

POSITION

From **Assoc. Prof. Dr. Nikolay Dimitrov, MD**

Department of Orthopedics and Traumatology,

Medical Faculty,

Medical University – Sofia

Regarding: Dissertation “**Shoulder Arthroplasty – An Analysis of Results and Complications**”
for the award of the educational and scientific degree Doctor.

By order of the Executive Director of UMHATSM "N. I. Pirogov",

No. RD-26-1933/04.12.10.2024, I have been appointed as a member of the Scientific Jury, and by decision of the latter, I have been assigned to present an opinion on the dissertation by **Dr. Mariya Andreeva Hadzhinikolova**, a free doctoral student at UMHATEM "N. I. Pirogov", for the award of the educational and scientific degree Doctor in the scientific specialty Orthopedics and Traumatology, in the professional field 7.1 Medicine from the area of higher education 7. Healthcare and Sports.

Shoulder arthroplasty was, until recently, a rare and highly specialized surgery, known to only a small number of surgical teams, particularly in Bulgaria. This was due, in part, to the lack of sufficient research proving the exact algorithms for sequential planning and successful technical treatment of irreparable fractures of the shoulder joint with osteosynthesis methods, and even more so for degenerative diseases of the shoulder. Thanks to the accumulation of global experience and the increasing number of patients with such pathologies, shoulder arthroplasty gained momentum in Bulgaria, facilitated by the advancement of several national teams. Despite the trends to oppose the different types of shoulder arthroplasty, it is proven that each of them has its own indications and appropriate patient groups. Hemishoulder arthroplasty has a longer history in Bulgaria. It was accepted as clearer and "easier" to perform. However, it turned out that this was not entirely true due to the complexity of "reconstructing" the tubercles to ensure normal function of the shoulder joint in the future. The situation becomes even more complicated when dealing with involvement of the glenoid cavity. At one point, the stage of total anatomical shoulder arthroplasty was somewhat overlooked, a technique that has its specific indications, though not as much in trauma cases. This led to the development of reverse shoulder arthroplasty (RSA), which does not require consideration of fractured parts of the humeral head, as these implants were specifically designed for degenerative shoulder changes, especially in the absence of the rotator cuff, whose function is replaced in this concept.

The fact that more and more local surgeons are facing these issues is proof of the increasing number of patients treated with these methods, and the advancement of this type of surgery in Bulgaria. However, it turns out that there is no standardized approach for

monitoring these patients following such surgeries. Against the backdrop of increased life expectancy, the insufficient number of studies on the long-term survivability of the implants raises the question of patient monitoring in the short, medium, and long term. The assessment is carried out through imaging (radiological and ultrasound) and clinical methods, based on various scales to evaluate functional outcomes

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The efforts of Dr. Mariya Hadzhinikolova are focused on analyzing the evidence in this study. By tracking the development of these methods, she highlights both their advantages at the time and their limitations for the future in her dissertation. The study of changes in the rotator cuff after shoulder arthroplasty is one of the easiest and most reliable methods for proving total or partial lesions. The dissertation by Dr. Hadzhinikolova is dedicated to identifying where efforts should be directed to reduce the adverse effects on these otherwise well-established surgical techniques, using new ultrasound methodologies like strain and SW elastography, which provide the ability to assess the elasticity of the deltoid muscle – the primary motor in reverse shoulder arthroplasty (RSA).

The dissertation is original due to the frequency of the pathology, and not because the nature of the pathology is unknown, but because of the lack of a systematic, combined analysis of results and functionality following these surgeries. Moreover, it is a well-known fact that when complications are specifically addressed, an optimal behavior algorithm can be achieved. This is another major advantage of this doctoral work.

For the first time, this dissertation addresses the problem in such a scientific format in the Bulgarian academic community, making it a highly significant and timely contribution.

The dissertation contains 170 pages, with 33 pages of bibliography. It is illustrated with 18 tables and 65 figures, graphs, and photos. The bibliography includes 520 literary sources. In the rest of the dissertation, Dr. Hadjinikolova formulates the aim and five related tasks of the study, the study cohort, the clinical methodology, the patient analysis techniques, her own results, personal analysis, and conclusions.

The relevance of this dissertation is indisputable, as proving the hypothesis posed will have broad practical implications, offering a reliable guideline for therapeutic management of the issue.

The literature review analyzes various factors affecting the outcomes, focusing on both the implants and surgical techniques. It explores all aspects of the problem in depth. Dr. Hadjinikolova demonstrates profound knowledge of the surgical anatomy of the shoulder joint components, laying the foundation for the logic of the forthcoming studies. A central focus of her work is the analysis of blood supply to the bone structures on one hand, and the muscle engines – the deltoid muscle and the rotator cuff – on the other. This is in relation to the doctoral student's ongoing efforts to characterize different surgical approaches based on the quality of the structures following trauma. This includes deciding whether to rely on restoring the anatomy of the shoulder in certain groups of patients or to shift to compensating for anatomical deficiencies with alternative types of shoulder arthroplasty, which, in turn, would alter the biomechanics of the joint to improve outcomes. The biomechanics of the shoulder joint, which is one of its most unique characteristics, is a critical aspect of her work. The complex combinations of shoulder joint movements serve as the foundation for further analysis of outcomes following different types of shoulder arthroplasty. Dr. Hadzhinikolova also examines postoperative complications from the perspective of the main theme of the dissertation—how restoring or altering the anatomy and biomechanics can lead to improved final results. Thus, **the review clearly outlines the main focus of the dissertation**: how to accurately assess the postoperative condition of patients treated with different approaches to shoulder arthroplasty.

The doctoral candidate systematically describes the various diagnostic methods for patients with implanted shoulder prostheses, which are well-known in the literature. However, particular emphasis is placed on the ultrasound examination of the shoulder joint, as it is easily accessible and without limitations due to the absence of artifacts from the implant. An interesting analysis is also presented through ultrasound elastography, which quantitatively or qualitatively assesses the stiffness or elasticity of the examined tissue—its mechanical properties. Two main elastography techniques are described: strain elastography

(SE), a qualitative method, and shear wave elastography (SWE). The postoperative characteristics of the deltoid muscle and rotator cuff using these methods are one of the main contributions of the dissertation, serving as evidential material for the conclusions.

This leads to the final section of the literature review, which analyzes:

- **Unipolar shoulder arthroplasty**, where the aim is to restore normal bone anatomy and soft tissue balance as much as possible, allowing for the recovery of the shoulder joint's normal biomechanics.
- **Bipolar anatomical shoulder arthroplasty**, where the comfort of the patient without pain and better joint function is weighed against the frequent complications arising from loosening of the glenoid component.
- **Bipolar reverse shoulder arthroplasty (RSA)**, where the main principles of this surgical method are analyzed:
 1. Medialization of the center of rotation (CR).
 2. Elongation of the deltoid muscle through distalization of the humerus.
 3. A constant center of rotation, leading to implant stability.
 4. A semi-constrained implant design that allows for greater freedom of movement, as well as combinations of these features in modern implant designs.

The literature review is tailored to the dissertation and demonstrates Dr. Hadzhinikolova's extensive knowledge on the topic. This is particularly evident from the presentation of these methods, which are clearly illustrated using the figures in the work.

Thus, the line of thought is established, showing that the studies in the current dissertation will be both original and relevant, as well as beneficial to the entire orthopedic community.

The objective is clearly outlined in **Chapter II** – "To perform a retrospective analysis of the results and complications in patients treated with unipolar and reverse shoulder prostheses." The five tasks are specific, clear, well-defined, and fully aligned with the stated goal.

Chapter III contains the methodology and clinical material. The originality of the dissertation lies in its goal of proving the advantages of a particular type of shoulder arthroplasty and how it impacts the results and complications.

The candidate used cases from the Orthopedics and Traumatology Clinics at the University Hospital "N. I. Pirogov" in Sofia for the period 2015-2021. A total of 58 patients were followed, with 33 patients receiving hemiarthroplasty and 26 receiving reverse

arthroplasty. Ultrasonographic assessment of the rotator cuff was performed at the final follow-up for all 33 patients.

The patients who underwent elastographic examination were divided into two groups:

- **Group 1** included the operated shoulder of patients with reverse shoulder prostheses.
- **Group 2** consisted of healthy controls.

Another important and valuable part of Dr. Hadzhinikolova's study for the Bulgarian orthopedic community is the sequential analysis and ultrasonographic assessment of the individual muscles of the rotator cuff and the deltoid muscle, as well as the use of ultrasound elastography for evaluating the deltoid muscle.

In the final stage of the study, the thoroughness of the research is evident through the precise verification and validation of the hypotheses using various accurate statistical methods: descriptive and comparative methods; comparison between two independent groups; univariate and bivariate frequency tables for data with non-normal distribution when comparing more than two independent groups; statistical significance is accepted if the empirical p-value is less than 0.05; measures of central tendency and dispersion for quantitative variables; statistical method for determining the type of frequency distribution of quantitative variables using the Kolmogorov-Smirnov test; statistical methods for identifying differences and relationships, utilizing the SPSS v.20 statistical software package.

The results of the study are correctly presented in **Chapter IV**. The final results are based on data from successive examinations of the patient groups, derived from statistical dependencies that can be broadly categorized into descriptive and analytical.

The results were accounted for using the aforementioned statistical methods. In the concluding, most insightful part of the chapter, the dissertation clearly and precisely formulates conclusions based on the statistically processed results, which form the essence of Dr. Hadzhinikolova's dissertation. Emphasis is placed on those conclusions where statistically significant correlations are found—such as the radiological analysis of tubercle non-union, migration of tubercles, or their resorption, as well as implant migration. Regarding glenoid erosion, it is demonstrated that it remains intact in patients with hemiarthroplasty. A statistical relationship is also found between tubercle resorption and implant migration on one hand, and rotator cuff lesions on the other, as assessed through ultrasonography. For RSA (reverse shoulder arthroplasty), the follow-up results show that tubercle resorption or non-union remains within minimal bounds, as proven statistically. If implant instability occurs, it manifests early, and here the risk factors are identified.

An interesting aspect of the results is the ultrasound assessment of the mechanical properties of the **deltoid muscle** through ultrasound elastography. The analysis compares different segments of the deltoid muscle between the operated and non-operated limbs. Along with the investigation of the relationship between the number of interventions and

muscle elasticity, as determined by **strain elastography**, the study reaches logically and statistically validated conclusions.

After the well-executed and strictly presented evidence, the dissertation raises the question of the applicability of this methodology in everyday clinical practice and the achievement of better outcomes.

In this chapter, the most constructive skills of the dissertation author are demonstrated—her ability to present her main conclusions, which are unequivocally supported by the evidential material presented throughout the dissertation. This also reflects Dr. Mariya Hadzhinikolova's high level of expertise and scholarly depth in the field. The results of the study are supported by highly informative tables and graphic materials.

In **Chapter V – Discussion**, the final analysis of the results is presented. The advantages and disadvantages of the two surgical strategies—**hemiprosthesis** and **RSA (Reverse Shoulder Arthroplasty)**—are highlighted. Issues such as non-union or resorption of the tubercles, dysfunction of the rotator cuff (RC) related to partial or complete lesions or resorption of the tubercles, are discussed for one surgical technique. For the other technique, complications such as early and late postoperative infections, iatrogenic or traumatic peripheral nerve damage, as well as shoulder instability due to malpositioning of components or dysfunction of the **m. deltoideus** and **m. subscapularis**, are addressed.

The dissertation emphasizes that **RSA** has proven to be a reliable method for treating patients with rotator cuff deficiency, shoulder pseudoparalysis, and is also applicable in the treatment of acute proximal humeral fractures.

The most fundamental aspect of the chapter—and the dissertation as a whole—is the analysis of the mechanical properties of the **deltoid muscle** in **RSA**-prothesized patients using **strain elastography**. This is the first time such an investigation has been conducted in specialized literature. The observed loss of muscle elasticity and higher rigidity post-surgery, especially in the clavicular segment of the deltoid muscle, raises many questions regarding improvements in **RSA** surgical techniques in the future. As shoulder arthroplasty is expected to become more frequent, with implants having a longer lifespan, the future follow-up process depends on establishing a follow-up algorithm, which remains controversial and undetermined in the literature.

Here, the doctoral candidate's efforts to systematically organize the available literature, identify existing gaps, and derive new conclusions based on her own results are clearly evident.

Chapter VI presents five important conclusions for practice. It is particularly emphasized that **unipolar shoulder arthroplasty** mainly leads to poor functional outcomes in patients who have undergone secondary arthroplasty. The conclusion is drawn that **reverse shoulder arthroplasty (RSA)** leads to faster and better functional results both in patients with **proximal humerus fractures** and those who have undergone secondary arthroplasty. **Ultrasound elastography** has the potential to establish itself as a method for assessing the function of the **m. deltoideus** in patients with reverse shoulder prostheses, as

well as its relationship with muscle elasticity and the patients' functional outcomes. The introduction of the protocol presented and proven by **Dr. Hadzhinikolova** would be extremely useful and is recommended.

In my opinion, following these authorial conclusions and recommendations, the goal of the dissertation has been achieved.

The bibliography presented in **Chapter IX** is arranged alphabetically. The dissertation is written in proper literary language. The graphics and images used are of high quality and informativeness, fully corresponding to the text.

Regarding the scientific work presented by Dr. Maria Hadjinikolova, I can point out the following major contributions:

Scientifically original contributions:

1. For the first time in the country, an **ultrasound methodology – elastography** is introduced for assessing the biomechanical characteristics of **m. deltoideus** in shoulder arthroplasty patients and its relationship with clinical outcomes.
2. An **algorithm for monitoring** patients with shoulder arthroplasty is proposed, which provides early monitoring of complications.

With a scientific-applied and confirmatory nature:

1. An analysis has been conducted on the relationship between **shoulder instability in reverse shoulder arthroplasty (RSA)** and factors that could lead to instability: BMI, size of the glenosphere, surgical approach, number of previous interventions, recovery of **m. subscapularis**, and developing infection.
2. For the first time, based on the analysis of a sufficiently large number of cases, a detailed and thorough comparative statistical analysis of the final results was carried out for both applied techniques based on statistical analysis of radiographic and ultrasound data, in relation to each of the examined complications.

Regarding the dissertation topic, the candidate presents five publications. These were published in peer-reviewed journals, meeting the **Minimal requirements for Area 7. Healthcare and Sports**, according to the **Regulations for the application of the law on the development of the academic staff in the Republic of Bulgaria** from 2018. They contain separate parts of the developed material. Additionally, the candidate has a publication accepted in a journal with an Impact Factor (IF), in accordance with the requirements outlined in Appendices 3 and 4 of the **Regulations for Academic Staff Development**.

The **Abstract** of the dissertation, consisting of 105 pages, is formatted according to the requirements outlined in **Appendix 8 of the Regulations**.

Conclusion: The dissertation presented to me demonstrates the candidate's ability to create an original methodology for testing hypotheses and consistently derive supporting

evidence to achieve the main goal set by the research. It also showcases the candidate's capability to apply statistical methods to obtain reliable conclusions on an original and not only useful but also educational topic for the Bulgarian orthopedic community, with significant practical implications – **“Shoulder Arthroplasty – Analysis of Results and Complications.”** The value of the dissertation is high due to its relevance, the analysis of a problem that is being addressed for the first time in Bulgaria, the presence of impeccable and applicable practical conclusions, as well as specific guidelines for future therapeutic approaches.

The dissertation fully meets the qualitative and quantitative criteria set for a dissertation for the award of the educational and scientific degree **“Doctor”** in the scientific specialty **Orthopedics and Traumatology** at the **Medical University of Sofia**. Therefore, I give a positive evaluation of the work and urge the members of the Scientific Jury to award **Dr. Mariya Andreeva Hadzhinikolova** the educational and scientific degree **“Doctor”** in the scientific specialty **Orthopedics and Traumatology**.

14.11.2024

Assoc. Prof. Dr. N. Dimitrov, MD