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Assessment of the use of an individual tool for knee arthroplasty

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Objective. On the basis of comparative radiometric analysis, before and after surgery, to assess the accuracy of the knee arthroplasty with an individual instrument. Methods. The analysis of knee arthroplasty of 26 patients operated with a special instrument was performed. Age: 50–59 years — 6, 0–69 — 12, 70–79 — 5, 80 and older — 3 patients. Men — 3, women — 18. Before the operation performed a computed tomography of the lower extremities, and after operation radiography of the lower extremities completely with the vertical positions of the feet. Patient specific instrument made according to the original method. The results of the analysis were performed by comparing X-ray parameters before and after operations: 1) position of the mechanical axis in the frontal plane on the plateau of the tibia in percent; 2) medial tibial resection angle to the mechanical axis; 3) the size of the components of the endoprosthesis (femoral, tibial and liner height). Results. Deviations in the values of the medial tibial and of the lateral femoral angles between the planned and actually obtained value was an average of 0.7 %, which can be considered a high indicator of the accuracy of the implant position. The position of the mechanical axis of the limb after the operation differed from the planned by a little more than 0.9 %. The dimensions of the endoprosthesis components and the height of the tibial insert fitted to the patients matched the planning results in 100 % of the cases, with the tibial insert height being 9 mm in all cases. The use of an individual tool made it possible to reduce the time of the operation, not to open the bone marrow canal of the thigh Conclusions. The use of the original individual tool for knee arthroplasty provided a high precision to install the components of the arthroplasty.

Мета. На підставі порівняльного рентгенометричного аналізу до та після операції оцінити точність встановлення ендопротеза колінного суглоба за допомогою індивідуального інструмента. Методи. Проаналізовано результати ендопротезування колінного суглоба 26 пацієнтів (8 чоловіків, 18 жінок), прооперованих за допомогою індивідуального інструмента. Вік хворих: 50–59 років — 6 осіб, 60–69 — 12, 70–79 — 5, 80 і старше — 3. До операції пацієнтам виконували комп'ютерну томограму нижніх кінцівок, а після неї — рентгенографію нижніх кінцівок повністю з вертикальним установленням положення стоп. Індивідуальний інструмент виготовляли за оригінальною методикою. Аналіз результатів провели шляхом порівняння рентгенометричних показників до та після операції: положення механічної осі нижньої кінцівки у фронтальній площині на плато великогомілкової кістки у відсотках; медіальний великогомілковий кут спилювання до механічної осі; розміри компонентів ендопротеза (стегновий, великогомілковий і висота вкладиша). Результати. Відхилення в значеннях медіального великогомілкового та латерального стегнового кутів між запланованим і фактично отриманим становили в середньому 0,7 %, що можна вважати високим показником точності розташування імплантатів. Позиція механічної осі кінцівки після операції відрізнялася від запланованої трохи більше ніж 1,8 %. Розміри компонентів ендопротеза та висота великогомілкового вкладиша, встановлені пацієнтам, співпали в 100 % випадків із результатами планування, причому у всіх випадках великогомілкова вставка мала висоту 9 мм. Застосування індивідуального інструмента дозволило скоротити час операції, не відкривати кістковомозковий канал стегна. Висновок. Застосування запропонованого індивідуального інструмента для ендопротезування колінного суглоба забезпечило високу точність встановлення компонентів ендопротеза, про що свідчить аналіз рентгенограм після операції. Ключові слова. Колінний суглоб, гонартроз, первинне ендопротезування, індивідуальний інструмент.

Key words. Knee joint, gonarthrosis, primary endoprosthesis, individual tool

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Introduction

Every year the number of knee joint replacement surgeries grows. Their results are improving due to the use of new technologies and implants, but at the same time, the demands and expectations of patients are increasing. They hope for better motor activity and the absence of pain, that is, for a more complete recovery of the function of the lower extremities [1–4]. Some patients cannot get rid of the feeling of having a replaced knee joint in their daily life. According to various studies, the percentage of patients whose expectations were not fulfilled after endoprosthetic repair reaches 20.0 % [2, 5, 6]. One of the significant problems resulting in many undesirable consequences is the mismatch of the position of the endoprosthesis components to the individual anatomy of the knee joint, which, according to various authors, ranges from 20 % to 40 % [3, 7–10]. Today, they are trying to solve this problem with the help of various methods, in particular, the use of an individual tool for installing implants and various computer navigation systems. The accuracy of setting endoprosthesis components can affect postoperative rehabilitation, complete recovery of function, survival of implants, and patient satisfaction with the treatment result. Existing approaches to the installation of a knee joint endoprosthesis differ in the principles of aligning the axis of the limb and restoring the line of the knee joint [7, 11–14]. There are three main concepts in practice today: mechanical, anatomical, and kinematic alignment. All these approaches are based on the reproduction of the desired frontal axis of the limb and the line of the knee joint. The debate about the advantages and disadvantages of these methods continues.

Today, the accuracy of reproduction of any type of alignment of the knee joint is determined by the tools and skills of the surgeon in using it to implement the operation plan, built following radiographic studies of the lower extremities in the frontal plane. A computer navigation system is an excellent tool in the hands of the surgeon, but it does not always allow to accurately take into account the three-dimensional shape of the limb. Another direction is a customized instrument for placement of knee arthroplasty components, which can provide high accuracy, but requires a CT scan of the lower extremities before surgery and has a certain learning curve and is more suitable for an experienced surgeon. Our clinic has developed an original method of designing and manufacturing an individual tool for knee arthroplasty.

Purpose of the study: on the basis of a comparative radiometric analysis before and after the operation, to assess the accuracy of the installation of the knee joint endoprosthesis with the help of an individual tool.

Material and methods

Clinical material

The study was approved by the Bioethics Committee of Zaporizhzhia State Medical University (Protocol No. 7 of 26.10.2016).

The study presents the results of primary knee arthroplasty in 26 patients who were operated on using individual tools at the traumatology and orthopedics department of the Motor Sich Clinic. In all cases, the patients were implanted with the same model of endoprosthesis Zimmer Biomet, Nex Gen with replacement of the posterior cruciate ligament. Age of patients: 50–59 years — 6 subjects, 60–69 — 12, 70–79 — 5, 80 and older — 3. There were 8 men, 18 women. Varus deformity in 25 patients did not exceed 18°, in one patient there was a valgus deformity of 8°. All patients had stage III–IV primary gonarthrosis. It was possible to fully examine 21 patients after surgery, whose radiographic studies were used for statistical analysis.

Evaluation of treatment outcomes

Before the operation, all patients underwent a complete CT scan of the lower limbs with the feet in a vertical position, after the operation, a complete radiographic examination of the lower limbs was also performed with the feet in a vertical position. To evaluate the result, the parameters before and after the operation were compared: the position of the mechanical axis of the lower limb in the frontal plane on the tibial plateau in percent; medial tibial resection angle to the mechanical axis; dimensions of endoprosthesis components (femoral, tibial, and insert height).

Statistical processing of the obtained numerical values was carried out using a computer and licensed packages Office Excel 2010 and STATISTICA 13.0 TIBCO Software Inc. (License JPZ804I382130ARCN10-J).

The method of building an individual tool

Having received a three-dimensional model of the lower extremities, we planned surgical intervention in the 3DFreeform+ software environment. The software is used to perform a virtual correction of the axis of the limb, select the resection planes of the femur and tibia, as well as the level of resection (Fig. 1).

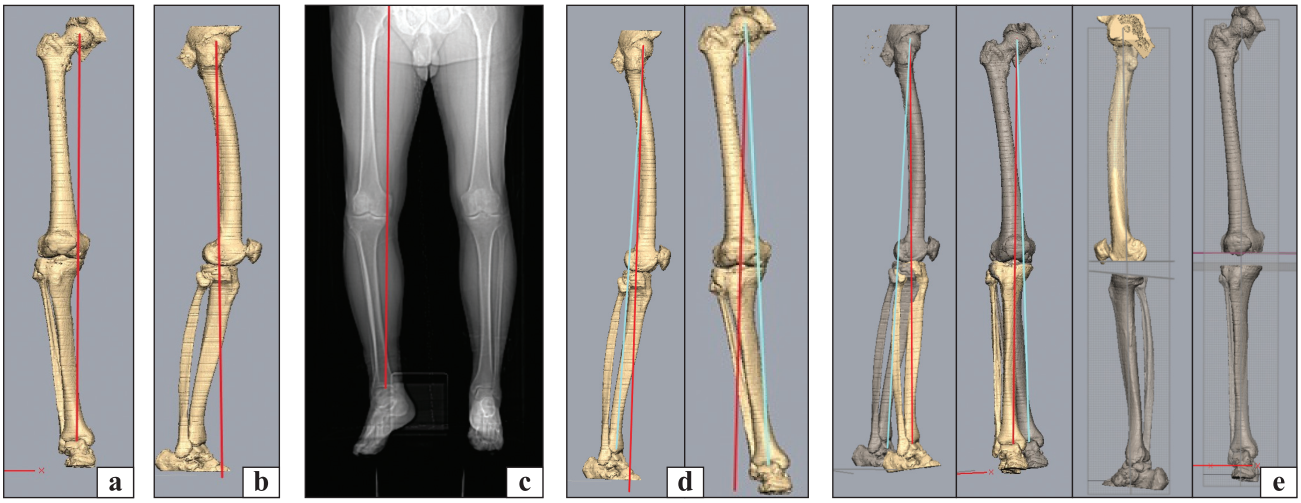

Fig. 1. Construction of a three-dimensional model of the lower limb, determination of the mechanical axis of the femur and the level of resection of the femur and tibia: model of the left limb, anterior (a) and lateral (b) views, radiographic image of the entire leg (c), setting the axis of the lower limb along the femur (d), correction of leg deformation to the physiological axis by setting the lower leg in the correct position (e)

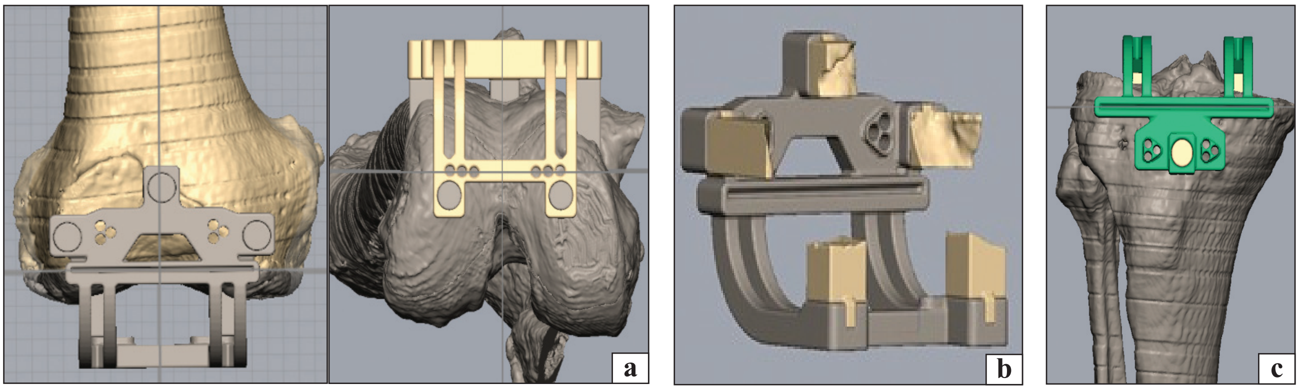

Fig. 2. Stages of individual tool modeling: a) femoral template according to the level of resection; b) the model of the femoral template from the inside is prepared for additive printing; c) tibial template according to the resection level

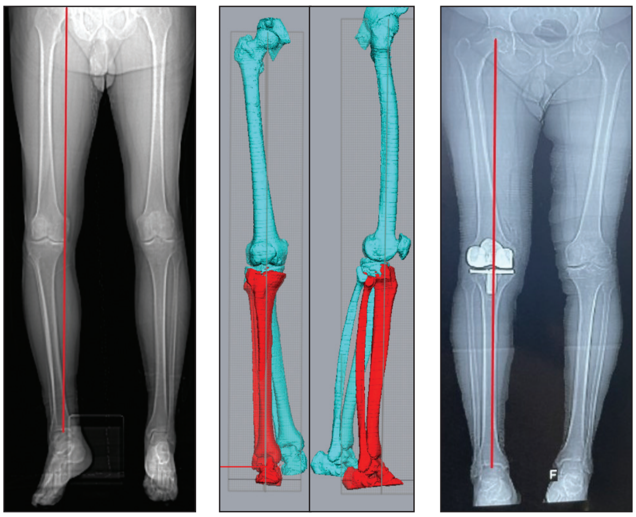

Fig. 3. A 70-year-old patient D., result of alignment of the right lower extremity, which was carried out exactly by analogy with the previously operated on left lower extremity. X-ray after surgery on the right knee shows a symmetrical position of the mechanical axis

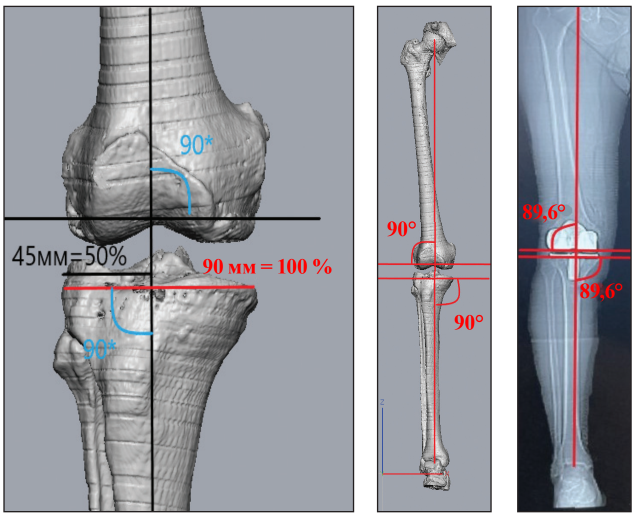

Fig. 4. The planned lateral femoral angle was equal to 90°, as a result of the operation it turned out to be 89.6°. The proximal medial tibial angle was planned to be 90°, as a result of the operation, 89.6° was obtained. Mechanical axis was planned to be 50 %, after surgery it shifted laterally by 0 %

To build an individual tool, it is necessary to know the thickness of the wall of the endoprosthesis, as well as the features of the conductors for resection of the femur and tibia. Our proprietary individual tool gives a possibility to set the correct position of the guide pins on which the conductor for bone resection is fixed in such a position allowing to perform the planned cut of the articular end. Fig. 2 shows the formation of templates for the individual installation of femur sawing blocks during knee arthroplasty. At the first stage, we set the position of the installation plane of the guide pins and combine with it a previously developed template, the legs of which fully correspond to the shape of the bone surface.

We measure the sawing thickness and determine the thickness of the insert. On the individual templates, we indicate the patient's last name, the thickness of the cuttings, the size of the implants and the thickness of the insert. We carry out 3D-printing of templates and articular ends of bones. We print the individual tool using the SLA method on the Anycubic Photon Mono 4K printer from Violadent Surgical Guide medical resin, which can be sterilized by autoclaving. Planning and manufacturing of an individual instrument after receiving a CT scan of the lower extremities takes 2–3 days. The method of construction and use was described by us earlier [15].

Technique of surgical intervention

After performing a standard arthrotomy, separating the femur and tibia, we install an individual template on the tibia. The correctness of the position is determined by comparing its position on the bone and its plastic model, on which the locations of individual instruments are pre-marked. We insert guide pins, remove the template, and put on the pins a conductor for sawing the tibia. Then we repeat the same procedure on the femur. In 26 patients operated on by us, the preoperative planning corresponded to the intraoperative situation, which did not require additional correction of the resection. Since the individual instrument corresponds to the resection blocks of a conventional prosthetic instrument, the resection height can be changed if necessary. In a situation where the axis of the limb does not correspond to the planned one, it is possible to use a conventional tool for endoprosthetic repair.

Results and their discussion

All patients underwent radiography of the lower extremities after surgery, in order to be able to measure the position of the mechanical axis on the tibial plateau, as well as the medial tibial and lateral femoral mechanical angles.

Fig. 3 shows radiographic images of the lower limbs of a 70-year-old patient D. before the operation on the right knee, the result of the three-dimensional alignment of the limb, and the radiographic image after the operation.

Fig. 4 presents the technique of radiometry of the lower extremity, showing three determined indicators and an example of measurement based on a model of the extremity with mechanical alignment and the result of the operation. The results of radiometry are given in Tables 1, 2 and Figures 5–7.

After the operation, 21 patients (80.7 % of all operated on) underwent complete X-ray of the limbs. Not all patients underwent mechanical alignment — 14 patients underwent anatomical alignment with reproduction of the medial slope of the knee joint line. The deviations of the values of the medial tibial and lateral femoral angles averaged 0.7 %, which can be considered a high indicator of the accuracy of the implant position. The average value of the relative error under the conditions of measuring the proximal medial tibial and distal lateral femoral angles in the postoperative period was equal to 0.7 % and 0.7 %, respectively, which can be considered a high level of accuracy of implant placement. There is one drawback of these measurements: before the operation, the measurement of the angle was absolutely accurate according to the three-dimensional model, and after the operation, we measured the angles with a flat radiography of the entire limb. No matter how accurate the rotation of the limbs is during such a study, there is no way to determine these angles strictly in the front plane, as was done during planning based on CT.

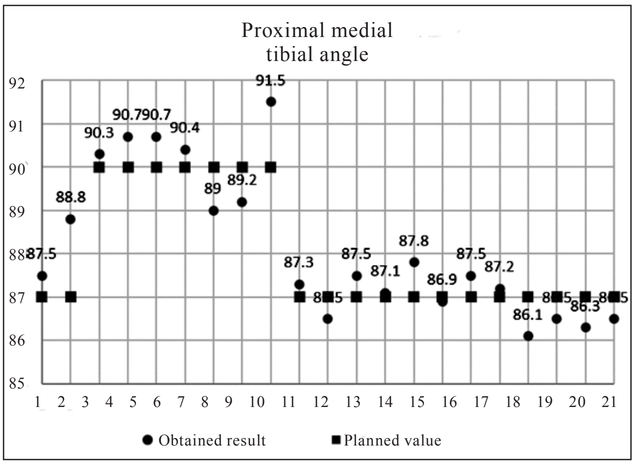

Fig. 5. Results of radiometric determination of the proximal medial tibial angle in patients operated on using an individual tool

Table 1

Results of radiometry of the lower extremity of patients operated on using an individual tool

Patient No.	Proximal medial tibial angle, degrees		Absolute error, °	Relative error, %	Distal lateral femoral angle, degrees		Absolute error, °	Relative error, %
	planned	result			planned	result		
1	87.0	87.5	0.5	0.6	87.0	88.1	1.1	1.3
2	87.0	88.8	1.8	2.1	87.0	86.5	0.5	0.6
3	90.0	90.3	0.3	0.3	90.0	90.3	0.3	0.3
4	90.0	90.7	0.7	0.8	90.0	90.7	0.7	0.8
5	90.0	90.7	0.7	0.88	90.0	90.4	0.4	0.4
6	90.0	90.4	0.4	0.4	90.0	88.4	1.6	1.8
7	90.0	89.0	1.0	1.1	90.0	89.0	1.0	1.1
8	90.0	89.2	0.8	0.9	90.0	91.2	1.2	1.3
9	90.0	91.5	1.5	1.7	90.0	91.0	1.0	1.1
10	87.0	87.3	0.3	0.3	87.0	86.7	0.3	0.3
11	87.0	86.5	0.5	0.6	87.0	87.5	0.5	0.6
12	87.0	87.5	0.5	0.6	87.0	86.5	0.5	0.6
13	87.0	87.1	0.1	0.1	87.0	86.9	0.1	0.1
14	87.0	87.8	0.8	0.9	8.0	86.2	0.8	0.9
15	87.0	86.9	0.1	0.1	87.0	87.1	0.1	0.1
16	87.0	87.5	0.5	0.6	87.0	86.5	0.5	0.6
17	87.0	87.2	0.2	0.2	87.0	87.6	0.6	0.7
18	87.0	86.1	0.1	0.1	87.0	86.2	0.8	0.9
19	87.0	86.5	0.5	0.6	87.0	86.5	0.5	0.6
20	87.0	86.3	0.3	0.3	87.0	86.7	0.3	0.3
21	87.0	86.5	0.5	0.6	87.0	86.4	0.6	0.7
Average value	88.0	88.2	0.6	0.7	88.0	87.9	0.6	0.7

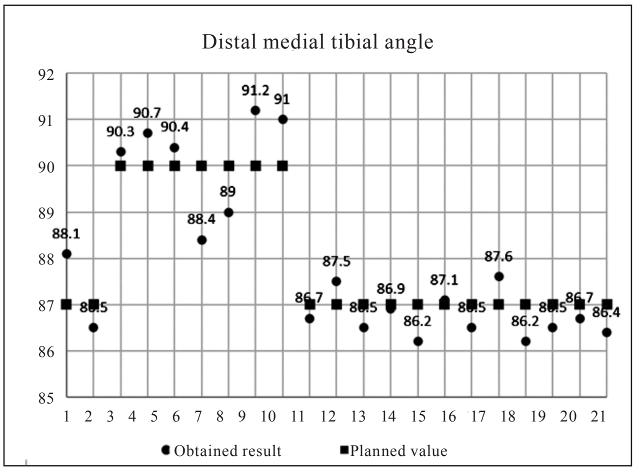

Fig. 6. Results of radiometric determination of the distal lateral femoral angle in patients operated on using an individual tool

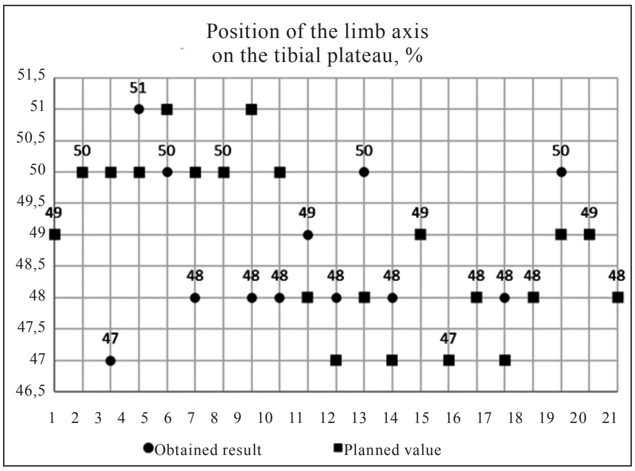

Fig. 7. Results of determining the position of the mechanical axis of the lower limb in patients operated on using an individual tool

This also applies to determining the position of the mechanical axis of the limb after surgery. During its measurement, the average value of the relative error was 1.8% of the planned values, which confirms the high level of reliability of using this method in preoperative planning before knee arthroplasty. The deviation of the position of the mechanical axis after the operation was on average 1.8 % (Table 2).

It should be noted that this group included patients who were operated on at the stage of mastering the technique. The dimensions of the endoprosthesis components and the height of the tibial insert installed in the patients coincided in 100 % of the cases with the planning results, and in all cases the height of the tibial insert was planned to be 9 mm.

Discussion

The study on three-dimensional modeling of the lower limbs allowed us not only to design and build an individual instrument for primary knee arthroplasty, but also to correctly assess the axis of the limb before surgery and determine the constitutional axis of the patient, which is important for performing kinematic alignment of the limb, being now one of the most popular and discussed techniques of knee joint replacement [12–14]. We paid attention to rotational deformations of the femur and tibia. Among our patients, there was none without significant (more than 20°) rotational deformities of the hip and/or lower leg. That is, all patients had rotational deformities of the lower limbs. All without exception had dysplasia of the femoral block (types B, C and D according to Dejour). The analysis of three-dimensional models of the lower limbs allows not only to determine the frontal and sagittal alignment of the leg, but also to evaluate rotational deformations, to see the position of the knee after arthroplasty.

The size of endoprosthetic components planned before the operation, the height of the insert in the program coincided with the result. The disadvantage of the technique is the need to master the software, acquire skills in using an individual tool, additional costs for its preparation and printing, as well as for CT.

The authors who studied the advantages of the individual tool also confirm the increase in the accuracy of bone resection and implant placement with its use [10, 16]. Some experts believe that a conventional tool is not inferior in accuracy in the case of mechanical alignment [14, 17]. According to various data, the accuracy of installing knee endoprostheses using an individual tool is 0.7–2.5% [10, 16, 18].

Table 2

Results of determining the position of the mechanical axis of the lower extremity of patients operated on using an individual tool

Patient No.	Position of the limb axis on the tibial plateau, %		Absolute error, %	Relative error, %
	planned	result		
1	49	48	0.0	0.0
2	50	50	0.0	0.0
3	50	47	3.0	6.0
4	50	51	1.0	2.0
5	51	50	1.0	1.9
6	505	48	2.0	4.0
7	50	50	0.0	0.0
8	51	48	3.0	5.9
9	50	48	2.0	4.0
10	48	49	1.0	2.1
11	47	48	1.0	2.1
12	48	50	2.0	4.2
13	47	48	1.0	2.1
14	49	49	0.0	0.0
15	47	47	0.0	0.0
16	48	48	0.0	0.0
17	47	48	1.0	2.1
18	48	48	0.0	0.0
19	49	50	1.0	2.0
20	49	49	0.0	0.0
21	48	48	0.0	0.0
Average value	48.9	48.7	0.9	1.8

It is believed that the individual tool simplifies the performance of surgical intervention for an experienced surgeon, and also ensures e implementation of the technique of kinematic alignment of the knee joint, which contributes to the achievement of the best functional outcomes [4, 19]. After mastering the described software, preoperative planning of knee joint surgery can be performed taking into account the individual characteristics of the patient: after assessing the condition of the lower extremities, one should choose a mechanical, anatomical or kinematic concept of alignment. The next stage is the manufacture of an individual tool followed by the operation with high precision of the installation of endoprosthesis components.

Conclusion

The deviations of the values of the medial tibial and lateral femoral angles were on average 0.7 %. The average value of the relative error after measuring the proximal medial tibial and distal lateral femoral angles in the postoperative period was equal to 0.7 % and 0.7 %. Deviation of the position of the mechanical axis after the operation from the planned was on average 1.8 %. X-ray analysis of the use of the proposed individual tool for knee arthroplasty showed high accuracy of the installation of the arthroplasty components.

Conflict of interest. The authors are developers of the method of manufacturing and using an individual tool for installing knee joint endoprosthesis components.

References

1. Annual Report. Hip, Knee & Shoulder Arthroplasty / *Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR).* Adelaide; AOA, 2020. P. 1–474. URL : https://aoanjrr.sahmri.com/annual-reports-2020.
2. Kahlenberg, C. A., Nwachukwu, B. U., McLawhorn, A. S., Cross, M. B., Cornell, C. N., & Padgett, D. E. (2018). Patient satisfaction after total knee replacement: a systematic review. *HSS Journal, 14*(2), 192–201. https://doi.org/10.1007/s11420-018-9614-8
3. Comfort, T., Daly, P., Drogt, J., Hoeffel, D., & Gioe, T. (2011). *HealthEast Joint Replacement Registry: 20 year report.* St. Paul, MN. http://www.healtheast.org/images/stories/ortho/joint_registry_20_yr_report.pdf
4. Niki, Y., Nagura, T., Nagai, K., Kobayashi, S., & Harato, K. (2018). Kinematically aligned total knee arthroplasty reduces knee adduction moment more than mechanically aligned total knee arthroplasty. *Knee surgery, sports traumatology, arthroscopy, 26*(6), 1629–1635. https://doi.org/10.1007/s00167-017-4788-z
5. Canadian Institute for Health Information. (2020, August). *Hip and Knee Replacements in Canada: CJRR Annual Statistics Summary, 2018–2019.* Ottawa, ON: CIHI. https://secure.cihi.ca/free_products/CJRR-annual-statistics-hip-knee-2018-2019-report-en.pdf
6. Price A. J., Alvand, A., Troelsen, A., Katz, J. N., Hooper, G., Gray, A., Carr, A., & Beard, D. (2018). Knee replacement. *Lancet, 392*(10158), 1672–1682. https://doi.org/10.1016/S0140-6736(18)32344-4
7. Parratte, S., Blanc, G., Boussemart, T., Ollivier, M., Le Corroller, T., & Argenson, J. N. (2013). Rotation in total knee arthroplasty: no difference between patient-specific and conventional instrumentation. *Knee surgery, sports traumatology, arthroscopy, 21*(10), 2213–2219. https://doi.org/10.1007/s00167-013-2623-8
8. Bonner, T. J., Eardley, W. G., Patterson, P., & Gregg, P. J. (2011). The effect of post-operative mechanical axis alignment on the survival of primary total knee replacements after a follow-up of 15 years. *The Journal of bone and joint surgery. British volume, 93*(9), 1217–1222. https://doi.org/10.1302/0301-620X.93B9.26573
9. Rauck, R. C., Swarup, I., Chang, B., Dines, D. M., Warren, R. F., Gulotta, L. V., & Henn III, R. F. (2018). Effect of preoperative patient expectations on outcomes after reverse total shoulder arthroplasty. *Journal of Shoulder and Elbow Surgery, 27*(11), e323–e329. https://doi.org/10.1016/j.jse.2018.05.026
10. Ehlinger, M., Favreau, H., Murgier, J., & Ollivier, M. (2023). Knee osteotomies: The time has come for 3D planning and patient-specific instrumentation. *Orthopaedics & traumatology, surgery & research : OTSR, 109*(4), 103611. https://doi.org/10.1016/j.otsr.2023.103611
11. Canovas, F., & Dagneaux, L. (2018). Quality of life after total knee arthroplasty. *Orthopaedics & Traumatology: Surgery & Research, 104*(1), S41–S46. https://doi.org/10.1016/j.otsr.2017.04.017
12. Howell, S. M. (2019). Calipered kinematically aligned total knee arthroplasty: an accurate technique that improves patient outcomes and implant survival. *Orthopedics, 42*(3), 126–135. https://doi.org/10.3928/01477447-20190424-02
13. Nedopil, A. J., Howell, S. M., & Hull, M. L. (2020). Deviations in femoral joint lines using calipered kinematically aligned TKA from virtually planned joint lines are small and do not affect clinical outcomes. *Knee surgery, sports traumatology, arthroscopy, 28*(10), 3118–3127. https://doi.org/10.1007/s00167-019-05776-w
14. Courtney, P. M., & Lee, G. C. (2017). Early outcomes of kinematic alignment in primary total knee arthroplasty: a meta-analysis of the literature. *The Journal of arthroplasty, 32*(6), 2028–2032. https://doi.org/10.1016/j.arth.2017.02.041
15. Golovakha, M., & Bondarenko, S. (2022). Method of preparation individual instrument for knee arthroplasty. *Orthopaedics, Traumatology and Prosthetics,* (3–4), 119–125. https://doi.org/10.15674/0030-598720223-4119-125
16. Voleti, P. B., Hamula, M. J., Baldwin, K. D., & Lee, G. C. (2014). Current data do not support routine use of patient-specific instrumentation in total knee arthroplasty. *The Journal of arthroplasty, 29*(9), 1709–1712. https://doi.org/10.1016/j.arth.2014.01.039
17. Parratte, S., Blanc, G., Boussemart, T., Ollivier, M., Le Corroller, T., & Argenson, J. N. (2013). Rotation in total knee arthroplasty: no difference between patient-specific and conventional instrumentation. *Knee surgery, sports traumatology, arthroscopy, 21*(10), 2213–2219. https://doi.org/10.1007/s00167-013-2623-8
18. Leon-Munoz, V. J., Martínez-Martínez, F., Lopez-Lopez, M., & Santonja-Medina, F. (2019). Patient-specific instrumentation in total knee arthroplasty. *Expert Review of Medical Devices, 16*(7), 555–567. https:// doi/abs/10.1080/17434440.2019.1627197
19. Bini, S. A., Howell, S. M., & Steele, G. D. (2021). *Calipered Kinematically aligned Total Knee Arthroplasty: Theory, Surgical Techniques and Perspectives.* Elsevier Health Sciences. https://doi.org/10.1016/C2018-0-05402-X

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ASSESSMENT OF THE USE OF AN INDIVIDUAL TOOL FOR KNEE ARTHROPLASTY

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