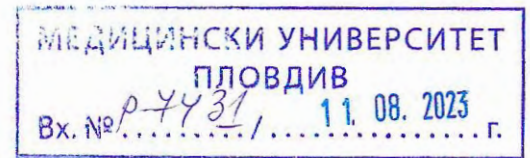


To the Chairman of the Scientific jury
Based on the Order № R-2205/28.07.2023
Of the Rector of MU-Plovdiv



REVIEW

From Prof. Dr. Rossen Gospodinov Kolarov, MD
Medical University - Varna, Faculty of Dental Medicine, Department of Oral and
Maxillofacial surgery
about a dissertation for the awarding of scientific and education degree "Doctor"

Field of higher education:

7. Healthcare and sport

Professional field:

7.1. Medicine

Doctoral program:

"Plastic and aesthetic surgery", Code of the specialty 03.01.43

Author: Dr. Kostadin Gigov

Department: „Propedeutics of surgical diseases“

Topic:

„EVALUATION OF TWO PALATOPLASTY TECHNIQUES IN PATIENTS WITH CLEFT PALATE“

Scientific supervisor: Prof. Jury Anastassov, MD, DSc – MU – Plovdiv, Department of propedeutic of surgical diseases.

1. General presentation of the procedure and the candidate

The review was prepared based on the Order of the Rector of the MU - Plovdiv No. R-2205/28.07.2023, with an appointed Scientific Jury under the procedure for public defense of the described dissertation work.

The set of materials on paper and electronic media are in accordance with Art. 115 (1) of the Procedure for the awarding of the scientific and education degree "Doctor" at the MU - Plovdiv; Regulations of MU-Plovdiv dated 06.11.2014 and were provided to me within the statutory period.

The candidate has attached seven publications and thirteen participations in scientific forums related to the topic of the dissertation work.

All documents are prepared and presented properly.

2. Brief biographical data of the candidate

Since 2005 until 2009, Dr. Gigov worked at the "Dr. Anton Tonev" Plastic Surgery Medical Center as a physician.

From 2009 until now, he has been working at the "St. George" UMHAT in Plovdiv in the Department of Plastic-reconstructive and aesthetic surgery for children as a plastic surgeon.

From 2015 until now, Dr. Gigov also works at the "St. Karidad" Plovdiv as a plastic surgeon.

In 2014 he acquired a specialty in "Plastic-reconstructive and aesthetic surgery" and in 2021 in "Health Management"

Dr. Gigov's work experience is 18 years.

From 21.04.2021, Dr. Gigov is a PhD student in the doctoral program "Plastic and aesthetic surgery" at the department of „Propaedeutics of surgical diseases" at MU-Plovdiv with scientific supervisor Prof. Dr. Yury Anastassov, MD.

Dr. Gigov is a member at:

- Bulgarian Medical Association (BMA),
- Bulgarian Association of Plastic, Reconstructive and Aesthetic Surgery (BulAPRAS)

He has excellent written and spoken English.

3. Actuality of the topic and appropriateness of the aim and objectives.

4. Relevance of the problem

In his dissertation work, Dr. Kostadin Gigov shows in-depth knowledge of the topic he is developing.

He has done a thorough critical analysis of the literature. It emphasizes that congenital clefts of the lip and palate represent a significant social problem. They affect almost 1 million

people in Europe and about 20,000 people in Bulgaria. It notes that there is still a lack of universally accepted optimal protocol for the treatment in terms of surgical technique, chronology of operations, multidisciplinary approach to guarantee excellent results with a minimum number of operations and general care. These children are often permanently disabled, despite considerable resources and efforts spent on treatment. Addressing the problem of congenital cleft palate without analyzing speech outcomes, dental-maxillary development and psycho-social factors would have no practical or scientific value. Understanding and analyzing the muscle pathology allows to change the behavior of the clinical forms with a smaller cleft width so that the surgical intervention is less traumatic.

The study would help to standardize diagnostic protocols in speech therapy and orthodontics. Thus, it would be possible to obtain information about the speech and dental-maxillary outcomes of patients with cleft palate operated on in the last 15 years in Bulgaria. Through the existing electronic system a large proportion of late outcomes can be evaluated.

Dr. Gigov shows skills for independent conduct of scientific research.

On the basis of the analysis of the scientific research carried out on the problem, the aim of the scientific development was deduced, as follows:

" Evaluation of early and late outcomes of palate repair in two surgical methods - Anastassov uranoplasty and Veau-Wardill-Kilner modification, in patients with congenital cleft lip and palate or isolated cleft palate and to determine the advantages and disadvantages of both techniques by assessing the early postoperative period, speech outcomes and dento-maxillofacial development."

The dissertation is written in good scientific language.

5. Methods

The realization of the aim was achieved through the implementation of three main objectives, namely:

1. Comparative assessment of fistulas rate, their size and localization, in the two main surgical techniques for palate repair- closed uranoplasty according to Anastassov and Veau-Wardill-Kilner modification.

2. Analysis of speech outcomes by standardized speech assessment protocols.

3. Assessment of dental arch development and dento-maxillofacial deformities

3.1 Assessment of the severity of dento- maxillofacial deformity

3.2 Determination of the upper dental arch width between canines and molars

3.3 Assessment of malocclusion in canines and molars

Study design

A single-center, retrospective, comparative study was conducted in two groups of patients with unilateral and bilateral cleft lip and palate, and isolated cleft palate, operated by two methods of uranoplasty-Anastassov closed uranoplasty and Veau-Wardill-Kilner modification.

Selection of study group

The study included patients with all forms of congenital cleft lip and palate and isolated cleft palate, hospitalized in the Department of Plastic, Reconstructive and Aesthetic Surgery for Children, UMHAT "St. George", Plovdiv for the period from 2005 until 2022.

All participants met the patient selection criteria.

Patient selection criteria

Inclusion criteria

- Patients with unilateral and/or bilateral cleft lip, alveolar crest and palate and isolated cleft palate.
- Age 4-15 years
- Signed written informed consent
- Speech therapy recording and speech evaluation by a qualified speech-language pathologist

Location of the research

The study was conducted in the department of plastic, reconstructive and aesthetic surgery for children, UMHAT "St. George", Plovdiv.

Material

Objective 1.

In patients with congenital cleft lip, alveolar ridge and palate, the lip was operated primarily between 1 and 3 months. Palate surgery was performed at the age of 9-12 months.

382 patients aged between 4 and 15 years were included in the study. They were divided into two groups according to the surgical technique used. Of the total number of patients, 204 (53%) were operated by the modified Veau-Wardill-Kilner technique and 178 (47%) by the Anastassov technique. The mean age of all patients at the time of analysis was 9,8 years, with a range of 4 and 15 years. 210 (55%) of the patients were male and 172 (45%) were female.

Objective 2.

The speech analysis included 178 patients operated on by Anastassov technique and 151 patients by modified Wardill-Kilner technique, divided into three age groups - 4-7 years, 8-12 years and over 12 years. According to the cleft type, the children were divided into patients with CLP with unilateral and bilateral clefts and patients with isolated cleft palate.

Objective 3.

The GOSLON Yardstick and the index of 5-year-old children were studied in 134 patients. 34 (25,3%) of them were operated using the Anastassov technique and 100 (74,6%) using the modified Wardill-Kilner technique.

Study units:

The study was conducted with the personal participation and control of the candidate.

The number of logical units is sufficient for the formulation of findings of sufficient scientific value.

Systematization, processing and analysis of primary data in the form of quantitative and qualitative variables were realized with statistical package of social science software IBM SPSS Statistics v. 26. A significance level of $p < 0,05$ was adopted for all tests. Graphical analysis was performed in an MS Office 365 using Excel.

The following statistical-mathematical methods were used to objectify the results of the analyses:

1. Descriptive analysis

- descriptive statistics for quantitative variables – normally distributed data were presented as mean (mean) \pm standard deviation (SD), while in the absence of normal distribution the data were presented using positional means – median (Me) and IQR (interquartile range) or 25th and 75th percentiles.

- descriptive statistics for qualitative variables – absolute and relative frequencies. Presented respectively as simple numerical values (n) and as a relative proportion (%).

2. Statistical hypothesis testing

- parametric analysis: z-test

- non-parametric analysis: Kolmogorov-Smirnov test, Mann-Whitney U test.

3. Correlation analysis

- Spearman's correlation coefficient

4. Regression analysis

- binary logistic regression

5. Graphical analysis

The results presentation was carried out through frequency tables (multidimensional tables of the frequency distribution) containing:

- absolute frequencies – the number of units in a separate group;

- measures of central tendency and measures of dispersion

- relative frequencies – the number of units in a separate group referred to the total number of units in the population.

- *p*-value

6. Structure and evaluation of the thesis

The dissertation work meets the requirements of the LDASRB and the relevant Rules of the MU-Plovdiv.

The dissertation work contains 208 pages. It includes 33 tables and 110 figures, 372 bibliographic reference are used, of which 25 are in Cyrillic and 347 are in Latin.

The results are comprehensively and correctly described, analyzed and interpreted. The discussion follows the same sequence as the order of results. After each of the objectives there are logically arranged findings. Findings are specific and reflect in summary the results related to

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1. The occurrence of oronasal fistulas is associated with the surgical technique in one-stage primary uranoplasty.
2. The cleft type and the presence of syndrome were not associated with fistula formation.
3. The operative method is important for the occurrence of oronasal fistulas in patients with an average preoperative severity score.
4. Preoperative severity of the palate reflects the risk of fistula formation. Average preoperative severity was associated with a reduced likelihood of fistula occurrence compared with severe and very severe. In patients with an average preoperative severity the Anastassov technique led to better postoperative results and fewer fistulas, therefore it is the method of choice in patients with a preoperative score of 4-10.
5. With severe and very severe preoperative severity regardless of surgical technique chosen and large defect, its correction using the Anastassov technique led to a better postoperative result.
6. An association was observed between surgical method used and corrective uranoplasty and pharyngoplasty. In patients operated using the Anastassov technique, the percentage of reoperations and pharyngoplasty was significantly lower.

The findings after discussing the results of objective 2 are as follows:

1. Based on our analysis of the speech of patients with congenital clefts, we have found that using either of the two primary uranoplasty surgical methods can lead to close speech results. This means that in most cases, the more gentle operative technique can be used to achieve positive results.
 2. It has been noted that patients who underwent the modified Wardill-Kilner technique tend to have more difficulty with consonant articulation due to pathological compensatory production, which may require additional speech therapy.
 3. Compensatory production that has an impact on speech may be prevented through the selection of appropriate surgical technique. It may be beneficial to focus on developing correct feeding mechanisms to help prevent compensatory production and potential difficulties with consonant articulation.
 4. Speech after early one-stage correction of CLP is satisfactory in terms of hypernasality frequency and speech intelligibility regardless of the specific method used for hard palate correction. Fistulas in uranoplasty patients may not have a significant impact on speech, causing relatively common but generally mild and intermittent symptoms.
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5. The Anastassov surgical method can lead to better speech intelligibility - cases with normal (subcategory 0) and different but understandable speech (subcategory 1) predominate.

1. No difference was found between the two uranoplasty techniques in the assessment of dental arch relationships.

2. In unilateral clefts, the assessment of the severity of dento-maxillary deformity was $3,00 \pm 0,35$ (category: fair) at the 5-year index and $3,12 \pm 0,10$ at the GOSLON Yardstick with no difference between the two surgical methods.

3. In unilateral clefts, the narrowing of the upper jaw had a minimum measured intercanine distance of $6,31 \pm 4,14$ mm and a maximum of $16,83 \pm 3,01$ mm. The intercanine distance in bilateral clefts was from $10,61 \pm 2,25$ to $13,29 \pm 2,28$ mm. No significant difference in the width of the dental arch was observed for the two surgical methods in the two age groups.

4. No difference in malocclusion was found between both techniques for unilateral clefts for classes I and II according to Angel's classification.

5. More patients with unilateral clefts operated on by the Wardill-Kilner method over the age of 8 years had definite dental class III medial occlusion in left canines

6. Additional follow-up of the patients at a later age and reporting the outcomes of the orthodontic treatment performed could partially compensate for the impact of surgical trauma.

The dissertation ends with a summary based on the results, the discussion, the conclusions and logically derived from them.

7. Contributions and significance for science and practice

The dissertation outlines the following original and confirmatory contributions as follows:

Original contributions

- For the first time in Bulgaria, an analysis of a large number of patients with congenital clefts of the lip and palate or isolated cleft palate for the period from 2010 to 2017 y was performed by evaluating surgical, speech and dental-maxillary treatment outcome.
- The dissertation is part of a project to create a national network for multidisciplinary treatment and dispensary monitoring of patients with facial anomalies, which is carried out by our center and ALA with the support of international organizations - Smile-Train from USA and Transforming Faces from Canada.
- Our center treats over 90% of cases in the country and the data represents a national report of treatment outcomes for cleft anomalies over the past 20 years.

- Speech and maxillofacial growth analysis were performed according to ALA outcome assessment protocols, which are in sync with international documentation protocols.
- The early treatment outcomes of two surgical methods of uranoplasty by two surgeons are analyzed for the first time in Bulgaria
- For the first time in Bulgaria, data on speech and maxillofacial growth are obtained when the same treatment protocol is applied by two surgeons in two surgical methods, and the less traumatic method can be applied successfully in 70% of all cases with cleft lip and palate.
- The study contributes to the development of a complex model for monitoring of patients with cleft lip and palate.

Confirmatory contributions

- The oronasal fistulas occurrence is associated with the surgical technique in one-stage primary uranoplasty, which is supported by other authors.
- Preoperative severity is associated with the risk of fistula formation.
- Patients with uranoplasty are more likely to develop fistulas. These fistulas do not affect speech in a fundamental way, causing relatively common but mostly mild and intermittent speech symptoms.
- Speech after early one-stage correction of CLP is satisfactory in terms of hypernasality and speech intelligibility regardless of the surgical method used.
- Surgical intervention has a positive impact on children's speech, but it does not absolutely depend on the surgical technique. Two different techniques can lead to similar positive preconditions for speech development.
- GY/ 5YO and their distribution are comparable to those of previous intercenter studies. This shows that similar results can be achieved with different surgical methods.
- The data support the results of other studies for maxillary narrowing regardless of the therapeutic approach.

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Scientific publications:

1. **Gigov, Kostadin**, Ginev G.Ivan, Velikova V. Radost, Dimova N. Gergana, Cleft lip and/or palate: a comprehensive review and our treatment approach. Acta Medica Bulgarica - in print

2. **Kostadin Gigov**, Simeon Lichev, Petra Kavradzhieva, Yourii Anastasov, Uranoplasty-analysis of two operative techniques for correction of the palate in patients with congenital unilateral cleft palate and lip. Scientific works of the Union of Scientists in Bulgaria Plovdiv, series G. Medicine, Pharmacy and Dental medicine, Vol. XXVI. ISSN 13119427 (Print), ISSN 2534-9392 (On-line). 2021, 249-252.
3. **Kostadin Gigov**, Simeon Lichev, Petra Kavradzhieva, Yourii Anastasov, Intravelar uranoplasty- our experience and results. Scientific works of the Union of Scientists in Bulgaria Plovdiv, series G. Medicine, Pharmacy and Dental medicine, Vol. XXVI. ISSN 13119427 (Print), ISSN 2534-9392 (On-line). 2021, 253-257.
4. Vjara Velikova, Radost Velikova, Yourii Anastasov, **Kostadin Gigov**, Elica Ruseva, Dimitar Filchev, Petia Carvulanova. A digital algorithm for the analysis and treatment of patients with congenital cleft lip and/or palate. Infodent. ISSN-1311-9842, 4/2021, 30-39.
5. Tamara Gateva, Nikolai Sirakov, Petia Kanazirska, Irina Angelova, **Kostadin Gigov**, Application of cone-beam computed tomography in patients with cleft lip and palate. IXth International Conference of Young Scientists 14-15 July 2022, Plovdiv, ISBN 978-619-7413-35-9, 140-141
6. Y. Anastassov, Gigov K., Markova Y, Khater R., Petrov P., Velikova R., Zhelyaskov Hr., Guylev At., Petkova T., Tsarvulanova P., Bojikova K., Slaninkova N., Pareva N., Kazakova M. Practical use of electronic medical record for facial anomalies in Bulgaria (EMFRA) for patients and specialists: A 5 years experience. Scientific works of IV National conference in plastic, esthetic and reconstructive surgery, ISBN 978-619-241-048-3, 2019, 58-66
7. Y. Anastassov, **Gigov K.**, Khater R., Velikova R., Kazakova M., Hashova N., Bojinov M., Tsarvulanova P. A web based national registry for facial anomalies (DFA) in Bulgaria: An Electronic Medical Record for Facial Anomalies. JCLPCA ISSN 2348-2125, 2017, 4, 1, S118-S125.

Personal participation of the candidate

10. Autor's abstract

The autor's abstract contains 70 pages, illustrated with 34 figures and 19 tables. It correctly describes the essence of the research and the results achieved in the dissertation. The conclusions are listed in it.

It has been prepared in accordance with the requirements of the LDASRB and the relevant Rules of the MU-Plovdiv.

11. Critical remarks and recommendations

The set of materials from the dissertation provided to me are complete and in accordance with the LDASRB and the rules for its implementation, as well as with the Rules of the MU - Plovdiv. I have no comments or recommendations.

12. Personal impressions

I have no personal impressions of the author of the dissertation. However, the text provided to me shows a thorough knowledge of the problem and gives me reason to take it as his personal work.

13. Recommendations for future use of dissertation contributions and results

I recommend that Dr. Gigov format and publish his dissertation as a monograph. Thus, his work would be more accessible to his colleagues and very useful in their daily practice.

CONCLUSION

I consider the dissertation work submitted to me for review by Dr. Kostadin Gigov, on **“Evaluation of two palatoplasty techniques in patients with cleft palate”** completed. The same meets the requirements of the Higher Education Institutions, the Rules for the implementation of LDASRB and the relevant Rules of MU-Plovdiv.

The topic of the work is current and well chosen.

The literature review is comprehensive and gives a clear idea of the current state of the problem. It concludes with a critical analysis that is a foundation for the research conducted.

Based on an analysis of scientific research carried out, the aim of the scientific development has been deduced. The assigned objectives give an opportunity to prove it.

The studies carried out are of interest to medical science and practice. The obtained results in the dissertation work, their interpretation, as well as the presented publications related to it, I consider to be the personal work of the author.

The dissertation shows that Dr. Gigov possesses theoretical knowledge and professional skills in the specialty "Plastic and aesthetic surgery" by demonstrating qualities and skills for independent conduct of scientific research.

Based on everything noted here, I accept that the requirements of the Law on the Development of the Academic Staff in the Republic of Bulgaria (LDASRB), the Rules for the Implementation of LDASRB and the relevant Rules of the MU - Plovdiv have been fulfilled. The presented materials and dissertation results fully correspond to the specific requirements of the MU - Plovdiv.

In conclusion: I confidently give a positive vote of the dissertation work on the topic: **“Evaluation of two palatoplasty techniques in patients with cleft palate”** and I will vote **"YES"** for the awarding the scientific and educational degree "Doctor" in the scientific specialty "Plastic and Aesthetic Surgery", code- 03.01.43 of **Dr. Kostadin Gigov.**

09.08.2023 r.

Review prepared by:
(Prof. Dr. Rossen Gospodinov Kolarov, MD,PhD)

Заличено на основание
Чл.5 §1, 6."В" Регламент (ЕС)2016/679