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Assessment of the accuracy of reproduction of the lower limb axis using an individual instrument during endoprosthetics with kinematic alignment of the knee joint

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Objective. To assess the accuracy of reproduction of the kinematic axis of the lower limb using an individual instrument during total knee arthroplasty (TKA) by comparative radiographic analysis before and after surgery. Methods. Using radiographic analysis, an analysis of the knee arthroplasty of 10 patients operated on using an individual instrument was performed, the kinematic axis was restored (3 men and 7 women). The age range was from 56 to 71 years. Before surgery, patients underwent computed tomography of the lower limbs, and after it, radiography with vertical positioning of the feet. The individual instrument was manufactured using the original method. Results. A comprehensive assessment of the accuracy of reproduction of spatial landmarks of the lower limb during TKA was carried out using an individual surgical instrument developed on the basis of computed tomography and the principles of kinematic alignment. Analysis of deviations of the proximal medial tibial angle in the postoperative period revealed a mean absolute error of 0.15°, with a mean relative error of 0.74 %. At the same time, for the distal lateral femoral angle, an absolute error of 0.24° and a relative error of 0.27 % were established. Preoperatively, the mean value of the planned axis was 88.71°, postoperatively — 86.58°, which corresponds to a mean varus deviation of 2.15° and a relative error of 2.47 %. At the same time, it was found that the technical axis indicators were 88.55° before surgery and 86.67° after, respectively, with a mean varus deviation of 1.88° and a relative error of 2.28 %. Conclusion. A custom instrument allows for accurate reproduction of the kinematic axis of the lower limb, which can be crucial for achieving functional outcome and patient satisfaction.

Мета. Оцінити точність відтворення кінематичної осі нижньої кінцівки за допомогою індивідуального інструмента під час тотального ендопротезування колінного суглоба (ТЕКС) шляхом порівняльного рентгенометричного аналізу до та після операції. Методи. Використовуючи рентгенометрію, проведено аналіз ендопротезування колінного суглоба 10 пацієнтів, оперованих за допомогою індивідуального інструмента. Було відновлено кінематичну вісь (3 чоловіки та 7 жінок). Віковий діапазон становив від 56 до 71 року. До операції хворим виконували комп'ютерну томографію нижніх кінцівок, а після неї рентгенографію з вертикальним установленням положення стоп. Індивідуальний інструмент виготовляли за оригінальною методикою. Результати. Здійснено комплексне оцінювання точності відтворення просторових орієнтирів нижньої кінцівки під час ТЕКС із застосуванням індивідуального хірургічного інструмента, розробленого на основі комп'ютерної томографії та принципів кінематичного вирівнювання. Аналіз відхилень проксимального медіального великогомілкового кута в післяопераційному періоді виявив середню абсолютну похибку 0,15°, за середньої відносної похибки 0,74 %. Водночас, для дистального латерального стегнового кута встановлено абсолютну похибку 0,24°, а відносну — 0,27 %. Доопераційно середнє значення запланованої осі становило 88,71°, післяопераційно — 86,58°, що відповідає середньому варусному відхиленню 2,15° та відносній похибці 2,47 %. Водночас, виявлено, що показники технічної осі становили відповідно 88,55° до операції та 86,67° після, із середнім варусним відхиленням 1,88° і відносною похибкою 2,28 %. Висновок. Індивідуальний інструмент дозволяє точно відтворити кінематичну вісь нижньої кінцівки, що може мати вирішальне значення для досягнення функціонального результату та задоволення пацієнтів. Ключові слова. Ендопротезування колінного суглоба, кінематична вісь, індивідуальний інструмент, рентгенографія, артропластика.

Keywords. Knee joint, endoprosthesis, kinematic axis, surgical treatment, individual instrument, radiography, arthroplasty

Introduction

For many years, total knee arthroplasty (TKA) has remained one of the leading treatment options for degenerative and dystrophic disorders of the knee joint. However, alongside the growing number of procedures performed, there has also been an increase in the proportion of patients who report dissatisfaction with the outcome — currently reaching up to 30 % [1, 2]. This trend has prompted the development of new technologies and refinement of existing techniques, including the introduction of computer navigation systems, patient-specific instruments, robotic-assisted platforms, and continuous improvement in surgical expertise [5, 6].

For a long time, mechanical alignment of the lower limb during prosthesis implantation was considered the «gold standard» [3]. Nevertheless, even proponents of this approach acknowledge that up to 20 % of patients remain unsatisfied with the results [4], which has driven the search for alternative concepts.

One such contemporary concept is kinematic alignment, which is based on individualizing component placement according to the patient's native anatomy. Although the idea itself is not new — first described by Hungerford, Kenna, and Krackow in the 1980s [9, 10], and approved by the FDA in 1984 — its practical implementation was limited for decades due to technological constraints. Only in 2006 were the first procedures performed using the kinematic alignment approach, at that time still employing conventional surgical instruments.

The essence of the method lies in positioning the prosthetic components in a manner that most accurately replicates the patient's pre-arthritic limb alignment, even if it differs from the mechanically neutral axis. The femoral component is implanted to reflect the patient's original anatomy prior to disease progression. The tibial component is likewise aligned to match the natural tibial slope and orientation, which helps achieve optimal soft tissue balance.

To date, an increasing body of literature supports the superiority of kinematic alignment over mechanical alignment in terms of functional outcomes [11–14], with revision rates remaining comparable to those of traditional mechanical alignment techniques [15, 16].

Objective: to evaluate the accuracy of reproducing the kinematic axis of the lower limb following total knee arthroplasty using a patient-specific instrument, based on a comparative analysis of preoperative and postoperative radiographic measurements.

Materials and Methods

The study was approved by the Bioethics Committee (protocol No. 8 dated December 26, 2022) in accordance with the ICH GCP guidelines, the 2002 Helsinki Declaration of Human Rights, the Council of Europe Convention on Human Rights and Biomedicine (adopted in 1977), and the current legislation of Ukraine. Statistical processing of the obtained numerical data was performed using a computer and licensed software packages Office Excel 2010 and STATISTICA 13.0 TIBCO Software Inc. (License JPZ804I382130ARCN10-J).

This study presents the results of total knee arthroplasty (TKA) in 10 patients who underwent surgery using patient-specific instrumentation (PSI) for kinematic alignment. All procedures were performed at the Department of Traumatology and Orthopedics of the «Motor Sich» Clinic. The study cohort included 10 patients treated for degenerative pathology of the knee joint. Among them were 3 men (30 %) and 7 women (70 %). The age range of the patients was from 56 to 71 years. Four patients (40 %) were classified as middle-aged (44–60 years), and six patients (60 %) as elderly (60–75 years).

The mean age of the cohort was 64.1 years, indicating a predominance of elderly patients. The body mass index (BMI) ranged from 24.3 to 32.3 kg/m², with an average value of 27.2 kg/m², reflecting a tendency toward overweight in the majority of cases. In three male patients, the BMI was within normal limits or slightly elevated (24.3–28.8 kg/m²). Among female patients, five were classified as overweight (25.7–27.2 kg/m²), and two had class I obesity (30.8 and 32.3 kg/m²).

All patients exhibited varus deformity of the lower limb, with angular deviation not exceeding 9°. The minimum measured value was 6°, and the maximum was 9°. The mean varus deformity was 7.8° (Table 1). These data were taken into account during preoperative assessment of limb alignment and planning of the surgical intervention.

Table 1

General characteristics of the patients

No.	Sex	Age (years)	BMI (kg/m²)	Varus (°)
1	M	58	24.5	7
2	M	60	28.8	8
3	M	62	24.3	9
4	W	56	26.1	6
5	W	63	25.7	7
6	W	65	26.8	8
7	W	67	27.2	7
8	W	69	25.9	8
9	W	70	30.8	9
10	W	71	32.3	9
Mean		64.1	27.2	7.8

Prior to surgery, all patients underwent full-length computed tomography (CT) scans of the lower limbs in a standing position with standardized foot alignment. Postoperatively, full-length weight-bearing radiographs of the lower limbs were performed using the same positioning protocol. To evaluate the outcome, the position of the kinematic axis in the frontal plane at the level of the tibial plateau was compared pre- and postoperatively.

Statistical analysis of the collected data was performed using Microsoft Office Excel 2010 and STATISTICA 13.0 (TIBCO Software Inc., License JP-Z804I382130ARCN10-J). The study protocol was approved by the Bioethics Committee of Zaporizhzhia State Medical and Pharmaceutical University (Protocol No. 7 dated October 26, 2016).

Results

All patients underwent postoperative full-length radiographic examination of the lower limbs in order to measure the kinematic axis, as well as the medial tibial and lateral femoral angles.

Figure 1 illustrates the radiograph of the lower limbs of patient S., 65 years old, prior to surgery on the left knee. The image shows the result of three-dimensional alignment of the limb and the postoperative radiograph.

Radiographic measurement methodology for the lower limb. The image illustrates the three key parameters assessed, along with an example of kinematic alignment measurement and the corresponding postoperative full-length radiograph (Fig. 2).

The results of the initial 10 cases of kinematic alignment planning using a patient-specific instrument are presented in Table 1.

Postoperative full-length radiographs of the lower limbs were successfully obtained for all 10 patients (100 % of those operated). Within the scope of this study, a comprehensive evaluation was conducted to assess the accuracy of reproducing the spatial anatomical landmarks of the lower limb during total knee arthroplasty using a patient-specific surgical instrument. This instrument was designed based on computed tomography data and the principles of kinematic alignment. The primary objective was to determine the degree of conformity between the actual positioning of the prosthetic components and the preoperatively planned parameters within the plane of the anatomical kinematic axis.

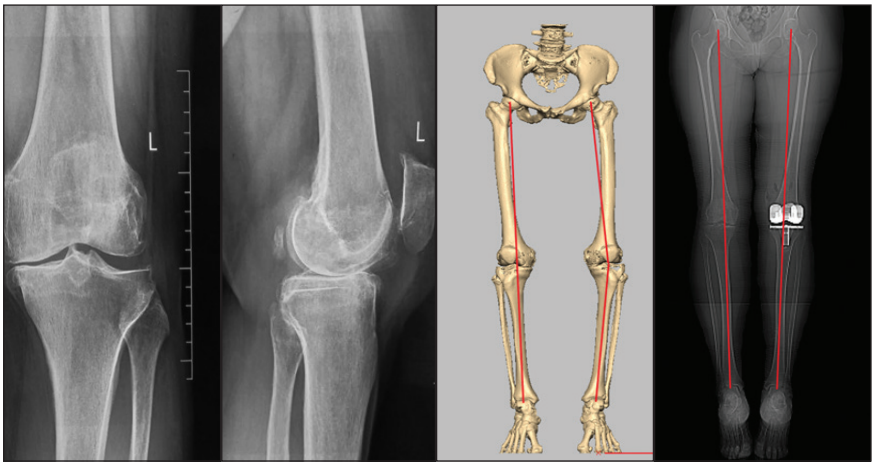

Fig. 1. Patient S., 65 years old. Alignment result of the left lower limb achieved precisely according to the kinematic alignment plan. The postoperative radiograph of the left knee demonstrates the reconstructed kinematic axis

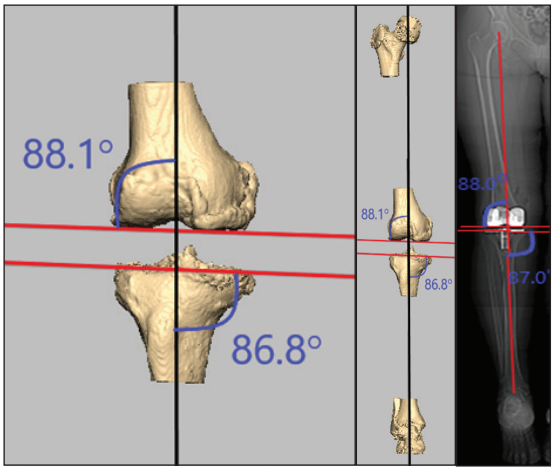

Fig. 2. Preoperative planning showed a distal lateral femoral angle of 88.1°, which postoperatively measured 88.0°. The planned proximal medial tibial angle was 86.8°, with a postoperative result of 87.0°. The planned kinematic axis demonstrated a 1° varus deviation

Analysis of deviations in the proximal medial tibial angle in the postoperative period revealed a mean absolute error of 0.15°, with a mean relative error of 0.74 %, indicating a high level of reproducibility for this anatomical landmark (Fig. 3). Meanwhile, assessment of the distal lateral femoral angle showed an absolute error of 0.24° and a relative error of 0.27 % (Fig. 4). These results demonstrate consistent accuracy in prosthetic component positioning at the distal femur and tibia when utilizing individualized preoperative planning.

Additionally, a comparison was made between the planned and achieved kinematic axis, derived from the aforementioned angular measurements (Table 2 and Fig. 5). The average preoperative planned axis was 88.71°, while the postoperative measurement was 86.58°, corresponding to a mean varus deviation of 2.15° and a relative error of 2.47 %. Similarly, when evaluating the actual (measured) axis based on the postoperative angular values, the preoperative value was 88.55° and the postoperative value was 86.67°, reflecting a mean varus deviation of 1.88° and a relative error of 2.28 %.

Discussion

The obtained results confirm that the use of patient-specific instrumentation (PSI) in total knee arthroplasty (TKA) allows for high-precision replication of both anatomical angles and the complete kinematic axis of the lower limb. The observed absolute and relative deviations remained within clinically acceptable limits, demonstrating the reliability of the technique and its suitability for routine application in orthopedic reconstructive surgery.

The application of kinematic alignment principles, as opposed to the traditional mechanical axis concept, enables a more physiological placement of prosthetic components, taking into account the patient's native rotational and coronal anatomy. This is particularly relevant in patients with pronounced individual anatomical variations, where a mechanically neutral axis may not correspond to the pre-arthritic limb configuration.

Table 2

Radiographic measurements of the lower limb in patients operated using a patient-specific instrument for kinematic axis restoration, before and after surgery

Patient number	Proximal medial tibial angle (°)		Absolute error (°)	Relative error (%)	Distal lateral femoral angle, °		Absolute error (°)	Relative error (%)
	according to plan	result			according to plan	result		
1	86.8	87.0	0.2	0.23	88.1	88.0	0.1	0.11
2	86.4	86.6	0.2	0.23	89.0	88.8	0.2	0.22
3	86.0	86.0	0	0	88.4	88.0	0.4	0.45
4	87.0	87.0	0	0	88.9	88.5	0.4	0.45
5	87.4	87.5	0.1	0.11	89.0	88.8	0.2	0.22
6	86.6	87.0	0.4	0.46	89.2	89.0	0.2	0.22
7	87.0	87.0	0	0	87.8	88.0	0.2	0.23
8	86.2	86.0	0.2	0.23	88.8	89.0	0.2	0.23
9	86.0	86.0	0	0	89.2	89.0	0.2	0.22
10	86.4	86.6	0.3	0.23	88.7	88.4	0.3	0.34
Average value	86.58	86.67	0.15	0.74	88.71	88.55	0.24	0.27

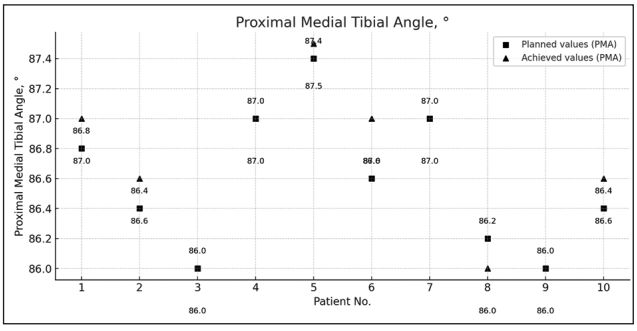

Fig. 3. Radiographic assessment of the proximal medial tibial angle in patients operated using a patient-specific instrument, before and after surgery

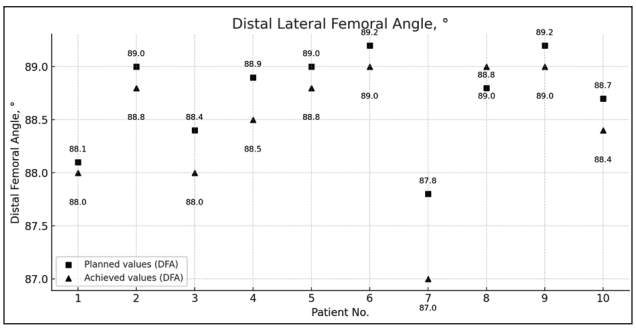

Fig. 4. Radiographic assessment of the distal lateral femoral angle in patients operated using a patient-specific instrument, before and after surgery

Table 3

Evaluation of the kinematic axis position of the lower limb in patients operated using a patient-specific instrument, before and after surgery

Patient number	The planned kinematic axis is formed by the proximal medial tibial angle (°) and distal lateral femoral angle (°)		Axis (°) (Varus)	Relative error (%)	The resulting kinematic axis is formed by the proximal medial tibial angle (°) and distal lateral femoral angle (°)		Absolute error (°) (Varus)	Relative error (%)
	before the operation	after surgery			before the operation	after surgery		
1	88.1	86.8	1.3	1.5	88.0	87.0	1.0	1.2
2	89.0	86.4	2.6	3.0	88.8	86.6	2.2	3.5
3	88.4	86.0	2.4	2.8	88.0	86.0	2.0	2.3
4	88.9	87.0	1.9	2.3	88.5	87.0	1.5	1.7
5	89.0	87.4	1.8	1.8	88.8	87.5	1.3	1.5
6	89.2	86.6	2.6	3.0	89.0	87.0	2.0	2.3
7	87.8	87.0	0.8	0.9	88.0	87.0	1.0	1.2
8	88.8	86.2	2.6	3.0	89.0	86.0	3.0	3.5
9	89.2	86.0	3.2	3.7	89.0	86.0	3.0	3.5
10	88.7	86.4	2.3	2.7	88.4	86.6	1.8	2.1
Average value	88.71	86.58	2.15	2.47	88.55	86.67	1.88	2.28

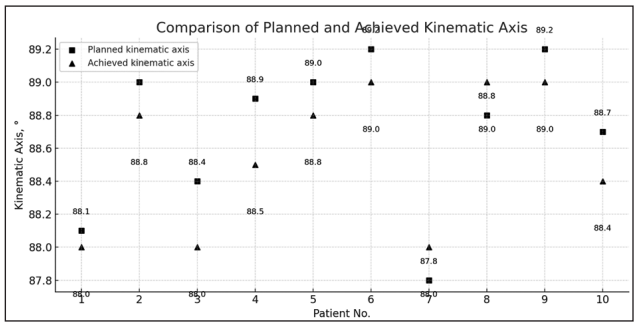

Fig. 5. Evaluation of the kinematic axis position of the lower limb in patients operated using a patient-specific instrument, before and after surgery

The positive outcomes associated with kinematic axis restoration suggest that patient-specific 3D planning can serve as an effective tool for improving component positioning accuracy and constructing a stable, balanced prosthesis functioning in accordance with the patient's natural biomechanics. Consequently, this approach may potentially reduce the risk of postoperative instability, revision surgeries, and contribute to improved long-term functional outcomes.

Our findings are consistent with those reported by other authors who have evaluated the efficacy of kinematic alignment in TKA. For instance, Sosio et al. (2023) analyzed 55 patients undergoing TKA using kinematic alignment in combination with a medial pivot implant design. The authors observed significant improvements in both clinical and functional outcomes, which persisted up to 24 months postoperatively, regardless of the final limb alignment. Radiographic analysis confirmed restoration of physiological limb alignment and joint line orientation parallel to the floor [17].

Moreover, Wang et al. (2024), in a randomized controlled trial, demonstrated that modified kinematic alignment provides a more physiological plantar pressure distribution during gait compared to mechanical alignment. This suggests more natural gait biomechanics following kinematically aligned TKA [18].

A meta-analysis by Gao et al. (2022) further supported these findings, showing that patients who underwent kinematically aligned TKA achieved better functional outcomes, including higher WOMAC and KSS scores, compared to those treated with mechanical alignment. These data emphasize the clinical advantage of KA in enhancing both functional recovery and patient satisfaction [19].

Thus, both our findings and those from current literature support the conclusion that kinematic alignment in TKA facilitates more accurate reproduction of native anatomy and knee biomechanics, which in turn improves functional outcomes and patient satisfaction. This highlights the rationale for considering KA as an effective alternative to conventional mechanical alignment in clinical practice.

Conclusion

A patient-specific instrument enables accurate reconstruction of the kinematic axis of the lower limb, which may play a crucial role in achieving favorable functional results and higher patient satisfaction.

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

Prospects for further research. research include expanding the study sample to improve the statistical significance of the results, as well as implementing a wider range of clinical scenarios. Long-term follow-up of patients after knee joint replacement is planned to assess the durability of the obtained results and their impact on the patients' quality of life. An important area of research is also the study of the effect of the individual instrument on postoperative rehabilitation, particularly on the speed of joint functionality recovery and the reduction of complication risks. Further clinical trials will allow for a more precise determination of the optimal parameters for planning knee replacement and reducing the percentage of patients dissatisfied with the results.

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Author's contribution. Golovakha M. L. — concept and design of the study, article editing, final approval of the article; Bondarenko S. A. — data collection, data analysis and interpretation, writing the article.

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ОЦІНЮВАННЯ ТОЧНОСТІ ВІДТВОРЕННЯ ОСІ НИЖНЬОЇ КІНЦІВКИ ЗА ДОПОМОГОЮ ІНДИВІДУАЛЬНОГО ІНСТРУМЕНТА ЗА ЕНДОПРОТЕЗУВАННЯ В РАЗІ КІНЕМАТИЧНОГО ВИРІВНЮВАННЯ КОЛІННОГО СУГЛОБА

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