

REVIEW

By **Prof. Dr. Asen Georgiev Baltov, DM,**

Member of the Scientific Jury

appointed by Order No. RD-26-1162/14.06.2024

University Multiprofile Hospital for Emergency Medical Aid "N.I. Pirogov" JSC - Sofia

Regarding:

The procedure for awarding the educational and scientific degree of "Doctor"

to Dr. Mariya Andreeva Hadzhinikolova for a dissertation on the topic:

SHOULDER ARTHROPLASTY - ANALYSIS OF RESULTS AND COMPLICATIONS

in the scientific specialty "Orthopedics and Traumatology" in professional field 7.1.

Medicine, from the field of higher education 7. Healthcare and Sports

Dr. Mariya Hadzhinikolova obtained her Masters degree in Medicine from the Medical University of Sofia in 2014. She acquired her specialty in Orthopedics and Traumatology in 2021. She has started a doctoral program in the same specialty in March 2019, her term was extended by one year, after which she was dismissed with the right to defend her thesis, with all procedural deadlines being met.

Dr. Hadzhinikolova has completed specializations and training abroad: AO Trauma Seminar - Pelvic and Acetabulum, London Osteotomy Virtual Masterclass, Practical course "The distal radio-ulnar joint", Geneva, Switzerland, Paris International Shoulder Course, Paris, France, Basic Principles of Fracture Management, Davos, Switzerland. She speaks English, German, and Russian. She works at Second Clinic of Orthopedics and Traumatology, University Multiprofile Hospital for Emergency Medical Aid "N.I. Pirogov" EAD - Sofia.

Shoulder arthroplasty, until 10 years ago, was considered boutique surgery in Bulgaria. This was due, on the one hand, to low interest from international companies and, on the other, to the high cost and lack of partial reimbursement from the National Health Insurance Fund (NHIF). Gradually, hemishoulder monoblock prostheses were introduced, followed by a second generation of modular prostheses, and only in the last 5 years we have universal, interchangeable prostheses available on the market, allowing conversion from hemishoulder to bipolar and reverse types. This is also due to the lack of reliable series of followed-up patients and the lack of treatment algorithms. Studies and articles in the global literature on reverse shoulder arthroplasty are commonplace. In Bulgaria, this surgery has gained momentum, especially in recent years, changing the treatment approach, particularly for patients with fractures and fracture-dislocations over 65 years of age. Current trends in global literature and experience show an increasing use of reverse shoulder joints. The change in the overall concept regarding the movement and function of the deltoid muscle allowed for a quick and efficient replacement of older treatment methods, such as open reduction with a

nail or plate, the use of frozen bone allografts, and mandatory anatomical restoration of the tubercles. Glenoid erosion and rotator cuff tears, as a consequence of unipolar arthroplasty, also showed shortcomings and narrowed the indications for this method. Shoulder arthroplasty is growing exponentially, both in Bulgaria and worldwide.

The monitoring of these methods is included in this work due to the lack of a standard approach, as well as the identification of necessary assessment methods - clinical, radiological, and ultrasound.

The dissertation comprises 170 pages and a 33-page bibliography. It is illustrated with 18 tables and 65 figures, graphs, and images. The aim that Dr. Hadzhinikolova has set is a retrospective analysis of the results and complications in patients treated with hemi and reverse shoulder prostheses. The study was conducted at the University Multiprofile Hospital for Emergency Medicine and Active Treatment "N.I. Pirogov". The monitoring algorithm includes an assessment of complications: non-union and resorption of the tubercles, implant migration, glenoid erosion (radiological monitoring), and assessment of the rotator cuff integrity (ultrasound). The algorithm for assessing complications after rTSA (reverse total shoulder arthroplasty) includes: instability, resorption, and non-union of the tubercles (radiological), and assessment of the mechanical properties of the m. deltoideus (ultrasound).

The literature review is 63 pages long. It contains a detailed section dedicated to surgical anatomy, another dedicated to the clinical assessment of patients after arthroplasty, and imaging diagnostics in patients with prostheses (computed tomography, MRT, ultrasound examination, ultrasound elastography, etc.). The main focus is a detailed presentation of the different types of shoulder arthroplasty.

A detailed description of the ultrasound examination of the shoulder joint is provided. Of particular interest is the analysis using ultrasound elastography, which quantitatively or qualitatively assesses the elasticity of the deltoid muscle. The two main elastography techniques are described: strain elastography (SE) – a qualitative method, and shear wave elastography (SWE). The post-operative characteristics of the deltoid muscle and rotator cuff using these methods are one of the main contributions of the dissertation as supporting evidence.

In the chapter "Aim and Objectives," five objectives are outlined:

1. To perform an analysis of the results from the literature.
2. To follow a sufficient number of patients treated with unipolar and reverse shoulder arthroplasty.
3. Based on the analysis of the clinical results, to assess the advantages and disadvantages of the two methods.
4. To test the use of B-mode ultrasound for assessing rotator cuff lesions in patients after unipolar shoulder arthroplasty and elastography for assessing the mechanical properties of the m. deltoideus in RSA patients.

5. To develop a standardized protocol for patient follow-up to optimize the early detection of potential complications using clinical and instrumental methods.

Chapter III, "Materials and Methods," contains 14 pages. The clinical material includes 33 patients with HA (hemishoulder arthroplasty) with a mean age of 66.5 years and 26 patients with rTSA (reverse total shoulder arthroplasty) with a mean age of 64.9 years. The average follow-up period was 20 months. Of these, 33 patients underwent ultrasound (US) examination with rotator cuff ultrasound for HA and elastosonography for 20 rTSA patients; 20 also had the contralateral arm examined, and 28 completely healthy patients were examined for standardization purposes.

The following were monitored for HA: non-union and resorption of the tubercles, migration of the HA, and glenoid erosion. For rTSA: instability, non-union and resorption of the tubercles, and deltoid muscle damage. Radiographic diagnostics were performed at 1, 3, 6, and 12 months, and then annually. For HA, the acromiohumeral distance (AHD), translation of the implant head center, and glenoid erosion (according to the Favard classification) were the most important parameters. For rTSA, congruency was the key parameter.

Ultrasound examinations measured the rotator cuff condition for HA and deltoid muscle elastography (divided into 5 longitudinal segments) for rTSA.

The statistical methods used were: descriptive statistics, calculation of central tendency and dispersion of quantitative changes, the Kolmogorov-Smirnov test, graphical analysis, statistical methods for determining differences and dependencies, and analysis to assess the diagnostic capabilities of the examined indicators. The critical significance level (alpha) was set at 0.05. The null hypothesis was rejected when the p-value was less than alpha. The SPSS v2.0 statistical package was used.

Section IV, "Results and Complications," contains 30 pages.

Radiographic results for HA: non-union of the tubercles 9.4%, resorption of the tubercles reaching up to 50%, with that of the greater tubercle increasing during the follow-up period. Migration of the HA (proximalization) increased from 24% at 6 months to 61% at the end of the follow-up, with the AXP measurement being the most reliable here. Glenoid erosion, observed in CT scans at the end of the 6-year period, was noted in 24 cases (E0-14, E1-10, or 75% total).

Ultrasound results for HA: only 22% (7 patients) showed an intact rotator cuff at the end of the follow-up.

Clinical results: CMS (Constant Murley Score): poor 15 (46.9%), satisfactory 9 (28.1%), and good 9 (28.1%). DASH Score (Disability of the Arm, Shoulder and Hand): satisfactory 25.93.

Radiographic results for rTSA: non-union of the tubercles in 2 (8%) cases, prosthesis instability in 3 (11.4%) cases, influenced by infection and resorption of the lesser tubercle, as well as the number of interventions performed.

Ultrasound elastography showed a change in SWE values in the operated arm compared to the healthy arm, which is considered entirely logical due to the altered function

of the deltoid muscle. The most significant difference was observed in segments A2, P1, and P2. Logically, lower elasticity was also observed after multiple interventions. Strain elastography showed reduced elasticity in segments A1 and A2.

Clinical results using the Constant-Murley Score (CMS): excellent 70%, good 9, satisfactory 8, and poor 2. In cases of non-union of the greater and lesser tubercles, the results were worse or satisfactory, with a high degree of correlation. The DASH score was good at 15.65; again, worse results were observed in patients with non-union or resorption of the greater and lesser tubercles.

Section V, "Discussion," contains 60 pages. This chapter presents many interesting observations and comparisons between the studied cohort and the data from the literature.

HA is indicated in complex and irreparable fractures of the proximal humerus in young patients with an intact rotator cuff, although problems with the rotator cuff, limited range of motion, glenoid erosion, and pain are expected in the long term.

Conversely, rTSA is less affected by complications related to the tubercles—non-union, resorption, and migration. The mandatory restoration of the subscapularis muscle and its insertion is crucial, improving stability and functional outcomes.

Therefore, the current concept is that if there is comminution or dysfunction of the greater tubercle (GT), it is reasonable to proceed with rTSA in patients over 60 years of age or as a salvage procedure after poor results with ORIF of proximal humerus fractures (PHF) or HA. The distalization and lateralization of the center of rotation of the prosthesis are crucial for the function of reverse shoulder prostheses.

The restoration of the tubercles is extremely important in HA. Various techniques can be used, and a good understanding of these is necessary. The discussion emphasizes the need for an algorithm for monitoring after shoulder arthroplasty. I personally did not find a clear statement regarding the duration of post-operative immobilization for HA and rTSA, as well as the mobilization and subsequent rehabilitation until the necessary functional results are achieved. Ultrasound monitoring of the rotator cuff in HA should ideally begin 6 months after arthroplasty, which I consider correct, allowing for early diagnosis of subsequent problems with proximalization and timely conversion to rTSA. The use of elastography in rTSA would be very useful in the early post-operative period to determine the stiffness of the deltoid muscle and the need to reduce it with oral muscle relaxants.

The clinical results show poor functional outcomes of HA in four-part fractures and fracture-dislocations of the proximal humerus in patients over 60 years of age, and better outcomes with rTSA.

The discussion mainly addresses the complications associated with HA and rTSA. Considering the learning curve associated with the introduction and use of a new treatment method, 20-50 cases are needed. This is one of the main limitations of the conducted study.

The main reason for the poor functional outcomes in HA is related to the tubercles; part of this is related to the surgical technique, while another part manifests after a certain

period and is associated with soft tissue problems of the rotator cuff, due to the asymmetry and shape of the humeral head prosthesis, the centering of the stem height, and muscle imbalance resulting from retroversion. Ultrasound monitoring for rotator cuff lesions is well-represented in the discussion and demonstrates its reliability as a method for monitoring subsequent complications after HA, and its specificity, since MRI is not applicable after shoulder arthroplasty.

Shoulder instability in rTSA ranges from 2% to 32% in various studies. The discussion gives it special attention, which is useful for future readers.

There are still few publications addressing the elasticity of the deltoid muscle after rTSA. While the idea of investigating it is good, the interpretation of the results is controversial and highly individual, related to the surgical technique and, importantly, to the lateralization and distalization of the glenoid sphere and the center of rotation. It would be interesting to know the condition of the deltoid muscle in HA patients, as well as the dynamic monitoring of rTSA over the period from 3 months to 2 years.

The discussed HA monitoring algorithm requires a more detailed explanation of the methods: radiography, CT, and ultrasound, as well as more frequent monitoring between 6 months and 2 years, which is when the most frequent complications occur in HA—erosions, rotator cuff tears, and muscle imbalance.

For rTSA, a similar monitoring algorithm to HA is proposed, which does not really reflect the specific features of this treatment method. The apparent expectation is that if a problem arises after the first year, it will be reported by the patient, rather than actively sought and prevented.

The bibliography is alphabetically ordered and includes 509 scientific publications in foreign languages and 11 in Bulgarian.

The dissertation is written in correct literary language. The graphs and photographic materials are of high quality and informative, fully corresponding to the text.

Contributions of the scientific work of Dr. Mariya Hadzhinikolova

Scientifically Original Contributions:

1. Ultrasound elastography is introduced for the first time in the country to assess the m. deltoideus in reverse shoulder arthroplasty.
2. An algorithm is proposed for monitoring patients undergoing shoulder arthroplasty and tracking complications.

Other Contributions:

1. A detailed retrospective analysis of the results and complications associated with unipolar and reverse shoulder arthroplasty has been performed.
2. An in-depth comparative statistical analysis of the final results for both methods has been conducted, considering complications such as non-union and resorption of the

tubercles, malposition of the greater tubercle, implant migration, rotator cuff lesions, glenoid erosion, and shoulder instability.

3. A conventional ultrasound method has been proposed for monitoring rotator cuff lesions in patients who have undergone unipolar shoulder arthroplasty.

Five publications have been presented on the dissertation topic, in accordance with the Regulations for the Implementation of the Law on the Development of Academic Staff in the Republic of Bulgaria from 2018. These publications contain individual parts of the developed material, and the dissertation author also has a publication accepted in a journal with an Impact Factor (IF).

The dissertation submitted for review demonstrates the dissertation author's ability to develop an original methodology for testing hypotheses and provide supporting evidence to achieve the main goal: "**Shoulder Arthroplasty - Analysis of Results and Complications**".

The dissertation fully meets the qualitative and quantitative criteria set forth in the requirements for obtaining the educational and scientific degree of "Doctor" at the Medical University of Sofia. I give a **positive assessment of the work** and recommend that the members of the Scientific Jury award **Dr. Mariya Andreeva Hadzhinikolova** the educational and scientific degree of "DOCTOR" in the scientific specialty "Orthopedics and Traumatology" in professional field 7.1. Medicine, from the field of higher education 7. Healthcare and Sports.

Sofia, November 24, 2024

Prof. Dr. Asen Georgiev Baltov, DM