

POSITION

Prof. Dr. Andrei Marinovich Yotov, MD, DSc

Head of the Clinic of Orthopedics and Traumatology, UMHAT "Sofiamed"

With reference to: dissertation defense of Dr. Lyubomir Simenonov Rusimov on the topic : **„Intramedullary allograft augmentation in unstable proximal humerus fractures fixed with locking plate”** for the acquisition of the educational and scientific degree "Doctor" (Ph.D.)

I was determined to present a position by order № RD 26-524 / 14.02.2022 from the executive director of UMHATEM "N. I. Pirogov".

The dissertation is dedicated to a topical issue: improving the results in the treatment of one of the problematic nosologies in traumatology – unstable fractures of the proximal humerus. It is a well-known fact that the delicate balance between stability and mobility required for normal functioning of the shoulder joint is easily disturbed even by banal fractures, and in the case of displaced unstable ones, the traumatologist faces a wide range of diverse and intractable problems, which in case of inadequate treatment cause the corresponding serious complications - inaccurate repositioning of fragments, ineffective stabilization, secondary dislocations, debricolage, vicious consolidation, nonunion, avascular necrosis – all leading to unacceptable clinical and functional outcomes and even mutilation of patients. Not surprisingly, almost all surgical stabilization methods known in traumatology have been used with varying degrees of success on fractures of the proximal humerus. Cerclages, spokes and screws, conventional and other plates of different designs, intramedullary nails of several generations and various external fixing devices have been tried more or less successfully, but too often the end result has been deplorable, which in turn has led to expand the indications for primary and reconstructive shoulder arthroplasty and launch of increasingly complex and sophisticated models of total shoulder joints - anatomical and "reverse".

The stage that gave rise to the greatest hopes that a final solution to the problems with unstable fractures of the proximal humerus has been found is the development and practical

utilization of anatomically contoured locking plates. Indeed, from a biomechanical point of view, proximal humerus locking plates demonstrate a number of advantages, their use has been the subject of numerous studies, and their comparison with other implants presupposes their widespread use. Their popularity is such that they are beginning to be recklessly placed in any fractures at the proximal end of the humerus. The illusion that the locking plates themselves miraculously solve all the problems of any fractures in this area and the underestimation, often bordering on ignoring factors such as the quality of reposition and bone biology, naturally leads to a series of failures that cooled the initial enthusiasm.

The percentage of complications is growing to the point that doubts about the appropriateness of surgical fracture fixation are beginning to creep into the studies of a number of authoritative researchers. The search for a more innocuous treatment strategy leads to a certain renaissance of non-surgical treatment, even in unstable fractures, especially in elderly patients or those with lower functional requirements.

With regard to younger and active patients, in-depth analysis inevitably supports the conclusion that both conservative treatment and prosthetics are not able to solve the problem, not least due to the lack of predictability in terms of long-term outcomes. The current views rehabilitate osteosynthesis with anatomically shaped locking plates as the most effective means of achieving optimal results in the majority of patients, especially younger and active ones, but also older ones with increased functional requirements and expectations.

The understanding crystallized, that an implant functions optimally only with good reposition, which in turn supports the processes of revascularization and bone healing. Often in proximal humerus fractures, the more difficult task than achieving reposition is retaining it until bone healing. In bone with good mechanical properties and preserved biology and in more stable fracture configurations, properly implanted locking plates usually provide the necessary prerequisites for this, but, as a number of studies have shown, in displaced unstable fractures, especially those with age-related osteoporosis, locking plates themselves are not always sufficient to ensure stable fixation for a longer period and need additional augmentation both for mechanical strengthening of fixation and for biological stimulation of reparative processes, revascularization and bone and callus formation. Conventional methods for osteoplasty – autologous spongy grafts, as well as extramedullary cortico-spongy ones do not meet one of the main goals - mechanical augmentation of the synthesis and they can hardly count on success

In recent years, several biomechanical and clinical studies have demonstrated excellent results, combining the benefits of locking plates and the properties of intramedullary allograft.

The dissertation work of Dr. Lyubomir Rusimov is dedicated to the study of this avant-garde approach.

The main hypothesis to be confirmed in the course of the study is: accurate reposition in combination with properly placed angularly stable plate and intramedullary allograft achieve optimal biomechanical stability, improve the chances of consolidation in the right position and reduce the risk of developing AVN in unstable PHFs, prone to ischemia. The dissertation of Dr. Rusimov has a volume of 174 pages and 22 pages of bibliography. It is illustrated with 34 tables and 49 figures, graphics and photos. The bibliography includes 389 literature sources.

The studies were conducted in UMHATEM "N. I. Pirogov" and in the Department of Biomechanics at the AO Research Institute (Davos, Switzerland).

The paper is structured as standard and contains an introduction, aim, tasks, usual sections (literature review, patients and method, results and complications, discussion), conclusion, conclusions and bibliography.

In the chapter "Literature Review" the author presents in detail the anatomy and biomechanics of the shoulder, the pathomorphology and mechanism of trauma, its systematics, clinical and imaging diagnostics. The existing non-operative and surgical therapeutic methods and the results of their application are comprehensively presented. According to the nature of the work, special attention is paid to the methods of augmentation in the synthesis with a locking plate, to which a separate subsection is devoted.

The goal - "to test the construction of an intramedullary graft and a locking plate in the treatment of unstable and prone to ischemia fractures of the proximal humerus" - is clearly defined.

6 tasks have been set for its implementation. The tasks are adequately formulated, goal-oriented and realistic.

Section I - "Materials, Patients and Methods" includes two subsections.

Subsection 1.1. "Biomechanical experiment" contains the design, description and results of the experimental study conducted in the Department of Biomechanics at the AO Research Institute, Switzerland (AO Research Institute Davos), where Dr. Rusimov specialized. The experiment aims to study the biomechanical behavior of the construction of locking plate and intramedullary graft tested in a four-fragment fracture model and compare it with conventional fixation with LP. The experiment was conducted extremely strictly and

high-tech, its technical side is described in detail, the data obtained are meticulously collected and systematized and processed with modern statistical tools.

Subsection 1.2 "Clinical trial" contains the clinical part of the study conducted in the Specialized Traumatology Complex of UMHATEM "N. I. Pirogov ", and includes the clinical contingent consisting of 47 patients with displaced unstable fractures of the proximal humerus, operated with a locking plate and intramedullary allograft of frozen fibula or lyophilized tibia. The clinical series is large enough for statistically significant conclusions. The operative technique (surgical approaches, repositioning techniques, allograft shaping and positioning, placement of the locking plate) is presented and illustrated in great detail. All patients were followed-up for a period of 12-79 months.

Section III "Results and Complications" presents the results of the experimental study and the clinical trial. The correct and meticulous presentation of both experimental and clinical data is impressive. Objective radiological parameters were used to report the anatomical results - intraoperative and final follow-up neck-shaft angle, intraoperative and final follow-up height of the humerus head. Functional results are reported according to established and modern evaluation systems: Constant - Murley score test and DASH Score test. The analysis of the anatomical results shows a statistically significant difference in the mean intraoperative and final follow-up values of both the neck-shaft angle and the height of the humeral head. However, these differences, although statistically significant, are not related to clinically significant deviations and their presence is evidence of accuracy in quantifying measurable characteristics rather than imperfection of the approach itself. Functional results are perfectly acceptable in the three variants of the scale: the average value of the absolute Constant - Murley score test is satisfactory, and the average values of the relative and individual test fall into the column "good". The subjective evaluation of the result according to the DASH questionnaire is also good. Complications are reported honestly and correctly. Of particular interest in their analysis is the fact that although avascular necrosis (AVN) is expected to be the most common complication 13 (27.7%), its percentage is relatively low compared to prognosis: 22 (47%) of fractures in the study, demonstrate the three Hertel criteria at the same time, which predicts a 97% risk of developing AVN. The author convincingly demonstrates that the main factor for this is the high quality of reposition and the stability of the achieved fixation in the long run, reducing avascular risk even in the most unfavorable fracture configurations. This confirms Hertel's own observations that good repositioning and reliable fixation can lead to revascularization of the humeral head. I consider the establishment and proving of this dependence to be one of the most important

theoretical and scientific-practical contributions of the dissertation. Particular attention should be paid to other, less common complications (secondary dislocations, subacromial implantation, glenohumeral arthrosis and etc.) and for each of them the objective and subjective causal factors are thoroughly considered.

Chapter IV "Discussion" contains a thorough and in-depth analysis of the results, summarizing the author's views on the subject and comparing them with those of other authors who have worked on the problem.

The results of the study have been thoroughly analyzed and discussed. Own data are objectively compared with those in the literature.

The role of a number of factors determining the prognosis of surgical treatment is discussed in detail: the condition of the medial calcar support, reposition, concomitant osteoporosis, the use of tight tendon suture, the biomechanical role of the intramedullary allograft. Based on this, the indications and contraindications for surgical treatment are specified and author's own algorithm for optimal surgical technique is proposed, the mandatory elements of which are:

- anatomical reposition of the humeral head (in terms of height and medial cortex)
- restoration of the medial cortical support;
- proper insertion of the graft;
- parachute technique for tubercles;

The in-depth discussion concludes with a reasoned and reasoned conclusion that "Augmentation with intramedullary allograft in fixation with LP of PHFs prone to ischemia is based on solid biomechanical foundations. From a clinical point of view, it is predictable, safe and effective.

The dissertation ends with the chapter "Deductions". The deductions are 5, they are accurate, specific, related to the tasks, objectively reflect the results of the study and have both theoretical and practical value.

10 titles in connection with the dissertation are presented, meeting the Minimum National Requirements of the Regulations for the Implementation of the Academic committee Development, of which 3 are actual publications and 7 - reports at scientific forums. Two of the titles are national and 8 - foreign, in 8 of them Dr. Lyubomir Rusimov is the first author.

In the dissertation of Dr. Rusimov I can highlight the following contributions:

1. The mechanical properties of the construct of a locking plate and intramedullary graft were tested in a reference laboratory on a sufficient number of specimens and the construct was applied in the treatment of a large enough number of patients to create their own database.

2. An in-depth and detailed statistical analysis was performed on the dependence of the final results and complications in the application of the method on various factors: age of the patients; surgical technique; quality of the achieved reposition; type of allograft; local bone quality.

3. Based on the analysis of the results and complications, the optimal surgical technique was tested with an algorithm for achieving anatomical reposition in unstable and threatened with ischemia fractures of the proximal humerus.

4. For the first time, a retrospective analysis was performed on the dependence of the method as an organ-preserving in ischemic fractures of the proximal humerus, taking into account the Hertel criteria, which have the highest prognostic value for the occurrence of this complication.

5. For the first time in experimental conditions the mechanical properties of the locking plate and intramedullary graft construct were tested in a four-fragment fracture model.

6. For the first time in experimental conditions, the mechanical properties of the locking plate and intramedullary graft construct were tested on a fracture model reproducing an osteoporotic fracture with a massive bone defect of the cancellous bone.

Dr. Rusimov's work is extremely precisely crafted and essentially does not provoke objective critical remarks. The only thing I would point out in this regard are the unnecessarily voluminous literature review and some structural features, such as the setting of the aim and tasks before the literature review and the deductions after the conclusion. The few critical remarks are of a purely technical nature and do not diminish the scientific qualities of the work.

CONCLUSION

I evaluate the dissertation presented for my opinion as a completed scientific development at a very high level. It examines a current problem, is prepared on the basis of high criteria for research methodology, structure, form and content, and has a contribution of theoretical and scientific-practical nature. Based on the above, I believe that *the work fully*

meets the requirements of the Regulations on the terms and conditions for obtaining scientific degrees and holding academic positions in the UMHATEM “N. I. Pirogov” for obtaining the educational and scientific degree“ DOCTOR ”and I propose that it be awarded to Dr. Lyubomir Rusimov.

Prof. Dr. Andrei Yotov, MD, DSc

11.04.2022

