Digital quantification of dental plaque based on intraoral scanner images

Ethical committee approval number: CAAE 85446624.8.0000.5506

Approved on March 25, 2025

SUMMARY

Abstract

Objective: To develop and validate a digital method for dental biofilm quantification based on three-dimensional images obtained by intraoral scanner, comparing its accuracy with traditional clinical assessment methods.

Methods: A prospective, evaluator-blinded clinical study including 20 participants (18-65 years) with at least 20 natural teeth and visible plaque index >20%. Participants will be evaluated at three time points in a single session: initial scanning (T0), after biofilm disclosure (T1), and after supervised toothbrushing (T2). Digital analysis will be performed using Geomagic Control X software, calculating the percentage of surface area covered by plaque. Data will be analyzed using Spearman correlation and repeated measures ANOVA or Friedman test.

Expected Results: This digital method will provide a more objective and precise assessment of dental biofilm, overcoming limitations of conventional methods.

Conclusion: The validation of this new digital approach could significantly contribute to advancing clinical practices and research in preventive dentistry.

Keywords: Dental Biofilm; Intraoral Scanner; Digital Diagnosis; Digital Methodology; Preventive Dentistry.

1. INTRODUCTION:

Plaque is the main etiological factor of periodontal diseases(Abdulkareem et al., 2023) Plaque is constantly present around the tooth near the gingival sulcus and elicits an immune-inflammatory response from the host. This inflammation remains confined to the gums, and if the local factor (Biofilm) is not resolved with home care, such as mechanical or chemical biofilm control measures, it will develop and result in gingivitis and periodontitis (Kinane et al., 2017; Könönen et al., 2019). Accurate assessment of biofilm quantity and distribution is critical for both clinical diagnosis and monitoring and preventive dentistry research(Pretty et al., 2005).

Traditionally, biofilm quantification is performed by visual indices, such as the Quigley-Hein Plaque Index modified by Turesky(Turesky et al., 1970). Although widely used, these methods have important limitations, including the subjectivity of the assessment, the need for calibration between examiners, and the difficulty of detecting small changes in plaque quantity(Carter et al., 2004).

In recent years, the advancement of digital technologies in dentistry has provided new possibilities for the quantitative evaluation of dental biofilm. The use of digital photographs and computerized image analysis has shown promising results, allowing for a more objective and accurate quantification of dental plaque(Guo et al., 2024; Joseph et al., 2015; You et al., 2020). However, these techniques are still limited by the two-dimensional nature of the images, which do not fully capture the three-dimensional complexity of tooth surfaces(Giese-Kraft et al., 2022).

Intraoral scanners, initially developed for applications in restorative dentistry and orthodontics, have gained ground as diagnostic tools and clinical documentation(Mangano et al., 2017). These devices are capable of capturing detailed three-dimensional images of the oral cavity, including information about the color and texture of tooth surfaces(Giese-Kraft et al., 2022; Zimmermann et al., 2015). Recent studies have explored the potential of intraoral scanners for the detection and quantification of dental plaque, showing promising results in terms of accuracy and reproducibility(Guo et al., 2024; Rikvold et al., 2023).

The development of a digital method for biofilm quantification based on intraoral scanner images represents an innovative approach that can overcome many of the limitations of conventional methods. In addition to providing a more objective and accurate assessment, this method has the potential to facilitate the storage and longitudinal comparison of data, as well as allow for more sophisticated analyses of plaque distribution and accumulation patterns(Giese-Kraft et al., 2022; Jung et al., 2022).

In this context, the present study aims to develop and validate a new digital method for quantification of dental plaque using three-dimensional images obtained by intraoral scanners. It is hoped that this approach can contribute to the advancement of clinical and research practices in preventive dentistry, offering a more accurate and objective tool for the evaluation of dental biofilm.

2. Hypothesis

The digital quantification method of dental biofilm through three-dimensional images obtained by intraoral scanner demonstrates non-inferiority in measurement when compared to the traditional method of visual clinical assessment with plaque disclosing solution, being able to detect and document the presence and distribution of biofilm on dental surfaces

3. OBJECTIVES:

Primary objective:

- To develop and validate a digital method for biofilm quantification based on three-dimensional images obtained by intraoral scanner.

Secondary objectives:

- To compare the accuracy and precision of the proposed digital method with the reference method of clinical assessment of dental biofilm.
- To investigate the capability of the digital method to detect changes in plaque quantity after toothbrushing.

- To analyze biofilm distribution patterns on dental surfaces using three-dimensional images obtained by the intraoral scanner.

4. METHODOLOGY:

4.1. Ethical considerations

This research project will be carried out at the Center for Clinical Studies of Univeritas UnG, in accordance with the resolution of the National Health Council and only after approval by the Research Ethics Committee of the University of Guarulhos. All subjects will be informed about the objectives and characteristics of the study and will be required to sign the Informed Consent Form (ICF) before being included. Privacy, secrecy and confidentiality policies will be strictly enforced in the project. All data, digital files, and images collected will be encoded with identification numbers, and images from the intraoral scanner will be anonymized prior to storage. Access to the data will be controlled by password and limited to authorized researchers. The data will be kept for a period of 5 years after the end of the research, and the dissemination of the results at scientific events, congresses and scientific articles will ensure the anonymity of the participants.

4.2. Study design

A prospective clinical study with clinical evaluation and blinded to the evaluator will be conducted.

Primary Outcome:

- Correlation between the percentage of dental surface area covered by biofilm quantified by the digital method (intraoral scanner) and the plaque index obtained by the traditional clinical method (Quigley-Hein Plaque Index modified by Turesky).

Secondary Outcome:

- Ability of the digital method to detect changes in the amount of biofilm, evaluated by the percentage difference in area covered between T0 (initial), T1 (after disclosure) and T2 (after professional brushing).
- Time required to perform the digital analysis compared to the evaluation time by the traditional method.

- Technical feasibility of the scanning protocol for biofilm quantification in a clinical setting.
- Tooth surface topographic analysis for between T0 (initial), and T2 (after professional brushing)
- Fluorescence imaging capabilities: Detection sensitivity for plaque, correlation with clinical findings, reproducibility of fluorescence measurements.
- Plaque volume/thickness changes analysis: utilize 3Shape's alignment of sequential scans to generate difference maps, enabling the visualization and evaluation of plaque changes (e.g., before and after cleaning), finding appropriate metrics for quantification, and correlating those with other features, such as disclosing agent color and fluorescence.
- Dental biofilm detection through intraoral photographs with different filters

4.3. Patient selection

20 participants of both sexes, aged between 18 and 65 years, will be selected, the dissemination of recruitment will be carried out through different communication channels, including informative posters distributed in the dental clinics of UnG, digital dissemination on the university's official website and its institutional social networks, direct invitation to patients who are on the waiting list of the periodontics clinic and dissemination by the professors of the undergraduate and graduate clinics. All promotional material will contain clear information about the inclusion and exclusion criteria, as well as the contacts for scheduling the initial screening and the ethics committee approval number. The sample size calculation was performed following a previous study(Del Rey et al., 2023), considering a power of 80% and a significance level of 5%.

4.4. Inclusion Criteria:

- Presence of at least 20 natural teeth
- Visible plaque index > 20% at initial assessment

4.5. Exclusion Criteria:

- Use of fixed orthodontic appliances
- Presence of extensive restorations or fixed dentures on the anterior teeth
- Systemic conditions that interfere with the formation of dental biofilm
- Use of medications that alter salivary flow

4.6. Clinical procedures

The clinical evaluations, scans, photos, and the supervised tooth brushing will be carried out by a team composed of 3 graduate students and professors from UnG, specialized in Periodontics and/or implantology. To ensure accuracy, a theoretical-practical training on the Turesky Plaque Index will be carried out, followed by intra-examiner calibration in 5 patients who did not participate in the study, with an accepted Kappa coefficient above 0.8. The study will be conducted according to the following visit schedule:

Visit	Procedures	Details
Visit 1	• Project explanation • General oral evaluation • Informed consent signing • Instructions for 24-hour no-brushing period	• Participants will receive detailed information about the study protocol • A preliminary oral assessment will be performed • Instructions will be provided for the 24-hour no-brushing period before Visit 2
Visit 2 (Experimental Session)	**Phase 1 - Initial Assessment (T0)** • Initial intraoral scanning • Standardized intraoral photographs **Phase 2 - After Plaque Disclosure (T1)** • Application of plaque disclosing solution • Intraoral scanning with disclosed biofilm • Standardized intraoral photographs • Clinical examination using Turesky Plaque Index **Phase 3 - After Oral Hygiene (T2)**	• The TRIOS 4 intraoral scanners will be used for all scans • Scans will capture the entire dental arch • Standardized photographs of vestibular surfaces will be taken at each phase • The Turesky Plaque Index (scale 0-5) will be used as the reference method

	• Supervised toothbrushing (Modified Bass technique, 2 minutes) • Final intraoral scanning • Standardized intraoral photographs	• Toothbrushing will be performed with a manual toothbrush and fluoridated toothpaste

4.7. Image analysis

The three-dimensional images obtained by the intraoral scanner will be analyzed using the Geomagic Control X software. A second examiner, blinded to the results of the clinical examination, will perform the following steps:

1. Segmentation of the tooth surfaces of interest
2. Identification of the areas covered by plaque shown in T1- disclosed images
3. Calculation of the percentage of area covered by plaque in relation to the total area of each tooth surface

This procedure will be performed for the images obtained at T0, T1 and T2 times.

4.8. Statistical analysis Plan (SAP)

Data will be tabulated and analyzed using the STATA 15 software. The normality of the data distribution will be verified by the Shapiro-Wilk test.

For comparison between the methods of plate evaluation (reference x digital), Spearman's correlation test will be used.

Differences in plaque amount between T0, T1, and T2 times will be analyzed using repeated measures of ANOVA or Friedman's test, depending on the distribution of the data.

The level of significance adopted will be 5% ($p<0.05$).

4.9. Risks

The possible risks associated with this study are minimal, since the procedures involved are non-invasive and routine in dental practice. Withholding oral hygiene for 24 hours before the procedure may cause mild discomfort and temporary bad breath. As for professional scaling and supervised brushing, these

are safe procedures that can cause temporary sensitivity. The visit will last a total of 1.5 to 2 hours, and may vary according to the specific needs of each patient. During the procedure, it is possible that the patient will experience some type of physical discomfort, such as tenderness or slight pain, especially in cases of deeper scaling or in areas with gingival inflammation. All procedures will be carried out following strict biosafety protocols and under qualified professional supervision.

4.10. Benefits

4.0.1. Direct benefits to participants:

• Detailed assessment of oral hygiene condition

•Professional guidance on brushing techniques

• Free of charge professional cleaning (scaling)

• Oral health monitoring during the study period

4.0.2. Indirect benefits to the scientific community and clinical practice:

• Validation of a new digital method for biofilm quantification

• Development of a more objective tool for clinical evaluation

• Possibility of better documentation and longitudinal follow-up of patients

• Potential improvement of oral health prevention practices

• Contribution to the advancement of digital and preventive dentistry

4.11. Criteria for suspending or terminating the search

The survey will be suspended if 50% of the participants are unable to attend the consultations or no longer wish to participate in the study. Other eventualities that may interfere with the inclusion criteria and the integrity and well-being of the participants may be considered grounds for suspending the research (e.g., medical impediment to undergo the research procedures). Whatever the reason that suspends or terminates the research for a given participant, the latter will not be affected by its treatment. In addition, the research participant will not have any loss in referrals for treatment in other dental specialties at Univeritas-UNG University.

5. SCHEDULE

Year	Month	Activity
2025	August-December	- Beginning of recruitment of participants - Beginning of clinical data collection and intraoral scans
2026	January-April	- 3D image processing and plaque quantification - Statistical analysis of the data
	May-June	- Beginning of the writing of the final report and scientific article - Continuation of statistical analysis of the data - Interpretation of results - Discussion of the results
	July	- Preparation of presentations for congresses - Revision and finalization of the manuscript - Submission of the article for publication

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7. Appendix 1: Ethical committee Approval

GUARULHOS UNIVERSITY - UNG

SUBSTANTIATED OPINION OF THE CEP

RESEARCH PROJECT DATA

Research Title: Digital quantification of dental plaque based on intraoral scanner images

Researcher: Mohamed Ahmed Hassan
Thematic Area:
Version: 2
CAAE: 85446624.8.0000.5506
Proponent Institution: GUARULHOS UNIVERSITY
Main Sponsor: Own Funding

OPINION DATA

Opinion Number: 7.463.010

Project Presentation:
Reporting based on the documents attached to the Plataforma Brasil, related to the CAAE project: 85446624.8.0000.5506
(Version 2), submitted on 02/12/2025, following the guidelines of Resolution 466/12, Operational Rule No. 001/2013 and Law No. 14,874, of May 28, 2024.

Objective: To develop and validate a digital method for biofilm quantification based on three-dimensional images obtained by intraoral scanner,
comparing its accuracy with the traditional method of clinical evaluation. Methods: Prospective, assessor-blinded clinical study, including 20
Participants (18-65 years old) with at least 20 natural teeth and visible plaque index >20%. Participants will be evaluated in three moments
in a single session: initial scan (T0), after biofilm evidence (T1) and after supervised brushing and professional scraping
(T2). The digital analysis will be carried out through the Geomagic Control X software, calculating the percentage of area covered by the plate. The data will be
analyzed using Spearman's correlation and repeated measures ANOVA or Friedman's test.
Expected Results: This Digital Method
will provide a more objective and accurate assessment of dental biofilm, overcoming limitations

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of conventional methods. Conclusion: Validation
This new digital approach can contribute significantly to the advancement of clinical and research practices in preventive dentistry.

Inclusion Criteria:-Presence of at least 20 natural teeth-Visible plaque index > 20% at baseline evaluation
Exclusion Criteria:-Use of fixed orthodontic appliances-Presence of extensive restorations or fixed prostheses in the anterior teeth-Systemic conditions that interfere with the formation of dental biofilm-Use of medications that alter salivary flow

Research Objective:

Primary Objective:
To develop and validate a digital method for biofilm quantification based on three-dimensional images obtained by intraoral scanner.
Secondary Objective:-To compare the accuracy and precision of the proposed digital method with the reference method of clinical evaluation of dental biofilm.-To investigate the ability of the digital method to detect changes in the amount of plaque after toothbrushing.-To analyze the patterns of biofilm distribution on tooth surfaces using the three-dimensional images obtained by the intraoral scanner

Assessment of Risks and Benefits:

Risks:
The possible risks associated with this study are minimal, since the procedures involved are non-invasive and routine in practice
Dental. Withholding oral hygiene for 24 hours before the procedure may cause mild discomfort and temporary bad breath. As for the
Professional scaling and supervised brushing are safe procedures that can cause temporary sensitivity. The visit will have a
total duration of 1.5 to 2 hours, which may vary according to the specific needs of each patient.
During the procedure, it is possible that the
patient experiences some type of physical discomfort, such as tenderness or slight pain, especially in cases of deeper scraping or in
areas with gingival inflammation. All procedures will be carried out following strict biosafety protocols and under supervision
qualified professional.

Benefits:

Direct benefits to participants:-Detailed assessment of oral hygiene condition-Professional guidance on brushing techniques-Free professional cleaning (scaling)-Follow-up of oral health during the study period

Indirect benefits for the scientific community and clinical practice:-Validation of a new digital method for biofilm quantification

-Development of a more objective tool for clinical evaluation-Possibility of better documentation and longitudinal follow-up of patients-Potential improvement of prevention practices in oral health-Contribution to the advancement of digital and preventive dentistry

Opinion: The risks and benefits are well described.

Comments and Considerations on the Research:

The research project presented is in accordance with Operational Norm No. 001/2013 and Law No. 14,874, of May 28, 2024., the non-conformities are described in Conclusions or Pending Issues.

Considerations for the Mandatory Terms:

According to Resolution 466/12, the following are the considerations on the terms of mandatory presentation, the non-conformities are described in Conclusions or Pending Issues:

- ICF: it is adequate.
- TALE: this does not apply.
- Cover page: it is adequate.
- Letter of consent and/or authorization: it is adequate.
- As for the Term of Trustee: it is adequate/does not apply.
- Schedule: it is adequate.
- Budget: it is adequate.
- Declaration of commitment: it is appropriate.

Conclusions or Pending Issues and List of Inadequacies:

Based on the guidelines of CNS Resolutions 466/12 and 510/16, Operational Rule No. 001/2013 and Law No. 14,874, of May 28, 2024, the project CAAE:85446624.8.0000.5506 (Version 2), submitted on 02/12/2025 was considered APPROVED.

Continuation of Opinion: 7.463.010

Final Considerations at the discretion of the CEP:

After a collegiate meeting and based on the guidelines of CNS Resolutions 466/12 and 510/16, Operational Rule No. 001/2013 and Law No. 14,874, of May 28, 2024, the project CAAE:85446624.8.0000.5506 (Version 2), submitted on 02/12/2025 was considered APPROVED.

This opinion was prepared based on the documents listed below:

Document Type	Archive	Post	Author	Situation
Basic Information of the Project	PB_INFORMAÇOES_BASICAS_DO_PROJETO_2466122.pdf	12/02/2025 10:53:08		Accepted
Detailed Design / Brochure Researcher	Projeto_Placa_2025.docx	12/02/2025 10:51:41	Mohamed Ahmed Hassan	Accepted
ICF / Terms of Assent / Justification of Absence	TCLE_Placa_2025.docx	12/02/2025 10:51:16	Mohamed Ahmed Hassan	Accepted
Schedule	Cronograma_2025.pdf	12/02/2025 10:49:16	Mohamed Ahmed Hassan	Accepted
Budget	orcamento_2025.pdf	05/02/2025 13:31:10	Mohamed Ahmed Hassan	Accepted
Other	carta_resposta.docx	05/02/2025 13:27:59	Mohamed Ahmed Hassan	Accepted
Statement of Researchers	04Declaraccao_de_Compromisso_dos_Pesquisadores.pdf	10/12/2024 22:31:03	Mohamed Ahmed Hassan	Accepted
Statement of Institution and Infrastructure	03Declaracao_de_Infraestrutura.pdf	10/12/2024 22:28:59	Mohamed Ahmed Hassan	Accepted
Cover Page	00Folha_DeRosta.pdf	10/12/2024 22:25:44	Mohamed Ahmed Hassan	Accepted

Status of the Opinion:

Approved

Needs CONEP Consideration:

No

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GUARULHOS, March 25, 2025

Signed by:
JOSE AUGUSTO RODRIGUES
(Coordinator)

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8. Appendix 2: Informed Consent

INFORMED CONSENT FORM

STUDY TITLE: Digital quantification of dental plaque based on intraoral scanner images

PRINCIPAL INVESTIGATOR: Prof. Dr. Mohamed Ahmed Hassan (UNG)

INSTITUTION: Center for clinical Studies and Research. Guarulhos University (UNG).

PHONE: (11) 972945957

OTHER RESEARCHERS: Prof. Dr. Jamil Awad Shibli (UNG), Profa. Dr. Luciene Cristina de Figueiredo (UNG), Lucas Daylor Aguiar da Silva (UNG)

Participant Initials: ____

Participant's date of birth: ____ ____ ____ dd/mm/yyyy

Participant Number: ____

RESEARCH ETHICS COMMITTEE CEP:

The Research Ethics Committee (CEP) is an interdisciplinary and independent collegiate body, of an advisory, deliberative and educational nature, created to defend the interests of the research subjects in their integrity and dignity and to contribute to the development of research within ethical standards. Ethics Committee for Research with Human Beings – UNG (5506); Guarulhos University – UNG. Address: Praça Tereza Cristina, 88 – Centro – Guarulhos/SP – CEP: 07023-070, 5º andar / Edifício E, e-mail: comite.etica@ung.br, Tel: (11) 2464-1664. Opening hours to the public: Monday - Friday: 10:00 am to 4:00 pm

INVITATION TO PARTICIPATE IN THE STUDY

With this informed consent form (ICF), we invite you to participate in this research project, which is a clinical study on digital quantification of dental plaque. This invitation confirms that your participation in the study is voluntary and that you can withdraw this consent and leave the project at any time during the research, without prejudice to the continuity of treatment.

The study will be conducted at the Center for Clinical Studies of the University of Guarulhos (UnG), where participants of both genders aged between 18 and 65 years who seek treatment at the clinics of the University of Guarulhos will be selected to obtain a sample number of (n= 20). This sample size calculation was based on previous studies and participants must comply with the inclusion and exclusion criteria described below.

STUDY OBJECTIVES

I certify that I have been verbally clarified that dental plaque is the main etiological factor of periodontal diseases and its accurate quantification is essential for diagnosis and clinical monitoring. The proposed treatment aims to develop a new digital method for quantification of dental plaque using three-dimensional images obtained by intraoral scanner.

As described in the project, the primary and secondary objectives are, respectively:

-The primary objective of the study will be to develop and validate a digital method for dental plaque quantification based on three-dimensional images obtained by intraoral scanner.

-The secondary objectives will be to compare the accuracy of the proposed digital method with the traditional method of clinical evaluation of dental plaque, to investigate the ability of the method to detect changes in the amount of plaque after tooth brushing, and to analyze the patterns of plaque distribution on tooth surfaces using three-dimensional images.

The study hypotheses:

The ability of the digital method to analyze plaque distribution patterns on tooth surfaces is not inferior to the traditional method, considering a non-inferiority margin of 10%.

PARTICIPATION IN THE STUDY

During the invitation to participate, it became clear that the study will be conducted at the Center for Clinical Studies of the University of Guarulhos (UnG), in which participants who have visible dental plaque will be selected. I was informed that to participate in this study, I must attend on the pre-established days and times, and not perform oral hygiene for 24 hours before the first appointment.

During my participation, a series of clinical procedures will be performed that include: digital scanning of the teeth using an intraoral scanner, application of a dental plaque highlighting solution, standardized photographs of the teeth, clinical visual examination and supervised brushing followed by a new scan. All these procedures will be performed by trained and qualified professionals.

As a study participant, I will have access to the results of all evaluations and examinations performed, as well as the results of the overall survey. The researchers undertake to keep me informed of the progress of the study and to clarify any doubts that may arise during my participation.

PROCEDURES

I was informed that during my participation in the study, the following clinical procedures will be performed in a single session: initially, a digital scan of my teeth will be done using an intraoral scanner, lasting 10 to 20 minutes. Then, a plaque highlighting solution will be applied, followed by a rinse with water for 10 seconds.

After disclosure, standardized photographs will be obtained and an examiner will perform a detailed clinical evaluation in about 10-20 minutes, followed by a new scan with the evidenced

plaque. Finally, I will perform a supervised brushing for 2 minutes and a final scan of my teeth will be done. The visit will have a total duration of 1.5 to 2 hours.

All procedures will be carried out by professors and graduate students in the area of periodontics and implantology at the University of Guarulhos, following strict biosafety protocols, and I will have access to the results of all evaluations carried out.

BENEFITS

I was clarified that the main benefit of participating in this study is to contribute to the development of a new technology that will allow a more accurate assessment of dental plaque. As a participant, I will receive personalized guidance on proper oral hygiene techniques and have a detailed follow-up of my oral health throughout the study period. Finally, the research participants who need it will receive a referral for treatment in the other dental specialties of the centers participating in the study.

RISKS AND DISCOMFORTS

I am aware that participation in this study involves LOW RISKS related to clinical evaluation procedures. Possible discomforts include the time required to not perform oral hygiene before the first consultation (24 hours), possible sensitivity during the application of the plate discloser, and possible discomfort during the scanning process due to the time required to capture the images. To minimize these risks, all procedures will be performed by trained professionals, following established clinical protocols.

TIME OF PROCEDURES

I was informed that the planned treatment will be carried out in a single session lasting approximately 2 hours. To evaluate the results, I will have to attend the research center two more times after the initial procedure for the control and data collection sessions, lasting approximately 30 minutes each.

EXPENSES AND PAYMENTS

I am aware that I will not have costs related to the treatment proposed here: 1) digital scanning; 2) clinical evaluation; 3) plaque discloser; 4) oral hygiene guidance; and 5) transportation cost for the visits determined in the project. I further declare that I am aware that I will not receive any remuneration or advantage for participating in the survey.

GUARANTEE OF CONFIDENTIALITY

I was informed that I have the guarantee of confidentiality that ensures my privacy in the study. Once the data are obtained, they can be published in scientific journals and conferences, but without my identity as a research participant.

RIGHT TO WITHDRAW

I am aware that my acceptance to participate in the survey may be undone. I will be guaranteed to receive further clarifications that I deem necessary before and during the research, and I will have full freedom to refuse to participate in the research at any time, without any prejudice or compromise of the treatment.

COMPENSATION

As a participant in this survey, you are entitled to reimbursement for expenses related to your attendance at the visits, including public transportation and a snack.

DATA REUSE

Do you authorize the use of your treatment information in other research?

( ) I do NOT authorize the use of data in another survey.

( ) YES I authorize the use of data in another research, provided that the new research is approved by the Research Ethics Committee

INDEMNIFICATION FOR ANY DAMAGES RESULTING FROM THE RESEARCH

It was informed that participation in the study will not cause expenses, and therefore there is no provision for reimbursement. Regarding the forms of compensation and the measures to repair in case of any damage, I am aware that participation in this study involves minimal risks, mainly related to possible discomfort during the evaluation procedures. In case of complications or adverse reactions, I will receive: Immediate care at the graduate clinic, follow-up by the researcher in charge, referral to specialties when necessary.

DATA CONFIDENTIALITY

I am aware that for the tabulation of the data each participant of the study will receive a code, and the information collected will be coded in such a way that only the researchers involved in the data collection will have the knowledge of the identification of the study participants.

CRITERIA FOR SUSPENDING OR TERMINATING THE SURVEY

The survey will be suspended if 50% of the participants are unable to attend the consultations or no longer wish to participate in the study. Other eventualities that may interfere with the inclusion criteria and the integrity and well-being of the participants may be considered grounds for suspending the research (e.g., medical impediment to undergo the research procedures). Whatever the reason that suspends or terminates the research for a given participant, the latter will not be affected by its treatment. In addition, the research participant will not have any loss in referrals for treatment in other dental specialties at Univeritas-UNG University.

CONTACT INFORMATION

I was informed that the result of the treatment will be directed by the principal investigator **Mohamed Ahmed Hassan** Telephone: (11-972945957) from Univeritas-UnG, to which I will have access to clarify any doubts throughout the study. I am aware that all the ethical norms of the present study are in accordance with the guidelines and norms of the National Health Council in Resolution No. 466/12.

But, if I have any considerations or questions, I can also contact the Research Ethics Committee (REC).

PARTICIPANT CONSENT

I confirm that I discussed until I was satisfied about my decision to participate in this study: **Digital quantification of dental plaque based on intraoral scanner images**. It was clear to me what the purposes of the study are, the procedures to be carried out, its discomforts and risks, the guarantees of confidentiality, how the data will be used and disseminated, and permanent clarifications. It was also clear that my participation is free of charge and that I am guaranteed access to treatment or guidance when needed. I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during it, without penalty or impairment or loss of any benefit I may have acquired, or in my attendance at this service.

This document was prepared in two copies, one for the research participant and the other for the responsible researcher.

/ /

Date

Participant Name: _____

Participant's signature: _____RG:_____

Name of the person who explained the consent: _____

Signature of the person who explained the consent: _____

Mohamed Ahmed Hassan
Principal Investigator
CROSP: 152,221
RG: 69.435.424-7

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