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Clinical evaluation and accuracy of mechanical axis alignment in robotic total knee arthroplasty

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Abstract

The first experience in robotic total knee arthroplasty (RoTKA) has been obtained resulting in the questions about clinical efficiency and accuracy of lower limb alignment. **Objective** To clarify clinical evaluation and accuracy of alignment of the mechanical axis of the lower limb in RoTKA. **Materials and methods** Twenty-nine patients with osteoarthritis of the knee of Kellgren-Lawrence stage 3-4 underwent RoTKA. The knee joint was assessed with VAS, WOMAC, FJS-12; the range of motion was measured. The changes in the axis of the lower limb were evaluated on the full limb length radiographs. **Results** Pain before the surgery according to VAS was 5.8 ± 1.5 points, on the first day after the surgery it was 8.5 ± 1.4, on day 3 – 5.9 ± 1.2, on day 12 – 2.9 ± 1.1. The range of motion on the first day after the surgery was 99.5° ± 1.4°, three months later – 115.1° ± 1.1°, six months later – 125.6 ± 1.5°, one year later– 127.5 ± 1.6°. The WOMAC score before the surgery was 32.7 ± 3.3, after the surgery 25.1 ± 2.1, three months later 7.3 ± 1.3, six months later 2.8 ± 0.2, and after one year – 1.3 ± 0.5. The FJS-12 score 3 months after the surgery was 68.2 ± 4.1, after 6 months 80.3 ± 2.9, after one year 94.0 ± 2.1. The analysis of postoperative full length roentgenograms in 72 % of cases (n = 21) did not reveal any deviation of the mechanical axis from the planned one and in 28 % of cases (n = 8) the deviation of the mechanical axis was up to 1° from the planned one. **Discussion** Neither technical difficulties nor complications inherent to RoTKA were found. According to the results of VAS, WOMAC and FJS-12 questionnaires, and the assessment of the range of motion, a positive dynamics was observed. According to the results of tele-roentgenograms, there was alignment of the limb axis and the accuracy of the position of the endoprosthesis components. **Conclusion** The study of this technology has demonstrated safety, accuracy of alignment of the mechanical axis, validity of indications and contraindications, and stable early clinical results.

Keywords: knee joint, robot, total knee arthroplasty, robotic total knee arthroplasy

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INTRODUCTION

Osteoarthritis is a chronic progressive disease that affects the joints and is characterized by degeneration of articular cartilage, structural changes in the subchondral bone and synovium [1]. Gonarthrosis (osteoarthritis of the knee joint (OAKJ) is a lesion of the knee joint, which manifests itself with pain, restriction of knee motion and axial disorders of the lower limb, leading to an impairment in the quality of life of the patient [2, 3]. Approaches to its treatment depend on the stage of the disease. The most common clinical and radiological classification was developed by Kellgren JH and Lawrence JS (1957), in which the authors proposed to distinguish four stages of the disease [4].

Gonarthrosis in stage 3-4 (K-L, 1957) is an indication for total knee arthroplasty (TKA) after failure of complex conservative therapy. This surgical intervention can relieve pain, eliminate deformity, restore the range of knee motion and quality of life [2, 3, 5-8].

The conventional (manual) technique of primary TKA is based on the use of an intra- and extramedullary guider. Its accuracy decreases in the absence of movements in the knee joint; rough extensive scars adhered to the underlying bone; ankylosis of the knee joint in the absence of pain; a history of previous injuries [9]. In gross deformities of the femur and tibia, anatomical landmarks change and make the alignment of the implant difficult. In such cases, computer navigation is used, but it is not feasible in ankylosis and severe contracture of the hip joint [10].

More than 20 years ago, robots were introduced into the clinical practice of arthroplasty to solve the problems of primary TKA. There are 2 groups of them: semi-active orthopaedic robots or surgical systems that help restore the axis of the lower limb by determining the levels and angles of corrective resections of the femur and tibia, but the resection itself is performed by the surgeon; and active orthopedic robots that perform resection autonomously according to the preoperative plan while the surgeon only controls the process. Autonomous work is visually controlled by the surgeon and the robot itself from undesirable effects, thereby ensuring the safety of the patient

during the operation. However, some surgeons doubt about the safety of using the robot [11-16].

The above facts, the inconsistency of the literature data, the uncertainty of indications and contraindications for various surgical methods, doubts about the safety and accuracy of lower limb axis alignment determined the relevance of studying these issues in our work.

Objective To determine the clinical efficacy and accuracy of mechanical axis alignment of the lower limb in robotic total knee arthroplasty.

MATERIALS AND METHODS

A prospective, uncontrolled single-centre study was conducted in the clinic of traumatology, orthopedics and joint pathology of the University Clinical Hospital No. 1 of the Department of Traumatology, Orthopaedics and Emergency Surgery of the First Moscow Sechenov State Medical University (Sechenov University) from 2019 to 2021.

Criteria for inclusion of patients in the study:

– age over 18 years, gonarthrosis in stage 3-4 according to the Kellgren-Lawrence classification with pain above 5 points on a 10-point VAS scale;

– risk of anesthesia on the ASA scale is not more than III;

– available written informed consent to perform the TKA operation according to the offered method.

Criteria for non-inclusion of patients into the study:

– risk of anesthesia on the ASA scale more than III (history of thromboembolic and infectious complications, uncorrectable diabetes mellitus, prednisolone-dependent systemic diseases, anemia and thrombophilia);

– BMI in accordance with the recommendations of the developer more than 35 kg/m^2;

– severe deformities of the knee joint (valgus > 15° or varus > 15°), primary bone defects;

– extensor contracture of the knee joint up to 90°;

– metal implants on the affected side.

Criteria for exclusion of patients from the study:

– refusal of the patient to further participate in the study;

– patient's non-compliance with the prescribed regimen.

Informed consent on the course of the study was obtained prior to enrollment in the study.

The clinical study enrolled 43 patients selected according to the inclusion and non-inclusion criteria, of which 14 patients were excluded from the study during the year. Twenty-nine patients were analyzed (82.76 % women (n = 24), 17.24 % men (n = 5), mean age was 67.1 ± 2.7 years, mean BMI (kg/m^2) was 31.2 ± 3.4, the mean range of motion was 86.03 ± 3.7°, the mean mechanical axis before surgery was 170 ± 1.8°. RoTKA using the TSolution One® robotic orthopedic system (THINK Surgical Inc., USA) was performed under spinal anesthesia using a medial parapatellar approach. Cemented knee endoprostheses Zimmer® Persona with preservation of the posterior cruciate ligament (Cruciate Retaining (CR)) with a fixed liner were used. Patellar plasty was not performed, but removal of osteophytes and circular denervation was part of the operation.

The following issues were studied in the process of preparation, planning of the operation, postoperative period and rehabilitation:

1) validity of indications and contraindications recommended by the manufacturer (range of motion of the knee joint less than 90°, varus or valgus deformity more than 15°, presence of metal on the affected side of the knee joint, BMI > 35 kg/m^2);

2) complications;

3) the level of pain in patients according to VAS, WOMAC scores, range of motion (ROM) of the knee joint before and after surgery, FJS-12 scores after surgery;

4) changes in the axis of the lower limb and positioning of implants based on CT scan before and after surgery.

Statistical processing of clinical material consisted of grouping data, calculating intensive and extensive indicators, determining the average error of relative values, determining the reliability of the difference between the compared values (t), the correspondence criterion K, the Pearson coefficient (Chi-square), the correlation coefficient of multifactorial systems using the IBM SPSS Statistics 22.0 (SPSS Inc., Chicago, Illinois) – Windows 10 Pro, computer – Asus UX 434, Intel Core i7 2.7 GHz processor, RAM – 16 GB. For true numeric (scale) variables (VAS, WOMAC, FJS-12, mechanical axis), frequency histograms and values of statistical parameters were calculated, including arithmetic mean (M), standard deviation (Б), statistical error of the mean (m), minimum and maximum value and median (Me). To analyze changes in indicators over time, Student's t-test was used, and a two-sided Student's test was used before and after surgery. Differences were considered significant statistically at $p < 0.05$.

The RoTKA technology consists of 3 stages: 1) CT examination of the lower extremities; 2) planning on TPLAN; 3) operation using the TCAT system (Fig. 1).

At stage 1, the patient undergoes a CT examination of the ower extremities with the capture of the hip and ankle joints in the supine position with a hollow calibration rod, which was fixed to the affected limb (Fig. 2).

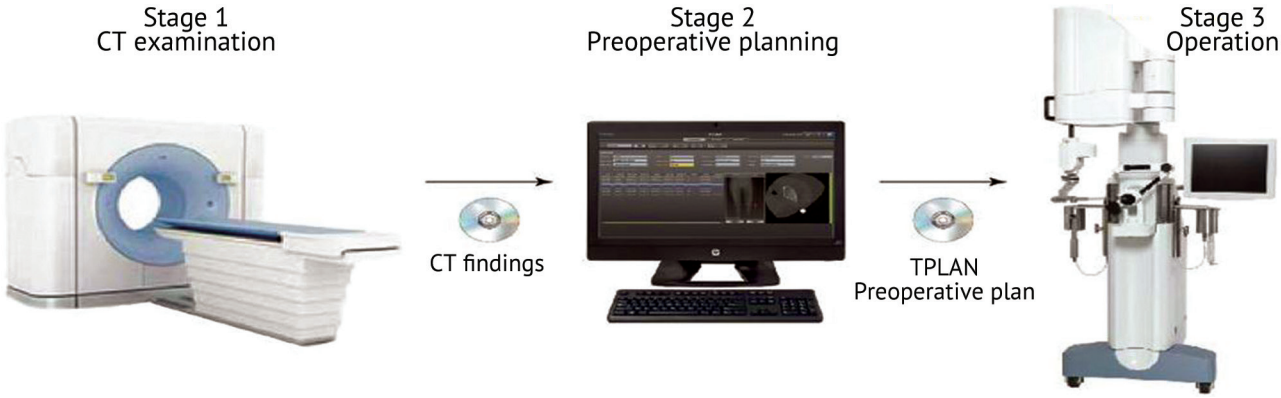

Fig. 1 Technological diagram of robotic orthopaedic system TSolution One® (THINK Surgical Inc., USA) operation

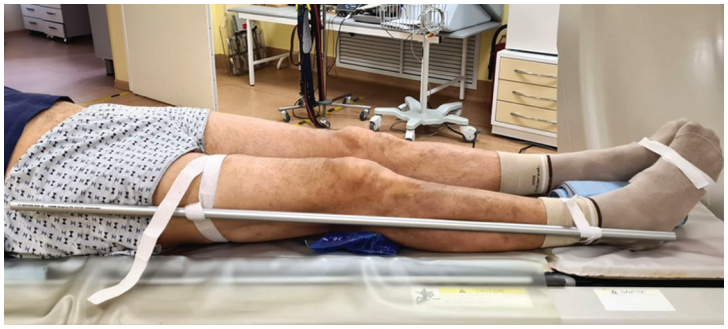

Fig. 2 Position of the patient with the calibration rod during CT-study

The calibration rod is included in the delivery of the robotic unit and must be displayed on all slices of the CT examination. The slice pitch is 1 mm; the number of slices is not fewer than 440 and not more than 1300. Patient movements during the CT examination are strictly prohibited.

At stage 2 (planning), the CT scan data (CD) is loaded into the TPLAN computer planner, step-by-step image analysis is performed: segmentation of the axial sections of the femur and tibia, marking bone growths (osteophytes). The computer converts images of separate sections into a 3D model of the patient's knee joint, on which it applies anatomical landmarks, builds axes, resection level, selects the size and position of the implant, which is evaluated and approved by the surgeon; and after which the operation plan is recorded on a CD (Fig. 3).

Surgical stage 3 begins with loading the CD plan into the TCAT Surgical System, and the robot systems and surgical instruments are tested. Non-sterile calibration of the robotic system is performed with the participation of an assistant and a robotic engineer, then the assistant and operating nurse perform draping and sterile calibration of the surgical instruments of the robot, after which the patient is delivered to the operation room.

After surgical field treatment, the limb is placed in a special holder fixed to the table in the position of 90-100° flexion. Anteromedial approach to the knee joint is performed and the patella is freely dislocated outwards. Osteophytes on the femur and tibia are not removed until bone registration. The lower limb of the patient is fixed in the position of flexion 90° to the TCAT system with special fixators and the calibration pin buttons and pin screws are installed in the femur and tibia (Fig. 4).

Upon lower limb fixation, bone motion sensors (Bone Motion Monitors (BMM's)) are installed to the femur and tibia; registration is performed using a special program in the robot's computer. Computed tomography points are combined with the corresponding virtual prototype of the femur and tibia, which were created during the planning of the operation, after which the robotic unit begins to "see" the real bone. In case of any inaccuracies, failures, movement of the patient or limb to more than 1 mm, the system stops the work and requires repeated bone registration using a pin button and a pin screw (Fig. 5, 6).

The program is designed in such a way that it is impossible to miss or incorrectly mark these landmarks; if the system does not see the anatomical landmarks, it will not switch. After the preparation of the robot (fixation and calibration) is completed, the resection stage is started.

Resection is performed with a cylindrical cutter (8 mm) at a speed of 8000 rpm and constant irrigation with saline to cool the surface of the bone and cutter (Fig. 7).

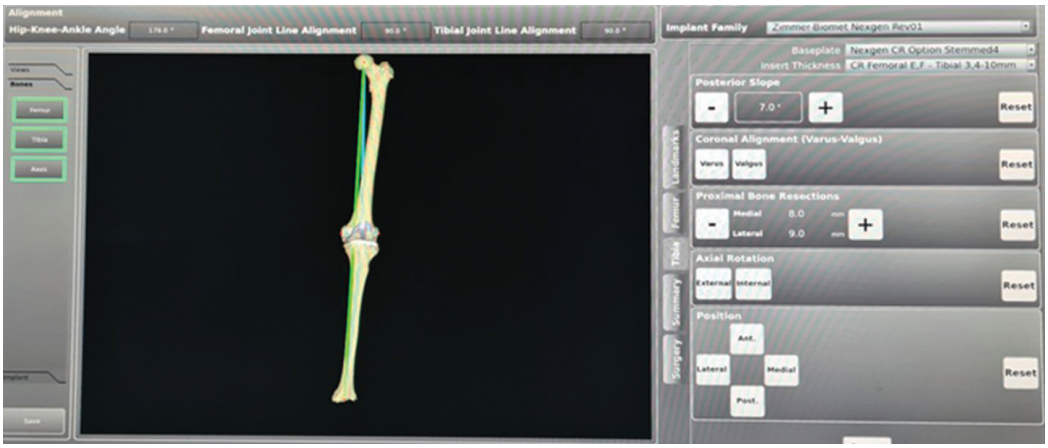

Fig 3 3D-model of the lower limb with the positioned components of the implant

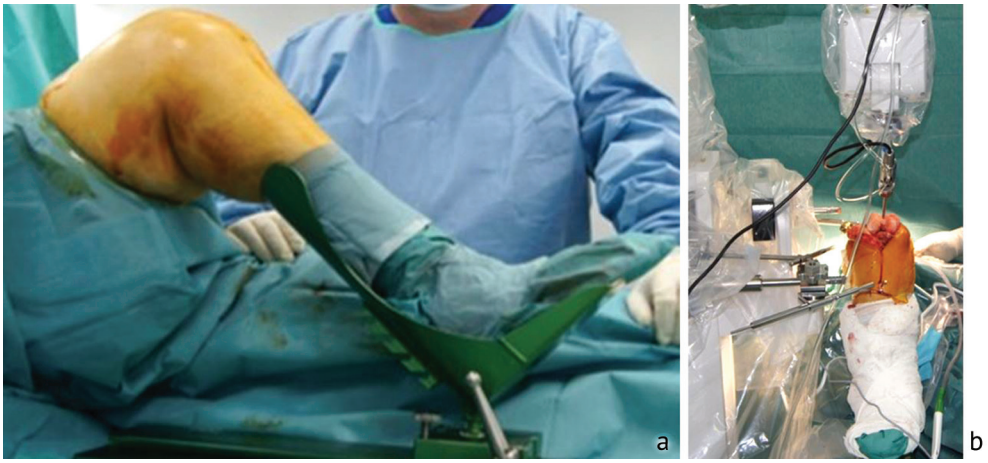

Fig. 4 Lower limb fixation: a into the holder; b to the robot

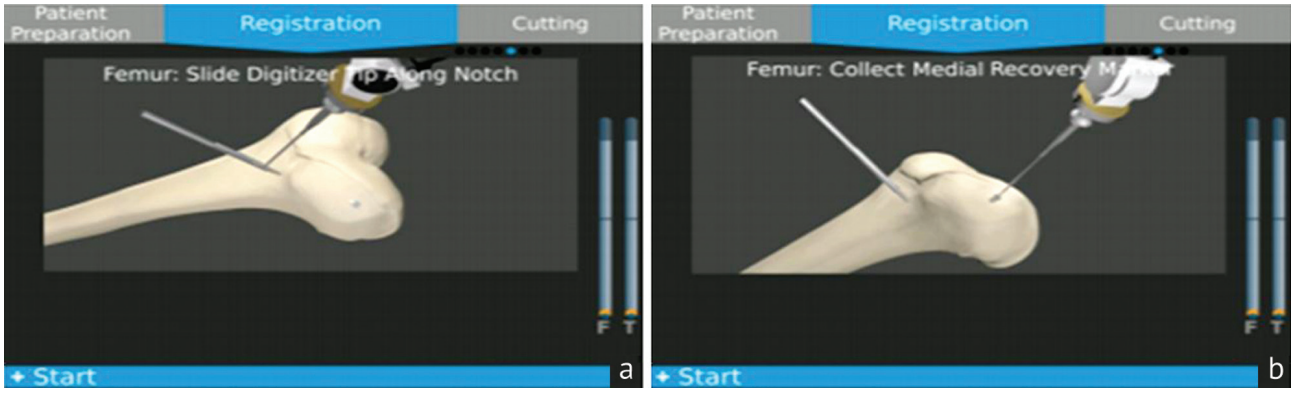

Fig. 5 Monitor screen by registration of the femur with the digitizer: a along the pin screw; b along pin button

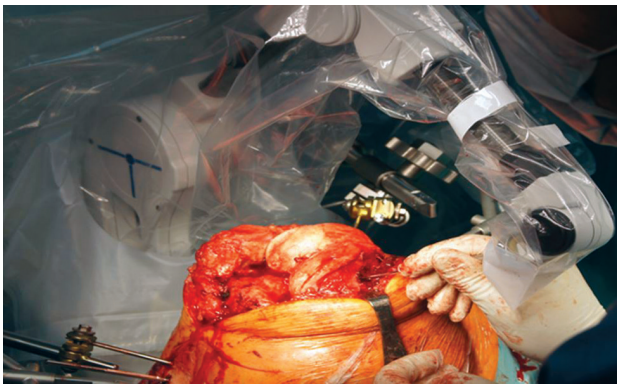

Fig 6 Registration of the femur point

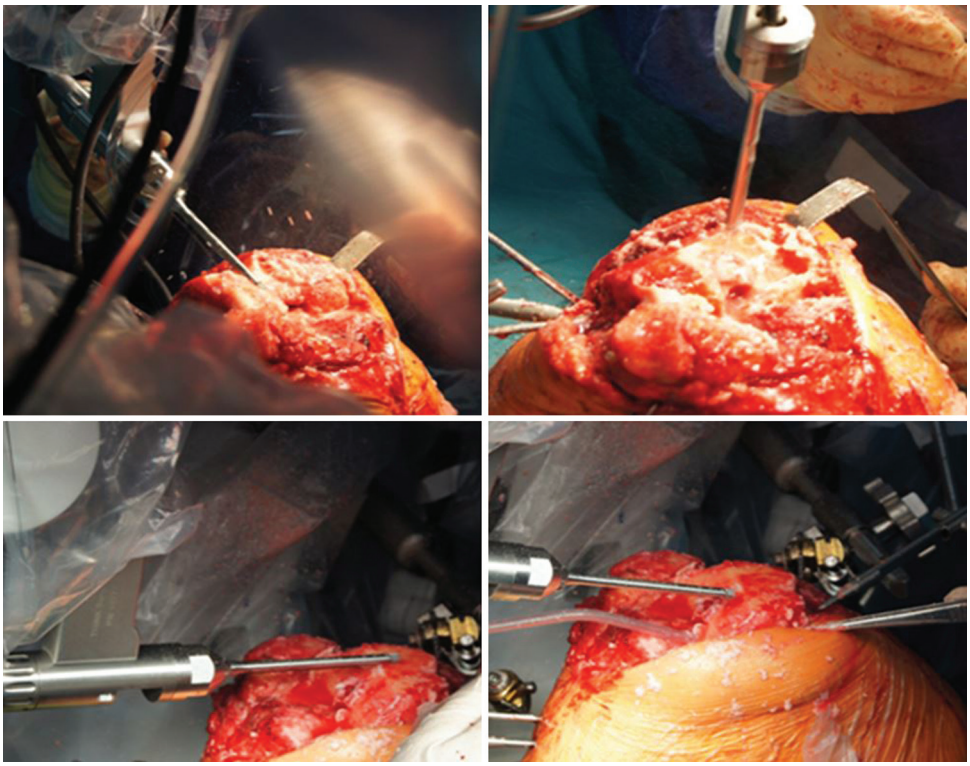

Fig. 7 The stage of bone resection

Thereby, the surgeon monitors the trajectory of the cutter and, in case of a threat to damage bone and soft tissues, has the opportunity to urgently stop the work of the robot, understand and eliminate the problem. If it is impossible to continue the robotic operation (bone shift, unrecoverable loss of landmarks, obstacle to the movement of the cutter and drive, or any other reason), the robot will stop, and then the surgeon will switch to the manual technique of the operation to ensure correct knee arthroplasty.

After the resection stage is completed, the robot is disconnected from the patient and pin buttons and pin screws are removed. The further course of the operation (fitting, balancing and fixation of the endoprosthesis in the bone) is carried out similarly to the traditional technique. Cemented implantation of components and wound closure are performed.

On the first day of the postoperative period, radiographic checking is performed on days 3-5: CT examination of the lower extremities under load (Fig. 8).

The postoperative rehabilitation program is similar to other arthroplasty methods.

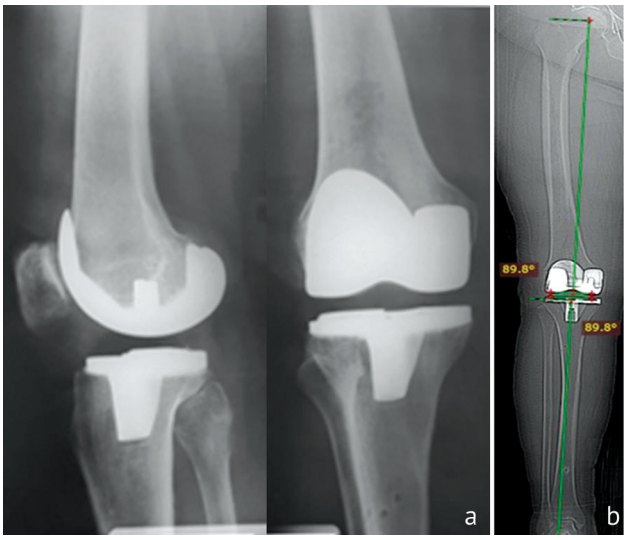

Fig 8 Postoperative knee joint radiographs in AP and lateral views (a) and full-length lower limb radiograph (b)

RESULTS

No complications, adverse events (damage to soft tissues, bones) were detected by performing RoTKA.

The average level of pain according to VAS before surgery was quite pronounced, 5.8 ± 1.5 points (95 % CI, p = 0.0248); it increased to 8.5 ± 1.4 on the first day after surgery (95 % CI), p = 0.0001). On the 3rd day there was a dynamic decrease to 5.9 ± 1.2 (CI 95 %, p = 0.0248), and on the 12th day the pain syndrome was significantly lower than before the operation, 2.9 ± 1.1 (95 % CI, p = 0.0248) (Fig. 9).

The range of motion in the knee joint on the first day after the operation (the ROM arch) was 99.5 ± 1.4°; three months after the operation, the range of motion increased to 115.1 ± 1.1°, after 6 months up

to 125.6 ± 1.5°. And one year after surgery, the mean ROM in the knee joint in 29 patients was 127.5 ± 1.6° ($p < 0.05$, two-tailed t-test) (Fig. 10).

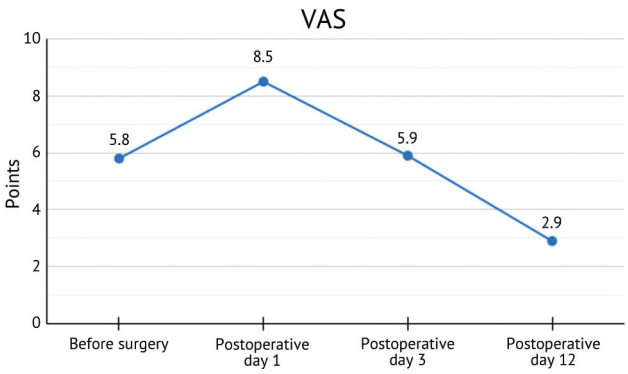

Fig. 9 VAS dynamics of pain

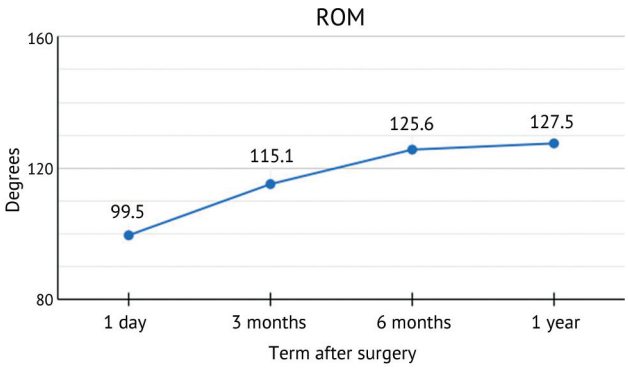

Fig. 10 Range of knee motion dynamics after the operation

Before the operation, the average WOMAC score was in the "satisfactory" range: 32.7 ± 3.3. After surgery, the mean score was 25.1 ± 2.1 points, three months after surgery 7.3 ± 1.3 points, 6 months after the operation 2.8 ± 0.2. 1 points, and a year after surgery the mean score for all 29 patients was 1.3 ± 0.5 points ($p = 0.0128$, two-tailed t-test) (Fig. 11).

Three months after RoTKA, the mean FJS-12 score was 68.2 ± 4.1. After 6 months, the average indicators increased to 80.3 ± 2.9. One year after surgery, all 29 patients had an average score of 94.0 ± 2.1 (Fig. 12).

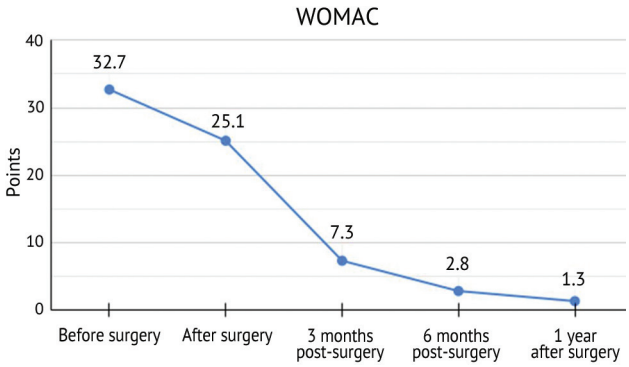

Fig. 11 Dynamics of WOMAC score (Points, Before surgery, After surgery, 3 months post-surgery, 6 months post-surgery, 1 year after surgery)

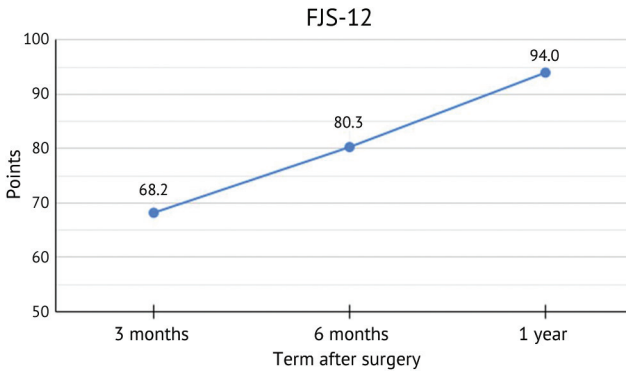

Fig 12 FJS-12 dynamics up to one year after RoTKA

The mechanical axis of the lower limb before surgery averaged 170.5 ± 1.8° of varus deformity, standard planning was 180°. After the operation, the mechanical axis was 179.6 ± 0.5°; a year after the operation, the axis was preserved at 179.7 ± 0.5°.

The analysis of postoperative full length radiographs showed that in 72 % (n = 21) of cases the deviation of the mechanical axis from the planned one was not found, in the remaining 28 % (n = 8) cases, deviation of the mechanical axis was up to 1° from the preoperative plan.

DISCUSSION

The study of the use of RoTKA in primary TKA showed its clinical effectiveness for treatment of gonarthrosis.

In the early postoperative period, according to the results of VAS, there was a positive tendency of pain relief after robotic arthroplasty. The same was shown by Kayani et^al. (2019), Batailler et al. (2021) and Wang et^al. (2022) that observed a reduction in the need for opiate analgesia compared to manual techniques. However, Hamilton et^al. (2021) found no significant difference in the intensity of pain syndrome by comparing the two methods [21, 22, 26-29].

ROM, WOMAC, and FJS-12 scores after surgery in our study were significantly improved compared to preoperative scores. It was also reflected in studies by other authors, but the degree of improvement requires comparison with manual technique and computer navigation [20, 21, 23, 25, 27, 30].

If patients have severe deformities of the lower extremities (varus/valgus > 15°), it is impossible to build axes on the TPLAN device, because in the technical condition (bone resection program), the head of the fibula limits the possibilities of resection, therefore deformities of more than 15° are a contraindication. A number of authors do not explain it in their studies,

but Chan et^al. (2020) and Stulberg et^al. (2021) included in their study patients with a deformity angle in the frontal plane of up to 20°. We could not confirm this by our study [11, 17-20].

Fixation of the lower limb is carried out in a special holder in the position of 90-100° knee flexion for correct operation of the robot. In extensor contracture, this stage cannot be performed, because the working area of the robot arm will not be in focus, which will be a contraindication [11, 17, 19, 21].

Features of preoperative planning and automatic functioning of the robot dictate a strict requirement: absence of metal or a hip joint endoprosthesis on the involved side, which can shield the bone during planning, making it impossible to mark anatomical landmarks, and interfere with the functioning of the robot during resection [11, 17-19].

Undesirable effects, specific complications inherent in RoTKA were not revealed during surgery and the examinations; and namely, damage to soft tissues and bones, what makes this technique safe for use. It was confirmed in the studies of other authors intra-operatively in patients and on cadaveric materials [16, 18, 22].

In our study series, there was no deviation of the mechanical axis from the preoperative plan by more than 1°. According to the literature, the alignment of the mechanical axis of the lower limb in TKA within ± 3° is acceptable. In the studies of Stulberg (2021) with RoTKA, deviations from the preoperative plan by more than ± 3° were detected only in 11.2 % of cases, in the study by Vaidya et^al. (2022) in 3.1 % of cases [11, 18, 20, 22-25].

Liow et^al. (2017) identified the following indications for RoTKA (ideal patient): patient age < 60 years; BMI < 25 kg/m^2; mild or moderate deformity in the frontal plane; intact neurovascular bundle of the affected limb. Relative contraindications included obesity with severe frontal deformity > 15°, fixed flexion contracture > 15°, inflammatory arthropathy, and ligament instability [17].

Chan et^al. (2020) conducted their study according to the following inclusion criteria: age from 21 years old, mature skeleton evidenced by closed growth zones. Exclusion criteria were previous open surgery on the affected knee joint; BMI > 40 kg/m^2; deformity in the frontal plane > 20°; flexion contracture > 15°; the need for a bilateral TKA; active systemic infection, infection in the knee joint area, previous infection of the knee joint; implants in the ipsilateral lower limb; insufficient bone stock; pathological condition of the bones [19].

In the study by Stulberg et^al. (2021), RoTKA was performed according to the following indications: no history of previous open surgeries on the affected knee joint; BMI ≤ 40 kg/m^2; deformity in the frontal plane < 20° or flexion contracture < 15° [11].

Unfortunately, the authors in their studies do not explain why RoTKA was performed according to these indications.

The authors understand the problems of the study presented above: single-center nature, small sample of patients, no long-term results, no studies with the constrained type without preserving the posterior cruciate ligament (Posterior Stabilized (PS)) and others. These problems require further investigation.

CONCLUSION

The study of RoTKA technology has demonstrated high clinical efficiency, accuracy of mechanical axis alignment and good early clinical results. The technology will speed up the return of patients to optimal motor activity and improve long-term clinical results.

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

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