MEDICAL UNIVERSITY
"PROF. DR. PARASKEV STOYANOV" – VARNA
FACULTY OF DENTAL MEDICINE
DEPARTMENT OF DENTAL MATERIALS SCIENCE AND PROSTHETIC DENTISTRY

ABSTRACT

of a dissertation

for the award of the educational and scientific degree of "DOCTOR"

on the topic:

REHABILITATION OF COMPLETELY EDENTULOUS PATIENTS WITH COMPLETE DENTURES FABRICATED THROUGH A DIGITAL WORKFLOW – POSSIBILITIES, ADVANTAGES, AND LIMITATIONS

Dr. Yordanka Donkova Shekerova

Doctoral Program: Prosthodontics

Supervisor:

Assoc. Prof. Desislava Atanasova Konstantinova, D.M.

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The dissertation comprises 232 standard pages and is illustrated with 70 tables, 119 figures, and 5 appendices. The bibliography includes 337 references, of which 13 are in Cyrillic and 324 in Latin script.

The dissertation has been reviewed and scheduled for defense by the Departmental Council of the Department of Dental Materials Science and Prosthetic Dental Medicine at MU – Varna on May 14, 2026 (Decision of the Departmental Council, Protocol No. 33/May 14, 2026).

The public defense of the dissertation will take place on September 1, 2026, Tuesday, at 1:30 p.m., in Room 111 of the Faculty of Dental Medicine, Varna Medical University and online via Webex at an open meeting of the Scientific Jury in a hybrid format.

Scientific Jury:
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The materials related to the defense are available at the Research Department of Medical University – Varna and are published on the MU – Varna website.

Note: In the abstract, the numbers of the tables and figures do not correspond to the numbers in the dissertation.

TABLE OF CONTENTS

ABBREVIATIONS USED

UJ	upper jaw
LD	lower jaw
2D	two-dimensional
3D	three-dimensional
ABS	acrylonitrile-butadiene-styrene
A-silicones (PVS)	additive silicones (polyvinyl siloxane)
α	level of statistical significance
CAD	computer-aided design (CAD)
CAD/CAM	Computer-Aided Design / Computer-Aided Manufacturing
CAE	Computer-Aided Engineering
CBCT	Cone Beam Computed Tomography
CEREC	Chairside Economical Restoration of Esthetic Ceramics
CI	Clinical Index
DICOM	Digital Imaging and Communications in Medicine
FDM	Fused Deposition Modeling
GC	General Corporation – manufacturer of dental materials
ISS	intraoral scanning systems
LED	Light Emitting Diode (LED)
Ls	sagittal dimension of the mandible
Lf	frontal dimension of the mandible
Mean	mean
p	p-value
PE	polyether
PEEK	polyetheretherketone
PLA	polylactic acid
PMMA	polymethyl methacrylate
SD	standard deviation
SPSS	Statistical Package for the Social Sciences
STL	Standard Tessellation Language
Us	sagittal dimension of the upper jaw
Uf	frontal dimension of the upper jaw
VDO	Vertical Dimension of Occlusion
VPES	vinyl-polyether-silicone
VPS	vinylpolysiloxane
χ^2	chi-square test

I. INTRODUCTION

Complete tooth loss is considered an extreme form of pathological condition in prosthetic dentistry due to its complex impact on basic vital functions such as eating, breathing, and speaking, as well as on the psycho-emotional state and facial aesthetics. The primary goal of prosthetic rehabilitation in completely edentulous patients is to restore these functions by fabricating a complete denture that replaces the missing dental structures and transmits masticatory forces via the mucosa-bone pathway.

Despite significant advances in modern dental medicine and the introduction of innovative methods for restoring the masticatory system, conventional full dentures remain a widely used therapeutic approach due to their relatively simple technology and lower cost. The traditional protocol requires the completion of several sequential clinical and laboratory stages.

In recent years, digital technologies—and CAD/CAM systems in particular—have been increasingly adopted as an alternative to conventional methods for fabricating complete dentures. Despite data indicating higher precision and reproducibility of digital approaches, their potential for completely edentulous patients has not yet been sufficiently explored.

Individual anatomical and morphological characteristics, as well as age-related and functional changes following complete edentulism, do not allow for a standardized protocol for prosthetic treatment. This necessitates the application of modern imaging diagnostic methods, as well as an in-depth analysis of the digital materials used, with the aim of optimizing the design and functional characteristics of the entire prosthetic constructions.

All of the listed factors make it impossible at this stage to formulate a universal and unambiguous protocol for the digital fabrication of complete dentures. Limited clinical experience and

existing variations in technological approaches lead to uncertainty and difficult-to-predict final results.

The relevance of this study is determined by the need to develop and optimize a scientifically sound protocol for the fabrication of functionally adequate full dentures through the application of CAD/CAM technologies and modern biomaterials, tailored to the distinct individual characteristics of the edentulous jaw.

II. OBJECTIVE AND TASKS

The objective of this dissertation is, based on clinical, experimental, and statistical studies, to investigate the possibilities, advantages, and disadvantages of using additive technologies in the rehabilitation of completely edentulous patients, while improving efficiency and precision through the development and implementation of an advanced digital protocol based on morphometric analysis, the experimental design of a custom tray, and a streamlined algorithm for clinical practice.

Tasks:

1. Investigation of the dimensional characteristics and morphological features of the prosthetic field in completely edentulous patients through analysis of 3D imaging studies.

2. Clinical evaluation of complete dentures fabricated using a digital protocol via additive technologies

3. Development and validation of an experimental model of a custom impression tray aimed at optimizing the digital clinical-laboratory protocol for the fabrication of complete dentures.

3.1. Legal protection of the developed model through registration of an industrial design patent.

3.2. Investigation of certain physicochemical and biological properties of the experimental impression tray.

4. Assessment of time efficiency in taking functional impressions of the upper and lower completely edentulous jaws using various materials and techniques.

5. Development and implementation of an algorithm for reducing the steps in the partial digital workflow for prosthetic rehabilitation of completely edentulous patients, based on the results of a conducted experimental study.

III. MATERIALS AND METHODS

IV.1. Materials and methods for Task 1

IV.1.1. Materials:

This study included a total of 39 patients referred to diagnostic imaging during the prosthetic examination for their upcoming dental treatment.

IV.1.2. Methodology:

All patients included in the study underwent three-dimensional imaging of the upper and lower jaws using cone-beam computed tomography (CBCT). The examinations were performed using an Orthopantomograph OP300 device, which allows for the acquisition of high-resolution three-dimensional images of the maxillofacial region.

All acquired tomographic scans (n = 39) were processed and analyzed using specialized Romexis Viewer software, version 4.6.2.R (Planmeca). As part of the analysis, biometric constants and anatomical landmarks were identified, which served as a stable basis for performing the morphometric measurements. The delineation of reference lines allowed for standardization of the measurement methodology and enabled an objective assessment of the spatial relationships between the individual structures of the maxillofacial complex.

To determine the dimensional measurements of the maxilla, the following markers were placed, and the corresponding lines were drawn:

Ut – a line tangent to the most prominent point of the tuber on the buccal side of the maxilla. This line was drawn on the left and right sides, respectively, after placing a marker on the most prominent point of the tuber maxillae on the left and right

Ud – a line connecting the most posterior (distal) points of the tuber on the left and right

Ua – a line tangent to the most prominent point of the frontal part of the alveolar ridge

To measure the size of the maxilla in the sagittal direction, a line Us was drawn and measured, passing through the tuber maxillae and perpendicular to the two Ut lines. To determine the vestibulo-oral dimension of the maxilla relative to the frontal plane, a line Uf was drawn passing through the midpoint of the hard palate and intersecting lines Ua and Ud perpendicularly. (Fig. 1) (Fig. 3)

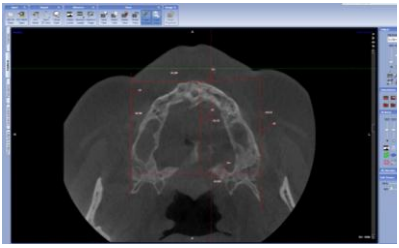


Fig. 1 *Reference lines defining the size of the maxilla*

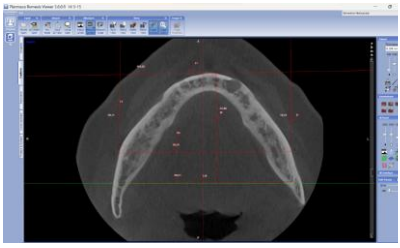


Fig. 2 *Reference lines for assessing the size of the mandible*

To measure the dimensions of the mandible in the three-dimensional imaging studies, the following lines were drawn:

Lt – a line tangent to markers on the most prominent buccal point of the retromolar trigone on the left and right

Ltd – a line connecting the most distal points of the two retromolar trigones

La – a line tangent to the most prominent point on the frontal part of the alveolar ridge

To determine the sagittal dimensions of the edentulous mandible, a line Ls was drawn, connecting the two most prominent points of the retromolar trigonum and perpendicular to the two Lt lines. Line Lf, which passed through the midline of the mandible and intersected lines La and Ltd perpendicularly, was drawn and

measured. It determined the vestibulo-oral dimension of the jaw relative to the frontal plane. (Fig. 2) (Fig. 4)

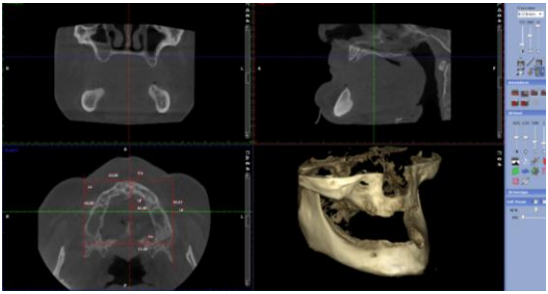


Fig. 3 *Representation of the upper edentulous jaw in various projections*

The linear distances thus determined and recorded allow for the development of a protocol for measuring the average dimensions of the jawbones. The results obtained are used to select an impression tray that is fully tailored to the patient's individual anatomical characteristics, facilitating clinicians' planning and treatment with removable dentures.

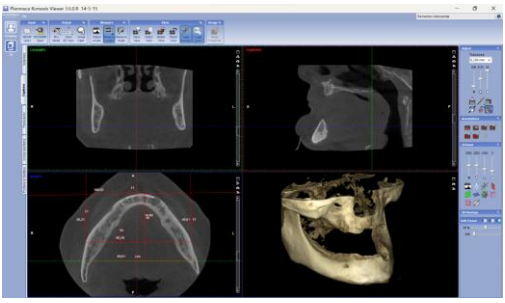


Fig. 4: *Illustration of the mandibular edentulous jaw*

Statistical analysis was performed using SPSS v. 20.0 for Windows. The following analyses were used: comparative, descriptive, and correlation analysis.

IV.2. Materials and Methods for Task 2

IV.2.1. Materials:

A total of 30 completely edentulous patients, including 17 men and 13 women, aged between 40 and 80 years, were included in this clinical study. All participants were selected in accordance with predefined criteria ensuring the homogeneity of the study group and the reliability of the results obtained. (Table 1)

Table 1 *Inclusion and exclusion criteria for study participants*

Inclusion criteria	Exclusion criteria
Age between 40 and 80 years	Age under 40 or over 80 years
Complete edentulism of the upper and lower jaws	Partial edentulism or presence of residual teeth
Absence of bone deformities and pathological changes in the prosthetic field	Pronounced bone deformities or pathological changes in the prosthetic field
Clinically healthy mucosa without active inflammatory processes	Active inflammatory, ulcerative, or neoplastic changes in the mucosa
Satisfactory general health and no history of allergies	Uncontrolled systemic diseases (e.g., decompensated diabetes, active osteoporosis) and a history of allergies
Ability to cooperate adequately and adhere to the clinical protocol	Inability to cooperate or cognitive impairments
Signed informed consent to participate in the study, approved by the Ethics Committee of the Faculty of Dentistry, Medical University of Varna	Refusal to participate or lack of informed consent

IV.2.2. Methodology:

The methodological design of the study was based on the integration of modern digital technologies, including intraoral

scanning, computer-aided design (CAD), and 3D printing. This approach allowed for comprehensive tracking and analysis of the relationship between the digital workflow, the morphological precision of the fabricated target prostheses, and their key clinical characteristics—retention, stability, adaptation, occlusal harmony, and patient subjective satisfaction.

Digital impressions were taken using the Aoralscan 3 (Shining 3D) intraoral scanning system.

Digital Impression Methodology:

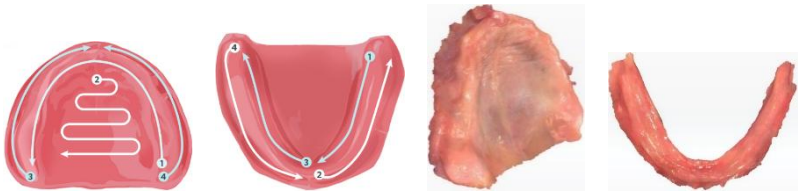
The Aoralscan 3 intraoral scanning system was calibrated according to the manufacturer's instructions.

Upper jaw scan:

The procedure began at the palatal surface, with the scanner moving along the entire length of the alveolar ridge. In the next step, a zigzag scan was performed to capture the hard palate in detail. The scanner was then directed in a vestibular direction to the left—from the tuber region toward the anterior section. The same sequence was repeated in a mirror image for the right side of the jaw (Figs. 5a and 5c)

Scanning of the lower jaw:

The Aoralscan 3 intraoral scanner was positioned lingually in the area of the left retromolar space, from where the scan began. The device was moved
along the edentulous alveolar ridge until reaching the midline. In the next step, the scanner was rotated toward the vestibular surface, sequentially scanning the vestibular slope and the palatal area until returning to the initial retromolar region. Scanning of the right half of the mandible began at the midline, with the scanner again positioned lingually. The device was moved toward the right retromolar space. Upon reaching this area, the scanner was rotated vestibularly, and the vestibular slope and the flap area were scanned. At the end of the procedure, the device returned to its starting position. (Figs. 5b and 5d)



a b c d

Fig. 5 *Schematic of scanning the upper (**a**) and lower (**b**) edentulous jaws according to Russo; digital impression of the upper (**c**) and lower (**d**) edentulous jaws*

The registration of interarch relationships and the determination of the vertical dimension of occlusion (VDO) were performed using a paste-like C-silicone material, which served as a temporary interocclusal registration. (Fig. 6)

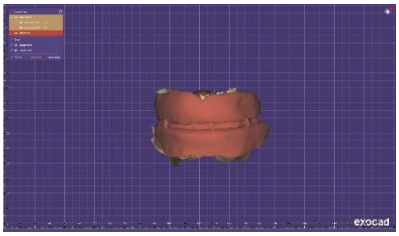
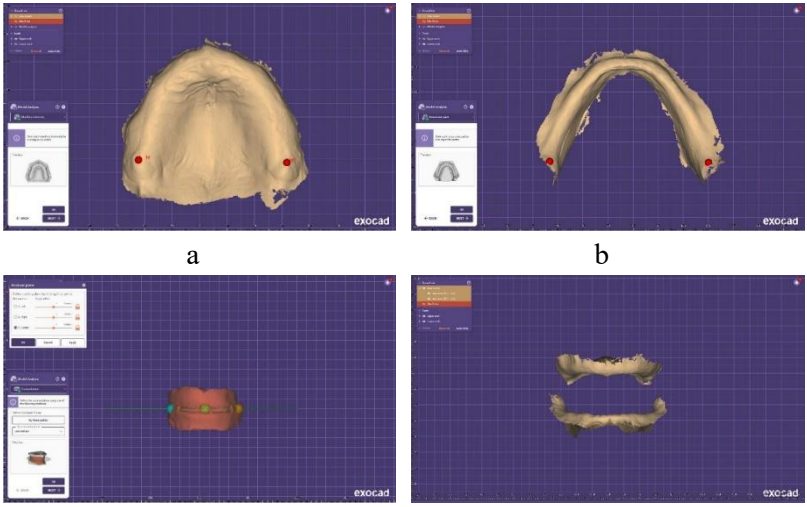


Fig. 6 *Intraocclusal registration*

The resulting .stl files were saved and exported to the specialized dental software Exocad DentalCAD 3.1 for subsequent computer modeling and processing. (Fig. 7a, b)

In the dental laboratory, digital design of upper and lower complete dentures was performed using Exocad. Occlusal relationships were analyzed and verified using a virtual articulator module, which allowed for precise control over functional contacts and balanced occlusion. (Fig. 7c, d)

After the final completion of the virtual design, the .stl files of the denture base and artificial teeth were exported as separate objects for the purpose of two-component additive manufacturing. (Fig. 8)



a b

c d

Fig. 7 *Digital models*

The denture bases were fabricated using photopolymerization (DLP) technology with the biocompatible resin NextDent Denture 3D+ (NextDent B.V., Netherlands).

Fig. 8 *Virtual design of upper and lower complete dentures*

The artificial teeth were printed separately using 3D technology with the high-performance photopolymer resin NextDent C&B MFH (Micro Filled Hybrid). Upon completion of the additive manufacturing process, all prosthetic structures underwent standardized post-processing: cleaning in isopropyl alcohol (≥96%) to remove residual unpolymerized material, followed by photopolymerization in a UV chamber. The artificial teeth were bonded to the prosthetic base using a light-curing adhesive composite cement recommended by the manufacturer of the NextDent system.

After completion of the dentures, a comprehensive clinical evaluation of the main functional and biomechanical parameters was performed, including retention, stability, adaptation to the denture field, occlusal relationships, and the patient's subjective satisfaction under real-world conditions.

Assessment of retention in the prosthetic field

The clinical evaluation was performed using a standardized manual test with moderate vertical pull. (Table 2)

Table 2 *Criteria for evaluating the retention of complete dentures*

Assessment	Clinical characteristic
0 – lack of retention	The denture detaches easily with a slight vertical pull
1 – partial retention	The denture detaches with moderate resistance
2 – good retention	The prosthesis remains firmly fixed when an attempt is made to detach it

Assessment of stability over the prosthetic field

The clinical assessment was performed with the patient in a seated position with the mouth slightly open. The examiner applied a controlled lateral force, sequentially on both sides, by pressing with the index finger in the premolar region. (Table 3)

Table 3 *Criteria for assessing the stability of complete dentures*

Assessment	Clinical characteristic
0 – unstable	The denture tilts or detaches when lateral force is applied
1 – moderate stability	The prosthesis shows moderate rotation without complete detachment
2 – stable	The prosthesis remains immobile when force is applied

Assessment of margins and peripheral fit on the prosthetic field

Table 4 *Criteria for evaluating the marginal fit*

Assessment	Clinical characteristic
0 – poor fit	Detachment with minimal functional movements; presence of air bubbles or hypersalivation.
1 – satisfactory fit	The margins remain stable during light movements but partially detach during maximum movements; functionally acceptable.
2 – Good fit	Complete peripheral stability; no detachment during all functional tests

The clinical assessment was performed using a functional test involving gentle pulling of the lips and cheeks. (Table 4)

Assessment of Patient Comfort During Functional Loading of the Dentures

Comfort while wearing the prosthesis was assessed as a subjective indicator reflecting the patient's individual sense of comfort, presence or absence of pain, and sensation of pressure. (Table 5)

Table 5: *Criteria for assessing comfort during functional loading of prostheses*

Assessment	Clinical characteristic
0 – presence of pain	Unsatisfactory comfort; presence of traumatic areas or improper adaptation
1 – presence of mild discomfort	Moderate comfort; additional adjustment is needed
2 – No pain and complete comfort	Optimal comfort; good tolerability and clinical efficacy

Phonetic Assessment

The clinical assessment of phonetics was performed by having the patient reproduce control phrases and sound clusters, including sibilant sounds (“s,” “sh”) and labiodental sounds (“f,” “v”). (Table 6)

Table 6 *Criteria for Phonetic Assessment*

Assessment	Clinical characteristic
0 – impaired phonetics	Difficult or unclear speech; the patient cannot pronounce certain sounds (“s,” “sh,” “f,” “v”) correctly.
1 – Partially preserved	Minor difficulties with rapid speech or with certain phonemes.
2 – normal phonetics	Clear and intelligible speech; no sound distortions or whistling.

Assessment of the aesthetic appearance of the prostheses

The aesthetic outcome of prosthetic treatment was assessed by analyzing the visual harmony of the prosthetic construction. (Table 7)

The results of the clinical evaluation were systematically documented using a standardized clinical form developed for the purposes of the study.

Table 7 *Criteria for evaluating the aesthetic appearance of the prostheses*

Assessment	Clinical characteristic
0 – unsatisfactory aesthetics	Presence of disproportionate, malpositioned, or artificial-looking teeth; disrupted smile line and adverse effect on facial harmony.
1 – acceptable aesthetics	Relatively harmonious appearance, but with minor discrepancies related to the color, shape, or position of the teeth, as well as slight deviations in the smile line.
2 – excellent aesthetics	Achievement of a completely natural appearance; the prosthesis integrates harmoniously with the facial structures and is visually indistinguishable from natural teeth; the patient expresses complete satisfaction with the aesthetic result.

Statistical analysis of the results

Statistical analysis of the data was performed using specialized statistical software (SPSS v. 20.0)

IV.3. Materials and Methods for Task 3

IV.3.1. Material:

The units of observation were 15 samples of upper and 15 samples of lower experimental custom trays. The design of the experimental trays was based on the concept of integrating two key clinical steps—taking functional impressions in edentulous patients and simultaneously determining the interarch relationship with a specially designed model.

IV.3.2. Methodology:

The initial prototype of the experimental tray was developed by digitizing standard polycarbonate trays for the upper and lower completely edentulous jaws using a 3Shape™ D850® extraoral laboratory scanner.

The prototype files with the .STL extension generated by the 3Shape Dental System® CAD system were imported into the specialized spatial modeling software Autodesk Meshmixer®. Using the architectural software ArchiCAD 22, an external matrix design was created on the resulting 3D models, with dimensions of 11.5 mm in height and a width of 6 mm in the anterior region and 8 mm in the distal region, intended for shaping the wax occlusal ridges. (Fig. 9)

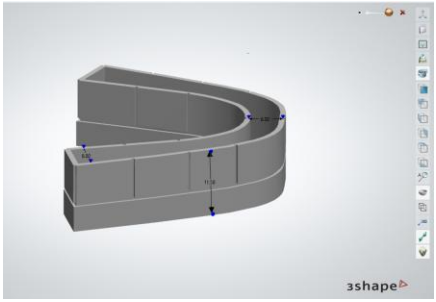


Fig. 9 *Dimensions of the external matrix*

The digital prototypes of the experimental upper (Fig. 10) and lower jaw (Fig. 11) were exported in *.STL* format and imported into the *Creality Slicer v.4.8.2*® software platform (Fig. 12) to prepare the files for 3D printing.

Fig. 10 *Digital prototype of the "Occlutray" for the upper jaw – occlusal, lateral, and palatal views*

Fig. 11 *Digital prototype of an experimental impression tray for the lower jaw – occlusal, lateral, and lingual views*

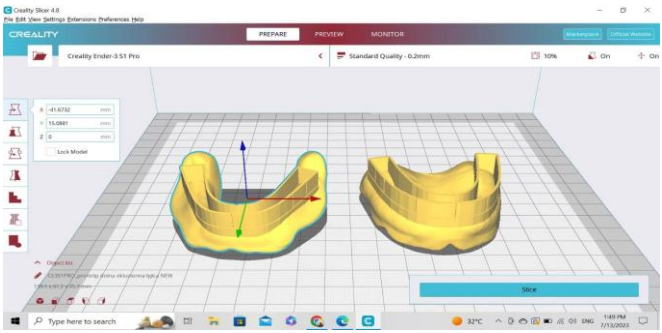


Fig. 12 *Digital prototypes in Creality Slicer 4.8.2.*®*print preparation software*

The experimental prototype trays were fabricated using additive manufacturing technology with an *Ender-3 S1 Pro* (Creality) filament 3D printer. (Fig. 13) The printing materials included **Everfil**

ABS (acrylonitrile-butadiene-styrene) manufactured by 3DKordo, as well as an *ecoPLA* variant.

Fig. 13 *Ender-3 S1 Pro filament printer*

The technical parameters were set in the Creality Slicer v.4.8.2® software environment and optimized for ecoPLA and Everfil ABS filaments when printing the prototype models of an experimental impression tray using the Ender-3 S1 Pro printer. (Table 8)

After the printing process was completed, the models were left to cool on the heated bed until they reached room temperature to prevent thermally induced deformations and ensure dimensional stability. They were then carefully removed from the platform using a flexible spatula, taking care to avoid mechanical stress on the edges and functional areas of the trays.The printed brim elements and support structures were removed manually using a scalpel and fine abrasive tools. The surfaces of the PLA prototypes were treated with isopropyl alcohol to remove dust residues, while the ABS prototypes underwent brief treatment with acetone vapor to achieve a smoother and more homogeneous surface. (Fig. 14)

All manufactured prototypes underwent a preliminary visual inspection to assess their structural and geometric conformity with the predefined digital model. The inspection was performed prior to proceeding to the subsequent experimental stages to ensure the reliability and reproducibility of the results obtained.

Only the samples that met the predefined quality criteria—preserved geometric integrity, correctly formed peripheral edges, and uniform material structure—were included in the subsequent stages of the experimental study.

Fig. 14 *Printed prototypes of experimental upper and lower trays*

IV.3.1. Materials and Methods for Task 3.1.

IV.3.1.1. Material:

To ensure the novelty, individual character, and reproducibility of the development, an application for industrial design registration was filed with the Patent Office of the Republic of Bulgaria prior to the start of clinical trials, pertaining to the appearance and configuration of the experimental custom tray. The registration was granted under Reg. No. BG – 9363, Application No. 12230, filing date: 02/02/2024, publication/registration date: 02/20/2024, with author(s)/designer(s): Yordanka Donkova Shekerova, Delian Krasimirov Georgiev, Desislava Atanasova Konstantinova. The scope of protection covers the submitted images/views and the description, granting the exclusive right to use and dispose of the design for the specified products (in accordance with the Industrial Design Act).

The materials used—PLA (polylactic acid) and ABS (acrylonitrile-butadiene-styrene)—are polymers with proven biocompatibility during short-term contact with oral tissues. The biological safety assessment complies with the requirements of the ISO 10993 series of standards (relevant parts 1, 5, 10, 12, 17, and 18), as well as with the specific requirements for dental devices according to ISO 7405.

IV.3.1.2. Methodology:

Protection procedure. Prior to publication and clinical validation, a prior art search was conducted, and a set of representative images (views), a description, and a Locarno classification were prepared, according to which it falls under Class 24 – Medical and laboratory equipment; Subclass 24-02 – Medical instruments (hand-operated). The basis for this was that the experimental tray is a hand-operated dental instrument for taking functional impressions of the upper and lower edentulous jaws and recording interarch relationships in cases of total edentulism. (Fig. 15)

Fig. 15 *View of upper and lower experimental trays*

The application for registration of an industrial design was filed with the Patent Office of the Republic of Bulgaria, which is the competent national authority for the protection of industrial property. The application was filed at in accordance with the established regulatory requirements, including the necessary graphic representations of the design, a description of its essential visual characteristics, as well as information regarding the applicant and the designer. (see Figs. 10 and 11)

After the application was filed, an official examination was conducted by the Patent Office. The formal examination was intended to ensure that the application met the established standards and could be admitted to the next stages of the procedure.

During the development and identification of the industrial design for the developed trays, the name Occlutray was assigned. The term Occlutray was constructed as a compound name derived from the English terms “occlusion” and “tray” (individual impression tray). In this way, the name itself reflects the functional concept of the development, which involves simultaneously accounting for occlusal relationships and the use of a specially designed impression tray.

IV.3.2. Materials and Methods for Task 3.2

IV.3.2.1. Material:

The patients studied, divided into age groups, constituted the clinical population from which the units of observation in the present study—the microbiological samples—were obtained. A sample was taken from each included patient using an experimental Occlutray-type tray made of PLA or ABS. In this way, the patients constituted the source of the biological material, while the actual units of observation in a statistical sense were the microbiological samples taken from the surface of the Occlutray. A total of 24 trays were analyzed, divided into two groups based on material:

n = 12, made of polylactic acid (PLA)

n = 12, made of acrylonitrile butadiene styrene (ABS)

Microbiological samples were taken from each tray at three consecutive stages of the process to track the dynamics of microbial contamination and the effectiveness of the decontamination procedures applied:

1. Before disinfection – immediately after clinical use;
2. After chemical disinfection – in accordance with an established clinical protocol;
3. After sterilization – following a standard sterilization cycle.

The total number of microbiological samples amounted to 72 observations (24 trays × 3 stages), which provided the opportunity for a statistically reliable assessment of the influence of the material and the technological stage on the degree of microbial contamination.

IV.3.2.2. Methodology:

After determining the appropriate size of the Occlutray experimental tray, it was positioned in the patient's oral cavity and pressed evenly against the prosthetic field to maximize the reproduction of clinical conditions during a standard functional

impression-taking procedure and to assess primary microbial contamination following intraoral exposure.

Immediately after removing the tray from the oral cavity, microbiological sampling was performed from its surface. Samples were collected using a sterile swab with Amies transport medium without charcoal. Using the swab, through rotational and sliding movements, both the inner (contact) and outer surfaces of the tray were sequentially swabbed to maximize the collection of the present microflora.

After sampling was completed, the swab was placed back into the transport medium, and each sample was individually labeled with an identification code indicating the tray material and the corresponding processing stage. After transport to the microbiology laboratory, the samples were processed immediately under aseptic conditions. Standardized aliquots of the resulting suspension were inoculated onto selective and non-selective culture media suitable for isolating aerobic and facultative anaerobic oral microflora.

Incubation was performed at 37°C for 24–48 hours under aerobic conditions. After the incubation period ended, the grown colonies were counted, and morphological and biochemical identification of the isolated microorganisms was performed as necessary.

The microbiological analysis was performed in the laboratory of the Department of Clinical Microbiology and Medical Parasitology at the Targovishte Regional Hospital. The studies were conducted in accordance with the internally validated laboratory protocol for monitoring and evaluating the effectiveness of disinfection and sterilization processes.

After the initial sampling, the experimental tray was subjected to chemical disinfection by complete immersion in a 2% solution of Orolin Multisept Plus for an exposure period of 60 minutes, in accordance with the manufacturer’s recommendations and the established internal disinfection protocol.

Upon completion of the disinfection cycle, the tray was rinsed with sterile saline solution to remove any residual disinfectant that could affect the microbiological analysis. Immediately thereafter, a repeat microbiological sampling was performed according to an identical standardized protocol, involving swabbing the inner and outer surfaces with a sterile swab containing Amies transport medium without charcoal.

Each experimental tray was individually wrapped in sterile medical wrapping paper. Sterilization was performed in a W&H/Lisa steam autoclave using a standard gravity program at a temperature of 121°C and an exposure time of 20 minutes.

After completion of the sterilization cycle, a microbiological control sample was collected from the surface of the tray by swabbing with a sterile swab, using the same standardized sampling protocol applied in the previous steps.

The sample material collected was placed in a transport medium and transported in a specialized container to the clinical microbiology laboratory for subsequent culture analysis.

The obtained samples were inoculated onto solid culture media — blood agar for the isolation and quantitative assessment of the total aerobic bacterial flora and McConkey agar for the selective isolation of members of the Enterobacteriaceae family in a thermostat at a temperature of 35–37°C for a period of 48 hours under aerobic conditions.

Samples in which bacterial growth was detected underwent subsequent biochemical identification over an additional 24 hours to determine the species of the isolated microorganisms.

The samples obtained in the post-sterilization stage were inoculated into a liquid culture medium—Tryptic Soy Broth—designed to detect the presence of viable aerobic and facultative anaerobic microorganisms at 35–37°C over a period of 14 days (Fig. 16)

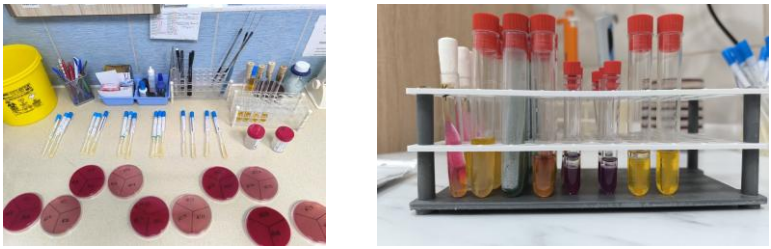


Fig. 16 *Microbiological samples inoculated onto solid culture media in Petri dishes and in soy-casein broth for a 14-day incubation period.*

In the absence of visible changes by the end of the 14-day period, the sample was considered negative for growth, which was interpreted as an effective sterilization process.

IV.4. Materials and Methods for Task 4

IV.4.1. Materials:

The study group included 31 patients (men and women) with clinically established complete edentulism of the upper and lower jaws. All participants were referred for prosthetic rehabilitation with complete dentures and met the predefined inclusion criteria.

Each jaw of each patient, processed using a specific impression technique (conventional or digital), was considered a separate statistical unit. (Table 8)

Table 8 *Number of statistical units*

Type of impression method	Upper jaw	Lower jaw
Custom tray + C-silicone	31	31
Occlutray + C-silicone	31	31
Occlutray + A-silicone	31	31
Occlutray + vinyl polyether silicone (VPES)	31	31
intraoral digital impression	31	31
Total number of impressions	155	155

IV.4.2. Methodology:

All participants underwent a standardized clinical protocol, including a detailed review of general and dental history, assessment of systemic status, as well as a thorough extraoral and intraoral examination. The clinical examination included an analysis of the condition of the prosthetic field, the degree of alveolar ridge resorption, the condition of the mobile and immobile mucosa, muscle tone, and the functional mobility of the perioral tissues.

By strictly applying the predefined inclusion and exclusion criteria, 31 patients with completely edentulous upper and lower jaws were selected. This resulted in a homogeneous clinical sample suitable for a comparative analysis of different prosthetic approaches.

Functional impressions were taken for each patient using custom impression trays, with five different methodological variants

applied, involving combinations of various impression materials and techniques. Each method was performed according to a standardized clinical algorithm, ensuring reproducibility of the procedure and the possibility of an objective comparison between the individual variants.

Description of the functional impression-taking methods studied

Within the scope of the study, five different methods were applied to obtain functional impressions in completely edentulous patients:

- Method 1 (control group): custom tray + C-silicone
- Method 2: Occlutray + C-silicone
- Method 3: Occlutray + A-silicone
- Method 4: Occlutray + vinyl polyether silicone (VPES)
- Method 5: Intraoral digital impression

Method 1 – Conventional functional impression with a custom tray and C-silicone (control group)

For each jaw (upper and lower), custom impression trays were fabricated from Elite LC Tray Round light-curing plastic (Zhermack, Italy). The trays were fabricated on prefabricated diagnostic models, ensuring a uniform relief space for the impression material.

This method was adopted as the control due to its widespread use in clinical practice and its established effectiveness in the fabrication of complete dentures.

Individual impression trays were fabricated in the laboratory, tailored to the anatomical features of the prosthetic field. The resulting trays underwent a clinical adjustment phase, including verification of the peripheral margins and the uniformity of the relief space.

Functional shaping of the margins was performed using Herbst movement tests to achieve optimal peripheral adaptation to the dynamics of the perioral muscles and the mobile mucosa.

The final functional impression was taken with Oranwash L (Zhermack, Italy); prior to application, the inner surface of the tray was treated with Zhermack Tray Adhesive, a universal adhesive for silicone impression materials, to ensure optimal retention and prevent the material from detaching from the tray.

The resulting impressions were disinfected according to the established protocol (2% solution, 5 minutes) and transported to the dental laboratory for further processing.

Method 2 – Taking a conventional impression with an experimental "Occlutray" tray and C-silicone

For each patient, an "Occlutray"-type impression tray was individually selected for the upper and lower jaws, with the choice of size based on the morphological characteristics of the prosthetic field and the results obtained from Task 1. The selection took into account the width and length of the alveolar ridge, the depth of the vestibule, the degree of resorption, and the mobility of the soft tissues, with the aim of ensuring optimal coverage of the prosthetic bed and uniform distribution of the impression material.

The impression technique consisted of a two-step, two-phase procedure. In the first step, a high-viscosity condensation silicone (C-silicone)—Thixoflex M (Zhermack)—was used to obtain a primary, anatomically oriented impression.

After homogenization, the impression material was applied directly into the selected "Occlutray," ensuring uniform distribution across the entire inner surface of the tray. The impression tray was inserted into the oral cavity with controlled pressure directed along the axis of the alveolar ridge to avoid displacement of the soft tissues and deformation of the impression material. The patient was instructed to perform gentle functional movements appropriate to the clinical situation, which contributed to a more accurate registration of the dynamic boundaries of the prosthetic field.

Following a clinical evaluation of the initial impression and confirmation of adequate coverage of the anatomical structures, the

second stage of the procedure—the corrective phase—was initiated. A condensation silicone with a fluid consistency, Oranwash L (Zhermack)—was used, characterized by high fluidity and the ability to accurately reproduce fine morphological details. The material was dispensed and mixed according to the manufacturer's instructions until a homogeneous consistency was achieved, after which it was applied evenly both inside the impression medium and, when necessary, directly onto the prosthetic field.

After final placement in the oral cavity, functional movements were reproduced, thereby ensuring dynamic modeling of the peripheral margins and optimal shaping of the valve area, while simultaneously achieving precise reproduction of the prosthetic field's topography. (Fig. 17)

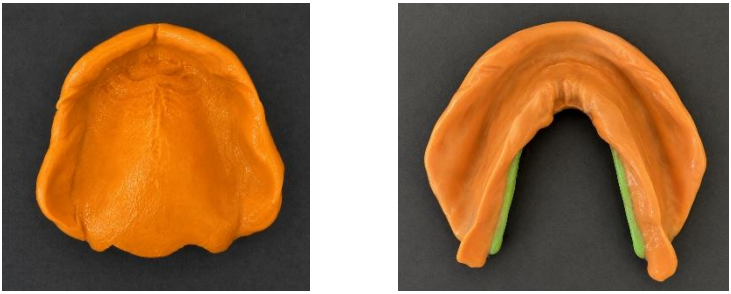


Fig. 17 *Functional working impression of the upper and lower jaws using the experimental "Occlutray" tray and Oranwash L condensation silicone, Zhermack*

After completing the disinfection protocol, the impression was rinsed with running water, carefully dried, and transported to the dental laboratory for further processing and fabrication of a working model.

Method 3 – Taking a conventional impression with the experimental "Occlutray" tray and A-silicone

Impression material of the Elite HD+ Regular Body type (Zhermack) was injected into the pre-selected, size-specific individual

impression tray for the upper and lower jaws (Occlutray) using a mixing cannula and an application gun. (Fig. 18)

The occlusal tray was positioned and adapted to the pre-dried prosthetic area in the patient's oral cavity. The patient was instructed to perform a series of functional movements, including raising and lowering the lips, sucking on the clinician's finger, as well as moving the tongue forward and to the sides (left/right)—respectively for a lower jaw impression. Passive tests, involving pulling the soft tissues—lips and cheeks—downward and forward for the upper jaw and upward and forward for the lower jaw, were performed by the dentist. The setting time of the impression material in the oral cavity was in accordance with the manufacturer's specifications.

Fig. 18 *Gun with mixing tips,*
Elite HD + Regular body impression material, Zhermack
and correction A – Hydrorise Light body silicone, Zhermack

After removing the primary impression, it was carefully dried, after which a corrective layer of low-viscosity additive silicone—Hydrorise Light Body (Zhermack)—was applied to its surface using a cannula and an application gun. The impression medium was repositioned in the oral cavity until the material reached the elastic phase, ensuring stability and detailed reproduction of the relief.

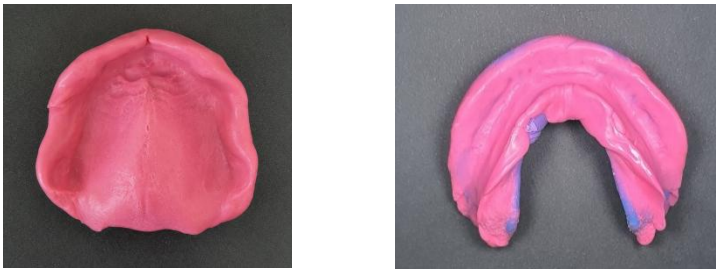


Fig. 19 *Impression of the edentulous upper and lower jaws using an experimental "Occlutray" tray and A-silicone*

Upon positive assessment of the quality of the obtained impression, it was transported to the dental laboratory for subsequent scanning. (Fig. 19)

Method 4 – Taking a conventional impression with the experimental "Occlutray" tray and VPES

After thorough drying of the prosthetic field, a functional impression was taken using an individual impression tray (Occlutray). High-viscosity impression material (EXE'lence Heavy Body Regular, GC) was applied to the occlusal " " tray using a mixing cannula and an application gun. (Fig. 20)

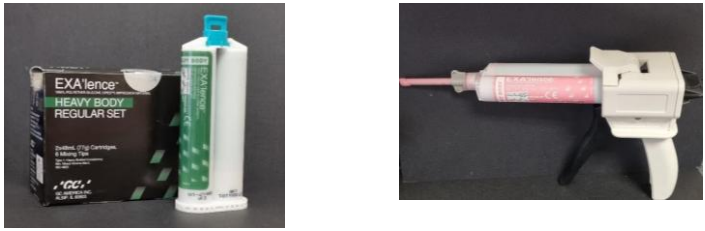


Fig. 20 *VPES – EXE'lence Heavy Body Regular, GC, and EXE'lence Light Body Regular, GC, in a gun with a mixing cannula*

The tray was positioned in the patient's mouth, where, after functional shaping of the impression margins and reaching the material's elastic phase, it was carefully removed from the prosthetic field.

After visual assessment and confirmation of the quality of the primary impression, a corrective layer of impression material with lower viscosity (EXE'lence Light Body Regular, GC) was applied to its surface.

The Occlutray experimental tray was carefully repositioned in the oral cavity. The impression was removed after the time required for the material to fully set, in accordance with the manufacturer's instructions. (Fig. 21)

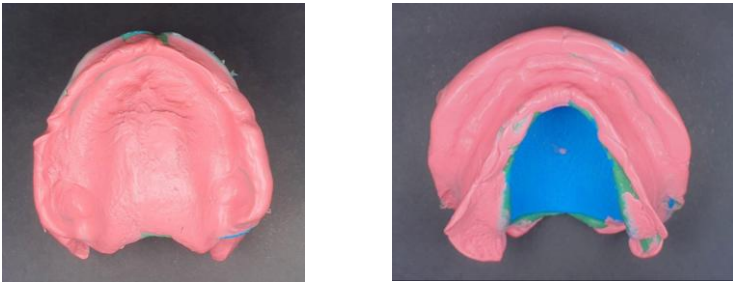


Fig. 21 *Adjustment impression of the upper and lower edentulous jaws using "Occlutray" and EXE'lence Light Body Regular, GC*

The impression was disinfected in accordance with the previously described protocol. It was transported to the dental laboratory in a hermetically sealed polyethylene bag to maintain sterility and prevent contamination.

Method 5 – Digital Intraoral Impression

To take a digital impression, patients were invited back after the conventional impressions were taken, in order to eliminate any potential influence of the manipulations on the soft tissues. The Aoralscan 3 (Shining 3D) intraoral scanning system was used. (see Fig. 20) Before starting each procedure, the device was calibrated according to the protocol and the manufacturer's instructions, which ensured the accuracy and reproducibility of the digital data.

Digital scans of the upper and lower completely edentulous jaws were performed sequentially. (see Fig. 5)

Assessment of efficiency and time parameters

The effectiveness and clinical parameters of the conventional functional impression technique were analyzed by objectively recording the total clinical time required to perform the procedure. The time interval was measured from the start of the functional shaping of the custom impression tray to the final removal of the impression from the prosthetic field after complete polymerization of the material used.

To ensure a more precise assessment and to eliminate the influence of anatomical differences between the upper and lower jaws, the time was recorded separately for each edentulous jaw, with each being considered as an independent observation unit.

With the digital impression technique, the time assessment began at the moment the intraoral scanner was activated, and the respective clinical case was initiated in the software, and ended with the completion of digital data processing, including verification of the completeness of the scanned prosthetic field and the absence of digital artifacts.

The time for each procedure was measured in seconds using a stopwatch integrated into a mobile device (Samsung Galaxy S21), which ensured high measurement precision and minimized the likelihood of technical error. The measurement was performed by the same operator to ensure standardization and reduce inter-subjective variations.

The obtained values were immediately entered into pre-structured data sheets (Appendix 4), containing the patient's identification code, the technique used, the anatomical region (upper/lower jaw), and the recorded time.

Statistical analysis of the empirical data was performed using the SPSS v.20.0 software package (IBM Corp., Armonk, NY, USA).

IV.5. Materials and Methods for Task 5

IV.5.1. Material:

This clinical trial included 10 patients (5 men and 5 women) aged between 58 and 74 years, with established total edentulism of the upper and lower jaws. Participant selection was based on predefined inclusion and exclusion criteria to ensure sample homogeneity and minimize the influence of potential confounding factors. (see Table 1)

All including patients signed an informed consent form to participate in the clinical trial after a detailed explanation of the study's objectives, methods, and potential risks.

The study was conducted in accordance with the principles of the Declaration of Helsinki on ethical standards in research involving human subjects and was approved by the Ethics Committee of the Faculty of Dental Medicine, Medical University of Varna (Protocol No. 128 of March 2, 2023).

IV.5.2. Methodology:

For the purposes of the study, upper and lower complete dentures were fabricated for each patient using a partial digital protocol with the aid of the developed experimental custom tray "Occlutray," designed for simultaneous functional impression taking and interocclusal registration. The tray was printed from PLA filament using FDM technology on an Ender-3 S1 Pro printer.

Prior to the start of the clinical phase, a detailed medical history was taken from each patient, and a thorough clinical examination was performed. The impression and registration procedure was performed in a single clinical visit and included the following steps:

1. Customization of the "Occlutray" experimental tray

Vinyl Polyether Silicone (VPES) – *EXA'lence* (GC America, USA) was used as the impression material:

- Heavy Body Regular Set – for basic customization and stabilization of the PLA tray;

- Light Body – for functional shaping of the impression margins.

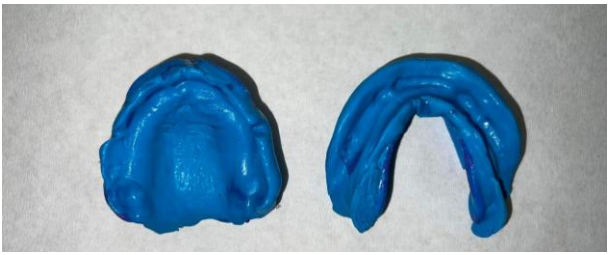


Fig. 22 *Functional impression of the upper and lower jaws with "OccluTray"*

Customization was performed intraorally by applying *Heavy Body* to the impression surface and peripherally along the tray edges, while the patient performed Herbst functional tests for the upper and lower jaws with the mouth open. After the material had been set, the upper and lower trays were removed from the patient's oral cavity. (Fig. 22)

2. Determination of the occlusal plane

The upper experimental tray was positioned over the prosthetic field and used as a guide to determine the future occlusal plane. After its stable adaptation, a clinical assessment of its spatial orientation relative to the extraoral anatomical reference lines was performed.

In the frontal region, parallelism was determined using Becker's line, ensuring harmonious alignment between the anterior part of the tray and the bipupillary line. In the lateral regions, the orientation of the occlusal plane was aligned with the Kampeer plane (ala nasi-tragus line), which served as a stable extraoral reference for restoring the physiological inclination of the prosthetic plane. Through visual control and height adjustment in the lateral zones, parallelism was achieved between the tray and the anatomical landmarks, ensuring functional harmony with the temporomandibular system. (Fig. 23)

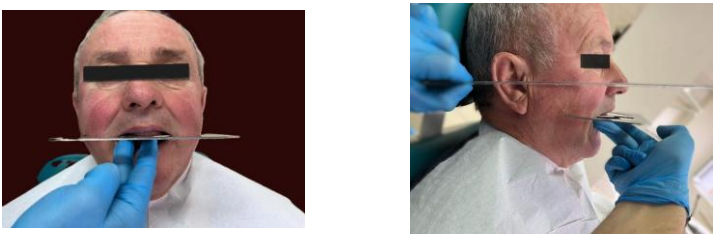


Fig. 23 *Determination of the occlusal plane*

3. Registration of the intermaxillary relationship

In the next clinical stage, the vertical dimension of occlusion (VDO) was determined. It was set 2–4 mm lower than the previously measured physiological resting vertical dimension (VDR) to ensure adequate freeway space and prevent functional overload.

The measurement of physiological rest was performed using extraoral landmarks and repeated clinical checks to verify the reproducibility of the position. The determined value was further verified through assessment of the facial profile, phonetic tests, and analysis of muscle tone.

Corrective impression material of appropriate consistency was applied to the experimental trays, after which they were repositioned in the oral cavity. The position of the lower jaw was determined using a bimanual technique (Dawson's bimanual manipulation), ensuring controlled guidance of the mandible to the centric relation. After establishing a stable and reproducible position, the interocclusal relationship was fixed with registration material until it had fully set.

This approach allowed for the acquisition of a functionally stable and clinically reproducible registration, necessary for subsequent laboratory modeling and fabrication of the prosthetic restoration. (Fig. 24)

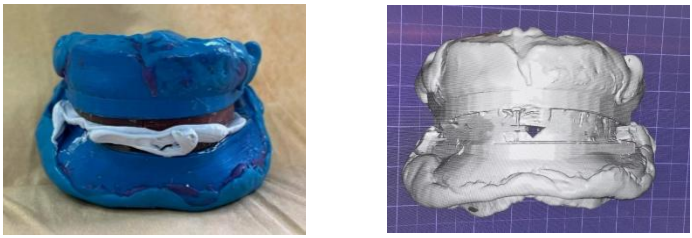


Fig. 24 *Determination of interarch relation*

4. Functional shaping of the final impression

The final functional modeling of the impression was performed using active functional tests conducted with the mouth closed. The patient was instructed to perform controlled movements—swallowing, slight movements of the lips and cheeks, as well as moderate activation of the tongue—in order to reproduce the physiological dynamics of the perioral muscles and the mobile mucosa.

Digitization and CAD Design of the Prostheses

The digitization of the final functional impressions and the recorded interocclusal relationship was performed using a Swing HD DOF laboratory scanner (DOF Inc., South Korea). Each impression was scanned at standardized parameters, ensuring high resolution and precise reproduction of the details of the prosthetic field. The resulting 3D files were generated in *.stl* format, which ensures compatibility with subsequent CAD processes.

The STL files were exported to the dental CAD software exocad DentalCAD 3.1, where the complete digital design of the upper and lower complete dentures was carried out. (Fig. 25)

The application of a digital CAD protocol ensured a high degree of reproducibility, data traceability, and precision in the design of the prosthetic constructions.

Fig. 25 *CAD design of upper and lower complete dentures*

To conduct the clinical trial with aligned teeth, trial dentures were fabricated using additive technology (3D printing) from NextDent Try-In photopolymer resin (NextDent B.V., Netherlands). The material is intended for the fabrication of temporary and try-in restorations, allowing for precise assessment of tooth alignment and occlusal relationships prior to final fabrication.

After printing, the dentures underwent standard post-processing, including removal of excess resin and additional photopolymerization according to the manufacturer's recommendations. To improve aesthetics and facilitate visual assessment by the patient, the surface was stained with Optiglaze photopolymer glazing varnishes (Japan), which allowed for a more realistic simulation of the final prosthetic restoration. (Fig. 26)

Fig. 26 *Try-in dentures*

Fabrication of the Definitive Dentures

The denture bases were fabricated via 3D printing using the biocompatible photopolymer resin NextDent Denture Base (NextDent B.V., Netherlands), designed for long-term prosthetic constructions. Printing was performed using a Photon Mono 4K LCD 3D printer (Anycubic, China).

After printing, the bases underwent standard post-processing, including removal of residual resin and additional light curing to achieve optimal mechanical properties. Three-layer denture relines were bonded to the fabricated bases using a photopolymer bonding resin, ensuring stable adhesion between the teeth and the denture base. (Fig. 27)

Clinical Evaluation of the Definitive Complete Dentures

After completion of the definitive complete dentures, a comprehensive clinical evaluation of their accuracy, fit, and functional characteristics in the oral cavity was performed. The evaluation was conducted immediately after their placement, under standardized clinical conditions.

Fig. 27 *Definitive full dentures fabricated using additive technology*

IV. RESULTS AND DISCUSSION

V.1. Results and Discussion for Task 1

A total of 39 edentulous patients were examined 20 were male (51.3%) and 19 were female (48.7%). The analysis reveals balanced gender distribution in the study (Fig. 28).

A total of 59 edentulous jaws were analyzed in the study, of which 27 were maxillary and 32 were mandibular.

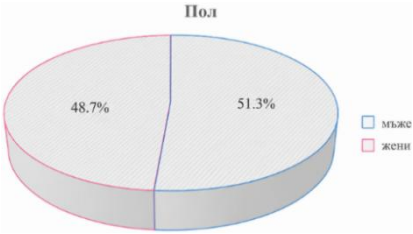


Fig. 28 *Presentation of the gender distribution*

The results show an almost even distribution of participants by gender, ensuring a balanced representation of both genders in the study sample.

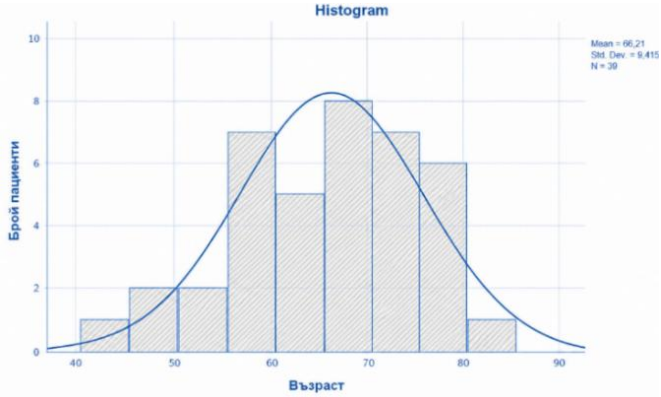


Fig. 29 *Presentation of the age distribution of the studied patients*

The graphical representation of the age distribution via a histogram confirms this trend and visualizes the structure of the study group, in which the main concentration of patients is observed in the age range between the sixth and seventh decades. (Fig. 29)

The morphometric analysis of the dimensional parameters of the maxilla and mandible, performed using cone-beam computed tomography (CBCT) in completely edentulous patients, yielded stable and reproducible results. (Table 9)

The results obtained allow us to conclude that the mean value of 58.35 mm represents a reliable and representative indicator of the Us parameter of the maxilla within the studied population.

Based on the statistical indicators obtained and taking into account the empirical distribution of values within the established range of variation (15.4 mm), the **Us** parameter was grouped using interval analysis. The results are presented in Table 12.

Table 9 *Presentation of the sagittal dimension Us of the maxilla*

Us of the maxilla /mm/	
Number of patients	27
Arithmetic mean	58.3519
Median	58.7000
Mode	56.80
Standard deviation	4.07434
Kurtosis	-.117
Minimum value	50.80
Maximum value	66.20

The obtained morphometric data can serve as a practical guideline for the preliminary selection of a standard impression tray, for sizing a custom tray within a conventional clinical protocol, as well as for digital design in a CAD environment. (Table 10)

Table 10 *Practical correlation between the Us parameter and the selection of an individual impression tray*

Parameter	Clinical Interpretation	Recommended tray size
Us < 54 mm	Narrow upper jaw, smaller prosthetic field volume	S (small)
Us 54–62 mm	Average jaw size – most patients fall into this category	M (medium)
Us > 62 mm	Wide or voluminous jaw, often with well-defined ridges	L (large)

The histogram graphically represents the frequency distribution of the measured values of the **Us** parameter of the upper jaw (in mm) in 27 examined patients. (Fig. 30)

The superimposed normal curve illustrates the theoretical normal distribution and demonstrates good agreement with the empirically obtained data.

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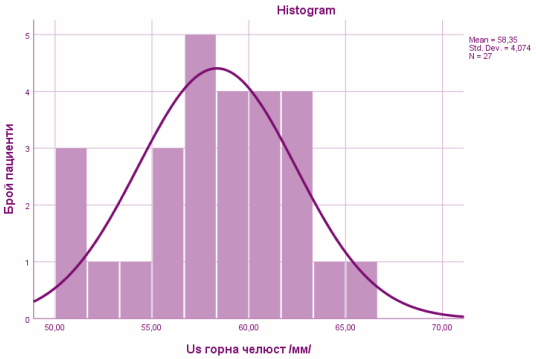

Fig. 30 *Presentation of the distribution of the measured values of Us*

The parameter **Uf** characterizes the vestibulo-oral dimension of the hard palate in its mid-section and reflects the transverse development of the maxilla. The mean value of approximately 47.7

mm can be interpreted as an indication of a well-formed palate. (Table 11)

Table 11 *Values of the vestibulo-oral dimension Uf of the maxilla*

Uf of the upper jaw /mm/	
Number of patients	27
Arithmetic mean	47.74
Median	47.60
Mode	47.60
Standard deviation	3.95
Kurtosis	-.267
Minimum value	40.10
Maximum value	54.70

Table 12 *Upper jaw size according to the vestibulo-oral dimension (Uf) and corresponding size of the individual impression tray*

Indicator	**Morphological characteristic**	**Recommended tray size**
Uf < 44 mm	Narrow maxilla with a deep palatal vault	S (small)
Uf 44–51 mm	Average dimensions with balanced vestibulo-oral width of the palate	M (medium)
Uf > 51 mm	Wide and flat upper jaw with an extended prosthetic field	L (large)

From a clinical perspective, the **Uf** parameter can serve as a reference indicator in the preliminary selection and sizing of an individual impression tray, in determining the width of the prosthetic base, as well as in assessing the symmetry and spatial proportions of the maxillary arch. (Table 12)

Table 13 *Combined morphometric classification of the maxilla according to the Us and Uf parameters and corresponding size of the custom impression tray*

Tray size	Us (tuber-to-tuber width)	Uf (vestibulo-oral dimension)	Morphological characteristics	Clinical notes
S (Small)	< 54 mm	< 44 mm	Narrow jaw with pronounced palatal arch	Requires customization of the periphery; increased risk of instability
M (Medium)	54–62 mm	44–51 mm	Average dimensions, harmoniously shaped palate	Most common type; standard tray volume
L (Large)	> 62 mm	> 51 mm	Wide and flat upper jaw, extensive prosthetic area	A wider tray is required; moderately good retention and stability

A combined morphometric approach was developed, based on the joint interpretation of the parameters **Us** (sagittal dimension) and **Uf** (transverse dimension), which allows for more accurate sizing of the individual impression tray. (Table 13)

An analysis of data from 32 patients revealed that the arithmetic mean of Ls is 71.13 mm. The standard deviation (6.69 mm) indicates moderate variability in the sagittal dimensions of the mandible.

Analysis of the results allows for the drawing of conclusions important for clinical practice: (Table 14)

Table 14 *Classification of the mandible according to sagittal dimension (Ls) and corresponding size of the individual impression tray*

Indicator	Morphological characteristic of the mandible	Recommended tray size
Ls < 65 mm	Short sagittal length, limited prosthetic field; often pronounced alveolar resorption in the distal regions	S (small)
Ls 65–76 mm	Medium size with balanced sagittal dimension and well-defined retromolar triangles	M (medium)
Ls > 76 mm	Long mandible with an extensive prosthetic field and a well-preserved retromolar region	L (large)

The graphical distribution shows that most patients fall within the range of approximately **70–75 mm**, which can be considered characteristic of an anatomically balanced mandibular configuration in completely edentulous individuals. (Fig. 31)

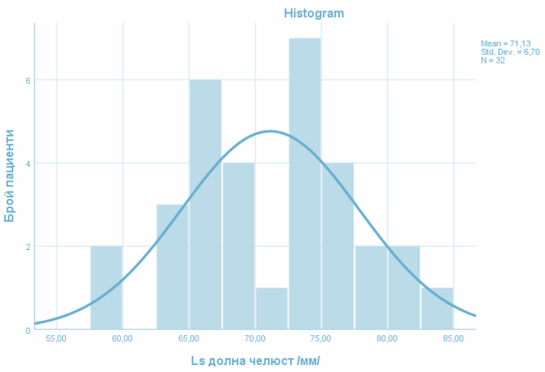

Fig. 31 *Distribution of measured Ls values*

Table 15 *Values of the vestibulo-oral dimension Lf of the mandible*

Lf of the mandible /mm/	
Number of patients	32
Arithmetic mean	45.39
Median	44.30
Mode	39.70
Standard deviation	4.99
Kurtosis	0.55
Minimum value	37.60
Maximum value	57.90

The data obtained confirm that Lf can be used as a reliable morphometric indicator in planning of individual impression trays, assessment of the vestibulo-oral dimension of the prosthetic field, and standardization of clinical stages in the fabrication of complete dentures. (Table 15; Table 16)

Table 16 *Classification of the mandible according to vestibulo-oral width (Lf) and corresponding size of the individual impression tray*

Indicator	Morphological characteristic of the mandible	Recommend ed tray size
Lf < 40 mm	Narrow mandible with reduced vestibulo-oral width and limited prosthetic field	S (small)
Lf 40–50 mm	Medium-type mandible with balanced transverse dimensions and a well-formed alveolar ridge	M (medium)
Lf > 50 mm	A wide and flat lower jaw with an extended prosthetic field and a large support surface	L (large)

The histogram demonstrates that most of the patients studied are characterized by mandibular arches of average width, in which the

vestibulo-oral dimension falls within the optimal morphometric limits. (Fig. 32)

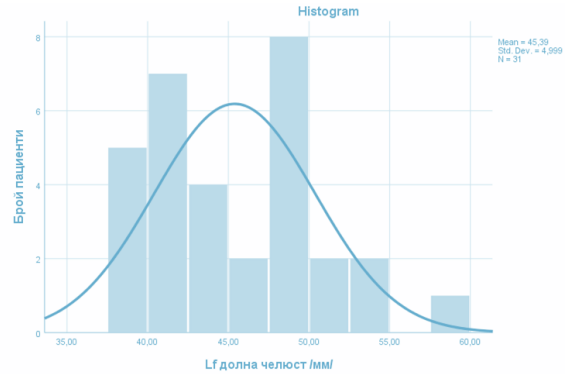

Fig. 32 *Presentation of the distribution of the measured Lf values*

A combined morphometric approach has been formulated, based on the joint interpretation of the parameters **Ls** (sagittal dimension) and **Lf** (transverse dimension), which allows for more accurate sizing of the individual impression tray. (Table 17)

Based on the morphometric measurements of the dimensional parameters of the maxilla and mandible in completely edentulous patients, a practical scheme for determining the size of individual impression trays has been developed. (Fig. 33)

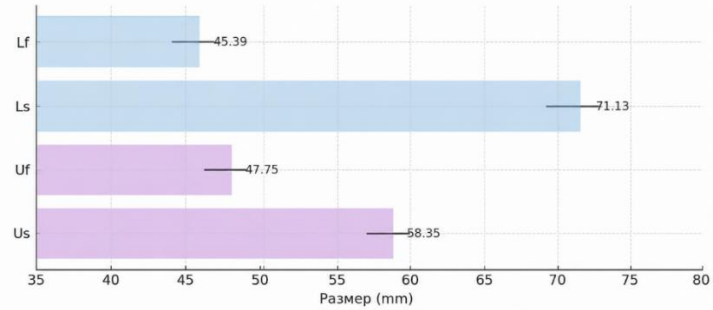

Fig. 33 *Graphical representation of mean values and confidence intervals of morphometric parameters of the edentulous upper and lower jaws*

Table 17 *Combined morphometric classification of the mandible according to the Ls and Lf parameters and corresponding size of the individual impression tray*

Tray size	Ls (mm)	Lf (mm)	Morphological characteristic of the mandible
S (Small)	< 65 mm	< 40 mm	Narrow and short mandible with limited prosthetic space; reduced vestibulo-oral width and shortened anteroposterior distance.
M (Medium)	65–76 mm	40–50 mm	Medium-sized jaw with balanced sagittal and transverse dimensions; well-defined retromolar regions and a harmonious alveolar ridge.
L (Large)	> 76 mm	> 50 mm	A wide and voluminous mandible with an extended prosthetic field and a large support area, favoring the retention and stability of the complete denture.

Systematization of the data allows for the distinction of three main size categories (S, M, L), corresponding to the established morphometric ranges presented in Table 18.

To assess possible relationships between age and the linear parameters studied, a correlation analysis was performed using a parametric test with Pearson's correlation coefficient.

Table 18 *Summary classification of the morphometric dimensions of the upper and lower jaws and corresponding dimensions of individual impression trays*

Parameter	Anatomical significance	S (small)	M (medium)	L (large)
Us	Tubero-tuberal width of the upper jaw	< 54 mm	54–62 mm	> 62 mm
Uf	Vestibulo-oral dimension of the maxilla	< 44 mm	44–51 mm	> 51 mm
Ls	Sagittal dimension of the mandible	< 65 mm	65–76 mm	> 76 mm
Lf	Vestibulo-oral dimension of the mandible	< 40 mm	40–50 mm	> 50 mm

The results show no statistically significant correlation between the factor variable “age” and the morphometric parameters Us, Uf, Ls, and Lf ($p > 0.05$ for all comparisons). The values of the correlation coefficient r range from weak to negligible correlation ($r < 0.30$), which demonstrates the absence of a linear relationship between age and the measured dimensions within the sample studied of 39 patients.

The four correlation analyses conducted demonstrate extremely weak linear relationships between age as a variable factor and the morphometric indices Us, Uf, Ls, and Lf. The values of Pearson’s correlation coefficient ($r < 0.06$) in all cases indicate a virtual absence of a linear relationship, with the coefficient of determination (r^2) remaining below 0.4%, meaning that age explains a negligible portion of the variation in the measured dimensions. At $p > 0.05$, none of the correlations reaches statistical significance. (Fig. 34)

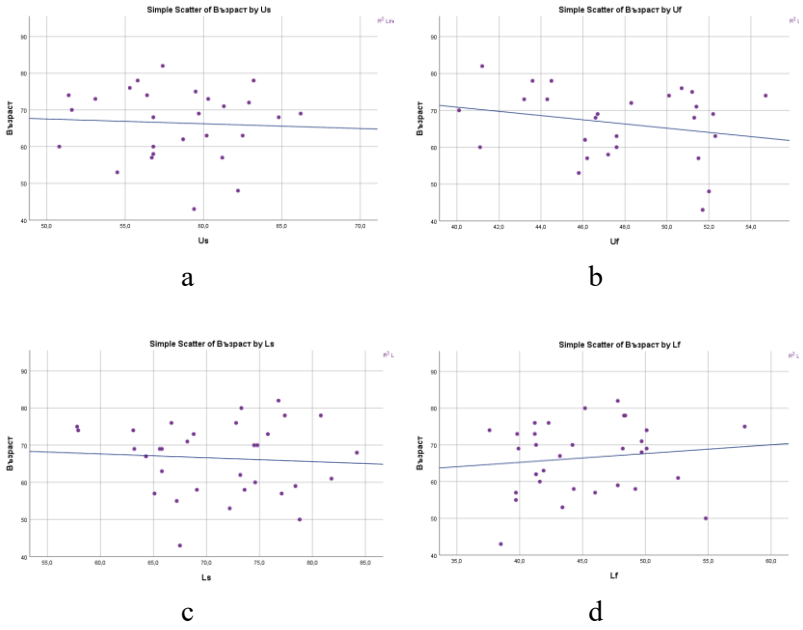

Fig. 34a, b, c, d *Graphical representation of the relationship between the age variable and the dimensions, Us, Uf, Ls, Lf*

From a practical standpoint, this makes them suitable for use as objective guidelines in standardizing the digital design of custom impression trays and complete dentures, while preserving the possibility of customization according to the anatomical characteristics of the specific patient.

A correlation analysis conducted between the individual dimensional parameters revealed a statistically significant moderate positive linear relationship between the indices Us, and Lf ($r = 0.473$; $p = 0.041 < \alpha = 0.05$).This indicates that in patients with better-preserved bone structure and less pronounced atrophy, higher values are observed for both parameters—both the sagittal dimension of the maxilla (Us) and the vestibulo-oral dimension of the mandible (Lf). (Fig. 35)

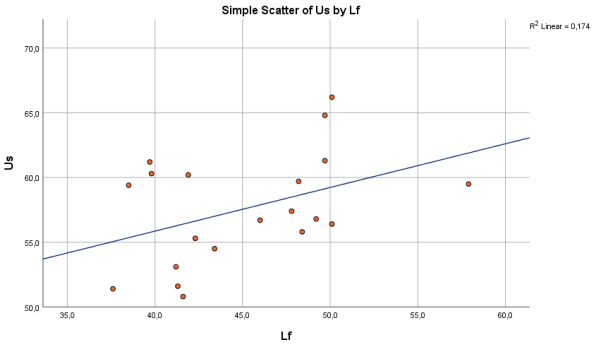

Fig. 35 *Graphical representation of the relationship between Us and Lf*

The established relationship between Us and Uf reflects the internal morphological interrelationship within the structure of the maxilla. In centripetal (medially directed) atrophy of the maxilla, characteristic of completely edentulous patients, a simultaneous reduction is observed in both the sagittal dimension (Us) and the vestibulo-oral dimension (Uf). (Fig. 36)

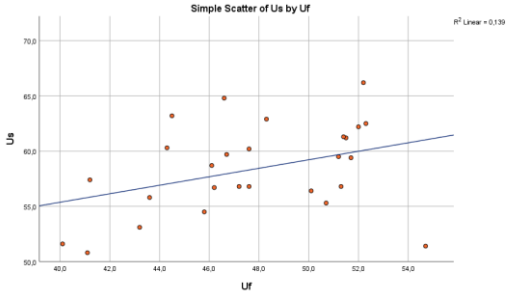

Fig. 36 *Graphical representation of the relationship between dimensions Us and Uf*

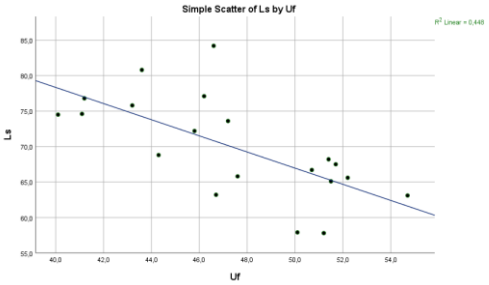

Fig. 37 *Graphical representation of the relationship between Ls and Uf*

The negative and statistically significant correlation between Uf and Ls ($r = –0.669$; $p < 0.05$) confirms that the degree and direction of bone atrophy in the maxilla and mandible follow anatomically opposite patterns. (Fig. 37)

Fig. 38 shows the distribution of the main morphometric parameters (Us, Uf, Ls, Lf) of the upper and lower jaws in men and women. The results indicate that gender differences in jaw dimensions are minimal and do not significantly influence prosthetic planning.

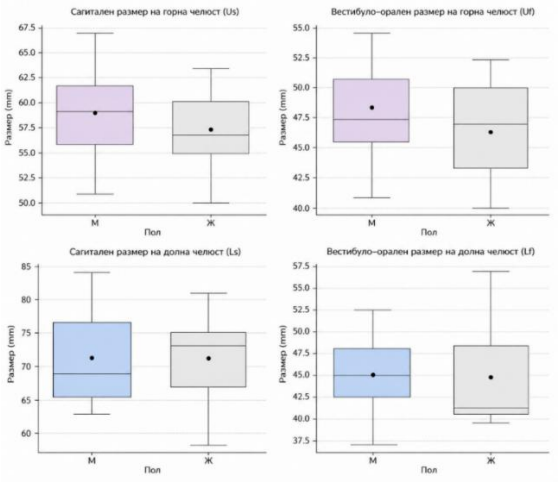

Fig. 38 *Distribution of morphometric parameters by sex*

V.2. Results and Discussion of Task 2

This section presents the results of the clinical evaluation of the fabricated complete dentures, based on the predefined functional and aesthetic indicators. The analysis covers both objective clinical parameters—retention, stability, and marginal fit—and subjective indicators—comfort, phonetics, and aesthetics. (Table 19)

Table 19 *Mean values (Mean ± SD) of clinical indicators and the clinical effectiveness index for upper and lower complete dentures*

Parameter	Upper denture (n = 30) Mean ± SD	Lower denture (n = 30) Mean ± SD	Range (Min–Max)	Average clinical index (%)
Retention	0.65 ± 0.48	0.45 ± 0.50	0–2	27.5
Stability	0.80 ± 0.55	0.60 ± 0.56	0 – 2	35.0
Peripheral fit	0.75 ± 0.50	0.55 ± 0.51	0 – 2	32.5
Comfort	0.95 ± 0.60	0.80 ± 0.58	0 – 2	43.8
Phonetics	1.20 ± 0.55	1.15 ± 0.52	0 – 2	58.8
Aesthetics	1.30 ± 0.50	1.25 ± 0.49	0 – 2	63.8
Overall score /12	5.65 ± 1.85	4.80 ± 1.92	1 – 10	-
Clinical efficacy index (%)	47.1 ± 15.4	40.0 ± 16.0	8.3 – 83.3	-

Analysis of the results shows that, overall, upper complete dentures demonstrate better clinical outcomes compared to lower ones, which is consistent with the anatomical and functional characteristics of the prosthetic field.

The graphical representation confirms the trends observed in the descriptive and comparative statistical analysis. (Fig. 39) A general trend toward higher values is observed for upper dentures for most of the analyzed indicators, including stability, comfort, and aesthetics.

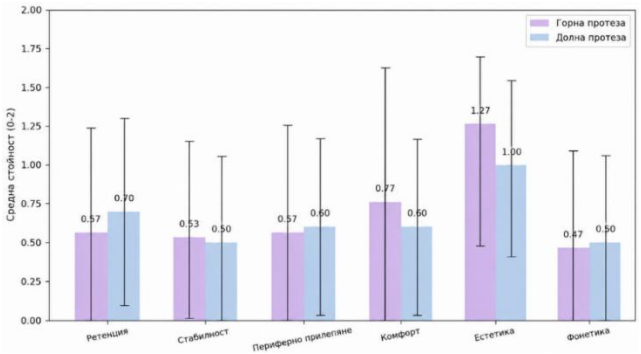

Fig. 39 *Mean values (Mean ± SD) of clinical indicators for upper and lower complete dentures*

Figure 40 presents a comparison of the mean values of the clinical effectiveness index (%) for upper and lower complete dentures, along with the corresponding 95% confidence intervals.

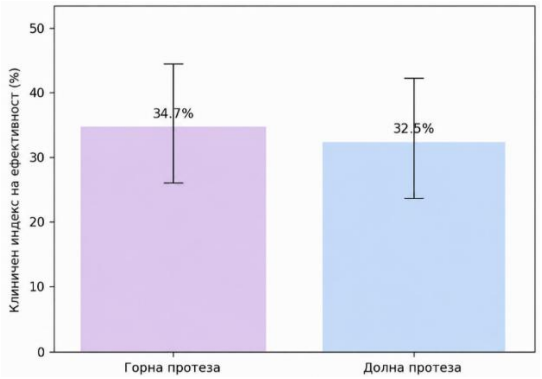

Fig. 40 *Mean values and 95% confidence intervals of the clinical effectiveness index for upper and lower complete dentures*

The graphical representation summarizes the overall trend of comparable effectiveness between the two types of dentures, despite the slight advantage of the upper dentures.

The radar chart presents the comparative profile of the main clinical indicators for upper and lower complete dentures,

demonstrating that upper complete dentures provide better clinical results compared to lower ones, especially in terms of aesthetics and comfort, while the remaining indicators show less pronounced differences or similar values. (Fig. 41)

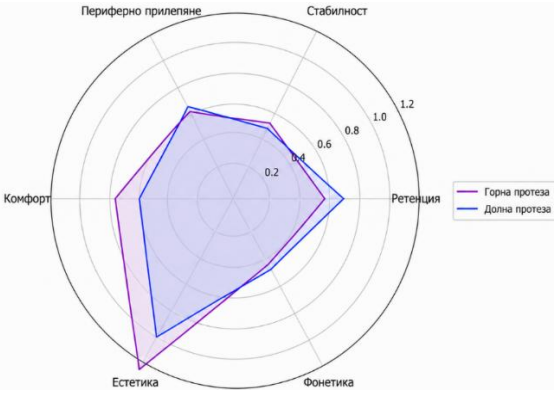

Fig. 41 *Comparative profile of clinical indicators for upper and lower complete dentures*

Given the ordinal nature of the data and the observed non-uniformity in the distribution, a nonparametric analysis was performed using the Mann–Whitney U test. The results are presented in Table 20.

The results of the nonparametric analysis confirm the reliability of the statistical conclusions, regardless of the data distribution.

Table 20 *Nonparametric analysis (Mann–Whitney U) of clinical indicators*

Type	Test	Statistics (U)	p-value
Upper	Mann–Whitney U	80.00	0.198
Lower	Mann–Whitney U	92.50	0.457
All	Mann–Whitney U	85.50	0.302

Figure 42 shows the distribution of the clinical efficacy index (%) in men and women using a box-plot diagram, including the median, interquartile range, and extreme values. A similar distribution of values is observed for both genders, with no significant differences in the medians or the range of variation.

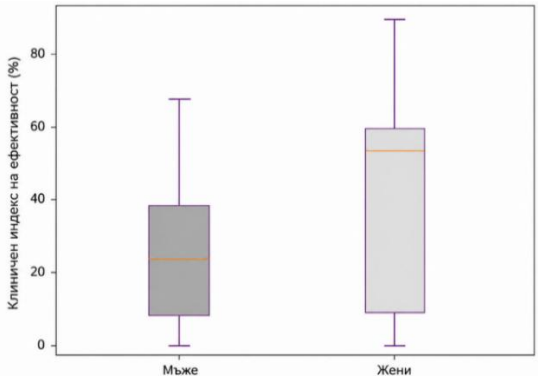

Fig. 42 *Distribution of the clinical efficacy index (%) by gender (box-plot diagram)*

Figure 43 illustrates the relationship between patient age and the clinical effectiveness index (%) for upper and lower complete dentures using correlation analysis. A negative correlation is observed between age and clinical effectiveness for both types of dentures, with this relationship being more pronounced for upper dentures ($r = -0.73$) compared to lower dentures ($r = -0.46$).

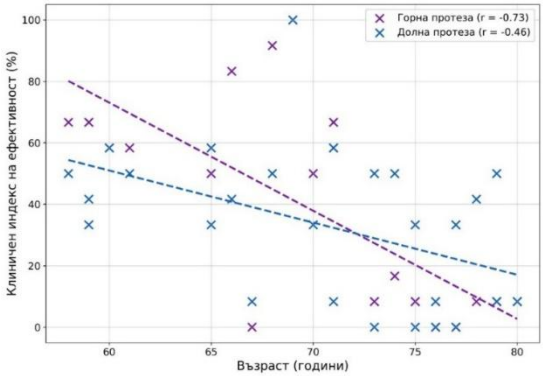

Fig. 43 *Correlation between patient age and the clinical effectiveness index (%) for complete dentures of the upper and lower jaws*

Figure 44 clearly demonstrates the influence of age on the clinical effectiveness of complete dentures, with the effect being more pronounced for upper dentures, while also highlighting the significant individual variability in the results

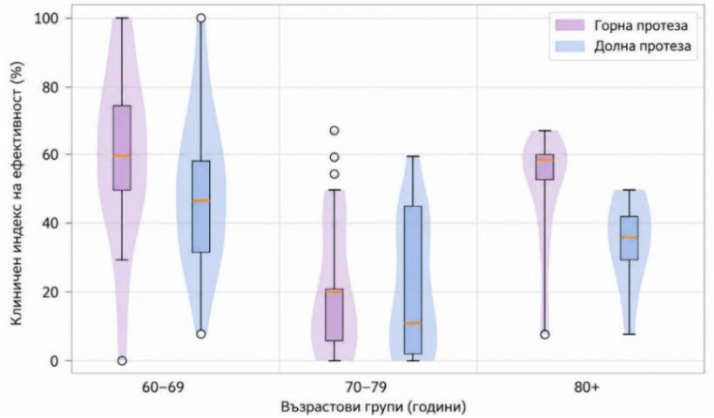

Fig. 44 *Distribution of the clinical effectiveness index (%) by age groups using a violin and boxplot diagram*

V.3. Results and Discussion for Task 3

In the present study, a morphometrically grounded and clinically validated innovative experimental design of an impression tray was developed and validated, intended for the simultaneous registration of a functional impression and interocclusal relationship.

Testing of the upper experimental tray

Analysis of the frequency of individual design modifications shows that the most common adjustments involve thinning along the A-line to 0 mm and distal beveling at 45° (15 cases each). This is followed by a reduction in the height of the outer matrix (11 cases) and adjustments in the area above the tuber (7 cases). (Fig. 45)

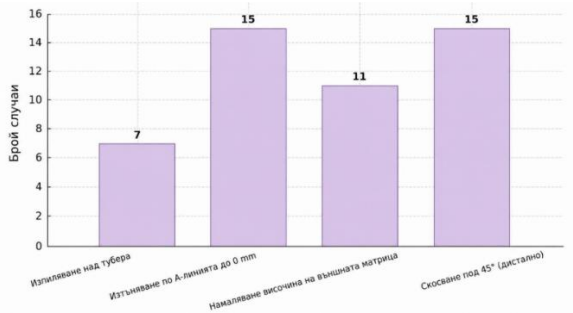

Fig. 45 *Distribution of adjustments in an experimental maxillary splint*

The graphically presented data confirm the trend toward a balanced percentage distribution, with moderate variations between groups.

This observed uniformity can be viewed as an indicator of the good design and fabrication of the experimental trays used in the study and their potential for integration and digitization of the workflow protocol for the fabrication of complete dentures. (Fig. 46)

Fig. 46 *Relative proportion of structural adjustments*

To assess the frequency distribution among the different types of adjustments, a χ^2 goodness-of-fit test was performed.

The analysis showed that the differences between the groups did not reach statistical significance – χ^2 (3) = 3.67, p = 0.30 (Fig. 47)

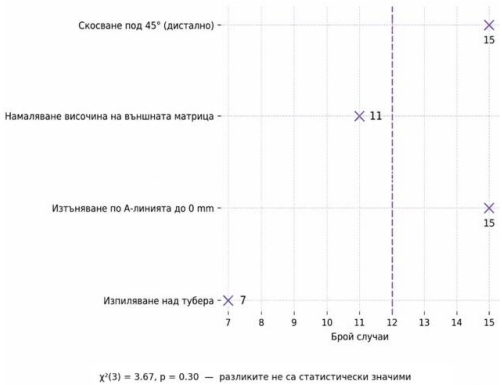

Fig. 47 *Scatter plot by correction zone – χ^2 test*

Trial fitting of the lower experimental splint

The fitting of the mandibular experimental tray showed a different adaptation profile compared to the maxillary model, which is

consistent with the specific anatomical and functional characteristics of the mandible.

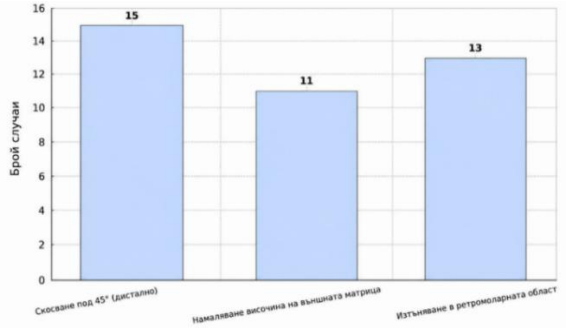

Fig. 48 *Distribution of corrections in mandibular experimental trays*

Figure 48 presents the frequency distribution of the various types of structural modifications in mandibular experimental trays. The data show that a 45° distal bevel is the most frequently recorded modification (n = 15), followed by thinning in the retromolar region (n = 13) and reduction of the outer matrix height (n = 11).

The total number of corrections made (n = 39) and the low variability (CV = 12.6%) underscore the high degree of reproducibility and standardization of the experimental protocol. The data indicates that the need for design adaptations is distributed proportionally according to the functional and anatomical characteristics of the mandible, with no concentration of problems in a specific area. (Fig. 49)

The results of a chi-square goodness-of-fit test indicate that the differences between the individual correction groups do not reach statistical significance—χ^2 (2) = 0.62, p = 0.74, which is significantly above the accepted level of significance (α = 0.05) (Fig. 50)

Fig. 49 *Relative share of structural corrections*

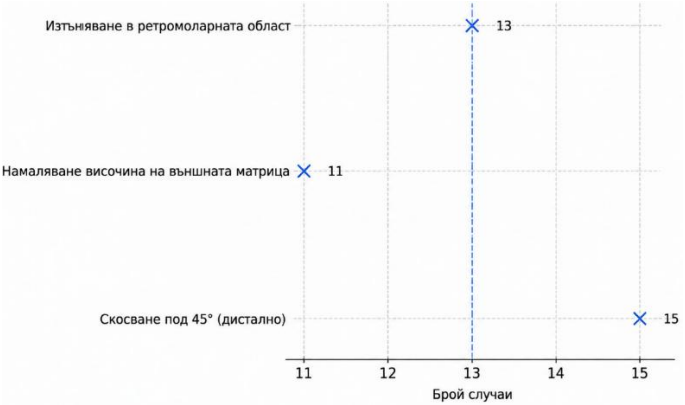

Fig. 50 *Scatter plot by correction zone – χ^2 test*

Figure 51 illustrates an asymmetric, right-skewed distribution, in which most values of the quantitative adjustments are concentrated around 1–2 mm, while individual observations reach up to 3–4 mm.

This pattern confirms that, regardless of the jaw, moderate-sized adaptations predominate, demonstrating good initial alignment of the digital design with clinical anatomy.

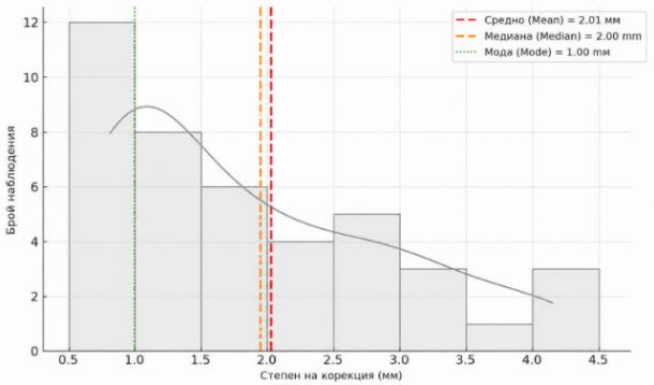

Fig. 51 *Distribution of quantitative corrections*

Figure 52 presents overlapping density curves of the distribution of the degree of structural correction (mm) for the maxillary and mandibular experimental trays.

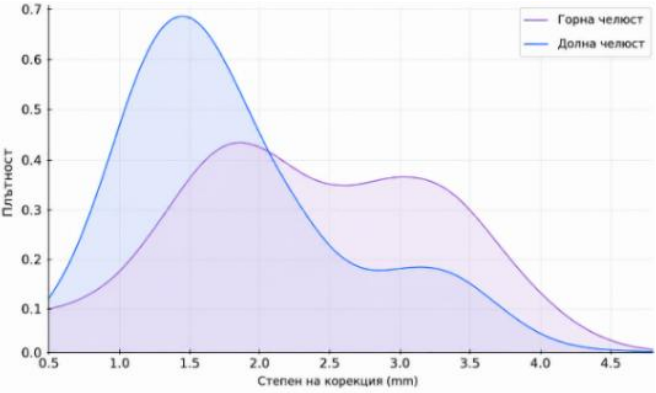

Fig. 52 *Density curves of the distribution of corrections in mm for upper and lower experimental trays*

In both groups, a slightly right-skewed distribution is observed, characterized by a concentration of values in the low range and isolated cases with higher values.

The diagram presents the individual values of the quantitative corrections for each jaw (points), as well as the mean values with error bars (black markers ± SD). (Fig. 53)

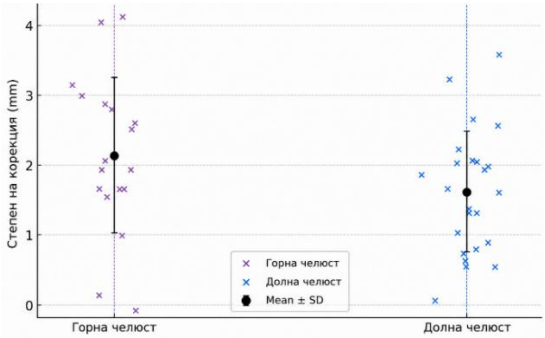

Fig. 53 *Dispersion of individual values for upper and lower experimental trays*

A tight clustering of points around the mean value and minimal dispersion is observed, confirming that, provided standardized modeling and printing conditions are followed repeatability of results and applicability of the experimental trays in the protocol for fabricating functionally suitable complete dentures are expected.

V.3.1. Results and Discussion for Task 3.1

Legal protection and conceptual validation of the experimental Occlutray.

During the course of the task, legal protection of the experimental custom tray was secured through the registration of an industrial design with the Patent Office of the Republic of Bulgaria: Reg. No. BG – 9363, Application No. 12230, filing date: February 2, 2024, date of publication/registration: February 20, 2024, with author(s)/designer(s): Yordanka Donkova Shekerova, Delian Krasimirov Georgiev, Desislava Atanasova Konstantinova. The registration confirms the innovation and unique character of the tray's appearance and configuration, including a handle-free design with an integrated external matrix for wax rolls, allowing for simultaneous functional impression of the prosthetic field's occlusal area and interarch registration in a single clinical step. (Fig. 54)

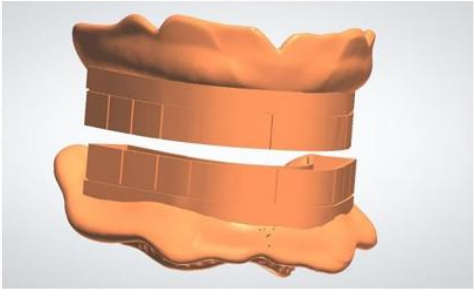

Fig. 54 *Experimental trays*

V.3.2. Results and Discussion for Task 3.2

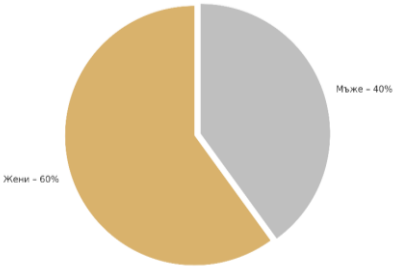

Fig. 55 *Distribution of patients by gender*

Figure 55 presents the distribution of the studied patients by gender. Of a total of 10 participants, 6 (60%) are women and 4 (40%) are men.

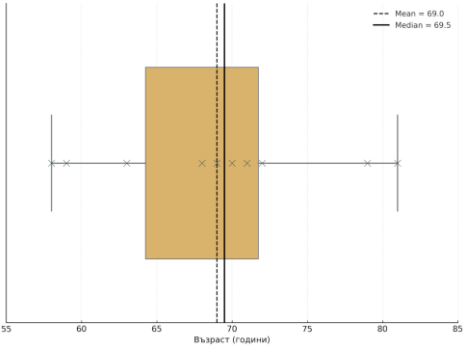

Fig. 56 *Age distribution of the patients studied*

Figure 56 presents the age distribution of the patients studied using a combined boxplot with individual values. The mean age is 69.0 ± 7.18 years, and the median is 69.5 years, indicating a symmetrical distribution of the data without significant deviations.

Table 21 *Summary of microbiological results by patient*

Patient	Specimen	Sample collection period	Isolated microorganism(s)	Result after disinfectio	Result after sterilizatio
1	PLA	Before disinfection	*Coagulase-negative Staphylococcus*	No growth	No growth
2	ABS	Before disinfection	*Klebsiella aerogenes*	No growth	No growth
3	PLA	Before disinfection	*Enterobacter cloacae*	No growth	No growth
4	ABS	Before disinfection	*Coagulase-negative Staphylococcus*	No growth	No growth
5	PLA	Before disinfection	*Coagulase-negative Staphylococcus*, *Klebsiella aerogenes*	No growth	No growth
6	ABS	Before disinfection	*Coagulase-negative Staphylococcus*	No growth	No growth
7	PLA	Before disinfection	*Klebsiella aerogenes*	No growth	No growth
8	ABS	Before disinfection	*Enterobacter cloacae*	No growth	No growth
9	PLA	Before disinfection	*Coagulase-negative Staphylococcus*	No growth	No growth
10	ABS	Before disinfection	*Coagulase-negative Staphylococcus*, *Enterobacter cloacae*	No growth	No growth

The results presented in Table 21 confirm that all experimental trays (PLA and ABS) were microbiologically contaminated immediately after intraoral use and prior to disinfection procedures. The isolated microorganisms include representatives of the normal oral and opportunistic flora, such as *coagulase-negative Staphylococcus*, *Klebsiella aerogenes,* and *Enterobacter cloacae.*

Figure 57 illustrates the percentage distribution of the isolated microorganisms prior to disinfection on 3D-printed experimental impression trays made of PLA and ABS. The analysis shows that for both materials, the dominant microorganism is *coagulase-negative Staphylococcus*, isolated from 70% of the PLA trays and 60% of the ABS trays.

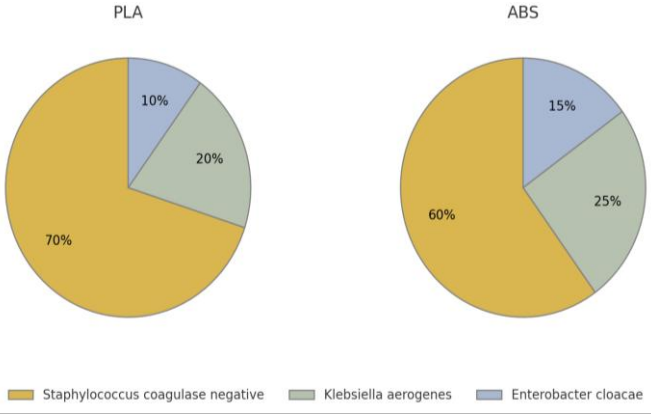

Fig. 57 *Distribution of isolated microorganisms prior to disinfection in PLA and ABS 3D-printed trays*

The percentage distribution of negative microbiological samples taken at the three treatment stages is presented in Fig. 58.

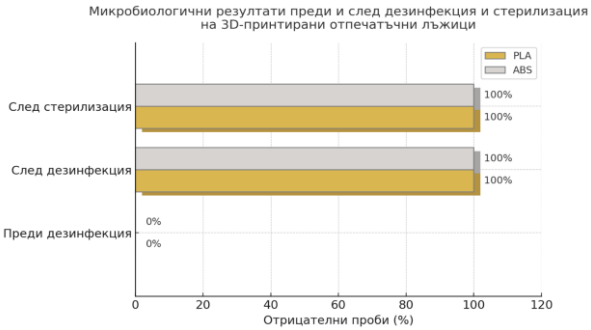

Fig. 58 *Microbiological results after treatment stages*

After disinfection with 2% Orolin for 60 minutes, a 100% negative result was observed in all samples, regardless of the material used. Identical sterility was also reported after the subsequent sterilization cycle (121°C, 20 min), with no residual microbial growth.

These data demonstrate the high efficacy of the applied decontamination procedure and confirm the microbiological safety of the experimental trays when a validated processing protocol is followed.

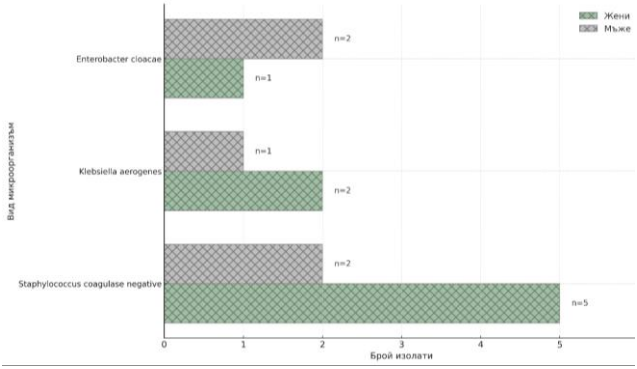

Fig. 59 *Distribution of isolated microorganisms by patient gender*

Fig. 59 shows the relationship between the microorganisms isolated from the surface of the experimental trays and the patients' gender prior to the disinfection stage. *Coagulase-negative*

Staphylococcus was isolated from five women and two men. *Klebsiella aerogenes* was detected in two women and one man, and *Enterobacter cloacae* in one woman and two men.

Statistically, no significant association was found between gender and the type of isolated microorganism ($p > 0.05$), indicating a similar microbiological distribution in both genders.

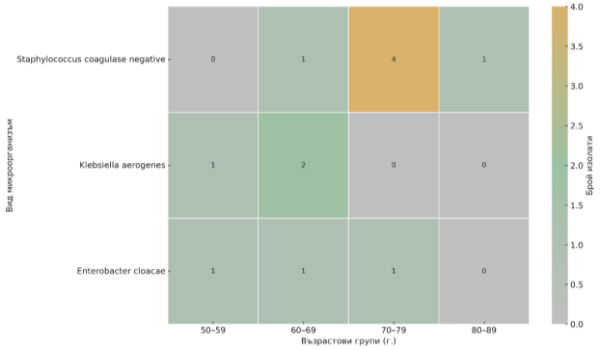

Fig. 60 *Relationship between age groups and the isolated microorganisms*

The relationship between age groups and the microorganisms isolated from the surface of the 3D-printed impression trays is presented in Fig. 60. The highest frequency of isolates is observed in the 70–79 age group, which also reflects the larger relative proportion of patients in this group.

In summary, the statistical analysis confirms that the combined disinfection–sterilization protocol is fully effective in eliminating microbial contamination on 3D-printed experimental impression trays made of PLA and ABS, with high-level disinfection being the key step in the decontamination process.

V.4. Results and Discussion for Task 4

The distribution of the study participants by gender shows a relatively even ratio between women and men. Women account for 51.6% (n = 16) of the total sample, while men account for 48.4% (n = 15). (Fig. 61)

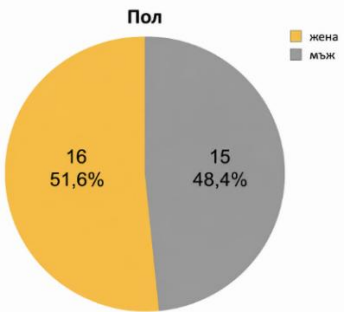

Fig. 61 *Graphical representation of the distribution by gender*

The age range of the participants varies between 49 and 80 years. The mean age is 69 years, and the median is 70 years, indicating a symmetrical distribution around this value. The standard deviation is ±6.846 years, reflecting a relatively homogeneous age structure with an approximate 7-year dispersion. (Fig. 62)

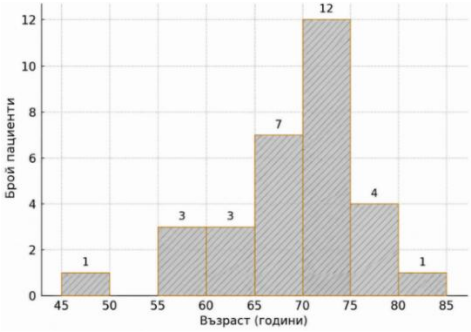

Fig. 62 *Graphical representation of the distribution of patients by age*

1. Time required for functional shaping of individual impression trays

Table 22 *Summary table – time for functional shaping of the lower and upper jaw trays*

No.	Summary indicators	Jaw	Arithmetic mean	Median	Standard deviation
1	Functional tests with individual tray and C-silicone [sec.]	Lower	388.81	389.00	3.772
		Upper	368.48	368.00	6.732
2	Functional tests with "Occlutray" and C-silicone [sec.]	Lower	270.55	271.00	2.767
		Upper	275.77	276.00	3.757
3	Functional tests with "Occlutray" and A-silicone [sec.]	Lower	261.74	261.00	3.076
		Upper	265.26	265.00	3.066
4	Functional tests with "Occlutray" and VPES [sec.]	Lower	250.29	250.00	2.819
		Upper	251.35	251.00	3.583

The summarized statistical indicators are presented in Table 22. Analysis of the arithmetic means for the time required to fabricate the functional tray reveals a clear hierarchy among the methods studied. The highest mean value was recorded for Method 1 (custom tray with C-silicone), followed in order by Method 2 (Occlutray + C-silicone), Method 3 (Occlutray + A-silicone), and Method 4 (Occlutray + Vinyl Polyether Silicone – VPES).

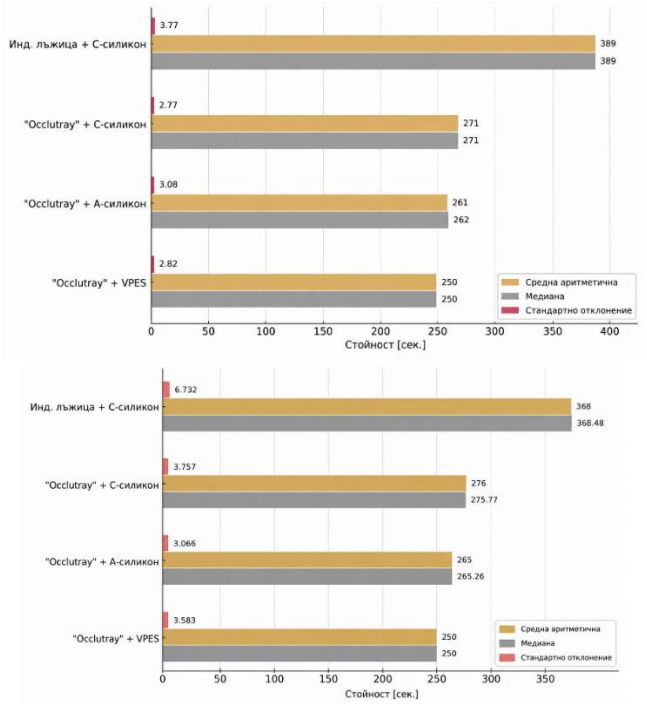

Fig. 63 *Comparison of indicators for different impression techniques*

Figure 63 illustrates a comparative analysis of the time required to perform functional tests using four different impression-taking techniques on completely edentulous upper and lower jaws. The graphical representation clearly demonstrates a consistent trend toward a reduction in the arithmetic means and medians when transitioning from the conventional method with an individual tray and C-silicone to protocols using the experimental “Occlutray” tray in combination with various elastomeric materials.

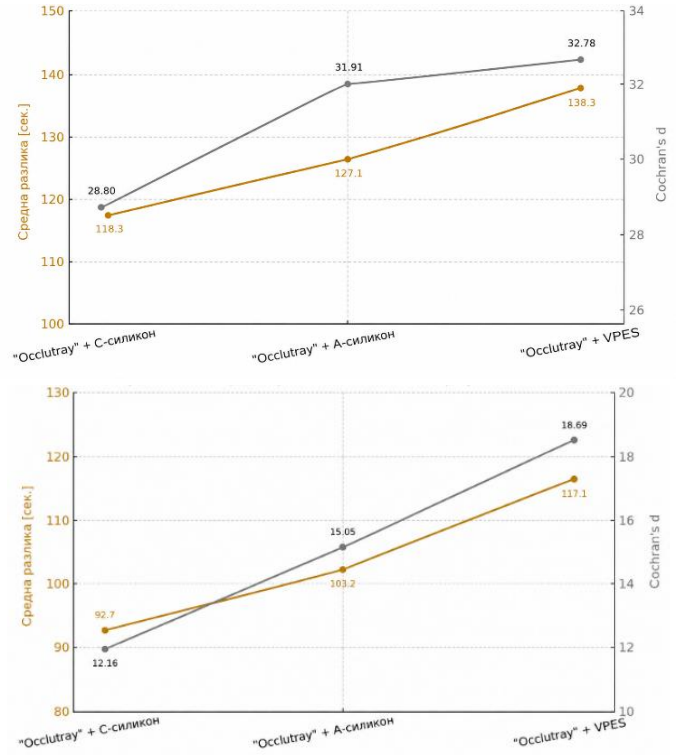

Fig. 64 *Comparison of mean difference and Cochran's d for the different methods*

The graphs clearly illustrate that all experimental methods demonstrate a statistically significant difference compared to the control group (custom tray with C-silicone). A consistent trend toward an increase in the mean difference in duration is observed when switching from the "Occlutray" experimental tray + C-silicone to "Occlutray" + A-silicone, and this trend is most pronounced with "Occlutray" + VPES. (Fig. 64)

2. Total impression-taking time

Table 23 *Summary table – total impression-taking time for the lower and upper jaws*

No.	Summary indicators	Jaw	Arithmetic mean	Median	Standard deviation
1	Final impression with individual tray and C-silicone [sec.]	Lower	638.87	640.00	4.904
		Upper	626.26	627.00	7,836
2	Final impression with "Occlutray" and C-silicone [sec.]	Lower	522.16	522.00	4.22
		Upper	530.81	531.00	5.167
3	Final impression with "Occlutray" and A-silicone [sec.]	Lower	504.19	503.00	6.988
		Upper	506.97	507.00	6,799
4	Final impression with "Occlutray" and VPES [sec.]	Lower	478.26	479.00	4.59
		Upper	479.65	479.00	5.964
5	Digital print [sec.]	Lower	284.77	279.00	25.275
		Upper	378.81	374.00	23.610

Table 23 presents the descriptive statistical indicators for the total duration of the impression-taking process for each of the methods studied. The highest average time was recorded for Method 1 (custom tray + C-silicone), followed in order by Methods 2, 3, and 4. Method 5 (digital intraoral scanning) demonstrated the lowest average duration, indicating the highest time efficiency among the studied protocols.

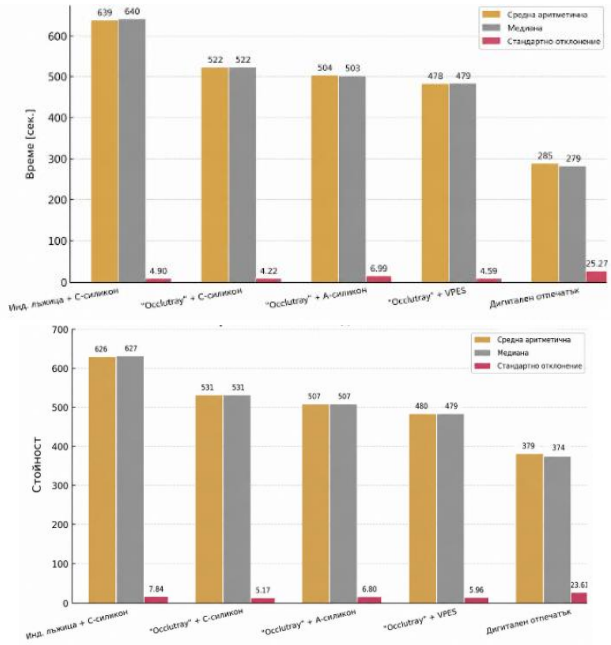

Fig. 65 *Comparison of the arithmetic mean, median, and standard deviation for the different impression methods*

Figure 65 illustrates the comparative analysis of the duration of the various impression-taking methods, clearly showing that the digital impression demonstrates the lowest average values. This confirms its high time efficiency in clinical settings.

In the graph, the columns illustrate the magnitude of the effect, while the red line reflects the average difference in duration. A clear and consistent trend is observed in both diagrams—all experimental methods demonstrate a significant difference compared to the control method (individual tray + C-silicone). (Fig. 66)

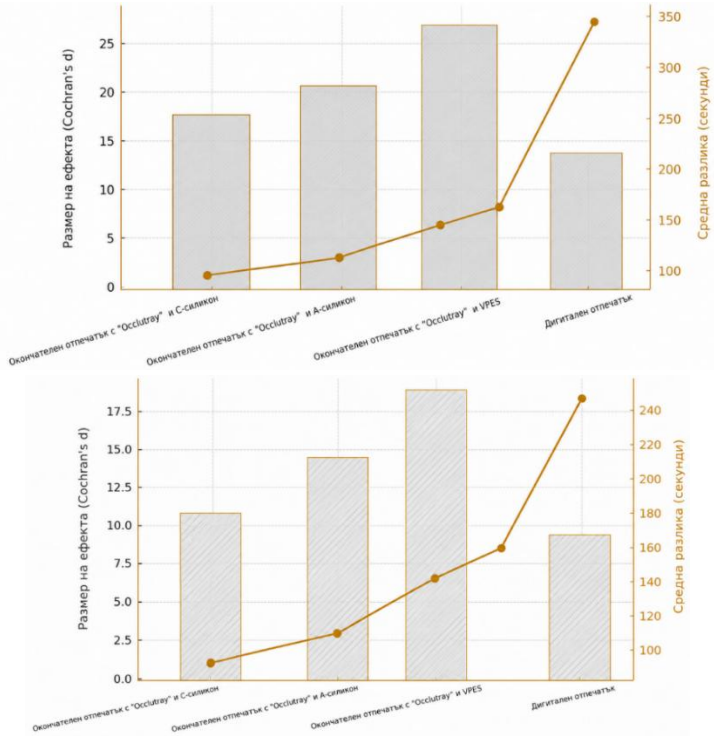

Fig. 66 *Combined graphical visualization of effect size and mean time difference*

The density curves clearly show a shift in the distributions relative to the control, confirming the significant reduction in impression time for all experimental methods compared to the traditional method. The largest average difference and most pronounced effect are observed with “Occlutray” + VPES, which underscores its high efficiency and reproducibility. (Fig. 67)

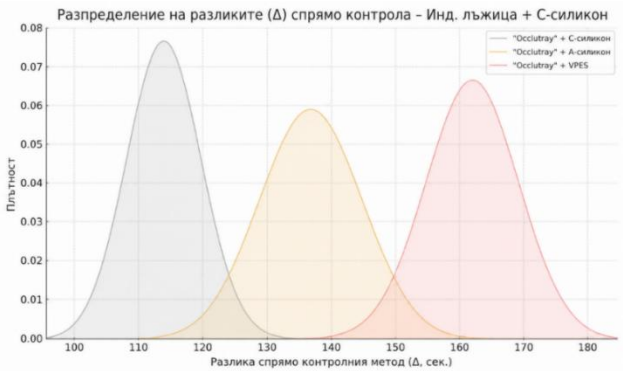

Fig. 67 *Distribution of differences (Δ) relative to the control method for different impression techniques*

3. Relationship between age and impression time

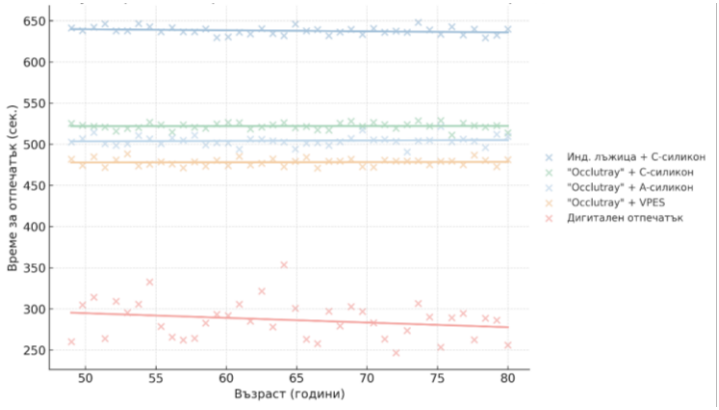

Fig. 68 *Graphical representation of the relationship between impression time and age for the mandible*

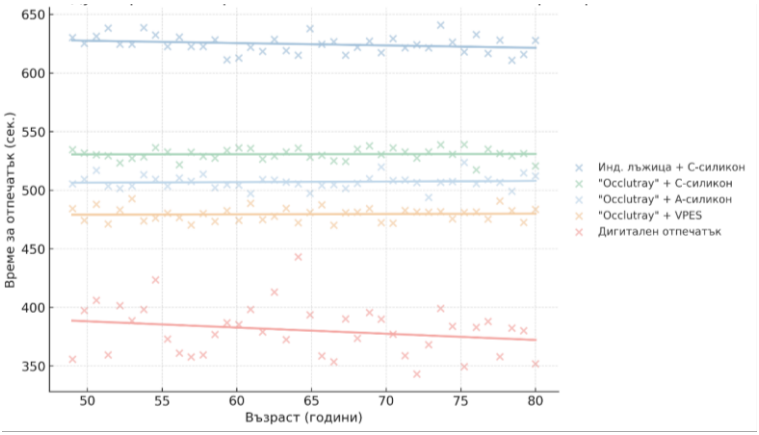

Fig. 69 *Graphical representation of the relationship between impression time and age for the maxilla*

The graphs demonstrate the relationship between the age of the subjects and the time required to make a final impression, with similar trends observed for both the upper and lower jaws. (Fig. 68) (Fig. 69)

For both jaws, a moderate positive correlation was found between age and the duration of the clinical procedure using Method 1 (custom tray + C-silicone) ($r = 0.39–0.63$; $p < 0.05$).

4. Relationship between gender and impression time

The results of the analysis did not reveal statistically significant differences in impression-taking time between men and women for any of the methods studied ($p > 0.05$). The mean values between the two groups are similar, and the differences fall within the standard variability of the measurements. (Table 24)

Table 24 *Summary table of the relationship between gender and final impression time for the mandible*

No.	Variables	Difference in means	P-value	Statistical significance at α = 0.05	Cochran's d	Effect size
1	Final impression with individual tray and C-silicone [sec.]	-5.03	0.003	significant difference	1.181	very large
2	Final impression with "Occlutray" and C-silicone [sec.]	0.130	0.841	insignificant difference	0.073	negligibly small
3	Final impression with "Occlutray" and A-silicone [sec.]	-5.83	0.018	significant difference	0.905	large
4	Final impression with "Occlutray" and VPES [sec.]	-4.150	0.009	significant difference	1.001	large
5	Digital footprint [sec.]	-18.263	0.048	significant difference	0.764	moderate to large

V.5. Results and Discussion for Task 5

The experimental protocol developed to streamline clinical steps within the partial digital protocol for prosthetic rehabilitation of completely edentulous patients demonstrates high clinical efficacy, good reproducibility, and predictable functional outcomes. The data obtained confirm that the one-step taking of a functional impression and registration of the interarch relationship using Occlutray is a clinically applicable and reliable method.

The summarized results show that for maxillary complete dentures, higher clinical scores are recorded in all evaluated parameters compared to mandibular dentures. The most pronounced differences are observed in retention, stability, and comfort, which reflects the anatomical advantages of the larger prosthetic surface area, the presence of a palatal support zone, and the possibility of vacuum retention. (Table 25)

The clinical success rate reached 96.2% for upper and 92.0% for lower complete dentures, reflecting a high overall clinical success rate of the developed protocol. The results demonstrate that reducing the number of clinical stages does not compromise functional and aesthetic outcomes; on the contrary, it ensures predictable and reproducible results in completely edentulous patients

All clinical parameters examined demonstrate mean values above 1.8, indicating a high degree of adaptation, functional stability, and satisfactory aesthetic results for the prostheses fabricated according to the experimental protocol. These data confirm that the applied methodology provides clinically predictable and consistent results regarding the main criteria for evaluating complete dentures. (Fig. 70)

Table 25 *Summary of clinical results in the evaluation of maxillary and mandibular complete dentures*

Parameter	Maxillary prosthesis	Lower denture (n	Range (Min–Max)	Average clinical index (%)

	(n = 10) Mean ± SD	= 10) Mean ± SD		
Retention	1.95 ± 0.10	1.45 ± 0.32	1.0 – 2.0	95.0
Stability	1.90 ± 0.15	1.75 ± 0.26	1.4 – 2.0	93.8
Peripheral fit	2.00 ± 0.00	1.95 ± 0.10	1.8 – 2.0	97.9
Comfort	1.95 ± 0.10	1.80 ± 0.25	1.5 – 2.0	94.0
Phonetics	1.90 ± 0.18	1.85 ± 0.16	1.6 – 2.0	93.8
Aesthetics	1.95 ± 0.10	1.85 ± 0.16	1.6 – 2.0	95.4
Overall score /12	11.65 ± 0.28	10.65 ± 0.45	10 – 12	-
Clinical efficacy index (%)	96.2 ± 3.1	92.0 ± 6.9	83.3 – 100.0	-

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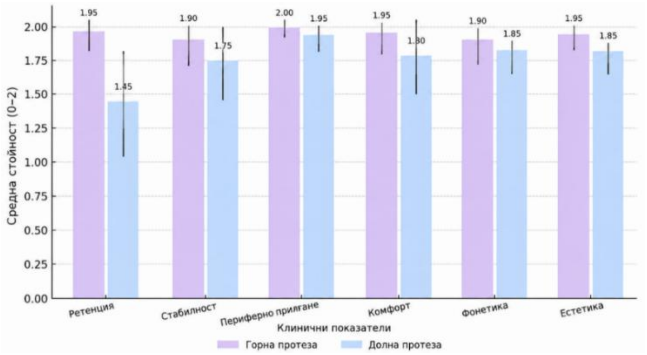

Fig. 70 *Mean values (Mean ± SD) of clinical parameters for upper and lower dentures*

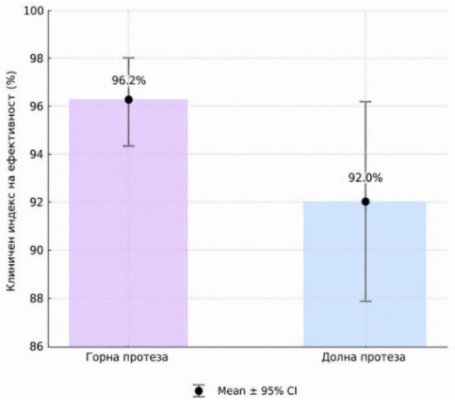

Fig. 71 *Mean values and 95% confidence intervals of the clinical effectiveness index*

Fig. 71 presents the mean values and 95% confidence intervals of the clinical effectiveness index for upper and lower complete dentures. A clear distinction is observed between the two groups—upper dentures demonstrate a higher mean value (96.2%), while for lower dentures the mean index amounts to 92.0%.

The difference between the two groups is statistically significant, as confirmed by a paired t-test ($p = 0.037$).

In summary, the experimental protocol demonstrated consistent efficacy in both jaws, with anatomically predictable differences maintained without compromising overall clinical success.

Table 26 *Comparison by Gender*

Type	Test	Statistic	p-value
Upper	Mann–Whitney U	6.00	0.179
Lower	Mann–Whitney U	8.00	0.263
All	Mann–Whitney U	33.00	0.317

Table 26 presents the results of the comparative analysis of the clinical index between men and women, conducted using the

nonparametric Mann–Whitney U test due to the non-normal distribution of the data.

In all three analyses performed, the p-values exceed the threshold level of statistical significance ($p > 0.05$), indicating that no statistically significant differences were found between the sexes regarding the clinical efficacy index.

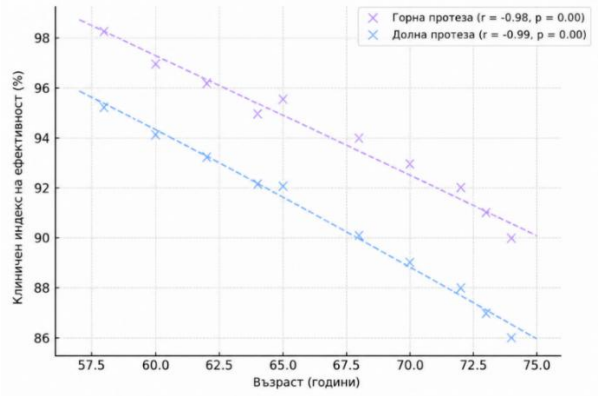

Fig. 72 *Correlation between patient age and clinical effectiveness index*

Figure 72 illustrates the relationship between patient age and the clinical effectiveness index (%) for upper and lower complete dentures. A weak negative trend is observed, which, however, does not reach statistical significance ($p > 0.05$). This indicates that age does not have a significant impact on the clinical effectiveness of the prostheses and confirms the stability and predictability of the tested experimental protocol.

The graphical representation illustrates the predominance of high values and highlights the clinical stability of the method when applied to a heterogeneous group of patients. (Fig. 73)

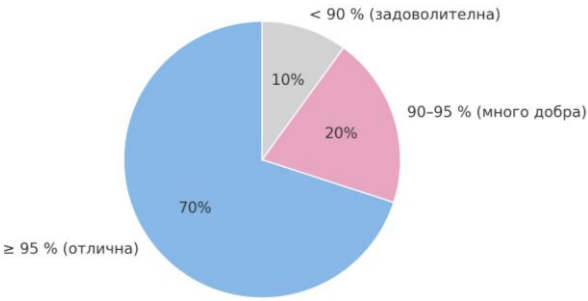

Fig. 73 *Frequency distribution of the clinical effectiveness index*

The observed distribution indicates that the fabrication of prostheses using the experimental protocol leads predominantly to clinically optimal results. The concentration of cases in the ≥95% range confirms the high functional effectiveness and stability of the method.

In this context, the obtained result demonstrates a high degree of predictability and clinical stability of the method, while preserving the possibility for individual adaptation in more complex anatomical conditions.

V. CONCLUSIONS

1. A two-component morphometric algorithm has been developed to determine the size and shape of the individual impression tray using CBCT in combination with CAD/CAM
2. In cases of parameter mismatch, the use of modified or hybrid designs is justified.
3. The sagittal dimension of the mandible (Ls) is significant for the stability of the prosthesis.
4. Age and gender do not have a statistically significant effect on morphometric parameters.
5. The digital prosthetic protocol improves the accuracy and reproducibility of treatment.
6. Clinical adaptation remains a mandatory step despite digital standardization.
7. The “Occlutray” tray allows for the development of a parametric digital model.
8. A differentiated approach is required for the upper and lower jaws.
9. The integrated design represents a biomechanically sound solution with digitally controlled geometry.
10. PLA and ABS are suitable materials for 3D-printed impression trays.
11. Microbiological safety depends primarily on the sterilization protocol, and 3D-printed trays can be used safely in clinical practice.
12. The “Occlutray” tray significantly reduces clinical time without compromising accuracy.
13. The digital method is the fastest but has lower predictability.
14. Conventional methods are more age dependent.
15. The validated protocol is effective, reproducible, and clinically applicable.

VI. CONCLUSION

This dissertation presents a comprehensive analysis of the capabilities of digital technologies in the prosthetic rehabilitation of completely edentulous patients by integrating a morphometric, clinical, and statistical approach.

The developed digital protocol, including CBCT analysis, CAD design, and additive manufacturing, demonstrates a high degree of reproducibility and clinical applicability. The creation of a two-component morphometric algorithm (Us + Uf) and the experimental "Occlutray" impression tray allow for the standardization and optimization of key stages of prosthetic treatment.

The results show that the digital protocol provides good aesthetic and phonetic outcomes but remains limited in terms of functional parameters such as retention, stability, and marginal fit. It was found that maxillary dentures demonstrate better clinical effectiveness, while mandibular dentures are characterized by greater variability, due to the anatomical and functional characteristics of the prosthetic field.

Analysis of the influence of age shows a statistically significant negative correlation with the clinical effectiveness index, which is more pronounced in maxillary dentures. In contrast, gender does not have a significant effect on clinical outcomes. These findings underscore the importance of individual anatomical and functional factors as key determinants of the success of prosthetic treatment.

Statistical analysis, incorporating parametric and nonparametric methods, confirms the reliability of the results and allows for an objective assessment of the digital protocol's effectiveness.

In practical terms, the study results indicate that digital technologies represent a promising tool in modern prosthetic dentistry, but their optimal application requires integration with clinical techniques, particularly in the functional design of the prosthetic field.

In conclusion, the digital prosthetic protocol can be considered an effective and viable alternative to conventional methods, if it is applied with the patient's individual characteristics in mind and in combination with clinically sound corrective approaches.

VII. CONTRIBUTIONS

I. Contributions of a scientific and applied nature

1.1. Original contributions

1. It has been demonstrated that the fully digital prosthetic protocol ensures high effectiveness in terms of aesthetic and phonetic indicators but remains limited in terms of functional parameters (retention, stability, and marginal fit), necessitating clinical optimization and a hybrid approach.
2. An original design model of the "Occlutray" impression tray has been developed and protected as an industrial design by the Patent Office of the Republic of Bulgaria: Reg. No. BG – 9363, intended for functional impression-taking and registration of interarch relationships within a digital protocol for completely edentulous patients.
3. A two-component morphometric algorithm (Us + Uf) has been developed to determine the size and shape of individual impression trays, applicable in the context of digital prosthetic planning.
4. A morphological proportionality between the dimensions of the maxilla and mandible has been established, with practical significance for parametric CAD design of complete dentures.
5. The concept of an anatomically differentiated digital approach to the design of impression trays for the maxilla and mandible is substantiated.
6. Differentiated clinical efficacy of fully digitally fabricated complete dentures has been established, with the superiority of maxillary constructions demonstrated in terms of functional indicators and higher variability in mandibular dentures.
7. Empirical foundations have been established for the parametric CAD design of the experimental "Occlutray" tray as part of the digital prosthetic protocol.

1.2. Confirming contributions

1. It has been demonstrated that age and gender do not exert a statistically significant influence on the morphometric parameters (Us, Uf, Ls, Lf) used in digital prosthetic planning.
2. The stability and age-independence of the morphometric indices as reliable guidelines for the rehabilitation of completely edentulous patients have been confirmed.
3. The clinical applicability and reproducibility of the digitally assisted protocol in a heterogeneous patient population have been confirmed.
4. It has been demonstrated that the microbiological safety of 3D-printed impression trays depends primarily on the sterilization protocol rather than on the material used (PLA/ABS).

II. Practical Contributions

1. Clinical guidelines have been formulated for optimizing the digital protocol, including the need for a hybrid approach in the functional design of the prosthetic field.
2. A partially digital protocol (CBCT–CAD–3D printing) has been introduced and optimized for the rehabilitation of completely edentulous patients with complete dentures while maintaining the reproducibility of results.
3. The clinical efficacy of the experimental "Occlutray" impression tray has been demonstrated as a time-saving alternative to conventional techniques, without compromising accuracy and stability.
4. The possibility of safe clinical use of 3D-printed impression trays within the digital protocol has been confirmed.
5. The advantages (timesaving, standardization, predictability) and limitations (need for clinical adaptation, variability in some methods) of the digital protocol in full-mouth prosthetic rehabilitation have been identified.

VIII. PUBLICATIONS RELATED TO THE DISSERTATION

1. Donkova Y, Konstantinova D, Georgiev D. Application of digital technologies for complete dentures. *J of IMAB.* 2023 Jul-Sep;29(3):5031-5035.
2. Donkova Y, Nenova-Nogalcheva A, Konstantinova D, Georgiev D. Anatomo-morphological features of an edentulous upper jaw. *J of IMAB.* 2023 Jul-Sep;29(3):5049-5051. [Crossref – 10.5272/jimab.2023293.5049]
3. Y Donkova, D Konstantinova, A Nenova-Nogalcheva. Methodology for determining the jaw bone dimensions via 3D imaging in patients with total edentulism. Journal of the Union of Scientists – Varna. Medicine and Ecology Series. 2024;29:70-77