

## STATEMENT

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**Subject:** defense of the dissertation of Dr. Biser Alexandrov Makelov, entitled "**One-staged externalized locked stabilization in the treatment of unstable proximal metadiaphyseal tibial fractures**" for the award of the educational and scientific degree "Doctor".

By the order of the Rector of Medical University of Varna № R - 109-511 / 29.11.2021 I was appointed as a member of the Scientific Jury and by the decision of the latter (Protocol №1 of 30.11. "Health and Sport" in professional field 7.1 "Medicine" and doctoral program "Orthopedics and Traumatology".

Unstable proximal tibial fractures with metadiaphyseal involvement are still a persistent problem in clinical practice due to the complexity of the injury, the high-energy nature of the injury, and the multiple comminutions. In the light of increasing urbanization and the increasing incidence of automobile and domestic trauma, these injuries tend to increase in frequency. This necessitates the need for a therapeutic algorithm , which is clinically and theoretically sound.

Polytrauma patients with the fractures described above require both a soft tissue sparing approach and stable fracture fixation. External fixators are the gold standard in the treatment of this pathology however, the equipment and surgical technique for their placement are often challenging. One-staged locked externalized stabilization offers a valuable alternative to this. The method is based on the application of indirect reduction techniques and definitive metadiaphyseal tibial stabilization with an externally placed locked plate. The undisputed innovation of the technique makes the dissertation work relevant in both clinical , and social aspects.

On the basis of clinical material and a generated three-dimensional biomechanical simulation model by the finite element method, a method of treatment of unstable tibial fractures with metadiaphyseal localization based on the principles of biological fixation is applied and analyzed.

**Compliance with Article 61(3).1. of the Regulations for the Development of the Academic Staff at MU-Varna - "Requirements for a Dissertation for the Acquisition of a PhD".** The dissertation is presented according to the usual structure for this type of theses in 178 pages, 20 tables and 83 figures (which include the graphs). It includes an introduction ( 4 pages), a literature review (46 pages), a bibliography (10 pages with 8 titles in Cyrillic and 171 in Latin). In the remainder of the dissertation, Dr. Makelov articulates the purpose and resulting four objectives, the study's contingent, the clinical methodology of the study and the surgical technique and postoperative protocol used, the treatment, the authors' own results, analysis, and conclusions. The thesis also includes 5 pages of contributions, a list of own publications in Bulgarian and international journals.

**The literature review** is detailed with a focus on the issues of metadiaphyseal tibial comminution and soft tissue status. The anatomical notes are presented in a concise and focused manner , without overloading the literature analysis. The emphasis on the reparative process at the cellular level is also noteworthy, which adds to the analytical value of the dissertation.

**The aim** is clearly stated - "To investigate the feasibility and evaluate the results of the application of one-stage external stabilization with locking plates in the treatment of unstable metadiaphyseal tibial fractures". The four objectives are specific, well defined and feasible. They correlate directly with the stated objective.

The dissertant used a series of 26 surgically treated patients with unstable tibial fractures in the period 2013 - 2021 in the Department of orthopedics at the University Hospital "Prof. Dr. Stoyan Kirkovich AD", Stara Zagora. The follow-up period was up to 5 years, and 18 patients were followed up during this period. The dissertant used the generally accepted AO classification as a working one. This makes it easy to classify the cases and analyze the collected data. The latter were handled statistically clearly and visually. Diagnostically, the dissertation mainly used radiographs and in individual cases CT scans. This is, in my opinion, a certain omission, especially as regards complex injuries and their analysis. It would be good if this were the main diagnostic tool in further analysis of such pathology. The dissertator notes the importance of angiographic examination, but there is no data on whether it is a standard examination or only in individual cases with soft tissue involvement.

Angle-stabled plates were mainly used as follows: in 9 pts. - LISS DF, in 2 pts. - LCP-broad/narrow, in 1sc. - LCP-PT - contralateral plates, LISS DF - contralateral plate in 6 sbl.

A protocol of postoperative management and follow-up with radiographs up to 24 postoperative hours at the third, sixth and twelfth weeks and then at two-month intervals is presented. Supervised partial limb loading began most often after the 2nd postoperative day and full limb loading by the 12th postoperative week. Thromboembolic drug prophylaxis is performed in all patients. In this chapter there is a citation of literature and studies, which is not appropriate in the chapter "Methods and Materials"

For the purpose of the thesis, a computational model using the finite element method was developed in collaboration with the AO Research Institute Davos. Differences in the effect of one standard internal and two external fixations with a LISS DF metaphyseal locking plate on the stability and interfragmentary mobility in the fracture defect zone of a simulated unstable, multifragmentary fracture of the proximal tibia are simulated. Three different groups were modeled for comparison with different distances of the plate from the bone. The parameters monitored in the simulation were: construct stiffness, interfragmentary motion and longitudinal deformation in the fracture zone. I consider this to be a very serious positive of the thesis. This methodology has long been set as the gold standard in biomechanical analysis in Europe and the USA. This allows data to be reliably analysed in small study groups or pathology and data to be extrapolated to a larger scale.

The results of the experimental part and the clinical series of the study are correctly presented in Chapter VI. Functional assessment was performed using the HSS assessment systems for the knee joint and the AOFAS for the ankle joint. The time of onset of fracture union and the operative duration of the intervention were selected for clinical evaluation. Intragroup comparison was performed in four groups - Age below and above 50 years, proximal or distal fracture location, simple and complex fractures, and degree of soft tissue damage assessed by Gustilo scale. I can make here as a critical remark, the lack of a defined control group with another methodology used. This in addition with the finite element model would have added clinical value to the work. In this chapter all the analyzed values are presented in detail: HSS, knee and ankle joint range of motion, surgical time, etc. The dissertation also presents three more significant complications: a patient with refracture without osteosynthesis breakdown corrected with autosteoplasty and plate reversed dynamization, a patient with septic arthritis and subsequent knee extension contracture, due to infection along the course of the cannulated screws and severe concomitant soft tissue trauma and one with varus deformity, mild antecurvation in the fracture zone and subsequent flexion

contracture in the knee joint of 15° and shortening of the lower limb of more than 1.5 cm. respectively. In the light of the severe pathology, which is the subject of the dissertation this is fully understandable. The clinical cases that are presented in the thesis are visually documented and give a visual insight into the work of the thesis.

In the Chapter "Discussion", Dr. Makelov presents an extensive comparative analysis of his results on the topic under discussion with those of other authors who have worked on the problem. Here, a critical self-analysis of the work is made against refereed authors in both positive and critical aspects. It concludes with the shortcomings of the study - a small number of patients indicated for inclusion, a relatively short follow-up period and the lack of a control group of patients treated by alternative methods, necessary for comparison and evaluation of the final results. This, as I outlined above, is compensated by the analysis of the final elements, which is innovative for Bulgaria. I admire Dr. Makelov's idea for this analysis, which is still difficult by our standards, requiring remote collaboration and extremely intensive energy.

The penultimate chapter draws five important conclusions for practice from the dissertation, which is the logical conclusion of the work. The bibliography presented in the last chapter is arranged visually in alphabetical order.

To the scientific work of Dr. Biser Makelov submitted to me for review, I can point out the following more important contributions. They are of high scientific and practical value:

1. This is one of the few dissertations in orthopaedic science using an experimental model. The developed three-dimensional computational biomechanical model provides a scientifically sound conclusion regarding the favorable biomechanical conditions for indirect bone healing by one-staged locked externalized stabilization in unstable metadiaphyseal tibial fractures. This, in my opinion, is of exceptional value.

2. For the first time in the country, a follow-up study of one-staged locked externalized stabilization in the operative treatment of unstable tibial fractures was performed.

3. The clinical analysis allows to derive a practicable operative methodology, easy to perform and minimally invasive in the setting of polytrauma.

On the dissertation topic, the dissertant presented three publications, seven presentations and one scientific project and meet the requirements of Annex 1 of the Regulations for the Development of Academic Staff at MU-Varna. They contain separate parts of the developed material. The abstract of the dissertation submitted to me in the volume of 62 pages is formatted according to the generally accepted requirements.

In conclusion, the dissertation fully meets the qualitative and quantitative criteria set out in the Requirements for a Dissertation for the Degree of Doctor of Education and Science of the Regulations for the Development of Academic Staff at MU-Varna. Therefore, I give a **positive** assessment of the work and I kindly offer on the members of the Scientific Jury to award to Dr. Biser Aleksandrov Makelov, educational and scientific degree "DOCTOR" in the scientific specialty "Orthopedics and Traumatology".

13.01.2022 г.

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