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PLANNING
IN TOTAL KNEE ARTHROPLASTY

ABSTRACT

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The defence materials are available at the Library of Medical University — Varna and on the University website.

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1. ABBREVIATIONS

TKA — total knee arthroplasty

CPAK — Coronal Plane Alignment of the Knee

aHKA — arithmetic hip–knee–ankle angle

JLO — joint line obliquity

LDFA — lateral distal femoral angle

MPTA — medial proximal tibial angle

CIM — customised individually made implant

HKA — hip–knee–ankle angle (mechanical axis of the lower limb)

rKA — restricted kinematic alignment

KA — kinematic alignment

MA — mechanical alignment

PSI — patient-specific instrumentation

CAS — computer-assisted surgery

OKS — Oxford Knee Score

VAS — visual analogue scale for pain

ROM — range of motion

MCID — minimal clinically important difference

ASA — American Society of Anesthesiologists

CT — computed tomography

IQR — interquartile range

SD — standard deviation

CI — confidence interval

2. INTRODUCTION

Total knee arthroplasty is among the most successful and most frequently performed orthopaedic procedures. Despite its high rate of clinical success, a substantial proportion of patients remain dissatisfied with the functional result, which sustains continuing interest in technologies for precise preoperative planning and reproducible intraoperative execution.

Over the past two decades the concept of alignment in TKA has evolved considerably. Strict mechanical alignment, which targets a neutral mechanical axis of 180° irrespective of individual anatomy, was long regarded as the gold standard because of its association with implant longevity. Accumulating evidence, however, indicates that a substantial proportion of the population has a natural (constitutional) varus or valgus alignment, and that forcing such a knee into a neutral axis may disturb soft tissue balance and impair the functional outcome. Kinematic and restricted Systematic description of this variability produced the two classifications that frame the current debate. The functional knee phenotypes of Hirschmann et al. (2019) stratify the HKA angle and the femoral and tibial mechanical angles into a matrix of 125 possible combinations, while the CPAK classification of MacDessi et al. (2021) describes the knee through the arithmetic HKA angle and joint line obliquity in a matrix of nine phenotypes. Both proceed from the observation that the neutral mechanical axis is not a universal norm.

kinematic alignment emerged in response to this limitation, seeking to restore the individual axis within a predefined safe corridor.

In parallel, the technological means of achieving the planned alignment have developed. Three-dimensional CT-based planning combined with a customised individually made implant and patient-specific instrumentation represents the maximum degree of

preoperative personalisation: the plan is constructed on a three-dimensional model of the individual patient and executed through cutting guides manufactured for that patient. Computer-assisted navigation pursues the same goal by a different route — intraoperative registration of anatomical references and real-time verification of every resection, using a standard off-the-shelf implant.

The two approaches differ substantially in their resource profile. The individualised approach requires preoperative computed tomography, which carries additional radiation exposure and diagnostic cost, as well as a manufacturing cycle that lengthens the interval to surgery and increases implant cost. The navigated approach requires no preoperative CT and uses a standard, considerably less expensive implant, but introduces additional intraoperative time for registration.

Direct comparison of the two approaches within a single methodology is sparsely represented in the literature. This gap motivated the present study, which compares individualised TKA using the Symbios Origin® implant with KNEE-PLAN® three-dimensional planning against computer-navigated TKA using the BBraun Columbus® system and the OrthoPilot® platform with restricted kinematic alignment. The central thesis is that the navigated approach with an off-the-shelf implant can achieve comparable functional results with lower radiation exposure, lower cost and a shorter logistical pathway for the patient.

3. AIM, OBJECTIVES AND WORKING HYPOTHESIS

3.1. Aim

The aim of the present study is to perform a comparative analysis of the accuracy of the achieved axial alignment and of the early clinical and functional results of two contemporary approaches to total knee arthroplasty: individualised TKA with the Symbios Origin® customised individually made implant and three-dimensional preoperative planning using KNEE-PLAN® software on the one hand, and computer-navigated TKA with the BBraun Columbus® system and the OrthoPilot® navigation platform applying restricted kinematic alignment on the other.

3.2. Objectives

1. To compare the achieved postoperative mechanical axis of the lower limb (HKA angle) between the two groups.
2. To assess the accuracy of execution relative to the preoperative plan (“plan versus reality”) for both methods.
3. To determine and compare the rate of outliers, defined within the framework of restricted kinematic alignment as residual deformity exceeding 5° in the direction of the preoperative axis or crossover to the opposite axis, allowing for a $\pm 1^\circ$ measurement tolerance.
4. To compare component positioning: frontal femoral angle (α), frontal tibial angle (β), tibial slope and femoral rotation.
5. To compare operative time between the two approaches.
6. To compare functional and clinical results — Oxford Knee Score, visual analogue scale for pain and range of motion — preoperatively and postoperatively, together with their changes.

7. To record and compare complications and revision rates in the two groups.
8. To compare the benefit-to-resource ratio (radiation exposure, cost, time) of the two methods in the context of the results achieved.

3.3. Working hypothesis

The working hypothesis is that computer-navigated TKA with restricted kinematic alignment achieves functional results (OKS, VAS, ROM) and alignment accuracy comparable to the individualised approach, with advantages in radiation exposure and cost. The null hypothesis assumes no statistically significant difference between the two groups in the functional measures; the alternative hypothesis assumes such a difference exists.

4. MATERIAL AND METHODS

4.1. Design, setting and period

A retrospective–prospective comparative study was conducted at the Clinic of Orthopaedics and Traumatology, St Marina University Hospital, Varna. The operations were performed between 2019 and 2024.

4.2. Patients, groups and unit of analysis

A total of 60 knees were analysed, allocated to two equal groups of 30 knees. The unit of analysis was the knee joint; in patients with bilateral arthroplasty each knee was included as a separate case.

Group 1 — Individualised TKA (IND, n = 30 knees): Symbios Origin® customised individually made implant, three-dimensional CT-based preoperative planning with KNEE-PLAN® software, single-use patient-specific instrumentation and personalised alignment (Origin Alignment©).

Group 2 — Computer-navigated TKA (NAV, n = 30 knees): standard BBraun Columbus® implant, intraoperative OrthoPilot® navigation applying restricted kinematic alignment, permitting up to 5° of varus–valgus deviation from the neutral axis in order to restore the natural kinematics of the knee.

Inclusion criteria: primary or post-traumatic gonarthrosis with an indication for primary TKA; age ≥ 18 years; available preoperative and postoperative follow-up with the required documentation. Exclusion criteria: revision TKA; active inflammatory or septic arthropathy; incomplete data for the primary measures.

4.3. Outcome measures and definitions

Alignment measures: postoperative HKA angle (180° = neutral mechanical axis; values below 180° indicate varus, above 180° valgus); residual deformity expressed as the absolute deviation from the neutral axis; frontal femoral angle (α) and frontal tibial angle (β); tibial slope; femoral rotation. For Group 1 the frontal component angles were derived from the corresponding femoral and tibial mechanical angles, equivalent to the α/β values measured by OrthoPilot® in Group 2.

Outlier definition: a knee was classified as an outlier if the postoperative residual deformity exceeded 5° in the direction of the preoperative axis, or if crossover to the opposite axis occurred. Given measurement by infrared sensors, a $\pm 1^\circ$ technical tolerance was accepted; accordingly, for a preoperatively varus knee an outlier was defined as postoperative HKA $< 174^\circ$ or $> 181^\circ$, and for a preoperatively valgus knee as HKA $> 186^\circ$ or $< 179^\circ$.

Functional measures: Oxford Knee Score on the current 0–48 scale, on which a higher value corresponds to better function; visual analogue scale for pain 0–10; range of motion in degrees, measured goniometrically as the difference between maximal flexion and extension deficit.

4.4. Data sources

Data for Group 2 were extracted from the operative protocols of the OrthoPilot® system. Data for Group 1, as well as the radiographic measures for both groups, were collected from hospital records and imaging. Functional measures were collected during a single postoperative telephone interview using a standardised questionnaire. At the same interview patients were also asked about their condition immediately before surgery; the preoperative OKS and VAS values therefore represent retrospective self-assessment rather than prospectively documented measurement.

4.5. Statistical analysis

Descriptive statistics are presented as mean $\pm$ standard deviation for normally distributed variables and as median with interquartile range otherwise. Normality was assessed with the Shapiro–Wilk test. Between-group comparisons used the independent Student t-test or the Mann–Whitney test; categorical variables were compared with the χ^2 test or Fisher’s exact test. Within-group comparisons used the paired t-test or the Wilcoxon test. Effect sizes were calculated (Cohen’s d; rank-biserial coefficient r). The significance threshold was $p < 0.05$.

4.6. Ethical considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki. Approval was obtained from the Research Ethics Committee of Medical University — Varna, Protocol No 12 of 27 March 2025. All patients provided written informed consent.

5. RESULTS

5.1. Baseline characteristics

The two groups were comparable with respect to sex, operated side, diagnosis, ASA distribution, type of deformity and preoperative HKA angle. Significant differences were found in age (younger patients in the IND group) and in follow-up duration (considerably longer in the IND group).

Variable	IND (n=30)	NAV (n=30)	p
Age (years), Me [IQR]	61.0 [57–66]	69.5 [65–74]	<0.001
Sex (male/female)	17/13	11/19	0.195
Side (left/right)	17/13	15/15	0.796
Diagnosis (primary OA / post-traumatic)	27/3	30/0	0.237
ASA (I/II/III/IV)	1/15/13/1	3/14/7/6	0.093
Deformity (varus/valgus/neutral)	25/4/1	24/6/0	1.000
Preoperative HKA (°), mean±SD	172.6±6.2	174.7±6.8	0.215
Follow-up (months), Me [IQR]	72 [72–81]	12 [12–24]	<0.001

Table 1. Baseline characteristics of the two groups.

5.2. Postoperative axial alignment

The achieved axial alignment was comparable between groups in median postoperative HKA angle, residual deformity and outlier rate. One outlier was recorded in the NAV group and none in the IND group.

Variable	IND	NAV	p
Postoperative HKA (°), Me [IQR]	178.0 [177–180]	179.0 [177–181]	0.714
Residual deformity (°)	2.0 [0–3]	1.5 [1–4]	0.361
Outliers (rKA, ±1° tol.), n (%)	0/30 (0%)	1/30 (3.3%)	1.000
Femoral α (°)	90 [90–92]	89 [88–91]	0.044
Tibial β (°)	88 [88–88]	90 [89–90]	<0.001
Tibial slope (°)	5 [3–5]	3 [2–3]	<0.001
Femoral rotation (°)	3 [3–3]	2 [1–3]	<0.001

Table 2. Postoperative axial alignment and component positioning.

The component angle values for the IND group represent the planned (nominal) targets generated by KNEE-PLAN® rather than independently measured postoperative values. The observed differences reflect the differing alignment philosophies and should not be interpreted as a difference in the quality of execution.

The relationship between preoperative and achieved alignment separates the two approaches more sharply than the group means do. Under the individualised approach the postoperative HKA angle follows the preoperative one almost linearly ($r = +0.94$; $R^2 = 0.88$), whereas under the navigated approach the relationship is weak ($r = +0.39$; $R^2 = 0.15$); the difference between the two correlation coefficients is statistically significant (Fisher $z = 4.83$; $p < 0.001$). The regression slope of achieved correction on baseline deformity is 0.93 for the navigated and 0.72 for the individualised approach, meaning that roughly one quarter of the constitutional deformity is deliberately preserved by the latter. Comparability of the group means therefore does not imply a comparable approach to the individual knee.

5.3. Functional and clinical results

Variable	IND	NAV	p
Postoperative OKS, Me [IQR]	45.5 [44–46]	45.5 [44–47]	0.504
ΔOKS	29.5 [28–31]	30.5 [29–32]	0.048
Postoperative VAS	0 [0–0]	0 [0–1]	0.050
ΔVAS	–9.0 [–9––8]	–9.0 [–10––9]	0.066
Postoperative ROM (°)	110 [110–140]	110 [110–138]	0.929
ΔROM (°)	35.0 [10–50]	20.0 [10–50]	0.450

Table 3. Functional results — between-group comparison.

Variable	IND	NAV
OKS	15.5 → 44.3 (Δ+28.7; $p < 0.001$)	14.6 → 45.0 (Δ+30.4; $p < 0.001$)
VAS	8.8 → 0.3 (Δ–8.4; $p < 0.001$)	9.4 → 0.4 (Δ–9.0; $p < 0.001$)
ROM (°)	85.7 → 121.7 (Δ+36.0; $p < 0.001$)	91.0 → 121.3 (Δ+30.3; $p < 0.001$)

Table 4. Within-group change (preoperative → postoperative).

Both groups demonstrated large and statistically significant within-group improvement across all three functional measures. Between groups the results were comparable: postoperative OKS and ROM were essentially superimposable. The statistically significant difference in Δ OKS of approximately one point lies well below the minimal clinically important difference of about 5 points and should not be interpreted as a clinical advantage of either method.

5.4. Operative time

Operative time was significantly shorter in the IND group (77.5 ± 16.0 min versus 98.3 ± 31.5 min; $p = 0.002$; Cohen's $d = -0.83$), reflecting the shorter intraoperative workflow afforded by patient-specific instrumentation compared with intraoperative navigation registration.

In the NAV group a statistically significant negative linear relationship was found between case sequence and operative time ($\beta = -1.41$ min per case; 95% CI $[-2.69; -0.14]$; $R^2 = 0.156$; $p = 0.031$); rank correlation confirmed the finding ($\rho = -0.433$; $p = 0.017$). Mean operative time fell from 117.8 ± 33.0 min in the first tertile to 83.2 ± 28.2 min in the third — a relative reduction of 29.4% ($p = 0.022$; $d = 1.13$). CUSUM analysis placed the inflection point at approximately the tenth case. This finding describes a learning curve and indicates that the difference in operative time between the two methods is partly dependent on accumulated experience with the navigation platform.

No such relationship was found in the individualised group ($\beta = -0.24$ min per case; 95% CI $[-0.94; +0.45]$; $p = 0.481$), consistent with the transfer of planning to the preoperative stage and with an intraoperative workflow predetermined by the patient-specific instrumentation.

5.5. Agreement between plan and execution

The operative protocols of the OrthoPilot® system record both the intraoperatively set targets and the achieved values, permitting a direct assessment of execution accuracy in the navigated group by the method of Bland and Altman. Mean deviation of achieved from planned value was $-0.57 \pm 1.45^\circ$ for the frontal femoral angle (93% of knees within $\pm 2^\circ$), $+0.61 \pm 1.31^\circ$ for the frontal tibial angle (all knees within $\pm 3^\circ$) and $-0.03 \pm 1.02^\circ$ for tibial slope (all knees within $\pm 2^\circ$).

The deviation in HKA angle ($-1.13 \pm 2.64^\circ$) requires separate interpretation: the planned value was recorded as 180° in every case and represents the neutral mechanical reference rather than the individual kinematic target. The observed deviation therefore expresses the magnitude of deliberately permitted restricted kinematic deviation, not inaccuracy of execution.

The femoral component was distributed evenly across sizes 4, 5 and 6 (nine knees each), and a 10 mm polyethylene insert was used in 27 of 30 knees. Femoral size differed significantly between the sexes ($p = 0.004$), consistent with the expected anthropometric difference.

5.6. Complications, revisions and follow-up

No perioperative complications or revision procedures were recorded in either group within the follow-up period (0/30 versus 0/30; $p = 1.000$). Follow-up was considerably longer in the IND group (median 72 versus 12 months).

Variable	Test	Effect size	p
Postoperative OKS	Mann–Whitney	$r = 0.10$	0.504
Δ OKS	Mann–Whitney	$r = 0.30$	0.048
Postoperative ROM	Mann–Whitney	$r = 0.01$	0.929
Postoperative HKA	Mann–Whitney	$r = 0.06$	0.714
Operative time	t-test	$d = -0.83$	0.002

Table 5. Effect sizes and tests applied for the key measures.

6. DISCUSSION

6.1. Principal findings

The principal finding is that both methods achieve comparable early functional results and comparable accuracy of axial alignment, with a significant advantage for the individualised approach in operative time and an advantage for the navigated approach in radiation exposure and cost. This is consistent with the working hypothesis and supports the thesis that comparable clinical results can be achieved with an off-the-shelf implant at a lower resource burden.

6.2. Accuracy of axial alignment

The low outlier rate in both groups is consistent with published data indicating that both patient-specific instrumentation and computer navigation reduce the proportion of alignment deviations compared with conventional mechanical technique. An important methodological point is that the definition of an outlier depends critically on the chosen reference frame. Under mechanical alignment an outlier is conventionally defined as deviation greater than 3° from the neutral axis; applying that definition to a kinematically aligned group would artificially inflate the outlier rate, since the neutral axis is not the target in that framework. The present study therefore applied a definition consistent with the philosophy of restricted kinematic alignment.

6.3. Functional results and clinical comparability

The very large mean change in OKS (approximately 29–30 points) warrants particular attention, as it substantially exceeds the typically reported value of about 16–20 points. The principal explanation is methodological: preoperative values were not documented before surgery but obtained retrospectively by patient recall during the postoperative telephone interview. Such a data

collection design systematically depresses the retrospectively rated baseline and correspondingly inflates the calculated within-group difference. The primary radiographic measures are unaffected by this limitation.

6.4. Restricted kinematic alignment

Restricted kinematic alignment occupies a position between two poles: pure kinematic alignment, which restores the pre-arthritis axis without constraint, and mechanical alignment, which imposes a neutral axis irrespective of individual anatomy. Constraining deviation within a predefined corridor seeks to combine the benefits of kinematic restoration with safety in respect of implant longevity. The present results support the clinical rationale of this balanced approach.

6.5. Operative time, radiation exposure and cost

From a health-economic perspective, the comparability of functional results shifts the focus to the resource profile of the two methods. Preoperative computed tomography entails additional radiation exposure and diagnostic cost, while manufacture of a patient-specific implant entails higher cost and a production cycle that lengthens the interval to surgery. The navigated approach eliminates preoperative CT and uses a standard, less expensive implant. The learning curve identified here further indicates that the difference in operative time is not a fixed property of the method but diminishes with accumulated experience.

6.6. Limitations

The study has substantial limitations. First, baseline differences exist between the groups — longer follow-up and younger age in the IND group. The difference in follow-up (median 72 versus 12 months) is particularly important and requires caution in directly comparing functional outcomes; it means that the observed

comparability is valid for the early postoperative period only. Second, the analysis is at knee level, so bilaterally operated patients introduce within-patient dependence. Third, the sample size limits statistical power. Fourth, preoperative functional values are retrospective self-assessment. Fifth, the component angles for the IND group are planned rather than independently measured postoperatively. An external limitation is the absence of a national arthroplasty register in Bulgaria, so all comparisons are made against published international series.

7. CONCLUSIONS

1. The achieved postoperative axial alignment (HKA) is comparable between individualised and navigated TKA, with no statistically significant difference.
2. The comparability of the group mean HKA values is achieved through different mechanisms: under the individualised approach the postoperative axis follows the preoperative one ($r = +0.94$), whereas under the navigated approach it is corrected towards neutral ($r = +0.39$). The difference between the two correlation coefficients is statistically significant ($p < 0.001$), showing that comparable means do not imply a comparable approach to the individual knee.
3. Both methods provide high accuracy of execution relative to the preoperative or intraoperative plan, with essentially complete correspondence in the individualised approach.
4. The outlier rate, defined within the framework of restricted kinematic alignment, is low and comparable between groups (0/30 versus 1/30).
5. The differences observed in the nominal targets for component positioning (β , slope, rotation) reflect the differing alignment philosophies; they do not represent a measured difference in achieved positioning, since the values for the IND group are planned rather than independently measured postoperatively.
6. Operative time is significantly shorter in the individualised approach (77.5 ± 16.0 versus 98.3 ± 31.5 min; $p = 0.002$). A statistically significant learning curve was documented in the navigated group ($\beta = -1.41$ min per case; $p = 0.031$), with a 29.4% reduction between the first and third tertile and an inflection at approximately the tenth case, which was absent in the individualised group ($p = 0.481$). The observed difference is

therefore partly a function of accumulated experience rather than wholly a property of the technique.

7. Functional results (OKS, VAS, ROM) are comparable between the two groups, with marked and significant within-group improvement and no clinically important between-group differences.
8. No complications or revisions were recorded in either group within the follow-up period.
9. Given comparable functional results, the navigated approach with an off-the-shelf implant offers advantages in radiation exposure and cost, supporting the central thesis of the dissertation.

8. CONTRIBUTIONS OF THE DISSERTATION

Original contributions

1. For the first time in Bulgaria, a direct comparison was performed between individualised TKA using a customised individually made implant with three-dimensional CT-based planning and computer-navigated TKA with restricted kinematic alignment, within a single methodology, by a single surgical team and at a single clinical centre.
2. The difference between the two approaches in preservation of the constitutional axis was quantified and statistically demonstrated ($r = +0.94$ versus $r = +0.39$; Fisher $z = 4.83$; $p < 0.001$; regression slopes 0.72 versus 0.93). It was shown that comparability of the group mean HKA values does not imply a comparable approach to the individual knee.
3. A clinically meaningful outlier definition was introduced and applied, consistent with the philosophy of restricted kinematic alignment and with the technical tolerance of navigation measurement, in place of the conventional definition relative to the neutral mechanical axis.

4. The learning curve in navigated TKA was documented and quantified through regression, rank-correlation and CUSUM analysis, together with the absence of such a curve in the individualised approach.
5. Agreement between intraoperatively set targets and achieved values was assessed by the method of Bland and Altman, with methodological separation of the HKA deviation, which reflects deliberately permitted deviation rather than inaccuracy of execution.

Confirmatory contributions

6. The low rate of alignment deviation was confirmed for both patient-specific instrumentation and computer navigation.
7. The comparability of early functional results between contemporary alignment algorithms was confirmed, with marked within-group improvement in both groups.
8. The distinction between statistical and clinical significance in small samples was demonstrated: the only significant functional difference lies well below the minimal clinically important difference.
9. The anthropometrically determined difference in femoral component size between the sexes was confirmed ($p = 0.004$).

Contributions of applied value

10. The applicability of navigated TKA with restricted kinematic alignment and an off-the-shelf implant as a resource-efficient alternative with comparable early functional results was substantiated.
11. Recommendations for clinical practice were formulated that take into account not only alignment accuracy but the overall resource profile of the method.

12. The identified inflection of the learning curve at approximately the tenth case provides a practical benchmark for institutions introducing navigated arthroplasty.
13. Bulgarian-language preoperative and postoperative questionnaires for recording OKS and VAS were prepared and introduced.

9. RECOMMENDATIONS FOR CLINICAL PRACTICE

The choice of method for TKA should take into account not only the accuracy of alignment but the overall resource profile — radiation exposure, cost and the logistical pathway for the patient. Navigated TKA with restricted kinematic alignment may be regarded as a fully adequate alternative in patients for whom avoidance of preoperative computed tomography and of higher implant cost is preferred. A prospective randomised study is recommended, with groups balanced for follow-up duration, predefined non-inferiority margins and a formal health-economic analysis.

10. PUBLICATIONS AND SCIENTIFIC PRESENTATIONS RELATED TO THE DISSERTATION

Publications:

1. Grigorov V, Dobrilov S, Mihov K, Zagorov M. [Functional knee phenotypes in young patients with osteoarthritis]. *Medicine and Sport*. 2022;(1):20–23. Bulgarian.
2. Grigorov V, Dobrilov S, Ivanov S, Krastev V. Functional outcomes from the early postoperative period in patients undergoing 3D preoperatively planned and computer-navigated total knee arthroplasty. *Journal of IMAB*. 2024;30(Suppl 3):79–82.

3. Grigorov V, Dobrilov S, Ivanov S, Ivanov K, Nenova G. Role of sonication in PJI. *Journal of IMAB*. 2024;30(Suppl 3):91–94.

Scientific presentations:

1. Functional outcomes from the early postoperative period in patients undergoing 3D preoperatively planned and computer-navigated total knee arthroplasty. 14th South-East European Conference “Infections and Cancer”, Ohrid, North Macedonia, 3–6 October 2024.
2. Role of sonication in PJI. 14th South-East European Conference “Infections and Cancer”, Ohrid, North Macedonia, 3–6 October 2024.

