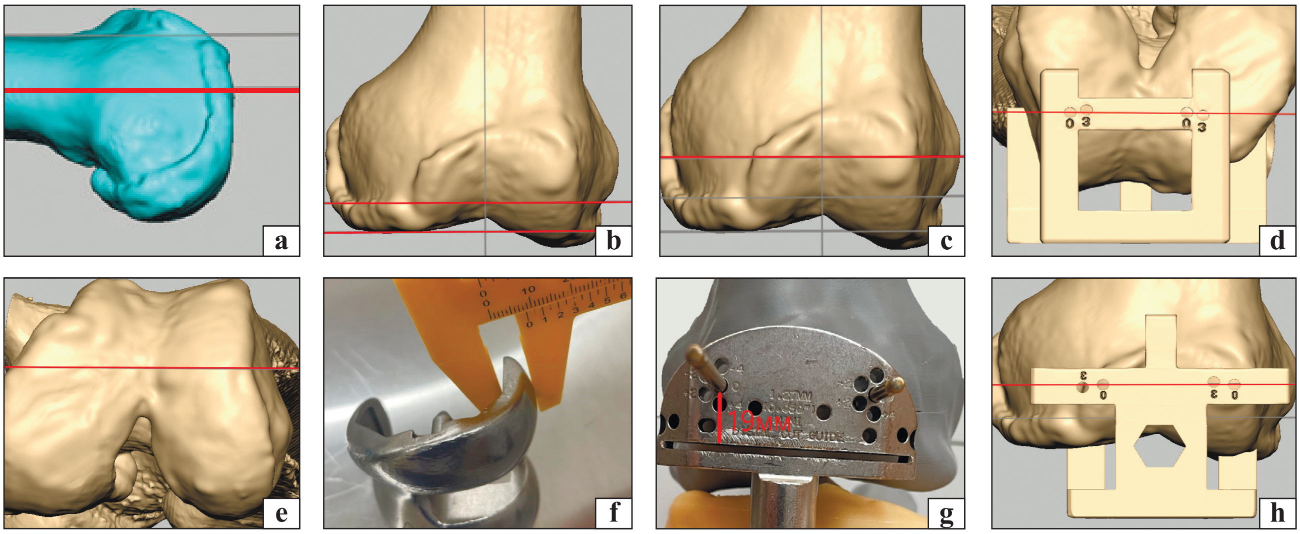

Fig. 5. Stages of constructing an individual femoral tool: a) determining the location of the pins for cutting the posterior edge of the femoral condyles, lateral projection; b) location of the resection plane depending on the type of alignment; c) the installation plane of the guide pins in accordance with the design of the tool; d) construction of a template in accordance with the planned section of the posterior edge of the condyles; e) location of pins for cutting the posterior edge of the femoral condyles, direct projection; f) thickness of the implant; g) installation of guide pins; i) construction of a template

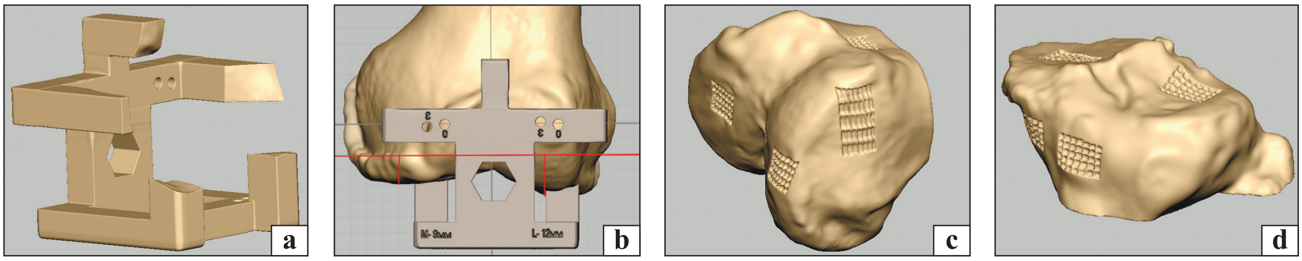

Fig. 6. Appearance of the finished individual instrument for the femur at the contact points (a), with markings of the thickness of the filed parts of the condyles and the alignment axes of the knee joint; points of contact of the tool with femur (c) and tibia (d) bones

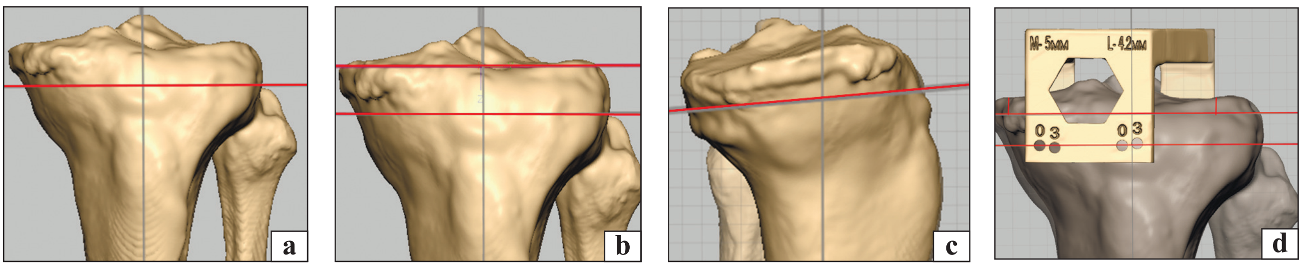

Fig. 7. Construction of the tibial individual tool: a, b) direct projection of the shin with the designation of the axis of the location of the pins and the cutting level (b); c) level of pins, lateral projection, plane of contact with the concave defect with specified frontal and sagittal slopes (90° varus, 5° slope); d) level of insertion of pins, cutting plane, direct projection, the thickness of the filed parts of the condyles and the alignment axis of the knee joint are marked

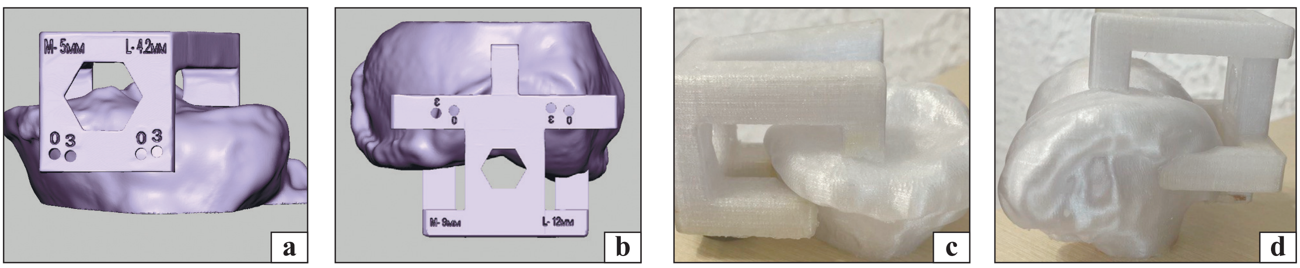

Fig. 8. Models for 3D printing: prepared templates for tibia (a) and femur (b) bones; printed individual tools for setting the resection block on the tibia (c) and femur (d)

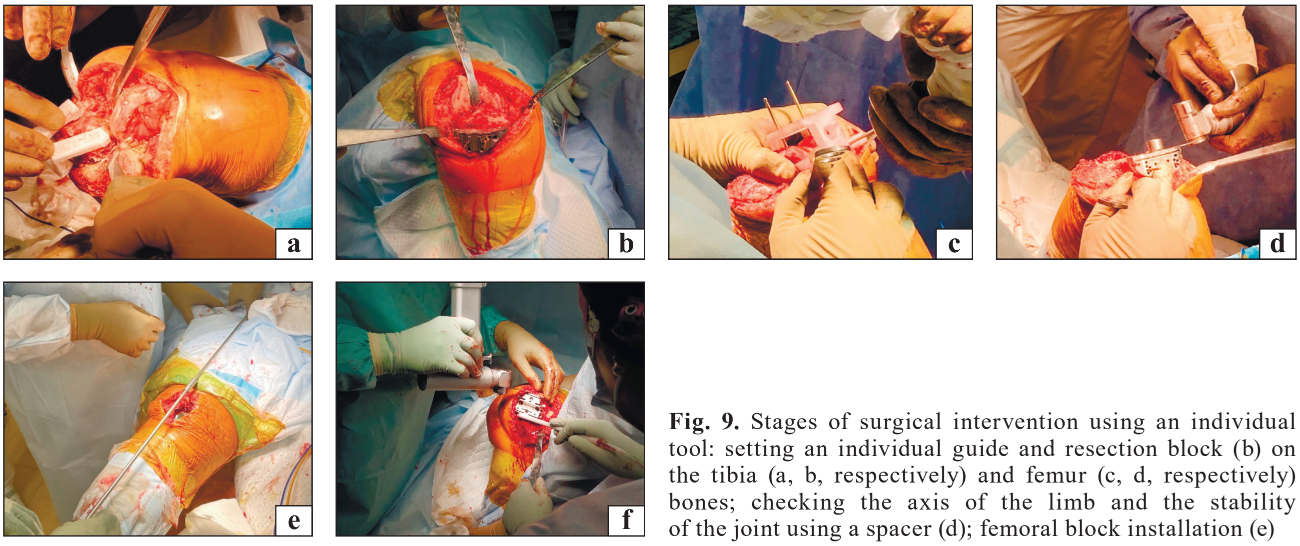

Fig. 9. Stages of surgical intervention using an individual tool: setting an individual guide and resection block (b) on the tibia (a, b, respectively) and femur (c, d, respectively) bones; checking the axis of the limb and the stability of the joint using a spacer (d); femoral block installation (e)

The method of using an individual tool

After the arthrotomy was performed and the tibia was isolated, an individual template was placed on it, checking the correctness of its position according to the 3D model that was on the operating table. Guide pins were inserted into the holes of the template, on which a standard tibial resection block was placed. Its position was then monitored using standard intraoperative navigation. The tibia was sawed off. The next stage involved the femur, and an individual instrument was also installed on it, through which pins were passed, on which first the distal and then the final resection blocks were put (Fig. 9).

Thus, on the basis of CT modeling of the limb, we learned not only to make an individual instrument for knee arthroplasty, but also to correctly use any of the three types of alignment in practice.

The results of the application of the individual tool were evaluated on the basis of radiography. The analysis showed that the position of the knee endoprosthesis components after surgery did not differ significantly from the one planned on the three-dimensional model.

It should be noted that 2–3 days pass from performing a CT scan of the patient's lower extremities to receiving templates ready for surgery. The methodology is not estimated, and planning is fast. With its help, it is possible to make individual guides for any system of primary knee arthroplasty. In our practice, the model is created by a traumatologist, not an engineer.

Conclusions

The application of the developed technique of three-dimensional modeling of the lower extremity made it possible to correctly design, manufacture and apply in clinical conditions the tool for endoprosthetic repair of the knee joint, taking into account the individual features of the patient's lower extremity anatomy.

Conflict of interest. The authors declare no conflict of interest.

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