

REVIEW

by **Assoc. Prof. Nedko Ivanov Dimitrov, Ph.D**

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Regarding dissertation on the topic:

“ONE-STAGED LOCKED EXTERNALIZED PLATING FOR THE TREATMENT OF UNSTABLE PROXIMAL METADIAPHYSEAL TIBIAL FRACTURES” with thesis supervisor Prof. Dr. Dimitar Raykov, M.D., Ph.D., DSc.

presented for defence before a scientific jury formed by order № R-109-511/29.11.2021 of the Rector of MU - Varna. I was appointed as a member of the scientific jury and by the decision of the latter (Protocol №1 of 30.11. 2021) I have been appointed to submit a review for the awarding a scientific and educational degree „Doctor“ on the dissertation of **Dr. Biser Aleksandrov Makelov**, an independent PhD - candidate in the scientific specialty "Orthopedics and Traumatology", at the Department of Orthopedics and Traumatology, Faculty of Medicine of Medical University ,Varna, professional field 7.1 "Medicine", 7. "Health and Sport".

The review complies with the requirements of the Academic Staff Development Act in the Republic of Bulgaria and the Regulations for its implementation.

Brief biographical information about the doctoral candidate

Dr. Biser Alexandrov Makelov is born on 06.07.1972 in the town of Sliven,Bulgaria. In 1991 he has graduated from the english language high school "Romain Rolland" Stara Zagora with honors. In 1997 he has graduated in medicine at the Medical Faculty of the Trakia University, Stara Zagora, and since 2004 he has been a recognized specialist in *orthopedics and traumatology*.

Dr Biser Aleksandrov Makelov is currently a teaching assistant professor since 2016 at the Department of Special Surgery of the Medical Faculty of Trakia University, Stara Zagora, and consultant at the Department of Orthopedics and Traumatology in University Hospital “Prof.dr.Stoyan Kirkovitch”, Stara Zagora. Over the years until the present moment he has continued his medical qualification by participating in numerous courses and seminars related to the principles of modern surgical treatment in *orthopedics and traumatology*.

Dr. Biser Makelov is a member of the BOTA, EORS, AO-trauma.

The topic of the dissertation is “Study and application of a new surgical technique - **One-Staged Locked Externalized Stabilization (OLES) in the treatment of unstable proximal metadiaphyseal tibial fractures (UPMTFs)**”. The author defines this technique as a combination of indirect repositioning and external bridging splinting with sparing of bony and soft tissue blood supply to achieve sufficient stability and axial alignment. The dissertator has justified his proposed method following a previously generated three-dimensional biomechanical simulation model in collaboration with scientist in AO Research Institute, Davos.

The thesis is structured in the usual way for a dissertation, respecting the ratios between sections. The dissertation has 177 pages, of which 11 pages are (without taken up by the) bibliography. The aim is on a single page and the 4 tasks are set by the author to achieve it. The next 165 pages contain the necessary sections - introduction, literature review, purpose and tasks, patients and methods, results and analysis, conclusion, summary points, contributions, bibliography. The thesis includes 20 tables and 83 high quality informative figures.

The aim of the work is formulated precisely and clearly: to investigate the possibilities and to evaluate the results of the application of one-stage externalized stabilization with locking plates in the treatment of unstable metadiaphyseal fractures of the tibia.

The four tasks set for its solution were accomplished and allowed the author to achieve it convincingly. The tasks are derived logically and clearly formulated from the aim: to perform a systematic review and critical analysis of the methods established for the treatment of unstable metadiaphyseal proximal tibial fractures; to investigate the biomechanical and biological aspects of locked external stabilization with LCP/LISS-DF plates by creating an experimental computational three-dimensional finite element model; to report, systematize and analyze the final clinical and functional outcomes; to present a comprehensive evaluation of the therapeutic effect of the proposed method for the treatment of unstable proximal tibia injuries when applied in the clinical practice.

First of all, I would note that the dissertation has been written very competently by someone who has gone deep into the problem posed.

The literature review is sufficiently extensive and allows those interested in the issue to gain sufficient information and knowledge. The subject of the thesis are 26 surgically treated patients with unstable tibial fractures in the Department of Orthopedics and Traumatology of the University Hospital "Prof. Dr. St. Kirkovich AD, Stara Zagora in the period from 2013 to 2021. Eighteen patients were followed up for up to 60 months from the time of application of the OLES. A standard

preoperative protocol was applied in all 26 patients, including: assessment of general and local status, type and localization of soft tissue injury, presence of open fracture, presence of joint dislocation, assessment of neurovascular status and symptoms of threatening acute compartment syndrome. An AP and lateral radiograph of the affected limb, including the knee and ankle joints was performed. CT scan for all intra-articular fractures was performed.

The surgical protocol included closed indirect reduction combined with percutaneous screw stabilization of the intra-articular component with subsequent 3D alignment of the limb in the coronal, sagittal and transverse planes and culminated in the externalized placement of the following locking plates:

LISS DF with 9, 11 and 13 holes; LCP-PT with 9 holes; LCP-broad/narrow with 12, 14 and 16 holes.

The presence of sufficient fracture union allows full weight-bearing of the limb for a month with plate left in place. In the absence of patient complaints, four weeks after controlled full weight bearing, without crutches and after new orthogonal radiographs, the plate was removed in an outpatient setting without anesthesia.

The author of this thesis inspired creation of a biomechanical computational model (FEA). The method is the basis on simulation software modeling and helps to find the weak points and areas of stress and strain distribution. In the present work, a virtual computer model based on CT scan data of a patient participant in the study, was generated to investigate the biomechanical parameters such as construct stiffness, interfragmentary motion and the degree of longitudinal deformation in the fracture zone in different implant configurations and plate-bone offsets.

The following statistical methods were used: descriptive analysis, graphical representations, normality test of distribution of quantitative changes and non-parametric statistical methods.

The results of the study are supported by highly informative graphical and tabular material. Functional assessment was performed using the HSS scoring systems for the knee joint and the AOFAS for the ankle joint in groups: at 4 weeks after surgery and at the final examination 1 month after removal of the locked externalized plate.

The clinical criterion for bone healing is painless full loading of the injured limb. Achieved bone union time averaged 20.7 weeks (12-28 weeks) for patients under 50 years and 20.9 weeks (16-29 weeks) for patients over 50 years. Fracture healing time was not statistically affected by age and fracture proximity. The complexity of the fractures was significant, with simple fractures healing shorter than complex ones.

Discussion of the results of the applied OLES technique, compared and supported by data from the literature, demonstrates Dr. Makelov's thorough training in the issues presented and understanding of

the limitations of his own study. The limitations of the present study are also shared: small number of patients, relatively short follow-up period and lack of a control group.

The following conclusions are logically drawn:

1. These fractures result from a high-energy traumatic mechanism, often combined with polytrauma, requiring emergency action for life-saving, when possible definitive fracture stabilization.
2. There is no one-size-fits-all approach that guarantees success and is accompanied by the fewest complications. Therefore, new alternative solutions are being sought that are safe for the patient and easy for the surgeon to implement.
3. Evolution of surgical methods towards minimizing soft tissue and fractured fragment damage from surgical techniques, as well as periosteum from direct contact with locked plate applied. Transition from absolute to relative fracture stability, from primary to secondary bone union, i.e., a method of biologic fracture stabilization.
4. Achieving natural bone healing with optimal interfragmentary motion using the OLES method.
5. Multifragmentary fractures with marked soft tissue injury, with or without associated multiple trauma, are indicated for OLES. Intra-articular fractures of the proximal tibia with fragmentation and impaction are relatively contraindicated.

The disadvantage of the OLES is the inability to correct the position after final locking the screws in the plate, the advantages are more: minimal soft tissue damage, low profile of the external locked plate, which makes it comfortable for the patient; one-stage treatment without immobilization of adjacent joints with the possibility of early mobilization; removal of the plate in outpatient clinics without anesthesia.

The contributions of the dissertation are confirmatory and original in nature and have a definite practical orientation.

Dr. Makelov submitted 3 publications on the dissertation topic (all of them meet the criteria for real publications). They were published in scientific journals meeting the minimum requirements for Area 7. Health and Sport, according to the Regulations for the Implementation of the Law on the Development of Academic Staff in the Republic of Bulgaria of 2020. They contain individual parts of the developed material. Separately, the dissertation has also been published in a journal with an IF as required in Annexes 3 and 4 of the RMPNSWASMUS.

The 62-page abstract of the dissertation submitted to me is formatted according to the requirements in Appendix 8 of the RMPNSZAMUS.

In conclusion: the dissertation submitted to me for review shows the ability of the dissertator to pose a scientific thesis, the methodology for its solution, his ability to select and process material, as well as to draw statistically reliable conclusions on a topical and specific topic - "**ONE-STAGE LOCKED EXTERNALIZED STABILIZATION IN THE TREATMENT OF UNSTABLE PROXIMAL METADIAPHYSARY TIBIAL FRACTURES**". The dissertation fully complies with the qualitative and quantitative criteria set out in the Requirements for a Dissertation for the Degree of *Doctor* of Education and Science of MU Varna. Due to this, and due to the fact that all the presented clinical material is entirely personally performed by Dr. Makelov surgical treatment, as well as the valuable scientific development of a simulation software model, I give *my positive evaluation* of the work and I offer to the members of the Scientific Jury to award to Dr. Biser Alexandrov Makelov, educational and scientific degree "DOCTOR" in the scientific specialty "Orthopedics and Traumatology".

Assoc.Prof. Dr. Nedko Dimitrov, M.D., Ph.D.



17. January 2022.

Stara Zagora