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Robot-assisted knee arthroplasty: first experience (a prospective randomized study)

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Abstract

Introduction Primary total knee arthroplasty has long been proven effective in the treatment of stage 3-4 knee osteoarthritis. It is well known that this intervention not only improves the quality of life, but also helps to restore the function of the joint and eliminate axial deformities. Purpose To compare early results of total knee arthroplasty using robot-assisted technology with conventional manual technique. Materials and Methods 20 patients diagnosed with stage 3 osteoarthritis of the knee joint and varus deformity of the knee joint axis were included in a prospective randomized study. Patients were divided into 2 representative groups, 10 subjects underwent robot-assisted knee arthroplasty, and the conventional manual technique was used in the other 10 patients. For clinical assessment, functional scales KSS, WOMAC, Lysholm Score were used, postoperative radiographs were evaluated. Results According to clinical functional scales, 10 days after surgery, there was an improvement in performance in the patients of both groups (p < 0.05); the duration of the operation in the patients of both groups did not differ in general; intra-operative blood loss in the group with robot-assisted arthroplasty was lower; and assessment of postoperative results by radiological imaging showed a better component positioning according to preoperative planning in the robotic group. Discussion When the operation is performed by experienced surgeons, one can expect the correct position of the components and the balance of the ligamentous apparatus in standard arthroplasty. However, the use of robot-assisted technology provides a secure intervention performance even at a hospital where a small number of such operations is performed. Conclusion Despite the high cost and the need for additional consumables, robot-assisted arthroplasty has a number of advantages over classical manual techniques. These advantages include: accurate restoration of the limb axis even in extra-articular deformities, correct position of the endoprosthesis components, reduction of intra-operative blood loss due to closed medullary canals, and safety for patients. However, the role of the surgeon in such operations remains paramount, as it is the surgeon who is responsible for planning the operation, performing it, and achieving soft tissue balance.

Keywords: robot-assisted arthroplasty, knee joint, osteoarthritis

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INTRODUCTION

Primary total knee replacement has long proven its effectiveness in the treatment of knee joint osteoarthritis in stages 3-4. It is well known that this intervention not only improves the quality of life, but helps restore joint function and eliminate axial deformities. About two million such operations are performed annually in the world [1, 2].

Robotic assistance in surgical interventions is a modern, actively developing area of scientific and practical studies, which covers many types of specialized surgical care for a variety of pathologies [3, 4, 5, 6]. Robotic surgery in surgical orthopedics was first described in 1993 [7]. In recent years, the use of robotic technologies in the treatment of diseases of the musculoskeletal system has received further development. The use of robotic assistance is considered one of the methods of knee replacement, in which the "robot arm" ensures resection of the femur and tibia and formation of the bone bed for the knee joint endoprosthesis under the supervision of a surgeon [8]. The operation of such a system includes two main stages [9]:

1) preoperative planning is performed on the basis of computed tomography data of the hip, knee and

ankle joints with a preliminary calculation of the cutting angles of the bones to be resected, the size and position of the components;

2) bone resection with an active system (robot "arm") based on preoperative individual planning, implantation of endoprosthetic components and control of soft tissue balance under navigation control.

There are numerous publications in the literature in which the authors describe that the use of robotic assistance during implantation of an endoprosthesis helps to more accurately calculate the level of the distal femur and proximal tibia cuts, select the optimal sizes of the endoprosthesis components and align the mechanical axis of the limb under navigation control [10, 11, 12], which, in turn, ensures good balance of the ligaments [13, 14, 15]. The study of Hampp et al. showed that the accuracy of the bone cuts and positioning of the implant components in robot-assisted operations is higher compared to manual total knee arthroplasty [16].

Purpose: comparison of early results of robotassisted knee joint arthroplasty with the conventional manual knee arthroplasty.

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MATERIALS AND METHODS

A prospective randomized study was conducted from 03.04.2023 to 28.04.2023 at the Center for Bone and Joint Surgery of the St. Petersburg Research Institute of Phthisiopulmonology. The study included 20 patients diagnosed with stage 3 idiopathic osteoarthritis of the knee joint and varus deformity of the joint axis (varus deformity up to 8° was taken into account). The stage was determined according to the Kellgren-Lawrence classification. For the purpose of randomization, using a computer random number generator, patients were divided into 2 groups: ten patients underwent implantation of a knee joint endoprosthesis using robotic technology (group 1), 10 patients underwent joint replacement with standard manual technology (group 2). Patients in group 1 were informed about the advantages and disadvantages of robotic arthroplasty. The gender and age characteristics of the patients and clinical parameters of the knee joint function before surgery are presented in Table 1.

Table 1 Patients' data and knee functions

Parameter		Group 1	Group 2	p – value
Age, years, Me (Q1-Q2)		61.4 (48-72)	63.4 (47-75)	> 0.05
Males	Abs.	4	3	
	%	40	30	
Females	Abs.	6	7	
	%	60	70	
Left side	Abs.	5	6	
	%	50	60	
Right side	Abs.	5	4	
	%	50	40	
Implant type CR	Abs.	9	7	
	%			
Type of implant PS	Abs.	1	3	
	%			
KSS, points, Me (Q1-Q2)		60.5 (49-68)	59 (44-66)	> 0.05
Lysholm scale, Me (Q1-Q2)		57 (47-64)	56.5 (46-62)	> 0.05
WOMAC, points, Me (Q1-Q2)		31 (27-35)	33 (29-39)	> 0.05

The data presented in the table indicate the absence of statistically significant differences between the studied groups of patients and the possibility of subsequent correct analysis of the results obtained.

Preoperative preparation In the preoperative period, patients in group 1 underwent computed tomography of the hip, knee and ankle joints for preoperative planning of component sizes, calculation of the angles of deviation of the axis of the lower limb and final positioning of the components considering axis correction. Patients in group 2 underwent standard planning based on X-ray telescopic images.

Surgical technique All patients received antibiotic prophylaxis and administration of tranexamic acid according to a standard regimen before incision. All operations were performed by one surgeon.

In all cases, a mechanical alignment philosophy was followed. Robot-assisted knee replacement also required the presence of an assistant to provide the computer part of the operation. The patients' limb was placed on a special fixator. Two pins with sensors for communication with navigation were installed in the distal femur and proximal tibia (Fig. 1).



Fig. 1 Limb position with sensors for navigation

In all cases, a standard medial parapatellar approach was performed. Check points were installed in the area of the medial epicondyle of the femur and the medial part of the tibial tuberosity to synchronize data with the robot. Next, anatomical landmarks were registered with a comparison of the patient's 3D computed tomography model (Fig. 2).

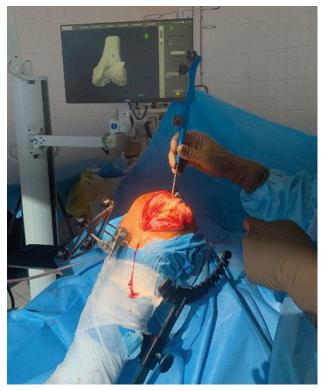


Fig. 2 Registration of anatomical landmarks

The next step was to position the robot's "arm" to make cuts of the femur and tibia. The cutting process was constantly shown on the monitor what was "unusual" when switching from the manual technique (Fig. 3, 4).

After cutting, the soft tissues were released; the tibial bed was processed for the endoprosthesis components, and the implant was installed using standard surgical techniques (Fig. 5).

Next, joint stability was assessed under navigation control and the tracking of the patella in the intercondylar groove was monitored (Fig. 6).



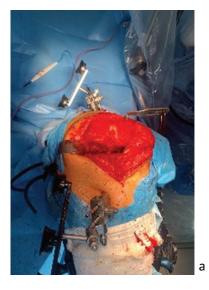
Fig. 3 Cutting of the distal femur



Fig. 4 Control of cutting on the monitor

In group 2, the conventional manual technique of knee arthroplasty using an extramedullary guide was performed. The postoperative period was similar in both groups, including the prevention of thromboembolic complications and a standard course of rehabilitation. The next day, radiographs were taken to monitor postoperative results and correctness of the installed components taking into account the restoration of the mechanical axis of the limb, the correspondence of the size of the components, and the possible filing of the femoral component into the anterior cortex. Patients were observed in the department for 10 days to assess early postoperative results.

Statistical analysis of the data obtained during the study was done in accordance with modern requirements of descriptive statistics in biomedical research [17]. We used specialized software: Statistica 13 and IBM SPSS® Statistics version 20.







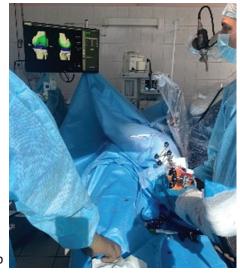


Fig. 6 Assessment of joint stability under navigation control

The normality of the distribution of quantitative characteristics was studied using the Shapiro-Wilk test; the distribution of the studied parameters was found to differ from normal. Therefore, further statistical analysis was carried out using nonparametric methods. The median (Me) and interquartile range (Q1-Q3) were calculated. For independent quantitative samples in study

groups, determination of the significance of statistical differences in indicators using the nonparametric Mann – Whitney U test, differences were considered significant at $p \le 0.05$. Comparison of indicators before and after treatment (dependent samples) was carried out using the Wilcoxon T-test; differences were considered significant at $p \le 0.05$.

RESULTS

In both groups of patients, early postoperative functional results were comparable. The range of motion in the knee joint in patients of both groups increased significantly. In group 1, the results improved by an average of 20 points after analyzing Me indicators on the KSS scale on post-surgery day 10, on the WOMAC scale by 19.9 points, on the Lysholm scale by 18 points. In robot-assisted surgery, intra-operative blood loss was on average 60 ml lower, and the duration of the operation was 10 minutes longer on average. In control radiographs of patients in group 1, the position

of the components fully corresponded to the preoperative planning, namely, the mechanical axis of the limb was restored, the dimensions of the implants corresponded to the anatomical dimensions of the bone in this location, and there was no "filing" of the femoral component. Among the patients of group 2, there was a slight filing of the femoral component into the anterior cortex in one case; the sizes of the components were selected correctly, but a residual varus of 2° was determined in 2 patients. Table 2 shows the dynamics of the studied postoperative parameters in both groups of patients.

Table 2

Postoperative parameters in both groups, Me (Q1-Q2)

Group 1 Group 2 Parameter p – value Before surgery | After surgery Before surgery After surgery 108 (100-110) | 127 (115-135) | < 0.01 < 0.01 Knee range Flexion, degrees 111 (105-115) 126,5 (120-130) of motion 173 (165-175) | 180 (180-182) | < 0.05 | 171.5 (165-175) | < 0.05 Extension, degrees 180 (180-180) Varus deformity 5.3 (4-6) $0.8^{\circ}(0-2)$ < 0.01 1 (0-3) < 0.01 4.5 (4-6) KSS, points 60.5 (49-68) 81 (75-84) < 0.01 59 (44-66) 76 (70-84) < 0.01 57 (47-64) 73 (68-79) Lysholm scale, points 77.5 (68-82) < 0.01 56.5 (46-62) < 0,01 31 (27-35) < 0.01 33 (29-39) WOMAC, points 10.1 (8-16) 13.3 (10-19) < 0.01 Intra-operative blood loss, ml 250 (150-270) 310 (280-350) < 0.05 75 (65-80) Duration of intervention, minutes 65 (55-75) > 0.05

DISCUSSION

Robot-assisted knee replacement has been actively introduced into orthopedic practice. Some authors believe that the advantages of using robots are leveled by the cost of consumables and the robot assistant itself [9]. After our clinical assessment, we observed comparable results in the increased range of motion and clinical outcome measures at 10 days. This, in our opinion, is explained by the fact that the operations were performed by one surgeon who has more than 100 similar operations per year and, accordingly, with one technique for working with soft tissues, as well as comparable patient parameters before surgery. It is evident that the assessment of the results after 10 days is preliminary in nature and does not present a complete picture of the function. This suggests the need for more in-depth studies.

According to some published data, the use of robots significantly increases the duration of the operation, and thereby the intra-operative blood loss may also increase [14]. Our data show that the volume of blood

loss was insignificantly but reliably lower in the group of robotic assistance. In our opinion, this is due to the preservation of closed intramedullary canals during surgery, which can be a source of bleeding during the surgery. This will likely have a positive effect on the patient's future life due to the importance of preserving red bone marrow in the metaepiphysis of the bones and yellow bone marrow in the medullary canal. In some situations, maintaining closed medullary canals is extremely important if consequences of inflammatory processes remain present. It should be noted that robot-assisted knee replacement allows increasing the accuracy of implant positioning and limb alignment in case of extra-articular limb deformities [18, 19], as well as reducing iatrogenic damage to periarticular soft tissues [20].

As for the duration of the operation, it was comparable between the study groups. Additional time is spent on installing navigation sensors on the thigh and lower leg; however, in our opinion, the operating time should be counted from the moment the incision in the knee joint area is made. No time is wasted on determining the size of components and their position (especially rotation), given that all this is performed at the preoperative planning stage.

It is clear that if the operation is performed by experienced surgeons, one can expect the correct position of the components and the balance oftheligamentousapparatuseveninstandardreplacement; however, the use of robot-assisted technology ensures patient's protection even in the hospitals with a small number of similar operations. This is confirmed by our results of postoperative radiation control.

Additional advantages of robot-assisted technology include the possibility of correcting cuts, location of components and, accordingly, balance at any stage of the operation, as well as a certain safety for soft tissues, taking into account the shutdown of the blade in deviation from the specified parameters of the bone location.

CONCLUSION

Robot-assisted knee replacement, despite its high cost and the need for additional consumables, has a number of advantages over conventional manual techniques. Such advantages include accurate restoration of the limb axis even in extra-articular deformities, correct position of endoprosthetic components, reduction of intra-operative blood loss by preservation of closed medullary canals, and safety for patients. However, the role of the surgeon in such

operations remains paramount, since it is the surgeon who is responsible for planning the operation, its execution and achieving soft tissue balance. Among the shortcomings of robotic assistance are the additional radiation exposure of the patient due to preoperative computed tomography, additional expensive equipment in the operating room, which also significantly reduces the working space for medical personnel.

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Informed consent Patients gave their voluntary written informed consents.

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Dziov Z.V. – writing – initial version, visualization.

Naumov D.G. - formal analysis.