

To the **chair** of the Scientific Jury
Decided with order № P-3450/08.07.2025
By the Vice-Rector of MU-Plovdiv.

STATEMENT

By Professor Rossen Gospodinov Kolarov MD, PhD
MU-Varna, Faculty of Medicine, Department of “General and Operative surgery”
Regarding a dissertation for the award of the educational and scientific degree “Doctor”

Higher education field:

7. Healthcare and sport

Professional field:

7.1. Medicine

Doctoral programme: „Plastic reconstructive and aesthetic surgery”

Author: Ivan Genchev Ginev MD

Full-time doctoral student of the Faculty of Medicine of MU-Plovdiv – city of Plovdiv

Department of “Propedeutics of surgical diseases” of Faculty of Medicine of MU - Plovdiv

Topic: „Evaluation of early and late results after cheiloplasty“

Scientific Supervisor: Professor Youri Anastassov MD, PhD

1. General Presentation of the Procedure and the Doctoral Candidate

This statement is written accordingly to Order № P-3450/08.07.2025 of the Rector of MU-Plovdiv with elected scientific jury for the procedure of public defense of the dissertation.

The submitted set of materials, both in paper and electronic format, is in compliance with Article 115 (1) of the Procedure for Acquisition of the Educational and Scientific Degree "Doctor" at MU – Plovdiv; Regulations of MU – Plovdiv from 06.11.2014, and was provided within the legally established deadline.

The doctoral candidate has included three publications and sixteen participations in scientific forums related to the topic of the dissertation.

All documents have been properly prepared and duly submitted.

2. Brief Biographical Data of the Doctoral Candidate

In 2021, Dr. Ivan Genchev Ginev graduated with honors in Medicine from the Faculty of Medicine at Sofia University “St. Kliment Ohridski.” Since the same year, 2021, he has been a full-time doctoral candidate at the Department of “Propedeutics of Surgical Diseases”, Section of Plastic, Reconstructive and Aesthetic Surgery, appointed under Order No. P2370/17.12.2021 by the Rector of MU – Plovdiv.

Currently, Dr. Ginev is a resident at the Department of Pediatric Plastic, Reconstructive, and Aesthetic Surgery at University Hospital "St. George" – Plovdiv. His scientific and professional interests are focused on congenital craniofacial anomalies.

Dr. Ginev has actively participated in numerous national conferences on the topic of congenital craniofacial anomalies, delivering lectures and presentations.

Dr. Ginev is a member of:

The Bulgarian Medical Association (BMA)

Associate Member of the Bulgarian Association of Plastic, Reconstructive and Aesthetic Surgery

He is fluent in written and spoken English and French.

3. Relevance of the Topic and Appropriateness of the Aims and Objectives

The dissertation addresses a current and significant issue in medical science and practice. The aim is clearly defined, the objectives are appropriately set, and modern research methods have been applied for their execution.

4. Knowledge of the subject matter

In his dissertation, Dr. Ivan Ginev demonstrates in-depth knowledge of the subject matter.

Cleft lip and palate (CLP) are among the most common craniofacial malformations, accounting for 15% of all congenital anomalies. In 80% of cases, they occur as non-syndromic isolated forms. These anomalies are epidemiologically, embryologically, and etiologically unique. Up-to-date data on the treatment outcomes of this pathology are of national importance. The analysis of treatment results over the past 20–25 years provides guidelines for future treatment strategies.

The literature review in the dissertation spans 35 pages and reflects a thorough understanding of the pathology and the complex multidisciplinary approach required for the treatment of congenital facial anomalies, specifically cleft lips. The anatomical pathology, embryological development in patients with CLP, and the evolution and nuances of surgical treatment of the anomaly are examined in depth. Dr. Ginev provides a critical and comprehensive analysis of the existing literature.

The exposition is written in well-structured scientific language.

Research Methodology:

Based on an analysis of previously conducted scientific studies, the aim of the current research is formulated as follows:

“To analyze the long-term outcomes after lip and nasal surgery in patients with cleft lip or cleft lip and palate, following the protocol used at the Center for Craniofacial Anomalies in Plovdiv over the past 25 years, which excludes primary nasal dissection during initial cheiloplasty.”

To achieve this goal, Dr. Ginev sets the following four main objectives:

1. To compare the number of surgical interventions on the lip and nose relative to the preoperative severity of the cleft.
2. To analyze postoperative lip and nasal defects, supplementing missing categories to date.

3. To establish a correlation between preoperative severity and postoperative outcomes across different age groups.
4. To improve the follow-up and documentation of CLP patients using the EMDLA system by creating new sections.

Study Design:

A single-center, retrospective, descriptive study was conducted on CLP patients who underwent primary surgery at the Center for Craniofacial Anomalies in Plovdiv.

Study Location:

The clinical research was carried out at the Department of "Propedeutics of Surgical Diseases", Faculty of Medicine, MU – Plovdiv, and the Department of Pediatric Plastic, Reconstructive and Aesthetic Surgery at University Hospital "St. George."

Study Period:

The study was conducted over the period from 1997 to 2024. The results were recorded using a specially developed clinical statistical form for the project.

5. Materials

The study included data from 166 patients with all forms of cleft lip and/or palate, hospitalized at the Department of Pediatric Plastic, Reconstructive and Aesthetic Surgery, University Hospital "St. George" – Plovdiv, during the period 1997–2024. Of these, 102 were male (61.40%) and 64 female (38.60%). The patients' age at primary lip surgery ranged from 1 to 13 months, with a median of 2 months and a mean of 2.80 ± 2.05 months. In males, the mean age at primary surgery was 2.82 ± 2.16 months, and in females – 2.78 ± 1.88 months, with no statistically significant difference ($p = 0.898$). In both sexes, as well as in the entire group, the median age was 2 months.

Research Supervision:

The study was conducted with the direct participation and supervision of the doctoral candidate.

The number of logical units is sufficient to draw scientifically valid conclusions.

All participants met the inclusion criteria.

Inclusion Criteria:

Patients with unilateral/bilateral cleft lip \pm cleft of the alveolar ridge \pm cleft palate.

Age over 14 years.

Signed written informed consent.

Photographic documentation and supporting records.

6. Results and Discussion

The results and discussions related to each objective are presented in great detail and well-justified across 61 pages. The outcomes of each task are discussed separately, with relevant conclusions drawn for each.

Of particular importance is the result and conclusion from Objective 1, which demonstrates that **preoperative severity**, rather than the diagnosis itself, is the most significant **prognostic factor** for the surgical therapeutic burden in each patient. Furthermore, the **preoperative assessment scale** is validated as a reliable tool for predicting the therapeutic effort, the presence of postoperative defects, and the final surgical outcomes in patients with cleft lip.

Objective 4 successfully improves patient follow-up and research through the creation of new functionalities within the **Electronic Medical Dossier for Facial Anomalies (EMRFA)**. The addition of a “**Virtual Consultation**” feature for each patient aligns with the global shift toward personalized medicine and telemedicine.

Statistical Methods:

To ensure the objectivity of the results, the following statistical and mathematical methods were used:

The methods applied were consistent with the aims and tasks of the dissertation and the types of variables involved (metric, categorical, ordinal, binary).

Metric variables were tested for normal distribution using the **Shapiro-Wilk test**:

If normal distribution was confirmed (Shapiro-Wilk $p > 0.05$), the variables were presented using **mean and standard deviation (SD)**, and **parametric methods** were used for analysis.

If not (Shapiro-Wilk $p < 0.05$), the variables were presented using the **median and interquartile range (IQR)**, and **non-parametric methods** were applied.

Categorical and binary variables were summarized using **counts and percentages**.

Significance Level:

All statistical analyses were performed with a **Type I error threshold (alpha) of 5%**. Results were interpreted as statistically significant at **$p < 0.05$** .

Software Used:

IBM SPSS Statistics for Windows, Version 27.0, IBM Corp., 2020

Minitab 22.1 Statistical Software (2024), Minitab, Inc.

Reliability of Preoperative Severity and Postoperative Outcome Assessments:

Two specialists independently assessed **preoperative severity** and **postoperative outcomes** for a randomly selected group of 55 patients. Both evaluations used ordinal scales:

Preoperative severity: mild, moderate, severe, very severe

Postoperative outcome: very poor, poor, average, very good, excellent

To determine the level of agreement between evaluators, the **Kappa statistic** was used:

For preoperative severity, a high agreement rate of **97.5%** was observed (**Weighted Kappa = 0.975**).

Similarly, for postoperative outcome, agreement reached **95.2%**.

Discrepancies were minimal and differed by only one grade.

Compliance and Structure of the Dissertation:

The dissertation meets the requirements for a doctoral dissertation as per the **Regulations of MU–Plovdiv and the Act for the Development of the Academic Staff in the Republic of Bulgaria**.

The dissertation is presented over **144 standard typed pages**, thoroughly illustrated with **80 figures and 38 tables**.

The literature review includes **209 sources**, **29** of which are in Cyrillic.

The results are comprehensively and accurately described, analyzed, and interpreted.

The discussion follows the same sequence as the presentation of the results.

The conclusions are specific and summarize the key aspects of the study.

The dissertation has been reviewed and approved for defense by the **Departmental Council of the Department of “Propedeutics of Surgical Diseases”**, Faculty of Medicine, MU – Plovdiv.

Final Conclusions

The dissertation concludes with findings based on the discussion and derived patterns, as follows:

The number of surgical interventions on the lip and nose, as well as the results of primary surgeries, correlate directly with the **preoperative severity** according to the used scale. No such correlation exists when comparing outcomes based only on **ICD diagnosis**, thereby validating the introduced scales for preoperative severity and postoperative outcomes.

The analysis of postoperative defects in the lip and nose has been enhanced with previously missing categories. The study also clarified the **frequency, significance, natural progression, and correction methods** of various defects at different ages.

A statistically significant relationship was established between **preoperative severity** and **postoperative outcome** across different age groups.

New evaluation categories such as **efficacy** and **quality of follow-up** were introduced and implemented in the existing **EMDCA** system.

Contributions and Scientific Significance of the Dissertation

1. Original Contributions:

- ✓ For the **first time in Bulgaria**, long-term outcomes following **primary and secondary lip and nose surgeries** in patients born with cleft lip and/or palate have been comprehensively studied.
- ✓ The **preoperative severity scale** has been **validated as a prognostic marker** related to the need for additional corrective surgeries.
- ✓ An analysis of the **most common lip and nasal defects post-surgery** and their evolution over time in the **Bulgarian population** has been presented, along with principles for their correction.
- ✓ A **new classification** of postoperative defects has been proposed, based on their methods of correction.
- ✓ Previously **undescribed defects** have been added to the existing defect scale, along with **correction strategies**.
- ✓ A clear **framework for the objectives** at different **growth stages** has been introduced.

- ✓ Follow-up methods have been enhanced through the introduction of a new functionality in EMRFA – the **Virtual Consultation**, improving patient documentation.
- ✓ The precise analysis of long-term outcomes based on the team’s surgical protocol provides a **benchmark for future comparisons**, should the protocol be modified.
- ✓ The new categories of **treatment efficacy** and **quality of follow-up** have been introduced as concepts and integrated into EMRFA functionalities.
- ✓ A new function for **tracking the quality of patient follow-up** through EMRFA was initiated, allowing period comparisons and quality assessments.

2. Confirmatory Contributions:

- ✓ The **epidemiological data** on CLP patients in Bulgaria aligns with European literature.
- ✓ The **distribution of cleft lip types by sex** mirrors what is reported in international sources.
- ✓ The effectiveness of **primary cheiloplasty without initial nasal dissection** on postoperative nasal deformities was confirmed.
- ✓ A **new classification** of postoperative defects based on their correction methods has been proposed.

7. Evaluation of the Publications Related to the Dissertation

Three publications and sixteen participations in scientific forums related to the dissertation topic have been presented.

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9. Author’s Abstract

The author’s abstract has been prepared in accordance with the requirements of the **Act for the Development of the Academic Staff in the Republic of Bulgaria** and the regulatory framework of **MU – Plovdiv**. It reflects the content of the dissertation accurately.

10. Critical Remarks and Recommendations

The set of materials provided for the dissertation is complete and in compliance with the Act for the Development of the Academic Staff in the Republic of Bulgaria, its implementation regulations, and the internal regulations of **MU – Plovdiv**. I have no remarks or recommendations.

11. Personal impressions

I have no personal impressions of Dr. Ginev. The dissertation he has submitted is a product of his own experience and scientific endeavors, grounded in his knowledge of the specialty. The provided text demonstrates a deep understanding of the subject matter.

12. Recommendations for Future Application of the Dissertation's Contributions and Results

I recommend that Dr. Ginev continue and further develop his scientific work in this important and practical area of medical knowledge.

CONCLUSION

The dissertation submitted for review by **Dr. Ivan Ginev**, full-time doctoral candidate, on the topic: **“Evaluation of Early and Late Results after Cheiloplasty”** is accepted as complete. It meets the requirements of the **Higher Education Act**, the **ADASRB**, its Implementation Regulations, and the Regulations of **MU – Plovdiv**.

The topic is timely and well chosen. The literature review is comprehensive and provides a clear understanding of the current state of the problem being addressed. It concludes with a critical analysis, which forms a solid basis for the conducted research.

Based on the analysis of previously conducted studies, the aim of the dissertation has been clearly defined. The set objectives allow for its validation. The conducted research is of interest to both medical science and practice. The obtained results, their interpretation, and the related publications are accepted as the personal work of the author.

The dissertation demonstrates that the doctoral candidate, **Dr. Ginev**, possesses in-depth theoretical knowledge and professional skills in the specialty **Plastic and Aesthetic Surgery**, showing qualities and abilities for independent scientific research.

Based on all of the above, I accept that the requirements of the **Act for the Development of the Academic Staff in the Republic of Bulgaria**, its implementation regulations, and the relevant regulations of **MU – Plovdiv** have been fulfilled. The submitted materials and dissertation results fully meet the specific requirements of **MU – Plovdiv**.

In conclusion: I confidently give a **positive evaluation** of the dissertation entitled: **“Evaluation of Early and Late Results after Cheiloplasty”**, and I will vote **“YES”** for awarding the **educational and scientific degree “Doctor”** in the scientific specialty **Plastic-Reconstructive and Aesthetic Surgery**, code – **03.01.43**, to **Dr. Ivan Genchev Ginev**.

30.07.2025

Reviewer:
(Professor Rossen Gospodinov Kolarov MD, PhD)