

STATEMENT

on a dissertation submitted for the award of the educational and scientific degree “Doctor”

Author of the dissertation: Veselin Vladislavov Grigorov

Title of the dissertation: PREOPERATIVE PLANNING IN TOTAL KNEE ARTHROPLASTY

Member of the scientific jury: Assoc. Prof. Vladimir Stefanov, MD, PhD Military Medical Academy, Sofia

appointed by Order No P-109-287/03.08.2026 of the Rector of the Medical University “Prof. Dr. Paraskev Stoyanov” – Varna

The dissertation submitted comprises 101 standard typewritten pages, illustrated with 12 tables and 23 figures. The bibliography includes 212 literature sources, of which 2 in Cyrillic and 210 in Latin script. The doctoral candidate's academic supervisor is Assoc. Prof. Svetoslav Lachezarov Dobrilov, MD, PhD.

The study was carried out at the Clinic of Orthopaedics and Traumatology of “St. Marina” University Hospital – Varna, on operative material from the period 2019–2024. The dissertation was discussed and referred for defence at a meeting of the Departmental Council of the Department of Orthopaedics and Traumatology at the Medical University “Prof. Dr. Paraskev Stoyanov” – Varna, under Protocol No 83 of 27.02.2025.

Relevance of the problem addressed in the dissertation in scientific, applied-scientific and applied terms. Degree and levels of relevance of the problem and of the specific tasks developed in the dissertation.

The dissertation addresses a problem that today stands at the very centre of knee arthroplasty: how the operation is to be planned and to how the knee is to be aligned. Total knee arthroplasty is among the most successful orthopaedic interventions, yet a persistently high proportion of operated patients remain dissatisfied with the functional result despite a radiographically impeccable operation. It is precisely this discrepancy between technical success and subjective outcome that sustains the interest in precise preoperative planning.

Over the past two decades the notion that the neutral mechanical axis is a universal target has been seriously challenged. The systematisation of anatomical variability – the functional phenotypes of Hirschmann and the CPAK classification of MacDessi – has shown that a substantial part of the population has constitutional varus or valgus alignment, the forcible correction of which to 180° disturbs the soft-tissue balance. From this derive both kinematic and restricted kinematic alignment. The two approaches compared in this work are familiar to me from my own practice as well – I have published articles about total knee arthroplasty performed with patient-specific cutting guides, on the application of computer technology in knee surgery, as well as on the individualisation of knee arthroplasty. For that reason I regard the choice of topic as an accurate one: the choice between these two paths is made daily in the operating theatre, yet it is rarely made with the support of comparable data.

The applied value of the work is greater still. The two approaches compared – a custom-made implant with three-dimensional computed-tomography planning on the one hand, and computer navigation with a standard implant on the other – differ substantially in their resource profile: preoperative computed tomography with additional radiation exposure, a manufacturing cycle and implant cost, as against additional intraoperative registration time. In the conditions of Bulgarian healthcare this question is not an abstract one, and in the absence of a national joint arthroplasty registry in this country every properly followed-up series of one's own carries independent value. The relevance of the problem and of the tasks addressed is beyond doubt.

Degree of familiarity with the state of the problem and creative interpretation of the literature review.

The literature review is built upon 212 sources, of which 210 in Latin script, which means that the doctoral candidate stands on the current international literature. The review follows a logical sequence – from the anatomy and biomechanics of the knee joint, through the evolution of alignment concepts, to the contemporary technological means of achieving the planned axis – and corresponds fully to the topic.

I value the fact that the candidate does not confine himself to describing the two classifications but uses them as an argument: both the functional phenotypes and the CPAK matrix arise from one and the same observation, namely that the neutral mechanical axis does not represent a universal norm. From there the review leads naturally to the working thesis of the dissertation. The information gap which the work fills is also clearly formulated: a direct comparison between maximal preoperative personalisation and intraoperative navigation within a single methodology is poorly represented in the literature.

Correspondence between the chosen research methodology, the aim and tasks of the dissertation, and the contributions achieved.

The aim – a comparative analysis of the accuracy of the achieved axial alignment and of the early clinical and functional results in individualised and in computer-navigated total knee arthroplasty – is clearly formulated and clinically significant. Eight tasks have been defined to achieve it, covering axial alignment, conformity with the plan, the rate of outliers, component positioning, operative time, functional results, complications, and the benefit-to-resource ratio. The working hypothesis is correctly formulated, with a clear distinction between the null and the alternative hypothesis – something encountered in dissertations in our speciality less often than it ought to be.

The material comprises 60 knees allocated to two equal groups of 30: individualised arthroplasty with a Symbios Origin® implant and KNEE-PLAN® planning, against navigated arthroplasty with the BBraun Columbus® system and the OrthoPilot® platform with restricted kinematic alignment. The inclusion and exclusion criteria are clearly defined, and the operations were performed by a single team in a single centre.

I consider it methodologically sound that the outlier has been defined in accordance with the philosophy of restricted kinematic alignment rather than with respect to the neutral mechanical axis. Applying the conventional 3° definition relative to 180° to a kinematically aligned group would artificially inflate the proportion of deviations, since the neutral axis is simply not the target there. Accounting for the $\pm 1^\circ$ technical tolerance of infrared measurement completes this correctness. The statistical processing is adequate to the nature of the data – normality tested by Shapiro–Wilk, the Mann–Whitney test and Student's t-test, χ^2 and Fisher's exact test, paired comparisons by Wilcoxon, calculated effect sizes, and, for the agreement between planned and achieved values, the method of Bland and Altman. The chosen methodology corresponds fully to the stated aim and tasks.

Scientific and applied-scientific contributions of the dissertation:

Thirteen contributions are defined in the dissertation, classified as original, confirmatory and applied. I accept them in full. I would single out the following:

For the first time in Bulgaria, a direct comparison has been carried out between individualised arthroplasty with a custom-made implant and computer-navigated arthroplasty with restricted kinematic alignment within a single methodology, with a single operating team and in a single clinical centre. In the absence of a national registry this constitutes a genuine point of reference for Bulgarian practice.

I rate particularly highly the second contribution, which in my view is also the most valuable element of the entire work. It has been established that the two approaches achieve comparable mean values of the postoperative HKA angle, but by fundamentally different means: with the individualised approach the postoperative axis follows the preoperative one almost linearly ($r = +0.94$), whereas with the navigated approach it is corrected towards the neutral axis ($r = +0.39$), the difference between the two correlation coefficients being statistically significant (Fisher $z = 4.83$; $p < 0.001$). The conclusion that comparability of group mean values does not mean a comparable approach to the individual knee is precisely formulated and bears directly on the way we read comparative series in this field. The regression slopes – 0.93 against 0.72 – quantitatively demonstrate that with the individualised approach approximately one quarter of the constitutional deformity is deliberately preserved.

The documentation of the learning curve in navigated arthroplasty by means of regression, rank-correlation and CUSUM analysis is a contribution of immediate practical value. The established 29.4% reduction in operative time between the first and the third tertile of cases, and the inflection point around the tenth case, provide a concrete point of reference for any department introducing navigation. Equally substantial is the observation that no such curve exists with the individualised approach – which is logical, given that planning there is moved to the preoperative stage.

I also value the distinction drawn between statistical and clinical significance. The only significant functional difference – approximately one point in Δ OXS – is declared by the author himself to be several times below the minimal clinically important difference and is not presented as an advantage of either method. Such restraint is a mark of scientific integrity.

Applied value attaches also to the Bulgarian-language preoperative and postoperative questionnaires developed and introduced for recording OKS and VAS, as well as to the substantiation of navigated arthroplasty with an off-the-shelf implant as a resource-efficient alternative with comparable early results.

Assessment of the publications related to the dissertation

The publications reflect and form part of the dissertation. Three publications related to the topic are presented: on the functional phenotypes of knee joints in young patients with osteoarthritis (Medicine and Sport, 2022) and two in the Journal of IMAB (2024) – on the early functional outcomes of three-dimensionally planned and computer- navigated arthroplasty, and on the role of sonication in periprosthetic joint infection. To these are added four further publications on related subject matter. The publication activity demonstrates a sustained interest of the author in the subject under consideration and meets the requirements for the award of the educational and scientific degree “Doctor”.

I make two remarks of a technical nature. The first is that the 2026 publication “Computer-Navigated versus Individual Total Knee Replacement: A Retrospective Study” is listed among the other publications, although by its content it relates directly to the topic of the dissertation; I would recommend that it be moved to those related to it. The second is that in the list of publications the two Journal of IMAB articles are given with identical page numbers and an identical DOI, which is evidently a transcription error.

Opinion, recommendations and remarks

My opinion of the dissertation presented is that it addresses a topical problem of contemporary orthopaedics and traumatology and resolves it with a well-chosen methodological apparatus. The work rests on the author's own clinical material, and the conclusions are not overstated – where the data show no advantage, the author does not attempt to prove one. I shall note expressly that the limitations of the study are set out openly and accurately, including those that do not favour the author's own thesis. Such honesty towards one's material is rarer than we should wish.

I have the following remarks on the work, which are of a methodological and technical nature and do not alter the conclusions drawn:

The two groups differ substantially in follow-up period – a median of 72 against 12 months. Since the operations span the period 2019–2024, this means that the groups also fall within different calendar periods, so that the comparison carries with it the difference in the team's general experience over those years. The learning curve established in the navigated group supports this possibility. I would recommend that the matter be discussed explicitly as a possible confounder, and that the conclusion of comparability be referred clearly to the early postoperative period.

The unit of analysis is the knee joint, with each knee of bilaterally operated patients included as a separate case. The number of patients, however, is nowhere stated, and with it the number of bilateral cases, which determines the weight of the within-patient dependence. I would recommend that these figures be added.

In the section on agreement between planned and achieved values, the femoral component is described as evenly distributed across sizes 4, 5 and 6 with nine knees each, which amounts to twenty-seven out of thirty. The distribution should be completed.

The opinion of the Ethics Committee bears Protocol No 12 of 27.03.2025, while the Departmental Council referred the work for defence under Protocol No 83 of 27.02.2025. The chronology of the two documents merits clarification, including with regard to the retrospective part of the material.

As a recommendation for future work I would fully endorse what the author himself proposes – a prospective study with groups balanced for follow-up period and with pre- defined non-inferiority margins, supplemented by a formal pharmacoeconomic analysis. To this I would add follow-up of the present cohort beyond the fifth year: it is precisely there that the question is expected to arise whether the deliberate preservation of the constitutional axis affects implant longevity.

Conclusion with a clear positive or negative assessment of the dissertation

The dissertation meets the requirements of relevance and applicability, contains the necessary scientific and applied-scientific achievements and is correctly presented, which gives me categorical grounds to give a positive assessment of the dissertation of Dr Veselin Grigorov submitted to me for opinion.

The work meets the requirements of the Act on the Development of the Academic Staff in the Republic of Bulgaria, of the Regulations for its implementation and of the Regulations on the Development of the Academic Staff of the Medical University “Prof. Dr. Paraskev Stoyanov” – Varna, and I therefore propose to the esteemed scientific jury that the author, Dr Veselin Vladislavov Grigorov, be awarded the educational and scientific degree “Doctor”.

15.09.2026 Sofia

Member of the jury:

/ Assoc. Prof. Vladimir Stefanov, MD, PhD /

Заличено на основание чл. 5,
§1, б. „В“ от Регламент (ЕС)
2016/679