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Robot-assisted Knee Arthroplasty: Randomized Clinical Trial

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Abstract

BACKGROUND: Osteoarthritis of the knee joint leads to a decrease in the volume of movements, a violation of the sliding of articular surfaces, and a change in the axis of the limb under load, which affects the biomechanics of walking.

AIM: This study aims to compare the results of robot-assisted total knee arthroplasty (TKA) and manual techniques, their influence on the biomechanical and podometric parameters of the patient's walk.

METHODS: A prospective randomized study of 68 patients was carried out in the period from 2020 to 2021. Our follow-up period was 1 year. All patients were performed arthroplasty of one knee joint. The main Group "A" included 33 patients TKA with the use of an active robotic setting "TSolution-One" ("THINK Surgical, Inc." [Fremont, California, USA]); the comparison Group "B" consisted of 35 patients with manual technic of TKA. We studied pain syndrome on the visual analog scale, functional state on the Oxford Knee Score (OKS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC), the volume of ROM movements, and the deviation of the mechanical axis by teleroentgenography of the lower limb. Objective analysis of limb function was performed on the «Alter-G» and the «C-mill».

RESULTS: Post-operative pain syndrome on the 1st day after surgery in Group A is stronger by 7.9%, but by the 5th day after surgery in Group A, the pain syndrome is lower by 14.3%. ROM in Group A is better by 16% by 3 months after surgery, after 1 year by 10%. The positioning accuracy of the implant in Group A is 30% better. There are no statistically significant differences in the OKS and WOMAC scales between the groups. The results of restoring normal step in Group A are 13.5% better than in Group B.

CONCLUSIONS: Robot-assisted TKA gives more accurate alignment of the mechanical axis, which improves the biomechanics of walking.

Introduction

Osteoarthritis is the most common form of joint damage and occupies a leading position among all diseases of the musculoskeletal system, it accounts for up to 55% of visits to an orthopedic doctor [1], [2]. In the structure of osteoarthritis, one-third falls on the knee joint (in 33.3% of cases), and in every third patient, the changes are bilateral [3], [4].

Chronic pain syndrome, contracture, and lameness lead to a restriction of functional activity, a significant decrease in working capacity and disability of people of working age [5], [6]. TKA effectively helps to solve this problem by reducing pain syndrome and restoring correct walking.

The accuracy of the mechanical alignment of the axes of the lower limb depends on the resection and the location of the components implant, which significantly affects the service life of the implant and the restoration of the patient's operability [7], [8]. With manual TKA technique, up to 40% of the implant position is affected, which affects the function and shortens the service life of the implant [9], [10]. One of the ways to solve the problem is the use of computer navigation, which makes it possible to improve the results of alignment of the axes and the position of the implant, but the number of errors remains quite large [11], [12].

The aim of this prospective randomized trial was to evaluate biomechanical and podometric parameters of the patient's walking after robot-assisted knee arthroplasty in comparison with manual technique.

Methods

In our study was included 68 patients, who underwent surgical treatment in the period from 2020 to 2021. Fifteen of them were men and 53 women with a body mass index of 31.6 ± 6.2 kg/m2. Mean age was 67.3 ± 3.7 years. Our follow-up period was 1 year. All patients were performed arthroplasty of one knee joint. Comorbidity and anesthetic risk of patients on the ASA scale was II for 48 patients (70.6%) and III for 20 patients (29.4%). We studied pain syndrome on the visual analog scale (VAS), functional state on Oxford Knee Score (OKS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC), the volume of ROM movements, and the deviation of the mechanical axis by teleroentgenography of the lower limb.

Inclusion criteria

Patients of both sexes aged 40–90 years with osteoarthritis of the knee joint Stage 3–4 ineffective long-term conservative therapy, pain in the knee joint according to VAS more than 4 points (10-point scale), knee joint contracture (restriction of flexion to 80–90° and extension to 170–175°), axial deformation (valgus/varus to 15°), and BMI from 25 to 40 kg/m^2.

Exclusion criteria

Patient's refusal to participate in the study, inability to monitor the patient after surgery and refusal to attend control inspection, and violation of the prescribed regimen by the patient were excluded from the study.

The patients conducted X-ray of the knee joint and teleroentgenography of the lower extremities (Figure 1), the mechanical axis was determined.

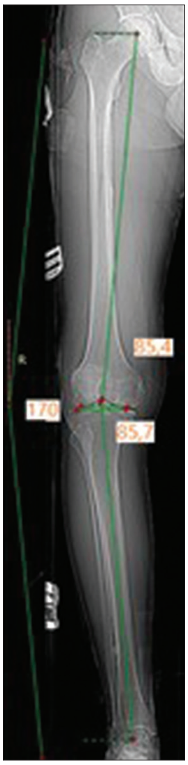

Figure 1: X-ray of the knee joint and teleroentgenography of the lower extremities

After the examination, the patients were randomized by the computer program into two groups, after that, the technique of the operation was determined. Patients signed informed consent, the study was approved by the local ethics committee (No. 25–20 of September 09, 2020).

The main Group "A" included 33 patients total knee arthroplasty (TKA) with the use of an active robotic setting "TSolution-One" ("THINK Surgical, Inc." [Fremont, California USA]); the comparison Group "B" consisted of 35 patients with manual technic of TKA.

The patients are similar in terms of gender and anthropometric data in the groups.

The pre-operative preparation in the groups was the same.

Surgical intervention was performed under subarachnoid anesthesia with intravenous sedation. A longitudinal medial parapatellar approach to the knee joint with an outward dislocation of the patella was used.

In Group A, the pre-operative plan was carried out by CT of the lower limb on a TPLAN device, after which a robot-assisted arthroplasty of the knee joint was performed (Figure 2).

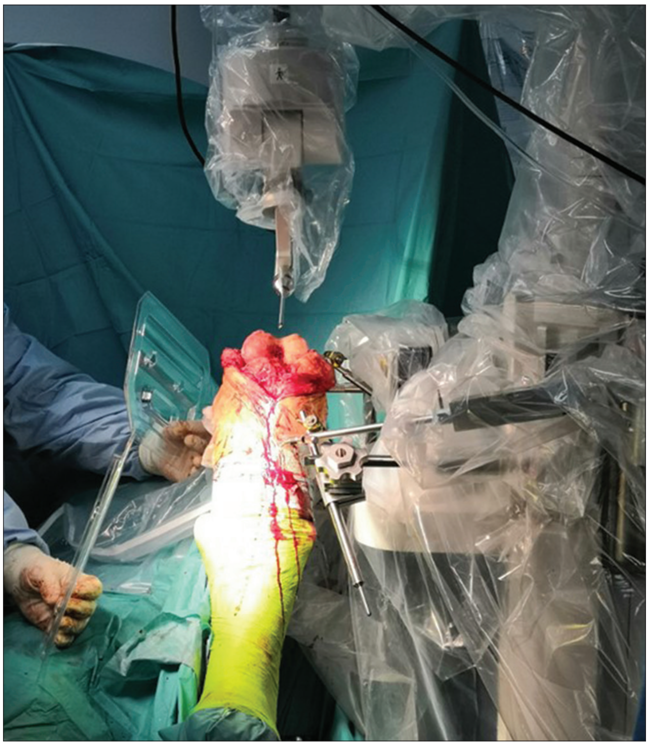

Figure 2: Intraoperative view of total knee arthroplasty with active robotic "TSolution-One"

In Group B, pre-operative planning was carried out using teleroentgenography and X-ray images using templates. The operation was performed using standard intra- and extramedullary guides.

Before suturing the wound, local infiltration anesthesia was performed, drainage was installed according to indications, suturing the wound with separate nodular sutures.

In the post-operative period, systemic multimodal analgesia was performed in both groups, followed by correction of the multiplicity and doses of drugs depending on the severity of the post-operative pain syndrome. Anticoagulant therapy and antibiotic prophylaxis were carried out.

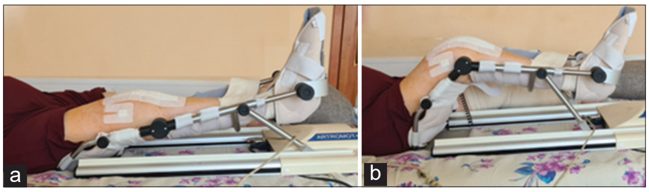

Figure 3: The 1st day after surgery, patient working on the Arthromot device: (a)Passive extension in joint, (b) passive flexion in joint

Post-operative rehabilitation started from 1 day, passive knee movements 6 h after surgery, active-passive mechanotherapy developed in the “Arthromot” device (DJO Global, USA) (Figure 3). Active movements, getting out of bed, walking with a limited load on crutches, taping, and physiotherapy treatment on the knee joint area began 24 h after surgery (Figure 4).

Figure 4: View of the popliteal area after taping

On the 10^{th} day after surgery, patients were transferred to a rehabilitation center, where an objective analysis of limb function was performed on the «Alter-G» antigravity track and the «C-mill» sensory treadmill with the selection of a set of exercises.

The «C-mill» treadmill is a screen and a moving canvas on which visual obstacles and tasks are displayed. The patient is put on a supporting device, which regulates the strength of the foot support on the track, thereby limiting the vertical load on the operated limb (Figure 5). The test takes 25 min (five programs of 5 min each), the results are displayed on the monitor in the form of graphs. The following walking parameters were evaluated: Stride width, uniformity, weight balance between legs, gait amplitude, and walking confidence.

Figure 5: Treadmill «C-mill» – (a), coordination test – (b), assessment of step width and imbalance – (c), test of body position in space and load distribution – (d)

Patients were trained 5 days a week, 2 times a day on each track, 1 month after the operation, the walking parameters were tested again, the results of the patient’s rehabilitation were displayed in the form of activity graphs for 1 month and analyzed.

Registration: NCT04667390 (ClinicalTrials.gov identifier).

Statistical data assessment

Statistica 10.0 software for Windows (StatSoft Inc., USA) was used for statistical analysis of the results. Quantitative variables were described using standard methods of variation statistics, where the arithmetic mean (M) and standard deviation were applied (δ). Average values are presented as M ± δ. Qualitative variables were described as absolute and relative frequency ratios. Differences were considered significant at $p < 0.05$. Methods of statistical analysis were used to evaluate the results: Student’s t-test. Ethics committee approval was obtained to conduct the study. The study was carried out in accordance with ethical standards. All patients who took part in the study gave their informed consent before their inclusion in the study.

Results

In the study of pain syndrome on the VAS before surgery (5.8 ± 2.3), there was no statistical difference in the groups. On the 1^{st} day after surgery, the pain increases sharply, while in Group A, it is more by 2.4% (8.5 ± 1.5) than in Group B (8.3 ± 1.3). By 3 days after surgery, the VAS indicator decreases evenly in both groups to 5.7 ± 1.4. On the 5^{th} day after surgery, the pain syndrome in Group A is 15% (3.5 ± 1.7) lower than in Group B (4.2 ± 1.6), by 12 days, the pain syndrome in Group A is 6.5% (2.9 ± 1.1) less than in Group B (3.1 ± 1.2), the dynamics of pain. The pain syndrome is indicated in Figure 6.

ROM (the volume of movements of knee joint) before surgery in both groups was approximately the same (86.7 ± 3.2).On the 1^{st} day after surgery, in Group A, the volume of movements was 10% greater (98.3 ± 2.4°) than in Group B (90.2 ± 3.2°), the ROM difference between the groups increased by 5 days after surgery: Group A (99.3 ± 1.2°) was 12% greater than in Group B (91.3 ± 1.7°). By 3 months after surgery, Group A had 5% (115 ± 2.9°) more movement volume compared to Group B (111 ± 3.5°). By 1 year after

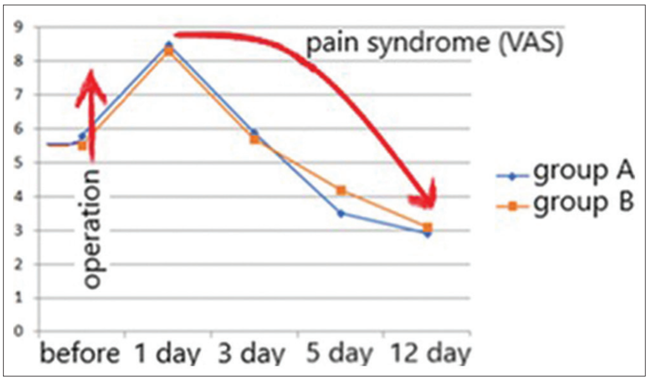

Figure 6: The dynamics of pain syndrome on the visual analog scale; p < 0.05

surgery in Group A the volume of movements (127.3 ± 2.1°) is 10% better than in Group B (116.2 ± 1.3°), Figure 7.

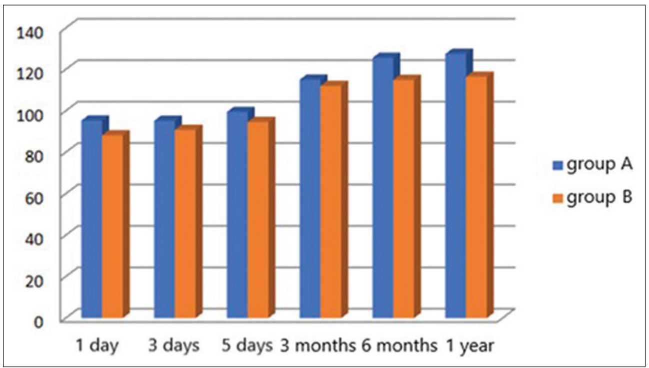

Figure 7: The volume of movements in the knee joint by groups; p < 0.05

Analysis of post-operative teleroentgenograms in comparison with the pre-operative plan revealed: in Group A, the average angle of the mechanical axis was 179.8 ± 1.1°, the spread up to 1° was 40%; in Group B, the average angle was 177.8 ± 2.3°, the spread up to 1° 35%, the spread from 1 to 3° in 45% of cases, more than 3°–20% of cases, which is shown in Figure 8.

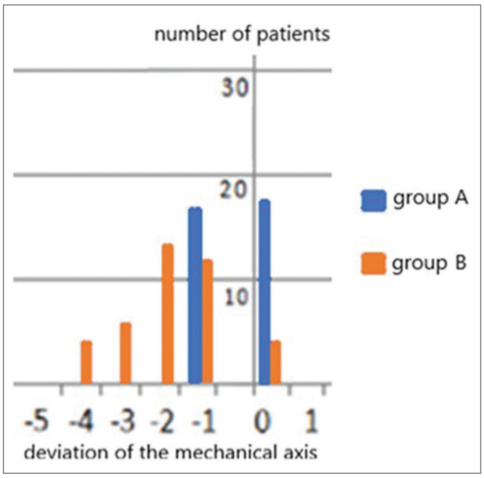

Figure 8: Alignment of the mechanical axis of the limb of patients after surgery in groups

When tested on the OKS before surgery, the average score in both groups was 18.86 ± 1.76. After the operation, there is a positive trend, an increase in scores in Group A of 27.1 ± 0.8 and in Group B of 26.55 ± 0.67, we did not receive a statistically significant difference. One year after surgery, there was a significant improvement in the condition of patients, an increase in score in Group A (44.97 ± 0.17) and in Group B (44.48 ± 0.20), no statistically significant differences were also found in the groups, Figure 9.

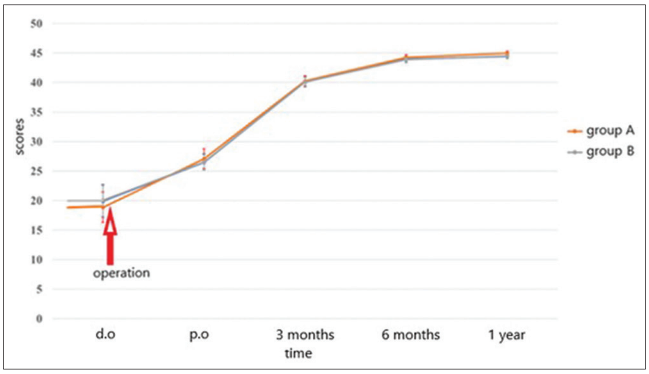

Figure 9: Dynamics of changes in knee joint on the Oxford Knee Score in groups

According to the WOMAC, the average score in the groups before surgery showed a satisfactory score of 33.66 ± 3.29, after surgery, the values decreased: Group A (25.14 ± 2.14) and Group B (24.65 ± 3.2), 1 year after surgery, they were in Group A (1.34 ± 0.48) and in Group B (1.59 ± 0.62), but there were no statistically significant changes in the results between the groups, Figure 10.

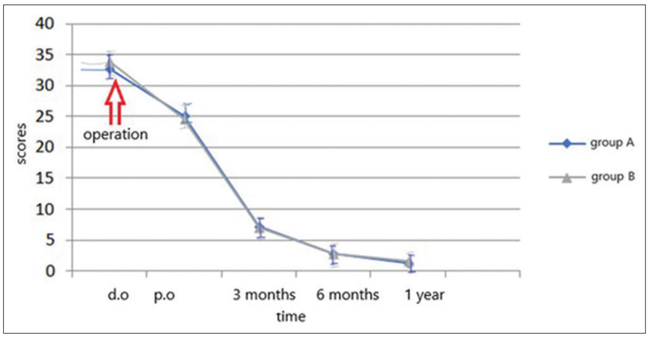

Figure 10: Dynamics of changes the results by Western Ontario and McMaster Universities Arthritis Index in groups

When analyzing the results of gait restoration on the 10th day after surgery, the duration of walking and the asymmetry of the step length in the groups were similar and had no statistically significant difference, however, the frequency, width, and length of the step in Group A were 3–5% better than in Group B.

The study of coordination abilities showed that in Group A, 90% of all patients coped with this exercise and 100% coped with the test to determine the strength of the leg muscles, 90% of patients coped with the endurance test. In Group B, 87% coped with the tasks.

A comparative analysis of the podometric parameters in patients on day 10 and in the early period after surgery (1 month later) who underwent walking stereotype training on the device revealed a significant

Table 1: The results of a comparative analysis of the podometric parameters of walking

Walking parameters	Group A	Group B	Group A	Group B	p-value
	10 days p.o		1 month p.o		
Time of step, seconds	15.32 ± 7.31	16.75 ± 9.50	21.48 ± 9.69	18.41 ± 11.32	< 0.01
The frequency of the step, steps/min	58.25 ± 6.71	56.51 ± 5.05	63.28 ± 3.28	58.15 ± 6.02	< 0.01
The width of the free gait step, millimeters	168.56 ± 9.11	164.31 ± 10.11	175.44 ± 7.93	168.42 ± 8.16	< 0.05
The length of the step of left leg, millimeters	341.3 ± 11.15	337.2 ± 10.19	350.9 ± 8.23	342.7 ± 10.19	< 0.05
The length of the step of right leg, millimeters	343.67 ± 12.93	348.7 ± 11.19	358.5 ± 9.48	353.2 ± 8.27	< 0.05
% asymmetries of length step between the leg	2.63 ± 0.48	2.68 ± 0.70	3.07 ± 0.42	2.77 ± 0.33	< 0.01

difference (p ≤ 0.05) between the achieved parameter values between the groups. The walking duration is 16% longer in Group A, the step frequency of free gait is 8% better in Group A, the step width is 4.8% greater in Group A than in Group B, the step length is 5.2% longer in Group A, and the asymmetry of the step length is 10.8% less in Group A, as shown in Table 1.

Evaluating all walking indicators, walking in Group A recovers 13.5% faster than in Group B.

Discussion

The introduction of robotic technologies makes it possible to increase the positioning accuracy of implants [13], however, we have not found the effect of axis alignment accuracy on the biomechanics of movement in the available literature, which was the purpose of our study.

In a prospective randomized study by Song *et al*. [9] and a group of authors from Hwaseong Hospital, Korea, consisting of 50 manual TKA and 50 robotic TKA, the results were compared. In the group of robotic TKA, the accuracy of mechanical alignment has been improved and the spread of more than 3° of rotation has been reduced, significantly more accurate adherence to the pre-operative plan.

American colleagues evaluated the safety and effectiveness of robot-assisted knee arthroplasty. One hundred and fifteen patients were analyzed within 6 months. According to the results of the study, not a single undesirable phenomenon occurred, and post-operative alignment of the limb with a deviation from the plan by ± 3° occurred in 11.2% of cases [14].

Kayani *et al*. conducted a prospective cohort study comparing the early functional results of 40 manual TKA and 40 robotic TKA. After the robotic TKA, there were fewer post-operative pains, the need for analgesics was reduced, patients became more active faster, and a better bending angle in the knee joint was achieved on discharge from the hospital. The need for inpatient physiotherapy was reduced compared to the manual group [15].

In another study, Marchand *et al.* compared the results of 28 robotic TKA and 20 manual TKA and showed that pain, patient satisfaction with implant, and function indicators based on the WOMAC scale were better in the robotic group at 6 months after surgery [16].

Our results demonstrate that post-operative pain syndrome on the 1st day after surgery in Group A is stronger by 7.9%, but by the 5th day after surgery in Group A, the pain syndrome is lower by 14.3%. ROM in Group A is better by 16% by 3 months after surgery, after 1 year by 10%. The positioning accuracy of the implant in Group A is 30% better. There are no statistically significant differences in the OKS and WOMAC scales between the groups, confirming the general opinion about the significant advantage of using an active robotic system.

It has been proven that TKA gives significant improvements in limb function, but the issue of implant positioning accuracy has not been fully resolved. The use of robotic systems that have recently appeared has not yet led to the accumulation of a significant database of the results obtained in the near and long term, which, combined with the variety of designs developed by various manufacturers, leaves many unresolved questions regarding their effectiveness and advantages over traditional methods. However, there is no consensus on the survival time of the implant and a significant difference in the functional results of recovery after surgery. Furthermore, we have not found the influence of axis alignment accuracy on the biomechanics of motion in the available literature.

Conclusions

Robot-assisted TKA provides more accurate positioning of the implant and alignment of the mechanical axis, which objectively improves the biomechanics of walking recovery, and has advantage in the function of the knee joint.

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