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STEVEN KADEEM MOORE

**DESENVOLVIMENTO E IMPLEMENTAÇÃO DE UMA ESCALA DE AUTOEFICÁCIA EM SAÚDE
ORAL PARA USUÁRIOS DE OVERDENTURE MANDIBULAR**

Goiânia

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STEVEN KADEEM MOORE

**DESENVOLVIMENTO E IMPLEMENTAÇÃO DE UMA ESCALA DE
AUTOEFICÁCIA EM SAÚDE ORAL PARA USUÁRIOS DE OVERDENTURE
MANDIBULAR**

**THE DEVELOPMENT AND USE OF AN ORAL HEALTH SELF-EFFICACY SCALE FOR PATIENTS
USING MANDIBULAR OVERDENTURES**

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Aos seis dias do mês de novembro do ano de dois mil e vinte e três, a partir das catorze horas, no Miniauditório, 3º andar da Faculdade de Odontologia realizou-se a sessão pública de Defesa de Dissertação intitulada “Desenvolvimento e implementação de uma escala de autoeficácia em saúde oral para usuários de overdenture mandibular.” Os trabalhos foram instalados pelo Orientador, Professor Doutor Cláudio Rodrigues Leles (PPGO/UFG) com a participação dos demais membros da Banca Examinadora: Professor Doutor Túlio Eduardo Nogueira (PPGO/UFG), membro titular interno e Professor Doutor Murali Srinivasan (Universidade de Zurique/Suíça), membro titular externo. Durante a arguição os membros da banca não fizeram sugestão de alteração do título do trabalho. A Banca Examinadora reuniu-se em sessão secreta a fim de concluir o julgamento da Dissertação, tendo sido o candidato aprovado pelos seus membros. Proclamados os resultados pelo Professor Doutor Cláudio Rodrigues Leles, Presidente da Banca Examinadora, foram encerrados os trabalhos e, para constar, lavrou-se a presente ata que é assinada pelos Membros da Banca Examinadora, aos seis dias do mês de novembro do ano de dois mil e vinte e três.

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RESUMO

Introdução: Autoeficácia, um conceito cunhado por Albert Bandura, refere-se à crença de um indivíduo em sua capacidade de executar comportamentos necessários para atingir metas específicas de desempenho. No contexto da saúde bucal, a autoeficácia desempenha um papel fundamental na influência de comportamentos relacionados à prática de higiene bucal.

Objetivo: Este estudo teve como objetivo desenvolver uma escala de autoeficácia em saúde bucal e avaliar a relação entre autoeficácia em saúde bucal e o estado de saúde peri-implantar de indivíduos que usam *overdentures* retidas por implantes.

Materiais e Método: Este foi um estudo observacional transversal aninhado a um ensaio clínico no Núcleo de Pesquisa em Prótese e Implante (NPPI) da Universidade Federal de Goiás (UFG), Goiânia, Brasil. O projeto recebeu aprovação do Comitê de Ética em Pesquisa da Universidade Federal de Goiás. Um questionário de 25 itens foi desenvolvido com base na Escala de Autoeficácia Dentária (DSE), revisado por um painel de especialistas, traduzido para o português brasileiro e um ensaio piloto foi feito para clareza. O questionário OHSE-OVER de 25 itens coletou dados em quatro dimensões (1) desafios na rotina – 4 itens; (2) desempenho autoavaliado – 5 itens; (3) atitudes em relação à saúde bucal – 6 itens; (4) desafios em ocasiões especiais – 10 itens. A pontuação do questionário foi calculada invertendo primeiro a escala das dimensões 1 e 4 e depois somando as pontuações de todas as dimensões. A pontuação final foi uma medida de autoeficácia em saúde bucal (pontuações mais altas significam maior autoeficácia em saúde bucal). O estudo incluiu pacientes com *overdentures* mandibulares retidas por implantes, que faziam parte de um estudo maior envolvendo mini-implantes. A randomização foi baseada em uma abordagem cirúrgica e protocolo de carga. Todos os procedimentos clínicos ocorreram no NPPI/UFG, sem custo para os participantes. As avaliações de acompanhamento de 12 meses incluíram avaliações de placa no pilar, sangramento peri-implantar e placa de superfície da prótese. Um único clínico conduziu as avaliações clínicas de todos os pacientes e, durante a avaliação, o clínico administrou o questionário Avaliação de autoeficácia em saúde bucal para usuários de *overdentures* (OHSE-OVER) em forma de entrevista. Os dados clínicos foram comparados com as respostas do questionário OHSE-OVER. Análises estatísticas, incluindo Análise Fatorial Confirmatória e regressão, foram conduzidas usando os softwares IBM-SPSS 22.0 e Mplus 8.8, com um nível de significância de $p < 0,05$.

Resultados: Dos 74 pacientes inicialmente convidados, 69 participaram do estudo. Entre eles, a maioria era do sexo feminino (63,8%), com idades entre 36 e 81 anos (média=65,0; DP=8,1), sendo quase metade fumantes atuais ou ex-fumantes (47,8%), e a maioria tomava

medicação regularmente (82,6%). Os escores de autoeficácia variaram entre diferentes dimensões, com uma pontuação geral média de 2,35. A escala demonstrou boa confiabilidade (alfa de Cronbach = 0,799). A análise fatorial confirmatória suportou o modelo de quatro fatores, com a remoção de dois itens devido aos seus baixos carregamentos fatoriais. A análise de regressão revelou que maior autoeficácia estava ligada a melhores resultados de higiene da prótese na escala geral, uma associação positiva entre autoeficácia em saúde bucal e sexo masculino, e também uma relação inversa entre autoeficácia em saúde bucal e índice de placa nas dimensões 1 e 2, respectivamente. Nenhuma associação significativa foi observada nas outras dimensões. **Conclusão:** A pesquisa destaca o papel fundamental da autoeficácia na determinação dos resultados de saúde bucal em indivíduos que utilizam *overdentures* retidas por implantes. Estabelece uma associação significativa entre a autoeficácia em saúde bucal e indicadores-chave de higiene oral, como índice de placa e higiene de próteses, em pacientes que dependem de *overdentures* retidas por implantes. Além disso, a validação da solidez psicométrica e da estrutura interna do OHSE-OVER reforça sua eficácia como um instrumento valioso especificamente desenvolvido para avaliar e abordar a autoeficácia em saúde bucal nessa população de pacientes, tanto em contextos clínicos quanto de pesquisa.

Palavras-chave: Autoeficácia, Overdentures, Implante Dentário, Validação, Psicometria, Pesquisas e Questionários

ABSTRACT

Introduction: Self-efficacy, a concept coined by Albert Bandura, refers to an individual's belief in their ability to perform behaviors necessary to achieve specific performance goals. In the context of oral health, self-efficacy plays a pivotal role in influencing behaviors related to oral hygiene practices. **Objective:** This study aimed to develop an oral health self-efficacy scale and evaluate the relationship between oral health self-efficacy and the peri-implant health status of individuals using implant-retained overdentures. **Materials and Methods:** This was a cross-sectional observational study nested within a clinical trial at the Prosthesis and Implant Research Center (NPPI) at the Federal University of Goiás (UFG), Goiânia, Brazil. The project received approval from the Ethics Committee for Research at the Federal University of Goiás. A 25-item questionnaire was developed based on the Dental Self-Efficacy Scale (DSE), revised by a panel of experts, translated into Brazilian Portuguese, and piloted for clarity. The 25-item OHSE-OVER questionnaire collected data across four dimensions: (1) routine challenges – 4 items; (2) self-rated performance – 5 items; (3) attitudes towards oral health – 6 items; (4) challenges in special occasions – 10 items. The questionnaire score was calculated by first reversing the scale of dimensions 1 and 4 and then summing the scores of all dimensions. The final score represented oral health self-efficacy (higher scores indicating greater oral health self-efficacy). The study included patients with mandibular overdentures retained by implants as part of a larger study involving mini-implants. Randomization was based on a surgical approach and loading protocol. All clinical procedures took place at NPPI/UFG, with no cost to the participants. Twelve-month follow-up assessments included pillar plaque evaluations, peri-implant bleeding, and denture surface plaque. A single clinician conducted clinical assessments for all patients and administered the Oral Health Self-Efficacy Evaluation for Overdenture Users (OHSE-OVER) questionnaire in an interview format during evaluation. Clinical data were compared with OHSE-OVER questionnaire responses. Statistical analyses, including Confirmatory Factor Analysis and regression, were conducted using IBM-SPSS 22.0 and Mplus 8.8 software, with a significance level of $p < 0.05$. **Results:** Out of the initially invited 74 patients, 69 participated in the study. Among them, the majority were female (63.8%), aged between 36 and 81 years (mean = 65.0; SD = 8.1), with nearly half being current or ex-smokers (47.8%), and most were taking regular medication (82.6%). Self-efficacy scores varied across different dimensions, with an overall mean score of 2.35. The scale demonstrated good reliability (Cronbach's alpha = 0.799). Confirmatory factor analysis supported the four-factor model, with the removal of two

items due to their low factor loadings. Regression analysis revealed that higher self-efficacy was linked to better denture hygiene outcomes in the overall scale, a positive association between oral health self-efficacy and sex(male), as well as an inverse relationship between oral health self-efficacy and plaque index in dimensions 1 and 2, respectively. No significant associations were observed in dimensions 3 and 4. **Conclusion:** The research underscores the fundamental role of self-efficacy in determining oral health outcomes in individuals using implant-retained overdentures. It establishes a significant association between oral health self-efficacy and key oral hygiene indicators, such as plaque index and denture hygiene, in patients relying on implant-retained overdentures. Additionally, the validation of the OHSE-OVER's psychometric robustness and internal structure reinforces its efficacy as a valuable instrument specifically developed to assess and address oral health self-efficacy in patients with mandibular overdentures, both in clinical and research contexts.

Keywords: Self-Efficacy, Overdentures, Dental Implants, Validation, Psychometry, Surveys, Questionnaires

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LIST OF ABBREVIATIONS AND ACRONYMS

CEP: Comitê de Ética em Pesquisa

CFA: Confirmatory Factor Analysis

CFI: Comparative Fit Index

CI: Confidence Interval

CNPq: Conselho Nacional de Desenvolvimento Científico e Tecnológico (National Council for Scientific and Technological Development)

DP: Desvio Padrão (Standard Deviation)

DSE: Dental Self-Efficacy Scale

GCUB: Grupo de Cooperação Internacional de Universidades Brasileiras (International Cooperation Group of Brazilian Universities)

GESEOH: Geriatric Self-Efficacy Oral Health Scale

IBM-SPSS: International Business Machine Statistical Package for Social Sciences

NPPI: Núcleo de Pesquisa em Prótese e Implante (Prosthetics and Implant Research Center)

OAS: Organization of American States

OHSE: Oral Health Self-Efficacy

OHSE-OVER: Oral Health Self-Efficacy Assessment for Overdenture Patients

PNS: Pesquisa Nacional de Saúde (National Health Survey)

PPGO/FO-UFG: Programa de Pós-Graduação em Odontologia/Faculdade de Odontologia-Universidade Federal de Goiás (Postgraduate Programme in Dentistry/Faculty of Dentistry-Federal University of Goiás)

QoL: Quality of Life

RMSEA: Root Mean Square Error of Approximation

SD: Standard Deviation

SRMR: Standardized Root Mean Square Residual

UFG: Universidade Federal de Goiás (Federal University of Goiás)

WLSMV: Weighted Least Square Mean and Variance

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1 INTRODUCTION

Edentulism refers to the condition of having no natural teeth (Adam, 2016) and has been described as the "ultimate indicator of oral health challenges" (McGarry et al., 1999). As the average age of the population continues to rise, the number of individuals experiencing edentulism is also on the increase, a trend that has persisted for over three decades in the United States (Douglass et al., 2019). This upward trajectory is similarly evident in Brazil, where it is projected that by 2040, more than 10% of the population will be affected by this significant marker of oral health issues. Consequently, these edentulous individuals will require various forms of restorative care, such as complete dentures, implant-retained overdentures, or implant-retained bridges (Cardoso et al., 2016).

The Research Centre for Prosthesis and Implants (NPPI), The Federal University of Goiás, Goiás, Brazil, is a research centre that integrates several research and service actions focused on clinical care in dentistry. The core is an integrated practice scenario, with the involvement of professors, undergraduate students, and postgraduate students in the area of oral rehabilitation, with an emphasis on osseointegrated implants. NPPI has had a long-standing relationship with the Straumann® Group, a Swiss company dedicated to the development and manufacturing of dental equipment, materials, and software, dating back to 2014. NPPI is currently carrying out a number of research projects funded by the Straumann® Group, most of which are particularly focused on gathering clinical data for the Straumann® Mini Implant System with Optiloc® Retentive System using a PEEK matrix insert.

During the course of executing a clinical research project, the research team observed disparities in the oral hygiene indicators of the patients during their follow-up visits. It is crucial to note that all post-operative hygiene instructions were identical for all patients. This discrepancy in oral hygiene and peri-implant health status among patients piqued the interest of the research team, prompting them to investigate potential factors contributing to these differences. Self-efficacy was proposed as a possible element influencing oral health outcomes among the participants in the clinical trial. Existing literature suggests that self-efficacy plays a role in oral hygiene results, with patients possessing lower self-efficacy being less successful in implementing plaque control measures, as indicated by Sarsilmazer and Atilla in 2020. Previously, self-efficacy scales such as the Dental Self-Efficacy (DSE) Scale (Syrjala et al., 1999) and the Self-Efficacy Scale for Selfcare (SESS) (Kakudate and Morit. 2012) were employed to establish a connection between self-efficacy and oral hygiene

outcomes. These scales assist clinicians in gauging a patient's overall confidence in their ability to carry out oral hygiene practices. However, in the study being conducted at NPPI, all the patients were fitted with implant-retained overdentures, which involve distinct oral hygiene protocols. Consequently, the self-efficacy scales used in previous research for patients without such appliances may not be applicable to the target population of this study. This underscores the necessity of developing an instrument tailored to this specific group.

Given the growing aging population, the rising prevalence of edentulism, and the heightened demand for complete oral rehabilitation (Douglass et al., 2022 and Cardoso et al., 2016), it has become imperative to embark on new research endeavors to enhance our understanding of the use and maintenance of implant-retained overdentures.

This study aims to create an oral health self-efficacy (OHSE) instrument and to address the following research question: Is there an association between oral health self-efficacy and oral health status in patients utilizing implant-retained overdentures?

2 LITERATURE REVIEW

2.1 Aging Population & Edentulism

The United States has seen a 79% increase in the population of people over 55 over the past 30 years, with an estimated 37.9 million people needing complete dentures, an increase of almost 5 million people (Douglass et al., 2019). Cardoso et al. (2016) predict that in Brazil, the number of edentulous people between the ages of 65-74 will continue to increase until 2040. To be more specific, it is expected that the number will exceed 64 million jaws. The study also was sure to note that in 1986, the percentage of edentulous patients among the elderly was high, but the absolute numbers were relatively low. The absolute numbers have however increased and will continue to increase because of the relative increase in size of the aforementioned population (Cardoso et al., 2016). More recently, Maia et al., (2020), published a study working with a sample population of persons over the age of 60 from a medium-sized town, Montes Claros in the State of Minas Gerais in Brazil. In the study, almost 50% of the population surveyed reported being completely edentulous.

2.2 Rehabilitation with Implant-Retained Overdentures

While complete dentures are a viable option, there exist alternatives such as implant-retained overdentures. Implant-retained overdentures were shown to significantly improve a patient's quality of life (QoL) when compared to complete dentures due to the marked improvement in stability and retention, higher comfort, and improved speech and nutrition (Bajunaid et al., 2022).

More recently, mini-implants were proposed as an alternative to standard-diameter implants for overdenture retention. They are more suitable for insertion in narrow ridges, are less invasive, simpler, less costly, and faster to perform, and are especially advantageous for older and frail patients who would benefit from more conservative and less burdensome treatments (Schiegnitz & Al-Nawas, 2018). A systematic review (Lemos et al., 2017) revealed that from 24 studies published up to September 2016, mini-implants should be considered a good alternative to conventional implants for retaining overdentures. The study revealed that when mini-implants were used to retain overdentures, there were greater survival rates, with a rate of 92.32% after an average follow-up period of 2.48 years. Overdentures retained by mini-implants also showed increased patient satisfaction and improvement in the patient's oral health-related quality of life (Lemos et al., 2017).

2.3 Peri-implantitis & Implant Survival

The long-term successful use of mini-implants is highly dependent on the lack of peri-implant diseases, including peri-implant mucositis and peri-implantitis, depending on whether bone loss has occurred (Rösing et al., 2019). Peri-implantitis seems to affect approximately 20% of patients who have received implants (Lee et al., 2017), and crucial measures to achieve long-term success with implant therapy include proper oral hygiene and mechanical plaque removal.

Although there are local predisposing factors for peri-implantitis, such as the lack of keratinized mucosa around the implants, the amount of keratinized mucosa has little influence on soft-tissue inflammation in the presence of good oral hygiene. However, suboptimal oral hygiene due to difficulty in accessing for plaque control in the areas of minimal keratinized mucosa may lead to greater tissue damage (Pranskunas et al., 2016).

A literature review conducted for the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions revealed that there is strong evidence that there is an increased risk of developing peri-implantitis in patients who have a history of chronic periodontitis, poor plaque control skills, and no regular maintenance care after implant therapy (Schwarz et al., 2018). Based on the conclusion of the above study, oral hygiene practices may have a direct impact on the lifespan of the implants.

Failed implants also come with consequences, including additional costs and procedures that the patient will have to undergo (Levin, 2008). Apart from the direct cost of the materials required for replacing the implant, failed implants also result in what is known as loss wage potential. Loss wage potential is the estimated time it takes to place a single fixture implant, restore it, then explant it when it fails, replace the implant and crown, along with all the follow-up visits. Loss wage potential is usually estimated to be about five hours (Killeen and Forum, 2022).

Nevertheless, even when the patient is properly instructed about the importance of oral health maintenance and proper hygiene methods, most of them are not able to perform satisfactory oral healthcare measures. Therefore, it is relevant to evaluate how a patient's self-efficacy impacts a patient's behaviour toward oral health.

2.4 Self-Efficacy & Oral Hygiene

Self-efficacy refers to an individual's belief in his or her capacity to execute behaviours necessary to produce specific performance attainments (Bandura, 1977 and Carey & Forsyth,

2009). Self-efficacy has also been highlighted as an important factor when it comes to health-related behaviours including dietary change, exercise, smoking cessation, and diabetes treatment compliance (Macnee & Talsma 1995, Skelly et al. 1995, Shannon et al. 1997, Fletcher & Banasik 2001). Bandura et al. (1977) indicated four sources of self-efficacy: performance accomplishments, vicarious experiences, verbal persuasion, and psychological and affective states (Bandura, 1977). When applied to oral health, a Woelber et al., (2014) study determined that self-efficacy has a significant impact on oral hygiene indicators and can serve as a potential predictor of future oral health-related behaviors.

2.5 Self-Efficacy Research Instruments

The literature reveals that there have been various oral health self-efficacy (OHSE) scales developed to measure oral health self-efficacy, such as the Dental Self-Efficacy Scale (DSE) (Syrjala, AMH et al., 1999) and the Geriatric Self-Efficacy Oral Health Scale (GESEOH) (Ohara, Y. et al 2016). In addition to the two scales named above, a self-efficacy scale for patients with dental implants was developed in China (Nie, R-B et al., 2019). All the above-mentioned self-efficacy scales were tested for and deemed to be reliable and valid.

The scales, however, did have some limitations, most notably, both the DSE and GESEOH scales accounted for dentate persons, partial or otherwise. While the GESEOH, due to its target demographic being geriatric patients, measured self-efficacy in oral health in patients with dentures, the DSE did not account for patients using any form of prostheses. The instrument designed by Nie et al. (2019) specifically targeted patients with dental implants, but none of the scales accounted for patients using overdentures, whether retained by natural teeth or dental implants.

A review of the literature garnered limited results of studies investigating self-efficacy in oral hygiene in patients using overdentures. A new instrument would therefore provide an avenue to capture data within this context-specific group. From the literature, it is known that lower levels of oral health-related self-efficacy were associated with a higher prevalence of poor self-rated oral health and greater impacts on oral health (Parker et al., 2022). It is also known that conducting research on self-efficacy in oral health outcomes in patients with implants can provide targeted guidance for oral health education for implant patients and improve the success rate of implant surgery (Nie Rong-bing, et al., 2019). A new instrument, much like the instrument for measuring self-efficacy in oral hygiene in patients with implants, would

therefore pave the way to formulate guidelines for patients using implant overdentures to improve the success rate of this treatment alternative for edentulous patients.

3 JUSTIFICATION

Currently, research has explored the impact of self-efficacy on oral health and its relationship with oral hygiene, yet no studies have delved into its influence on peri-implant health status. Given that the durability of dental implants significantly hinges on peri-implant health status, which in turn depends on hygiene practices, this study seeks to address these gaps.

The literature review uncovered that although there are existing scales to measure oral health self-efficacy (OHSE) with established reliability and validity in various contexts, only one scale has been developed specifically for assessing OHSE in patients with dental implants. Moreover, the existing OHSE scale for implant patients lacks consideration for context-specific scenarios, such as those involving mini-implants and implant-retained overdentures. Consequently, this research endeavours to contribute valuable insights to bridge these knowledge gaps.

4 OBJECTIVES

4.1 General Objective

- To develop a psychometrically sound oral health self-efficacy instrument for patients using mandibular overdentures.

4.2 Specific Objectives

- To examine the factor structure and psychometric properties (reliability, validity) of the oral health self-efficacy questionnaire for patients using mandibular overdentures.
- To verify if there is an association between Oral Health Self-Efficacy Assessment for Overdenture Patients (OHSE-OVER) scores and the peri-implant health status of patients using mandibular overdentures.

5 HYPOTHESES

1. The OHSE-OVER can be used to measure oral health self-efficacy in patients using mandibular overdentures.
2. There is a positive association between oral health self-efficacy and peri-implant health status in patients with implant-retained overdentures.

6 METHODOLOGY

6.1 Study Design

This is a cross-sectional observational study nested in a larger clinical trial being carried out by a research team at the Prosthesis and Implant Research Centre (NPPI) at the Faculty of Dentistry, The Federal University of Goiás, Goiânia, Goiás, Brazil.

6.2 Ethical Considerations

The project was submitted as an addition/amendment to the prospective clinical study and approved by the Federal University of Goiás Research Ethics Committee (No 6.158.954, Annex A)

6.3 Setting

All clinical procedures were performed at the Prosthesis and Implant Research Centre (NPPI) at the School of Dentistry, The Federal University of Goiás, Goiânia, Goiás, Brazil. Participants were not charged for any treatment costs.

6.4 Research Instrument

A questionnaire containing a preliminary pool of question items (Appendix A) was generated with inspiration from the Dental Self-Efficacy (DSE) Scale developed by Syrjala et. al (1999), as well as expert opinions. Subsequently, the questionnaire was translated into Brazilian Portuguese.

The questions reflected different aspects of self-efficacy related to oral hygiene, and the responses were measured on a Likert scale with five options ranging from 1 to 5: (1) not at all; (2) very little; (3) neutral; (4) somewhat; (5) to a great extent. A five-member expert panel of dental professionals (clinicians and researchers) in the fields of prosthodontics, implantology and psychometry was invited to review the contents for relevance and clarity, submitting their feedback using (1) a document to evaluate the relevance of the questions (Appendix B) and (2) a document to suggest changes to the questionnaire (Appendix C). The feedback provided by the experts included and was not limited to suggesting additional questions, rating each question's relevance to the study, as well as, suggesting changes to questions. The suggested modifications were made to the research instrument and a pilot test was done with a sample size of 5 patients. The pilot study revealed that some patients had difficulty understanding some of the questions, and the questions were revised to improve semantics. The revised questions were then sent to the experts to conduct a second review and

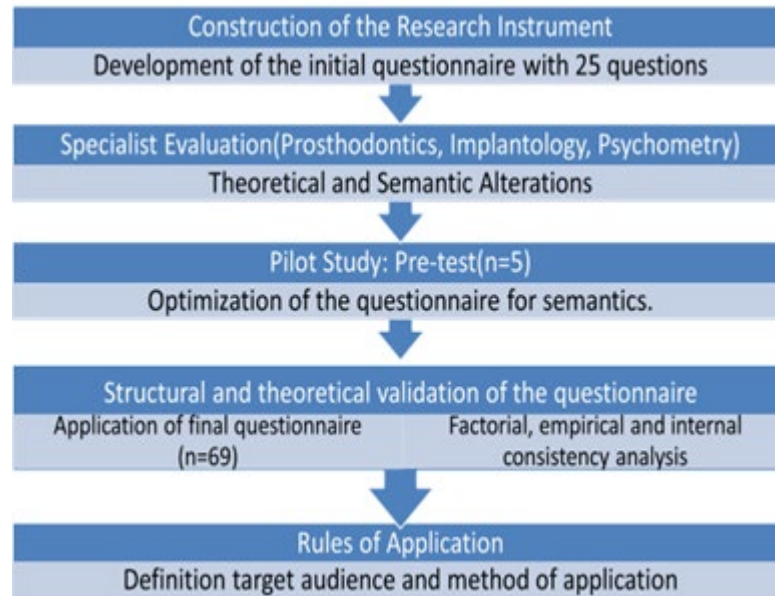
following the review, the questionnaire as approved by the experts was constructed (Appendix D).

The questionnaire comprised 25 items, grouped into four categories (dimensions) related to the perception of the self-efficacy related to oral hygiene and health: (1) challenges in routine – 4 items; (2) self-rated performance – 5 items; (3) attitudes towards oral health – 6 items; (4) challenges in special occasions – 10 items.

The scoring protocol for the questionnaire was devised as follows:

1. The scores for dimensions one and four were reversed as follows:
 - For each question in Dimensions 1 and 4, the score was subtracted from the total number of possible responses plus one.
 - The OHSE-OVER used a five-point scale (1 = strongly disagree, 5 = strongly agree), which therefore meant, the reversed score was calculated using the formula:
$$\text{Reversed score} = 6 - \text{original score}$$
2. The total score for each respondent was calculated:
 - The scores for each question were summed up to get a total score.
3. Interpret the total scores according to the scoring rubric.
 - Assign each respondent a level of oral health self-efficacy based on their total score. The higher the total score, the higher the oral health self-efficacy.

Figure 1. Flowchart of the OHSE-OVER development process.



Source: Author

6.5 Sample

A cohort of 74 patients undergoing a current study involving implant-retained mandibular overdentures, using four Straumann® Mini-implants, were invited to take part in the study. All participants received four one-piece, 2.4mm diameter, titanium-zirconium mini-implants commercially known as the Straumann® Mini Implant System (Straumann Group, Basel, Switzerland) with an Optiloc® Retentive System using a PEEK matrix insert (Straumann Group, Basel, Switzerland). The surgery followed the workflow for the surgical procedure recommended by the manufacturer concerning preoperative planning, implant bed preparation and implant insertion. The patients have received a mandibular overdenture which was converted from their existing well-fitting and functioning lower denture via a chairside procedure in which the Optiloc® Retentive System was fitted to the denture. According to the original clinical trial protocol, patients were randomized to treatment groups according to the surgical approach (flapless versus flapped) and loading protocol (immediate versus delayed). Findings related to the original clinical trial were previously published elsewhere (Leles et al., 2022 and Leles et al., 2023).

6.5.1 Inclusion Criteria

Patients must have been using implant-retained mandibular overdentures for at least one year.

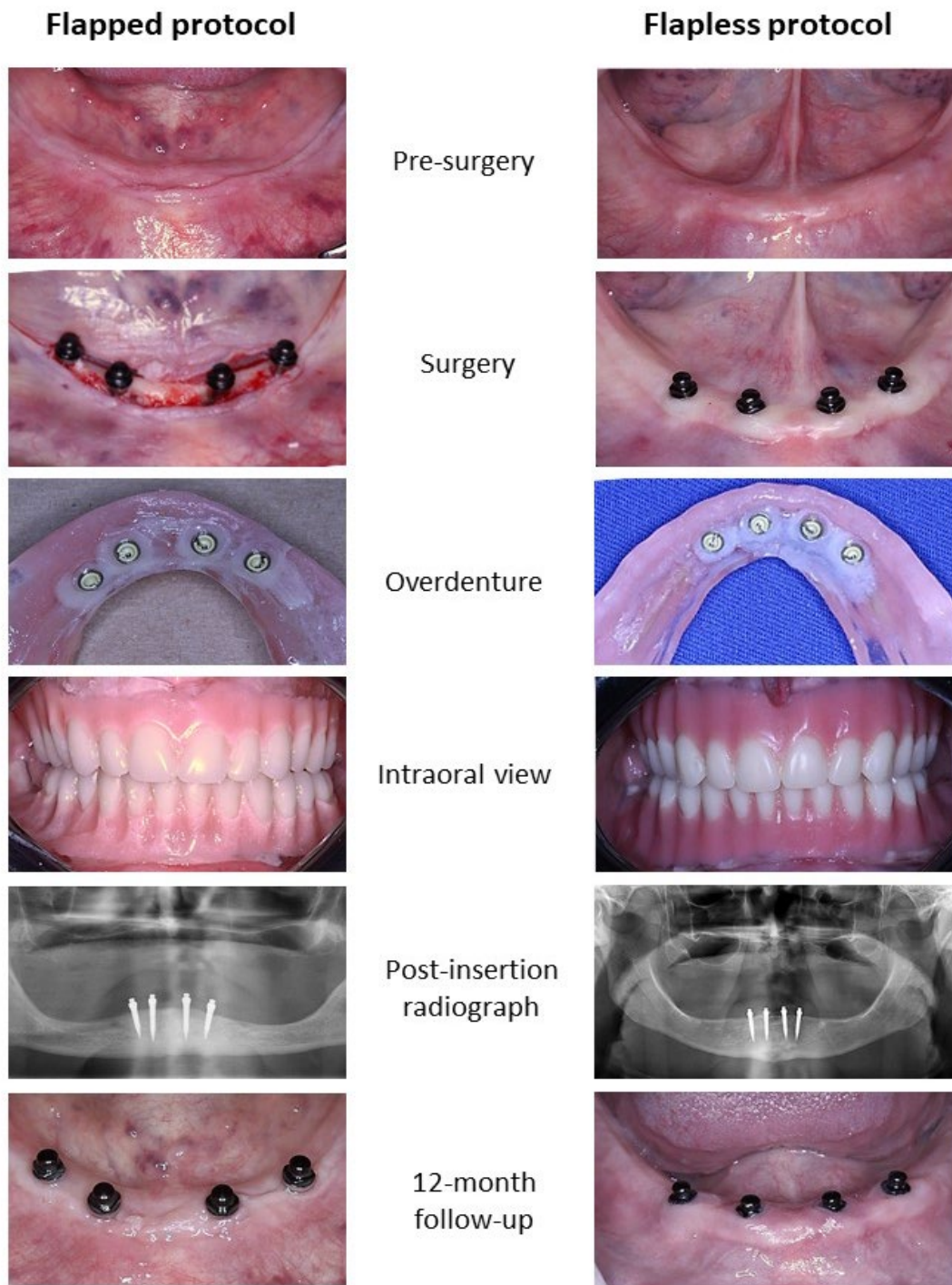
6.5.2 Exclusion Criteria

Patients who abandoned treatment and or failed to attend their prescribed follow-up visits.

Patients with one or more failed mini-implants.

Patients who were unable to complete the questionnaire.

Figure 2. Surgical protocol for mini-implant supported overdentures.



(Curado et al., 2023)

6.6 Clinical Evaluation/Data Collection

During the patient's one-year follow-up a clinician performed a clinical assessment. Assessment criteria were considered as follows:

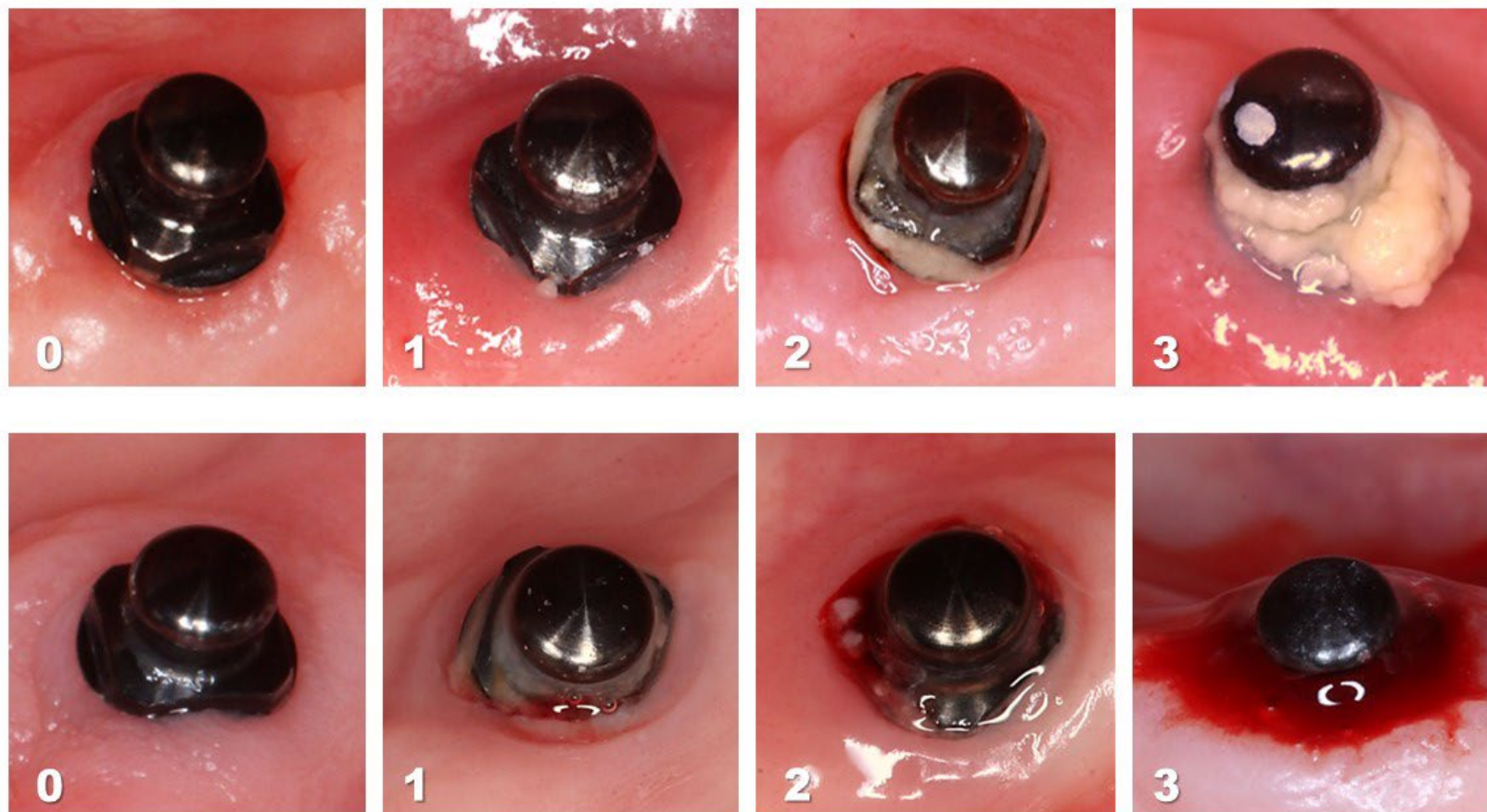
- Plaque evaluation was performed with a modified plaque index through scores (Mombelli et al., 1987):
 - 0 – No plaque detection.
 - 1 – Plaque detected only when probing the surface around the implant platform.
 - 2 – Plaque can be detected with the naked eye.
 - 3 – Presence of plaque in abundance.
- Likewise, the bleeding index was modified for this evaluation with the following scores (Mombelli et al., 1987):
 - 0 – No bleeding when the periodontal probe travels along the gingival margin around the implant.
 - 1 – The presence of spot visible bleeding.
 - 2 – Bleeding forms a confluent line at the margin.
 - 3 – Abundant and profuse bleeding.

The clinical assessments were performed with the Hu-Friedy Colorvue™ UNC 12 Probe (Henry Schein Incorporated, Melville, New York, United States of America) at four points, buccal, mesial, distal, and lingual at each of the four implants individually, thus obtaining 4 plaque scores and 4 bleeding scores for each patient. The same clinician conducted the clinical assessment of all the patients.

An assessment of the plaque accumulation on the denture surfaces was performed at the same clinical visit. The dentures were rinsed with tap water and then examined with the naked eye with no use of plaque-disclosing solution. The maxillary and mandibular dentures were classified as (0) no visible plaque; (1) plaque in the inner or outer surface of the denture; (2) presence of plaque and calculus on the denture surfaces.

The OHSE-OVER was administered by the clinician during the clinical assessments. The clinician asked the questions in order of their appearance, and the patient chose the answers they deemed appropriate. There was no time limit associated with the questionnaire and the patient was able to ask the clinician to repeat questions if deemed necessary.

Figure 3. Plaque Score and Bleeding References Photos



(Curado et al., 2023)

6.7 Statistical Analysis

Descriptive and analytical statistics were performed using the IBM-SPSS 22.0 (IBM., Chicago, Illinois, United States of America) and Mplus 8.8 (Muthén & Muthén, Los Angeles, California, United States of America) software. First, a descriptive analysis of the questionnaire items and categories was performed, and summary scores for each category were obtained. Subsequently, the structure of the self-efficacy instrument was analyzed through Confirmatory Factor Analysis, using Weighted Least Square Mean and Variance adjusted (WLSMV). Factor loadings were considered adequate, if higher than 0.40. Model goodness of fit was assessed by the Comparative Fit Index (CFI), the Root Mean Square Error of Approximation (RMSEA) and the Standardised Root Mean Square Residual (SRMR; Hu & Bentler, 1999). The following thresholds were adopted to adjudge model fit: CFI > .90, RMSEA < .06, and SRMR < .10 for adequate fit; CFI > .95, RMSEA < .06, and SRMR < .08 for acceptable fit. We also reported the chi-square (χ^2) statistic, although this index is less useful, as it tends to be oversensitive to sample size and minor model misspecifications (Hu & Bentler, 1999).

Then, bivariate correlation tests and regression analysis were performed to assess the association between the self-efficacy dimensions and clinical data related to peri-implant status and denture cleaning. Sex and age were also tested as independent variables. The model parameter estimates were expressed as regression coefficients and their standard errors. Factor scores were used in the analysis. The significance level was set at $p < 0.05$ for statistical inferences.

7 RESULTS

A total of 74 patients were initially invited to participate in the study. However, five patients were excluded from the final analysis. Two of them failed to attend their 12-month follow-up appointment, and three were unable to complete the questionnaire. Consequently, the study focused on 69 edentulous patients who underwent mandibular overdenture treatment, as opposed to receiving a conventional maxillary complete denture. Self-efficacy assessments were conducted during the patients' 12-month follow-up visits.

Among the participants, 44 of them were female, accounting for 63.8% of the sample. The age range of the participants varied from 36 to 81 years old (mean=65.0; SD=8.1) at the time of data collection. Current or former smokers were 47.8% of the participants (n=33), and 82.6% of the patients were taking regular medication (n=57).

Table 1. Summary of patient demographics.

Characteristic	Values
Sex:	
Female	44 (63.8%)
Male	25 (36.2%)
Age Range	36 to 81 years old (mean=65.0; SD=8.1)
Smokers	33 (47.8%)
Taking Prescription Medication	57 (82.6%)

The self-efficacy questionnaire was administered, and complete responses were obtained from all participants. Table 2 shows the summary data for all the items of the questionnaire, according to the pre-defined dimensions. The mean (and standard deviation) of the grouped items were 1.17 (± 0.43), 3.83 (± 0.84), 3.36 (± 0.80), and 1.46 (± 0.64), for dimensions 1 (challenge in routine), 2 (self-rated performance), 3 (attitudes towards oral health), and 4 (challenge in special occasions), respectively. The overall mean score was 2.35 (± 0.33).

Then, scores were reversed for the negatively-keyed items (dimensions 1 and 4) to ensure that all of the items – those that are originally negatively-keyed and those that are positively-keyed – are consistent with each other, in terms of what a “positive” or “negative” self-efficacy imply. Consequently, after this procedure, an overall scale was obtained containing the 25

items. The reliability of the overall scale was good (Cronbach's $\alpha = 0.799$). The mean scores for the overall scale ranged from 3.0 to 4.8 (mean=4.16; SD=0.42).

Subsequently, confirmatory factor analysis (CFA) was performed to verify the factor structure of the set of observed variables and to test the hypothesis that a relationship between observed variables and their underlying latent constructs exists. The model fit of the CFA model is shown in Figure 4, representing the four-factor model and its structure. Two items were removed to show low factor loadings and non-significant values, resulting in a 23-item questionnaire (Appendix E), with the theoretical basis supporting the exclusion of the items. The excluded items were:

- Question 12: Does having missing teeth bother you?
- Question 13: Do you feel guilty about losing your teeth?

The four-factor model was tested with 23 items and showed an acceptable model fit and factor loadings (Figure 4). Results indicated that the model fit of the four-factor model for this patient sample was acceptable.

Therefore, the construct originated factor scores for each participant for all the selected 23 items. The factor loadings for the overall scale and for each dimension were calculated as the mean score of the scale and subscale items. Figure 5 shows the distribution of plaque scores, peri-implant bleeding scores and combined denture hygiene scores. Figure 6 illustrates the distribution of the loading scores overall as well as the distribution of the loading scores for each of the four dimensions.

The data illustrated in both figures were used to conduct the regression analysis illustrated in Table 3. The regression analysis served to determine whether there is an association between self-efficacy measures (dependent variable), and oral hygiene outcomes and demographic markers. On the overall scale, it was found that there was an association between self-efficacy and denture hygiene scores; the greater the self-efficacy, the lower the denture hygiene score indicating improved denture hygiene outcomes. In both dimension one and dimension two, named "Challenges in Routine" and "Self-performance" respectively, there exists an association between self-efficacy and sex as well as self-efficacy and plaque index. Men had greater self-efficacy than women, and therefore, better oral hygiene outcomes.

In dimensions three and four, referred to as "Attitudes toward oral health" and "Challenges in special occasions," there was no independent variable found to have a discernible association with these dimensions.

Table 2. Summary values of the responses to the question items, according to the four dimensions of the questionnaire. (n=69).

Dimension / Questions	Median (IQR)	Mean (SD)
Challenges in routine (Dimension 1)		
Do you find it difficult to keep your mouth clean?	1.0 (0.0)	1.14 (0.52)
Do you find it difficult to clean your upper denture?	1.0 (0.0)	1.07 (0.40)
Do you find it difficult to clean your lower denture?	1.0 (0.0)	1.13 (0.45)
Do you find it difficult to keep your implants clean?	1.0 (0.0)	1.32 (0.65)
Self-performance (Dimension 2)		
Do you believe that your upper denture is well-cleaned?	4.0 (1.0)	3.97 (0.86)
Do you believe that your lower denture is well-cleaned?	4.0 (2.0)	3.94 (0.94)
Do you believe that your implants are well-cleaned?	4.0 (2.0)	3.83 (0.96)
Do you believe that you are able to keep your mouth clean most of the time?	1.0 (2.0)	3.74 (1.05)
Do you feel you will be able to keep your mouth cleaned by yourself when you become older?	4.0 (1.0)	3.66 (1.13)
Attitudes towards oral health (Dimension 3)		
Are you afraid that your implants fail and have to be removed?	1.0 (3.0)	2.39 (1.62)
How important for you is to keep your mouth clean?	5.0 (1.0)	4.55 (0.50)
Does having missing teeth bother you?	4.0 (4.0)	3.03 (1.76)
Do you feel guilty about losing your teeth?	2.0 (3.0)	2.78 (1.71)
Do you believe that you lost your teeth because you couldn't take good care of them?	4.0 (4.0)	3.06 (1.74)
Do you feel good with your dentures?	4.0 (1.0)	4.36 (0.66)
Challenges in special occasions (Dimension 4)		
How difficult is it to properly clean your dentures when you are tired at night?	1.0 (0.0)	1.33 (0.87)
How difficult is it to properly clean your dentures when you have an appointment with the dentist?	1.0 (0.0)	1.20 (0.68)
How difficult is it to properly clean your dentures when you are travelling or out of your usual daily routine?	1.0 (2.0)	1.86 (1.20)
How difficult is it to properly clean your dentures when you are very busy?	1.0 (0.0)	1.41 (0.91)
How difficult is it to properly clean your dentures when you are feeling sick?	1.0 (0.0)	1.55 (1.04)
How difficult is it to properly clean your implants when you are tired at night?	1.0 (0.0)	1.26 (0.75)
How difficult is it to properly clean your implants when you have an appointment with the dentist?	1.0 (0.0)	1.24 (0.67)
How difficult is it to properly clean your implants when you are travelling or out of your usual daily routine?	1.0 (1.0)	1.78 (1.05)
How difficult is it to properly clean your implants when you are very busy?	1.0 (1.0)	1.49 (0.87)
How difficult is it to properly clean your implants when you are feeling sick?	1.0 (1.0)	1.49 (0.94)

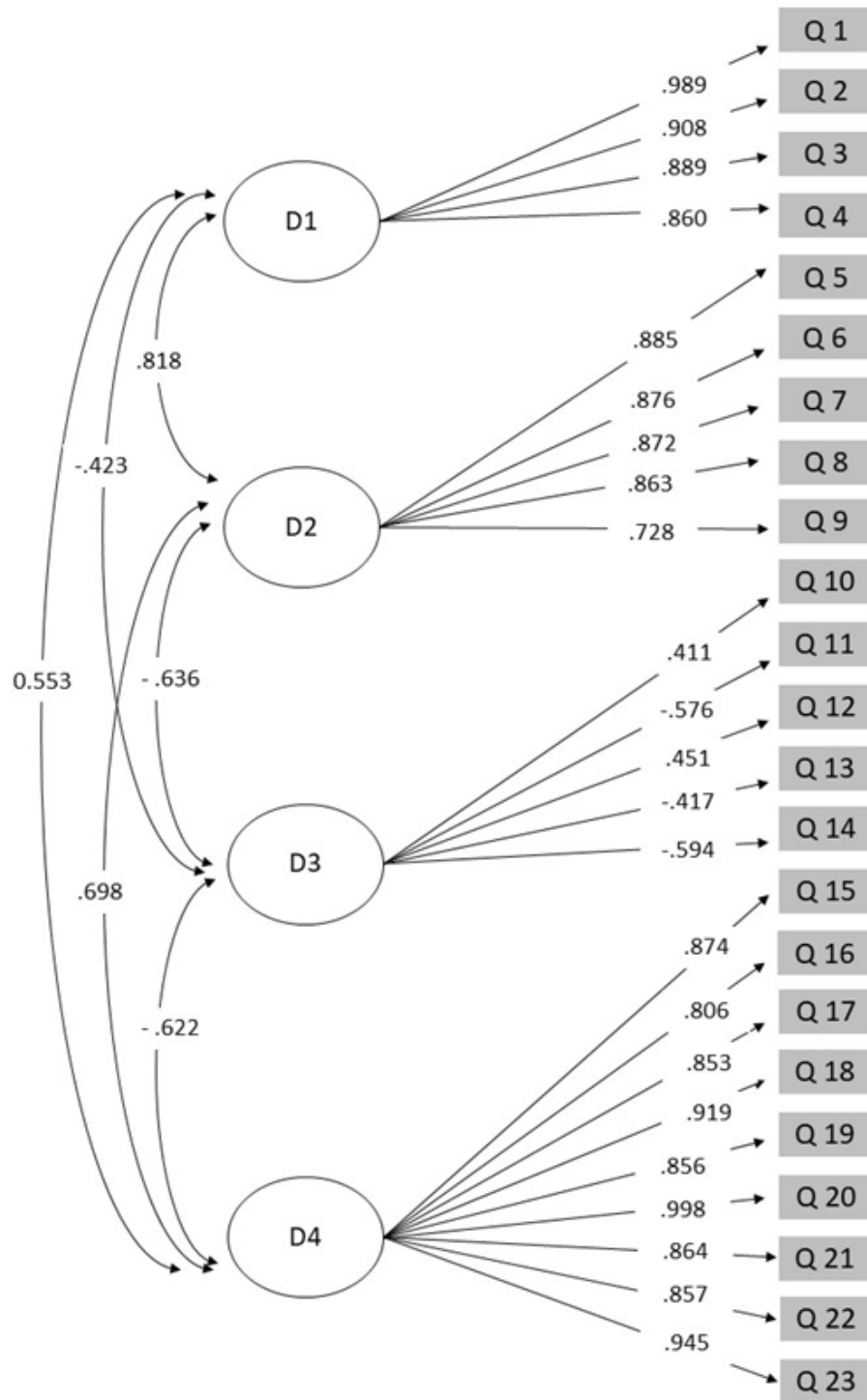


Figure 4. The four-factor model and its structure among the overdenture patient sample (n=69). Model fit indices: $\chi^2 = 328.415$ (df = 224, $p < .01$), CFI = .959, RMSEA = .078 ($p < .05$, 90%-CI = .058-.097). Left – correlation among dimensions; Right – factor loadings.

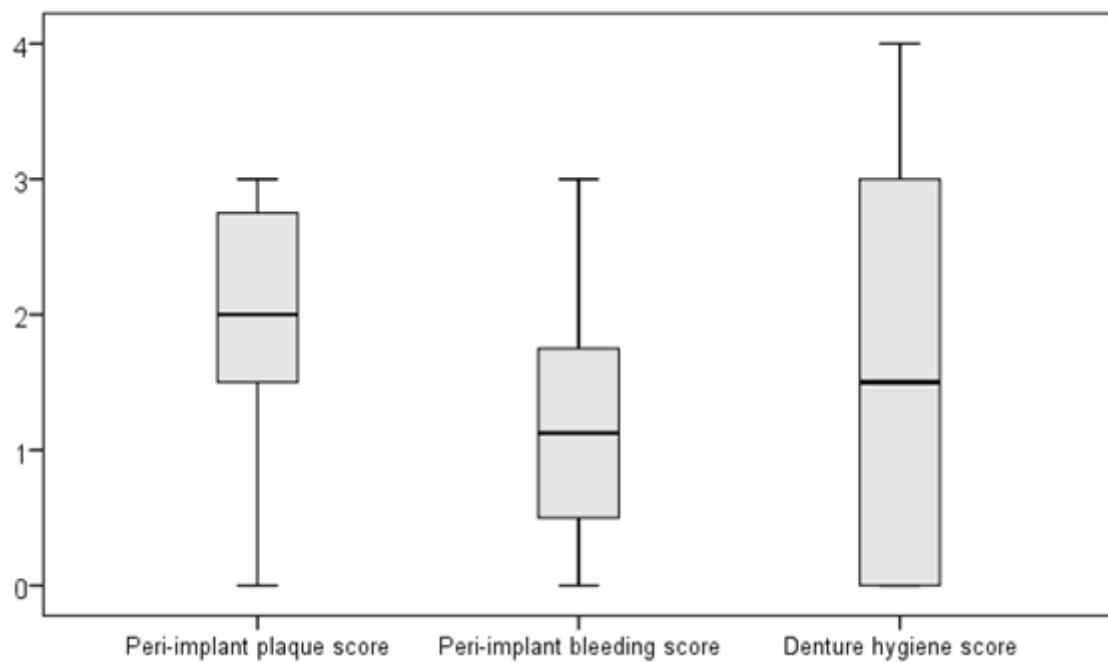


Figure 5. Distribution of plaque scores, peri-implant bleeding scores and combined denture hygiene scores.

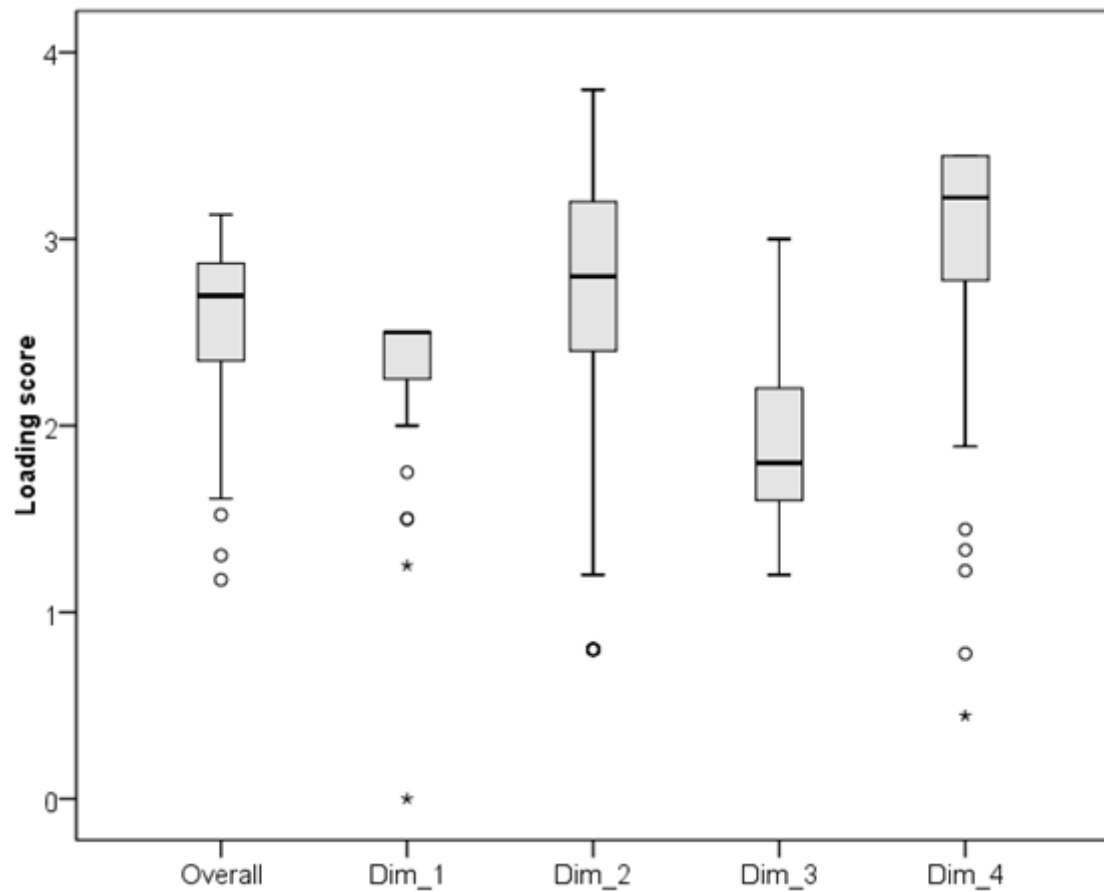


Figure 6. Distribution of the loading scores overall as well as the distribution of the loading scores for each of the four dimensions. Dimension 1: challenge in routine; dimension 2: self-rated performance; dimension 3: attitudes towards oral health; and dimension 4: challenge in special occasions.

Table 3. Multiple linear regression models. Data are expressed as regression coefficients (standard error) and p-values (n=69). Significant associations are highlighted in bold.

Independent variables	Overall scale	Dimension 1	Dimension 2	Dimension 3	Dimension 4
Sex (female)	-0.208 (0.12) p=0.086	-0.225 (0.10) p=0.022	-0.489 (0.22) p=0.032	0.114 (0.12) p=0.351	-0.214 (0.19) p=0.262
Age (50% older)	0.013 (0.11) p=0.906	0.098 (0.09) p=0.273	-0.100 (0.021) p=0.627	-0.064 (0.11) p=0.570	0.095 (0.17) p=0.586
Plaque index	-0.026 (0.08) p=0.751	-0.137 (0.07) p=0.041	-0.215 (0.15) p=0.162	0.119 (0.08) p=0.157	0.057 (0.13) p=0.661
Bleeding index	0.094 (0.08) p= 0.257	0.106 (0.07) p=0.114	0.209 (0.15) p=0.178	0.034 (0.08) p=0.684	0.052 (0.13) p=0.691
Denture hygiene index	-0.071 (0.04) p=0.046	-0.044 (0.03) p=0.120	-0.115 (0.07) p=0.084	-0.10 (0.04) p=0.769	-0.096 (0.06) p=0.087
R square	0.106	0.189	0.135	0.082	0.067

8 DISCUSSION

8.1 Self-Efficacy and Oral Health Outcomes:

The objective of the study was to develop a research instrument to assess the association between oral health self-efficacy and peri-implant health status in patients with implants retained overdentures. Results of the study revealed that there exists a significant association between self-efficacy and oral hygiene outcomes, particularly as it relates to denture hygiene. Patients with higher self-efficacy levels had greater success at maintaining denture hygiene, a finding which was consistent with the broader literature on self-efficacy in oral hygiene.

This finding is clinically important, as it highlights the need for the inclusion of self-efficacy assessments and addressing self-efficacy beliefs in the management of patients with implant-retained overdentures. Clinically, the OHSE-OVER can be used to identify patients with low self-efficacy on oral hygiene, and tailor their treatment plan to include methods to improve patient confidence and skills in maintaining proper oral hygiene, which can, in turn, positively impact peri-implant health. Possible interventions may include personalized oral hygiene instructions, demonstrations of effective oral hygiene techniques, and ongoing support and encouragement through more frequent recall/follow-up visits (Hashemi et al., 2021, Stewart et al., 1996, and Dolatabadi et al., 2022). As this was an observational study, these interventions were not assessed, and could possibly be studied in the future to evaluate the most appropriate intervention methods within this demographic.

8.2 The Oral Health Self-Efficacy Assessment for Overdenture Patients

The Oral Health Self-Efficacy Assessment for Overdenture Patients is a context-specific questionnaire that fills a crucial gap in the fields of self-efficacy research and dental implant research. Previously, there existed scales to assess self-efficacy in dentate patients and in patients with dentures, but there existed no instrument to address the needs of patients with implant-retained overdentures. The OHSE-OVER was deemed reliable and valid and can therefore be used by researchers and clinicians alike to accurately measure self-efficacy in this specific population.

8.3 Sex Differences in Self-Efficacy and Plaque Index

The study revealed an association between self-efficacy and sex; men exhibited greater self-efficacy in oral health practices than women. This is a finding that contradicts what exists in current literature. Women are said to generally have a more positive attitude toward dental care, as well as greater self-efficacy (Lipsky et al., 2021 and Zetu et al., 2014).

The underlying reasons for this finding were not explored in this study, but it may suggest the existence of cultural and social factors that influence self-efficacy in oral hygiene. The finding highlights the need for tailored treatment planning to account for sex-specific factors when addressing self-efficacy and oral health outcomes. Having a better understanding of these disparities can help clinicians develop more effective strategies for oral health promotion in patients with implant-retained overdentures, resulting in more equitable oral health outcomes.

There was an association between self-efficacy and plaque index observed in dimension one, “challenges in routine” and dimension two “self-performance”, which emphasizes the role of self-efficacy in plaque control. Patients with higher self-efficacy had lower plaque scores, indicating that self-efficacy can be a key determinant of oral health behaviours and outcomes (Sarsilmazer & Atilla, 2020).

8.4 Limitations and Future Research:

The study was carried out on patients at a single clinic, all of whom were using Straumann® mini-implants, which may challenge the applicability of this study to the wider population, especially patients using other implant systems. Further studies employing a larger and more diverse sample of patients to validate the study’s findings may be something to consider.

The current study model is a cross-sectional study, which only gives a snapshot at a particular point in time, in the case of this study, one-year post-surgery. It would be worthwhile to consider a longitudinal study to assess how self-efficacy influences peri-implant health status and implant survival over time. This would provide better scope on the long-term effects of self-efficacy on oral health outcomes in patients with implant-retained overdentures. Long-term studies are important because from the literature we know that, with interventions, self-efficacy can change over time and therefore, change oral health outcomes (Stewart et al., 1996).

Almost 50% of the participants were either current or former smokers. While this was not explored in the study, it is a factor that could have been considered when exploring patient outcomes. It is important to note that smokers generally have a higher incidence of peri-implant disease and lower implant survival rates. (Balaguer et al., 2015, Chrcanovic et al., 2015, and Stoker et al., 2011). A systematic review and meta-analysis of 292 publications between 1993 and 2021 concluded that smokers had a high incidence of marginal bone loss and presented a 140.2% higher risk of implant failure (Mustapha et al., 2021).

Apart from smoking, 82.6% of the participants were prescribed medications to manage chronic health conditions. While the specific ailments were not documented in this particular study, Malta and Szwarcwald, referencing the 2013 National Health Survey (PNS), reported that 21.4% of the Brazilian population self-reported having arterial hypertension, and 6.2% self-reported diabetes (Malta & Szwarcwald, 2015). In the subsequent 2019 PNS, as cited in Malta et al., there was an increase in the self-reported prevalence of arterial hypertension at 23.9% (Malta et al., 2022). It is worth noting these statistics are significant because hyperglycemia (linked to poorly controlled diabetes) and cardiovascular diseases, particularly arterial hypertension, can impact the process of osseointegration. However, it's important to mention that cardiovascular diseases do not have a major influence on the long-term success of dental implants (Dutta et al., 2020). Therefore, future studies should consider including information about the chronic illnesses within the sample and the specific medications employed to manage these conditions.

Finally, further studies could explore the types of interventions that may improve self-efficacy among this patient population. These interventions might include and are not limited to educational programs and behavioral counseling designed to improve patients' confidence and skills in maintaining good oral hygiene.

9 CONCLUSIONS

1. The study highlights the role of oral health self-efficacy in oral health outcomes among individuals with implant-retained overdentures.
2. There is an association between oral health self-efficacy and oral hygiene outcomes (plaque index and denture hygiene) in patients using implant-retained overdentures.
3. The OHSE-OVER is psychometrically sound for use in clinical studies and the internal structure was validated indicating that it is valuable instrument for researchers and clinicians to assess and address self-efficacy in patients with implant-retained overdentures.

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Appendix

A - Initial - Questionnaire - Oral Health Self-Efficacy Assessment for Overdenture Patients

Por favor, leia as frases com cuidado e CIRCULE a opção que melhor descreve sua <u>situação atual</u> para cada uma das frases		Nem um pouco	Pouco	Nem pouco nem muito	Muito	Bastante
Percepção da autoeficácia em relação à higiene oral						
1	Você tem dificuldade em manter a sua boca limpa	1	2	3	4	5
2	Você tem dificuldade em limpar as suas próteses	1	2	3	4	5
3	Você tem dificuldade em manter os seus implantes limpos	1	2	3	4	5
4	Você acha que as suas próteses estão bem limpas	1	2	3	4	5
5	Você acha que os seus implantes estão bem limpos	1	2	3	4	5
6	Você acha que consegue manter a sua boca bem higienizada a maior parte do tempo	1	2	3	4	5
7	Você acha que vai conseguir manter a saúde da sua boca até a idade avançada	1	2	3	4	5
Atitudes em relação à saúde bucal						
8	Manter a boca bem limpa é importante para você	1	2	3	4	5
9	Você tem medo de perder os seus implantes	1	2	3	4	5
10	Você acha que perdeu os seus dentes porque não conseguiu cuidar bem deles	1	2	3	4	5
11	Você tem culpa em ter perdido os seus dentes	1	2	3	4	5
12	Ter perdido os seus dentes te incomoda	1	2	3	4	5
13	Usar próteses totais te incomoda	1	2	3	4	5
14	Você se sente bem com suas próteses	1	2	3	4	5

Por favor, leia as frases com cuidado e CIRCULE a opção que melhor descreve sua <u>situação atual</u> para cada uma das frases		Nem um Pouco	Pouco	Nem pouco nem muito	Muito	Bastante
Autoeficácia para limpar as próteses						
Quanto de dificuldade você sente para limpar bem as suas próteses...						
1	...quando você está cansado à noite	1	2	3	4	5
2	...quando você tem uma consulta agendada com o dentista	1	2	3	4	5
3	...quando você está de férias	1	2	3	4	5
4	...quando você tem muito trabalho	1	2	3	4	5
5	...quando você tem dor de cabeça	1	2	3	4	5
6	...quando você se sente doente	1	2	3	4	5
Autoeficácia para limpar a região dos implantes						
Quanto de dificuldade você sente para limpar bem os seus implantes...						
1	...quando você está cansado à noite	1	2	3	4	5
2	...quando você tem uma consulta agendada com o dentista	1	2	3	4	5
3	...quando você está de férias	1	2	3	4	5
4	...quando você tem muito trabalho	1	2	3	4	5
5	...quando você tem dor de cabeça	1	2	3	4	5
6	...quando você se sente doente	1	2	3	4	5

B -Document for the evaluation of relevance of the questions



Documento para avaliação da relevância e representatividade dos itens

Preencha as tabelas para avaliar a relevância/representatividade de cada item, onde:

- 1 – Não relevante ou não representativo
- 2 – Item necessita de grande revisão para ser representativo
- 3 – Item necessita de pequena revisão para ser representativo
- 4 – Item relevante ou representativo

O número que representa a relevância/representatividade deve ser sublinhado para cada item

Relevância/representatividade do item:

Percepção da autoeficácia em relação à higiene oral					
1	Você tem dificuldade em manter a sua boca limpa	1	2	3	4
2	Você tem dificuldade em limpar as suas próteses	1	2	3	4
3	Você tem dificuldade em manter os seus implantes limpos	1	2	3	4
4	Você acha que as suas próteses estão bem limpas	1	2	3	4
5	Você acha que os seus implantes estão bem limpos	1	2	3	4
6	Você acha que consegue manter a sua boca bem higienizada a maior parte do tempo	1	2	3	4
7	Você acha que vai conseguir manter a saúde da sua boca até a idade avançada	1	2	3	4
Atitudes em relação à saúde bucal					
8	Manter a boca bem limpa é importante para você	1	2	3	4
9	Você tem medo de perder os seus implantes	1	2	3	4
10	Você acha que perdeu os seus dentes porque não conseguiu cuidar bem deles	1	2	3	4
11	Você tem culpa em ter perdido os seus dentes	1	2	3	4
12	Ter perdido os seus dentes te incomoda	1	2	3	4
13	Usar próteses totais te incomoda	1	2	3	4
14	Você se sente bem com suas próteses	1	2	3	4

Continue preenchendo as tabelas para avaliar a relevância/representatividade de cada item,
onde:

- 1 – Não relevante ou não representativo**
- 2 – Item necessita de grande revisão para ser representativo**
- 3 – Item necessita de pequena revisão para ser representativo**
- 4 – Item relevante ou representativo**

O número que representa a relevância/representatividade deve ser sublinhado para cada item

Relevância/representatividade do item:

Autoeficácia para limpar as próteses					
Quanto de dificuldade você sente para limpar bem as suas próteses...					
1	...quando você está cansado à noite	1	2	3	4
2	...quando você tem uma consulta agendada com o dentista	1	2	3	4
3	...quando você está de férias	1	2	3	4
4	...quando você tem muito trabalho	1	2	3	4
5	...quando você tem dor de cabeça	1	2	3	4
6	...quando você se sente doente	1	2	3	4
Autoeficácia para limpar a região dos implantes					
Quanto de dificuldade você sente para limpar bem os seus implantes...					
1	...quando você está cansado à noite	1	2	3	4
2	...quando você tem uma consulta agendada com o dentista	1	2	3	4
3	...quando você está de férias	1	2	3	4
4	...quando você tem muito trabalho	1	2	3	4
5	...quando você tem dor de cabeça	1	2	3	4
6	...quando você se sente doente	1	2	3	4

C - Document for the suggestion of alternations to the questionnaire



Documento para inclusão de sugestões de alterações dos itens

Caso você considere que algum item deva ser alterado para melhor descrever o comportamento avaliado, por favor, preencha sua sugestão de como este item deveria ser escrito. No final da tabela, também há um campo para que você possa indicar quais itens considera redundantes.

Sugestões e redundância dos itens:

	Item atual	Sugestão de alteração
Percepção da autoeficácia em relação à higiene oral		
1	Você tem dificuldade em manter a sua boca limpa	<i>(Inserir a sugestão aqui)</i>
2	Você tem dificuldade em limpar as suas próteses	<i>(Inserir a sugestão aqui)</i>
3	Você tem dificuldade em manter os seus implantes limpos	<i>(Inserir a sugestão aqui)</i>
4	Você acha que as suas próteses estão bem limpas	<i>(Inserir a sugestão aqui)</i>
5	Você acha que os seus implantes estão bem limpos	<i>(Inserir a sugestão aqui)</i>
6	Você acha que consegue manter a sua boca bem higienizada a maior parte do tempo	<i>(Inserir a sugestão aqui)</i>
7	Você acha que vai conseguir manter a saúde da sua boca até a idade avançada	<i>(Inserir a sugestão aqui)</i>
Quais itens considera redundantes?		<i>(Inserir a sugestão aqui)</i>
Você sugere a adição de algum novo item? Qual?		<i>(Inserir a sugestão aqui)</i>
Atitudes em relação à saúde bucal		
8	Manter a boca bem limpa é importante para você	<i>(Inserir a sugestão aqui)</i>
9	Você tem medo de perder os seus implantes	<i>(Inserir a sugestão aqui)</i>
10	Você acha que perdeu os seus dentes porque não conseguiu cuidar bem deles	<i>(Inserir a sugestão aqui)</i>
11	Você tem culpa em ter perdido os seus dentes	<i>(Inserir a sugestão aqui)</i>
12	Ter perdido os seus dentes te incomoda	<i>(Inserir a sugestão aqui)</i>
13	Usar próteses totais te incomoda	<i>(Inserir a sugestão aqui)</i>
14	Você se sente bem com suas próteses	<i>(Inserir a sugestão aqui)</i>
Quais itens considera redundantes?		<i>(Inserir a sugestão aqui)</i>
Você sugere a adição de algum novo item? Qual?		<i>(Inserir a sugestão aqui)</i>

Percepção da autoeficácia em relação à higiene oral		
	Item atual	Sugestão de alteração
Autoeficácia para limpar as próteses		
Quanto de dificuldade você sente para limpar bem as suas próteses...		
1	...quando você está cansado à noite	<i>(Inserir a sugestão aqui)</i>
2	...quando você tem uma consulta agendada com o dentista	<i>(Inserir a sugestão aqui)</i>
3	...quando você está de férias	<i>(Inserir a sugestão aqui)</i>
4	...quando você tem muito trabalho	<i>(Inserir a sugestão aqui)</i>
5	...quando você tem dor de cabeça	<i>(Inserir a sugestão aqui)</i>
6	...quando você se sente doente	<i>(Inserir a sugestão aqui)</i>
Quais itens considera redundantes?		<i>(Inserir a sugestão aqui)</i>
Você sugere a adição de algum novo item? Qual?		<i>(Inserir a sugestão aqui)</i>
Autoeficácia para limpar a região dos implantes		
Quanto de dificuldade você sente para limpar bem os seus implantes...		
1	...quando você está cansado à noite	<i>(Inserir a sugestão aqui)</i>
2	...quando você tem uma consulta agendada com o dentista	<i>(Inserir a sugestão aqui)</i>
3	...quando você está de férias	<i>(Inserir a sugestão aqui)</i>
4	...quando você tem muito trabalho	<i>(Inserir a sugestão aqui)</i>
5	...quando você tem dor de cabeça	<i>(Inserir a sugestão aqui)</i>
6	...quando você se sente doente	<i>(Inserir a sugestão aqui)</i>
Quais itens considera redundantes?		<i>(Inserir a sugestão aqui)</i>
Você sugere a adição de algum novo item? Qual?		<i>(Inserir a sugestão aqui)</i>

D – Questionnaire Approved by Expert Panel – Oral Health Self-Efficacy Assessment for Overdenture Patients

Por favor, leia as perguntas com cuidado e CIRCULE a opção que melhor descreve sua <u>situação atual</u> para cada uma das frases		Nem um pouco	Pouco	Nem pouco nem muito	Muito	Muitíssimo
Percepção da autoeficácia em relação à higiene oral						
1	Você tem dificuldade em manter a sua boca limpa?	1	2	3	4	5
2	Você tem dificuldade em limpar a sua dentadura de cima?	1	2	3	4	5
3	Você tem dificuldade em limpar a sua dentadura de baixo?	1	2	3	4	5
4	Você tem dificuldade em manter os seus implantes limpos?	1	2	3	4	5
5	Você acha que a sua dentadura de cima está bem limpa?	1	2	3	4	5
6	Você acha que a sua dentadura de baixo está bem limpa?	1	2	3	4	5
7	Você acha que os seus implantes estão bem limpos?	1	2	3	4	5
8	Você acha que consegue manter a sua boca bem limpa a maior parte do tempo?	1	2	3	4	5
9	Você acha que vai conseguir manter a saúde da sua boca sozinho até quando estiver com idade bem avançada?	1	2	3	4	5
Atitudes em relação à saúde bucal						
10	Você tem medo de que seus implantes falhem e tenham que ser retirados?	1	2	3	4	5
11	Manter a boca bem limpa é importante para você?	1	2	3	4	5
12	Ter perdido os seus dentes naturais te incomoda?	1	2	3	4	5
13	Você se sente culpado por ter perdido os seus dentes?	1	2	3	4	5
14	Você acha que perdeu os seus dentes naturais porque não conseguiu cuidar bem deles?	1	2	3	4	5
15	Você se sente bem com suas dentaduras?	1	2	3	4	5

Por favor, leia as perguntas com cuidado e CIRCULE a opção que melhor descreve sua <u>situação atual</u> para cada uma das frases		Nem um pouco	Pouco	Nem pouco nem muito	Muito	Muitíssimo
Autoeficácia para limpar as dentaduras						
Quanto de dificuldade você sente para limpar bem as suas dentaduras...						
1	...quando você está cansado à noite?	1	2	3	4	5
2	...quando você tem uma consulta agendada com o dentista?	1	2	3	4	5
3	...quando você está em viagem ou fora da rotina?	1	2	3	4	5
4	...quando você tem muito trabalho?	1	2	3	4	5
5	...quando você não se sente bem de saúde?	1	2	3	4	5
Autoeficácia para limpar a região dos implantes						
Quanto de dificuldade você sente para limpar bem os seus implantes...						
1	...quando você está cansado à noite?	1	2	3	4	5
2	...quando você tem uma consulta agendada com o dentista?	1	2	3	4	5
3	...quando você está em viagem ou fora da rotina?	1	2	3	4	5
4	...quando você tem muito trabalho?	1	2	3	4	5
5	...quando você não se sente bem de saúde?	1	2	3	4	5

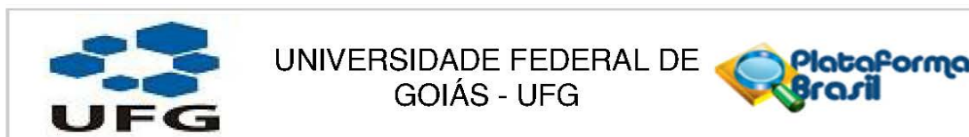
E – Final 23 Item Questionnaire – Oral Health Self-Efficacy Assessment for Overdenture Patients

Por favor, leia as perguntas com cuidado e CIRCULE a opção que melhor descreve sua <u>situação atual</u> para cada uma das frases		Nem um pouco	Pouco	Nem pouco nem muito	Muito	Muitíssimo
Percepção da autoeficácia em relação à higiene oral						
1	Você tem dificuldade em manter a sua boca limpa?	1	2	3	4	5
2	Você tem dificuldade em limpar a sua dentadura de cima?	1	2	3	4	5
3	Você tem dificuldade em limpar a sua dentadura de baixo?	1	2	3	4	5
4	Você tem dificuldade em manter os seus implantes limpos?	1	2	3	4	5
5	Você acha que a sua dentadura de cima está bem limpa?	1	2	3	4	5
6	Você acha que a sua dentadura de baixo está bem limpa?	1	2	3	4	5
7	Você acha que os seus implantes estão bem limpos?	1	2	3	4	5
8	Você acha que consegue manter a sua boca bem limpa a maior parte do tempo?	1	2	3	4	5
9	Você acha que vai conseguir manter a saúde da sua boca sozinho até quando estiver com idade bem avançada?	1	2	3	4	5
Atitudes em relação à saúde bucal						
10	Você tem medo de que seus implantes falhem e tenham que ser retirados?	1	2	3	4	5
11	Manter a boca bem limpa é importante para você?	1	2	3	4	5
12	Você acha que perdeu os seus dentes naturais porque não conseguiu cuidar bem deles?	1	2	3	4	5
13	Você se sente bem com suas dentaduras?	1	2	3	4	5

Por favor, leia as perguntas com cuidado e CIRCULE a opção que melhor descreve sua <u>situação atual</u> para cada uma das frases		Nem um pouco	Pouco	Nem pouco nem muito	Muito	Muitíssimo
Autoeficácia para limpar as dentaduras						
Quanto de dificuldade você sente para limpar bem as suas dentaduras...						
1	...quando você está cansado à noite?	1	2	3	4	5
2	...quando você tem uma consulta agendada com o dentista?	1	2	3	4	5
3	...quando você está em viagem ou fora da rotina?	1	2	3	4	5
4	...quando você tem muito trabalho?	1	2	3	4	5
5	...quando você não se sente bem de saúde?	1	2	3	4	5
Autoeficácia para limpar a região dos implantes						
Quanto de dificuldade você sente para limpar bem os seus implantes...						
1	...quando você está cansado à noite?	1	2	3	4	5
2	...quando você tem uma consulta agendada com o dentista?	1	2	3	4	5
3	...quando você está em viagem ou fora da rotina?	1	2	3	4	5
4	...quando você tem muito trabalho?	1	2	3	4	5
5	...quando você não se sente bem de saúde?	1	2	3	4	5

ANNEX

A - Ethical Approval



PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Mini-implantes de TiZi de corpo único associada a conexão protética miniaturizada e superfície revestida por carbono: um ensaio clínico fatorial randomizado para testar os desfechos do carregamento imediato ou tardio e cirurgia aberta ou sem retalho

Pesquisador: Claudio Rodrigues Leles

Área Temática:

Versão: 2

CAAE: 24833219.4.0000.5083

Instituição Proponente: Faculdade de Odontologia da Universidade Federal de Goiás

Patrocinador Principal: International Team for Implantology

DADOS DO PARECER

Número do Parecer: 6.158.954

Apresentação do Projeto:

Trata-se da solicitação de EMENDA. Título da Pesquisa: Mini-implantes de TiZi de corpo único associada a conexão protética miniaturizada e superfície revestida por carbono: um ensaio clínico fatorial randomizado para testar os desfechos do carregamento imediato ou tardio e cirurgia aberta ou sem retalho. Pesquisador Responsável: Claudio Rodrigues Leles. N. CAAE: 24833219.4.0000.5083. Instituição Proponente: Faculdade de Odontologia da Universidade Federal de Goiás.

Objetivo da Pesquisa:

Justificativa da Emenda:

Foi incluído um instrumento adicional a ser aplicado na última avaliação longitudinal dos participantes que receberam o tratamento prescrito no estudo clínico experimental. Será aplicado um questionário na avaliação longitudinal entre 1 e dois anos após a instalação das próteses retidas sobre implantes para afiliar a auto-eficácia em relação à manutenção da saúde bucal e saúde periimplantar. Trata-se de uma análise observacional transversal aninhado à análise prospectiva do ensaio clínico original. Os participantes que estejam usando as overdentures implantossuportadas da marca Straumann retidas por implante por um período mínimo de um ano serão recrutados para o estudo e sua apresentação clínica será cruzada com suas respostas a um

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instrumento de autoeficácia (questionário).

A hipótese é de que a baixa autoeficácia na saúde bucal está associada ao mau estado de saúde peri-implantar em pacientes que usam overdentures implantossuportadas mandibulares.

Resultados previstos: Espera-se que o estudo forneça alguma previsibilidade sobre quão bem os pacientes são capazes de manter sua saúde peri-implantar, auxiliando os médicos a tomar melhores decisões em seu planejamento de tratamento para pacientes com implantes e overdentures implantossuportadas

Avaliação dos Riscos e Benefícios:

Não houve alteração dos riscos e benefícios avaliados em parecer emitido anteriormente.

Comentários e Considerações sobre a Pesquisa:

Informam apenas que será realizado novo instrumento de coleta de dados e exames clínicos para verificar a qualidade do tratamento proposto.

Acrescentaram:

"Auto-eficácia relacionada à manutenção da saúde bucal e periimplantar Um questionário contendo um conjunto preliminar de perguntas foi gerado com base na revisão da literatura existente, bem como nas opiniões de especialistas. As questões refletiam diferentes aspectos da autoeficácia em relação à higiene bucal, e o formato de resposta foi uma escala Likert, com cinco opções variando de discordo totalmente a concordo totalmente. Um painel de cinco membros especialistas em odontologia será convidado para revisar o conteúdo quanto à relevância e clareza. Os especialistas fornecerão feedback e modificações foram feitas no instrumento de pesquisa e novamente enviadas aos especialistas para realizar uma segunda revisão. Após a segunda revisão, todas as sugestões recomendadas para mudanças serão consideradas e feitas no questionário.

O questionário inicial contém as seguintes dimensões e itens:

Dimensão 1: Percepção da autoeficácia em relação à higiene oral

Dimensão 2: Atitudes em relação à saúde bucal

Dimensão 3: Autoeficácia para limpar as próteses

Dimensão 4: Autoeficácia para limpar a região dos implantes

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Continuação do Parecer: 6.158.954

Considerações sobre os Termos de apresentação obrigatória:

Apresentam os adendos ao instrumento de coleta de dados no arquivo do projeto de pesquisa.

Conclusões ou Pendências e Lista de Inadequações:

Após análise das informações apresentadas somos favoráveis à aprovação da presente emenda.

Considerações Finais a critério do CEP:

Informamos que o Comitê de Ética em Pesquisa/CEP-UFG considera a presente solicitação de Emenda APROVADA, pois a mesma foi considerada em acordo com os princípios éticos vigentes. Reiteramos a importância deste Parecer Consubstanciado, e lembramos que o(a) pesquisador(a) responsável deverá encaminhar ao CEP-UFG o Relatório Final baseado na conclusão do estudo e na incidência de publicações decorrentes deste, de acordo com o disposto na Resolução CNS n. 466/12 e Resolução CNS n. 510/16. O prazo para entrega do Relatório é de até 30 dias após o encerramento da pesquisa, previsto para janeiro de 2024.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_2145010_E1.pdf	09/06/2023 11:16:23		Aceito
Projeto Detalhado / Brochura Investigador	Projeto_CEP_com_emenda.pdf	09/06/2023 11:14:31	Claudio Rodrigues Leles	Aceito
Folha de Rosto	Folha_de_rosto.pdf	31/10/2019 11:21:19	Claudio Rodrigues Leles	Aceito
Declaração de Pesquisadores	Modelo_Termo_Compromisso.pdf	30/10/2019 19:23:07	Claudio Rodrigues Leles	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	30/10/2019 18:38:01	Claudio Rodrigues Leles	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

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Continuação do Parecer: 6.158.954

GOIANIA, 03 de Julho de 2023

Assinado por:
Rosana de Moraes Borges Marques
(Coordenador(a))

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